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Title 3—

Proclamation 9567 of January 12, 2017

The President

Establishment of the Reconstruction Era National Monument

By the President of the United States of America

A Proclamation

The Reconstruction Era, a period spanning the early Civil War years until the start of Jim Crow racial segregation in the 1890s, was a time of significant transformation in the United States, as the Nation grappled with the challenge of integrating millions of newly freed African Americans into its social, political, and economic life. It was in many ways the Nation's Second Founding, as Americans abolished slavery and struggled earnestly, if not always successfully, to build a nation of free and equal citizens. During Reconstruction, Congress passed the Thirteenth, Fourteenth, and Fifteenth constitutional amendments that abolished slavery, guaranteed due process and equal protection under the law, and gave all males the ability to vote by prohibiting voter discrimination based on race, color, or previous condition of servitude. Ultimately, the unmet promises of Reconstruction led to the modern civil rights movement a century later.

The Reconstruction Era began when the first United States soldiers arrived in slaveholding territories, and enslaved people on plantations and farms and in cities escaped from their owners and sought refuge with Union forces or in free states. This happened in November 1861 in the Sea Islands or "Lowcountry" of southeastern South Carolina, and Beaufort County in particular. Just seven months after the start of the Civil War, Admiral Samuel F. DuPont led a successful attack on Port Royal Sound and brought a swath of this South Carolina coast under Union control. The white residents (less than twenty percent of the population), including the wealthy owners of rice and cotton plantations, quickly abandoned their country plantations and their homes in the town of Beaufort as Union forces came ashore. More than 10,000 African Americans—about one-third of the enslaved population of the Sea Islands at the time—refused to flee the area with their owners.

Beaufort County became one of the first places in the United States where formerly enslaved people could begin integrating themselves into free society. While the Civil War raged in the background, Beaufort County became the birthplace of Reconstruction, or what historian Willie Lee Rose called a "rehearsal for Reconstruction." With Federal forces in charge of the Sea Islands, the Department of the Treasury, with the support of President Lincoln and the War Department, decided to turn the military occupation into a novel social experiment, known as the Port Royal Experiment, to help former slaves become self-sufficient. They enlisted antislavery and religious societies in the North to raise resources and recruit volunteers for the effort. Missionary organizations headquartered in the Northeast established outposts in Beaufort County.

In and around Beaufort County during Reconstruction, the first African Americans enlisted as soldiers, the first African American schools were founded, early efforts to distribute land to former slaves took place, and many of the Reconstruction Era's most significant African American politicians, including Robert Smalls, came to prominence. African American political influence and land ownership endured there long after setbacks in other regions. In short, events and people from Beaufort County illustrate

the most important challenges of Reconstruction—crucial questions related to land, labor, education, and politics after the destruction of slavery—and some early hopeful efforts to address them. The significant historical events that transpired in Beaufort County make it an ideal place to tell stories of experimentation, potential transformation, hope, accomplishment, and disappointment. In Beaufort County, including St. Helena Island, the town of Port Royal, and the city of Beaufort, many existing historic objects demonstrate the transformative effect of emancipation and Reconstruction.

Freed people hungered for education, as South Carolina had long forbidden teaching slaves to read and write. In 1862, Laura M. Towne and Ellen Murray from Pennsylvania were among the first northern teachers to arrive as part of the Port Royal Experiment. They established a partnership as educators at the Penn School on St. Helena Island that lasted for four decades. Charlotte Forten, a well-educated African American woman from a prominent abolitionist family in Philadelphia, joined the faculty later that year. The first classes for the former slaves were held at The Oaks plantation house, headquarters of the occupying U.S. military forces in the region. In 1863, Murray and Towne moved their school into Brick Church, a Baptist church near the center of the island. In the spring of 1864, supporters in Philadelphia purchased school buildings for Towne and Murray, and construction of Penn School began across the field from Brick Church on 50 acres of property donated by Hastings Gantt, an African American landowner.

Penn School helped many African Americans gain self-respect and self-reliance and integrate into free society. Towne and Murray strove to provide an education comparable to that offered in the best northern schools. The faculty also provided other support, including medical care, social services, and employment assistance. Penn School would evolve into the Penn Center in the 20th century, and remain a crucial place for education, community, and political organizing for decades to come. As a meeting place in the 1950s and 60s for civil rights leaders, including Dr. Martin Luther King, Jr., and the staff of the Southern Christian Leadership Conference, this historic place links the democratic aspirations of Reconstruction to those of the modern civil rights movement. Darrah Hall is the oldest standing structure on the site of the Penn School grounds. Students and community members built it around 1903, during the transition in the South from the Reconstruction Era to an era of racial segregation and political disenfranchisement.

The Brick Church where Towne and Murray held classes in 1863–64 is today the oldest church on St. Helena Island. Once freed from their owners, African Americans in Beaufort County wanted to worship in churches and join organizations they controlled. The Brick Church—also known as the Brick Baptist Church—was built by slaves in 1855 for the white planters on St. Helena Island. When the white population fled from the Sea Islands in 1861, the suddenly freed African Americans made the church their own. The Brick Church has been a place of worship and gathering ever since, and continues to serve the spiritual needs of the community to this day.

Camp Saxton in Port Royal—formerly the site of a plantation owned by John Joyner Smith—is where the First South Carolina Regiment Volunteers mustered into the U.S. Army and trained from November 1862 to January 1863. In August 1862, U.S. Brigadier General Rufus Saxton, the military governor of the abandoned plantations in the Department of the South, received permission to recruit five thousand African Americans, mostly former slaves, into the Union Army. The former slaves assumed that military service would lead to rights of citizenship. Saxton selected Captain Thomas Wentworth Higginson of the 51st Massachusetts, a former Unitarian minister, abolitionist, and human rights activist, to command the regiment. An important ally of Higginson and the African American troops was Harriet Tubman, the famed conductor on the Underground Railroad, who in May of 1862

arrived in Beaufort as part of the Port Royal Experiment and who served skillfully as a nurse at Camp Saxton.

Camp Saxton was also the location of elaborate and historic ceremonies on January 1, 1863, to announce and celebrate the issuance of the Emancipation Proclamation, which freed all slaves in states then “in rebellion” against the United States. General Saxton himself had attended church services at the Brick Church in the fall of 1862 to recruit troops and to invite everyone, African American and white, “to come to the camp . . . on New Year’s Day, and join in the grand celebration.” This Emancipation Proclamation celebration was particularly significant because it occurred in Union-occupied territory in the South where the provisions of the Proclamation would actually take effect before the end of the war.

Over five thousand people, including freed men, women, and children, Union military officials, guest speakers, and missionary teachers, gathered around the speakers’ platform built in a grove of live oaks near the Smith plantation house. One of the majestic witness trees has become known as the Emancipation Oak. Of all the prayers, hymns, and speeches during the three-hour ceremony, one of the most moving was the spontaneous singing of “My country, tis of thee; Sweet land of liberty” when the American flag was presented to Higginson. As part of the celebration, the military had prepared a feast of roasted oxen for all to enjoy.

The town of Beaufort was the center of the County’s social, political, cultural, and economic life during the Reconstruction Era. Before the Battle of Port Royal Sound in November 1861, Beaufort was where the planters spent the summer months in their grand homes. Beaufort served as the depot for plantation supplies transported there by steamship. The Old Beaufort Firehouse, built around 1912, stands near the heart of Reconstruction Era Beaufort, across the street from the Beaufort Arsenal, and within walking distance of over fifty historic places. The Beaufort Arsenal, the location today of the Beaufort History Museum, was built in 1799, rebuilt in 1852, and renovated by the Works Progress Administration in 1934, and served historically as the home of the Beaufort Volunteer Artillery Company that fought in the Revolutionary and Civil Wars.

Several historic Beaufort properties within walking distance of the Firehouse are associated with Robert Smalls, the most influential African American politician in South Carolina during the Reconstruction Era. Robert Smalls was born in Beaufort in 1839, the son of slaves of the Henry McKee family. When Smalls was twelve years old, his owner hired him out to work in Charleston, where he learned to sail, rig, and pilot ships. In May 1862, Smalls navigated the *CSS Planter*, a Confederate ship, through Charleston harbor, past the guns of Fort Sumter, and turned it over to Union forces. This courageous escape made him an instant hero for the Union, and he soon began working as a pilot for the U.S. Navy. Smalls and his family used prize money awarded for the *Planter* to purchase the house in Beaufort once owned by the family that had owned him.

In 1864, Smalls was named to a delegation of African American South Carolinians to the Republican National Convention in Baltimore, where the delegation unsuccessfully petitioned the party to make African American enfranchisement part of its platform. Elected to the Beaufort County School Board in 1867, Smalls began his advocacy for education as the key to African American success in the new political and economic order.

In the years immediately following the end of the Civil War, the United States fiercely debated issues critical to Reconstruction. Southern Democrats tried to regain the power they held before the Civil War. The Republican majorities in the U.S. Congress rebuffed them, and proceeded to pass legislation and constitutional amendments to implement the principles of the Union victory. In 1867, Congress passed the Military Reconstruction Acts that called for military administration of southern states and new state constitutions. Voters elected Robert Smalls as a delegate to the South Carolina Constitutional Convention that met in Charleston in January 1868, where

he successfully advocated for public education with compulsory attendance. The resulting constitution also provided for universal male suffrage and racial, political, and legal equality. In this new political order, Robert Smalls was elected to the South Carolina General Assembly from 1868 to 1874, first as a representative and then as a senator. In 1874, Smalls was elected to the U.S. House of Representatives, where he served five terms.

The success of Smalls and other African American lawmakers who had been enslaved only a handful of years before infuriated South Carolina's Democrats. Some of them turned to violence, carried out by the Ku Klux Klan and others. On more than one occasion, a homegrown vigilante group known as the Red Shirts terrorized Robert Smalls.

As a result of the contested Presidential and South Carolina gubernatorial elections of 1876, deals were made that effectively ended political and military Reconstruction in 1877. Smalls, however, continued to serve in Congress until 1886. He then returned to Beaufort, and served for many years as the Presidentially appointed customs collector for the Port of Beaufort.

In 1895, Smalls was elected a delegate to his second South Carolina Constitutional Convention. Twenty years after Democrats had regained control of the State government, they had figured out how to take back African Americans' rights as citizens. Smalls spoke eloquently at the Convention against this blow to democracy and representative government, but ultimately rights hard won three decades before were struck down. South Carolina voters ratified a new constitution that effectively eliminated African Americans from electoral politics and codified racial segregation in law for decades to come.

Even as Jim Crow laws and customs limited political participation and access to public accommodations, African Americans maintained visions of freedom and built strong community institutions. Ownership of land, access to education, and churches and civic organizations that took root during the Reconstruction Era laid the foundation for the modern civil rights movement.

The many objects of historic interest described above stand testament to the formative role of the Reconstruction Era—and the enormous contributions of those who made it possible—in our shared history.

WHEREAS, section 320301 of title 54, United States Code (known as the "Antiquities Act"), authorizes the President, in his discretion, to declare by public proclamation historic landmarks, historic and prehistoric structures, and other objects of historic or scientific interest that are situated upon the lands owned or controlled by the Federal Government to be national monuments, and to reserve as a part thereof parcels of land, the limits of which shall be confined to the smallest area compatible with the proper care and management of the objects to be protected;

WHEREAS, the Beaufort National Historic Landmark District, which contains many objects of historic interest including the Old Beaufort Firehouse, was designated in 1973; and the Penn School National Historic Landmark District, which also contains many objects of historic interest including Darrah Hall and the Brick Baptist Church, was designated in 1974;

WHEREAS, the Camp Saxton Site was listed in the National Register of Historic Places in 1995;

WHEREAS, portions of the former Camp Saxton Site are located today on lands administered by the U.S. Department of the Navy at Naval Support Facility Beaufort, South Carolina;

WHEREAS, Penn Center, Inc., has donated to the United States fee title to Darrah Hall at Penn Center, St. Helena Island, South Carolina, with appurtenant easements, totaling approximately 3.78 acres of land and interests in land;

WHEREAS, Brick Baptist Church has donated to the United States a historic preservation easement in the Brick Baptist Church and associated cemetery located on St. Helena Island, South Carolina, an interest in land of approximately 0.84 acres;

WHEREAS, the Paul H. Keyserling Revocable Trust and Beaufort Works, LLC, have donated to the United States fee title to the Old Beaufort Firehouse at 706 Craven Street, Beaufort, South Carolina, approximately 0.08 acres of land;

WHEREAS, the designation of a national monument to be administered by the National Park Service would recognize the historic significance of Brick Baptist Church, Darrah Hall, Camp Saxton, and the Old Beaufort Firehouse, and provide a national platform for telling the story of Reconstruction;

WHEREAS, it is in the public interest to preserve and protect these sites;

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by the authority vested in me by section 320301 of title 54, United States Code, hereby proclaim the objects identified above that are situated upon lands and interests in lands owned or controlled by the Federal Government to be the Reconstruction Era National Monument (monument) and, for the purpose of protecting those objects, reserve as a part thereof all lands and interests in lands owned or controlled by the Federal Government within the boundaries described on the accompanying map, which is attached to and forms a part of this proclamation. The reserved Federal lands and interests in lands encompass approximately 15.56 acres. The boundaries described on the accompanying map are confined to the smallest area compatible with the proper care and management of the objects to be protected.

All Federal lands and interests in lands within the boundaries described on the accompanying map are hereby appropriated and withdrawn from all forms of entry, location, selection, sale, or other disposition under the public land laws, from location, entry, and patent under the mining laws, and from disposition under all laws relating to mineral and geothermal leasing.

The establishment of the monument is subject to valid existing rights. If the Federal Government acquires any lands or interests in lands not owned or controlled by the Federal Government within the boundaries described on the accompanying map, such lands and interests in lands shall be reserved as a part of the monument, and objects identified above that are situated upon those lands and interests in lands shall be part of the monument, upon acquisition of ownership or control by the Federal Government.

The Secretary of the Interior shall manage the monument through the National Park Service, pursuant to applicable legal authorities, consistent with the purposes and provisions of this proclamation. The Secretary of the Interior shall prepare a management plan within 3 years of the date of this proclamation, with full public involvement, and to include coordination with Penn Center, Inc., Brick Baptist Church, the Department of the Navy, Atlantic Marine Corps Communities, LLC, the City of Beaufort, and the Town of Port Royal. The management plan shall ensure that the monument fulfills the following purposes for the benefit of present and future generations: (1) to preserve and protect the objects of historic interest associated with the monument, and (2) to interpret the objects, resources, and values related to the Reconstruction Era. The management plan shall, among other things, set forth the desired relationship of the monument to other related resources, programs, and organizations, both within and outside the National Park System.

The Secretary of the Navy, or the Secretary of the Navy's designee, shall continue to have management authority over Department of the Navy lands within the monument boundary at the Camp Saxton site, including the authority to control access to these lands. The Secretaries of the Navy

and the Interior shall enter into a memorandum of agreement that identifies and assigns the responsibilities of each agency related to such lands, the implementing actions required of each agency, and the processes for resolving interagency disputes.

The National Park Service is directed to use applicable authorities to seek to enter into agreements with others to address common interests and promote management efficiencies, including provision of visitor services, interpretation and education, establishment and care of museum collections, and preservation of historic objects.

Given the location of portions of the monument on an operating military facility, the following provisions concern U.S. Armed Forces actions by a Military Department, including those carried out by the United States Coast Guard:

1. Nothing in this Proclamation precludes the activities and training of the Armed Forces; however, they shall be carried out in a manner consistent with the care and management of the objects to the extent practicable.

2. In the event of threatened or actual destruction of, loss of, or injury to a monument resource or quality resulting from an incident caused by a component of the Department of Defense or any other Federal agency, the appropriate Secretary or agency head shall promptly coordinate with the Secretary of the Interior for the purpose of taking appropriate action to respond to and mitigate the harm and, if possible, restore or replace the monument resource or quality.

3. Nothing in this proclamation or any regulation implementing it shall limit or otherwise affect the U.S. Armed Forces' discretion to use, maintain, improve, or manage any real property under the administrative control of a Military Department or otherwise limit the availability of such real property for military mission purposes.

Nothing in this proclamation shall be deemed to revoke any existing withdrawal, reservation, or appropriation; however, the monument shall be the dominant reservation.

Nothing in this proclamation shall be construed to alter the authority or responsibility of any party with respect to emergency response activities within the monument.

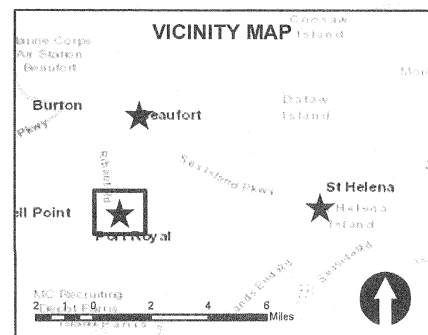
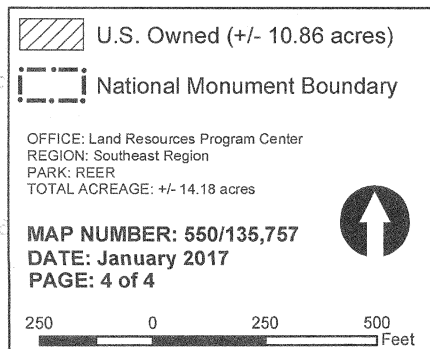
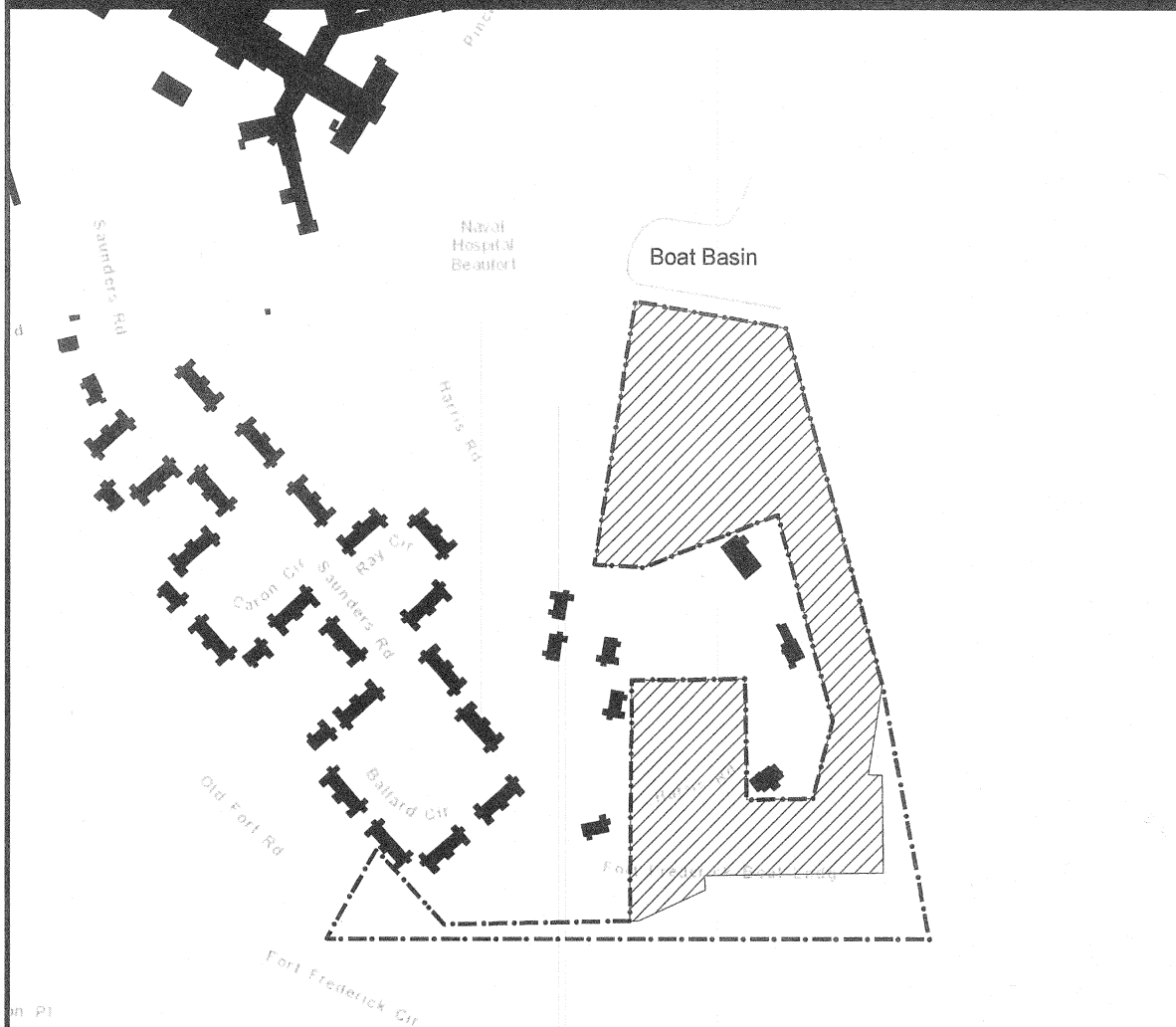
Warning is hereby given to all unauthorized persons not to appropriate, injure, destroy, or remove any feature of this monument and not to locate or settle upon any of the lands thereof.

IN WITNESS WHEREOF, I have hereunto set my hand this twelfth day of January, in the year of our Lord two thousand seventeen, and of the Independence of the United States of America the two hundred and forty-first.

A handwritten signature in black ink, appearing to be "Donald Trump", with a large circular flourish and a horizontal line extending to the right.

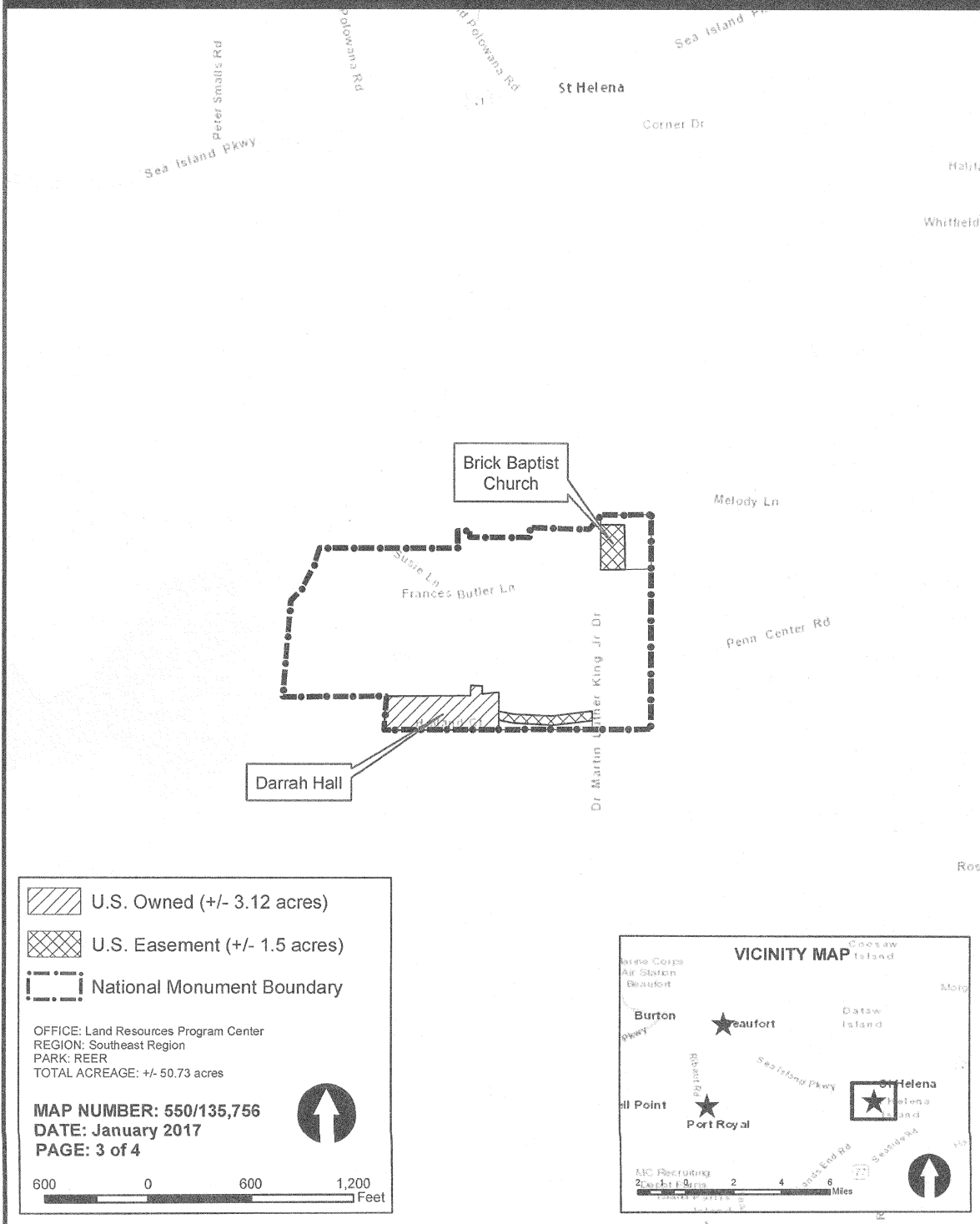
Reconstruction Era National Monument Camp Saxton

National Park Service
U.S. Department of the Interior

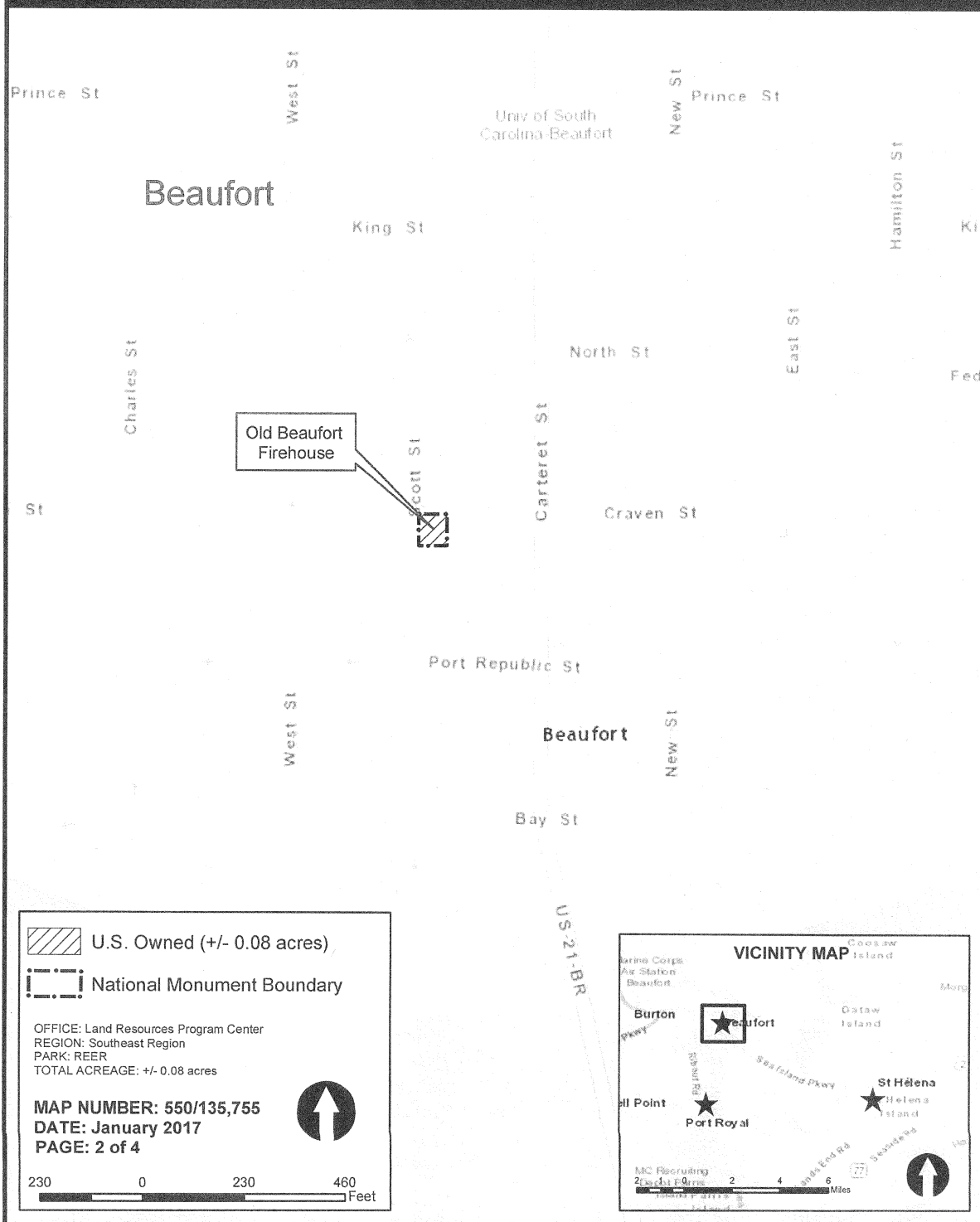


Reconstruction Era National Monument Darrah Hall and Brick Baptist Church

National Park Service
U.S. Department of the Interior

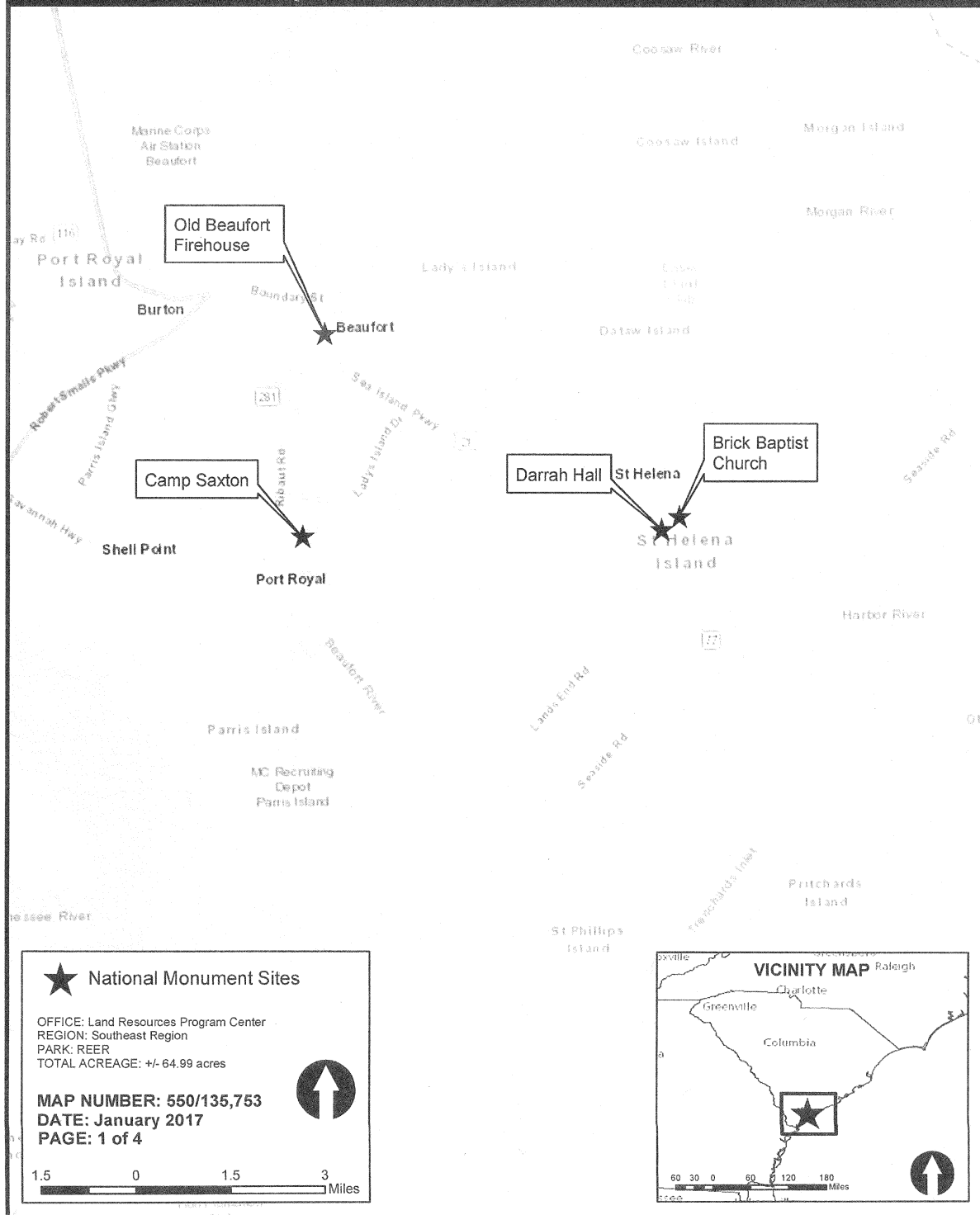


National Park Service
U.S. Department of the Interior



Reconstruction Era National Monument Overview Map

National Park Service
U.S. Department of the Interior



Presidential Documents

Memorandum of January 12, 2017

Promoting Diversity and Inclusion in Our National Parks, National Forests, and Other Public Lands and Waters

Memorandum for the Heads of Executive Departments and Agencies

Our Federal lands and waters are among our Nation's greatest treasures—from our National Parks and National Forests, to our wild and scenic rivers, recreation areas, and other public lands and waters. These natural and historic sites give us fresh air and clean water, places for recreation and inspiration, and support for our local communities and economies. As a powerful sign of our democratic ideals, these lands belong to all Americans—rich and poor, urban and rural, young and old, from all backgrounds, genders, cultures, religious viewpoints, and walks of life.

Our public lands and waters are treasured in part because they tell the story of our Nation. They preserve the history from our Nation's wars, protect cultural sites considered sacred to countless Americans, and honor the accomplishments of distinctly American leaders ranging from Harriet Tubman to Abraham Lincoln to Cesar Chavez. I am proud that my Administration has greatly expanded the stories that our protected public lands and waters tell about our Nation through designating a diverse collection of cultural and historic sites as new parks and monuments and by restoring the Koyukon Athabascan name of Denali to the tallest mountain in North America. I am proud, too, that my Administration has sought to expand access to our public lands and waters and to make them more welcoming to all Americans, especially those who have not regularly visited our Nation's great outdoors or had the means to do so easily. Initiatives like "Every Kid in a Park" complement additional, ongoing efforts by Federal agencies to improve accessibility, but more work must be done to honor the promise and opportunity of the idea that our public lands belong to every American. Over the last 8 years, Federal land and water management agencies have also shown a renewed commitment to promoting equal opportunity for all employees and in creating work environments where everyone is empowered to reach their full potential.

The purpose of this memorandum is to ensure that all Americans have the opportunity to experience and enjoy our public lands and waters, that all segments of the population have the chance to engage in decisions about how our lands and waters are managed, and that our Federal workforce—not just the sites it manages—is drawn from the rich range of the diversity in our Nation. In this memorandum, "diversity" refers to a range of characteristics including national origin, language, race, color, disability, ethnicity, age, religion, sexual orientation, gender (including gender identity), socioeconomic status, veteran status, and family structure. The term "inclusion" refers to a culture that connects each employee to the organization; encourages collaboration, flexibility, and fairness; and promotes diversity throughout the organization so that all individuals have opportunities to participate and contribute to their full potential.

This memorandum is directed at the Department of the Interior, the U.S. Forest Service, the Office of the Assistant Secretary of the Army for Civil Works, and the National Oceanic and Atmospheric Administration (covered agencies).

Promoting diversity and inclusion is not the sole responsibility of one office within a Federal agency but a joint effort that requires engagement by senior leadership and the entire workforce. In implementing the guidance in this memorandum, each covered agency shall ensure its diversity and inclusion practices are fully integrated into broader planning efforts and supported by sufficient resource allocations and effective programs that promote a wide range of investments in personnel development, public engagement, and opportunities for inclusive access.

Therefore, by the authority vested in me as President by the Constitution and the laws of the United States of America, I hereby direct the following:

Section 1. *Diversity and Inclusion in the Federal Workforce.* The quality and integrity of our National Parks, National Forests, and other public lands and waters depend on the public servants who steward them for the benefit of current and future generations. To ensure we are managing these resources responsibly, we must have a diverse and inclusive Federal workforce practicing public land management that recognizes the challenges facing communities across the Nation. A more diverse and inclusive Federal workforce also creates a more welcoming experience for all Americans, no matter their background or where they live, and encourages engagement with Federal agencies on the management and future of our public lands and waters. Consistent with existing authorities, each covered agency shall prioritize building a more diverse and inclusive Federal workforce reflective of our Nation and its citizens.

Federal agencies are subject to existing authorities aimed at addressing the leadership role and obligations of the Federal Government as an employer. For example, Executive Order 13583 of August 18, 2011 (Establishing a Coordinated Government-wide Initiative to Promote Diversity and Inclusion in the Federal Workforce), requires Federal agencies to take action to promote equal opportunity, diversity, and inclusion in the Federal workforce. Federal agencies also are required by section 717 of title VII of the Civil Rights Act of 1964 to take proactive steps to ensure equal opportunity for all Federal employees and applicants for Federal employment. This memorandum directs each of the covered agencies to pursue additional actions that create and maintain a diverse and inclusive Federal workforce. Toward that end, each covered agency shall integrate the following activities in its efforts to comply with related statutory mandates, Executive Orders, regulatory requirements, and individual agency policies:

(a) Provide professional development opportunities and tools. A diverse and inclusive work environment enhances the ability of each covered agency to create, retain, and sustain a strong workforce by allowing all employees to perform to their full potential and talent. Professional development opportunities and tools are key to fostering that potential, and ensuring that all employees have access to them should be a priority for all agencies, consistent with merit system principles. Accordingly, each covered agency shall:

- (i) Develop a mechanism to conduct periodic interviews with a voluntary representative cross-section of its workforce to gain a more complete understanding of the reasons that employees choose to stay with their organizations, as well as to receive feedback on workplace policies, professional development opportunities, and other issues;
- (ii) Provide optional exit interviews or surveys for all departing personnel;
- (iii) Collect information as needed to identify methods for attracting applicants to Federal employment and retaining diverse workplace talent through existing workforce programs and initiatives;
- (iv) Prioritize resources, as appropriate, to expand professional development opportunities that support mission needs, such as academic and fellowship programs, private-public exchanges, and detail assignments to private or international organizations, State, local and tribal governments, or other branches of the Federal Government;

(v) Offer, or sponsor employees to participate in, a Senior Executive Service Candidate Development Program or other program that trains employees to gain the skills required for senior-level appointments. Each covered agency shall consider the number of expected senior-level vacancies as one factor in determining the number of candidates to select for such programs. In the selection process for these programs, each covered agency shall consider redacting personal information, including applicant names, from all materials provided for review to reduce the potential for unconscious bias. Each covered agency also shall evaluate on a retroactive basis the placement rate of program graduates into senior-level positions, including available demographic data, on an annual basis to look for ways to improve outreach and recruitment for these programs consistent with merit system principles. Each covered agency shall consult with the Office of Personnel Management (OPM) on the development or enhancement of data-collection tools to conduct these evaluations; and

(vi) Seek additional opportunities for the development and implementation of upward mobility programs.

(b) Strengthen leadership engagement and accountability. Senior leadership and supervisors play an important role in fostering diversity and inclusion in the workforce they lead and setting an example for cultivating this and future generations of talent. Toward that end, each covered agency shall:

(i) Reward and recognize efforts to promote diversity and inclusion in the workforce. Consistent with merit system principles, each covered agency is strongly encouraged to consider implementing performance and advancement requirements that reward and recognize senior leaders' and supervisors' success in fostering diverse and inclusive workplace environments and in cultivating talent, such as through participation in mentoring programs or sponsorship initiatives, recruitment events, and other opportunities. Each covered agency also is encouraged to identify opportunities for senior leadership and supervisors to participate in outreach events and discuss issues related to promoting diversity and inclusion in its workforce on a regular basis with support from any existing employee resource group, as appropriate; and

(ii) Expand training on unconscious bias, diversity and inclusion, and flexible work policies. Each covered agency shall expand its provision of training on unconscious bias, diversity and inclusion, and flexible work policies and make unconscious bias training mandatory for senior leadership and management positions, including for employees responsible for outreach, recruitment, hiring, career development, promotion, and law enforcement. The provision of training may be implemented in a phased approach commensurate with agency resources. Each covered agency shall also make available training on a 2-year cycle for bureaus, directorates, or divisions for which inclusion scores, such as those measured by the New IQ index, demonstrate no improvement since the previous training cycle. Special attention should be given to ensure the continuous incorporation of research-based best practices, including those to address the relationship between certain demographics and job positions.

(c) Analyze existing data and identify opportunities for improvement. Each covered agency shall continue to evaluate and eliminate existing barriers to the successful growth of diversity and inclusion in the Federal workplace. The following actions shall be taken to ensure continued progress on this issue:

(i) Each covered agency shall integrate the activities described under subsections (a) and (b) of this section in the priorities and actions outlined in Executive Order 13583 and the periodic agency self-assessments and barrier analyses required by Equal Employment Opportunity Commission Management Directive 715, and shall make such assessments and analyses publicly available;

(ii) Human resources and any appropriate diversity and leadership staff from each of the covered agencies shall meet at least twice each year

with agency leadership to discuss actions pursued under sections 1(a) and 1(b) of this memorandum, including working to identify and eliminate barriers to promoting diversity and inclusion in agency workforces and to discuss potential actions to improve hiring programs, recruitment, and workforce training and development. Where data gaps are identified, each covered agency is encouraged to collect additional information as needed in order to identify methods for attracting and retaining talent from diverse populations, with particular attention to senior and management positions. Each covered agency shall consult with OPM on the development or enhancement of data-collection tools to collect this information; and

(iii) OPM shall continue to review covered agency-specific diversity and inclusion plans and provide recommended modifications for agency consideration, including recommendations on strategies to promote diversity and inclusion in agency workforces and potential improvements to the use of existing agency hiring authorities.

Sec. 2. *Enhancing Opportunities for all Americans to Experience Public Lands and Waters.* (a) Recognizing that our public lands belong to all Americans, it is critical that all Americans can experience Federal lands and waters and the benefits they provide, and that diverse populations are able to provide input to inform the management and stewardship of these important resources. In order to achieve this goal, each covered agency shall:

(i) Identify site-specific opportunities. As each covered agency periodically updates or develops new management plans for its lands and waters, it shall evaluate specific barriers and opportunities, as appropriate, to improve visitation, access, and recreational opportunities for diverse populations;

(ii) Update policies to ensure engagement with diverse constituencies. As policy manuals and handbooks are updated, each covered agency shall ensure that these materials reflect the importance of engaging with diverse populations in resource protection, land and water management, and program planning and decisionmaking, as appropriate;

(iii) Establish internal policies for recipients of Federal funding. Each covered agency shall ensure that State, local, tribal, and private sector recipients of Federal funding are taking action to improve visitation, access, and recreational opportunities for diverse populations;

(iv) Identify public liaisons. Within 90 days of the issuance of this memorandum, each covered agency shall identify multiple public liaisons with a diversity of backgrounds and perspectives to be charged with facilitating input from and engaging with diverse populations in land and water management processes;

(v) Identify opportunities on advisory councils and stakeholder committees. Within 120 days of the issuance of this memorandum, each covered agency shall identify opportunities to promote participation by diverse populations in advisory councils and stakeholder committees established to support public land or water management; environmental, public health, or energy development planning; and other relevant decisionmaking; and

(vi) Develop an action plan. Within 1 year of the issuance of this memorandum, each covered agency shall provide a publicly available action plan to the Chair of the White House Council on Environmental Quality identifying specific actions the agency will take to 1) improve access for diverse populations—particularly for minority, low-income, and disabled populations and tribal communities—to experience and enjoy our Federal lands and waters, and 2) address barriers to their participation in the protection and management of important historic, cultural, or natural areas. Each covered agency shall identify in its action plan any critical barriers to achieving both of these goals. This barrier evaluation should draw on internal staff input as well as external perspectives, including interviews, surveys, and engagement with non-governmental entities, as

appropriate and as resources allow. Each action plan should include specific steps that the covered agency will take to address identified barriers, including national as well as regional strategies, and, where appropriate, site-specific initiatives. Each covered agency should work through the Federal Recreation Council (FRC) to assist with the development of this action plan and use the FRC to share best practices and recommendations regarding specific programs and initiatives.

(b) In identifying actions to improve opportunities for all Americans to experience our Federal lands and waters, each covered agency should consider a range of actions including the following:

(i) Conducting active outreach to diverse populations—particularly minority, low-income, and disabled populations and tribal communities—to increase awareness about specific programs and opportunities;

(ii) Focusing on the mentoring of new environmental, outdoor recreation, and preservation leaders to increase diverse representation in these areas and on our public lands;

(iii) Forging new partnerships with State, local, tribal, private, and non-profit partners to expand access for diverse populations, particularly those in the immediate vicinity of a protected area;

(iv) Identifying and making improvements to existing programs to increase visitation and access by diverse populations—particularly minority, low-income, and disabled populations and tribal communities;

(v) Creating new programs, especially those that could address certain gaps that are identified;

(vi) Expanding the use of multilingual and culturally appropriate materials, including American Sign Language, in public communications and educational strategies, including through social media strategies, as appropriate, that target diverse populations;

(vii) Continuing coordinated, interagency efforts to promote youth engagement and empowerment, including fostering new partnerships with diversity- and youth-serving organizations and new partnerships with urban areas and programs; and

(viii) Identifying possible staff liaisons to diverse populations, particularly those in the immediate vicinity of a given protected area.

(c) In identifying actions to improve opportunities for all Americans to participate in the protection and management of important historic, cultural, and natural areas, each covered agency shall consider a range of actions including the following:

(i) Considering recommendations and proposals from diverse populations to protect at-risk historic, cultural, and natural sites;

(ii) Improving the availability and distribution of relevant information about ongoing land and water management planning and policy revisions;

(iii) Identifying agency staff charged with outreach to diverse populations;

(iv) Identifying opportunities to facilitate public participation from interested diverse populations facing financial barriers, including through partnerships, where appropriate, with philanthropic organizations and tribal, State, and local governments; and

(v) Taking other actions to increase opportunities for diverse populations to provide input and recommendations on protecting, improving access to, or otherwise managing important historic, cultural, or natural areas, with an emphasis on stakeholders facing significant barriers to participation.


Sec. 3. General Provisions. (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof, or the status of that department or agency within the Federal Government; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This memorandum shall be implemented consistent with applicable law, and subject to the availability of appropriations.

(c) The Secretary of the Interior is hereby authorized and directed to publish this memorandum in the *Federal Register*.

A handwritten signature in black ink, appearing to be "Donald Trump", with a large circular flourish and a horizontal line extending to the right.

THE WHITE HOUSE,
Washington, January 12, 2017.

Presidential Documents

Notice of January 13, 2017

Continuation of the National Emergency With Respect to Cuba and of the Emergency Authority Relating to the Regulation of the Anchorage and Movement of Vessels

On February 25, 2016, by Proclamation 9398, the national emergency with respect to Cuba was modified and continued to reflect the re-establishment of diplomatic relations between the United States and Cuba. The unauthorized entry of any U.S.-registered vessel into Cuban territorial waters continues to be detrimental to the foreign policy of the United States. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing the national emergency with respect to Cuba and the emergency authority relating to the regulation of the anchorage and movement of vessels set out in Proclamation 6867 as amended by Proclamation 7757 and as further modified by Proclamation 9398.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
January 13, 2017.

Presidential Documents

Notice of January 13, 2017

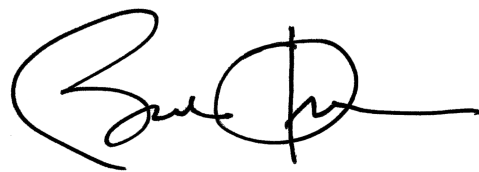
Continuation of the National Emergency With Respect to Iran

On March 15, 1995, by Executive Order 12957, the President declared a national emergency with respect to Iran to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States constituted by the actions and policies of the Government of Iran. On May 6, 1995, the President issued Executive Order (E.O.) 12959, imposing more comprehensive sanctions on Iran to further respond to this threat. On August 19, 1997, the President issued E.O. 13059, consolidating and clarifying the previous orders. I took additional steps pursuant to this national emergency in E.O. 13553 of September 28, 2010, E.O. 13574 of May 23, 2011, E.O. 13590 of November 20, 2011, E.O. 13599 of February 5, 2012, E.O. 13606 of April 22, 2012, E.O. 13608 of May 1, 2012, E.O. 13622 of July 30, 2012, E.O. 13628 of October 9, 2012, and E.O. 13645 of June 3, 2013.

On July 14, 2015, the P5+1 (China, France, Germany, Russia, the United Kingdom, and the United States), the European Union, and Iran reached a Joint Comprehensive Plan of Action (JCPOA) to ensure that Iran's nuclear program is and will remain exclusively peaceful. January 16, 2016, marked Implementation Day under the JCPOA, when the International Atomic Energy Agency (IAEA) issued a report verifying that Iran had completed key nuclear-related steps as specified in the JCPOA, and the Secretary of State confirmed the report's findings. As a result, the United States lifted nuclear-related sanctions on Iran consistent with its commitments under the JCPOA, including the termination of a number of Executive Orders that were issued pursuant to this national emergency. While nuclear-related sanctions were lifted pursuant to our JCPOA commitments, a number of non-nuclear sanctions remain in place.

Since Implementation Day, the IAEA has repeatedly verified, and the Secretary of State has confirmed, that Iran continues to meet its nuclear commitments pursuant to the JCPOA. However, irrespective of the JCPOA, which continues to ensure that Iran's nuclear program is and remains exclusively peaceful, certain actions and policies of the Government of Iran continue to pose an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States. For this reason, the national emergency declared on March 15, 1995, must continue in effect beyond March 15, 2017. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency with respect to Iran declared in E.O. 12957. The emergency declared by E.O. 12957 constitutes an emergency separate from that declared on November 14, 1979, by E.O. 12170. This renewal, therefore, is distinct from the emergency renewal of November 2016.

This notice shall be published in the *Federal Register* and transmitted to the Congress.

A handwritten signature in black ink, appearing to be "Donald Trump", with a large circular flourish and a vertical line through it.

THE WHITE HOUSE,
January 13, 2017.

[FR Doc. 2017-01367
Filed 1-18-17; 8:45 am]
Billing code 3295-F7-P

Presidential Documents

Notice of January 13, 2017

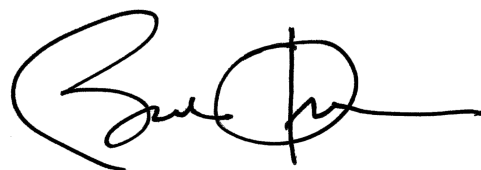
Continuation of the National Emergency With Respect to Libya

On February 25, 2011, by Executive Order 13566, I declared a national emergency pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the actions of Colonel Muammar Qadhafi, his government, and close associates, who took extreme measures against the people of Libya, including by using weapons of war, mercenaries, and wanton violence against unarmed civilians. In addition, there was a serious risk that Libyan state assets would be misappropriated by Qadhafi, members of his government, members of his family, or his close associates if those assets were not protected. The foregoing circumstances, the prolonged attacks, and the increased numbers of Libyans seeking refuge in other countries caused a deterioration in the security of Libya and posed a serious risk to its stability.

The situation in Libya continues to pose an unusual and extraordinary threat to the national security and foreign policy of the United States, and we need to protect against the diversion of assets or other abuse by certain members of Qadhafi's family and other former regime officials.

For this reason, the national emergency declared on February 25, 2011, must continue in effect beyond February 25, 2017. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 13566.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
January 13, 2017.

Presidential Documents

Notice of January 13, 2017

Continuation of the National Emergency With Respect to Ukraine

On March 6, 2014, by Executive Order 13660, I declared a national emergency pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the actions and policies of persons that undermine democratic processes and institutions in Ukraine; threaten its peace, security, stability, sovereignty, and territorial integrity; and contribute to the misappropriation of its assets.

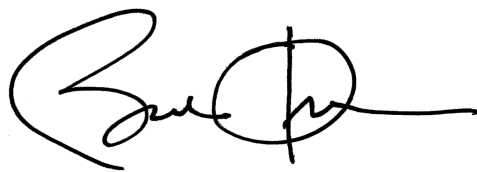
On March 16, 2014, I issued Executive Order 13661, which expanded the scope of the national emergency declared in Executive Order 13660, and found that the actions and policies of the Government of the Russian Federation with respect to Ukraine undermine democratic processes and institutions in Ukraine; threaten its peace, security, stability, sovereignty, and territorial integrity; and contribute to the misappropriation of its assets.

On March 20, 2014, I issued Executive Order 13662, which further expanded the scope of the national emergency declared in Executive Order 13660, as expanded in scope in Executive Order 13661, and found that the actions and policies of the Government of the Russian Federation, including its purported annexation of Crimea and its use of force in Ukraine, continue to undermine democratic processes and institutions in Ukraine; threaten its peace, security, stability, sovereignty, and territorial integrity; and contribute to the misappropriation of its assets.

On December 19, 2014, I issued Executive Order 13685, to take additional steps to address the Russian occupation of the Crimea region of Ukraine.

The actions and policies addressed in these Executive Orders continue to pose an unusual and extraordinary threat to the national security and foreign policy of the United States. For this reason, the national emergency declared on March 6, 2014, and the measures adopted on that date, on March 16, 2014, on March 20, 2014, and on December 19, 2014, to deal with that emergency, must continue in effect beyond March 6, 2017. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 13660.

This notice shall be published in the *Federal Register* and transmitted to the Congress.

A handwritten signature in black ink, appearing to be "Donald Trump", with a large circular flourish and a vertical line through it.

THE WHITE HOUSE,
January 13, 2017.

[FR Doc. 2017-01369
Filed 1-18-17; 8:45 am]
Billing code 3295-F7-P

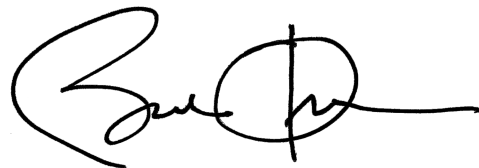
Presidential Documents

Notice of January 13, 2017

Continuation of the National Emergency With Respect to Venezuela

On March 8, 2015, I issued Executive Order 13692, declaring a national emergency with respect to the situation in Venezuela, including the Government of Venezuela's erosion of human rights guarantees, persecution of political opponents, curtailment of press freedoms, use of violence and human rights violations and abuses in response to antigovernment protests, and arbitrary arrest and detention of antigovernment protestors, as well as the exacerbating presence of significant government corruption. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 13692.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
January 13, 2017.

Presidential Documents

Notice of January 13, 2017

Continuation of the National Emergency With Respect to Zimbabwe

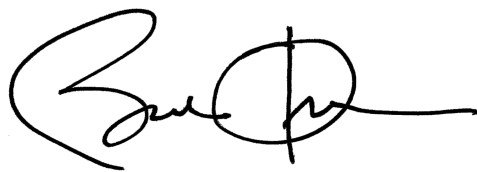
On March 6, 2003, by Executive Order 13288, the President declared a national emergency and blocked the property of certain persons, pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706), to deal with the unusual and extraordinary threat to the foreign policy of the United States constituted by the actions and policies of certain members of the Government of Zimbabwe and other persons to undermine Zimbabwe's democratic processes or institutions. These actions and policies had contributed to the deliberate breakdown in the rule of law in Zimbabwe, to politically motivated violence and intimidation in that country, and to political and economic instability in the southern African region.

On November 22, 2005, the President issued Executive Order 13391 to take additional steps with respect to the national emergency declared in Executive Order 13288 by ordering the blocking of the property of additional persons undermining democratic processes or institutions in Zimbabwe.

On July 25, 2008, the President issued Executive Order 13469, which expanded the scope of the national emergency declared in Executive Order 13288 and authorized the blocking of the property of additional persons undermining democratic processes or institutions in Zimbabwe.

The actions and policies of these persons continue to pose an unusual and extraordinary threat to the foreign policy of the United States. For this reason, the national emergency declared on March 6, 2003, and the measures adopted on that date, on November 22, 2005, and on July 25, 2008, to deal with that emergency, must continue in effect beyond March 6, 2017. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 13288.

This notice shall be published in the *Federal Register* and transmitted to the Congress.

A handwritten signature in black ink, appearing to be "Donald Trump", with a large circular flourish and a vertical line through it.

THE WHITE HOUSE,
January 13, 2017.

[FR Doc. 2017-01371
Filed 1-18-17; 8:45 am]
Billing code 3295-F7-P

Rules and Regulations

Federal Register

Vol. 82, No. 12

Thursday, January 19, 2017

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 532

RIN 3206-AN40

Prevailing Rate Systems; Definition of Kent County, Michigan, and Cameron County, Texas, to Nonappropriated Fund Federal Wage System Wage Areas

AGENCY: U.S. Office of Personnel Management.

ACTION: Final rule.

SUMMARY: This rule amends the geographic boundaries of two nonappropriated fund (NAF) Federal Wage System (FWS) wage areas. Based on recommendations of the Federal Prevailing Rate Advisory Committee (FPRAC), the U.S. Office of Personnel Management (OPM) is defining Kent County, Michigan, as an area of application county to the Macomb, MI, NAF FWS wage area and Cameron County, Texas, as an area of application county to the Nueces, TX, NAF FWS wage area. These changes are necessary due to NAF FWS employees working in Kent and Cameron Counties, and the counties are not currently defined to NAF wage areas.

DATES: *Effective date:* This regulation is effective on January 19, 2017.

Applicability date: This change applies on the first day of the first applicable pay period beginning on or after February 21, 2017.

FOR FURTHER INFORMATION CONTACT: Madeline Gonzalez, by telephone at (202) 606-2858 or by email at pay-leave-policy@opm.gov.

SUPPLEMENTARY INFORMATION: On August 24, 2016, OPM issued a proposed rule (81 FR 57809) to define Kent County, Michigan, as an area of application county to the Macomb, MI, NAF FWS wage area and Cameron County, Texas,

as an area of application county to the Nueces, TX, NAF FWS wage area.

FPRAC, the national labor-management committee responsible for advising OPM on matters concerning the pay of FWS employees, reviewed and recommended this change by consensus.

The proposed rule had a 30-day comment period, during which OPM received no comments.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they will affect only Federal agencies and employees.

List of Subjects in 5 CFR Part 532

Administrative practice and procedure, Freedom of information, Government employees, Reporting and recordkeeping requirements, Wages.

U.S. Office of Personnel Management.

Beth F. Cobert,

Acting Director.

Accordingly, OPM is amending 5 CFR part 532 as follows:

PART 532—PREVAILING RATE SYSTEMS

■ 1. The authority citation for part 532 continues to read as follows:

Authority: 5 U.S.C. 5343, 5346; § 532.707 also issued under 5 U.S.C. 552.

■ 2. The table in appendix D to subpart B is amended by revising the wage area listing for the Macomb, MI, and Nueces, TX, wage areas to read as follows:

Appendix D to Subpart B of Part 532—Nonappropriated Fund Wage and Survey Areas

* * * * *

DEFINITIONS OF WAGE AREAS AND WAGE AREA SURVEY AREAS

* * * * *

MICHIGAN Macomb

Survey Area

Michigan:
Macomb

Area of Application. Survey area plus:

Michigan:
Alpena
Calhoun
Crawford
Grand Traverse

DEFINITIONS OF WAGE AREAS AND WAGE AREA SURVEY AREAS—Continued

Huron
Iosco
Kent
Leelanau
Ottawa
Saginaw
Washtenaw
Wayne

Ohio:
Ottawa

* * * * *

TEXAS

* * * * *

Nueces

Survey Area

Texas:

Nueces

Area of Application. Survey area plus:

Texas:

Bee
Calhoun
Cameron
Kleberg
San Patricio
Webb

* * * * *

[FR Doc. 2017-00574 Filed 1-18-17; 8:45 a.m.]

BILLING CODE 6325-39-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 331

9 CFR Part 121

[Docket No. APHIS-2014-0095]

RIN 0579-AE08

Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List; Amendments to the Select Agent and Toxin Regulations

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: In accordance with the Agricultural Bioterrorism Protection Act of 2002, we are amending and republishing the list of select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products. The Act

requires the biennial review and republication of the list of select agents and toxins and the revision of the list as necessary. This action will amend the regulations in several ways, including the addition of provisions to address the inactivation of select agents, provisions addressing biocontainment and biosafety, and clarification of regulatory language concerning security, training, incident response, and records. These changes will increase the usability of the select agent regulations as well as providing for enhanced program oversight. After carefully considering the technical input of subject matter experts and recommendations from Federal advisory groups, we have decided not to finalize the proposed changes to the contents of the list of select agents and toxins at this time. In a companion document published in this issue of the **Federal Register**, the Centers for Disease Control and Prevention has made parallel regulatory changes.

DATES: Effective February 21, 2017.

FOR FURTHER INFORMATION CONTACT: Dr. Freeda Isaac, National Director, Agriculture Select Agent Services, APHIS, 4700 River Road, Unit 2, Riverdale, MD 20737–1231; (301) 851–3300, Option 3.

SUPPLEMENTARY INFORMATION:

Background

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (referred to below as the Bioterrorism Response Act) provides for the regulation of certain biological agents that have the potential to pose a severe threat to both human and animal health, to animal health, to plant health, or to animal plant health, or to animal and plant products. The Animal and Plant Health Inspection Service (APHIS) has the primary responsibility for implementing the provisions of the Act within the United States Department of Agriculture (USDA). Veterinary Services (VS) select agents and toxins are those that have been determined to have the potential to pose a severe threat to animal health or animal products. Plant Protection and Quarantine (PPQ) select agents and toxins are those that have the potential to pose a severe threat to plant health or plant products. Overlap select agents and toxins are those that have been determined to pose a severe threat to both human and animal health or to human health and animal products. Overlap select agents are subject to regulation by both APHIS and the Centers for Disease Control and Prevention (CDC), which has the

primary responsibility for implementing the provisions of the Bioterrorism Response Act for the Department of Health and Human Services (HHS).

Subtitle B (which is cited as the “Agricultural Bioterrorism Protection Act of 2002” and referred to below as the Act), section 212(a), provides, in part, that the Secretary of Agriculture (the Secretary) must establish by regulation a list of each biological agent and each toxin that the Secretary determines has the potential to pose a severe threat to animal or plant health, or to animal or plant products. Paragraph (a)(2) of section 212 requires the Secretary to review and republish the list every 2 years and to revise the list as necessary. In this document, we are amending and republishing the list of select agents and toxins based on the findings of our fourth biennial review of the list.

In determining whether to include an agent or toxin on the list, the Act requires that the following criteria be considered:

- The effect of exposure to the agent or the toxin on animal and plant health, and on the production and marketability of animal or plant products;
- The pathogenicity of the agent or the toxin and the methods by which the agent or toxin is transferred to animals or plants;
- The availability and effectiveness of pharmacotherapies and prophylaxis to treat and prevent any illness caused by the agent or toxin; and
- Any other criteria that the Secretary considers appropriate to protect animal or plant health, or animal or plant products.

We use the term “select agents and toxins” throughout the preamble of this rule. Unless otherwise specified, the term “select agents and toxins” will refer to all agents or toxins listed by APHIS. When it is necessary to specify the type of select agent or toxin, we will use the following terms: “PPQ select agents and toxins” (for the plant agents and toxins listed in 7 CFR 331.3), “VS select agents and toxins” (for the animal agents and toxins listed in 9 CFR 121.3), or “overlap select agents and toxins” (for the overlap agents and toxins listed in both 9 CFR 121.4 and 42 CFR 73.4).

On January 19, 2016, we published in the **Federal Register** (81 FR 2762–2774, Docket No. APHIS–2014–0095) a proposal¹ to amend and republish the list of select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or

plant products, and amend the regulations in order to add definitions and clarify language concerning security, training, biosafety, biocontainment, and incident response.

We solicited comments concerning our proposal for 60 days ending March 21, 2016. We received 24 comments by that date. They were from researchers, scientific organizations, industry groups, laboratories, and universities. Eighteen were supportive of the proposed action. The remaining six comments are discussed below by topic.

Removal of Select Agents and Toxins

We proposed to amend the list of PPQ select agents and toxins listed in 7 CFR 331.3 by removing three PPQ select agents and toxins from the list: *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*), *Sclerophthora rayssiae*, and *Phoma glycinicola* (formerly *Pyrenochaeta glycines*).

We also proposed to remove three overlap select agents and toxins from the list set out in 9 CFR 121.4(b): *Bacillus anthracis* (Pasteur strain), *Brucella abortus* and *Brucella suis*.

After carefully considering the technical input of subject matter experts and recommendations from Federal advisory groups, we have decided not to finalize the proposed changes to the list of select agents and toxins at this time.

Definitions

In 7 CFR 331.1 and 9 CFR 121.1, we proposed to add definitions for *inactivation* and *kill curve* to clarify terms contained within the proposed inactivation provisions. As detailed later in this final rule, we have removed the requirement for generation of a kill curve. We are therefore not including the definition in the regulations.

One commenter suggested that we specify that a “validated method” was used for inactivation. The commenter said that the addition of the word “validated” would ensure that tested and appropriate methods of inactivation would be utilized.

We are eliminating the definition for *inactivation* and instead adding a definition of *validated inactivation procedure* to the regulations. This definition encompasses the prior definition of inactivation as well as providing further detail which we believe will be useful for regulated entities. *Validated inactivation procedure* is defined as a procedure, whose efficacy is confirmed by data generated from a viability testing protocol, to render a select agent non-viable but allows the select agent to retain characteristics of interest for

¹ To view the proposed rule and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0095>.

future use; or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use. While the commenter suggested we use the term “method,” we have decided to use the term “procedure” in response to comments received on the CDC docket.

The same commenter suggested that we add definitions of *validated sterility test* and *safety margin* as these terms were both proposed for use in the biocontainment and biosafety sections and could prove confusing or be subject to misinterpretation.

Given that we are adding a definition of *validated inactivation procedure* as described previously, we are not adding a definition of *validated sterility test*. We are not adding a definition of *safety margin* since that term will not be in the regulations.

While we did not receive any further comments regarding definitions, in response to comments received by CDC and in the interests of maintaining parity between the APHIS and CDC regulations, we are adding a definition for *viability testing protocol*. That term, which is now used in §§ 331.3, 121.3, and 121.4, is defined as, “a protocol to confirm the validated inactivation procedure by demonstrating the inability of a select agent to replicate.”

Exclusions and Inactivation

We proposed to amend 7 CFR 331.3(d)(2), 9 CFR 121.3(d)(2), and 9 CFR 121.4(d)(2), which exclude nonviable select agents or nonfunctional toxins from the requirements of the regulations, in order to clarify our policy that an entity must use a validated procedure to render a select agent nonviable or regulated nucleic acids non-infectious for future use. This means that the method must be scientifically sound and that it will produce consistent results each time it is used.

One commenter stated that we need to consistently address toxins throughout the regulations and suggested adding language specifying that required methods would also render a select toxin as nonfunctional.

We did not include language concerning toxins because, unlike select agents, toxins do not replicate. An inactivation failure with a toxin therefore represents a lower level of risk and thus does not justify the potential additional recordkeeping and reporting burden for registered entities at this time. We may revisit this issue in the future.

We proposed that inactivation include the use of one of the following: The exact conditions of a commonly

accepted method that has been validated as applied (e.g., autoclaving), a published method with adherence to the exact published conditions (i.e., extrapolations or deductions are to be avoided), or in-house methods, only if validation testing includes the specific conditions used and appropriate controls.

The same commenter also suggested that we require that the inactivation process be repeatable.

We agree with the commenter that the inactivation process has to be validated so that the results are repeatable. The definition of *validated inactivation procedure* states that the procedure must be supported by data generated from viability testing. A process that is not repeatable would never be validated.

We also proposed that the entity develop a site-specific kill curve in order to define the conditions of inactivation for each select agent or regulated nucleic acid. If there are strain-to-strain variations in the resistance of a select agent to the inactivation procedure, then a specific kill curve would have to be developed for each strain that undergoes the inactivation procedure. A new kill curve would have to be created upon any change in procedure or inactivation equipment. In addition, a validated sterility testing protocol would have to be conducted in order to ensure that the inactivation method has rendered a select agent nonviable or regulated nucleic acids non-infectious.

Several commenters raised objections regarding development and use of the kill curve. We have considered these comments and determined that the kill curve and safety margin requirements are not applicable to all inactivation procedures and should therefore not be included in the regulations. We are instead requiring that registered entities develop a validated inactivation procedure by establishing parameters for quantities of starting material and measures of uncertainty for repeated successful inactivation. This is a broad performance standard that will allow for flexibility given the variety of select agents and toxins under regulation.² In addition, for the sake of clarity and efficiency, we have removed the requirements specific to extracts of select agents, instead including them within the overall performance standard for select agents and toxins as a whole.

One commenter said that, without more specific direction, the subjectivity

of individual inspectors would be the principal factor in determining acceptable inactivation verification.

We will not review or approve inactivation protocols. We believe this activity should be approved at the entity, which will allow for researchers to continue to develop new inactivation procedures. However, inspectors will verify that the entity has developed a validated inactivation procedure and will review viability testing results during the entity's inspection.

Another commenter asked that we provide minimum requirements for the sterility testing protocol and specify whether or not this must be site-specific or if validated methods of sterility testing given in published journal articles may be followed.

We recognize that the limits of detection of the viability testing procedures and expected variation from run to run, even when following an inactivation procedure precisely precludes demonstrating full sterility of an inactivated sample. These sources of error must be considered when the entity establishes performance parameters for inactivation procedures. While complete sterility is not a feasible goal for material that is intended for further use, we expect that the risk of live agent in materials that are removed from containment and are thus no longer subject to select agent requirements will be as low as realistically possible from both a safety and security perspective. We will be addressing the need for onsite validation of both inactivation protocols and viability testing in guidance.

The same commenter cited the guidance document entitled “Non-viable Select Agents and Nonfunctional Select Toxins and Rendering Samples Free of Select Agents and Toxins,”³ which states that, “this guidance does not apply to inactivation for waste disposal.” The commenter urged us to clearly and accurately describe what is intended regarding verification of non-viability in the regulations, stating that they had received comments from some inspectors indicating confusion between inactivation validation requirements for moving materials to a lower containment level and inactivation validation requirements for waste disposal.

We have modified the reporting requirements to require the responsible official to investigate any viability of material that was subjected to a validated inactivation protocol to

² Additional guidance regarding this performance standard has been developed and is available on the Internet at www.selectagents.gov.

³ You may view this guidance document on the Internet at <http://www.selectagents.gov/guidance-nonviable.html>.

determine the reason of the inactivation failure. If the responsible official is unable to determine the reason for this failure, he or she must report the inactivation failure to CDC or APHIS. Our intention is to require registered entities to create an environment where inactivation failures are investigated to determine the root source of the errors instead of re-subjecting the material to an inactivation method that may be flawed or faulty. The revised language only requires reporting of inactivation failures to CDC or APHIS when the responsible official cannot determine the reason for the inactivation failure. We are also clarifying that these provisions apply only to those select agents inactivated for future use as non-select agents and not those intended for waste disposal.

Two commenters asked about the minimum percentage of samples required to be tested to constitute a “representative sample.” Another commenter suggested that inactivated lots be stored with documentation that demonstrates that the lot has met the established standard, but added that it is impractical to conduct validated sterility testing on every sample that is inactivated. The commenter claimed that implementing such a requirement would waste specimens where limited volumes are available, be costly in terms of technical time and resources, and is scientifically unjustified.

Successful implementation of the required validated inactivation procedure and the subsequent data derived from viability testing using that procedure will determine the extent of sampling required. We have removed the sterility testing requirement to allow entities flexibility in establishing and utilizing individualized, validated inactivation procedures.

We also proposed to require that an entity conduct an annual review of their site-specific standard operating procedures to ensure that select agents or regulated nucleic acids that can produce infectious forms of any select agent virus are inactivated by a safety margin and revise as necessary.

Two commenters questioned our use of the term “safety margin.” The commenters requested that we remove or define the term, as its meaning is unclear. The commenters further stated that the need for including a safety margin is unclear and appears superfluous if the intent of the requirement is to define the conditions that achieve conditions that render 100 percent of the select agent non-viable or noninfectious.

We are not defining “safety margin” as the proposed regulatory text using

this term will not be incorporated into the final rule.

Finally, we proposed that written records be kept for any select agent that has been rendered nonviable or regulated nucleic acids that have been rendered non-infectious.

Two commenters asked for clarification of the actions constituting review, including description of any documentation that will be expected to demonstrate compliance with the requirement. The commenters wanted to know if it was our expectation that the kill curve and sterility testing be repeated and verified annually, or if this is a review of data and written procedures.

In response, we have modified the language regarding review of site-specific standard operating inactivation procedures to clarify that the entity should review these procedures to determine if they are being adhered to by staff. The annual review requirement does not necessarily involve revalidating inactivation procedures. This review may simply take the form of an evaluation of the site-specific standard operating inactivation procedures to ensure the inactivation conditions used and upper agent limits found in validation data are consistent and that the entity staff are following the site-specific standard operating inactivation procedures. At times an entity may need to revalidate inactivation procedures during the annual review. For example, review may be needed if the entity finds that staff are not adhering to standard operating procedures or if the entity wants to deviate from the established, validated inactivation procedure.

While we did not receive any further comments on this issue, in response to comments received by CDC and in the interests of maintaining parity between the APHIS and CDC regulations, we have made the following changes:

- Establishing that surrogate strains that are known to possess properties equivalent to select agents may be used to validate the required inactivation procedures under certain conditions;
- Replacing the term “extract” with “material containing a select agent” to clarify that the inactivation requirements apply to such materials as serums or liquid cultures from which select agents are typically removed via filtration without first undergoing inactivation. This is intended to more accurately describe an element of a two-step process: An inactivation step to destroy the select agent and a second step intended to remove any remaining, viable select agent; and

- Clarification of when an entity may submit a waiver request to the Administrator as well as the procedure for such determinations.

Finally, in 7 CFR 331.3(d)(2), 9 CFR 121.3(d)(2), and 9 CFR 121.4(d)(2), we are replacing the term “nonfunctional toxin” with “nontoxic toxin.” We have determined that the term “nonfunctional” is overbroad and has caused confusion. Our intent was to exclude toxins that can no longer exert their toxic effect and cause disease. For example, Botulinum neurotoxin has three functional domains: Binding domain, translocation domain, and catalytic domain. Each functional domain may be solely manipulated such that the toxin is no longer toxic and does not cause disease even though the other two domains may remain functional. Note that the example provided is for a CDC toxin due to the fact that APHIS does not currently regulate any select toxins.

Exemptions for Select Agents and Toxins

The provisions of 7 CFR 331.5, 9 CFR 121.5, and 9 CFR 121.6 concern conditions under which entities may be exempted from the requirements of the regulations. We proposed to add language to paragraph (a) in 7 CFR 331.5, 9 CFR 121.5, and 9 CFR 121.6 that specifies that entities may be required to report identification of agents or toxins to other appropriate authorities when required by Federal, State, or local law. Specifically, we proposed to add provisions that state that we do not regulate material containing select agents or toxins when it is in a patient care setting and is not being collected or otherwise tested or retained, nor do we regulate waste generated during delivery of patient care. However, once delivery of patient care for the select agent or toxin infection has concluded, waste would become subject to the requirements of the regulations. If an entity cannot meet these requirements, then the material may be transferred to another entity according to the select agent regulations or destroyed using an approved method. The decision to retain, transfer, or destroy any specimens must be made within 7 calendar days of the conclusion of patient care.

One commenter disagreed with adding such a provision to 9 CFR 121.5. The commenter said that VS should have authority to regulate waste and carcasses from animals (*i.e.*, veterinary patients) naturally infected with select agents to ensure that infection does not spread to other livestock or poultry. The commenter asked that we alter the

wording of the proposed section in order to specify that the requirement refers to human patients only.

The provisions the commenter refers to relate to the care of human patients only. However, it should be noted that any waste or carcasses from animals infected with a select agent, provided the select agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source, are already listed as excluded in §§ 121.3(d)(1) and 121.4(d)(1) of the regulations.

While we did not receive any further comments on this issue, in response to comments received by CDC and in the interests of maintaining parity between the APHIS and CDC regulations, we are amending the text to clarify the following:

- That patient care refers to actions by health care professionals;
- To clarify that destruction and transfer requirements apply solely to waste generated in the course of patient care and not specimens or samples taken from the patient; and
- That specimens taken from a patient are not subject to the regulations during the period in which they are directly associated with the diagnosis, but all specimens taken and kept more than 7 days after the conclusion of patient care are subject to the regulations.

Security, Biocontainment/Biosafety, and Incident Response Plans

The regulations require registered entities to develop and implement a number of plans in order to ensure the safety and security of the select agents they handle. These are:

- A security plan, as described by the regulations in 7 CFR 331.11 and 9 CFR 121.11, that provides for measures sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release;
- A biocontainment plan, in the case of PPQ select agents, or a biosafety plan, in the case of VS and overlap select agents, as described in the regulations in 7 CFR 331.12 and 9 CFR 121.12, that provides for measures sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards); and
- An incident response plan, as described in the regulations in 7 CFR 331.14 and 9 CFR 121.14, that provides for measures that the registered entity will implement in the event of theft, loss, or release of a select agent or toxin; inventory discrepancies; security breaches (including information systems); severe weather and other

natural disasters; workplace violence; bomb threats and suspicious packages; and emergencies such as fire, gas leak, explosion, power outage, etc. The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such agent or toxin.

All of these plans require annual review and revision as necessary. Drills or exercises must also be conducted at least annually to test and evaluate the effectiveness of the plans. The plans must be reviewed and revised, as necessary, after any drill or exercise and after any incident. We proposed to require that these drills or exercises be documented to include how the drill or exercise tested and evaluated the plan, any problems identified, any corrective action taken, and the names of the individuals who participated in the drill or exercise. This will provide a more thorough accounting of required activities as well as increasing the efficacy of the plans via testing and entity-directed improvements. We proposed to add these requirements to 7 CFR 331.11(h), 331.12(e), 331.14(f), 9 CFR 121.11(h), 121.12(e), and 121.14(f).

One commenter stated that the requirement to record the names of the individuals who participated in a given drill or exercise should be limited to registered entity personnel and not include first responders or others who participate. The commenter suggested that a list of the participating external agencies (e.g., emergency management, emergency medical services, fire department, etc.) could be included.

We agree with the commenter's suggestion and have updated the regulations in order to clarify that only the names of individuals at the registered entity are required to be listed. The entity may choose to list the names of external agencies (e.g., fire department, police department, etc.) that participated in the drill or exercise.

Comments on more specific proposed changes to these plans may be found below.

Biocontainment/Biosafety Plan

Paragraph (a) of 7 CFR 331.12 and 9 CFR 121.12 requires that the biocontainment or biosafety plan contain sufficient information and documentation to describe the biosafety and containment procedures for each select agent or toxin that the registered entity will possess. The plan must also include a description of the biosafety and containment procedures for any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. We proposed to additionally require that

laboratory-specific biocontainment and/or biosafety manuals must be accessible to individuals working in those laboratories. This change will help to foster an enhanced culture of responsibility by ensuring that appropriate biocontainment and/or biosafety resources are available to all staff with access to select agents and toxins within a select agent laboratory.

One commenter suggested that the specific practice of making manuals accessible is already employed by registered entities. The commenter therefore questioned the need for a separate requirement.

We agree with the commenter and have removed the requirement.

Two commenters urged that, "a description of the biosafety and containment procedures for any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent" should clearly refer not only to animals within the laboratory but also wildlife, domestic, and stray animals outside of the buildings if they are potentially exposed via accidental release. The commenter added that there should be a system in place to detect such incidents if they occur.

The term "any animals" includes both laboratory animals as well as the wild, domestic, and stray animals described by the commenters. We will, however, add specific clarification to the guidance documents associated with the biocontainment and biosafety plans.

One commenter requested clarification regarding the term "laboratory." The commenter wanted to know whether the term refers to a single room, a building, or to a group of rooms (e.g., laboratory, animal room, and necropsy) used by a principal investigator for a research project. The commenter also requested clarification regarding the phrase, "must be available to each individual working in the laboratory," asking if this would require creation of a specific biocontainment or biosafety manual for each room.

We have clarified the language to state that "biosafety and containment procedures specific to use of the select agent or toxin by the principal investigator must be available to each individual involved with that project." This more appropriately ties the creation and distribution of biocontainment and biosafety manuals to specific projects, select agents, and people.

We also proposed to add specific provisions to the biocontainment and biosafety plans that would require completion of a written risk assessment for each procedure.

Two commenters stated that these requirements are unnecessary and would prove excessively burdensome to researchers and the responsible official and should be removed. The commenters said that the new requirements regarding validation of inactivation procedures would serve the same security function. The commenters added that APHIS already has opportunity to review and require amendment of an entity's biocontainment or biosafety plan as a condition of registration or as a result of inspection.

We agree with the commenter that this level of detail would prove unnecessarily burdensome. We have instead added language to 7 CFR 331.12(a)(1) and 9 CFR 331.12(a)(1) to explicitly require that the biocontainment and biosafety plans include a description of the hazardous characteristics of each agent or toxin listed on the entity's registration and the biosecurity or biosafety risk associated with laboratory procedures related to the select agent or toxin.

One commenter asked that we define "risk assessment," given that it is a very broad term and therefore open to interpretation. This commenter and another requested that we provide basic templates for these new required sections and indicate where registered entities and entities seeking registration may find these templates.

We have revised and condensed the proposed language as a result of this and other comments. It no longer includes the term "risk assessment."

Training

We proposed to amend the regulations in 7 CFR 331.15 and 9 CFR 121.15, which concern provision of mandatory training for staff and visitors who work in or visit areas where select agents or toxins are handled or stored. We proposed to require that all individuals who have received approval to have access to select agents and toxins must undergo training regardless of whether they have access to those select agents or toxins. The training would have to be completed within a year of that individual's approval or prior to entry into an area where select agents and toxins are used or stored, whichever occurs first.

Two commenters objected to the proposed addition, stating that we should include a description of the level of training necessary for personnel in varying positions with highly disparate job duties and responsibilities. The commenters requested that we clarify that required training will be conducted at a level appropriate to the registered

person's role and level of access to select agents.

We agree with the commenters' point and have altered the required training language to clearly delineate the types of training required for individuals with varying access levels.

One commenter asked that we clearly specify the requirements for both initial and annual training. The commenter also asked that we consider making training a prerequisite for access to select agents and toxins.

While we made no changes to our regulatory language based on this comment, the document entitled, "Guidance for Meeting the Training Requirements of the Select Agent Regulations"⁴ will be updated to provide further detail and assistance regarding the content of initial and annual training. The regulations in 7 CFR 331.15(a)(1) and 9 CFR 121.15(a)(1) already require that each approved individual receive information and training on biosecurity/biosafety, security (including security awareness), and incident response before that individual has access to any select agents and toxins.

Records

The regulations in 7 CFR 331.17 and 9 CFR 121.17 concern required recordkeeping procedures for regulated entities as those records relate to select agents and toxins. Paragraph (a)(3)(x) requires that registered entities record the destruction of any toxins by specifically noting the quantity of toxin destroyed, the date of such action, and by whom. However, there is not an equivalent requirement regarding the destruction of select agents. We proposed to add this requirement in order to ensure consistency with the toxin provisions and ensure proper tracking of select agents from acquisition to destruction.

While we did not receive any comments on this issue, in response to comments received by CDC and in the interests of maintaining parity between the APHIS and CDC regulations, we are amending the text to stipulate that registered entities must maintain a record of the select agent used, purpose of use, and, when applicable, final disposition (including destruction) for each select agent held in long-term storage.

We also proposed to state that any records created that contain information related to an entity's registration or its select agents and toxins must be

provided promptly upon request. We proposed to specify that such records may include, but are not limited to, biocontainment certifications, laboratory notebooks, institutional biosafety and/or animal use committee minutes and approved protocols, and records associated with occupational health and suitability programs.

One commenter expressed concern regarding the requirement to keep laboratory notebooks for inspection purposes. The commenter stated that items may include proprietary intellectual property and requested clarification regarding the information needed from the notebooks. The commenter asked that we amend the regulatory language in order to protect intellectual property interests and specify if any information would be required from laboratory notebooks apart from that collected for inventory purposes.

We agree with the commenter and we have clarified that only information related to the requirements of the regulations must be produced upon request. Such information may be found in biocontainment certifications, laboratory notebooks, institutional biosecurity/biosafety and/or animal use committee minutes and approved protocols, and records associated with occupational health and suitability programs. Accordingly, we will only be reviewing relevant portions of any laboratory notebooks or documents and only if they contain information related to any requirements of the regulations.

To ensure the accuracy of handwritten records, we also proposed to specify that such records must be legible.

Another commenter suggested that we require that records be written in ink and not pencil and should be signed and dated when appropriate.

We acknowledge this suggestion as good practice. However, in the interests of not being overly prescriptive, we are leaving the interpretation of "legible" up to individual registered entities.

Records for Select Agents in Long-Term Storage

Paragraph (a)(1) in both 7 CFR 331.17 and 9 CFR 121.17 requires entities to maintain an accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) held in long-term storage. We continue to receive comments critical of that portion of the regulations. Criticism is typically focused on the belief that a container-based inventory requirement is not a

⁴ You may view this document on the Internet at <http://www.selectagents.gov/guidance-training.html>.

useful mechanism to track inventory of biological agents, since small amounts could be stolen without detection and used to grow larger quantities.

However, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 obliges APHIS and CDC to include a requirement for “the prompt notification of the Secretary, and appropriate Federal, State, and local law enforcement agencies, of the theft or loss of listed agents and toxins” in the regulations. We therefore solicited comment regarding what regulatory requirement or requirements should be implemented such that a registered entity could quickly determine whether a select agent had been lost or stolen from long-term storage without that registered entity first having an accurate, current inventory for each select agent held in long-term storage. Additionally, we solicited ideas concerning ways in which the current regulations could be amended to address the possibility of theft of a select agent from a container held in long-term storage.

One commenter stated that, while they understand the need for such inventory and notification requirements, an enormous amount of time and effort is spent during inspections validating that inventories are accurate. The commenter said that this has resulted in the loss of valuable virus isolates due to unintentional thawing, failure of ultralow temperature freezers due to repeated opening and the resulting loss of ultralow temperature, and inefficient use of employee time. The commenter said that measuring the volumes of stored vials of bacteria and viruses in the manner that toxins or other non-replicative select agents are inventoried is illogical. The commenter acknowledged that it is important to indicate the nature of the pathogens stored and the numbers of vials in freezer stocks, but even the most fastidious recordkeeping could not demonstrate that vials of replicative organisms had not been accessed. The commenter stated that current select agent practices allow for these stocks to be maintained in tamper-evident stocks (e.g., security ties on freezer boxes) so that vials are not individually removed, thawed, and measured. The commenter concluded that requiring the use of tools of this nature in the case of replicative organisms is a logical step that would not eliminate the need to inventory, but which also would not degrade samples and allow for detection of samples that may have disappeared.

We appreciate this comment and will continue to consider how the recognition of theft and loss might be

addressed through alternative approaches.

Miscellaneous Changes

We are also adding a definition of *principal investigator* to the regulations in 7 CFR 331.1 and 9 CFR 121.1 as it is used but not defined in the APHIS regulations. The addition also serves to maintain parity with the CDC regulations. Our definition is identical to that used by CDC.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule with the changes discussed in this document.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

In accordance with 5 U.S.C. 604, we have performed a final regulatory flexibility analysis, which is summarized below, regarding the economic effects of this rule on small entities. Copies of the full analysis are available on the *Regulations.gov* Web site (see footnote 1 in this document for a link to *Regulations.gov*) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Sections 201 and 212(a)(2) of the Act require a biennial review and republication of the select agent and toxin list, with revisions as appropriate in accordance with this law. This final rule will implement the recommendations of the fourth biennial review of select agent regulations and has finalized changes that will increase their usability as well as provide for enhanced program oversight. These amendments include new provisions regarding the inactivation of select agents, specific biosafety and toxin requirements and clarification of regulatory language concerning security, training, and records. The final rule will require that entities develop a validated inactivation procedure by establishing parameters for quantities of starting material and measures of uncertainty for repeated successful inactivation. This is a broad performance standard that will allow for flexibility given the variety of select agents and toxins under regulation to define conditions of inactivation for each select agent or regulated infectious nucleic acid and maintain written records of having done so. Costs of complying with this amendment are expected to be modest.

Currently, there are 291 entities registered with APHIS and CDC. Of

these entities, there are 240 registered to possess Tier 1 select agents and toxins, including 78 academic, 29 commercial, 80 State government, 37 Federal government, and 16 private (non-profit) institutions, most of which are considered to be small entities. Based on current recordkeeping and reporting requirements, an additional 10 to 20 hours per year may be required for maintaining records associated with select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agents. At an imputed cost of \$33.40 per hour (GS-12, step 2), this additional time requirement per entity will cost between \$334 and \$668 per year, or in total for all registered entities between \$80,000 and \$160,000. Assuming that costs of the rule could be considered to be significant if they exceeded 1 percent of revenue earned by the affected entities, revenues would need to average less than \$33,400 to \$66,800 for this to be the case. While the vast majority of the entities in industries potentially affected by this rule, other than post-secondary institutions, can be considered small, average annual revenues are well above this range.

Due to the reasons summarized here and explained in the analysis accompanying this rule, the Administrator certifies that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and

Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

The Animal and Plant Health Inspection Service has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a Tribe requests consultation, the Animal and Plant Health Inspection Service will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the reporting, recordkeeping, and third-party disclosure requirements included this rule are in the process of being reinstated by the Office of Management and Budget under 0579–0213.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at 301–851–2483.

List of Subjects

7 CFR Part 331

Agricultural research, Laboratories, Plant diseases and pests, Reporting and recordkeeping requirements.

9 CFR Part 121

Agricultural research, Animal diseases, Laboratories, Medical research, Reporting and recordkeeping requirements.

Accordingly, 7 CFR part 331 and 9 CFR part 121 are amended as follows:

Title 7—Agriculture

PART 331—POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

■ 1. The authority citation for part 331 continues to read as follows:

Authority: 7 U.S.C. 8401; 7 CFR 2.22, 2.80, and 371.3.

■ 2. Section 331.1 is amended by adding, in alphabetical order,

definitions of *principal investigator*, *validated inactivation procedure*, and *viability testing protocol* to read as follows:

§ 331.1 Definitions.

* * * * *

Principal investigator. The one individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program.

* * * * *

Validated inactivation procedure. A procedure, whose efficacy is confirmed by data generated from a viability testing protocol, to render a select agent non-viable but allows the select agent to retain characteristics of interest for future use; or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use.

* * * * *

Viability testing protocol. A protocol to confirm the validated inactivation procedure by demonstrating the material is free of all viable select agent.

■ 3. Section 331.3 is amended as follows:

■ a. By revising paragraph (d)(2).

■ b. By redesignating paragraph (d)(3) as paragraph (d)(9)

■ c. By adding paragraphs (d)(3) through (8) and (e)(3).

The additions and revision read as follows:

§ 331.3 PPQ select agents and toxins.

* * * * *

(d) * * *

(2) Nonviable select agents or nontoxic toxins.

(3) A select agent or toxin that has been subjected to decontamination or a destruction procedure when intended for waste disposal.

(4) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol. Surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactivation procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.

(5) Material containing a select agent that is subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material

is subjected to a viability testing protocol to ensure that the removal method has rendered the material free of all viable select agent.

(6) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus not subjected to a validated inactivation procedure or material containing a select agent not subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is determined by the Administrator to be effectively inactivated or effectively removed. To apply for a determination an individual or entity must submit a written request and supporting scientific information to APHIS. A written decision granting or denying the request will be issued.

(7) A PPQ select toxin identified in an original food sample or clinical sample.

(8) Waste generated during the delivery of patient care by health care professionals from a patient diagnosed with an illness or condition associated with a select agent, where that waste is decontaminated or transferred for destruction by complying with State and Federal regulations within 7 calendar days of the conclusion of patient care.

* * * * *

(e) * * *

(3) An individual or entity may make a written request to the Administrator for reconsideration of a decision denying an application for the exclusion of an attenuated strain of a select agent or a select toxin modified to be less potent or toxic. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

* * * * *

■ 4. Section 331.5 is amended as follows:

■ a. By revising paragraph (a)(1).

■ b. In paragraph (a)(2), by removing “; and” and adding a period in its place.

■ c. By revising paragraph (a)(3).

The revisions read as follows:

§ 331.5 Exemptions.

(a) * * *

(1) Unless directed otherwise by the Administrator, within 7 calendar days after identification of the select agent or toxin, the select agent or toxin is transferred in accordance with § 331.16 or destroyed on-site by a recognized sterilization or inactivation process.

* * * * *

(3) The identification of the agent or toxin is reported to APHIS or CDC, the specimen provider, and to other appropriate authorities when required by Federal, State, or local law by telephone, facsimile, or email. This report must be followed by submission of APHIS/CDC Form 4 to APHIS or CDC within 7 calendar days after identification.

* * * * *

■ 5. Section 331.7 is amended as follows:

■ a. By redesignating paragraphs (b) through (k) as paragraphs (c) through (l), respectively.

■ b. By adding a new paragraph (b).

The addition reads as follows:

§ 331.7 Registration and related security risk assessments.

* * * * *

(b) As a condition of registration, each entity is required to be in compliance with the requirements of this part for select agents and toxins listed on the registration regardless of whether the entity is in actual possession of the select agent or toxin. With regard to toxins, the entity registered for possession, use, or transfer of a toxin must be in compliance with the requirements of this part regardless of the amount of toxins currently in its possession.

* * * * *

■ 6. Section 331.9 is amended as follows:

■ a. By removing the semicolons at the ends of paragraphs (a)(1) through (4) and “; and” at the end of paragraph (a)(5) and adding periods in their place.

■ b. In paragraph (a)(6), by removing the word “laboratory” and adding the words “registered space” in its place and by adding the words “and the corrections documented” at the end of the second sentence after the words “must be corrected”.

■ c. By adding paragraphs (a)(7), (8), and (9).

The additions read as follows:

§ 331.9 Responsible official.

(a) * * *

(7) Ensure that individuals are provided the contact information for the USDA Office of Inspector General Hotline and the HHS Office of Inspector General Hotline so that they may anonymously report any biosafety/biocontainment or security concerns related to select agents and toxins.

(8) Investigate to determine the reason for any failure of a validated inactivation procedure or any failure to remove viable select agent from material. If the responsible official is

unable to determine the cause of a deviation from a validated inactivation procedure or a viable select agent removal method; or receives any report of any inactivation failure after the movement of material to another location, the responsible official must report immediately by telephone or email the inactivation or viable agent removal method failure to APHIS or CDC.

(9) Review, and revise as necessary, each of the entity’s validated inactivation procedures or viable select agent removal methods. The review must be conducted annually or after any change in principal investigator, change in the validated inactivation procedure or viable select agent removal method, or failure of the validated inactivation procedure or viable select agent removal method. The review must be documented and training must be conducted if there are any changes to the validated inactivation procedure, viable select agent removal method, or viability testing protocol.

* * * * *

■ 7. In § 331.10, paragraph (e) is amended by adding a sentence at the end of the paragraph to read as follows:

§ 331.10 Restricting access to select agents and toxins; security risk assessments.

* * * * *

(e) * * * A responsible official must immediately notify the responsible official of the visiting entity if the person’s access to select agents or toxins has been terminated.

* * * * *

■ 8. Section 331.11 is amended as follows:

■ a. In paragraph (c)(5), by adding the word “keycards,” after the word “keys,” and by removing the word “numbers” and adding the word “permissions” in its place.

■ b. In paragraph (d)(7)(iv), by removing the word “and”.

■ c. By adding paragraph (d)(7)(vi).

■ d. By adding a sentence at the end of paragraph (h).

The additions read as follows:

§ 331.11 Security.

* * * * *

(d) * * *

(7) * * *

(vi) Any loss of computer, hard drive or other data storage device containing information that can be used to gain access to select agents or toxins; and

* * * * *

(h) * * * Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan,

any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.

■ 9. Section 331.12 is amended as follows:

■ a. By revising paragraph (a).

■ b. By adding a sentence at the end of paragraph (e).

The addition and revision read as follows:

§ 331.12 Biocontainment.

(a) An individual or entity required to register under this part must develop and implement a written biocontainment plan that is commensurate with the risk of the select agent or toxin, given its intended use.⁴ The biocontainment plan must contain sufficient information and documentation to describe the biocontainment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. The current biocontainment plan must be submitted for initial registration, renewal of registration, or when requested. The biocontainment plan must include the following provisions:

(1) The hazardous characteristics of each agent or toxin listed on the entity’s registration and the biocontainment risk associated with laboratory procedures related to the select agent or toxin;

(2) Safeguards in place with associated work practices to protect entity personnel, the public, and the environment from exposure to the select agent or toxin including, but not limited to: Personal protective equipment and other safety equipment; containment equipment including, but not limited to, biological safety cabinets, animal caging systems, and centrifuge safety containers; and engineering controls and other facility safeguards;

(3) Written procedures for each validated method used for disinfection, decontamination, or destruction, as appropriate, of all contaminated or presumptively contaminated materials including, but not limited to: Cultures and other materials related to the propagation of select agents or toxins, items related to the analysis of select agents and toxins, personal protective equipment, arthropod containment systems, extracted plant and/or arthropod tissues, laboratory surfaces and equipment, and effluent material; and

(4) Procedures for the handling of select agents and toxins in the same

⁴ Technical assistance and guidance may be obtained by contacting APHIS.

spaces with non-select agents and toxins to prevent unintentional contamination.

* * * * *

(e) * * * Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.

■ 10. Section 331.14 is amended as follows:

■ a. By adding a sentence at the end of paragraph (a).

■ b. By adding a sentence at the end of paragraph (f).

The additions read as follows:

§ 331.14 Incident response.⁵

(a) * * * The current incident response plan must be submitted for initial registration, renewal of registration, or when requested.

* * * * *

(f) * * * Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.

■ 11. Section 331.15 is amended as follows:

■ a. By revising paragraph (a).

■ b. By adding paragraph (e).

The addition and revision read as follows:

§ 331.15 Training.

(a) An individual or entity required to register under this part must provide information and training on biocontainment, biosafety, security (including security awareness), and incident response to:

(1) Each individual with access approval from the Administrator or HHS Secretary. The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins. The training must be accomplished prior to the individual's entry into an area where a select agent is handled or stored, or within 12 months of the date the individual was approved by the Administrator or the HHS Secretary for access, whichever is earlier.

(2) Each individual not approved for access to select agents and toxins by the Administrator or HHS Secretary before that individual enters areas under escort where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms,

greenhouses, storage areas, shipping/receiving areas, production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored. The training must be accomplished prior to the individual's entry into where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.).

* * * * *

(e) The responsible official must ensure and document that individuals are provided the contact information of the USDA Office of Inspector General Hotline and the HHS Office of Inspector General Hotline so that they may anonymously report any safety or security concerns related to select agents and toxins.

■ 12. In § 331.16, paragraph (b) introductory text is revised to read as follows:

§ 331.16 Transfers.

* * * * *

(b) A transfer may be authorized if:

* * * * *

■ 13. Section 331.17 is amended as follows:

■ a. In paragraph (a)(1)(iii), by adding the words "or other storage container" after the word "freezer".

■ b. By revising paragraph (a)(1)(v).

■ c. In paragraph (a)(3)(v), by adding the words "or other storage container" after the word "freezer".

■ d. By removing the word "and" at the end of paragraph (a)(6) and removing the period at the end of paragraph (a)(7) and adding "; and" in its place.

■ e. By adding paragraph (a)(8).

■ f. By revising paragraphs (b) and (c).

The addition and revisions read as follows:

§ 331.17 Records.

(a) * * *

(1) * * *

(v) The select agent used, purpose of use, and, when applicable, final disposition;

* * * * *

(8) For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent:

(i) A written description of the validated inactivation procedure or viable select agent removal method used, including validation data;

(ii) A written description of the viability testing protocol used;

(iii) A written description of the investigation conducted by the entity responsible official involving an inactivation or viable select agent removal failure and the corrective actions taken;

(iv) The name of each individual performing the validated inactivation or viable select agent removal method;

(v) The date(s) the validated inactivation or viable select agent removal method was completed;

(vi) The location where the validated inactivation or viable select agent removal method was performed; and

(vii) A certificate, signed by the principal investigator, that includes the date of inactivation or viable select agent removal, the validated inactivation or viable select agent removal method used, and the name of the principal investigator. A copy of the certificate must accompany any transfer of inactivated or select agent removed material.

(b) The individual or entity must implement a system to ensure that all records and databases created under this part are accurate and legible, have controlled access, and that their authenticity may be verified.

(c) The individual or entity must promptly produce upon request any information that is related to the requirements of this part but is not otherwise contained in a record required to be kept by this section. The location of such information may include, but is not limited to, biocontainment certifications, laboratory notebooks, institutional biosafety and/or animal use committee minutes and approved protocols, and records associated with occupational health and suitability programs. All records created under this part must be maintained for 3 years.

Title 9—Animals and Animal Products

PART 121—POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

■ 14. The authority citation for part 121 continues to read as follows:

Authority: 7 U.S.C. 8401; 7 CFR 2.22, 2.80, and 371.4.

■ 15. Section 121.1 is amended by adding, in alphabetical order, definitions of *principal investigator*, *validated inactivation procedure*, and *viability testing protocol* to read as follows:

§ 121.1 Definitions.

* * * * *

⁵ Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

Principal investigator. The one individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program.

* * * * *

Validated inactivation procedure. A procedure, whose efficacy is confirmed by data generated from a viability testing protocol, to render a select agent non-viable but allows the select agent to retain characteristics of interest for future use; or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use.

* * * * *

Viability testing protocol. A protocol to confirm the validated inactivation procedure by demonstrating the material is free of all viable select agent.

* * * * *

■ 16. Section 121.3 is amended as follows:

- a. By revising paragraph (d)(2).
- b. By redesignating paragraph (d)(3) as paragraph (d)(4).
- c. By adding a new paragraph (d)(3).
- d. By revising newly redesignated paragraph (d)(4).
- e. By adding paragraphs (d)(5) through (9) and (e)(3).

The additions and revisions read as follows:

§ 121.3 VS select agents and toxins.

* * * * *

(d) * * *

(2) Nonviable VS select agents or nontoxic VS toxins.³

(3) A select agent or toxin that has been subjected to decontamination or a destruction procedure when intended for waste disposal.

(4) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol. Surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactivation procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.

(5) Material containing a select agent that is subjected to a procedure that removes all viable select agent cells,

spores, or virus particles if the material is subjected to a viability testing protocol to ensure that the removal method has rendered the material free of all viable select agent.

(6) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus not subjected to a validated inactivation procedure or material containing a select agent not subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is determined by the Administrator to be effectively inactivated or effectively removed. To apply for a determination an individual or entity must submit a written request and supporting scientific information to APHIS. A written decision granting or denying the request will be issued.

(7) A VS select toxin identified in an original food sample or clinical sample.

(8) Waste generated during the delivery of patient care by health care professionals from a patient diagnosed with an illness or condition associated with a select agent, where that waste is decontaminated or transferred for destruction by complying with State and Federal regulations within 7 calendar days of the conclusion of patient care.

(9) Any low pathogenic strains of avian influenza virus, avian paramyxovirus serotype-1 (APMV-1) viruses which do not meet the criteria for Newcastle disease virus,⁴ including those identified as pigeon paramyxovirus-12⁵ isolated from a non-poultry species, all subspecies *Mycoplasma capricolum* except subspecies *capripneumoniae* (contagious caprine pleuropneumonia), and all subspecies *Mycoplasma mycoides* except subspecies *mycoides* small colony (*Mmm* SC) (contagious bovine pleuropneumonia), provided that the individual or entity can identify that the agent is within the exclusion category.

(e) * * *

(3) An individual or entity may make a written request to the Administrator for reconsideration of a decision denying an application for the exclusion

⁴ An APMV-1 virus isolated from poultry which has an intracerebral pathogenicity index in day-old chicks (*Gallus gallus*) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

⁵ Pigeon paramyxovirus (PPMV-1) is a species-adapted APMV-1 virus which is endemic in pigeons and doves in the United States and can be identified through monoclonal antibody testing and demonstration of their characteristic amino acid signature at the fusion gene cleavage site.

of an attenuated strain of a select agent or a select toxin modified to be less potent or toxic. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

* * * * *

■ 17. Section 121.4 is amended as follows:

■ a. In paragraph (c)(1), by redesignating footnote 4 as footnote 6.

■ b. In paragraph (c)(2) introductory text, by removing the word “functional” and adding in its place the word “toxic”.

■ c. By revising paragraph (d)(2).

■ d. By redesignating paragraph (d)(3) as paragraph (d)(9).

■ e. By adding paragraphs (d)(3) through (8) and (e)(3).

The additions and revision read as follows:

§ 121.4 Overlap select agents and toxins.

* * * * *

(d) * * *

(2) Nonviable overlap select agents or nontoxic overlap toxins.⁷

(3) A select agent or toxin that has been subjected to decontamination or a destruction procedure when intended for waste disposal.

(4) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol. Surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactivation procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.

(5) Material containing a select agent that is subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is subjected to a viability testing protocol to ensure that the removal method has rendered the material free of all viable select agent.

(6) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus not subjected

³ However, the importation and interstate movement of these nonviable select agents may be subject to the permit requirements under part 122 of this subchapter.

⁷ However, the importation and interstate movement of these nonviable overlap select agents may be subject to the permit requirements under part 122 of this subchapter.

to a validated inactivation procedure or material containing a select agent not subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is determined by the Administrator or HHS Secretary to be effectively inactivated or effectively removed. To apply for a determination an individual or entity must submit a written request and supporting scientific information to APHIS or CDC. A written decision granting or denying the request will be issued.

(7) An overlap select toxin identified in an original food sample or clinical sample.

(8) Waste generated during the delivery of patient care by health care professionals from a patient diagnosed with an illness or condition associated with a select agent, where that waste is decontaminated or transferred for destruction by complying with State and Federal regulations within 7 calendar days of the conclusion of patient care.

* * * * *

(e) * * *

(3) An individual or entity may make a written request to the Administrator or HHS Secretary for reconsideration of a decision denying an application for the exclusion of an attenuated strain of a select agent or a select toxin modified to be less potent or toxic. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The Administrator or HHS Secretary will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

* * * * *

■ 18. In § 121.5, paragraph (a) is revised as follows:

§ 121.5 Exemptions for VS select agents and toxins.

(a) Diagnostic laboratories and other entities that possess, use, or transfer a VS select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the Administrator, within 7 calendar days after identification of the select agent or toxin, the select agent or toxin is transferred in accordance with § 121.16 or destroyed on-site by a recognized sterilization or inactivation process;

(2) The agent or toxin is secured against theft, loss, or release during the

period between identification of the agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported;

(3) Unless otherwise directed by the Administrator, the clinical or diagnostic specimens collected from a patient infected with a select agent are transferred in accordance with § 121.16 or destroyed on-site by a recognized sterilization or inactivation process within 7 calendar days after delivery of patient care by health care professionals has concluded; and

(4) The identification of the agent or toxin is reported to APHIS or CDC, the specimen provider, and to other appropriate authorities when required by Federal, State, or local law by telephone, facsimile, or email. This report must be followed by submission of APHIS/CDC Form 4 to APHIS or CDC within 7 calendar days after identification.

* * * * *

■ 19. Section 121.6 is amended as follows:

■ a. By revising paragraph (a)(1).

■ b. In paragraph (a)(2), by removing the word “and” at the end of the paragraph.

■ c. By redesignating paragraph (a)(3) as paragraph (a)(4).

■ d. By adding new paragraph (a)(3).

■ e. By revising newly redesignated paragraph (a)(4).

The addition and revisions read as follows:

§ 121.6 Exemptions for overlap select agents and toxins.

(a) * * *

(1) Unless directed otherwise by the Administrator, within 7 calendar days after identification of the select agent or toxin, the select agent or toxin is transferred in accordance with § 121.16 or destroyed on-site by a recognized sterilization or inactivation process;

* * * * *

(3) Unless otherwise directed by the Administrator or HHS Secretary, the clinical or diagnostic specimens collected from a patient infected with a select agent are transferred in accordance with § 121.16 or destroyed on-site by a recognized sterilization or inactivation process within 7 calendar days after delivery of patient care by health care professionals has concluded; and

(4) The identification of the agent or toxin is reported to APHIS or CDC, the specimen provider, and to other appropriate authorities when required by Federal, State, or local law by telephone, facsimile, or email. This report must be followed by submission

of APHIS/CDC Form 4 to APHIS or CDC within 7 calendar days after identification.

* * * * *

■ 20. Section 121.7 is amended as follows:

■ a. By redesignating paragraphs (b) through (k) as paragraphs (c) through (l), respectively.

■ b. By adding a new paragraph (b).

■ c. In newly redesignated paragraph (d)(3) introductory text, by redesignating footnote 6 as footnote 8.

■ d. In newly redesignated paragraph (i)(1), by redesignating footnote 7 as footnote 9.

The addition reads as follows:

§ 121.7 Registration and related security risk assessments.

* * * * *

(b) As a condition of registration, each entity is required to be in compliance with the requirements of this part for select agents and toxins listed on the registration regardless of whether the entity is in actual possession of the select agent or toxin. With regard to toxins, the entity registered for possession, use, or transfer of a toxin must be in compliance with the requirements of this part regardless of the amount of toxins currently in its possession.

* * * * *

§ 121.8 [Amended]

■ 21. In § 121.8, footnote 8 is redesignated as footnote 10.

■ 22. Section 121.9 is amended as follows:

■ a. By removing the semicolons at the ends of paragraphs (a)(1) through (4) and “; and” at the end of paragraph (a)(5) and adding periods in their place.

■ b. In paragraph (a)(6), by removing the word “laboratory” and adding the words “registered space” in its place and by adding the words “and the corrections documented” at the end of the second sentence after the words “must be corrected”.

■ c. By adding paragraphs (a)(7), (8), and (9).

The additions read as follows:

§ 121.9 Responsible official.

(a) * * *

(7) Ensure that individuals are provided the contact information for the USDA Office of Inspector General Hotline and the HHS Office of Inspector General Hotline so that they may anonymously report any biosafety/biocontainment or security concerns related to select agents and toxins.

(8) Investigate to determine the reason for any failure of a validated

inactivation procedure or any failure to remove viable select agent from material. If the responsible official is unable to determine the cause of a deviation from a validated inactivation procedure or a viable select agent removal method; or receives any report of any inactivation failure after the movement of material to another location, the responsible official must report immediately by telephone or email the inactivation or viable agent removal method failure to APHIS or CDC.

(9) Review, and revise as necessary, each of the entity's validated inactivation procedures or viable select agent removal methods. The review must be conducted annually or after any change in principal investigator, change in the validated inactivation procedure or viable select agent removal method, or failure of the validated inactivation procedure or viable select agent removal method. The review must be documented and training must be conducted if there are any changes to the validated inactivation procedure, viable select agent removal method, or viability testing protocol.

* * * * *

■ 23. In § 121.10, paragraph (e) is amended by adding a sentence at the end of the paragraph to read as follows:

§ 121.10 Restricting access to select agents and toxins; security risk assessments.

* * * * *

(e) * * * A responsible official must immediately notify the responsible official of the visited entity if the person's access to select agents and toxins has been terminated.

* * * * *

■ 24. Section 121.11 is amended as follows:

■ a. In paragraph (c)(5), by adding the word "keycards," after the word "keys," and by removing the word "numbers" and adding the word "permissions" in its place.

■ b. In paragraph (d)(7)(iv), by removing the word "and".

■ c. By adding paragraph (d)(7)(vi).

■ d. By adding a sentence at the end of paragraph (h).

The additions read as follows:

§ 121.11 Security.

* * * * *

(d) * * *

(7) * * *

(vi) Any loss of computer, hard drive or other data storage device containing information that could be used to gain access to select agents or toxins; and

* * * * *

(h) * * * Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.

■ 25. Section 121.12 is amended as follows:

■ a. By revising paragraph (a).

■ b. By removing paragraph (c)(2).

■ c. By redesignating paragraph (c)(3) as paragraph (c)(2), and in newly redesignated paragraph (c)(2), removing the words "NIH Guidelines for Research Involving Recombinant DNA Molecules" and adding in their place the words "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules".

■ d. By adding a sentence at the end of paragraph (e).

The addition and revision read as follows:

§ 121.12 Biosafety.

(a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use.¹¹ The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested. The biosafety plan must include the following provisions:

(1) The hazardous characteristics of each agent or toxin listed on the entity's registration and the biosafety risk associated with laboratory procedures related to the select agent or toxin;

(2) Safeguards in place with associated work practices to protect entity personnel, the public, and the environment from exposure to the select agent or toxin including, but not limited to: Personal protective equipment and other safety equipment; containment equipment including, but not limited to, biological safety cabinets, animal caging systems, and centrifuge safety containers; and engineering controls and other facility safeguards;

(3) Written procedures for each validated method used for disinfection, decontamination, or destruction, as appropriate, of all contaminated or presumptively contaminated materials

including, but not limited to: Cultures and other materials related to the propagation of select agents or toxins, items related to the analysis of select agents and toxins, personal protective equipment, animal caging systems and bedding (if applicable), animal carcasses or extracted tissues and fluids (if applicable), laboratory surfaces and equipment, and effluent material; and

(4) Procedures for the handling of select agents and toxins in the same spaces with non-select agents and toxins to prevent unintentional contamination.

* * * * *

(e) * * * Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.

■ 26. Section 121.14 is amended as follows:

■ a. In the section heading, by redesignating footnote 10 as footnote 12.

■ b. In paragraph (a), by redesignating footnote 11 as footnote 13, and by adding a sentence at the end of the paragraph.

■ c. In paragraph (f), by adding a sentence at the end of the paragraph.

The additions read as follows:

§ 121.14 Incident response.¹²

(a) * * * The current incident response plan must be submitted for initial registration, renewal of registration, or when requested.

* * * * *

(f) * * * Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.

■ 27. Section 121.15 is amended as follows:

■ a. By revising paragraph (a).

■ e. By adding paragraph (e).

The addition and revision read as follows:

§ 121.15 Training.

(a) An individual or entity required to register under this part must provide information and training on biocontainment, biosafety, security (including security awareness), and incident response to:

(1) Each individual with access approval from the Administrator or HHS Secretary. The training must address the particular needs of the individual, the

¹¹ Technical assistance and guidance may be obtained by contacting APHIS.

¹² Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

work they will do, and the risks posed by the select agents or toxins. The training must be accomplished prior to the individual's entry into an area where a select agent is handled or stored, or within 12 months of the date the individual was approved by the Administrator or the HHS Secretary for access, whichever is earlier.

(2) Each individual not approved for access to select agents and toxins by the Administrator or HHS Secretary before that individual enters areas under escort where select agents or toxins are handled or stored (*e.g.*, laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored. The training must be accomplished prior to the individual's entry into where select agents or toxins are handled or stored (*e.g.*, laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.).

* * * * *

(e) The responsible official must ensure and document that individuals are provided the contact information of the USDA Office of Inspector General Hotline and the HHS Office of Inspector General Hotline so that they may anonymously report any safety or security concerns related to select agents and toxins.

■ 28. Section § 121.16 is amended as follows:

■ a. In paragraph (a), by redesignating footnote 12 as footnote 14.

■ b. By revising paragraph (b) introductory text.

■ c. By adding paragraph (l).

The addition and revision read as follows:

§ 121.16 Transfers.

* * * * *

(b) A transfer may be authorized if:

* * * * *

(l) Transfer the amounts only after the transferor uses due diligence and documents that the recipient has a legitimate need (*e.g.*, prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such toxins. Information to be documented includes, but is not limited, to the recipient information, toxin and amount transferred, and declaration that the recipient has legitimate purpose to store and use such toxins.

■ 29. Section 121.17 is amended as follows:

■ a. In paragraph (a)(1)(iii), by adding the words "or other storage container" after the word "freezer".

■ b. By revising paragraph (a)(1)(v).

■ c. In paragraph (a)(3)(v), by adding the words "or other storage container" after the word "freezer".

■ d. By removing the word "and" at the end of paragraph (a)(6) and removing the period at the end of paragraph (a)(7) and adding the word "; and" in its place.

■ e. By adding paragraph (a)(8).

■ f. By revising paragraphs (b) and (c). The addition and revisions read as follows:

§ 121.17 Records.

(a) * * *

(1) * * *

(v) The select agent used, purpose of use, and, when applicable, final disposition;

* * * * *

(8) For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent:

(i) A written description of the validated inactivation procedure or viable select agent removal method used, including validation data;

(ii) A written description of the viability testing protocol used;

(iii) A written description of the investigation conducted by the entity responsible official involving an inactivation or viable select agent removal failure and the corrective actions taken;

(iv) The name of each individual performing the validated inactivation or viable select agent removal method;

(v) The date(s) the validated inactivation or viable select agent removal method was completed;

(vi) The location where the validated inactivation or viable select agent removal method was performed; and

(vii) A certificate, signed by the principal investigator, that includes the date of inactivation or viable select agent removal, the validated inactivation or viable select agent removal method used, and the name of the principal investigator. A copy of the certificate must accompany any transfer of inactivated or select agent removed material.

(b) The individual or entity must implement a system to ensure that all records and databases created under this part are accurate and legible, have controlled access, and that their authenticity may be verified.

(c) The individual or entity must promptly produce upon request any information that is related to the requirements of this part but is not otherwise contained in a record required to be kept by this section. The location of such information may include, but is not limited to, biocontainment certifications, laboratory notebooks, institutional biosafety and/or animal use committee minutes and approved protocols, and records associated with occupational health and suitability programs. All records created under this part must be maintained for 3 years.

Done in Washington, DC, this 10th day of January 2017.

Elvis S. Cordova,

Acting Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 2017-00857 Filed 1-18-17; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 981

[Doc. No. AMS-SC-16-0047; SC16-981-3 FIR]

Almonds Grown in California; Change in Quality Control Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: The Department of Agriculture (USDA) is adopting, as a final rule, without change, an interim rule implementing a recommendation from the Almond Board of California (Board) that relaxed the quality control requirements prescribed under the California almond marketing order (order). The Board locally administers the order and is comprised of growers and handlers operating within California. The interim rule relaxed incoming quality requirements by increasing the inedible kernel tolerance from 0.50 percent to 2 percent. This relaxation decreases California almond handlers' disposition obligation. This change also allows handlers more flexibility in their operations while continuing to maintain quality control and ensuring compliance with the order's requirements.

DATES: Effective January 20, 2017.

FOR FURTHER INFORMATION CONTACT: Andrea Ricci, Marketing Specialist or Jeffrey Smutny, Regional Director, California Marketing Field Office,

Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (559) 487-5901, Fax: (559) 487-5906, or Email: Andrea.Ricci@ams.usda.gov or Jeffrey.Smutny@ams.usda.gov.

Small businesses may obtain information on complying with this and other marketing order regulations by viewing a guide at the following Web site: <http://www.ams.usda.gov/rules-regulations/moa/small-businesses>; or by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250-0237; Telephone: (202) 720-2491, Fax: (202) 720-8938, or Email: Richard.Lower@ams.usda.gov.

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Order No. 981, as amended (7 CFR part 981), regulating the handling of almonds grown in California, hereinafter referred to as the "order." The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), hereinafter referred to as the "Act."

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Orders 12866, 13563, and 13175.

Section 981.442 of the order regulates almond quality, including the percentage of inedible (low quality) kernels required to be disposed of by handlers. Previously, the weight of inedible kernels in excess of 0.50 percent of kernel weight of almonds received by each handler constituted the handler's disposition obligation. Handlers must satisfy their obligation by disposing of the inedible kernels in Board-accepted, non-human outlets such as animal feed or oil.

In the past several years, total inedible kernel percentages have been trending lower. This is partially due to good agricultural practices used by growers and better technologies in handler facilities. At the same time, the market value of almonds has increased significantly. As a result, some of the Board-accepted outlets have started to clean and repurpose almonds disposed under the obligation causing concern that product is being sold for human consumption without following the order's outgoing quality requirements. Increasing the inedible kernel tolerance to 2 percent provides handlers more control over low quality product, helping ensure any product destined for human consumption is compliant with the order's outgoing quality requirements. In an interim rule

published in the **Federal Register** on August 17, 2016, and effective on August 18, 2016, (81 FR 54719, Doc. No. AMS-SC-16-0047, SC16-981-3 IR), § 981.442(a)(4)(i) was amended by changing the disposition obligation from 0.5 percent to 2 percent. This rule continues in effect that action.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 6,800 almond growers in the production area and approximately 100 handlers subject to regulation under the marketing order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts of less than \$750,000, and small agricultural service firms are defined as those whose annual receipts are less than \$7,500,000 (13 CFR 121.201).

The National Agricultural Statistics Service (NASS) reported in its 2012 Agricultural Census that there were 6,841 almond farms in the production area (California), of which 6,204 had bearing acres. The following computation provides an estimate of the proportion of producers (farms) and agricultural service firms (handlers) that would be considered small under the SBA definitions.

The NASS Census data indicates that out of the 6,204 California farms with bearing acres of almonds, 4,471 (72 percent) have fewer than 100 bearing acres.

For the almond industry's most recently reported crop year (2015), NASS reported an average yield of 2,130 pounds per acre, and a season average grower price of \$2.84 per pound. A 100-acre farm with an average yield of 2,130 pounds per acre would produce about 213,000 pounds of almonds. At \$2.84 per pound, that farm's production would be valued at \$604,920. Since Census of Agriculture indicates that the majority of California's almond farms are smaller than 100 acres, it could be

concluded that the majority of growers had annual receipts from the sale of almonds in 2015 of less than \$604,920, which is below the SBA threshold of \$750,000. Thus, over 70 percent of California's almond growers would be considered small growers according to SBA's definition.

According to information supplied by the Board, approximately 30 percent of California's almond handlers shipped almonds valued under \$7,500,000 during the 2014-15 crop year, and would, therefore, be considered small handlers according to the SBA definition.

This rule continues in effect the revision of § 981.442(a)(4)(i), which relaxed incoming quality requirements by increasing the inedible kernel tolerance from 0.50 percent to 2 percent. This relaxation decreases California almond handlers' disposition obligation, and also allows handlers more flexibility in their operations while continuing to maintain quality control and ensuring compliance with the order's requirements. Authority for this action is provided in § 981.42(a) of the order.

Regarding the impact of this action on affected entities, increasing the inedible kernel tolerance reduces disposition obligation on handlers and provides handlers with more flexibility and control over the low quality product. This rule is not expected to change handler inspection costs, as handlers currently are required to have all lots inspected to determine the percentage of inedible kernels.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581-0178 (Vegetable and Specialty Crops.) No changes are necessary in those requirements as a result of this action. Should any changes become necessary, they would be submitted to OMB for approval.

This rule will not impose any additional reporting or recordkeeping requirements on either small or large almond handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. In addition, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

Further, the Board's meeting was widely publicized throughout the almond industry and all interested

persons were invited to attend the meeting and participate in Board deliberations. Like all Board meetings, the April 12, 2016, meeting was a public meeting and all entities, both large and small, were able to express their views on this issue.

Comments on the interim rule were required to be received on or before October 17, 2016. Two comments were received. One commenter stated that this change will allow almond handlers to have more flexibility with their operations. The other commenter stated the increase in tolerance should lead to a decrease in price. Marketing orders do not regulate price. Therefore, for the reasons given in the interim rule, we are adopting the interim rule as a final rule, without change.

To view the interim rule, go to: <https://www.regulations.gov/docket?D=AMS-SC-16-0047>.

This action also affirms information contained in the interim rule concerning Executive Orders 12866, 12988, 13175, and 13563; the Paperwork Reduction Act (44 U.S.C. Chapter 35); and the E-Gov Act (44 U.S.C. 101).

After consideration of all relevant material presented, it is found that finalizing the interim rule, without change, as published in the **Federal Register** (81 FR 54719) will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 981

Almonds, Marketing agreements, Nuts, Reporting and recordkeeping requirements.

PART 981—ALMONDS GROWN IN CALIFORNIA

■ Accordingly, the interim rule that amended 7 CFR part 981 and that was published 81 FR 54719 on August 17, 2016, is adopted as a final rule, without change.

Dated: January 9, 2017.

Bruce Summers,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2017-00589 Filed 1-18-17; 8:45 am]

BILLING CODE 3410-02-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. APHIS-2014-0032]

RIN 0579-AD92

Importation of Beef From a Region in Argentina

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule; technical amendment.

SUMMARY: In a final rule published in the **Federal Register** on July 2, 2015, and effective on September 1, 2015, we amended the regulations governing the importation of certain animals, meat, and other animal products to allow, under certain conditions, the importation of fresh (chilled or frozen) beef from a region in Argentina located north of Patagonia South and Patagonia North B, referred to as Northern Argentina. However, we inadvertently limited the requirement for the maturation of carcasses to meat derived from bovines. Therefore, we are amending the paragraph to remove the limitation.

DATES: Effective January 19, 2017.

FOR FURTHER INFORMATION CONTACT: Dr. Roberta Morales, Import Risk Analyst, Regional Evaluation Services, National Import Export Services, VS, APHIS, 920 Main Campus Drive, Suite 200, Raleigh, NC; (919) 855-7735; Roberta.A.Morales@aphis.usda.gov.

SUPPLEMENTARY INFORMATION: In a final rule¹ that was published in the **Federal Register** on July 2, 2015 (80 FR 37935-37953, Docket No. APHIS-2014-0032), and effective on September 1, 2015, we amended the regulations governing the importation of certain animals, meat, and other animal products to allow, under certain conditions, the importation of fresh (chilled or frozen) beef from a region in Argentina located north of Patagonia South and Patagonia North B, referred to as Northern Argentina. These requirements appear in 9 CFR 94.29, which provides for the importation of fresh beef and ovine meat from certain regions. However, when we added the requirements, we inadvertently limited the requirements in paragraph (i), which provides the requirements for the maturation of carcasses, to meat derived from bovines.

¹ To view the final rule and supporting documents, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0032>.

Therefore, we are amending the paragraph to remove the limitation.

Lists of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, we are amending 9 CFR part 94 as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, NEWCASTLE DISEASE, HIGHLY PATHOGENIC AVIAN INFLUENZA, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, SWINE VESICULAR DISEASE, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ 1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 450, 7701-7772, 7781-7786, and 8301-8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

§ 94.29 [Amended]

■ 2. In § 94.29, paragraph (i) is amended by removing the word “bovine”.

Done in Washington, DC, this 12th day of January 2017.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017-01019 Filed 1-18-17; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2016-9319; Airspace Docket No. 16-AGL-24]

RIN 2120-AA66

Amendment of Multiple Air Traffic Service (ATS) Routes; North Central United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, technical amendment.

SUMMARY: The FAA is amending seven high altitude Area Navigation (RNAV) Q-routes (Q-140, Q-816, Q-818, Q-822, Q-824, Q-917, and Q-935) that cross the United States (U.S.)/Canada border in the north central U.S. to update the geographic latitude/longitude coordinates for five Canadian waypoints listed in the Q-route descriptions contained in the FAA and Canadian aeronautical databases.

DATES: Effective date 0901 UTC, April 27, 2017. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11A, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267-8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11A at NARA, call (202) 741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Airspace Policy Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267-8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend the route structure as required to preserve the safe and efficient flow of air traffic.

History

On September 26, 2014, the FAA published in the **Federal Register** a final rule (79 FR 57758), Docket No. FAA-2014-0295, that amended, removed, and established multiple ATS routes in the north central U.S. to reflect and

accommodate route changes being made in Canadian airspace as part of a Canadian airspace redesign project. On December 5, 2014, the FAA published in the **Federal Register** a final rule, technical amendment (79 FR 72135), Docket No. FAA-2014-0986, that further amended a number of the routes to reflect changes made by NAV CANADA as part of their airspace redesign effort after publication of the original final rule. During a recent aeronautical review, the FAA identified waypoint coordinate updates for the Canadian waypoints OMRAC, PEPLA, TAGUM, TANKO, and VIGLO.

This rule makes the corrections to be in concert with FAA and Canadian aeronautical databases.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

The FAA is amending Title 14, Code of Federal Regulations (14 CFR) part 71 by modifying RNAV routes Q-140, Q-816, Q-818, Q-822, Q-824, Q-917, and Q-935. The route modifications correct the OMRAC, PEPLA, TAGUM, TANKO, and VIGLO waypoint geographic coordinates used in the routes to match the FAA and Canadian aeronautical database information. The amendments ensure safe and efficient across border connectivity.

The RNAV route modifications accomplished by this action are outlined below.

Q-140: Change the PEPLA waypoint geographic coordinates from "lat. 43°47'51.00" N., long. 080°01'02.00" W." to read "lat. 43°47'50.98" N., long. 080°00'53.56" W."

Q-816: Change the OMRAC waypoint geographic coordinates from "lat. 43°16'06.00" N., long. 082°16'25.00" W." to read "lat. 43°16'15.45" N., long. 082°15'52.31" W."

Q-818: Change the TANKO waypoint geographic coordinates from "lat. 43°01'32.00" N., long. 082°22'43.00" W." to read "lat. 43°01'32.48" N., long. 082°23'02.38" W."

Q-822: Change the TANKO waypoint geographic coordinates from "lat. 43°01'32.00" N., long. 082°22'43.00" W."

to read "lat. 43°01'32.48" N., long. 082°23'02.38" W."

Q-824: Change the TAGUM waypoint geographic coordinates from "lat. 43°28'47.00" N., long. 082°10'37.00" W." to read "lat. 43°28'54.05" N., long. 082°09'46.39" W."

Q-917: Change the VIGLO waypoint geographic coordinates from "lat. 45°23'28.00" N., long. 082°25'11.00" W." to read "lat. 45°23'48.00" N., long. 082°25'11.00" W.", and the PEPLA waypoint geographic coordinates from "lat. 43°47'51.00" N., long.

080°01'02.00" W." to read "lat. 43°47'50.98" N., long. 080°00'53.56" W." Q-935: Change the OMRAC waypoint geographic coordinates from "lat. 43°16'06.00" N., long. 082°16'25.00" W." to read "lat. 43°16'15.45" N., long. 082°15'52.31" W."

High altitude United States RNAV Q-routes are published in paragraph 2006 and high altitude Canadian RNAV Q-routes are published in paragraph 2007 of FAA Order 7400.11A dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR 71.1. The high altitude United States and Canadian RNAV Q-routes listed in this rule will be subsequently published in the Order.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action of modifying seven high altitude RNAV Q-routes qualifies for categorical exclusion under the National Environmental Policy Act and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, *Environmental Impacts: Policies and Procedures*, Paragraph 5-6.5a, which categorically excludes from further environmental impact review

rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points). This action is not expected to cause any potentially significant environmental impacts. In accordance with FAAO 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, this action has been reviewed for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis, and it is determined that no extraordinary circumstances exist that

warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016, is amended as follows:

Paragraph 2006 United States Area Navigation Routes.

* * * * *

Q–140 WOBE, WA to YODAA, NY [Amended]

| | | |
|---------------|-----|--|
| WOBE, WA | WP | (Lat. 48°36'01.07" N., long. 122°49'46.52" W.) |
| GETNG, WA | WP | (Lat. 48°25'30.57" N., long. 119°31'38.98" W.) |
| CORDU, ID | FIX | (Lat. 48°10'46.41" N., long. 116°40'21.84" W.) |
| PETIY, MT | WP | (Lat. 47°58'46.55" N., long. 114°36'20.31" W.) |
| CHOTE, MT | FIX | (Lat. 47°39'56.68" N., long. 112°09'38.13" W.) |
| LEWT, MT | WP | (Lat. 47°23'00.21" N., long. 110°08'44.78" W.) |
| SAYOR, MT | FIX | (Lat. 47°13'58.34" N., long. 104°58'39.28" W.) |
| WILTN, ND | FIX | (Lat. 47°04'58.09" N., long. 100°47'43.84" W.) |
| TTAIL, MN | WP | (Lat. 46°41'28.00" N., long. 096°41'09.00" W.) |
| CESNA, WI | WP | (Lat. 45°52'14.00" N., long. 092°10'59.00" W.) |
| WISCN, WI | WP | (Lat. 45°18'19.45" N., long. 089°27'53.91" W.) |
| EEGEE, WI | WP | (Lat. 45°08'53.00" N., long. 088°45'58.00" W.) |
| DAYYY, MI | WP | (Lat. 44°10'10.00" N., long. 084°22'23.00" W.) |
| RUBKI, Canada | WP | (Lat. 44°14'56.00" N., long. 082°15'25.99" W.) |
| PEPLA, Canada | WP | (Lat. 43°47'50.98" N., long. 080°00'53.56" W.) |
| SKBO, Canada | WP | (Lat. 43°39'13.00" N., long. 079°20'57.00" W.) |
| MEDAV, Canada | WP | (Lat. 43°29'19.00" N., long. 078°45'46.00" W.) |
| AHPAH, NY | WP | (Lat. 43°18'19.00" N., long. 078°07'35.11" W.) |
| HANKK, NY | FIX | (Lat. 42°53'41.82" N., long. 077°09'15.21" W.) |
| BEEPS, NY | FIX | (Lat. 42°49'13.26" N., long. 076°59'04.84" W.) |
| EXTOL, NY | FIX | (Lat. 42°39'27.69" N., long. 076°37'06.10" W.) |
| MEMMS, NY | FIX | (Lat. 42°30'59.71" N., long. 076°18'15.43" W.) |
| KODEY, NY | FIX | (Lat. 42°16'47.53" N., long. 075°47'04.00" W.) |
| ARKKK, NY | WP | (Lat. 42°03'48.52" N., long. 075°19'00.41" W.) |
| RODYY, NY | WP | (Lat. 41°52'25.85" N., long. 074°35'49.39" W.) |
| YODAA, NY | FIX | (Lat. 41°43'21.19" N., long. 074°01'52.76" W.) |

Excluding the airspace within Canada.

* * * * *

Paragraph 2007 Canadian Area Navigation Routes.

* * * * *

Q–816 HOCKE, MI to HANAA, NY [Amended]

| | | |
|-----------|-----------|--|
| HOCKE, MI | WP | (Lat. 43°15'43.38" N., long. 082°42'38.27" W.) |
| OMRAK, | Canada WP | (Lat. 43°16'15.45" N., long. 082°15'52.31" W.) |
| AGDOX, | Canada WP | (Lat. 43°17'01.71" N., long. 079°05'29.29" W.) |
| KELTI, | NY WP | (Lat. 43°16'57.00" N., long. 078°56'00.00" W.) |
| AHPAH, | NY WP | (Lat. 43°18'19.00" N., long. 078°07'35.11" W.) |
| GOATR, | NY WP | (Lat. 43°17'26.08" N., long. 076°39'07.75" W.) |
| ARNII, | NY WP | (Lat. 43°14'59.92" N., long. 074°20'00.14" W.) |
| HANAA, | NY WP | (Lat. 43°11'52.06" N., long. 073°36'46.17" W.) |

Excluding the airspace within Canada.

Q–818 Flint, MI (FNT) to GAYEL, NY [Amended]

| | | |
|-----------------|--------|--|
| Flint, MI (FNT) | VORTAC | (Lat. 42°58'00.38" N., long. 083°44'49.08" W.) |
| TANKO, Canada | WP | (Lat. 43°01'32.48" N., long. 082°23'02.38" W.) |
| KITOK, Canada | WP | (Lat. 43°02'30.00" N., long. 081°55'34.00" W.) |
| DERLO, Canada | WP | (Lat. 43°03'59.00" N., long. 081°05'43.00" W.) |
| IKNAV, Canada | WP | (Lat. 42°57'43.00" N., long. 078°59'04.00" W.) |
| WOZEE, NY | WP | (Lat. 42°56'01.65" N., long. 078°44'19.64" W.) |
| KELIE, NY | FIX | (Lat. 42°39'37.32" N., long. 077°44'41.05" W.) |
| VIEEW, NY | FIX | (Lat. 42°26'22.07" N., long. 077°01'33.30" W.) |

| | | |
|----------------------|--------|--|
| Binghamton, NY (CFB) | VORTAC | (Lat. 42°09'26.96" N., long. 076°08'11.30" W.) |
| BUFFY, PA | FIX | (Lat. 41°56'27.98" N., long. 075°36'45.35" W.) |
| STOMP, NY | WP | (Lat. 41°35'46.78" N., long. 074°47'47.79" W.) |
| MSLIN, NY | FIX | (Lat. 41°29'30.82" N., long. 074°33'14.28" W.) |
| GAYEL, NY | FIX | (Lat. 41°24'24.09" N., long. 074°21'25.75" W.) |

Excluding the airspace within Canada.

Q-822 Flint, MI (FNT) to SINVI, Canada [Amended]

| | | |
|---------------------|---------|--|
| Flint, MI (FNT) | VORTAC | (Lat. 42°58'00.38" N., long. 083°44'49.08" W.) |
| TANKO, Canada | WP | (Lat. 43°01'32.48" N., long. 082°23'02.38" W.) |
| KITOK, Canada | WP | (Lat. 43°02'30.00" N., long. 081°55'34.00" W.) |
| DERLO, Canada | WP | (Lat. 43°03'59.00" N., long. 081°05'43.00" W.) |
| HOZIR, NY | WP | (Lat. 43°06'03.59" N., long. 079°02'05.27" W.) |
| GONZZ, NY | WP | (Lat. 43°05'22.00" N., long. 076°41'12.00" W.) |
| PUPPY, NY | WP | (Lat. 43°03'26.46" N., long. 075°17'39.29" W.) |
| PAYGE, NY | FIX | (Lat. 43°00'50.48" N., long. 074°15'12.76" W.) |
| Cambridge, NY (CAM) | VOR/DME | (Lat. 42°59'39.44" N., long. 073°20'38.47" W.) |
| Kennebunk, ME (ENE) | VOR/DME | (Lat. 43°25'32.42" N., long. 070°36'48.69" W.) |
| AJJAY, ME | WP | (Lat. 43°43'40.55" N., long. 069°36'08.22" W.) |
| ALLEX, ME | WP | (Lat. 44°25'00.00" N., long. 067°00'00.00" W.) |
| SINVI, Canada | WP | (Lat. 44°48'15.00" N., long. 064°19'27.00" W.) |

Excluding the airspace within Canada.

Q824 Flint, MI (FNT) to TAGUM, Canada [Amended]

| | | |
|-----------------|--------|--|
| Flint, MI (FNT) | VORTAC | (Lat. 42°58'00.38" N., long. 083°44'49.08" W.) |
| HOCKE, MI | WP | (Lat. 43°15'43.38" N., long. 082°42'38.27" W.) |
| TAGUM, Canada | WP | (Lat. 43°28'54.05" N., long. 082°09'46.39" W.) |

Excluding the airspace within Canada.

* * * * *

Q-917 Sault Ste Marie, MI (SSM) to WOZEE, NY [Amended]

| | | |
|---------------------------|---------|--|
| Sault Ste Marie, MI (SSM) | VOR/DME | (Lat. 46°24'43.60" N., long. 084°18'53.54" W.) |
| ULUTO, Canada | WP | (Lat. 46°18'16.00" N., long. 084°05'41.00" W.) |
| VIGLO, Canada | WP | (Lat. 45°23'48.00" N., long. 082°25'11.00" W.) |
| SASUT, Canada | WP | (Lat. 44°39'59.00" N., long. 081°17'47.00" W.) |
| PERLA, Canada | WP | (Lat. 43°47'50.98" N., long. 080°00'53.56" W.) |
| HOZIR, NY | WP | (Lat. 43°06'03.59" N., long. 079°02'05.27" W.) |
| WOZEE, NY | WP | (Lat. 42°56'01.65" N., long. 078°44'19.64" W.) |

Excluding the airspace within Canada.

* * * * *

Q-935 MONEE, MI to Boston, MA (BOS) [Amended]

| | | |
|-------------------|---------|--|
| MONEE, MI | FIX | (Lat. 43°14'25.80" N., long. 084°27'50.95" W.) |
| HOCKE, MI | WP | (Lat. 43°15'43.38" N., long. 082°42'38.27" W.) |
| OMRAK, Canada | WP | (Lat. 43°16'15.45" N., long. 082°15'52.31" W.) |
| DERLO, Canada | WP | (Lat. 43°03'59.00" N., long. 081°05'43.00" W.) |
| IKNAV, Canada | WP | (Lat. 42°57'43.00" N., long. 078°59'04.00" W.) |
| WOZEE, NY | WP | (Lat. 42°56'01.65" N., long. 078°44'19.64" W.) |
| HANKK, NY | FIX | (Lat. 42°53'41.82" N., long. 077°09'15.21" W.) |
| JOSSY, NY | WP | (Lat. 42°53'29.93" N., long. 077°02'36.80" W.) |
| AUDIL, NY | FIX | (Lat. 42°52'18.74" N., long. 076°26'35.07" W.) |
| FABEN, NY | WP | (Lat. 42°51'12.04" N., long. 075°57'07.91" W.) |
| PONCT, NY | WP | (Lat. 42°44'48.83" N., long. 073°48'48.07" W.) |
| Gardner, MA (GDM) | VOR/DME | (Lat. 42°32'45.32" N., long. 072°03'29.48" W.) |
| Boston, MA (BOS) | VOR/DME | (Lat. 42°21'26.82" N., long. 070°59'22.37" W.) |

Excluding the airspace within Canada.

Issued in Washington, DC, on January 10, 2017.

Leslie M. Swann,

Acting Manager, Airspace Policy Group.

[FR Doc. 2017-01036 Filed 1-18-17; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF COMMERCE**Bureau of Industry and Security****15 CFR Parts 740, 748, and 762**

[Docket No. 161230999–7013–01]

RIN 0694–AH11

Support Document Requirements With Respect to Hong Kong**AGENCY:** Bureau of Industry and Security, Commerce.**ACTION:** Final rule.

SUMMARY: This rule requires persons intending to export or reexport *to* Hong Kong any item subject to the Export Administration Regulations (EAR) and controlled on the Commerce Control List (CCL) for national security (NS), missile technology (MT), nuclear nonproliferation (NP column 1), or chemical and biological weapons (CB) reasons to obtain, prior to such export or reexport, a copy of a Hong Kong import license or a written statement from the Hong Kong government that such a license is not required.

This rule also requires persons intending to reexport *from* Hong Kong any item subject to the EAR and controlled for NS, MT, NP column 1, or CB reasons to obtain a Hong Kong export license or a statement from the Hong Kong government that such a license is not required.

DATES: The rule is effective April 19, 2017.

FOR FURTHER INFORMATION CONTACT: Tracey Patts, Foreign Policy Division, Bureau of Industry and Security, Phone: (202) 482–4252.

SUPPLEMENTARY INFORMATION:**Background**

The government of the Hong Kong Special Administrative Region maintains an import and export control system. The “Import and Export (Strategic Commodities) Regulations” are an integral part of that system. Schedules in those regulations identify articles that may not be imported or exported without a license from Hong Kong’s Director-General of Trade and Industry. Those schedules and much of the CCL are based on the control lists published by four multilateral export control regimes. Export control classification number (ECCN) entries on the CCL identify one or more reason(s) for which listed items are controlled. Four of these reasons for control are based on the four multilateral export control regimes, as follows: The Wassenaar Arrangement on Export Controls for Conventional Arms and

Dual-Use Goods and Technologies (NS on the CCL), the Missile Technology Control Regime (MT on the CCL), the Nuclear Suppliers Group (NP column 1 on the CCL), and the Australia Group (CB on the CCL). Because the Hong Kong schedules and most of the CCL are developed from these same four sources, large portions of both sets of documents cover the same items.

The government of the Hong Kong Special Administrative Region uses information from the import licenses that it issues to identify articles that require an export license. This rule imposes new support documentation requirements affecting items subject to the EAR that are exported or reexported to Hong Kong or are reexported from Hong Kong. BIS is taking this action to provide greater assurance that U.S. origin items that are subject to the multilateral control regimes noted above will be properly authorized by the United States to their final destination, even when those items first pass through Hong Kong. This rule does not impose any new license requirements.

Exports and Reexports to Hong Kong

This rule requires exporters and reexporters using a BIS license or a license exception to export or reexport to Hong Kong items controlled for NS, MT, NP column 1, or CB reasons to obtain certain documents that verify the items’ status under the Hong Kong Import and Export (Strategic Commodities) Regulations. The exporter or reexporter must obtain from its client or consignee a copy of a valid import license issued to the Hong Kong importer by the Hong Kong government authorizing import of the item(s) to be shipped to Hong Kong, or a copy of a written statement issued by the Hong Kong government stating that no import license is required to import the item(s) into Hong Kong. The exporter or reexporter must have the copies in its possession, and any Hong Kong import license must not have expired at the time of the export or reexport to Hong Kong. For purposes of this requirement, a written statement issued by the Hong Kong government includes either a written communication to a license applicant informing the applicant that the item does not require a license or a statement available to the general public (including a statement on a Web site by the Hong Kong government) that a license is not required for the item.

Reexports From Hong Kong

This rule also requires reexporters in Hong Kong intending to reexport from Hong Kong items subject to the EAR that are controlled for NS, MT, NP column

1, or CB reasons to obtain from the Hong Kong government a license authorizing export from Hong Kong of the items, or a copy of a written statement issued by the Hong Kong government stating that no export license is required from Hong Kong to export the items. If a Hong Kong license is issued, the reexport must be in accordance with the terms of that license and must be completed during the validity period of the Hong Kong-issued export license. For purposes of this requirement, a written statement issued by the Hong Kong government includes a written communication to a license applicant informing the applicant that the item does not require a license or a statement available to the general public (including a statement on a Web site by the Hong Kong government) that a license is not required for the item.

Export Administration Act

Since August 21, 2001, the Export Administration Act of 1979, as amended, has been in lapse. However, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013), and as extended by the Notice of August 4, 2016, 81 FR 52587 (August 8, 2016), has continued the EAR in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This rule includes an expansion of an existing collection of information approved

under OMB control number 0694–0093—Import Certificate and End-User Certificate, for which the current burden estimates are 5,872 responses and 1,618 hours annually. BIS expects that this rule will increase the number of transactions for which exporters and reexporters will have to acquire support documentation by about 12,000 transactions annually, with a corresponding increase in the number of burden hours. Send comments regarding this burden estimate or any other aspect of this collections of information, including suggestions for reducing the burden, to Jasmeet K. Seehra, Office of Management and Budget, by email at jseehra@omb.eop.gov or by fax to (202) 395–7285 and to Hillary Hess, BIS, at hillary.hess@bis.doc.gov.

3. This rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a 30-day delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States (5 U.S.C. 553(a)(1)). Therefore, we are issuing this action as a final rule. This action will foster effective administration of and compliance with the export control regulations of the Hong Kong Special Administrative Region with respect to U.S.-origin items. Those regulations apply to items that are listed on the control lists of multilateral export control regimes of which the United States is a member. Effective control over such items imported into Hong Kong by the government of the Hong Kong Special Administrative Region serves the United States' national security and foreign policy interests directly, because many of these items are controlled due to their national security significance or their potential to be used in activities that would promote proliferation of weapons of mass destruction or in regional destabilizing activities.

This rule also enhances the effectiveness of the multilateral control regimes, which serves United States interests in two ways. First, widespread consistent implementation of those regime-based export controls promotes peace and stability throughout the world generally. Second, this rule signals to other nations, regime member states and non-members alike, the United States' determination that distribution of U.S. origin items throughout the world will be in

accordance with its regime commitments.

Moreover, BIS expects that in nearly all instances, this rule requires only that a party in Hong Kong obtain a license that is already required under Hong Kong law. In those instances, no new action is required by persons reexporting from Hong Kong and the only new action with respect to exports and reexports to Hong Kong is for the person in Hong Kong to send a copy of the license to its supplier. In the limited instances where the CCL covers items with one or more of the reasons for control noted above that are not listed on the Hong Kong control, such as when the Hong Kong Government and the United States Government update their control lists in response the changes in the multilateral export control regime lists at different times, the party in Hong Kong will have to obtain a written statement from the Hong Kong Government that a Hong Kong license is not required. However, the rule gives the party in Hong Kong several options for providing the required information. Various documents, including the Hong Kong government's specific response to a license application informing the applicant that a license is not required and more general statements downloaded from a Hong Kong Government Web site, will be adequate to fulfill this requirement. One document may be used for multiple shipments as long as the document remains accurate.

Despite the importance of prompt publication and effectiveness to our foreign policy goals as noted above, BIS recognizes that some exporters and reexporters will need time to obtain the required documentation from their customers for all transactions subject to this rule. Therefore, the effective date of this final rule is ninety days after publication.

List of Subjects

15 CFR Parts 740 and 748

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Part 762

Administrative practice and procedure, Business and industry, Confidential business information, Exports, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, parts 740, 742, and 762 of the Export Administration Regulations (15 CFR parts 730 through 774) are amended as follows:

PART 740—LICENSE EXCEPTIONS

■ 1. The authority citation for part 740 is revised to read as follows:

Authority: 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 7201 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 4, 2016, 81 FR 52587 (August 8, 2016).

■ 2. In § 740.2, add paragraphs (a)(19) and (20) to read as follows:

§ 740.2 Restrictions on all License Exceptions.

(a) * * *

(19) The exporter or reexporter to Hong Kong of any item subject to the EAR and controlled on the CCL for NS, MT, NP Column 1, or CB reasons has not received one of the following with respect to the item:

(i) A copy of an import license issued to the Hong Kong importer by the Government of the Hong Kong Special Administrative Region, pursuant to the Hong Kong Import and Export (Strategic Commodities) Regulations, that covers all items to be exported or reexported pursuant to that license exception for which a Hong Kong import license is required and that is valid on the date of the export or reexport that is subject to the EAR; or

(ii) A copy of a written statement issued by the Government of the Hong Kong Special Administrative Region that no import license is required to import into Hong Kong the item(s) to be exported or reexported. The statement may have been issued directly to the Hong Kong importer or it may be a written statement available to the general public. The statement may be used for more than one export or reexport to Hong Kong so long as it remains an accurate statement of Hong Kong law.

(20) The reexporter from Hong Kong of any item subject to the EAR controlled on the CCL for NS, MT, NP column 1, or CB reasons has not received one of the following with respect to the item:

(i) An export license issued by the Government of the Hong Kong Special Administrative Region, pursuant to the Hong Kong Import and Export (Strategic Commodities) Regulations, that covers all items to be reexported pursuant to that license exception for which a Hong Kong export license is required and that is valid on the date of the reexport that is subject to the EAR; or

(ii) A copy of a written statement issued by the Government of the Hong Kong Special Administrative Region that no Hong Kong export license is required for the item(s) to be reexported.

The statement may have been issued directly to the Hong Kong reexporter or it may be a written statement available to the general public. The statement may be used for more than one reexport from Hong Kong so long as it remains an accurate statement of Hong Kong law.

PART 748—APPLICATIONS (CLASSIFICATION, ADVISORY, AND LICENSE) AND DOCUMENTATION

■ 3. The authority citation for part 748 is revised to read as follows:

Authority: 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 4, 2016, 81 FR 52587 (August 8, 2016).

■ 4. 748.9(b) is amended by revising the section heading, revising paragraph (b) and all notes to paragraph (b), and adding two sentences to the end paragraph of (e)(1), to read as follows:

§ 748.9 Support documents for evaluation of foreign parties in license applications and/or for promoting compliance with license requirements.

* * * * *

(b) *Requirements to obtain support documents for license applications.* Unless an exception in paragraph (c) of this section applies, a support document is required for certain license applications for:

(1) The People's Republic of China (PRC) other than the Hong Kong Special Administrative Region (see §§ 748.10 and 748.11(a)(2));

(2) "600 Series Major Defense Equipment" (see § 748.11);

(3) Firearms and related commodities to member countries of the Organization of American States (see § 748.12); and

(4) The Hong Kong Special Administrative Region of the People's Republic of China (see § 748.13).

Note 1 to Paragraph (b): On a case-by-case basis, BIS may require license applicants to obtain a support document for any license application.

Note 2 to Paragraph (b): For End-Use Certificate requirements under the Chemical Weapons Convention, see § 745.2 of the EAR.

* * * * *

(e) * * *

(1) * * * The documents issued by the Government of the Hong Kong Special Administrative region that are required pursuant to § 748.13 are not used to evaluate license applications. They must be obtained before shipment and need not be obtained before submitting a license application.

* * * * *

■ 5. Redesignate § 748.13 as § 748.14 and add new § 748.13 to read as follows:

§ 748.13 Hong Kong import and export licenses.

(a) *Requirement to obtain the document—*(1) *Exports and reexports to Hong Kong.* An exporter or reexporter must obtain the documents described in paragraph (a)(1)(i) or (a)(1)(ii) of this section before using a license issued by BIS to export or reexport to Hong Kong any item subject to the EAR and controlled on the CCL for NS, MT, NP column 1, or CB reasons. Collectively, the documents issued by Hong Kong must cover all of the items to be exported or reexported pursuant to a license.

(i) A copy of an import license issued to the Hong Kong importer by the Government of the Hong Kong Special Administrative Region, pursuant to the Hong Kong Import and Export (Strategic Commodities) Regulations, that covers the items to be exported or reexported pursuant to that BIS license for which a Hong Kong import license is required and that is valid on the date of the export or reexport that is subject to the EAR; or

(ii) A copy of a written statement issued by the Government of the Hong Kong Special Administrative Region that no import license is required to import into Hong Kong the item(s) to be exported or reexported to Hong Kong. The statement may have been issued directly to the Hong Kong importer or it may be a written statement available to the general public. The statement may be used for more than one export or reexport to Hong Kong so long as it remains an accurate statement of Hong Kong law.

(2) *Reexports from Hong Kong.* No license issued by BIS may be used to reexport from Hong Kong any item subject to the EAR controlled on the CCL for NS, MT, NP column 1, and/or CB reasons unless the reexporter has received either:

(i) An export license issued by the Government of the Hong Kong Special Administrative Region, pursuant to the Hong Kong Import and Export (Strategic Commodities) Regulations, that covers all items to be reexported pursuant to that BIS license for which a Hong Kong export license is required and that is valid on the date of the reexport that is subject to the EAR; or

(ii) A copy of a written statement issued by the Government of the Hong Kong Special Administrative Region that no export license is required from Hong Kong for the item(s) to be reexported. The statement may have been issued directly to the Hong Kong

reexporter or it may be a written statement available to the general public. The statement may be used for more than one reexport from Hong Kong so long as it remains an accurate statement of Hong Kong law.

(b) *Recordkeeping.* The documents required to be obtained by paragraph (a) of this section must be retained and made available to the U.S. Government upon request in accordance with part 762 of the EAR.

PART 762—RECORDKEEPING

■ 6. The authority citation for part 762 continues to read as follows:

Authority: 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 4, 2016, 81 FR 52587 (August 8, 2016).

■ 7. In § 762.2 remove the word "and" from the end of paragraph (b)(52); remove the period from the end of paragraph (b)(53) and add in its place a semicolon followed by the word "and"; add paragraph (b)(54) to read as follows:

§ 762.2 Records to be retained.

* * * * *

(b) * * *

(54) § 748.13, Certain Hong Kong import and export licenses.

* * * * *

Dated: January 6, 2017.

Kevin J. Wolf,

Assistant Secretary for Export Admiration.

[FR Doc. 2017–00446 Filed 1–18–17; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 742 and 748

[Docket No. 170104015–7015–01]

RIN 0694–AH26

Amendments to the Export Administration Regulations Implementing an Additional Phase of India-U.S. Export Control Cooperation

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: In this final rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) to implement the India-U.S. Joint Statement of June 7, 2016 (June Statement), which recognized the United States and India as Major Defense Partners. This rule amends the EAR by establishing a licensing policy of general approval for exports or

reexports to or transfers within India of items subject to the EAR and controlled only for National Security or Regional Stability reasons. In addition, BIS amends the end use and end user provisions of the Validated End User (VEU) authorization to state that items obtained under authorization VEU in India may be used for either civil or military end uses *other* than those that are for use in nuclear, “missile,” or chemical or biological weapons activities.

DATES: This rule is effective January 19, 2017.

FOR FURTHER INFORMATION CONTACT: Alexander Lopes, Director, Office of Nonproliferation Controls and Treaty Compliance, Bureau of Industry and Security, Phone: (202) 482–3825.

SUPPLEMENTARY INFORMATION:

Background

As announced by President Obama and India’s Prime Minister Singh in a U.S.-India Joint Statement on November 8, 2010, the United States and India formally committed to work together to strengthen the global nonproliferation and export control framework and further transform bilateral export control cooperation to realize the full potential of the global strategic partnership between the two countries. The leaders agreed to take mutual steps to expand cooperation in civil space, defense, and other high-technology sectors. The steps agreed to by the United States included the removal of Indian defense and space-related entities from the Entity List (Supplement No. 4 to part 744 of the EAR) and the realignment of India in U.S. export control regulations. Additionally, the 2010 Joint Statement announced that the United States “intend[ed] to support India’s full membership in the four multilateral export control regimes (Nuclear Suppliers Group, Missile Technology Control Regime, Australia Group, and Wassenaar Arrangement) in a phased manner, and to consult with regime members to encourage the evolution of regime membership criteria,” while maintaining these regimes’ core principles, “as the Government of India took steps towards the full adoption of the regimes’ export control requirements to reflect its prospective membership, with both processes moving forward together.”

To date, BIS has published two rules implementing the President’s and Prime Minister’s commitments. The first rule, published on January 25, 2011 (76 FR 4228), revised certain export and reexport controls for India, including

the removal of nine Indian entities from the Entity List. In addition, BIS amended the EAR to remove India from Country Groups D:2, D:3 and D:4, and added India to Country Group A:2.

In the second rule, published January 23, 2015 (80 FR 3463), BIS amended the EAR, in furtherance of the United States’ commitment to the bilateral understanding, by removing India from Crime Control (CC) columns 1 and 3 and from Regional Stability (RS) column 2 on the Commerce Country Chart in Supplement No. 1 to Part 738 of the EAR, because the Government of India had taken appropriate steps to ensure that U.S.-origin items controlled for CC and RS reasons are not reexported from India without a license. Although the second rule removed the license requirement for the majority of items controlled for CC or RS reasons and destined for India, a license requirement remained for items controlled under export control classification numbers (ECCNs) 6A003.b.4.b and 9A515.e for RS column 2 reasons when destined to India.

In addition, BIS published on August 17, 2016, a third rule (81 FR 54721) that was not specific to the bilateral understanding but nonetheless removed a related requirement to include a destination control statement on shipping documents for items controlled for CC columns 1 and 3, and RS column 2 reasons when the items are exported to India.

New Amendments

In this rule, BIS implements an additional step in furtherance of the U.S.-India bilateral understanding and global strategic partnership. On June 7, 2016, the United States and India issued a Joint Statement entitled, “The United States and India: Enduring Global Partners in the 21st Century.” Specifically, in this rule, BIS implements the understanding between the United States and India expressed in the June Statement regarding U.S. export control policy toward India by establishing a new paragraph (b)(8) in § 742.4 (National Security) and a new paragraph (b)(5) in § 742.6 (Regional Stability). These new provisions establish licensing policies of general approval for exports or reexports to or transfers within India of items subject to the EAR, including “600 series” military items, for civil or military end uses in India or for the ultimate end use by the Government of India, for reexport to a Country Group A:5 country, or for return to the United States, so long as such items are not for use in nuclear, “missile,” or chemical or biological weapons activities. This rule does not

amend any other licensing policies in part 742 such as those with respect to Missile Technology items. The rule also does not amend any licensing policies pertaining to naval nuclear propulsion. The Country Group A:5 countries are listed in Supplement Number 1 to part 740 and are often informally referred to as the “STA–36” countries because they are the list of countries to which exports under License Exception Strategic Trade Authorization are authorized pursuant to the conditions and limitations of section 740.20(b)(3).

In addition, BIS amends the end user and end use provisions of the Validated End User (VEU) authorization in § 748.15 (Authorization Validated End-User (VEU)), paragraphs (a) (eligible end user provision) and (d) (end-use restrictions), to allow that items obtained under authorization VEU in India may be used for civil or military end uses other than those that involve items controlled for MT reasons, or if for use in nuclear, “missile,” or chemical or biological weapons activities. Section 748.15(c) does not change the January 23, 2015 (80 FR 3463), amendment to the EAR regarding the export and reexport of Crime Control (CC) columns 1 and 3 items to India. Conforming changes are made to paragraph (7)(ii) in Supplement No. 8 to Part 748 (Information Required in Requests for Validated End-User (VEU) Authorization). No other material changes are made in this rule to the VEU program, such as the process for approving a VEU, VEU compliance obligations, the rules pertaining to VEU in China, or the process of identifying approved VEU and eligible items and facilities in Supplement No. 7 to Part 748.

Export Administration Act

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013), and as extended most recently by the Notice of August 4, 2016, 81 FR 52587 (August 8, 2016), has continued the EAR in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and

benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) control number. This rule involves a collection of information approved under OMB control number 0694-0088—Simplified Network Application Process—Redesign System (SNAP-R) and the Multipurpose Export License Application, which carries an annual estimated burden of 31,833 hours. BIS believes that this rule will not have a material impact on that burden because this rule does not increase or decrease BIS's existing licensing requirements. To the extent that it has any impact, BIS believes that the benefits of this rule justify any additional (and likely minimal) additional burden it might create. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Jasmeet K. Seehra, Office of Management and Budget, by email at jseehra@omb.eop.gov or by fax to (202) 395-7285.

3. This rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking and the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military or foreign affairs function of the United States (*see* 5 U.S.C. 553(a)(1)). This rule advances essential foreign policy, national security, and nonproliferation goals of the United States and a critical strategic partner, India. Subsequent agency deliberations following the June Statement culminated in this framework

for regulatory implementation of the Statement. Delay in implementing this rule to obtain public comment or for any other reason would undermine the good faith timeliness in which the United States signed, and now implements, the Statement and, therefore, would undermine the foreign policy objectives that the rule is intended to serve. Further, no other law requires that a notice of proposed rulemaking or an opportunity for public comment be given for this rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required for this rule under 5 U.S.C. 553, or by any other law, the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable.

List of Subjects

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 748

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

Accordingly, 15 CFR parts 742 and 748 of the EAR (15 CFR parts 730 through 774) are amended as follows:

PART 742—CONTROL POLICY—CCL BASED CONTROLS

■ 1. The authority citation for 15 CFR part 742 continues to read as follows:

Authority: 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23, 68 FR 26459, 3 CFR, 2004 Comp., p. 320; Notice of November 12, 2015, 80 FR 70667 (November 13, 2015); Notice of August 4, 2016, 81 FR 52587 (August 8, 2016).

■ 2. Section 742.4 is amended by adding paragraph (b)(8) to read as follows:

§ 742.4 National security.

* * * * *

(b) * * *

(8) For India, there is a general policy of approval for license applications to export, reexport, or transfer items, including “600 series” items, for civil or military end uses in India, for ultimate end use by the Government of India, for reexport to countries in Country Group A:5, or for return to the United States, so long as such items are not for use in

nuclear, “missile,” or chemical or biological weapons activities.

* * * * *

■ 3. Section 742.6 is amended by adding paragraph (b)(7) to read as follows:

§ 742.6 Regional Stability.

* * * * *

(b) * * *

(7) For India, there is a general policy of approval for license applications to export, reexport, or transfer items, including “600 series” items, for civil or military end uses in India, for ultimate end use by the Government of India, for reexport to countries in Country Group A:5, or for return to the United States, so long as such items are not for use in nuclear, “missile,” or chemical or biological weapons activities.

* * * * *

PART 748—APPLICATIONS (CLASSIFICATION, ADVISORY, AND LICENSE) AND DOCUMENTATION

■ 4. The authority citation for 15 CFR part 748 continues to read as follows:

Authority: 50 U.S.C. 4601 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23, 68 FR 26459, 3 CFR, 2004 Comp., p. 320; Notice of November 12, 2015, 80 FR 70667 (November 13, 2015); Notice of August 4, 2016, 81 FR 52587 (August 8, 2016).

■ 5. Section 748.15 is amended by revising paragraphs (a)(2) and (d) introductory text to read as follows:

§ 748.15 Authorization Validated End-User (VEU).

* * * * *

(a) * * *

(2) In evaluating an end user for eligibility under authorization VEU, the ERC will consider a range of information, including such factors as: The entity's record of exclusive engagement in appropriate end-use activities; the entity's compliance with U.S. export controls; the need for an on-site review prior to approval; the entity's capability of complying with the requirements of authorization VEU; the entity's agreement to on-site reviews by representatives of the U.S. Government to ensure adherence to the conditions of the VEU authorization; and the entity's relationships with U.S. and foreign companies. In addition, when evaluating the eligibility of an end user, the ERC will consider the status of

export controls and the support and adherence to multilateral export control regimes of the government of the eligible destination.

* * * * *

(d) *End-use restrictions.* Items obtained under authorization VEU in China may be used only for civil end uses and may not be used for any activities described in part 744 of the EAR. Items obtained under authorization VEU in India may be used for either civil or military end uses and may not be used for any activities described in part 744 of the EAR. Exports, reexports, or transfers made under authorization VEU may be made to an end user listed in Supplement No. 7 to this part only if the items will be consigned to and for use by the validated end user. Eligible end-users who obtain items under VEU may only:

* * * * *

■ 6. Paragraph (7)(ii) of the section titled *Required Information for Validated End-User Authorization Requests* in Supplement No. 8 to part 748 is revised to read as follows:

**Supplement No. 8 to Part 748—
Information Required in Requests for
Validated End-User (VEU)
Authorization**

* * * * *

*Required Information for Validated End-User
Authorization Requests*

* * * * *

(7) * * *

(ii) Understands and will abide by all authorization VEU end-use restrictions, including the requirement that items received under authorization VEU will only be used for authorized end-uses and may not be used for any activities described in part 744 of the EAR;

* * * * *

Dated: January 6, 2017.

Kevin J. Wolf,

*Assistant Secretary for Export
Administration.*

[FR Doc. 2017-00439 Filed 1-18-17; 8:45 am]

BILLING CODE 3510-33-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 902

50 CFR Part 300

[Docket No. 120201087-6641-02]

RIN 0648-BB86

International Affairs; Antarctic Marine Living Resources Convention Act

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: This final rule sets forth changes to the regulations that implement conservation measures adopted by the Commission for the Conservation of Antarctic Marine Living Resources (CCAMLR or Commission). This final rule streamlines and clarifies the regulations for Antarctic marine living resources, shifts deadlines for advance notice of intended fishing activities, distinguishes between first receivers and dealers of Antarctic marine living resources (AMLR), reduces the time for advance notice of imports of *Dissostichus* species, and adds transshipment notification requirements. The sections of these regulations are reorganized to group requirements related to the trade of Antarctic marine living resources and those that apply to fishing activities. Additionally, this action updates the regulations to reflect Commission-adopted revisions to existing conservation measures and changes made to the Antarctic Marine Living Resources Convention Act through the Illegal, Unreported, and Unregulated Fishing Enforcement Act of 2015.

DATES: This rule is effective February 21, 2017.

FOR FURTHER INFORMATION CONTACT: Mi Ae Kim, Office of International Affairs and Seafood Inspection, NMFS (phone 301-427-8365, or email mi.ae.kim@noaa.gov).

SUPPLEMENTARY INFORMATION:

Background

The United States is a Contracting Party to the Convention on the Conservation of Antarctic Marine Living Resources (Convention). Under Article VII of the Convention, contracting parties established and agreed to maintain the Commission to give effect to the Convention's objective—conservation of AMLR. The United

States, along with 23 other countries and the European Union, are members of the Commission and meet annually to formulate, adopt and revise conservation measures. Article IX(6) of the Convention requires the Commission to notify conservation measures to all members and, 180 days thereafter, such measures become binding. If a member objects to a measure within 90 days of notification, the measure is not binding on that member and, should that occur, Article IX(6)(d) of the Convention includes a procedure that allows other members to notify that they can no longer accept that measure.

The Antarctic Marine Living Resources Convention Act of 1984 (AMLRCA), codified at 16 U.S.C. 2431, *et seq.*, provides the statutory authority for the United States to carry out its obligations under the Convention, including implementation of Commission-adopted conservation measures. AMLRCA section 305(a)(1) authorizes the Secretary of State, with the concurrence of the Secretary of Commerce and the Director of the National Science Foundation, to decide whether the United States is unable to accept or can no longer accept a Commission-adopted conservation measure (16 U.S.C. 2434(a)(1)). AMLRCA also gives the Secretary of Commerce authority to promulgate regulations as necessary and appropriate to implement the Act. This authority has been delegated to the Assistant Administrator for Fisheries (Assistant Administrator), who has implemented Commission-adopted conservation measures that are binding on the United States under Article IX of the Convention through regulations at 50 CFR part 300, subpart G (AMLR regulations).

Through the “Illegal, Unreported, and Unregulated Fishing Enforcement Act” (IUU Fishing Enforcement Act), Public Law 114–81 (2015), Congress amended AMLRCA section 306, 16 U.S.C. 2435, which specifies unlawful activities; section 307, 16 U.S.C. 2436, which provides the Secretary of Commerce authority to promulgate regulations that are necessary and appropriate to implement AMLRCA; and section 308(a), 16 U.S.C. 2437(a), which specifies the penalties available for violations of the Act. Public Law 114–81 (2015), Title I, 106(1)–(2).

At each annual meeting, the Commission may adopt new conservation measures or revise existing measures. While all conservation measures are subject to revision at the annual meeting, some (particularly those in the fishery regulation category)

expire after one or two fishing seasons and so must be revised annually or biennially, to reflect management or monitoring needs identified during Commission deliberations, changes in catch limits or bycatch limits, or other considerations.

Through this action, NMFS reorganizes, streamlines, and updates the regulations that implement AMLRCA and Commission-adopted conservation measures. These revisions incorporate regulatory changes that were finalized on August 3, 2016 (80 FR 51126) regarding the collection of trade documentation within the government-wide International Trade Data System and required electronic information collection. Certain sections are rearranged so that regulations applicable to the trade of AMLR are grouped together while other sections that are obsolete are removed. This action removes sections that implement annual measures which will be implemented through vessel permits if applicable to the permitted fishing activities.

On July 21, 2016, NMFS published a notice of proposed rulemaking for this action (81 FR 47325) to reorganize and update the regulations implementing U.S. obligations under the Convention. The preamble of the proposed rule (81 FR 47325) provides a detailed description of the changes to these regulations as well as NMFS's implementation of annual or biennial measures as conditions to vessel permits instead of through regulations. Responses to public comments received on the proposed rule are set forth below.

Changes From the Proposed Rule

With the exception of minor, non-substantive editorial corrections, this final rule includes no changes to the regulatory text that was published in the proposed rule.

Responses to Public Comments

NMFS received two public comments on the proposed rule which are addressed below.

CCAMLR Ecosystem Monitoring Program Sites

Comment 1: A commenter expressed concern over the removal of the list of CCAMLR Ecosystem Monitoring Program (CEMP) sites from the regulations.

Response: This final rule removes the list of CEMP sites because these sites (Seal Islands, South Shetland Islands and Cape Shirreff and the San Telmo Islands) are no longer protected under CCAMLR conservation measures. The Scientific Committee advised during the 2007 meeting of the Commission that:

“because research on the Seal Island CEMP site was no longer undertaken, Conservation Measure 91–03 should be discontinued.” As a result, the Commission discontinued Conservation Measure 91–03 (Report of the Twenty-Sixth Meeting of the Commission: Paragraphs 7.1 and 7.2). Similarly, during the 2009 meeting of the Commission, upon advice from the Scientific Committee, the Commission rescinded Conservation Measure 91–02 (Protection of the Cape Shirreff CEMP site) to avoid duplication of effort on the part of researchers, national governments and the secretariats of CCAMLR and Antarctic Treaty System and noting that the site would continue to be protected under the management plan of an Antarctic Specially Protected Area (ASPA) (Report of the Twenty-Eighth Meeting of the Commission: Paragraph 12.5). ASPAs, as well as Antarctic Specially Managed Areas (ASMAs) are designated and managed under the Antarctic Treaty, and CCAMLR cooperates in implementing these designations and management plans by having Contracting Parties ensure that their fishing vessels are aware of the location and relevant management plan of all designated ASPAs and ASMAs.

Regulatory Structure

Comment 2: NMFS received a comment from United States Seafoods, LLC suggesting that NMFS consider its experience on managing fisheries under the Magnuson-Stevens Fishery Conservation and Management Act (MSA) to establish a stable regulatory environment for U.S. vessels that intend to fish in the CCAMLR Convention Area.

Response: U.S. fishing vessels have not operated within the Convention Area for over a decade. For U.S. vessels interested in fishing in the Convention Area, NMFS established procedures and requirements under the AMLR regulations and, through this rulemaking, makes improvements to that regulatory framework. One improvement is that, under this rule, NMFS may implement annual and biennial measures adopted by CCAMLR as conditions to vessel permits instead of through regulations. Given the short time period between the adoption of new measures by CCAMLR in the fall and the start of the fishing season on December 1, this approach will make the regulatory process more efficient for U.S. vessels and NMFS.

Section 300.101 of the rule defines “annual or biennial measure” as a conservation measure that: (1) Applies to the operation of the Convention’s

commercial or exploratory fisheries such as gear, catch, and effort restrictions and time and area closures; (2) generally expires after one or two fishing season(s); and (3) does not require the development of policy options or a regulatory framework. This approach will apply only to conservation measures that do not require the development of policy options or a regulatory framework. NMFS will provide for notice-and-comment rulemaking when implementation of a conservation measure implicates other requirements of domestic law or when NMFS needs to interpret or expand upon a conservation measure.

Under this final rule, an application for a vessel permit must be submitted by April 1 for the fishing season that will commence on or after December 1 of that year. Therefore, as part of the vessel permit application process and through the permit itself once issued by NMFS, the applicant would have notice of applicable measures in advance of the start of the fishing season. Moreover, annual and biennial measures, along with all CCAMLR conservation measures currently in force are updated every year following the Commission’s annual meeting and made available on the Commission’s Web site, www.ccamlr.org and are, therefore, available to all interested members of the public, including prospective participants in CCAMLR fisheries. NMFS may reconsider its approach to implementation of annual and biennial measures if participation by U.S. fishing vessels in CCAMLR fisheries increases.

Classification

This rule is published under the authority of Antarctic Marine Living Resources Convention Act, codified at 16 U.S.C. 2431 *et seq.*

Regulatory Flexibility Act (RFA)

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) at the proposed rule stage that this rule is not expected to have a significant economic impact on a substantial number of small entities (81 FR 47330, July 21, 2016). The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a regulatory flexibility analysis is not required and none has been prepared.

Paperwork Reduction Act

This rule contains a Paperwork Reduction Act (PRA) collection-of-

information approved by the Office of Management and Budget (OMB) under control number 0648–0194. The table appearing at 15 CFR part 902 is updated to reflect the reorganization of regulations under this final rule. The current, approved collection of information includes permit applications (CEMP, vessel permit, dealer permit, and pre-approval of toothfish imports), vessel and gear marking requirements, installation of and reporting through a vessel monitoring unit, import tickets, and other items.

This rule also contains a new PRA collection-of-information that requires advance notification of transshipments of AMLRs, bait, fuel, or other goods and materials to the CCAMLR Secretariat and submission of a confirmation of the notification to NMFS Headquarters, including information on the vessels involved in the transshipment and the details of the materials being transshipped. The new information collection requirements have been approved by OMB under control number 0648–0742.

Notwithstanding any other provision of the law, no person is required to respond to, and no person shall be subject to penalty for failure to comply with, a collection-of-information subject to the requirements of the PRA, unless that collection-of-information displays a currently valid OMB control number.

List of Subjects

15 CFR Part 902

Reporting and recordkeeping requirements.

50 CFR Part 300

Antarctica, Antarctic marine living resources, Catch documentation scheme, Fisheries, Fishing, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: January 5, 2017.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, NMFS amends 15 CFR part 902 and 50 CFR part 300 as follows:

TITLE 15: COMMERCE AND FOREIGN TRADE

PART 902—NOAA INFORMATION COLLECTION REQUIREMENTS UNDER THE PAPERWORK REDUCTION ACT: OMB CONTROL NUMBERS

■ 1. The authority citation for part 902 continues to read as follows:

Authority: 44 U.S.C. 3501 *et seq.*

■ 2. In § 902.1, the table in paragraph (b) under “50 CFR” is amended by removing the entries for 300.103(a), 300.104(d), 300.104(e), 300.105(c), 300.106(e), 300.107, 300.108(a), 300.108(c), 300.112, and 300.113 and adding entries in numeric order to read as follows:

§ 902.1 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

| CFR part or section where the information collection requirement is located | Current OMB control number (all numbers begin with 0648–) |
|---|---|
| 50 CFR: | |
| 300.103(b) and (c) | –0194 |
| 300.104 | –0194 |
| 300.105 | –0194 |
| 300.106 | –0194 |
| 300.107(c) and (l) | –0194 |
| 300.107(k) | –0724 |
| 300.108 | –0194 |
| 300.109(c) | –0194 |
| 300.110(e) | –0194 |
| 300.111 | –0194 |
| 300.112 | –0194 |
| 300.113(a) | –0194 |

Title 50: Wildlife and Fisheries

PART 300—INTERNATIONAL FISHERIES REGULATIONS

■ 3. The authority citation for part 300 continues to read as follows:

Authority: 16 U.S.C. 951 *et seq.*, 16 U.S.C. 1801 *et seq.*, 16 U.S.C. 5501 *et seq.*, 16 U.S.C. 2431 *et seq.*, 31 U.S.C. 9701 *et seq.*

■ 4. Revise subpart G to read as follows:

Subpart G—Antarctic Marine Living Resources

| Sec. | |
|---------|--|
| 300.100 | Purpose and scope. |
| 300.101 | Definitions. |
| 300.102 | Relationship to other treaties, conventions, laws, and regulations. |
| 300.103 | Scientific research. |
| 300.104 | International Fisheries Trade Permits and AMLR first receiver permits. |
| 300.105 | Preapproval for importation of frozen <i>Dissostichus</i> species. |
| 300.106 | Catch Documentation Scheme (CDS) documentation and other requirements. |
| 300.107 | Vessel permits and requirements. |
| 300.108 | Vessel and gear identification. |
| 300.109 | Initiating a new fishery. |

| | |
|---------|---|
| 300.110 | Exploratory fisheries. |
| 300.111 | Scientific observers. |
| 300.112 | Vessel monitoring system. |
| 300.113 | CCAMLR Ecosystem Monitoring Program sites. |
| 300.114 | Prohibitions. |
| 300.115 | Facilitation of enforcement and inspection. |
| 300.116 | Penalties. |

Subpart G—Antarctic Marine Living Resources

Authority: 16 U.S.C. 2431 *et seq.*, 31 U.S.C. 9701 *et seq.*

§ 300.100 Purpose and scope.

(a) This subpart implements the Antarctic Marine Living Resources Convention Act of 1984 (AMLRCA or Act), 16 U.S.C. 2431 *et seq.*

(b) This subpart regulates—

(1) The harvesting of Antarctic marine living resources and other associated activities by any person subject to the jurisdiction of the United States or by any vessel of the United States.

(2) The import, export, and re-export into the United States of any Antarctic marine living resource.

§ 300.101 Definitions.

In addition to the terms defined in § 300.2, in the Act, and in the Convention on the Conservation of Antarctic Marine Living Resources, done at Canberra, Australia, May 7, 1980 (Convention) the terms used in this subpart have the following meanings for purposes of this subpart. If a term is defined differently in § 300.2, than in the Act, or Convention, the definition in this section shall apply.

ACA means the Antarctic Conservation Act of 1978 (16 U.S.C. 2401, *et seq.*).

Annual or biennial measure means a conservation measure that:

(1) Applies to the operation of the Convention's commercial or exploratory fisheries such as gear, catch, and effort restrictions and time and area closures;

(2) Generally expires after one or two fishing season(s); and

(3) Does not require the development of policy options or a regulatory framework.

Antarctic convergence means a line joining the following points along the parallels of latitude and meridians of longitude:

| Lat. | Long. |
|-------------|---------|
| 50° S | 0. |
| 50° S | 30° E. |
| 45° S | 30° E. |
| 45° S | 80° E. |
| 55° S | 80° E. |
| 55° S | 150° E. |
| 60° S | 150° E. |

| Lat. | Long. |
|-------------|--------|
| 60° S | 50° W. |
| 50° S | 50° W. |
| 50° S | 0. |

Antarctic marine living resources or AMLR(s) means:

(1) The populations of finfish, mollusks, crustaceans, and all other species of living organisms, including birds, found south of the Antarctic Convergence;

(2) All parts or products of those populations and species set forth in paragraph (1) of this definition.

Centralized Vessel Monitoring System (C-VMS) means the system operated by the Secretariat of CCAMLR that receives reports of positional and other information from satellite-linked mobile transceiver units located on vessels that are submitted to the CCAMLR Secretariat, either directly from the vessel or through the relevant flag State.

Commission or CCAMLR means the Commission for the Conservation of Antarctic Marine Living Resources established under Article VII of the Convention.

Convention Area means all waters south of the Antarctic Convergence.

Dealer means a person who imports AMLRs into, or exports or re-exports AMLRs from, the United States.

Dissostichus catch document (DCD) is a document generated through CCAMLR's electronic catch documentation scheme (CDS), containing information relating to the harvest, landing, and transshipment of *Dissostichus* species.

Dissostichus export document (DED) is a document generated through the CCAMLR's electronic CDS, containing information relating to the export of *Dissostichus* spp.

Dissostichus re-export document (DRED) is a document generated through CCAMLR's electronic CDS, containing information relating to the re-export of *Dissostichus* spp.

Dissostichus species or *Dissostichus* spp. means Patagonian toothfish and Antarctic toothfish, and any parts or products therefrom.

Enhanced mobile transceiver unit or EMTU means a transceiver or communication device, including all hardware and software, carried and operated on a vessel as part of a vessel monitoring system.

Export means any movement of fish or fish product from a territory under the control of the State or free trade zone of landing, or where that State or free trade zone forms part of a customs union, any other Member State of that customs union.

First receiver means the person who first receives AMLRs landed from a vessel licensed under 50 CFR 300.107 at a U.S. port.

Fish means finfish, mollusks, and crustaceans.

Fishery means:

(1) One or more stocks of fish that are treated as a unit for purposes of conservation and management and that are identified on the basis of geographical, scientific, technical, recreational, and economic characteristics.

(2) Any fishing for such stocks.

Harvesting vessel means any vessel of the United States (including any boat, ship, or other craft), that is used for, equipped to be used for, or of a type that is normally used for harvesting.

Import means the physical entering or bringing of a fish or fish product into any part of the geographical territory under the control of a State, except where the catch is landed or transshipped within the definitions of landing or transshipment.

Individual permit means a National Science Foundation (NSF) permit issued under 45 CFR part 670; or an NSF award letter (demonstrating that the individual has received an award from NSF to do research in the Antarctic); or a marine mammal permit issued under § 216.31 of this chapter; or an endangered species permit issued under § 222.21 of this chapter.

Inspection vessel means a vessel carrying a CCAMLR inspector and displaying the pennant approved by CCAMLR to identify such vessel.

International observer means a scientific observer operating in accordance with the CCAMLR Scheme of International Scientific Observation and the terms of a bilateral arrangement concluded between the United States and another member of CCAMLR for the placement of a U.S. national onboard a vessel flagged by another member of CCAMLR or for the placement of the national of another member of CCAMLR onboard a vessel of the United States.

Land or Landing means to begin offloading any fish, to arrive in port with the intention of offloading any fish, or to cause any fish to be offloaded. However, for purposes of catch documentation as provided for in § 300.106, land or landing means the initial unloading or transfer of *Dissostichus* spp. in any form from a vessel to dockside even if such fish are subsequently transferred to a container or to another vessel in a port or free trade zone.

National observer means a U.S. national placed and operating onboard a

vessel of the United States as a scientific observer in accordance with § 300.111.

National Seafood Inspection Laboratory means the NMFS laboratory located at 3209 Frederic Street, Pascagoula, MS 39567, telephone (228) 769-8964, email PTFReporting@noaa.gov.

Office of Law Enforcement (OLE) refers to the NOAA Office of Law Enforcement.

Port-to-port means from the time the vessel leaves port to the time that the vessel returns to port and at all points in between.

Real-time means as soon as possible, but at least every hour with no more than a 1-hour delay.

Recreational fishing means fishing with hook and line for personal use and not for sale.

Re-export means any movement of a fish or fish product from a territory under the control of a State, free trade zone, or Member State of a customs union of import unless that State, free trade zone, or any Member State of that customs union is the first place of landing, in which case the movement is an export within the definition of export.

Seal excluder device means a barrier within the body of a trawl comprised of a metal frame, nylon mesh, or any material that results in an obstruction to seals between the mouth opening and the cod end of the trawl. The body of the trawl net forward of the barrier must include an escape opening through which seals entering the trawl can escape.

Specially Validated Dissostichus Catch Document (SVDCD) means a *Dissostichus* catch document that has been specially issued by a State to accompany seized or confiscated *Dissostichus* spp. offered for sale or otherwise disposed of by the State.

Transship or transshipment means the transfer of fish or fish products, other AMLRs, or any other goods or materials directly from one vessel to another. However, for purposes of catch documentation as provided for in § 300.106, transship or transshipment means the transfer of *Dissostichus* spp. that has not been previously landed, from one vessel directly to another, either at sea or in port.

Vessel Monitoring System (VMS) means a system that uses satellite-linked EMTUs installed on vessels to allow a flag State or other entity to receive automatic transmission of positional and other information related to vessel activity.

§ 300.102 Relationship to other treaties, conventions, laws, and regulations.

(a) Other conventions and treaties to which the United States is a party and other Federal statutes and implementing regulations may impose additional restrictions on the harvesting and importation into the United States of AMLRs.

(b) The ACA implements the Antarctic Treaty Agreed Measures for the Conservation of Antarctic Fauna and Flora (12 U.S.T. 794). The ACA and its implementing regulations (45 CFR part 670) apply to certain defined activities of U.S. citizens south of 60° S. lat.

(c) The Marine Mammal Protection Act of 1972 (16 U.S.C. 1361 *et seq.*), the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*), the Migratory Bird Treaty Act (16 U.S.C. 701 *et seq.*), and their implementing regulations also apply to the harvesting and importation of AMLRs.

(d) Rule making exceptions. When implementing conservation measures adopted and notified by CCAMLR, NMFS may apply the following exceptions to Administrative Procedure

Act (APA) rulemaking requirements at 5 U.S.C. 553(b)–(d):

(1) The foreign affairs function exception of the APA, 5 U.S.C. 553(a)(1); or

(2) The exception under subsection 307(b) of AMLRCA, 16 U.S.C. 2436(b), that provides that, notwithstanding 5 U.S.C. 553(b)–(d), NMFS may publish in the **Federal Register** a final regulation to implement any CCAMLR-adopted conservation measure—

(i) That has been in effect for 12 months or less, beginning on the date that the Commission notifies the United States of the conservation measure under Article IX of the Convention; and

(ii) With respect to which the Secretary of State does not notify the Commission in accordance with section 305(a)(1) of AMLRCA within the time period allotted for objections under Article IX of the Convention.

(e) Annual or biennial measures. NMFS may implement annual or biennial measures adopted by CCAMLR as conditions to vessel permits issued under section 300.107, instead of through rulemaking.

§ 300.103 Scientific research.

(a) This section applies to any person, using a vessel for research purposes, who intends to catch more than 1 tonne of finfish or krill or use gear other than longline, trawl, or pot to catch *Dissostichus* spp.

(b) Any person planning to use a vessel for research purposes, when the estimated research catch is expected to be less than 50 tonnes of finfish in a season, and no more than the amounts specified in Table 1, must notify the Assistant Administrator at least 2 months in advance of the planned research using the CCAMLR Format for Notification of Research Vessel Activity, Format 1. A copy of the format is available from NMFS Headquarters. The format requires:

- (1) Name and registration number of vessel;
- (2) Division and subarea in which research is to be carried out;
- (3) Estimated dates of entering and leaving the Convention Area;
- (4) Purposes of research; and
- (5) Fishing equipment to be used (bottom trawl, midwater trawl, longline, crab pots, other).

TABLE 1—TAXA-SPECIFIC THRESHOLDS FOR NOTIFICATION OF RESEARCH VESSEL ACTIVITY

| Taxon | Gear type | Expected catch |
|--------------------------------------|----------------|--|
| Thresholds for finfish taxa: | | |
| <i>Dissostichus</i> spp | Longline | 5 tonnes. |
| | Trawl | 5 tonnes. |
| | Pot | 5 tonnes. |
| | Other | 0 tonnes. |
| <i>Champscephalus gunnari</i> | All | 10 tonnes. |
| Thresholds for non-fish taxa: | | |
| Krill | All | 0.1 percent of the catch limit for a given area. |
| Squid. | | |
| Crabs. | | |

(c) Any person planning to use any vessel for research purposes, when the estimated research catch is expected to be more than 50 tonnes or greater than the amounts specified in Table 1 must report the details of the research plan to NMFS using CCAMLR Format 2 for Notification of Research Vessel Activity. The format must be submitted to Assistant Administrator at least 7 months in advance of the planned start date for the research. A copy of the format is available from NMFS Headquarters. The format requires:

- (1) Description of the main objective of the research;
- (2) Description of the fishery operations;
- (3) Description of the survey design, data collection, and analysis;
- (4) Proposed catch limit;

(5) Description of the research capability; and

(6) Description of the reporting for evaluation and review.

(d) Where the expected catch is more than 50 tonnes of fish or greater than the amounts specified in Table 1, the planned fishing for research purposes shall not proceed until the Assistant Administrator authorizes the person in writing that he or she may proceed. Such authorization may be provided after completion of review of the scientific research plan by the CCAMLR Scientific Committee and Commission.

(e) A summary of the results of any research subject to these provisions must be provided to the Assistant Administrator within 150 days of the completion of the research and a full report must be provided within 11 months.

(f) Catch, effort, and biological data resulting from the research must be reported using the reporting format for research vessels in accordance with relevant conservation measures, with a copy to NMFS Headquarters.

§ 300.104 International Fisheries Trade Permits and AMLR first receiver permits.

(a) *General.* (1) A person may import, export, or re-export AMLR into the United States only under a NMFS-issued International Fisheries Trade Permit (IFTP). For AMLRs to be released for entry into the United States, the product must be accompanied by a vessel permit, individual permit, AMLR first receiver permit, or IFTP.

(2) All shipments of *Dissostichus* spp. must also be accompanied by accurate, complete and valid CDS documentation (including all required validations and

DEds/DREds) as described in § 300.106, and, in the case of shipments of frozen *Dissostichus* species, a preapproval certificate issued under § 300.105, as well as verifiable information that the harvesting vessel was reporting to C-VMS from port-to-port, regardless of where the fish were harvested. For purposes of entry of *Dissostichus* spp. into the United States, NMFS will only accept electronic CDS documents described in § 300.106.

(3) Imports of fresh or frozen *Dissostichus* spp. accompanied by an SVDCD are prohibited.

(b) *International Fisheries Trade Permit*. A person intending to import, export, or re-export AMLR must possess a valid IFTP issued under § 300.322 and file required data sets electronically with Customs and Border Protection (CBP) at the time, or in advance, of importation, exportation or re-exportation. "Required data set" has the same meaning as § 300.321 (see definition of "Documentation and data sets required"). See § 300.322 for IFTP application procedures and permit regulations. The IFTP holder may only conduct those specific activities stipulated by the IFTP.

(c) *AMLR First Receiver Permits*. (1) *General*. First receivers of AMLR catch landed from a vessel permitted under § 300.107 at a U.S. port of landing must possess an AMLR first receiver permit and may only conduct those activities described in the permit. A person issued, or required to have been issued a first receiver permit under this subpart may only receive fish from a U.S. vessel that has a valid vessel permit issued under § 300.107 as well as a valid High Seas Fishing Permit issued under 50 CFR part 300, subpart R.

(2) *Application*. Applications for the AMLR first receiver permit are available from NMFS Headquarters.

(3) *Issuance*. NMFS may issue an AMLR first receiver permit if the permit application is complete and NMFS determines that the activity proposed by the first receiver meets the requirements of the Act. First receivers of AMLR required to have a first receiver permit may only receive AMLR that were harvested in a manner consistent with CCAMLR conservation measures and this subpart.

(4) *Duration*. Unless revoked or suspended, an AMLR first receiver permit is valid from its date of issuance to its date of expiration.

(5) *Prohibition on transfer or assignment*. AMLR first receiver permits are valid only for the person to whom NMFS issued the permit and may not be transferred or assigned.

(6) *Changes in information submitted by permit applicants or permit holders*:

(i) *Changes in pending applications*.

Applicants for an AMLR first receiver permit must report any change in the information contained in the application to the Assistant Administrator in writing as soon as possible.

(ii) *Changes occurring after permit issuance*. An AMLR first receiver permit holder must report any change to information previously submitted to the Assistant Administrator in writing within 15 days of the change. Based on such information, the Assistant Administrator may revise the permit effective upon notification to the permit holder.

(7) *Fees*. NMFS may charge a fee to recover the administrative expenses of permit issuance. NMFS will determine the fee in accordance with the procedures in the NOAA finance handbook, available from NMFS, for calculating administrative costs of special products and services.

(8) *Reporting and recordkeeping requirements*. First receivers of AMLRs who have been issued, or are required to have, a first receiver permit under this subpart must:

(i) Accurately maintain all reports and records required by their first receiver permit and this subpart at their place of business;

(ii) Maintain the original permit at their place of business;

(iii) Make their permit, and all required reports and records, available for inspection upon the request of an authorized officer; and

(iv) Within the time specified in the permit, submit a copy of such reports and records to NMFS at an address designated by NMFS.

(d) *Revision, suspension, or revocation*. NMFS may revise, suspend, or revoke an IFTP, or first receiver permit, issued under this section based upon a violation of the permit, the Act, or this subpart.

(e) A person may not import a marine mammal into the United States unless authorized and accompanied by an import permit issued under the Marine Mammal Protection Act and/or the Endangered Species Act.

§ 300.105 Preapproval for importation of frozen *Dissostichus* species

(a) A NMFS-issued preapproval certificate is required to import each shipment of frozen *Dissostichus* species.

(b) *Application*. Application forms for a preapproval certificate are available from NMFS Headquarters and the National Seafood Inspection Laboratory. With the exception of the U.S. Customs

7501 entry number, a complete and accurate application must be received by NMFS for each preapproval certificate at least 10 working days before the anticipated date of the importation. Dealers must supply the U.S. Customs 7501 entry number at least three working days prior to the expected arrival of a shipment of frozen *Dissostichus* species at a U.S. port.

(c) *Fees*. A person must include the processing fee with each preapproval certificate application. NMFS will determine the fee under the NOAA finance handbook procedures for calculating administrative costs of special products and services and user fees collected for administrative expenses associated with processing applications for preapproval certificates.

(d) *Issuance*. NMFS may issue a preapproval certificate for importation of a shipment of frozen *Dissostichus* species if the preapproval application form is complete and NMFS determines that the activity proposed by the applicant meets the requirements of the Act and that the resources were not harvested in violation of any CCAMLR conservation measure or in violation of any regulation in this subpart. No preapproval will be issued for *Dissostichus* species without verifiable documentation that the harvesting vessel reported to C-VMS continuously and in real-time from port-to-port, regardless of where such *Dissostichus* species were harvested.

(e) *Duration*. A preapproval certificate is valid until the *Dissostichus* product specified in the preapproval application is imported.

(f) *Transfer*. A person may not transfer or assign a preapproval certificate.

(g) *Changes in information*—(1) For pending preapproval certificates, applicants must report in writing to NMFS any changes in the information submitted in their preapproval certificate applications. NMFS may extend the processing period for the application as necessary to review and consider any changes.

(2) *Issued preapprovals*. For issued preapproval certificates, the certificate holder must report in writing to NMFS any changes to information included in the preapproval certificate application. Any changes related to fish being imported, such as harvesting vessel or country of origin, type and quantity of the fish to be imported or Convention statistical subarea from which the resource was harvested, will void the preapproval certificate and the shipment may not be imported unless authorized by NMFS through issuance of a revised or new preapproval certificate.

(3) The provision of false information in a preapproval application, or the failure to report a change in the information contained in a preapproval application, voids the application or preapproval as applicable.

(h) NMFS will not issue a preapproval certificate for any shipment of *Dissostichus* species:

(1) Identified as originating from a high seas area designated by the Food and Agriculture Organization of the United Nations as Statistical Area 51 or Statistical Area 57 in the eastern and western Indian Ocean outside and north of the Convention Area;

(2) Determined to have been harvested or transshipped in contravention of any CCAMLR Conservation Measure in force at the time of harvest or transshipment;

(3) Determined to have been harvested or transshipped by a vessel identified by CCAMLR as having engaged in illegal, unreported and unregulated (IUU) fishing; or

(3) Accompanied by inaccurate, incomplete, invalid, or improperly validated CDS documentation or by a SVDCD.

§ 300.106 Catch Documentation Scheme (CDS): Documentation and other requirements.

(a) *General.* (1) CCAMLR CDS document(s) must accompany all shipments of *Dissostichus* species as required in this section.

(2) No shipment of *Dissostichus* species shall be released for entry into the United States unless accompanied by an accurate, complete, valid and validated CCAMLR CDS document.

(3) *Dissostichus* species shall not be released for entry into the United States unless all of the applicable requirements of the CCAMLR Conservation Measures and U.S. regulations have been met.

(b) *Harvesting vessels.* (1) A U.S. vessel harvesting or attempting to harvest *Dissostichus* species, whether within or outside of the Convention Area, must possess a valid vessel permit issued under § 300.107, a valid High Seas Fishing Permit issued under 50 CFR part 300, subpart R, as well as DCD issued by NMFS, which is non-transferable. The master of the harvesting vessel must ensure that catch and other information specified on the DCD are accurately recorded.

(2) Prior to offloading *Dissostichus* species, the master of the harvesting vessel must:

(i) Electronically convey, by the most rapid means possible, catch and other information to NMFS and record on the DCD a confirmation number received from NMFS;

(ii) Obtain on the DCD (or copies thereof) the signature(s) of the following

persons: If catch is offloaded for transshipment, the master of the vessel(s) to which the catch is transferred; or if catch is offloaded for landing, the signature of both the responsible official(s) designated by NMFS in the vessel permit and the recipient of the catch at the port(s) of landing; and

(iii) Sign the DCD (or copies thereof), electronically convey by the most rapid means possible each copy to NMFS and provide a copy to each recipient of the catch.

(3) The master of the harvesting vessel must submit the original DCD (and all copies thereof with original signatures) to NMFS no later than 30 days after the end of the fishing season for which the vessel permit was issued and retain copies of the DCD for a period of 2 years.

(c) *Transshipment vessels.* (1) A U.S. vessel transshipping or attempting to transship *Dissostichus* species, whether within or outside of the Convention Area, must possess a valid vessel permit issued under § 300.107 and a valid High Seas Fishing Permit issued under subpart R of this part. The master of a U.S. vessel receiving *Dissostichus* species by transshipment must, upon receipt of *Dissostichus* species, sign each DCD provided by the master of the vessel that offloads *Dissostichus* species.

(2) Prior to landing *Dissostichus* species, the master of the transshipping vessel must:

(i) Obtain on each DCD (or copies thereof) the signature(s) of both the responsible official(s) designated by NMFS in the vessel permit and the recipient of the catch at the port(s) of landing; and

(ii) Sign each DCD (or copies thereof), and electronically convey by the most rapid means possible each copy to NMFS and to the flag state(s) of the offloading vessel(s) and provide a copy to each recipient of *Dissostichus* species.

(3) The master of the transshipping vessel must submit all DCDs with original signatures to NMFS no later than 30 days after offloading and retain copies for a period of 2 years.

(d) *First receivers.* Any person who receives *Dissostichus* species landed by a vessel at a U.S. port must hold an AMLR first receiver permit issued under § 300.104 and must sign the DCD(s) provided by the master of the vessel and retain copies at their place of business for a period of 2 years. A person issued, or required to have been issued, a first receiver permit under this subpart may only receive fish from a U.S. vessel that has a valid vessel permit issued under § 300.107 as well as a valid High Seas

Fishing Permit issued under 50 CFR part 300, subpart R.

(e) *Import.* (1) A person who imports fresh *Dissostichus* species must hold an IFTP issued under § 300.322. To import frozen *Dissostichus* species into the United States, a person must:

(i) Obtain a preapproval certificate issued under § 300.105 for each shipment. Among the information required on the application, applicants must provide the document number and export reference number on the DED or DRED corresponding to the intended import shipment and, if requested by NMFS, additional information for NMFS to verify that the harvesting vessel reported to the C-VMS continuously and in real-time, from port-to-port, regardless of where the fish were harvested;

(ii) Ensure that the quantity of toothfish listed on the DED (or the *Dissostichus* re-export document if product is a re-export) matches the quantity listed on the preapproval application within a variance of 10 percent; and

(iii) Provide copies of the DED or DRED as needed to persons who re-export *Dissostichus* species.

(2) Imports of fresh *Dissostichus* species do not require a preapproval certificate. If the amount or value of the fresh *Dissostichus* species to be imported is below thresholds that trigger the requirement to file entry documentation with U.S. Customs and Border Protection via the Automated Commercial Environment (see definition in § 300.321), the importer must complete a report of each shipment and submit the report to NMFS within 24 hours following importation. Verification of the harvesting vessel's reporting to C-VMS from port-to-port is not required for imports of fresh *Dissostichus* species.

(f) *Re-export.* (1) To re-export *Dissostichus* species, a person must hold an IFTP issued under § 300.322 and:

(i) Submit to NMFS a complete and accurate application for a NMFS *Dissostichus* re-export document, and

(ii) Obtain validation by a responsible official(s) designated by NMFS and receive an electronically-generated DRED.

(2) When applying for a re-export approval, a person must reference or include the approval number issued by NOAA, for the original validated *Dissostichus* import document.

(g) *Export.* (1) To export U.S.-harvested *Dissostichus* species, the person must possess an IFTP issued under § 300.322 and:

(i) Submit to NMFS a complete and accurate NMFS application for a DED; and

(ii) Obtain validation by a responsible official(s) designated by NMFS and receive an electronically-generated DED.

(2) Any person who exports *Dissostichus* species must include the original validated DED with the export shipment.

(h) *Recordkeeping.* Any person who imports, exports or re-exports *Dissostichus* spp. must:

(1) Retain a copy of all CDS documents at the person's place of business for a period of 2 years from the date on the documents and provide copies as needed to NMFS; and

(2) Make the IFTP and all CDS documents and other records and reports required by this subpart available for inspection upon request of an authorized officer.

§ 300.107 Vessel permits and requirements.

(a) *General.* In addition to the High Seas Fishing Permit requirements at 50 CFR part 300, subpart R:

(1) Every vessel of the United States that attempts to harvest or harvests any AMLR must have a vessel permit authorizing the harvest issued under this subpart, unless the attempt or harvest occurs during recreational fishing or is covered by an individual permit. Boats launched from a vessel issued a vessel permit do not require a separate permit, but are covered by the permit issued to the launching vessel. Any enforcement action that results from the activities of a launched boat will be taken against the owner and operator of the launching vessel.

(2) Any vessel of the United States that receives or attempts to receive any harvested AMLR from another vessel at sea, regardless of whether such transshipment occurs in the Convention Area or that receives, or attempts to receive any other goods or materials from another vessel in the Convention Area, must have a vessel permit authorizing transshipment issued under this subpart. Transshipment vessels must comply with the permitting provisions of this section. This requirement does not apply to scientific research vessels or to transshipments covered under an individual permit.

(3) Permits issued under this section do not authorize vessels or persons subject to the jurisdiction of the United States to harass, capture, harm, kill, harvest, or import marine mammals. No marine mammals may be taken in the course of commercial fishing operations unless the taking is authorized under the Marine Mammal Protection Act and/

or the Endangered Species Act pursuant to an exemption or permit granted by the appropriate agency.

(b) *Responsibility of owners and operators.* (1) The owners and operators of vessels permitted, or required to be permitted, under this subpart are jointly and severally responsible for compliance with the Act, this subpart, and any permit issued under the Act and this subpart.

(2) The owners and operators of each such vessel are responsible for the acts of their employees and agents constituting violations, regardless of whether the specific acts were authorized or forbidden by the owners or operators, and regardless of knowledge concerning their occurrence.

(3) The owner of a vessel issued a vessel permit under this subpart must report any sale, change in ownership, or other disposition of the vessel to the Assistant Administrator as soon as possible but no later than 15 days after the change.

(4) The owner and operator of a harvesting vessel issued a permit to fish for krill in the Convention Area using trawl gear must install a seal excluder device and may not possess onboard or deploy trawl gear without a seal excluder device installed.

(c) *Application.* Application forms for vessel permits are available from NMFS Headquarters.

(1) A separate, fully completed and accurate application is required for each vessel for which a permit is requested.

(2) NMFS must receive applications for vessel permits no later than April 1 for the fishing season that will commence on or after December 1 of that year.

(3) Applications for a permit to harvest krill must, to the extent possible, identify the products to be derived from the anticipated krill catch.

(4) NMFS will only accept permit applications for vessels that have been issued an International Maritime Organization (IMO) number.

(5) NMFS may charge a fee to recover the administrative expense of permit issuance. NMFS will determine the fee in accordance with procedures in the NOAA finance handbook, available from NMFS, for calculating administrative costs of special products and services and user fees.

(d) *Issuance.* The Assistant Administrator may issue a vessel permit if the Assistant Administrator determines that the harvesting or transshipment activities described in the application will meet the requirements of the Act and will not:

(1) Decrease the size of any harvested population to levels below those that

ensure its stable recruitment. For this purpose, the Convention provides that its size should not be allowed to fall below a level close to that which ensures the greatest net annual increment.

(2) Upset the ecological relationships between harvested, dependent, and related populations of AMLRs and the restoration of depleted populations to levels that will ensure stable recruitment.

(3) Cause changes or increase the risk of changes in the marine ecosystem that are not potentially reversible over 2 or 3 decades, taking into account the state of available knowledge of the direct and indirect impact of harvesting, the effects of the introduction of alien species, the effects of associated activities on the marine ecosystem and the effects of environmental changes, with the aim of making possible the sustained conservation of AMLRs.

(4) Violate the Convention or any conservation measures in force with respect to the United States under the Convention. The Convention and the schedule of conservation measures in force can be found on the CCAMLR Web site: www.ccamlr.org.

(e) *Duration.* A vessel permit is valid from its date of issuance to its date of expiration unless it is revoked or suspended.

(f) *Transfer.* Permits are not transferable or assignable. A permit is valid only for the vessel to which it is issued.

(g) *Display.* Each vessel must have on board, at all times, a valid vessel permit and the vessel operator must produce it for inspection upon the request of an authorized officer or CCAMLR inspector.

(h) *Changes in information submitted by permit applicants or holders—(1) Changes in pending applications.*

Applicants for a vessel permit must report to the Assistant Administrator in writing any change in the information contained in the application. The processing period for the application will be extended as necessary to review the change.

(2) *Changes occurring after permit issuance—(i) Requested changes in the location, manner, or amount of harvesting.* Any changes in the location, manner or amount of harvesting must be proposed in writing to the Assistant Administrator and may not be undertaken unless authorized by the Assistant Administrator through a permit revision or issuance of a new permit. If the Assistant Administrator determines that the requested change in the location, manner, or amount of harvesting could significantly affect the

status of any Antarctic marine living resource, the Assistant Administrator will treat the requested change as an application for a new permit and so notify the holder.

(ii) *Changes other than in the location, manner or amount of harvesting.* For changes other than those addressed in paragraph (h)(2)(i) of this section, the owner or operator of a vessel that has been issued a vessel permit must report to the Assistant Administrator in writing any change in previously submitted information as soon as possible but no later than within 15 days after the change. Based on such reported information, the Assistant Administrator may revise the permit and any revised permit would be effective upon notification to the permit holder.

(i) *Conditions and restrictions.* The vessel permit will contain conditions and restrictions that the Assistant Administrator deems necessary for implementation of conservation measures that apply to the harvesting or transshipment activities. The Assistant Administrator may revise the vessel permit to include additional conditions and restrictions on the harvesting vessel as necessary to implement conservation measures in force with respect to the United States or to achieve the purposes of the Convention or the Act. Any additional conditions or restrictions will be effective upon notification to the permit holder.

(j) *Revision, suspension, or revocation for violations.* A vessel permit may be revised, suspended, or revoked if the harvesting vessel is involved in the commission of any violation of its permit, the Act, or this subpart. The Assistant Administrator may deny a vessel permit if the applicant or harvesting vessel was previously involved in the commission of any violation of its permit, the Act, or this subpart. Failure to report a change in the information contained in an application within 15 days of the change is a violation of this subpart and voids the application or permit, as applicable. If a change in vessel ownership is not reported, the violation is chargeable to the previous owner.

(k) *Transshipment notification.* The vessel operator must notify the CCAMLR Secretariat of transshipments of AMLRs, bait, or fuel, and submit a confirmation of the notification to NMFS Headquarters, no later than 72 hours before the transshipment will take place. The vessel operator must notify the CCAMLR Secretariat of transfers of all other goods, and submit a confirmation of the notification to NMFS Headquarters, no later than 2

hours before the transshipment will take place. Notifications of intended transshipments shall include the following information, for all vessels involved:

- (1) Names, registration numbers, and IMO numbers;
- (2) International radio call signs;
- (3) Flag State;
- (4) Type of vessels, length, gross registered tonnage and carrying capacity;
- (5) Proposed time and position, in latitude and longitude, of transshipment; and
- (6) Details of the type and amount of catches and/or other goods, such as food stores and fuel, involved in the transshipment.

(l) *Reporting and recordkeeping requirements.* The operator of any vessel required to have a vessel permit under this subpart must:

- (1) Accurately maintain on board the vessel all CCAMLR reports and records required by its permit.
- (2) Make such reports and records available for inspection upon the request of an authorized officer or CCAMLR inspector.
- (3) Within the time specified in the vessel permit, submit a copy of such reports and records to NMFS.
- (4) Install a NMFS-approved EMTU on board U.S. flagged vessels harvesting AMLR for use in real-time C-VMS port-to-port reporting to a NMFS-designated land-based fisheries monitoring center or centers. The requirements for the installation and operation of the VMS are set forth in § 300.112.
- (5) Provide advance notice of the vessel's entry into port using the CCAMLR Port Inspection Report, including the written declaration that the vessel has not engaged in or supported illegal, unreported and unregulated (IUU) fishing in the Convention Area and has complied with relevant CCAMLR requirements. The CCAMLR Port Inspection Report, and instructions for its submission, is available from NMFS Headquarters.

§ 300.108 Vessel and gear identification.

(a) *Vessel identification.* (1) A vessel issued a permit under this subpart must be marked with the vessel's name and its International Radio Call Sign (IRCS) amidships on both the port and starboard sides of the superstructure or hull, so that it is visible at all times from an enforcement or inspection vessel. Fixtures inclined at an angle to the vessel's side or superstructure would be considered as suitable provided that the angle of inclination would not prevent sighting of the IRCS from another vessel or from the air. The vessel's IRCS shall

also be marked on the deck. Should an awning or other temporary cover be placed so as to obscure the mark on the deck, the awning or cover shall also be marked with the IRCS. The marks should be placed athwartship with the top of the numbers or letters towards the bow.

(2) Boats, skiffs and craft carried by the vessel for fishing operations shall bear the same mark as the vessel, except that a numerical suffix specific for the boat, skiff, or craft must follow the IRCS.

(3) The vessel identification must be in a color in contrast to the background and must be permanently affixed to the vessel in block Roman alphabet letters and Arabic numerals using good quality marine paints. The letters and numbers shall be: At least 1 meter in height (h) for the IRCS placed on the hull, superstructure and/or inclined surfaces and at least 0.3 meter for marks placed on deck. The length of the hyphen shall be half the height of the letters and numbers. The width of the stroke for all letters, numbers and the hyphen shall be h/6. The space between letters and/or numbers shall not exceed h/4 nor be less than h/6. The space between adjacent letters having sloping sides (e.g., A and V) shall not exceed h/8 nor be less than h/10. If a contrasting color is used for the background of the marks, it shall extend to provide a border around the mark of at least h/6.

(4) The marks and the background shall be maintained in good condition at all times.

(b) *Navigational lights and shapes.* Each vessel issued a vessel permit must display the lights and shapes prescribed by the International Regulations for Preventing Collisions at Sea, 1972 (TIAS 8587, and 1981 amendment TIAS 10672), for the activity in which the harvesting vessel is engaged (as described at 33 CFR part 81).

(c) *Gear identification.* (1) The operator of each fishing vessel must ensure that all deployed fishing gear is clearly marked at all times at the surface with a buoy displaying the vessel identification of the harvesting vessel (see paragraph (a) of this section) to which the gear belongs, a light visible for 2 miles at night in good visibility, and a radio buoy.

(2) The operator of each harvesting vessel must ensure that deployed longlines and strings of traps or pots, and gillnets are clearly marked at all times at the surface at each terminal end with a buoy displaying the vessel identification of the harvesting vessel to which the gear belongs (see paragraph (a) of this section), a light visible for 2 miles at night in good visibility, and a radio buoy.

(3) Unmarked or incorrectly identified fishing gear may be considered abandoned and may be disposed of in accordance with applicable CCAMLR Conservation Measures in force with respect to the United States by any authorized officer or CCAMLR inspector.

(d) *Maintenance.* The operator of each vessel issued a vessel permit must:

(1) Keep the vessel and gear identification clearly legible and in good condition at all times;

(2) Ensure that nothing on the vessel obstructs the view of the markings from an enforcement or inspection vessel or aircraft; and

(3) Ensure that the proper navigational lights and shapes are displayed for the vessel's activity and are properly functioning.

§ 300.109 Initiating a new fishery.

(a) A new fishery, for purposes of this section, is a fishery that uses bottom trawls on the high seas of the Convention Area or a fishery for a species, using a particular method, in a statistical subarea or division for which:

(1) Information on distribution, abundance, demography, potential yield and stock identity from comprehensive research/surveys or exploratory fishing has not been submitted to CCAMLR;

(2) Catch and effort data have never been submitted to CCAMLR; or

(3) Catch and effort data from the two most recent seasons in which fishing occurred have not been submitted to CCAMLR.

(b) Persons intending to develop a new fishery shall notify the Assistant Administrator no later than April 1 for the fishing season that will commence on or after December 1 and shall not initiate the fishery pending NMFS and CCAMLR review or until a vessel permit has been used under this subpart.

(c) The notification shall be accompanied by a complete vessel permit application required under § 300.107 and information on:

(1) The nature of the proposed fishery, including target species, methods of fishing, proposed region and maximum catch levels proposed for the forthcoming season;

(2) Biological information on the target species from comprehensive research/survey cruises, such as distribution, abundance, demographic data and information on stock identity;

(3) Details of dependent and related species and the likelihood of them being affected by the proposed fishery;

(4) Information from other fisheries in the region or similar fisheries elsewhere that may assist in the evaluation of potential yield; and

(5) If the proposed fishery will be undertaken using bottom trawl gear, the known and anticipated impacts of this gear on vulnerable marine ecosystems, including benthos and benthic communities.

§ 300.110 Exploratory fisheries.

(a) An exploratory fishery, for purposes of this section, is a fishery that was previously defined as a new fishery under § 300.109.

(b) A fishery continues to be classified by CCAMLR as an exploratory fishery until sufficient information is available to:

(1) Evaluate the distribution, abundance, and demography of the target species, leading to an estimate of the fishery's potential yield;

(2) Review the fishery's potential impacts on dependent and related species; and

(3) Allow the CCAMLR Scientific Committee to formulate and provide advice to the Commission on appropriate harvest catch levels and fishing gear.

(c) The operator of any vessel engaging in an exploratory fishery must submit, by the date specified in the vessel permit issued under § 300.107, catch, effort, and related biological, ecological, and environmental data as required by a data collection plan for the fishery formulated by the CCAMLR Scientific Committee.

(d) In addition to the requirements in § 300.107, any person planning to enter an exploratory fishery must notify the Assistant Administrator no later than April 1 for the fishing season that will commence on or after December 1 and shall not enter the fishery pending NMFS and CCAMLR review or until a vessel permit has been used under this subpart. The Assistant Administrator will not issue a permit to enter an exploratory fishery until after the requirements of § 300.107 have been met and CCAMLR has considered the notification.

(e) The notification shall be accompanied by a complete vessel permit application required under § 300.107 and information on:

(1) The nature of the exploratory fishery, including target species, methods of fishing, proposed region and maximum catch levels proposed for the forthcoming season;

(2) Specification and full description of the types of fishing gear to be used;

(3) Biological information on the target species from comprehensive research/survey cruises, such as distribution, abundance, demographic data and information on stock identity; details of dependent and related species

and the likelihood of their being affected by the proposed fishery;

(4) Information from other fisheries in the region or similar fisheries elsewhere that may assist in the evaluation of potential yield;

(5) If the proposed fishery will be undertaken using bottom trawl gear, information on the known and anticipated impacts of this gear on vulnerable marine ecosystems, including benthos and benthic communities; and

(6) Any other information the Assistant Administrator requires to fully implement the relevant conservation measures.

§ 300.111 Scientific observers.

(a) Except as otherwise specified, this section applies to both national observers and international observers, as well as to vessels of the United States carrying, or required to carry, such observers.

(b) All vessels of the United States fishing in the Convention Area must carry one or more scientific observers as required by CCAMLR conservation measures or as specified in a vessel permit issued under this subpart.

(c) All vessels of the United States conducting longline sink rate testing outside the Convention Area and pursuant to CCAMLR protocols must carry one or more scientific observers as specified in the vessel permit issued under this subpart.

(d) *Procurement of observers by vessel.* Owners of vessels required to carry scientific observers under this section must arrange for observer services in coordination with the NMFS Southwest Fisheries Science Center Antarctic Ecosystem Research Division. The vessel owner is required to pay for observer services through an observer service provider who has provided observer services to the Federal government within the past year. In situations where no qualified observer is available through a qualified observer provider, the Secretary may authorize a vessel owner to arrange for an observer by alternative methods. An observer may not be paid directly by the vessel owner.

(e) *Vessel responsibilities.* An operator of a vessel required to carry one or more scientific observers must:

(1) *Accommodations and food.* Provide, at no cost to the observers or the United States, accommodations and food on the vessel for the observer or observers that are equivalent to those provided for officers of the vessel; and

(2) *Safe conditions.* Maintain safe conditions on the vessel for the protection of observers including

adherence to all U.S. Coast Guard and other applicable rules, regulations, or statutes pertaining to safe operation of the vessel and have on board:

(i) A valid Commercial Fishing Vessel Safety Decal issued within the past 2 years that certifies compliance with regulations found in 33 CFR chapter I and 46 CFR chapter I;

(ii) A certificate of compliance issued pursuant to 46 CFR 28.710; or

(iii) A valid certificate of inspection pursuant to 46 U.S.C. 3311.

(3) *Health and safety regulations.* Comply with the observer health and safety regulations at part 600 of this title.

(4) *Transmission of data.* Facilitate transmission of observer data by allowing observers, on request, to use the vessel's communications equipment and personnel for the confidential entry, transmission, and receipt of work-related messages.

(5) *Vessel position.* Allow observers access to, and the use of, the vessel's navigation equipment and personnel, on request, to determine the vessel's position, course and speed.

(6) *Access.* Allow observers free and unobstructed access to the vessel's bridge, trawl or working decks, holding bins, processing areas, freezer spaces, weight scales, cargo holds, and any other space that may be used to hold, process, weigh, or store fish or fish products at any time.

(7) *Prior notification.* Notify observers at least 15 minutes before fish are brought on board, or fish and fish products are transferred from the vessel, to allow sampling the catch or observing the transfer, unless the observers specifically request not to be notified.

(8) *Records.* Allow observers to inspect and copy the vessel's DCD, product transfer forms, any other logbook or document required by regulations or CCAMLR conservation measures, printouts or tallies of scale weights, scale calibration records, bin sensor readouts, and production records.

(9) *Assistance.* Provide all other reasonable assistance to enable observers to carry out their duties, including, but not limited to:

(i) Measuring decks, codends, and holding bins;

(ii) Providing the observers with a safe work area adjacent to the sample collection site;

(iii) Collecting bycatch when requested by the observers;

(iv) Collecting and carrying baskets of fish when requested by observers; and

(v) Allowing observers to determine the sex of fish when this procedure will

not decrease the value of a significant portion of the catch.

(10) *Transfer at sea.* (i) Ensure that transfers of observers at sea via small boat or raft are carried out during daylight hours, under safe conditions, and with the agreement of observers involved.

(ii) Notify observers at least 3 hours before observers are transferred, such that the observers can collect personal belongings, equipment, and scientific samples.

(iii) Provide a safe pilot ladder and conduct the transfer to ensure the safety of observers during transfers.

(iv) Provide an experienced crew member to assist observers in the small boat or raft in which any transfer is made.

(f) *Insurance.* The observer service provider or vessel owner must provide insurance for national observers that provides compensation in the event of an injury or death during the entire deployment, from the point of hire location to return, equivalent to the standards of the North Pacific Groundfish Observer Program set forth in § 679.50 of this title.

(g) *Educational requirements.*

National observer candidates must:

(1) Have a Bachelor's degree or higher from an accredited college or university with a major in one of the natural sciences; or

(2) Have successfully completed a minimum of 30 semester hours or equivalent in applicable biological sciences with extensive use of dichotomous keys in at least one course.

(h) *Health requirements.* National observers, and U.S. observers deployed as international observers, must have a signed and dated statement from a licensed physician that he or she has physically examined the observer. The statement must confirm that, based upon the physical examination, the observer does not have any health problems or conditions that would jeopardize that individual's safety or the safety of others while deployed, or prevent the observer from performing his or her duties satisfactorily. The statement must declare that, prior to the examination, the physician was made aware of the duties of an observer and the dangerous, remote and rigorous nature of the work. The physician's statement must be submitted to the NMFS Southwest Fisheries Science Center Antarctic Ecosystem Research Division program office prior to approval of an observer. The physical exam must have occurred during the 12 months prior to the observer's deployment. The physician's statement will expire 12 months after the physical

exam occurred. A new physical exam must be performed, and accompanying statement submitted, prior to any deployment occurring after the expiration of the statement.

(i) *Standards of observer conduct.* (1) Observers: (i) Must not have a direct financial interest in the fishery being observed, including but not limited to:

(A) Any ownership, mortgage holder, or other secured interest in a vessel, shoreside or floating stationary processor facility involved in the catching, taking, harvesting or processing of fish;

(B) Any business involved with selling supplies or services to any vessel, shoreside or floating stationary processing facility; or

(C) Any business involved with purchasing raw or processed products from any vessel, shoreside or floating stationary processing facilities.

(ii) Must not solicit or accept, directly or indirectly, any gratuity, gift, favor, entertainment, loan, or anything of monetary value from anyone who either conducts activities that are regulated by NMFS or has interests that may be substantially affected by the performance or nonperformance of the observers' official duties.

(iii) Must not serve as observers on any vessel or at any shoreside or floating stationary processing facility owned or operated by a person who previously employed the observers.

(iv) Must not solicit or accept employment as a crew member or an employee of a vessel, shoreside processor, or stationary floating processor while employed by an observer provider.

(2) Provisions for remuneration of observers under this section do not constitute a conflict of interest.

(j) *Standards of observer behavior.* Observers must: (1) Avoid any behavior that could adversely affect the confidence of the public in the integrity of the CCAMLR Scheme of International Scientific Observation or of the government, including but not limited to the following:

(2) Perform their assigned duties as described in the CCAMLR Scientific Observers Manual and must complete the CCAMLR Scientific Observer Logbooks and submit them to the CCAMLR Data Manager at the intervals specified by the Data Manager.

(3) Accurately record their sampling data, write complete reports, and report accurately any observations of suspected violations of regulations relevant to conservation of marine resources or their environment.

(4) Not disclose collected data and observations made on board the vessel

or in the processing facility to any person, except the owner or operator of the observed vessel or processing facility or NMFS.

(5) Refrain from engaging in any illegal actions or any other activities that would reflect negatively on their image as professional scientists, on other observers, or on the CCAMLR Scheme of International Scientific Observation as a whole. This includes, but is not limited to:

(i) Refrain from engaging in the use, possession, or distribution of illegal drugs; or

(ii) Refrain from engaging in physical sexual contact with personnel of the vessel or processing facility to which the observer is assigned, or with any vessel or processing plant personnel who may be substantially affected by the performance or non-performance of the observer's official duties.

(k) *Sampling station*—(1) *Minimum work space aboard at sea processing vessels.* The observer must have a working area of 4.5 square meters, including the observer's sampling table, for sampling and storage of fish to be sampled. The observer must be able to stand upright and have a work area at least 0.9 meter (m) deep in the area in front of the table and scale.

(2) *Table aboard at-sea processing vessels.* The observer sampling station must include a table at least 0.6 m deep, 1.2 m wide and 0.9 m high and no more than 1.1 m high. The entire surface area of the table must be available for use by the observer. Any area for the observer sampling scale is in addition to the minimum space requirements for the table. The observer's sampling table must be secured to the floor or wall.

(3) *Other requirement for at-sea processing vessels.* The sampling station must be in a well-drained area that includes floor grating (or other material that prevents slipping), lighting adequate for day or night sampling, and a hose that supplies fresh or sea water to the observer.

§ 300.112 Vessel monitoring system.

(a) *Requirement for use.* Within 30 days after NMFS publishes in the **Federal Register** a list of approved EMTUs and associated communications service providers for the AMLR fishery, an owner or operator of a vessel that has been issued a vessel permit under § 300.107 must ensure that such vessel has a NMFS-type-approved, operating EMTU installed and continuously operating for the duration of any fishing trip involving the harvesting of AMLR.

(b) *Installing and activating the EMTU.* Only EMTUs that have been approved by NMFS for use in the AMLR

fishery may be used. The vessel owner or operator shall obtain and have installed on the fishing vessel, by a qualified marine electrician and in accordance with any instructions provided by the VMS Helpdesk or OLE, a NMFS type-approved EMTU.

(c) *Interference with the EMTU.* No person may interfere with, tamper with, alter, damage, disable, or impede the operation of the EMTU, or attempt any of the same.

(d) *Interruption of operation of the VMS.* When a vessel's EMTU is not operating properly, the owner or operator must immediately contact OLE, and follow instructions from that office. If notified by NMFS that a vessel's EMTU is not operating properly, the owner and operator must follow instructions from that office. In either event, such instructions may include, but are not limited to, manually communicating to a location designated by NMFS the vessel's positions or returning to port until the EMTU is operable.

(e) *Access to data.* OLE is authorized to receive and relay transmissions from the EMTU. OLE will share a vessel's position data obtained from the EMTU, if requested, with other NMFS offices, the USCG, and their authorized officers and designees.

(f) *Installation and operation of the VMS.* NMFS has authority over the installation and operation of the EMTU. NMFS may authorize the connection or order the disconnection of additional equipment, including a computer, to any EMTU when deemed appropriate by NMFS.

§ 300.113 CCAMLR Ecosystem Monitoring Program sites.

(a) *General.* (1) Any person subject to the jurisdiction of the United States must apply for and be granted an entry permit authorizing specific activities prior to entering a CCAMLR Ecosystem Monitoring Program (CEMP) site designated in accordance with the CCAMLR conservation measure describing the procedure for according protection for CEMP sites.

(2) If a CEMP site is also a site specially protected under the Antarctic Treaty (or the Protocol on Environmental Protection to the Antarctic Treaty and its Annexes, such as the sites listed in 45 CFR 670.29), an applicant seeking to enter such site must apply to the Director of the NSF for a permit under applicable provisions of the ACA or any superseding legislation. The permit granted by NSF shall constitute a joint CEMP/ACA Protected Site permit and any person holding such a permit must comply

with the appropriate CEMP site management plan. In all other cases, an applicant seeking a permit to enter a CEMP site must apply to the Assistant Administrator for a CEMP permit in accordance with the provisions of this section.

(b) *Responsibility of CEMP permit holders and persons designated as agents under a CEMP permit.* (1) The CEMP permit holder and person designated as agents under a CEMP permit are jointly and severally responsible for compliance with the Act, this subpart, and any permit issued under this subpart.

(2) The CEMP permit holder and agents designated under a CEMP permit are responsible for the acts of their employees and agents constituting violations, regardless of whether the specific acts were authorized or forbidden by the CEMP permit holder or agents, and regardless of knowledge concerning their occurrence.

(c) *Prohibitions regarding the Antarctic Treaty System and other applicable treaties and statutes.* Holders of permits to enter CEMP Protected Sites are not authorized to undertake any activities within a CEMP Protected Site that are not in compliance with the conditions of the CEMP permit and the provisions of:

(1) The Antarctic Treaty, including the Agreed Measures for the Conservation of Antarctic Fauna and Flora (including the Protocol on the Environmental Protection to the Antarctic Treaty and its Annexes), as implemented by the ACA and any superseding legislation. (Persons interested in conducting activities subject to the Antarctic Treaty or the Protocol should contact the Office of Polar Programs, NSF).

(2) The Convention for the Conservation of Antarctic Seals.

(3) The Convention and its Conservation Measures in force, implemented under the Act.

(d) *Prohibitions on takings.* Permits issued under this section do not authorize any takings as defined in the applicable statutes and implementing regulations governing the activities of persons in Antarctica.

(e) *Issuance criteria.* Permits designated in this section may be issued by the Assistant Administrator upon a determination that:

(1) The specific activities meet the requirements of the Act;

(2) There is sufficient reason, established in the CEMP permit application, that the scientific purpose for the intended entry cannot be served elsewhere; and

(3) The actions permitted will not violate any provisions or prohibitions of the site's management plan submitted in compliance with the CCAMLR Conservation Measure describing the procedure for according protection to CEMP sites.

(f) *Application process.* An applicant seeking a CEMP permit from the Assistant Administrator to enter a CEMP site shall include the following in the application.

(1) A detailed justification that the scientific objectives of the applicant cannot be accomplished elsewhere and a description of how said objectives will be accomplished within the terms of the site's management plan.

(2) A statement signed by the applicant that the applicant has read and fully understands the provisions and prohibitions of the site's management plan. Prospective applicants may obtain copies of the relevant management plans and the CCAMLR Conservation Measure describing the procedure for according protection to CEMP sites by requesting them from NMFS Headquarters.

(g) *Conditions.* CEMP permits issued under this section will contain special and general conditions including a condition that the permit holder shall submit a report describing the activities conducted under the permit within 30 days of the expiration of the CEMP permit.

(h) *Transfer.* CEMP permits are not transferable or assignable. A CEMP permit is valid only for the person to whom it is issued.

(i) *Additional conditions and restrictions.* The Assistant Administrator may revise the CEMP permit effective upon notification of the permit holder, to impose additional conditions and restrictions as necessary to achieve the purposes of the Convention, the Act and the CEMP Management Plan. The CEMP permit holder must, as soon as possible, notify any and all agents operating under the permit of any and all revisions or modifications to the permit.

(j) *Revocation or suspension.* CEMP permits may be revoked or suspended based upon information received by the Assistant Administrator and such revocation or suspension shall be effective upon notification to the permit holder.

(1) A CEMP permit may be revoked or suspended based on a violation of the permit, the Act, or this subpart.

(2) Failure to report a change in the information submitted in a CEMP permit application within 10 days of the change is a violation of this subpart and voids the application or permit, as

applicable. Title 15 CFR part 904 governs permit sanctions under this subpart.

(k) *Exceptions.* Entry into a CEMP site is lawful if committed under emergency conditions to prevent the loss of human life, avoid compromising human safety, prevent the loss of vessels or aircraft, or to prevent environmental damage.

(l) *Protected sites.* Sites protected by the Antarctic Treaty and regulated under the ACA are listed at 45 CFR part 670 subpart F.

§ 300.114 Prohibitions.

In addition to the prohibitions in § 300.4, it is unlawful for any person to:

(a) Harvest any AMLR without a permit for such activity as required by § 300.107.

(b) Import into, or export or re-export from, the United States any AMLR: Taken by a vessel of the United States without a permit issued under this subpart or by a foreign-flagged vessel without valid authorization from the applicable flag state to harvest those resources; without accurate, complete, valid and properly validated CDS documentation as required by § 300.106; without an IFTP as required by § 300.104; or in violation of the terms and conditions for such import, export or re-export as specified on the IFTP.

(c) Engage in or benefit from harvesting or other associated activities in violation of the provisions of the Convention or in violation of a conservation measure in force with respect to the United States under Article IX of the Convention.

(d) Ship, transport, offer for sale, sell, purchase, import, export, re-export or have custody, control or possession of, any AMLR that was harvested in violation of a conservation measure in force with respect to the United States under Article IX of the Convention or in violation of any regulation promulgated under the Act, without regard to the citizenship of the person that harvested, or vessel that was used in the harvesting of, the AMLR.

(e) Refuse to allow any CCAMLR inspector or authorized officer to board a vessel of the United States or a vessel subject to the jurisdiction of the United States for the purpose of conducting any search, investigation, or inspection authorized by the Act, this subpart, or any permit issued under the Act.

(f) Refuse to provide appropriate assistance, including access as necessary to communications equipment, to any CCAMLR inspector or authorized officer.

(g) Refuse to sign a written notification of alleged violations of

CCAMLR conservation measures in force prepared by a CCAMLR inspector.

(h) Assault, resist, oppose, impede, intimidate, or interfere with a CCAMLR inspector or authorized officer in the conduct of any boarding, search, investigation, or inspection authorized by the Act, this subpart, or any permit issued under the Act.

(i) Use any vessel to engage in harvesting, or receive, import, export or re-export, AMLRs after the revocation, or during the period of suspension, of an applicable permit issued under the Act.

(j) Fail to identify, falsely identify, fail to properly maintain, or obscure the identification of a harvesting vessel or its gear as required by this subpart.

(k) Fish in an area where fishing is prohibited by the Commission, other than for scientific research purposes in accordance with § 300.103.

(l) Violate or attempt to violate any provision of this subpart, the Act, any other regulation promulgated under the Act or the conditions of any permit issued under the Act.

(m) Provide incomplete or inaccurate information about the harvest, transshipment, landing, import, export, or re-export of applicable species on any document required under this subpart.

(n) Receive AMLR from a vessel, without holding an AMLR first receiver permit as required under § 300.104, or receive AMLR from a fishing vessel that does not hold a valid vessel permit issued under § 300.107.

(o) Import, export or re-export *Dissostichus* spp. harvested or transshipped by a vessel identified by CCAMLR as having engaged in illegal, unreported and unregulated (IUU) fishing, originating from a high seas area designated by the Food and Agriculture Organization of the United Nations as Statistical Area 51 or Statistical Area 57 or accompanied by inaccurate, incomplete, invalid, or improperly validated CDS documentation or import or re-export *Dissostichus* spp. accompanied by a SVDCD.

(p) Import shipments of frozen *Dissostichus* spp. without a preapproval issued under § 300.105.

(q) *Observers.* (1) Assault, resist, oppose, impede, intimidate, harass, bribe, or interfere with an observer.

(2) Interfere with or bias the sampling procedure employed by an observer, including physical, mechanical, or other sorting or discarding of catch before sampling.

(3) Tamper with, destroy, or discard an observer's collected samples, equipment, records, photographic film, papers, or personal effects without the express consent of the observer.

(4) Prohibit or bar by command, impediment, threat, coercion, or by refusal of reasonable assistance, an observer from collecting samples, conducting product recovery rate determinations, making observations, or otherwise performing the observer's duties.

(5) Harass an observer by conduct that has sexual connotations, has the purpose or effect of interfering with the observer's work performance, or otherwise creates an intimidating, hostile, or offensive environment.

(6) Fish for or process fish without observer coverage required under § 300.111.

(7) Require, pressure, coerce, or threaten an observer to perform duties normally performed by crew members, including, but not limited to, cooking, washing dishes, standing watch, vessel maintenance, assisting with the setting or retrieval of gear, or any duties associated with the processing of fish, from sorting the catch to the storage of the finished product.

(8) Refuse to provide appropriate assistance, including access as necessary to communications equipment, to an observer.

(r) *Vessel monitoring systems.* (1) Use any vessel of the United States issued, or required to be issued, an AMLR vessel permit to conduct fishing operations unless that vessel carries a NMFS-type-approved EMTU and complies with the requirements described in this subpart.

(2) Fail to install, activate, repair or replace an EMTU prior to leaving port as specified in this subpart.

(3) Fail to operate and maintain an EMTU on board the vessel at all times as specified in this subpart.

(4) Tamper with, damage, destroy, alter, or in any way distort, render useless, inoperative, ineffective, or inaccurate the EMTU required to be installed on a vessel or the EMTU position reports transmitted by a vessel as specified in this subpart.

(5) Fail to contact OLE or follow OLE instructions when automatic position reporting has been interrupted as specified in this subpart.

(6) Register an EMTU to more than one vessel at the same time.

(7) Connect, or leave connected, additional equipment to an EMTU without the prior approval of the OLE.

(8) Make a false statement, oral or written, to an authorized officer regarding the installation, use, operation, or maintenance of an EMTU or communication service provider.

(9) Fail to report to NMFS and to CCAMLR's C-VMS from port-to-port on any trip during which AMLR are, or are

expected to be, harvested regardless of whether the vessel operates, or is expected to operate, inside the Convention Area.

(s) Trawl for krill in Convention Area fisheries without a seal excluder device or possess trawl gear without a seal excluder device installed onboard a vessel permitted, or required to be permitted, under this subpart to harvest krill with trawl gear.

(t) Harvest any AMLR in the Convention Area without a vessel permit required by this subpart.

(u) Ship, transport, offer for sale, sell, purchase, import, export, re-export or have custody, control, or possession of, any frozen *Dissostichus* species without verifiable documentation that the harvesting vessel reported to CCAMLR's C-VMS continuously and in real-time, from port-to-port, regardless of where such *Dissostichus* species were harvested.

§ 300.115 Facilitation of enforcement and inspection.

In addition to the facilitation of enforcement provisions of § 300.5, the following requirements apply to this subpart.

(a) *Access and records.* (1) The owners and operator of each harvesting vessel must provide authorized officers and CCAMLR inspectors access to all spaces where work is conducted or business papers and records are prepared or stored, including but not limited to personal quarters and areas within personal quarters. If inspection of a particular area would interfere with specific on-going scientific research, and if the operator of the harvesting vessel makes such assertion and produces an individual permit that covers that specific research, the authorized officer or CCAMLR inspector will not disturb the area, but will record the information pertaining to the denial of access.

(2) The owner and operator of each harvesting vessel must provide to authorized officers and CCAMLR inspectors all records and documents pertaining to the harvesting activities of the vessel, including but not limited to production records, fishing logs, navigation logs, transfer records, product receipts, cargo stowage plans or records, draft or displacement calculations, customs documents or records, and an accurate hold plan reflecting the current structure of the vessel's storage and factory spaces.

(3) Before leaving vessels that have been inspected, the CCAMLR inspector will give the master of the vessel a Certificate of Inspection and a written notification of any alleged violations of

CCAMLR conservation measures in effect and will afford the master the opportunity to comment on it. The ship's master must sign the notification to acknowledge receipt and the opportunity to comment on it.

(4) Any person issued a first receiver permit under this subpart, or an IFTP under § 300.322, must as a condition of that permit, allow an authorized officer access to any facility from which they engage in the first receipt, import, export or re-export of AMLR for the purpose of inspecting the facility and any fish, equipment or records therein.

(b) *Reports by non-inspectors.* All scientists, fishermen, and other non-inspectors present in the Convention Area and subject to the jurisdiction of the United States are encouraged to report any violation of CCAMLR conservation measures observed in the Convention Area to the Office of Ocean and Polar Affairs (CCAMLR Violations), Department of State, Room 5801, Washington, DC 20520.

(c) *Storage of AMLR.* The operator of each harvesting vessel storing AMLR in a storage space on board a vessel must ensure that non-resource items are neither stowed beneath nor covered by resource items, unless required to maintain the stability and safety of the vessel. Non-resource items include, but are not limited to, portable conveyors, exhaust fans, ladders, nets, fuel bladders, extra bin boards, or other moveable non-resource items. These non-resource items may be in a resource storage space when necessary for the safety of the vessel or crew or for the storage of the items. Lumber, bin boards, or other dunnage may be used for shoring or bracing of product to ensure the safety of crew and to prevent shifting of cargo within the space.

§ 300.116 Penalties.

Any person or harvesting vessel found to be in violation of the Act, this subpart, or any permit issued under this subpart will be subject to the civil and criminal penalty provisions and forfeiture provisions prescribed in the Act, 15 CFR part 904, and other applicable laws.

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DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 1**

[TD 9811]

RIN 1545-BK09

Application of Modified Carryover Basis to General Basis Rules

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations regarding the application of the modified carryover basis rules of section 1022 of the Internal Revenue Code (Code). Specifically, the final regulations modify provisions of the Treasury Regulations involving basis rules by including a reference to section 1022 where appropriate. The regulations will affect property transferred from certain decedents who died in 2010. The regulations reflect changes to the law made by the Economic Growth and Tax Relief Reconciliation Act of 2001 and the Tax Relief, Unemployment Insurance Reauthorization, and Job Creation Act of 2010.

DATES: *Effective Date:* The regulations are effective on January 19, 2017.

Applicability Date: The regulations are applicable on January 19, 2017.

FOR FURTHER INFORMATION CONTACT: Mayer R. Samuels at (202) 317-6859 (not a toll-free number).

SUPPLEMENTARY INFORMATION:**Background**

This document contains amendments to 26 CFR part 1 under various provisions of the Code in response to statutory changes made by the Economic Growth and Tax Relief Reconciliation Act of 2001, Public Law 107-16 (EGTRRA) and the Tax Relief, Unemployment Insurance Reauthorization, and Job Creation Act of 2010, Public Law 111-312 (TRUIRJA).

Section 501(a) of EGTRRA enacted section 2210 of the Code, which made chapter 11 (the estate tax) inapplicable to the estate of any decedent who died after 2009. Section 542 of EGTRRA also enacted section 1022. While section 1014 generally provides that the recipient's basis in property passing from a decedent is the fair market value of the property on the decedent's date of death, section 1022 sets forth a modified carryover basis system applicable after 2009 generally providing that the recipient's basis in property acquired from a decedent is the lesser of the decedent's adjusted basis in

the property or the fair market value of the property on the decedent's date of death. Section 901(a) of EGTRRA, known as the "sunset clause", provided that all provisions of and amendments made by EGTRRA do not apply to estates of decedents dying, gifts made, or generation-skipping transfers after December 31, 2010. The sunset clause effectively limited the application of sections 501(a) and 542 of EGTRRA to 2010.

Section 301(a) of TRUIRJA, which became law on December 17, 2010, retroactively reinstated the estate tax and repealed section 1022 with respect to the estates of decedents who died in 2010. However, section 301(c) of TRUIRJA allowed the executor of the estate of a decedent who died in 2010 to elect to apply the Code and regulations thereunder as though section 301(a) of TRUIRJA did not apply with respect to chapter 11 and with respect to property acquired or passing from the decedent (within the meaning of section 1014(b) of the Code). Thus, section 301(c) of TRUIRJA allowed the executor of the estate of a decedent who died in 2010 to elect not to have the provisions of chapter 11 apply to the decedent's estate, but rather to have the provisions of section 1022 apply (a Section 1022 Election).

To provide executors with guidance regarding the making of a Section 1022 Election and certain other collateral issues arising from the determination of basis under section 1022, on August 29, 2011, the Treasury Department and the IRS issued Notice 2011-66 (2011-35 IRB 184) and Revenue Procedure 2011-41 (2011-35 IRB 188). Although section 1022 was applicable only to decedents dying in calendar year 2010, basis determined pursuant to that section will continue to be relevant until all of the property whose basis is determined under that section has been sold or otherwise disposed of in a transaction in which gain or loss is recognized. Accordingly, on May 11, 2015, the Treasury Department and the IRS published in the **Federal Register** (80 FR 26873) a notice of proposed rulemaking (REG-107595-11, 2015-21 IRB 986) proposing amendments to existing regulations under various sections of the Code to take into account the application of the modified carryover basis rules of section 1022. The IRS received written comments responding to the notice of proposed rulemaking. No public hearing was requested or held.

After consideration of the comments received on the proposed regulations, this Treasury decision adopts the proposed regulations without

modification as final regulations. However, the final regulations adopt certain nonsubstantive, clarifying changes. The comments received on the proposed regulations are discussed in the remainder of this preamble.

Summary of Comments

One commenter noted that the proposed regulations proposed to amend § 1.742-1 to provide that the basis of a partnership interest acquired from a decedent is determined under section 1022 if the decedent died in 2010 and the decedent's executor made a Section 1022 Election with respect to the decedent's estate. The commenter noted that there was no similar amendment proposed to be made to § 1.1367-1(j), relating to the basis of stock of an S corporation where a portion of the value of the stock is attributable to items constituting income in respect of a decedent (IRD). The commenter recommended that the final regulations amend § 1.1367-1(j) with language referencing section 1022.

After considering this comment, the Treasury Department and the IRS have determined that no change is necessary. Section 1.1367-1(j) states, "[t]he basis determined under section 1014 of any stock in an S corporation is reduced by the portion of the value of the stock that is attributable to items constituting income in respect of a decedent." This regulation section, with its required basis adjustment for IRD, is limited to situations in which section 1014 applies. Section 1.1367-1(j) does not apply when a Section 1022 Election is made because there is no basis adjustment under section 1022 to the date of death value of S corporation stock. Without an adjustment to date of death value, no further adjustment to the basis of S corporation stock is required to account for IRD. Therefore, the final regulations do not adopt this comment.

A commenter noted that the proposed regulations only propose amendments to finalized regulations, and not to proposed regulations or temporary regulations. That commenter specifically requested guidance with respect to proposed regulation § 1.465-69(a) (which provides that a successor to a decedent's amount at risk in an activity is increased by the amount by which the successor's basis in the activity is increased under section 1014) and temporary regulation § 16A.1255-2(b)(2) (which provides that if, as of the date a person acquires section 126 property from a decedent, the basis of the property is determined under section 1014, then on that date the aggregate of excludable portions under

section 126 in the hands of such transferee is zero). This Treasury decision cannot modify provisions of the proposed or temporary regulations referenced by the commenter without adopting those provisions as final or temporary regulations. The Treasury Department and the IRS continue to study these areas, and therefore are not prepared to adopt modifications to the proposed or temporary regulations referenced by the commenter at this time. Accordingly, the final regulations do not adopt this comment. However, the Treasury Department and the IRS expect that, if those proposed or temporary regulations are adopted as final or temporary regulations in the future, such regulations will be updated as appropriate to account for the existence of section 1022.

Another commenter asked why the preamble to the proposed regulations omitted any discussion of the revisions made to regulations under six particular sections of the Code, and requested an explanation as to why changes to those regulatory provisions were considered less significant than the changes for which an explanation was given. Generally, the Treasury Department and the IRS included descriptions of the proposed changes in that preamble that involved more than a mere insertion of a reference to section 1022 in addition to an existing reference to section 1014. In such cases, it was determined that an explanation or clarification of the substance or effect of the proposed revision would be helpful. In the case of the proposed amendments to regulations under the six Code sections mentioned by the commenter, the only change proposed was the mere insertion of references to section 1022 in addition to existing references to section 1014. Accordingly, the Treasury Department and the IRS determined that no further explanation of those changes was necessary.

A commenter also asked why the proposed regulations did not incorporate the treatment of items under the various Code sections addressed in Revenue Procedure 2011-41, 2011-35 IRB 188. That revenue procedure provides a safe harbor that determines the effect on the application of various Code sections of a Section 1022 Election. The provisions relating to that safe harbor are available only if the executor of the estate makes a Section 1022 Election and takes no position contrary to a provision in that revenue procedure. Nothing in these final regulations changes or invalidates the provisions of Revenue Procedure 2011-41, so the safe harbor will remain available to qualifying taxpayers.

Consequently, it is unnecessary to incorporate the revenue procedure into these regulations.

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. The Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply to these final regulations because the final regulations do not impose a collection of information requirement on small entities. Therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding this regulation has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business, and no comments were received.

Drafting Information

The principal author of these final regulations is Mayer R. Samuels, Office of the Associate Chief Counsel (Passthroughs and Special Industries). Other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.48-12 is amended by revising the last sentence of paragraph (b)(2)(vii)(B) and adding paragraph (g) to read as follows:

§ 1.48-12 Qualified rehabilitated building; expenditures incurred after December 31, 1981.

* * * * *

(b) * * *

(2) * * *

(vii) * * *

(B) * * * If a transferee's basis is determined under section 1014 or section 1022, any expenditures incurred by the decedent within the measuring period that are treated as having been incurred by the transferee under

paragraph (c)(3)(ii) of this section shall decrease the transferee's basis for purposes of the substantial rehabilitation test.

* * * * *

(g) *Effective/applicability date.* This section applies on and after January 19, 2017. For rules before January 19, 2017, see § 1.48-12 as contained in 26 CFR part 1 revised as of April 1, 2016.

■ **Par. 3.** Section 1.83-4 is amended by revising the last sentence of paragraph (b)(1) and adding paragraph (d) to read as follows:

§ 1.83-4 Special rules.

* * * * *

(b) * * *

(1) * * * Such basis shall also reflect any adjustments to basis provided under sections 1015, 1016, and 1022.

* * * * *

(d) *Effective/applicability date.* The provisions in this section are applicable for taxable years beginning on or after July 21, 1978. The provisions of paragraph (b)(1) of this section relating to section 1022 are effective on and after January 19, 2017.

■ **Par. 4.** Section 1.179-4 is amended by revising the first sentence of paragraph (c)(1)(iv) to read as follows:

§ 1.179-4 Definitions.

* * * * *

(c) * * *

(1) * * *

(iv) The property is not acquired by purchase if the basis of the property in the hands of the person acquiring it is determined in whole or in part by reference to the adjusted basis of such property in the hands of the person from whom acquired, is determined under section 1014(a), relating to property acquired from a decedent, or is determined under section 1022, relating to property acquired from certain decedents who died in 2010. * * *

* * * * *

■ **Par. 5.** Section 1.179-6 is amended by:

■ 1. Revising the section heading and the first sentence of paragraph (a).

■ 2. Adding paragraph (d).

The revision and addition read as follows:

§ 1.179-6 Effective/applicability dates.

(a) * * * Except as provided in paragraphs (b), (c), and (d) of this section, the provisions of §§ 1.179-1 through 1.179-5 apply for property placed in service by the taxpayer in taxable years ending after January 25, 1993. * * *

* * * * *

(d) *Application of § 1.179-4(c)(1)(iv).* The provisions of § 1.179-4(c)(1)(iv)

relating to section 1022 are effective on and after January 19, 2017.

■ **Par. 6.** Section 1.197–2 is amended by revising paragraphs (h)(5)(i) and (h)(12)(viii) and adding paragraph (l)(5) to read as follows:

§ 1.197–2 Amortization of goodwill and certain other intangibles.

* * * * *

(h) * * *

(5) * * *

(i) The acquisition of a section 197(f)(9) intangible if the acquiring taxpayer's basis in the intangible is determined under section 1014(a) or 1022; or

* * * * *

(12) * * *

(viii) *Operating rule for transfers upon death.* For purposes of this paragraph (h)(12), if the basis of a partner's interest in a partnership is determined under section 1014(a) or 1022, such partner is treated as acquiring such interest from a person who is not related to such partner, and such interest is treated as having previously been held by a person who is not related to such partner.

* * * * *

(l) * * *

(5) *Application of section 1022.* The provisions of § 1.197–2(h)(5)(i) and (h)(12)(viii) relating to section 1022 are effective on and after January 19, 2017.

■ **Par. 7.** Section 1.267(d)–1 is amended by revising paragraph (a)(3) to read as follows:

§ 1.267(d)–1 Amount of gain where loss previously disallowed.

(a) * * *

(3) The benefit of the general rule is available only to the original transferee but does not apply to any original transferee (for example, a donee or a person acquiring property from a decedent where the basis of property is determined under section 1014 or 1022) who acquired the property in any manner other than by purchase or exchange.

* * * * *

■ **Par. 8.** Section 1.267(d)–2 is amended by revising the section heading and adding a sentence to the end of the paragraph to read as follows:

§ 1.267(d)–2 Effective/applicability dates.

* * * The provisions of § 1.267(d)–1(a)(3) relating to section 1022 are effective on and after January 19, 2017.

■ **Par. 9.** Section 1.273–1 is revised to read as follows:

§ 1.273–1 Life or terminable interests.

(a) *In general.* Amounts paid as income to the holder of a life or a

terminable interest acquired by gift, bequest, or inheritance shall not be subject to any deduction for shrinkage (whether called by depreciation or any other name) in the value of such interest due to the lapse of time. In other words, the holder of such an interest so acquired may not set up the value of the expected future payments as corpus or principal and claim deduction for shrinkage or exhaustion thereof due to the passage of time. For the treatment generally of distributions to beneficiaries of an estate or trust, see Subparts A, B, C, and D (section 641 and following), Subchapter J, Chapter 1 of the Code, and the regulations thereunder. For basis of property acquired from a decedent and by gifts and transfers in trust, see sections 1014, 1015, and 1022, and the regulations thereunder.

(b) *Effective/applicability date.* The provisions in this section are applicable for taxable years beginning on or after September 16, 1958. The provisions of this section relating to section 1022 are effective on and after January 19, 2017.

■ **Par. 10.** Section 1.306–3 is amended by removing the last sentence of paragraph (e) and adding two sentences in its place to read as follows:

§ 1.306–3 Section 306 stock defined.

* * * * *

(e) * * * Section 306 stock ceases to be so classified if the basis of such stock is determined by reference to its fair market value on the date of the decedent-stockholder's death under section 1014 or the optional valuation date under section 2032. Section 306 stock continues to be so classified if the basis of such stock is determined under section 1022.

* * * * *

■ **Par. 11.** Section 1.306–4 is added to read as follows:

§ 1.306–4 Effective/applicability date.

The provisions of §§ 1.306–1 through 1.306–3 are applicable on or after June 22, 1954. The provisions of § 1.306–3 relating to section 1022 are effective on and after January 19, 2017.

■ **Par. 12.** Section 1.336–1 is amended by revising paragraph (b)(5)(i)(A) to read as follows:

§ 1.336–1 General principles, nomenclature, and definitions for a section 336(e) election.

* * * * *

(b) * * *

(5) * * *

(i) * * *

(A) The basis of the stock in the hands of the purchaser is not determined in whole or in part by reference to the

adjusted basis of such stock in the hands of the person from whom the stock is acquired, is not determined under section 1014(a) (relating to property acquired from a decedent), or is not determined under section 1022 (relating to the basis of property acquired from certain decedents who died in 2010);

* * * * *

■ **Par. 13.** Section 1.336–5 is amended by revising the section heading and adding a sentence to the end of the paragraph to read as follows:

§ 1.336–5 Effective/applicability dates.

* * * The provisions of § 1.336–1(b)(5)(i)(A) relating to section 1022 are effective on and after January 19, 2017.

■ **Par. 14.** Section 1.355–6 is amended by revising paragraphs (d)(1)(i)(A)(2) and (g) to read as follows:

§ 1.355–6 Recognition of gain on certain distributions of stock or securities in controlled corporation.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(A) * * *

(2) Under section 1014(a) or 1022; and

* * * * *

(g) *Effective/applicability dates.* This section applies to distributions occurring after December 20, 2000, except that they do not apply to any distributions occurring pursuant to a written agreement that is (subject to customary conditions) binding on December 20, 2000, and at all later times. The provisions of paragraph (d)(1)(i)(A)(2) of this section relating to section 1022 are effective on and after January 19, 2017.

■ **Par. 15.** Section 1.382–1 is amended by revising the entry for § 1.382–9(d)(6) to read as follows:

§ 1.382–9 Special rules under section 382 for corporations under the jurisdiction of a court in a title 11 or similar case.

* * * * *

(d) * * *

(6) Effective/applicability date.

* * * * *

■ **Par. 16.** Section 1.382–9 is amended by revising paragraphs (d)(5)(ii)(D) and (d)(6)(i) to read as follows:

§ 1.382–9 Special rules under section 382 for corporations under the jurisdiction of a court in a title 11 or similar case.

* * * * *

(d) * * *

(5) * * *

(ii) * * *

(D) The transferee's basis in the indebtedness is determined under

section 1014, 1015, or 1022 or with reference to the transferor's basis in the indebtedness;

* * * * *

(6) *Effective/applicability date*—(i) *In general.* This paragraph (d) applies to ownership changes occurring on or after March 17, 1994. The provisions of paragraph (d)(5)(ii)(D) of this section relating to section 1022 are effective on and after January 19, 2017.

* * * * *

■ **Par. 17.** Section 1.421–2 is amended by:

■ 1. Revising paragraphs (c)(4)(i)(a) and (c)(4)(ii).

■ 2. Revising the heading of paragraph (f) and adding paragraph (f)(3).

The revisions and addition read as follows:

§ 1.421–2 General rules.

* * * * *

(c) * * *

(4)(i)(a) In the case of the death of an optionee, the basis of any share of stock acquired by the exercise of an option under this paragraph (c), determined under section 1011, shall be increased by an amount equal to the portion of the basis of the option attributable to such share. For example, if a statutory option to acquire 10 shares of stock has a basis of \$100, the basis of one share acquired by a partial exercise of the option, determined under section 1011, would be increased by 1/10th of \$100, or \$10. The option acquires a basis, determined under section 1014(a) or under section 1022, if applicable, only if the transfer of the share pursuant to the exercise of such option qualifies for the special tax treatment provided by section 421(a). To the extent the option is so exercised, in whole or in part, it will acquire a basis equal to its fair market value (or the basis as determined under section 1022, if applicable) at the date of the employee's death or, if an election is made under section 2032, its value at its applicable valuation date. In certain cases, the basis of the share is subject to the adjustments provided by paragraphs (c)(4)(i)(b) and (c) of this section, but such adjustments are only applicable in the case of an option that is subject to section 423(c).

* * * * *

(ii) If a statutory option is not exercised by the estate of the individual to whom the option was granted, or by the person who acquired such option by bequest or inheritance or by reason of the death of such individual, the option shall be considered to be property that constitutes a right to receive an item of income in respect of a decedent to which the rules of sections 691 and

1014(c) (or section 1022(f), if applicable) apply.

* * * * *

(f) *Effective/applicability date.* * * *

* * * * *

(3) *Application of section 1022.* The provisions of paragraph (c) of this section relating to section 1022 are effective on and after January 19, 2017.

■ **Par. 18.** Section 1.423–2 is amended by:

■ 1. Revising the third sentence of paragraph (k)(2).

■ 2. Adding a sentence to the end of paragraph (l).

The revision and addition read as follows:

§ 1.423–2 Employee stock purchase plan defined.

* * * * *

(k) * * *

(2) * * * If the special rules provided in this paragraph (k) are applicable to a share of stock upon the death of an employee, then the basis of the share in the hands of the estate or the person receiving the stock by bequest or inheritance shall be determined under section 1014 or under section 1022, if applicable, and shall not be increased by reason of the inclusion upon the decedent's death of any amount in the decedent's gross income under this paragraph (k). * * *

* * * * *

(l) * * * The provisions of this section relating to section 1022 are effective on and after January 19, 2017.

■ **Par. 19.** Section 1.424–1 is amended by revising the last sentence of paragraph (c)(2) and adding paragraph (g)(3) to read as follows:

§ 1.424–1 Definitions and special rules applicable to statutory options.

* * * * *

(c) * * *

(2) * * * For determination of basis in the hands of the survivor where joint ownership is terminated by the death of one of the owners, see section 1014 or section 1022, if applicable.

* * * * *

(g) * * *

(3) *Application of section 1022.* The provisions of paragraph (c)(2) of this section relating to section 1022 are effective on and after January 19, 2017.

■ **Par. 20.** Section 1.467–7 is amended by revising paragraph (c)(2) and revising the first sentence of paragraph (c)(4) to read as follows:

§ 1.467–7 Section 467 recapture and other rules relating to dispositions and modifications.

* * * * *

(c) * * *

(2) *Dispositions at death.* Paragraph (a) of this section does not apply to a disposition if the basis of the property in the hands of the transferee is determined under section 1014(a) or section 1022. However, see paragraph (c)(4) of this section for dispositions of property subject to section 1022 by transferees. This paragraph (c)(2) does not apply to property that constitutes a right to receive an item of income in respect of a decedent. See sections 691, 1014(c), and 1022(f).

* * * * *

(4) * * * If the recapture amount with respect to a disposition of property (the first disposition) is limited under paragraph (c)(1) or (c)(3) of this section, or under paragraph (c)(2) of this section because the basis of the property in the hands of the transferee is determined under section 1022, and the transferee subsequently disposes of the property in a transaction to which paragraph (a) of this section applies, the prior understated inclusion determined under paragraph (b)(2) of this section is computed by taking into account the amounts attributable to the period of the transferor's ownership of the property prior to the first disposition. * * *

* * * * *

■ **Par. 21.** Section 1.467–9 is amended by revising the section heading and adding paragraph (f) to read as follows:

§ 1.467–9 Effective/applicability dates and automatic method changes for certain agreements.

* * * * *

(f) *Application of section 1022.* The provisions of § 1.467–7(c)(2) and (4) relating to section 1022 are effective on and after January 19, 2017.

■ **Par. 22.** Section 1.617–3 is amended by revising paragraph (d)(5)(ii)(b) to read as follows:

§ 1.617–3 Recapture of exploration expenditures.

* * * * *

(d) * * *

(5) * * *

(ii) * * *

(b) The transactions referred to in paragraph (d)(5)(ii)(a) of this section are:

(1) A disposition that is in part a sale or exchange and in part a gift;

(2) A disposition that is described in section 617(d) through the incorporation by reference of the provisions of section 1245(b)(3) (relating to certain tax free transactions); or

(3) A transfer at death where basis of property in the hands of the transferee is determined under section 1022.

* * * * *

■ **Par. 23.** Section 1.617–4 is amended by revising the second sentence of paragraph (c)(1)(i) to read as follows:

§ 1.617–4 Treatment of gain from disposition of certain mining property.

* * * * *

(c) * * *

(1)(i) * * * For purposes of this paragraph (c), the term *gift* means, except to the extent that paragraph (c)(1)(ii) of this section applies, a transfer of mining property that, in the hands of the transferee, has a basis determined under the provisions of section 1015(a) or 1015(d) (relating to basis of property acquired by gift) or section 1022 (relating to the basis of property acquired from certain decedents who died in 2010). * * *

* * * * *

■ **Par. 24.** Section 1.617–5 is added to read as follows:

§ 1.617–5 Effective/applicability date.

Sections 1.617–3 and 1.617–4 apply on and after January 19, 2017. For rules before January 19, 2017, see §§ 1.617–3 and 1.617–4 as contained in 26 CFR part 1 revised as of April 1, 2016.

■ **Par. 25.** Section 1.684–3 is amended by revising paragraph (c) to read as follows:

§ 1.684–3 Exceptions to general rule of gain recognition.

* * * * *

(c) *Certain transfers at death—(1) Section 1014 basis.* The general rule of gain recognition under § 1.684–1 shall not apply to any transfer of property to a foreign trust or foreign estate or, in the case of a transfer of property by a U.S. transferor decedent dying in 2010, to a foreign trust, foreign estate, or a nonresident alien, by reason of death of the U.S. transferor, if the basis of the property in the hands of the transferee is determined under section 1014(a).

(2) *Section 1022 basis election.* For U.S. transferor decedents dying in 2010, the general rule of gain recognition under § 1.684–1 shall apply to any transfer of property by reason of death of the U.S. transferor if the basis of the property in the hands of the foreign trust, foreign estate, or the nonresident alien individual is determined under section 1022. The gain on the transfer shall be calculated as set out under § 1.684–1(a), except that adjusted basis will reflect any increases allocated to such property under section 1022.

* * * * *

■ **Par. 26.** Section 1.684–5 is revised to read as follows:

§ 1.684–5 Effective/applicability dates.

(a) Sections 1.684–1 through 1.684–4 apply to transfers of property to foreign trusts and foreign estates after August 7, 2000, except as provided in paragraph (b) of this section.

(b) In the case a U.S. transferor decedent dying in 2010, § 1.684–3(c) applies to transfers of property to foreign trusts, foreign estates, and nonresident aliens after December 31, 2009, and before January 1, 2011.

■ **Par. 27.** Section 1.691(a)–3 is amended by revising the last two sentences of paragraph (a) and adding paragraph (c) to read as follows:

§ 1.691(a)–3 Character of gross income.

(a) * * * The provisions of section 1014(a), relating to the basis of property acquired from a decedent, and section 1022, relating to the basis of property acquired from certain decedents who died in 2010, do not apply to these amounts in the hands of the estate and such persons. See sections 1014(c) and 1022(f).

* * * * *

(c) *Effective/applicability dates.* The last two sentences of paragraph (a) of this section apply on and after January 19, 2017. For rules before January 19, 2017, see § 1.691(a)–3 as contained in 26 CFR part 1 revised as of April 1, 2016.

■ **Par. 28.** Section 1.742–1 is revised to read as follows:

§ 1.742–1 Basis of transferee partner's interest.

(a) *In general.* The basis to a transferee partner of an interest in a partnership shall be determined under the general basis rules for property provided by part II (section 1011 and following), Subchapter O, Chapter 1 of the Internal Revenue Code. Thus, the basis of a purchased interest will be its cost. Generally, the basis of a partnership interest acquired from a decedent is the fair market value of the interest at the date of his death or at the alternate valuation date, increased by his estate's or other successor's share of partnership liabilities, if any, on that date, and reduced to the extent that such value is attributable to items constituting income in respect of a decedent (see section 753 and §§ 1.706–1(c)(3)(v) and 1.753–1(b)) under section 691. See section 1014(c). However, the basis of a partnership interest acquired from a decedent is determined under section 1022 if the decedent died in 2010 and the decedent's executor elected to have section 1022 apply to the decedent's estate. For basis of contributing partner's interest, see section 722. The basis so determined is then subject to

the adjustments provided in section 705.

(b) *Effective/applicability date.* This section applies on and after January 19, 2017. For rules before January 19, 2017, see § 1.742–1 as contained in 26 CFR part 1 revised as of April 1, 2016.

■ **Par. 29.** Section 1.743–1 is amended by revising paragraphs (k)(2)(ii) and (l) to read as follows:

§ 1.743–1 Optional adjustment to basis of partnership property.

* * * * *

(k) * * *

(2) * * *

(ii) *Special rule.* A transferee that acquires, on the death of a partner, an interest in a partnership with an election under section 754 in effect for the taxable year of the transfer, must notify the partnership, in writing, within one year of the death of the deceased partner. The written notice to the partnership must be signed under penalties of perjury and must include the names and addresses of the deceased partner and the transferee, the taxpayer identification numbers of the deceased partner and the transferee, the relationship (if any) between the transferee and the transferor, the deceased partner's date of death, the date on which the transferee became the owner of the partnership interest, the fair market value of the partnership interest on the applicable date of valuation set forth in section 1014 or section 1022, the manner in which the fair market value of the partnership interest was determined, and the carryover basis as adjusted under section 1022 (if applicable).

* * * * *

(l) *Effective/applicability date.* The provisions in this section apply to transfers of partnership interests that occur on or after December 15, 1999. The provisions of this section relating to section 1022 are effective on and after January 19, 2017.

■ **Par. 30.** Section 1.755–1 is amended by:

■ 1. Revising paragraphs (a)(4)(i)(C) and the first sentence of (b)(4)(i).

■ 2. Revising the heading of paragraph (e) and paragraph (e)(2).

The revisions read as follows:

§ 1.755–1 Rules for allocation of basis.

(a) * * *

(4) * * *

(i) * * *

(C) *Income in respect of a decedent.* Solely for the purpose of determining partnership gross value under this paragraph (a)(4)(i), where a partnership interest is transferred as a result of the death of a partner, the transferee's basis

in its partnership interest is determined without regard to section 1014(c) or section 1022(f), and is deemed to be adjusted for that portion of the interest, if any, that is attributable to items representing income in respect of a decedent under section 691.

* * * * *

(b) * * *

(4) * * *

(i) * * * Where a partnership interest is transferred as a result of the death of a partner, under section 1014(c) or section 1022(f), the transferee's basis in its partnership interest is not adjusted for that portion of the interest, if any, that is attributable to items representing income in respect of a decedent under section 691. * * *

* * * * *

(e) *Effective/applicability dates.* * * *

(2) *Special rules.* Paragraphs (a) and (b)(3)(iii) of this section apply to transfers of partnership interests and distributions of property from a partnership that occur on or after June 9, 2003. The provisions of paragraphs (a)(4)(i)(C) and (b)(4)(i) of this section relating to section 1022 are effective on and after the date January 19, 2017.

■ **Par. 31.** Section 1.995-4 is amended by revising the first sentence of paragraph (d)(2) and adding paragraph (f) to read as follows:

§ 1.995-4 Gain on disposition of stock in a DISC.

* * * * *

(d) * * *

(2) * * * For purposes of this section, the period during which a shareholder has held stock includes the period he is considered to have held it by reason of the application of section 1223 and, if his basis is determined in whole or in part under the provisions of section 1014(d) (relating to special rule for DISC stock acquired from decedent) or section 1022 (relating to property acquired from certain decedents who died in 2010), the holding period of the decedent.

* * *

* * * * *

(f) *Effective/applicability date.* This section applies on and after January 19, 2017. For rules before January 19, 2017, see § 1.995-4 as contained in 26 CFR part 1 revised as of April 1, 2016.

■ **Par. 32.** Section 1.1001-1 is amended by revising the last sentence of paragraph (a), revising paragraph (f)(1), and adding paragraph (i) to read as follows:

§ 1.1001-1 Computation of gain or loss.

(a) * * * Section 1001(e) and paragraph (f) of this section prescribe the method of computing gain or loss

upon the sale or other disposition of a term interest in property the adjusted basis (or a portion) of which is determined pursuant, or by reference, to section 1014 (relating to the basis of property acquired from a decedent), section 1015 (relating to the basis of property acquired by gift or by a transfer in trust), or section 1022 (relating to the basis of property acquired from certain decedents who died in 2010).

* * * * *

(f) * * *

(1) *General rule.* Except as otherwise provided in paragraph (f)(3) of this section, for purposes of determining gain or loss from the sale or other disposition after October 9, 1969, of a term interest in property (as defined in paragraph (f)(2) of this section), a taxpayer shall not take into account that portion of the adjusted basis of such interest that is determined pursuant, or by reference, to section 1014 (relating to the basis of property acquired from a decedent), section 1015 (relating to the basis of property acquired by gift or by a transfer in trust), or section 1022 (relating to the basis of property acquired from certain decedents who died in 2010) to the extent that such adjusted basis is a portion of the adjusted uniform basis of the entire property (as defined in § 1.1014-5). Where a term interest in property is transferred to a corporation in connection with a transaction to which section 351 applies and the adjusted basis of the term interest:

(i) Is determined pursuant to sections 1014, 1015, or 1022; and

(ii) Is also a portion of the adjusted uniform basis of the entire property, a subsequent sale or other disposition of such term interest by the corporation will be subject to the provisions of section 1001(e) and this paragraph (f) to the extent that the basis of the term interest so sold or otherwise disposed of is determined by reference to its basis in the hands of the transferor as provided by section 362(a). See paragraph (f)(2) of this section for rules relating to the characterization of stock received by the transferor of a term interest in property in connection with a transaction to which section 351 applies. That portion of the adjusted uniform basis of the entire property that is assignable to such interest at the time of its sale or other disposition shall be determined under the rules provided in § 1.1014-5. Thus, gain or loss realized from a sale or other disposition of a term interest in property shall be determined by comparing the amount of the proceeds of such sale with that part of the adjusted basis of such interest that is not a portion of the

adjusted uniform basis of the entire property.

* * * * *

(i) *Effective/applicability date.* Except as provided in paragraphs (g) and (h) of this section, this section applies on and after January 19, 2017. For rules before January 19, 2017, see § 1.1001-1 as contained in 26 CFR part 1 revised as of April 1, 2016.

■ **Par. 33.** Section 1.1014-1 is amended by revising paragraph (a) and adding paragraph (d) to read as follows:

§ 1.1014-1 Basis of property acquired from a decedent.

(a) *General rule.* The purpose of section 1014 is, in general, to provide a basis for property acquired from a decedent that is equal to the value placed upon such property for purposes of the federal estate tax. Accordingly, the general rule is that the basis of property acquired from a decedent is the fair market value of such property at the date of the decedent's death, or, if the decedent's executor so elects, at the alternate valuation date prescribed in section 2032, or in section 811(j) of the Internal Revenue Code (Code) of 1939. However, the basis of property acquired from certain decedents who died in 2010 is determined under section 1022, if the decedent's executor made an election under section 301(c) of the Tax Relief, Unemployment Insurance Reauthorization, and Job Creation Act of 2010, Public Law 111-312 (124 Stat. 3296, 3300 (2010)). See section 1022. Property acquired from a decedent includes, principally, property acquired by bequest, devise, or inheritance, and, in the case of decedents dying after December 31, 1953, property required to be included in determining the value of the decedent's gross estate under any provision of the Code of 1954 or the Code of 1939. The general rule governing basis of property acquired from a decedent, as well as other rules prescribed elsewhere in this section, shall have no application if the property is sold, exchanged, or otherwise disposed of before the decedent's death by the person who acquired the property from the decedent. For general rules on the applicable valuation date where the executor of a decedent's estate elects under section 2032, or under section 811(j) of the Code of 1939, to value the decedent's gross estate at the alternate valuation date prescribed in such sections, see § 1.1014-3(e).

* * * * *

(d) *Effective/applicability date.* This section applies on and after January 19, 2017. For rules before January 19, 2017,

see § 1.1014–1 as contained in 26 CFR part 1 revised as of April 1, 2016.

■ **Par. 34.** Section 1.1014–4 is amended by revising the first sentence of paragraph (a)(1), revising the second sentence of paragraph (a)(2), and adding paragraph (d) to read as follows:

§ 1.1014–4 Uniformity of basis; adjustment to basis.

(a) * * *

(1) The basis of property acquired from a decedent, as determined under section 1014(a) or section 1022, is uniform in the hands of every person having possession or enjoyment of the property at any time under the will or other instrument or under the laws of descent and distribution. * * *

(2) * * * Accordingly, there is a common acquisition date for all titles to property acquired from a decedent within the meaning of section 1014 or section 1022, and, for this reason, a common or uniform basis for all such interests. * * *

* * * * *

(d) *Effective/applicability date.* This section applies on and after January 19, 2017. For rules before January 19, 2017, see § 1.1014–4 as contained in 26 CFR part 1 revised as of April 1, 2016.

■ **Par. 35.** Section 1.1014–5 is amended by revising paragraph (b) to read as follows:

§ 1.1014–5 Gain or loss.

* * * * *

(b) *Sale or other disposition of certain term interests—*(1) *In general.* In determining gain or loss from the sale or other disposition after October 9, 1969, of a term interest in property (as defined in § 1.1001–1(f)(2)) the adjusted basis of which is determined pursuant, or by reference, to section 1014 (relating to the basis of property acquired from a decedent), section 1015 (relating to the basis of property acquired by gift or by a transfer in trust), or section 1022 (relating to the basis of property acquired from certain decedents who died in 2010), that part of the adjusted uniform basis assignable under the rules of paragraph (a) of this section to the interest sold or otherwise disposed of shall be disregarded to the extent and in the manner provided by section 1001(e) and § 1.1001–1(f).

(2) *Effective/applicability date.* The provisions of paragraph (b)(1) of this section relating to section 1022 are effective on and after January 19, 2017. For rules before January 19, 2017, see § 1.1014–5 as contained in 26 CFR part 1 revised as of April 1, 2016.

■ **Par. 36.** Section 1.1223–1 is amended by adding a sentence to the end of

paragraph (b) and adding paragraph (l) to read as follows:

§ 1.1223–1 Determination of period for which capital assets are held.

* * * * *

(b) * * * Similarly, the period for which property acquired from a decedent who died in 2010 was held by the decedent must be included in determining the period during which the property was held by the recipient, if the recipient's basis in the property is determined under section 1022.

* * * * *

(l) *Effective/applicability date.* This section applies January 19, 2017. For rules before January 19, 2017, see § 1.1223–1 as contained in 26 CFR part 1 revised as of April 1, 2016.

■ **Par. 37.** Section 1.1245–2 is amended by revising paragraph (c)(2)(ii) and adding paragraph (d) to read as follows:

§ 1.1245–2 Definition of recomputed basis.

* * * * *

(c) * * *

(2) * * *

(ii) The transactions referred to in paragraph (c)(2)(i) of this section are:

(A) A disposition that is in part a sale or exchange and in part a gift (see § 1.1245–4(a)(3));

(B) A disposition (other than a disposition to which section 1245(b)(6)(A) applies) that is described in section 1245(b)(3) (relating to certain tax-free transactions);

(C) An exchange described in § 1.1245–4(e)(2) (relating to transfers described in section 1081(d)(1)(A)); or

(D) A transfer at death where the basis of property in the hands of the transferee is determined under section 1022.

* * * * *

(d) *Effective/applicability date.* This section applies on and after January 19, 2017. For rules before January 19, 2017, see § 1.1245–2 as contained in 26 CFR part 1 revised as of April 1, 2016.

■ **Par. 38.** Section 1.1245–3 is amended by revising paragraph (a)(3) and adding paragraph (d) to read as follows:

§ 1.1245–3 Definition of section 1245 property.

(a) * * *

(3) Even though property may not be of a character subject to the allowance for depreciation in the hands of the taxpayer, such property may nevertheless be section 1245 property if the taxpayer's basis for the property is determined by reference to its basis in the hands of a prior owner of the property and such property was of a character subject to the allowance for depreciation in the hands of such prior

owner, or if the taxpayer's basis for the property is determined by reference to the basis of other property that in the hands of the taxpayer was property of a character subject to the allowance for depreciation, or if the taxpayer's basis for the property is determined under section 1022 and such property was of a character subject to the allowance for depreciation in the hands of the decedent. Thus, for example, if a father uses an automobile in his trade or business during a period after December 31, 1961, and then gives the automobile to his son as a gift for the son's personal use, the automobile is section 1245 property in the hands of the son.

* * * * *

(d) *Effective/applicability date.* This section applies on and after January 19, 2017. For rules before January 19, 2017, see § 1.1245–3 as contained in 26 CFR part 1 revised as of April 1, 2016.

■ **Par. 39.** Section 1.1245–4 is amended by revising the second sentence of paragraph (a)(1) and adding paragraph (i) to read as follows:

§ 1.1245–4 Exceptions and Limitations.

(a) * * *

(1) * * * For purposes of this paragraph (a), the term *gift* means, except to the extent that paragraph (a)(3) of this section applies, a transfer of property that, in the hands of the transferee, has a basis determined under the provisions of section 1015(a) or 1015(d) (relating to basis of property acquired by gifts) or section 1022 (relating to basis of property acquired from certain decedents who died in 2010). * * *

* * * * *

(i) *Effective/applicability date.* This section applies on and after January 19, 2017. For rules before January 19, 2017, see § 1.1245–4 as contained in 26 CFR part 1 revised as of April 1, 2016.

■ **Par. 40.** Section 1.1250–4 is amended by adding paragraphs (c)(5) and (h) to read as follows:

§ 1.1250–4 Holding period.

* * * * *

(c) * * *

(5) A transfer at death where the basis of the property in the hands of the transferee is determined under section 1022.

* * * * *

(h) *Effective/applicability date.* This section applies on and after January 19, 2017. For rules before January 19, 2017, see § 1.1250–4 as contained in 26 CFR part 1 revised as of April 1, 2016.

■ **Par. 41.** Section 1.1254–2 is amended by revising the second sentence of paragraph (a)(1) to read as follows:

§ 1.1254-2 Exceptions and limitations.

(a) * * *

(1) * * * For purposes of this paragraph (a), the term *gift* means, except to the extent that paragraph (a)(2) of this section applies, a transfer of natural resource recapture property that, in the hands of the transferee, has a basis determined under the provisions of section 1015(a) or 1015(d) (relating to basis of property acquired by gift) or section 1022 (relating to the basis of property acquired from certain decedents who died in 2010). * * *

* * * * *

■ **Par. 42.** Section 1.1254-3 is amended by revising paragraphs (b)(2)(ii) and (iii) and adding paragraph (b)(2)(iv) to read as follows:

§ 1.1254-3 Section 1254 costs immediately after certain acquisitions.

* * * * *

(b) * * *

(2) * * *

(ii) A transaction described in section 1041(a);

(iii) A disposition described in § 1.1254-2(c)(3) (relating to certain tax-free transactions); or

(iv) A transfer at death where basis of property in the hands of the transferee is determined under section 1022.

* * * * *

■ **Par. 43.** Section 1.1254-4 is amended by revising paragraph (e)(4) introductory text to read as follows:

§ 1.1254-4 Special rules for S corporations and their shareholders.

* * * * *

(e) * * *

(4) * * * If stock is acquired in a transfer that is a gift, in a transfer that is a part sale or exchange and part gift, in a transfer that is described in section 1041(a), or in a transfer at death where the basis of property in the hands of the transferee is determined under section 1022, the amount of section 1254 costs with respect to the property held by the corporation in the acquiring shareholder's hands immediately after the transfer is an amount equal to—

* * * * *

■ **Par. 44.** Section 1.1254-5 is amended by revising paragraph (c)(2)(iv) introductory text to read as follows:

§ 1.1254-5 Special rules for partnerships and their partners.

* * * * *

(c) * * *

(2) * * *

(iv) * * * If an interest in a partnership is transferred in a transfer that is a gift, in a transfer that is a part sale or exchange and part gift, in a

transfer that is described in section 1041(a), or in a transfer at death where the basis of property in the hands of the transferee is determined under section 1022, the amount of the transferee partner's section 1254 costs with respect to property held by the partnership immediately after the transfer is an amount equal to—

* * * * *

■ **Par. 45.** Section 1.1254-6 is revised to read as follows:

§ 1.1254-6 Effective/applicability date.

(a) Sections 1.1254-1 through 1.1254-3 and 1.1254-5 are effective with respect to any disposition of natural resource recapture property occurring after March 13, 1995. The rule in § 1.1254-1(b)(2)(iv)(A)(2), relating to a nonoperating mineral interest carved out of an operating mineral interest with respect to which an expenditure has been deducted, is effective with respect to any disposition occurring after March 13, 1995, of property (within the meaning of section 614) that is placed in service by the taxpayer after December 31, 1986. Section 1.1254-4 applies to dispositions of natural resource recapture property by an S corporation (and a corporation that was formerly an S corporation) and dispositions of S corporation stock occurring on or after October 10, 1996. Sections 1.1254-2(d)(1)(ii) and 1.1254-3(b)(1)(i), (b)(1)(ii), (d)(1)(i), and (d)(1)(ii) are effective for dispositions of property occurring on or after October 10, 1996.

(b) The provisions of §§ 1.1254-2(a)(1), 1.1254-3(b)(2), 1.1254-4(e)(4), and 1.1254-5(c)(2)(iv) that relate to section 1022 are effective on and after January 19, 2017.

■ **Par. 46.** Section 1.1296-1 is amended by revising paragraphs (d)(4) and (j) to read as follows:

§ 1.1296-1 Mark to market election for marketable stock.

* * * * *

(d) * * *

(4) *Stock acquired from a decedent.* In the case of stock of a PFIC that is acquired by bequest, devise, or inheritance (or by the decedent's estate) and with respect to which a section 1296 election was in effect as of the date of the decedent's death, notwithstanding section 1014 or section 1022, the basis of such stock in the hands of the person so acquiring it shall be the adjusted basis of such stock in the hands of the decedent immediately before his death (or, if lesser, the basis that would have been determined under

section 1014 or section 1022 without regard to this paragraph (d)).

* * * * *

(j) *Effective/applicability date.* The provisions in this section are applicable for taxable years beginning on or after May 3, 2004. The provisions of paragraph (d)(4) of this section relating to section 1022 are effective on and after January 19, 2017.

■ **Par. 47.** Section 1.1312-7 is amended by revising paragraph (b) and adding paragraph (d) to read as follows:

§ 1.1312-7 Basis of property after erroneous treatment of a prior transaction.

* * * * *

(b)(1) For this section to apply, the taxpayer with respect to whom the erroneous treatment occurred must be:

(i) The taxpayer with respect to whom the determination is made; or

(ii) A taxpayer who acquired title to the property in the erroneously treated transaction and from whom, mediately or immediately, the taxpayer with respect to whom the determination is made derived title in such a manner that he will have a basis ascertained by reference to the basis in the hands of the taxpayer who acquired title to the property in the erroneously treated transaction; or

(iii) A taxpayer who had title to the property at the time of the erroneously treated transaction and from whom, mediately or immediately, the taxpayer with respect to whom the determination is made derived title, if the basis of the property in the hands of the taxpayer with respect to whom the determination is made is determined under section 1015(a) (relating to the basis of property acquired by gift) or section 1022 (relating to the basis of property acquired from certain decedents who died in 2010).

(2) No adjustment is authorized with respect to the transferor of the property in a transaction upon which the basis of the property depends, when the determination is with respect to the original transferee or a subsequent transferee of the original transferee.

* * * * *

(d) *Effective/applicability date.* This section applies on and after January 19, 2017. For rules before January 19, 2017,

see § 1.1312–7 as contained in 26 CFR part 1 revised as of April 1, 2016.

John Dalrymple,
Deputy Commissioner for Services and Enforcement.

Approved: November 11, 2016.

Mark J. Mazur,
Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2017–01365 Filed 1–18–17; 8:45 am]

BILLING CODE 4830–01–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022

Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe interest assumptions under the regulation for valuation dates in February 2017. The interest assumptions are used for paying benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

DATES: Effective February 1, 2017.

FOR FURTHER INFORMATION CONTACT: Deborah C. Murphy (*Murphy.Deborah@pbgc.gov*), Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005, 202–326–4400 ext. 3451. (TTY/TDD users may call the Federal relay service toll-free at

1–800–877–8339 and ask to be connected to 202–326–4400 ext. 3451.)

SUPPLEMENTARY INFORMATION: PBGC's regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribes actuarial assumptions—including interest assumptions—for paying plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions in the regulation are also published on PBGC's Web site (*http://www.pbgc.gov*).

PBGC uses the interest assumptions in Appendix B to Part 4022 to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Appendix C to Part 4022 contains interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC's historical methodology. Currently, the rates in Appendices B and C of the benefit payment regulation are the same.

The interest assumptions are intended to reflect current conditions in the financial and annuity markets. Assumptions under the benefit payments regulation are updated monthly. This final rule updates the benefit payments interest assumptions for February 2017.¹

The February 2017 interest assumptions under the benefit payments regulation will be 1.25 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. In comparison with the interest assumptions in effect for January 2017, these interest assumptions are unchanged.

PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public

interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the payment of benefits under plans with valuation dates during February 2017, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a “significant regulatory action” under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

In consideration of the foregoing, 29 CFR part 4022 is amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, Rate Set 280, as set forth below, is added to the table.

Appendix B to Part 4022—Lump Sum Interest Rates For PBGC Payments

* * * * *

| Rate set | For plans with a valuation date | | Immediate annuity rate (percent) | Deferred annuities (percent) | | | | | |
|----------|---------------------------------|--------|----------------------------------|------------------------------|-------|-------|-------|-------|--|
| | On or after | Before | | i_1 | i_2 | i_3 | n_1 | n_2 | |
| * | * | | * | * | * | * | | * | |
| 280 | 2–1–17 | 3–1–17 | 1.25 | 4.00 | 4.00 | 4.00 | 7 | 8 | |

■ 3. In appendix C to part 4022, Rate Set 280, as set forth below, is added to the table.

Appendix C to Part 4022—Lump Sum Interest Rates for Private-Sector Payments

* * * * *

¹ Appendix B to PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes interest assumptions for valuing

benefits under terminating covered single-employer plans for purposes of allocation of assets under

ERISA section 4044. Those assumptions are updated quarterly.

| Rate set | For plans with a valuation date | | Immediate annuity rate (percent) | Deferred annuities (percent) | | | | | |
|----------|---------------------------------|--------|----------------------------------|------------------------------|-------|-------|-------|-------|---|
| | On or after | Before | | i_1 | i_2 | i_3 | n_1 | n_2 | |
| * | * | | * | * | * | * | * | * | * |
| 280 | 2-1-17 | 3-1-17 | 1.25 | 4.00 | 4.00 | 4.00 | 7 | 8 | |

Issued in Washington, DC.

Deborah Chase Murphy,

Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

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DEPARTMENT OF THE TREASURY

Fiscal Service

31 CFR Part 347

RIN 1530-AA13

Regulations Governing Retirement Savings Bonds

AGENCY: Bureau of the Fiscal Service, Fiscal Service, Treasury.

ACTION: Final rule.

SUMMARY: Currently, the Bureau of the Fiscal Service (Fiscal Service) of the United States Department of the Treasury (Treasury), issues nonmarketable, electronic retirement savings bonds to an individual retirement account (IRA) custodian designated by Fiscal Service to act as a custodian for Roth IRAs under Treasury's myRA[®] program. In this Final Rule, Treasury offers nonmarketable, electronic retirement savings bonds for certain retirement savings programs established by states or certain of their political subdivisions (states). The bonds will be issued to a trustee or custodian (custodian) of a Roth IRA or traditional IRA designated by a state under its retirement savings program (whether or not the program provides for automatic enrollment). Interest will be earned at a rate available to federal employees invested in the Government Securities Investment Fund (G Fund) of the federal Thrift Savings Plan.

This offering does not affect the terms of retirement savings bonds issued to the custodian of Treasury's retirement savings program, myRA[®], which are held in participants' Roth IRAs. More information on myRA[®] is available at www.myra.gov.

DATES: This Final Rule is effective January 19, 2017.

FOR FURTHER INFORMATION CONTACT:

Technical information: Gregory Till, myRA Bureau Director, at (202) 622-6970 or Gregory.Till@treasury.gov.

Legal information: Elizabeth Spears, Senior Counsel, at (304) 480-8647 or Lisa.Spears@fiscal.treasury.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Approximately one third of private-sector employees in the United States lack access to a retirement savings plan through their employers.¹ To fill this gap, several states are establishing or considering establishing programs that will encourage employees to save for their retirement, including through individual retirement accounts into which employees are automatically enrolled and through other approaches (collectively referred to here as Auto-IRAs, whether or not they use automatic enrollment).² Under an Auto-IRA program, employee contributions are deposited into an IRA and invested in accordance with the design of the Auto-IRA program and the wishes of the participant. Generally, it is expected that an Auto-IRA program will offer a safe and low-cost investment option as an alternative to a risk-bearing diversified investment, such as a target date fund. In order to assist states in offering savers the option of a principal-protected investment, Fiscal Service will offer retirement savings bonds to state Auto-IRA programs. Fiscal Service reserves the right, however, to decline to issue retirement savings bonds to state Auto-IRA programs on a case-by-case basis, based on considerations such as the structure and reasonableness of associated fees, plans to control fees and expenses, whether participants have reasonable access to their funds, and oversight of providers designated to operate state Auto-IRA programs.

¹ National Compensation Survey, Bureau of Labor Statistics (July 2016), *Employee Benefits in the United States*—March 2016 (<http://www.bls.gov/news.release/pdf/ebs2.pdf>). These data show that 66 percent of 114 million private-sector workers have access to a retirement plan through their employers. By extension, approximately 34 percent of the 114 million private-sector workers (39 million) do not have access to a retirement plan through work.

² The Department of Labor has published regulations relating to state payroll deduction savings programs. 81 FR 59464 (Aug. 30, 2016) and 81 FR 92639 (Dec. 20, 2016).

II. Section-by-Section Analysis

Subpart A—General Information

Section 347.0 Offering of securities. This section is amended to offer retirement savings bonds to Auto-IRA custodians for certain state retirement savings programs.

Section 347.1 Applicability. This section is amended to include the Auto-IRA custodians for state retirement savings programs under this part.

Section 347.2 Official agencies. This section clarifies that Fiscal Service is responsible for issuing retirement savings bonds to the Auto-IRA custodians and that states are responsible for administering their own Auto-IRA retirement savings programs.

Section 347.3 Definitions. Several new definitions, including “Auto-IRA,” “state Auto-IRA program,” “IRA,” “Custodian,” “State,” and “Auto-IRA custodian” have been added for ease of reference in Subpart C—Auto-IRA Programs and minor changes have been made to some existing definitions.

Subpart B—Treasury's Retirement Savings Program

Miscellaneous changes have been made to the sections pertaining to retirement savings bonds issued to the custodian of Treasury's retirement savings program, myRA[®], which are held in participants' Roth IRAs. These changes, which were made to accommodate revised definitions and other minor or technical revisions, do not affect the terms of these bonds. See, e.g., §§ 347.10 through 347.16.

Subpart C—Auto-IRA Programs

Section 347.30 Plan requirements for State Auto-IRA programs.

Subsection (a) of this new section specifies that retirement savings bonds will be issued to Auto-IRA custodians for certain state Auto-IRA programs, and that no other registrations under Subpart C are permitted. As defined in § 347.3, an Auto-IRA custodian is “an entity designated by a state (including, for the purpose of these regulations, certain political subdivisions of states) to act as the trustee or custodian for Auto-IRAs, in the form of Roth IRAs or traditional IRAs, for or opened on behalf of participants in a state Auto-IRA program.” Subsection (b) lists topics

that must be addressed by documentation that programs are required to provide and certify to Fiscal Service annually. The documentation must address: (1) Administration of retirement savings bonds, (2) account monitoring, (3) ability to transfer proceeds, (4) IRA withdrawals, (5) consumer protection, (6) state Auto-IRA program costs of administration, (7) oversight of Auto-IRA custodian, (8) pooling prohibitions, (9) default investments, and (10) consumer education. The Commissioner of the Fiscal Service may use the documentation, among other purposes, in exercising any of the rights reserved under § 347.37, which includes the right to require information addressing additional topics. Subsection (c) provides for a successor Auto-IRA custodian, if needed.

Section 347.31 Crediting of retirement savings bond. This new section requires each bond issued to an Auto-IRA custodian to be credited to an individual's IRA under a state Auto-IRA program.

Section 347.32 Annual additions to retirement savings bond. This new section provides that the initial contribution and additions to a bond on behalf of a participant are subject to the annual contribution limits provided under the Internal Revenue Code and regulations, and that the total value of a retirement savings bond held by an Auto-IRA custodian in an IRA on behalf of any participant cannot exceed \$15,000.00.

Section 347.33 Individual additions to retirement savings bond. This new section authorizes Fiscal Service to establish minimum amounts for initial and additional contributions to a retirement savings bond.

Section 347.34 Payment (redemption). Under this new section, an Auto-IRA custodian is responsible for making certain certifications as a condition of the issuance and redemption of a retirement savings bond. Subsection (a) explains how the Auto-IRA custodian will request that Fiscal Service make payment on matured retirement savings bonds as well as those that have been fully or partially redeemed. Under subsection (b), Fiscal Service will make payment on any bonds that it calls for redemption without the Auto-IRA custodian having to make a request. Under § 347.37(4), the Commissioner of the Fiscal Service may exercise discretion to call the bonds for redemption. This might occur for a variety of reasons, including, for example, in the event that a state Auto-IRA program changed significantly such

that ongoing use of retirement savings bonds is no longer consistent with these regulations, or in the event that a state Auto-IRA program might have failed to comply with program instructions identified by Fiscal Service or might have failed to provide or comply with documentation required pursuant to § 347.30. Subsection (b) clarifies how bonds called for redemption will be paid, which is in the same manner as bonds submitted for redemption under subsection (a).

Section 347.35 Computation of interest. This new section provides that the interest rate on the retirement savings bonds will track the annual percentage rate on securities in the Government Securities Investment Fund (G Fund) in the Thrift Savings Plan for federal employees and that interest will cease at maturity or call.

Section 347.36 Maturity. This new section provides that the maturity dates for the retirement savings bonds may differ for each bond. The longest possible maturity is 30 years (an original maturity period of 20 years and an extended maturity period of 10 years). A bond will mature at the earlier of 30 years from the date the bond is first issued to the Auto-IRA custodian on behalf of the participant or when its value reaches \$15,000.00.

Section 347.37 Reservation of rights. Under this new section, the Commissioner of the Fiscal Service reserves certain rights, including: (1) The right to require a senior official to certify program information to Fiscal Service before the retirement savings bonds are issued to an Auto-IRA custodian; (2) the right to refuse to issue retirement savings bonds to an Auto-IRA custodian in any particular case or class of cases; (3) the right to suspend or cease offering retirement savings bonds to an Auto-IRA custodian; (4) the right to call for redemption of any outstanding retirement savings bond (this might occur for a variety of reasons, including, for example, if a state Auto-IRA program has changed significantly such that ongoing use of retirement savings bonds is no longer consistent with these regulations, or if a state has failed to provide or comply with documentation required pursuant to § 347.30); or (5) the right to determine any appropriate remedy under this subpart.

Subpart D—Miscellaneous Provisions for Retirement Savings Bonds

Subpart D contains miscellaneous provisions (§§ 347.40 through 347.42) that apply to retirement savings bonds issued to the custodians, on behalf of

participants, in Treasury's and the states' programs.

III. Procedural Requirements

A. Administrative Procedure Act

Because this rule relates to United States securities, which are contracts between Treasury and the owners of the securities, this rule falls within the contract exception to the Administrative Procedures Act (APA) at 5 U.S.C. 553(a)(2). As a result, the notice, public comment, and delayed effective date provisions of the APA are inapplicable to this rule.

B. Congressional Review Act

This rule is not a major rule pursuant to the Congressional Review Act (CRA), 5 U.S.C. 801 *et seq.*

C. Paperwork Reduction Act

This final rule contains a new collection of information that is subject to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The collection of information contained in this final rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)).

D. Regulatory Flexibility Act

The provisions of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, do not apply to this rule because, pursuant to 5 U.S.C. 553(a)(2), it is not required to be issued with notice and opportunity for public comment.

E. Executive Order 12866

This rule is not a significant regulatory action pursuant to Executive Order 12866.

List of Subjects in 31 CFR Part 347

Government securities, Savings bonds.

For the reasons set forth in the preamble, we amend 31 CFR part 347 as follows:

PART 347—REGULATIONS GOVERNING RETIREMENT SAVINGS BONDS

■ 1. The authority citation for part 347 continues to read as follows:

Authority: 5 U.S.C. 301; 12 U.S.C. 90; 31 U.S.C. 3105.

■ 2. Revise § 347.0 to read as follows:

§ 347.0 Offering of securities.

The Secretary of the Treasury (the Secretary), under the authority of Title 31, Chapter 31, offers retirement savings bonds to the IRA custodian for Treasury's retirement savings program and to the Auto-IRA custodians for certain state Auto-IRA programs. The nonmarketable bonds are issued to and held by the custodians, on behalf of participants, in Treasury's program and state programs. This offering will continue until terminated by the Secretary or the Secretary's designee. Treasury's Fiscal Assistant Secretary is authorized to act on behalf of the Secretary on all matters contained in these regulations. The Commissioner of the Fiscal Service, as designee of the Secretary, is delegated the responsibility to administer this part through the Bureau of the Fiscal Service (Fiscal Service).

■ 3. Revise § 347.1 to read as follows:

§ 347.1 Applicability.

The regulations in this part apply to retirement savings bonds issued, on behalf of participants, to the IRA custodian for Treasury's retirement savings program and to the Auto-IRA custodians for state Auto-IRA programs.

■ 4. Revise § 347.2 to read as follows:

§ 347.2 Official agencies.

(a) Fiscal Service is responsible for administering Treasury's retirement savings program and for issuing the retirement savings bonds to the IRA custodian for Treasury's retirement savings program and to the Auto-IRA custodians for certain state Auto-IRA programs. The states are responsible for administering their Auto-IRA retirement savings programs, including the designation of Auto-IRA custodians to perform all operational responsibilities associated with the retirement savings bonds issued by Fiscal Service.

(b) Communications concerning transactions relating to an individual's IRA should be addressed to the appropriate custodian.

■ 5. In § 347.3:

■ a. Redesignate paragraphs (a) through (g) as paragraphs (g) through (m);

■ b. Add new paragraphs (a) through (f); and

■ c. Revise newly redesignated paragraphs (g) through (j).

The additions and revisions read as follows:

§ 347.3 Definitions.

(a) *Auto-IRA* means an individual retirement account for or opened on behalf of a participant in a state retirement savings program (whether or

not the program provides for automatic enrollment).

(b) *State Auto-IRA program* means a state Auto-IRA retirement savings program.

(c) *IRA* means an individual retirement account.

(d) *Custodian* means a trustee or custodian of a Roth IRA or traditional IRA.

(e) *State* means any of the 50 states, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, the Commonwealth of the Northern Mariana Islands, or certain of their political subdivisions.

(f) *Auto-IRA custodian* means an entity designated by a state (including, for the purpose of these regulations, political subdivisions of states) to act as the trustee or custodian for Auto-IRAs, in the form of Roth IRAs or traditional IRAs, for or opened on behalf of participants in a state Auto-IRA program.

(g) *Retirement savings bond*, as used in this part, means an interest-bearing electronic United States savings bond issued to an Auto-IRA or IRA custodian.

(h) *IRA custodian* means an entity designated by Fiscal Service to act as a custodian for Roth IRAs opened by or on behalf of participants in Treasury's retirement savings program.

(i) *Individual* means a person eligible to have an IRA in Treasury's retirement savings program or in a state Auto-IRA program.

(j) *Participant* means an individual who has an IRA in Treasury's retirement savings program or in a state Auto-IRA program.

* * * * *

■ 6. Revise the heading of subpart B to read as follows:

Subpart B—Treasury's Retirement Savings Program

■ 7. Revise §§ 347.10 and 347.11 to read as follows:

§ 347.10 Authorized form of registration.

(a) Retirement savings bonds are issued to the IRA custodian for Treasury's retirement savings program. No other registrations under this subpart are permitted.

(b) In the event Fiscal Service designates a successor IRA custodian, Fiscal Service may reissue retirement savings bonds held by the predecessor custodian to the successor custodian.

§ 347.11 Crediting of retirement savings bond.

Each retirement savings bond issued to the IRA custodian must be credited

to a single Roth IRA established through Treasury's retirement savings program with the custodian.

■ 8. Remove the headings for subparts C, D, and E and transfer §§ 347.20, 347.21, 347.30, 347.40, and 347.41 to subpart B, and redesignate them as §§ 347.12 through 347.16, respectively.

■ 9. Revise newly redesignated §§ 347.12 through 347.16 to read as follows:

§ 347.12 Annual additions to retirement savings bond.

The amount that initially may be contributed or added to a retirement savings bond in a calendar year by the IRA custodian on behalf of any participant is limited by the applicable annual contribution limits provided under the Internal Revenue Code and regulations. The total value of a retirement savings bond that may be held by the IRA custodian in an IRA on behalf of any participant shall not exceed \$15,000.

§ 347.13 Individual additions to retirement savings bond.

Fiscal Service is authorized to establish minimum amounts for initial and additional contributions to a retirement savings bond under this subpart.

§ 347.14 Payment (redemption).

Payment of retirement savings bonds will be made to the IRA custodian upon the custodian's submission of a request for redemption to Fiscal Service. The custodian shall request the redemption of all retirement savings bonds at their respective maturity. The custodian shall request the full or partial redemption of a bond held on behalf of a participant upon the request of the participant or other authorized person entitled to amounts in the IRA. Retirement savings bond redemptions will be rounded to the nearest one cent.

§ 347.15 Computation of interest.

Retirement savings bonds under this subpart earn interest at the same annual percentage rate as securities issued to the Government Securities Investment Fund (G Fund) in the Thrift Savings Plan for federal employees. The Secretary calculates the G Fund interest rate pursuant to 5 U.S.C. 8438(e)(2). The retirement savings bond interest rate compounds daily at 1/360 of the annual percentage rate. Retirement savings bonds will cease to accrue interest on the date of their maturity.

§ 347.16 Maturity.

The maturity date for retirement savings bonds is indeterminate and may

be different for each bond issued, but shall not exceed the sum of an original maturity period of 20 years and an extended maturity period of 10 years. A retirement savings bond purchased by the IRA custodian on behalf of a participant will mature at the earlier of 30 years from the date the bond is first issued to the custodian on behalf of the participant or when its value reaches \$15,000.

■ 10. Add a new subpart C to read as follows:

Subpart C—Auto-IRA Programs

Sec.

347.30 Plan requirements for State Auto-IRA programs.

347.31 Crediting of retirement savings bond.

347.32 Annual additions to retirement savings bond.

347.33 Individual additions to retirement savings bond.

347.34 Payment (redemption).

347.35 Computation of interest.

347.36 Maturity.

347.37 Reservation of rights.

Subpart C—Auto-IRA Programs

§ 347.30 Plan requirements for State Auto-IRA programs.

(a) *Authorized form of registration.* Retirement savings bonds are issued to Auto-IRA custodians for state Auto-IRA programs. No other registrations under this subpart are permitted.

(b) *Documentation.* A state Auto-IRA program must provide documentation to Fiscal Service annually, in a form and manner acceptable to Fiscal Service, addressing the following topics:

(1) *Administration*—servicing of the retirement savings bonds, such as account maintenance, recordkeeping, and establishment of procedures for automatic payroll direct deposit contributions (or other funding means permitted under state Auto-IRA programs);

(2) *Account monitoring*—tracking and, when applicable, redeeming and reallocating retirement savings bond holdings (which may include investment diversification strategies) no later than when a retirement savings bond that may be held by the Auto-IRA custodian on behalf of a participant in a state Auto-IRA program reaches the \$15,000 maximum dollar threshold or 30 years, whichever occurs first;

(3) *Ability to transfer*—addressing how the state Auto-IRA program enables participants, at their discretion, to redeem their retirement savings bonds prior to maturity and transfer their retirement savings bond proceeds to another investment available in the State Auto-IRA program or to another provider, without imposing

unreasonable restrictions on voluntary investment diversification (which might occur through a transfer within or outside of a state Auto-IRA program);

(4) *Withdrawals*—addressing how the state Auto-IRA program enables participants, at their discretion, to make reasonable withdrawals from their Auto-IRAs;

(5) *Consumer protection*—addressing consumer protections in the program, including disclosures provided to participants;

(6) *Costs of administration*—describing any fees or other costs or expenses passed on to or otherwise borne by participants under the state Auto-IRA program (e.g., no more than reasonable administrative, custodial, asset management, or other fees, costs, or expenses);

(7) *Oversight*—addressing state Auto-IRA program oversight of Auto-IRA custodians and describing any protections in place for participants' funds invested in retirement savings bonds, including information relating to the protection of participants' funds in the event that the Auto-IRA custodian files for bankruptcy or otherwise experiences financial stress;

(8) *Pooling*—prohibiting the inclusion of retirement savings bonds as a component of another investment or asset category (such as a mutual fund or target-date fund);

(9) *Default investment*—obtaining, if applicable, Fiscal Service's further consent before any use of retirement savings bonds as a default, sole, or mandatory investment, even if temporary;

(10) *Consumer education*—describing plans to provide financial education to participants; and

(11) *Certification*—requiring a statement signed by an authorized senior official certifying that the documentation provided to Fiscal Service is accurate and complete, and that procedures are in place to timely notify Fiscal Service of any material changes in the future.

(c) *Successor custodian.* In the event a state Auto-IRA program designates a successor Auto-IRA custodian, that program may request that Fiscal Service reissue the retirement savings bonds held by the predecessor custodian to the successor custodian.

§ 347.31 Crediting of retirement savings bond.

Each retirement savings bond issued to an Auto-IRA custodian must be credited to an IRA under the state Auto-IRA program with the custodian.

§ 347.32 Annual additions to retirement savings bond.

The amount that initially may be contributed or added to a retirement savings bond in a calendar year by an Auto-IRA custodian on behalf of any participant is limited by the applicable annual contribution limits provided under the Internal Revenue Code and regulations. The total value of a retirement savings bond that may be held by an Auto-IRA custodian in an IRA on behalf of any participant shall not exceed \$15,000 for each state Auto-IRA program.

§ 347.33 Individual additions to retirement savings bond.

Fiscal Service is authorized to establish minimum amounts for initial and additional contributions to a retirement savings bond under this subpart.

§ 347.34 Payment (redemption).

The issuance and redemption of a retirement savings bond is conditioned on an Auto-IRA custodian certifying compliance with these regulations and with any additional program instructions identified by Fiscal Service that pertain to that bond.

(a) *Payment upon maturity.* Payment of retirement savings bonds will be made to an Auto-IRA custodian upon the custodian's submission of a request for redemption to Fiscal Service. The custodian shall request the redemption of all retirement savings bonds at their respective maturity. The custodian shall request the full or partial redemption of a bond held on behalf of a participant upon the request of the participant or other authorized person entitled to amounts in the IRA. Retirement savings bond redemptions will be rounded to the nearest one cent.

(b) *Payment upon call.* Final interest on any called bonds will be paid with the principal (amount contributed minus withdrawals taken) at redemption and rounded to the nearest one cent.

§ 347.35 Computation of interest.

Retirement savings bonds under this subpart earn interest at the same annual percentage rate as securities issued to the Government Securities Investment Fund (G Fund) in the Thrift Savings Plan for federal employees. The Secretary calculates the G Fund interest rate pursuant to 5 U.S.C. 8438(e)(2). The retirement savings bond interest rate compounds daily at 1/360 of the annual percentage rate. Retirement savings bonds will cease to accrue interest on the date of their maturity or call.

§ 347.36 Maturity.

The maturity date for retirement savings bonds is indeterminate and may be different for each bond issued, but shall not exceed the sum of an original maturity period of 20 years and an extended maturity period of 10 years. A retirement savings bond purchased by the Auto-IRA custodian on behalf of a participant will mature at the earlier of 30 years from the date the bond is first issued to the custodian on behalf of the participant or when its value reaches \$15,000.

§ 347.37 Reservation of rights.

The Commissioner of the Fiscal Service may decide, in his or her sole discretion, to take any of the following actions with respect to the retirement savings bonds offered under this subpart. Such actions are final. Specifically, the Commissioner reserves the right under this subpart:

(a) As a condition of Fiscal Service's issuance of retirement savings bonds to an Auto-IRA custodian under a state Auto-IRA program, to require a state Auto-IRA program to provide information to Fiscal Service concerning the state Auto-IRA program and retirement savings bonds offered under this subpart, including a certification by a senior official to the completeness and accuracy of the information requested;

(b) To refuse to issue retirement savings bonds to an Auto-IRA custodian in any particular case or class of cases;

(c) To suspend or cease offering retirement savings bonds to an Auto-IRA custodian;

(d) To call for redemption of any outstanding retirement savings bond; or

(e) To determine any appropriate remedy under this subpart.

■ 11. Redesignate subpart F (consisting of §§ 347.50, 347.51, and 347.52) as subpart D (consisting of §§ 347.40 through 347.42) and revise newly redesignated subpart D to read as follows:

Subpart D—Miscellaneous Provisions for Retirement Savings Bonds

Sec.

347.40 Waiver of regulations.

347.41 Additional requirements; bond of indemnity.

347.42 Supplements, amendments, or revisions.

Subpart D—Miscellaneous Provisions for Retirement Savings Bonds**§ 347.40 Waiver of regulations.**

The Commissioner of the Fiscal Service may waive or modify any provision or provisions of the regulations in this part. He or she may do so in any particular case or class of

cases for the convenience of the United States or in order to relieve any person or persons of unnecessary hardship:

(a) If such action would not be inconsistent with law or equity;

(b) If it does not impair any material existing rights; and

(c) If he or she is satisfied that such action would not subject the United States to any substantial expense or liability.

§ 347.41 Additional requirements; bond of indemnity.

The Commissioner of the Fiscal Service may require:

(a) Such additional evidence to support a requested action as he or she may consider necessary or advisable; or

(b) A bond of indemnity, with or without surety, in any case in which he or she may consider such a bond necessary for the protection of the interests of the United States.

§ 347.42 Supplements, amendments, or revisions.

The Secretary may at any time, or from time to time, prescribe additional, supplemental, amendatory, or revised rules and regulations governing retirement savings bonds.

David A. Lebryk,

Fiscal Assistant Secretary.

[FR Doc. 2017-01038 Filed 1-18-17; 8:45 am]

BILLING CODE 4810-AS-P

DEPARTMENT OF DEFENSE**Office of the Secretary****32 CFR Part 269**

[Docket ID: DOD-2016-OS-0045]

RIN 0790-ZA12

Civil Monetary Penalty Inflation Adjustment

AGENCY: Under Secretary of Defense (Comptroller), Department of Defense.

ACTION: Final rule.

SUMMARY: This final rule is being issued to adjust for inflation each civil monetary penalty (CMP) provided by law within the jurisdiction of the United States Department of Defense (Department of Defense). The Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996 and the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act), requires the head of each agency to adjust for inflation its CMP levels in effect as of November 2, 2015, under a revised methodology that

was effective for 2016 and for each year thereafter.

DATES: This rule is effective January 19, 2017 and is applicable beginning on January 13, 2017.

FOR FURTHER INFORMATION CONTACT: Brian Banal, 703-571-1652.

SUPPLEMENTARY INFORMATION:**Background Information**

The Federal Civil Penalties Inflation Adjustment Act of 1990, Public Law 101-410, 104 Stat. 890 (28 U.S.C. 2461, note), as amended by the Debt Collection Improvement Act of 1996, Public Law 104-134, April 26, 1996, and further amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act), Public Law 114-74, November 2, 2015, required agencies to annually adjust the level of CMPs for inflation to improve their effectiveness and maintain their deterrent effect. The 2015 Act required that not later than July 1, 2016, and not later than January 15 of every year thereafter, the head of each agency must adjust each CMP within its jurisdiction by the inflation adjustment described in the 2015 Act. The inflation adjustment is determined by increasing the maximum CMP or the range of minimum and maximum CMPs, as applicable, for each CMP by the cost-of-living adjustment, rounded to the nearest multiple of \$1. The cost-of-living adjustment is the percentage (if any) for each CMP by which the Consumer Price Index (CPI) for the month of October preceding the date of the adjustment (January 15), exceeds the CPI for the month of October in the previous calendar year.

The initial catch up adjustments for inflation to the Department of Defense's CMPs were published as an interim final rule in the **Federal Register** on May 26, 2016 (81 FR 33389-33391) and became effective on that date. The interim final rule was published as a final rule without change on September 12, 2016 (81 FR 62629-62631), effective that date. The revised methodology for agencies for 2017 and each year thereafter provides for the improvement of the effectiveness of CMPs and to maintain their deterrent effect. Effective 2017, agencies' annual adjustments for inflation to CMPs shall take effect not later than January 15. The Department of Defense is adjusting the level of all civil monetary penalties under its jurisdiction by the Office of Management and Budget (OMB) directed cost-of-living adjustment multiplier for 2017 of 1.01636 prescribed in OMB Memorandum M-17-11, "Implementation of the 2017

annual adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015,” dated December 16, 2016. The Department of Defense’s 2017 adjustments for inflation to CMPs apply only to those CMPs, including those whose associated violation predated such adjustment, which are assessed by the Department of Defense after the effective date of the new CMP level.

Statement of Authority and Costs and Benefits

Pursuant to 5 U.S.C. 553(b)B, there is good cause to issue this rule without prior public notice or opportunity for public comment because it would be impracticable and unnecessary. The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Section 701(b)) requires agencies, effective 2017, to make annual adjustments for inflation to CMPs notwithstanding section 553 of title 5, United States Code. Additionally, the methodology used, effective 2017, for adjusting CMPs for inflation is established in statute, with no discretion provided to agencies regarding the substance of the adjustments for inflation to CMPs. The Department of Defense is charged only with performing ministerial computations to determine the dollar amount of adjustments for inflation to CMPs.

Further, there are no significant costs associated with the regulatory revisions that would impose any mandates on the Department of Defense, Federal, State or local governments, or the private sector. Accordingly, prior public notice and an opportunity for public comment are not required for this rule. The benefit of this rule is the Department of Defense anticipates that civil monetary penalty collections may increase in the future due to new penalty authorities and other changes in this rule. However, it is difficult to accurately predict the extent of any increase, if any, due to a variety of factors, such as budget and staff resources, the number and quality of civil penalty referrals or leads, and the length of time needed to investigate and resolve a case.

Regulatory Procedures

Executive Order 12866, “Regulatory Planning and Review” and Executive Order 13563, “Improving Regulation and Regulatory Review”

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a “significant regulatory action,” because it does not: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy; a section of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in these Executive Orders.

Unfunded Mandates Reform Act (2 U.S.C. Chapter 25)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1532) requires agencies to assess anticipated costs and benefits before issuing any rule the mandates of which require spending in any year of \$100 million in 1995 dollars, updated annually for inflation. In 2016, that threshold is approximately \$146 million. This rule will not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs.

Public Law 96–354, “Regulatory Flexibility Act” (5 U.S.C. Chapter 6)

Because notice of proposed rulemaking and opportunity for comment are not required pursuant to 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) are inapplicable. Therefore, a regulatory flexibility analysis is not required and has not been prepared.

Public Law 96–511, “Paperwork Reduction Act” (44 U.S.C. Chapter 35)

The Department of Defense determined that provisions of the Paperwork Reduction Act of 1995, Public Law 104–13, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this rule because there are no new or revised recordkeeping or reporting requirements.

Executive Order 13132, “Federalism”

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule will not have a substantial effect on State and local governments.

List of Subjects in 32 CFR Part 269

Administrative practice and procedure, Penalties.

Accordingly, 32 CFR part 269 is amended as follows.

PART 269—[AMENDED]

■ 1. The authority citation for 32 CFR part 269 continues to read as follows:

Authority: 28 U.S.C. 2461 note.

■ 2. Revise § 269.4(d) to read as follows:

§ 269.4 Cost of living adjustments of civil monetary penalties.

* * * * *

(d) Inflation adjustment. Maximum civil monetary penalties within the jurisdiction of the Department are adjusted for inflation as follows:

| United States Code | Civil Monetary Penalty Description | Maximum Penalty Amount as of 05/26/16 | New Adjusted Maximum Penalty Amount |
|---|---|---------------------------------------|-------------------------------------|
| National Defense Authorization Act for FY 2005, 10 U.S.C 113, note. | Unauthorized Activities Directed at or Possession of Sunken Military Craft. | \$124,588 | 126,626 |
| 10 U.S.C. 1094(c)(1) | Unlawful Provision of Health Care | 10,940 | 11,119 |
| 10 U.S.C. 1102(k) | Wrongful Disclosure—Medical Records | | |
| | First Offense | 6,469 | 6,575 |
| | Subsequent Offense | 43,126 | 43,832 |

| United States Code | Civil Monetary Penalty Description | Maximum Penalty Amount as of 05/26/16 | New Adjusted Maximum Penalty Amount |
|----------------------------|--|---------------------------------------|-------------------------------------|
| 10 U.S.C. 2674(c)(2) | Violation of the Pentagon Reservation Operation and Parking of Motor Vehicles Rules and Regulations. | 1,782 | 1,811 |
| 31 U.S.C. 3802(a)(1) | Violation Involving False Claim | 10,781 | 10,957 |
| 31 U.S.C. 3802(a)(2) | Violation Involving False Statement | 10,781 | 10,957 |

Dated: January 9, 2017.

Aaron Siegel,

Alternate OSD Federal Register Liaison
Officer, Department of Defense.

[FR Doc. 2017-00619 Filed 1-18-17; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2015-1088]

RIN 1625-AA00

Safety Zone; Pleasure Beach Bridge, Bridgeport, CT

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters of Pleasure Beach, Bridgeport, CT for Pleasure Beach Bridge. This temporary final rule is necessary to provide for the safety of life on navigable waters. Entry into, transit through, mooring, or anchoring within the safety zone is prohibited unless authorized by Captain of the Port (COTP), Sector Long Island Sound.

DATES: This rule is effective without actual notice from January 19, 2017 until June 30, 2017. For the purposes of enforcement, actual notice will be used from January 1, 2017 until January 19, 2017.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG-2015-1088 and USCG-2015-1123 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, contact Petty Officer Jay TerVeen, Prevention Department, U.S. Coast Guard Sector Long Island Sound, telephone (203) 468-4446, email Jay.C.TerVeen@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
LIS Long Island Sound
NPRM Notice of Proposed Rulemaking
NAD 83 North American Datum 1983

II. Background Information and Regulatory History

This rulemaking establishes a safety zone for the waters around Pleasure Beach Bridge, Bridgeport, CT. Corresponding regulatory history is discussed below.

The Coast Guard was made aware on December 9, 2015, of damage to Pleasure Beach Bridge, the result of which created a hazard to navigation. On December 22, 2015, the Coast Guard published a temporary final rule entitled, "Safety Zone; Pleasure Beach Bridge, Bridgeport, CT" in the **Federal Register** (80 FR 79480). On June 23, 2016, the Coast Guard published a second temporary final rule entitled, "Safety Zone; Pleasure Beach Bridge, Bridgeport, CT" in the **Federal Register** (81 FR 40814). On July 25, 2016, the Coast Guard published a third temporary final rule entitled, "Safety Zone; Pleasure Beach Bridge, Bridgeport, CT" in the **Federal Register** (81 FR 48329). The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM with respect to this rule because doing so would be impracticable and contrary to the public interest. A solution to remedy the safety hazards associated with this bridge was initially projected to be completed prior to the expiration of the current safety zone, but has been delayed. It would be impracticable and contrary to the public interest to delay

promulgating this rule, as it is necessary to protect the safety of waterway users.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), and for the same reasons stated in the preceding paragraph, the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

III. Legal Authority and Need for Rule

The legal basis for this temporary rule is 33 U.S.C. 1231.

On December 09, 2015, the Coast Guard was made aware of damage sustained to Pleasure Beach Bridge, Bridgeport, CT that has created a hazard to navigation. After further analysis of the bridge structure, the Coast Guard concluded that the overall condition of the structure created a continued hazard to navigation. The COTP Sector LIS has determined that the safety zone established by this temporary final rule is necessary to provide for the safety of life on navigable waterways.

IV. Discussion of the Rule

The safety zone established by this rule will cover all navigable waters of the entrance channel to Johnsons Creek in the vicinity of Pleasure Beach Bridge, Bridgeport, CT. This safety zone will be bound inside an area that starts at a point on land at position 41-10.2 N., 073-10.7 W. and then east along the shoreline to a point on land at position 41-9.57 N., 073-9.54 W. and then south across the channel to a point on land at position 41-9.52 N., 073-9.58 W. and then west along the shoreline to a point on land at position 41-9.52 N., 073-10.5 W. and then north across the channel back to the point of origin.

This rule prohibits vessels from entering, transiting, mooring, or anchoring within the area specifically designated as a safety zone during the period of enforcement unless authorized by the COTP or designated representative.

The Coast Guard will notify the public and local mariners of this safety zone through appropriate means, which may include, but are not limited to, publication in the **Federal Register**, the Local Notice to Mariners, and Broadcast Notice to Mariners.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on these statutes and executive orders and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget. The Coast Guard determined that this rulemaking is not a significant regulatory action for the following reasons: (1) Persons or vessels desiring to enter the safety zone may do so with permission from the COTP Sector LIS or a designated representative; and (2) the Coast Guard will notify the public of the enforcement of this rule via appropriate means, such as via Local Notice to Mariners and Broadcast Notice to Mariners to increase public awareness of this safety zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business,

organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions

that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This temporary rule involves the establishment of a safety zone. It is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination, a Categorical Exclusion Determination, and EA Checklist, will be in the docket for review. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protestors. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for Part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; and Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T01–1088 to read as follows:

§ 165.T01–1088 Safety Zone; Pleasure Beach Bridge, Bridgeport, CT.

(a) *Location.* The following area is a safety zone: All navigable waters of the entrance channel to Johnsons Creek in the vicinity of Pleasure Beach Bridge, Bridgeport, CT bound inside an area that starts at a point on land at position 41°10'02.964" N., 073°10'08.148" W. and then east along the shoreline to a point on land at position 41°09'57.996" N., 073°09'54.324" W. and then south across the channel to a point on land at position 41°09'52.524" N., 073°09'58.861" W. and then west along the shoreline to a point on land at position 41°09'52.776" N., 073°10'04.944" W. and then north across the channel back to the point of origin.

(b) *Enforcement Period.* This section will be enforced from 12:00 a.m. on January 1, 2017 to 12:00 a.m. June 30, 2017.

(c) *Definitions.* The following definitions apply to this section: A “designated representative” is any commissioned, warrant, or petty officer of the U.S. Coast Guard who has been designated by the Captain of the Port (COTP), Sector Long Island Sound, to act on his or her behalf. The designated representative may be on an official patrol vessel or may be on shore and will communicate with vessels via VHF-FM radio or loudhailer. “Official patrol vessels” may consist of any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the COTP Sector Long Island Sound. In addition, members of the Coast Guard Auxiliary may be present to inform vessel operators of this regulation.

(d) *Regulations.* (1) The general regulations contained in 33 CFR 165.23 apply.

(2) In accordance with the general regulations in 33 CFR 165.23, entry into or movement within this zone is prohibited unless authorized by the COTP, Long Island Sound.

(3) Operators desiring to enter or operate within the safety zone should contact the COTP Sector Long Island Sound at 203-468-4401 (Sector Sector Long Island Sound Command Center) or the designated representative via VHF channel 16 to obtain permission to do so.

(4) Any vessel given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP Sector Long Island Sound, or the designated on-scene representative.

(5) Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light or other means, the operator of the vessel shall proceed as directed.

Dated: December 29, 2016.

A.E. Tucci,

Captain, U.S. Coast Guard, Captain of the Port Sector Long Island Sound.

[FR Doc. 2017-01068 Filed 1-18-17; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF EDUCATION

34 CFR Part 99

Family Educational Rights and Privacy Act

AGENCY: Office of the Chief Privacy Officer, Office of Management, Department of Education.

ACTION: Final rule.

SUMMARY: The Secretary amends the Family Educational Rights and Privacy Act (FERPA) regulations to change the name of the office designated enforcement functions by the Secretary from the Family Policy Compliance Office to the Office of the Chief Privacy Officer. The purpose of this amendment is to reflect additional resources committed to protecting student privacy and to increase internal efficiency.

DATES: These regulations are effective February 21, 2017.

FOR FURTHER INFORMATION CONTACT: Kathleen Styles, U.S. Department of Education, 400 Maryland Avenue SW., Room 2E315, Washington, DC 20202. Telephone: (855) 249-3072 or via email: privacyTA@ed.gov.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

SUPPLEMENTARY INFORMATION: FERPA, 20 U.S.C. 1232g(g), requires the Secretary to establish or designate an office within the Department of Education (Department) for the purpose of investigating, processing, reviewing, and adjudicating violations and complaints. As part of an expansion of student privacy operations at the Department, the designated office will change from the Family Policy Compliance Office to the Office of the Chief Privacy Officer. This change will not directly impact the public. This change is being made:

1. To allow the Department to more effectively make use of new resources dedicated to student privacy;
2. To permit efficiencies relating to specialization of work; and
3. To clarify responsibilities within the Department.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is “significant” and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of \$100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities in a material way (also referred to as an “economically significant” rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles stated in the Executive order.

This final regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed these regulations under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only on a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency “to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.” The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include “identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.”

We are issuing these final regulations only on a reasoned determination that their benefits justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that these final regulations are consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action does not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs associated with this regulatory action are those resulting from statutory requirements and those we have determined as necessary for administering the Department’s programs and activities.

Upon review of the cost, we have determined there is no financial or resource burden associated with these changes.

Waiver of Proposed Rulemaking

Under the Administrative Procedure Act (5 U.S.C. 553), the Department generally offers interested parties the opportunity to comment on proposed regulations. However, these amendments merely reflect changes in internal organization and procedure. The changes do not establish or affect substantive policy. Therefore, under 5 U.S.C. 553(b)(B), the Secretary has determined that proposed regulations are unnecessary and contrary to the public interest.

Regulatory Flexibility Act Certification

The Secretary certifies that these regulations will not have a significant economic impact on a substantial

number of small entities. These regulations contain technical changes to current regulations. The changes will not have a significant economic impact on any of the entities affected because the regulations do not impose excessive burdens or require unnecessary Federal supervision.

Paperwork Reduction Act of 1995

These regulations do not contain any information collection requirements.

Intergovernmental Review

This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

Accessible Format: Individuals with disabilities may obtain this document in an alternative format (e.g., braille, large print, audiotope, or compact disc) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: www.gpo.gov/fdsys. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

List of Subjects in 34 CFR Part 99

Administrative practice and procedure, Privacy, Reporting and recordkeeping requirements, Students.

Denise L. Carter,

Acting Assistant Secretary for Management.

For the reasons discussed in the preamble, the Secretary amends title 34 of the Code of Federal Regulations as follows:

PART 99—FAMILY EDUCATIONAL RIGHTS AND PRIVACY ACT

■ 1. The authority citation for part 99 continues to read as follows:

Authority: 20 U.S.C. 1232g, unless otherwise noted.

■ 2. Amend § 99.60 paragraph (a) by removing “Family Policy Compliance

Office” and adding, in its place, “Office of the Chief Privacy Officer”.

[FR Doc. 2017–00958 Filed 1–18–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

34 CFR Part 668

RIN 1840–AD22

[Docket ID ED–2015–OPE–0103]

Student Assistance General Provisions

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Final rule with request for comments.

SUMMARY: The Secretary amends the Student Assistance General Provisions regulations governing participation in the student financial assistance programs authorized under Title IV of the Higher Education Act of 1965, as amended (title IV, HEA programs). The amended regulations update the Department’s hearing procedures for actions to establish liability against an institution of higher education, and establish procedural rules governing recovery proceedings under the Department’s borrower defense regulations.

DATES: *Effective date:* These regulations are effective January 19, 2017.

Comment due date: We will accept comments on or before March 20, 2017. We may consider the comments received and may conduct additional rulemaking based on the comments.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

If you are submitting comments electronically, we strongly encourage you to submit any comments or attachments in Microsoft Word format. If you must submit a comment in Portable Document Format (PDF), we strongly encourage you to convert the PDF to print-to-PDF format or to use some other commonly used searchable text format. *Please do not submit the PDF in a scanned format.* Using a print-to-PDF format allows the U.S. Department of Education (the Department) to electronically search and copy certain portions of your submissions.

• *Federal eRulemaking Portal*: Go to www.regulations.gov to submit your comments electronically. Information on using *Regulations.gov*, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under “Help.”

• *Postal Mail, Commercial Delivery, or Hand Delivery*: The Department strongly encourages commenters to submit their comments electronically. However, if you mail or deliver your comments about these regulations, address them to Jean-Didier Gaina, U.S. Department of Education, 400 Maryland Ave. SW., Room 6W232B, Washington, DC 20202.

Privacy Note: The Department’s policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at www.regulations.gov. Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT:

Annamarie Weisman, U.S. Department of Education, 400 Maryland Avenue SW., Room 6W425, Washington, DC 20202–6244. Telephone: (202) 453–6712 or by email: annmarie.weisman@ed.gov.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Invitation To Comment

As discussed below, these regulations do not establish substantive policy, but instead establish procedures that must be followed. As procedural regulations, there is no requirement for a comment period. Although these regulations are final regulations, we are interested in whether you think we should make any changes in these regulations and thus we are inviting your comments. We will consider these comments in determining whether to revise the regulations. To ensure that your comments have maximum effect, we urge you to identify clearly the specific section or sections of the regulations that each of your comments addresses and to arrange your comments in the same order as the regulations. See **ADDRESSES** for instructions on how to submit comments.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirements of reducing regulatory burden that might result from these regulations. Please let us know of any

further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the Department’s programs and activities.

During and after the comment period, you may inspect all public comments about these regulations by accessing *Regulations.gov*. You may also inspect the comments in person in room 6W245, 400 Maryland Avenue SW., Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Eastern time, Monday through Friday of each week except Federal holidays. If you want to schedule time to inspect comments, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record

On request, we will supply an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for these regulations. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Background

On November 1, 2016, the Department of Education promulgated new regulations governing the William D. Ford Federal Direct Loan Program to establish a new Federal standard and a process for determining whether a borrower has a defense to repayment on a loan based on an act or omission of a school (the borrower defense regulations). If the Department determines that a borrower is eligible for relief under the borrower defense regulations, it has the authority to recover losses stemming from such borrower relief from the institution whose conduct gave rise to the borrower defense. These regulations establish the procedural rules that would govern such borrower defense and institutional recovery proceedings, and are designed to ensure that institutions are afforded a full and fair opportunity to defend themselves in such proceedings.

These regulations amend the Department’s existing regulations governing proceedings to assess a fine, limitation, suspension, or termination against an institution by adding procedures for a recovery proceeding under the borrower defense regulations. Such a proceeding may be used when pursuing an action under either the Department’s new borrower defense regulation at 34 CFR 685.222 or its

precursor at 34 CFR 685.206. These regulations are designed to balance important interests by ensuring that institutions are protected by due process of law prior to the imposition of any monetary liability under the borrower defense regulations, while also ensuring that determinations of the validity of borrower defense claims asserted against institutions are resolved fairly, efficiently, and expeditiously for all parties. In addition, these regulations clarify and update the procedural provisions more broadly applicable to fine, limitation, suspension, and termination proceedings.

Under the borrower defense regulations at 34 CFR 685.222, effective July 1, 2017, the applicable process for filing and reviewing claims will depend on whether a borrower’s application is considered by the Department as an individual claim or if the Department identifies the application as factually similar to other applications such that the Department identifies a group of borrowers (potentially including borrowers who have not submitted applications) with similar claims. The process will also depend on whether the relevant institution is “open” or “closed”, as those terms are described in the regulations. See 34 CFR 685.222(g)through(h).

The Department has the authority to pursue claims for recovery for losses that the Department has already incurred in granting individual borrower relief, either as stand-alone actions or in combination with group proceedings where those individual claims presented the same facts and circumstances as the group claims. In those instances, the determination of the validity of the individual’s discharge claim does not depend on the hearing official’s decision, and the Department does not rescind a discharge already granted to an individual if the Department does not succeed in proving the validity of that claim in this proceeding.

Beginning July 1, 2017, the Department will use these procedural regulations both to determine the validity of borrower claims the Department asserts on behalf of borrowers in group claims against “open” institutions, and to hold the institutions liable for losses on those claims in accordance with 34 CFR 685.222(h). In these instances, the hearing official determines the validity of the borrower claims and, correspondingly, whether relief will be granted to these group borrowers. Borrowers may opt out of the group process. When the Department seeks to recover for losses for claims approved

under current authority and before July 1, 2017, the Department will use the procedures in these regulations to pursue recovery from the institution. As with any other proceedings to recover on claims already approved, the outcome of a proceeding brought to recover for claims already approved prior to July 1, 2017 will not affect relief already granted to borrowers, but only the accountability of the institution. At its discretion, the Department may also use these regulations to bring actions against “closed” institutions, as defined in 34 CFR 685.222(g), in order to establish an institution’s liability for damages due to the Department as a result of individual or group borrower defense relief.

The Department bears the burden of proof in any recovery action against an institution for all claims the Department asserts. The Department must therefore prove the merit of the claims it asserts for members of the group. A hearing official will determine the merit of the claims, the relief for members of the group, and the liability of the institution. The Department must also prove in the hearing process the merit of claims it asserts for losses on discharges it has already approved as individual claims, although, as previously indicated, individual discharges already granted by the Department will not be affected if the Department is not successful in proving the claim in this proceeding against the institution.

These regulations are only applicable to actions initiated by the Department to fine an institution, to limit, suspend, or terminate the eligibility of an institution or servicer, or to recover from an institution for losses from borrower defense claims, and do not encompass the process by which the Department evaluates individual borrower claims or claims for which the Department does not seek to obtain a recovery. That process is set forth in the borrower defense regulations at 34 CFR 685.222(e). In addition, the Department plans to issue a borrower guide before the borrower defense regulations go into effect to ensure borrowers understand the application process and criteria for seeking debt relief.

Waiver of Proposed Rulemaking, Negotiated Rulemaking, and Delayed Effective Date

Under the Administrative Procedure Act (5 U.S.C. 553), the Department generally offers interested parties the opportunity to comment on proposed regulations. These regulations only govern the procedures for initiating an action against an institution and the

hearing rules applicable to such a proceeding. As such, these regulations make procedural changes only and do not establish substantive policy. The regulations are therefore rules of agency practice and procedure, and exempt from notice and comment rulemaking under 5 U.S.C. 553(b)(A). However, the Department is providing a 60-day comment period and invites interested persons to participate in this rulemaking by submitting written comments. The Department may consider the comments received and may conduct additional rulemaking based on the comments.

The APA also generally requires that regulations be published at least 30 days before their effective date, unless the agency has good cause to implement its regulations sooner (5 U.S.C. 553(d)(3)). Again, because these final regulations are merely rules of agency practice and procedure, there is good cause to make them effective on the day they are published. For the same reasons, the Secretary has determined, under section 492(b)(2) of the HEA, 20 U.S.C. 1098a(b)(2), that these regulations should not be subject to negotiated rulemaking.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is “significant” and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of \$100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities in a material way (also referred to as an “economically significant” rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles stated in the Executive order.

This final regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed these regulations under Executive Order

13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only on a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency “to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.” The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include “identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.”

We are issuing these final regulations only on a reasoned determination that their benefits justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that these final regulations are consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action does not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs associated with this regulatory action

are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities. There are no costs additional to those described under *Regulatory Impact Analysis* in the notice of final regulations for the borrower defense regulations published in the **Federal Register** on November 1, 2016 (81 FR 75926). These regulations will benefit institutions by ensuring that, in any action to fine an institution, to limit, suspend, or terminate the eligibility of an institution to participate in the title IV, HEA programs, or to determine the validity of claims against the institution, there are established procedures that provide both due process as well as an efficient process for the timely resolution of claims.

Clarity of the Regulations

Executive Order 12866 and the Presidential memorandum "Plain Language in Government Writing" require each agency to write regulations that are easy to understand.

The Secretary invites comments on how to make these regulations easier to understand, including answers to questions such as the following:

- Are the requirements in the regulations clearly stated?
- Do the regulations contain technical terms or other wording that interferes with their clarity?
- Does the format of the regulations (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce their clarity?
- Would the regulations be easier to understand if we divided them into more (but shorter) sections? (A "section" is preceded by the symbol "\$" and a numbered heading; for example, § 668.81.)
- Could the description of the regulations in the **SUPPLEMENTARY INFORMATION** section of this preamble be more helpful in making the regulations easier to understand? If so, how?
- What else could we do to make the regulations easier to understand?

To send any comments that concern how the Department could make these regulations easier to understand, see the instructions in the **ADDRESSES** section.

Regulatory Flexibility Act Certification

The Secretary certifies that these regulations will not have a significant economic impact on a substantial number of small entities. The small entities that are affected by these regulations are small postsecondary institutions. These regulations do not have a significant economic impact on these entities because all substantive

rules that govern determinations of liability have already been established in the Department's borrower defense regulations promulgated November 1, 2016.

Paperwork Reduction Act of 1995

The Paperwork Reduction Act of 1995 does not require you to respond to a collection of information unless it displays a valid OMB control number. We display the valid OMB control number assigned to a collection of information in final regulations at the end of the affected section of the regulations.

Intergovernmental Review

This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

Assessment of Educational Impact

The Secretary particularly requests comments on whether these regulations require transmission of information that any other agency or authority of the United States gathers or makes available.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotope, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: www.gpo.gov/fdsys. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or PDF. To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

(Catalog of Federal Domestic Assistance Number: 84.268, Federal Direct Student Loans)

List of Subjects in 34 CFR Part 668

Administrative practice and procedure, Aliens, Colleges and universities, Consumer protection, Grant programs—education, Loan programs—education, Reporting and recordkeeping requirements, Selective

Service System, Student aid, Vocational education.

Dated: January 11, 2017.

John B. King, Jr.,

Secretary of Education.

For the reasons discussed, the Secretary amends part 668 of title 34 of the Code of Federal Regulations as follows:

PART 668—STUDENT ASSISTANCE GENERAL PROVISIONS

■ 1. The authority citation for part 668 continues to read as follows:

Authority: 20 U.S.C. 1001–1003, 1070a, 1070g, 1085, 1087b, 1087d, 1087e, 1088, 1091, 1092, 1094, 1099c, 1099c–1, 1221e–3, and 3474, unless otherwise noted.

■ 2. Section 668.81 is amended by:

- A. Adding paragraph (a)(5).
- B. Adding paragraphs (e) through (g).
- C. Revising the authority citation.

The additions and revision read as follows:

§ 668.81 Scope and special definitions.

- (a) * * *
- (5) The determination of—
- (i) Borrower defense to repayment claims that are brought by the Department against an institution under § 685.206 or § 685.222; and
- (ii) Liability of an institution to the Secretary for losses to the Secretary arising from these claims.

* * * * *

(e) The proceedings described in this subpart provide the institution's sole opportunity for a hearing on the existence and amount of the debt that is required by applicable law prior to the Department collecting the debt from any available funds, including but not limited to offsetting the debt or any liability against funds to be provided to an institution pursuant to any Title IV, HEA program in which that institution participates.

(f) Nothing contained in this subpart limits the right of the Department to gather information, including by subpoena, or conduct any examination, audit, program review, investigation, or other review authorized by other applicable law.

(g) Unless directed by a court of competent jurisdiction, the hearing official, or the Secretary for good cause, if a collateral attack is brought in any court concerning all or any part of any proceeding under this subpart, the challenged proceeding shall continue without regard to the pendency of that court proceeding. No default or other failure to timely act as directed in a proceeding authorized by this subpart shall be excused based on the pendency of such court proceeding.

(Authority: 20 U.S.C. 1094)

§ 668.83 [Amended]

■ 3. In § 668.83(f)(1), remove “§ 668.90(c)” and add, in its place, “§ 668.91(c)”.

■ 4. In § 668.84 revise paragraphs (b)(3) and (b)(4) to read as follows:

§ 668.84 Fine proceedings.

* * * *

(b) * * *

(3) If the institution or servicer requests a hearing by the time specified in paragraph (b)(1)(iii) of this section, the designated department official transmits the request for hearing and response to the Office of Hearings and Appeals, which sets the date and the place. The date is at least 15 days after the designated department official receives the request.

(4) A hearing official conducts a hearing in accordance with § 668.89.

* * * *

■ 5. Section 668.85 is amended by:

■ A. In paragraph (b)(1)(iii), removing “§ 668.90(b)(2)” and adding, in its place, “§ 668.91(b)(2)”.

■ B. Revising paragraph (b)(3).

■ C. In paragraph (b)(4), removing “§ 668.88” and adding, in its place, “§ 668.89”.

The revision reads as follows:

§ 668.85 Suspension proceedings.

* * * *

(b) * * *

(3) If the institution or servicer requests a hearing by the time specified in paragraph (b)(1)(iii) of this section, the designated department official transmits the request for hearing and response to the Office of Hearings and Appeals, which sets the date and the place. The date is at least 15 days after the designated department official receives the request. The suspension does not take place until the requested hearing is held.

* * * *

■ 6. Section 668.86 is amended by:

■ A. In paragraph (a)(3), removing “§§ 668.93 and 668.94” and adding, in its place, “§§ 668.94 and 668.95”.

■ B. Revising paragraphs (b)(3) and (b)(4).

The revisions read as follows:

§ 668.86 Limitation or termination proceedings.

* * * *

(b) * * *

(3) If the institution or servicer requests a hearing by the time specified in paragraph (b)(1)(iii) of this section, the designated department official transmits the request for hearing and

response to the Office of Hearings and Appeals, which sets the date and place. The date is at least 15 days after the designated department official receives the request. The limitation or termination does not take place until after the requested hearing is held.

(4) A hearing official conducts a hearing in accordance with § 668.89.

* * * *

§§ 668.87 through 668.98 [Redesignated as §§ 668.88 through 668.99]

■ 7. Redesignate §§ 668.87 through 668.98 as §§ 668.88 through 668.99.

■ 8. Add § 668.87 to read as follows:

§ 668.87 Borrower defense and recovery proceedings.

(a) *Procedures.* (1) A designated department official begins a borrower defense and recovery proceeding against an institution by sending the institution a notice by certified mail, return receipt requested. This notice—

(i) Informs the institution of the Secretary’s intent—

(A) To determine the validity of borrower defense claims on behalf of a group under § 685.222(h), to demonstrate the validity of borrower defense claims already approved, or both, as applicable; and

(B) To recover from the institution by offset, by claim on a letter of credit or other protection provided by the institution, or otherwise, for losses on account of borrower defense claims asserted on behalf of the group and borrower defense claims already approved, as applicable;

(ii) Includes a statement of facts and law sufficient to show that the Department is entitled to grant any borrower defense relief asserted within the statement, and recover for the amount of losses to the Secretary caused by the granting of such relief;

(iii) Specifies the date on which the Secretary intends to take action to recover the amount of losses arising from the granting of such relief, which date will be at least 20 days from mailing of the notice of intent and informs the institution that the Secretary will not take action to recover the amount of such loss on the date specified if the designated department official receives, by that date, a written response from the institution indicating why the Secretary should not recover. The notice shall also inform the institution that if it wishes to request a hearing pursuant to this subpart, the institution must include such a request with its written response; and

(iv) Informs the institution whether the designated Department official intends to proceed with—

(A) A single action; or

(B) An action in two phases—

(1) The determination whether the institution’s act or omission gave rise to valid borrower defense claims; and

(2) The determination of the amount of borrower defense relief.

(2) Although the hearing official shall have the discretion to bifurcate proceedings with, or without, a motion of either party, any decision by the designated department official to bifurcate the proceeding in accordance with paragraph (a)(1)(iv)(B) of this section may only be modified on motion with good cause shown.

(3) A hearing official conducts a hearing in accordance with § 668.89.

(b) *Effect of a response by the institution.* (1) If the institution submits a written response, but does not therein request a hearing, the designated department official, after considering that material, notifies the institution whether the Secretary will take the proposed recovery action for borrower defense claims and, if so, the date of such action and the amount of losses.

(2) If the institution submits a response and requests a hearing by the time specified in the notice under paragraph (a)(1)(iii) of this section, the designated department official may, in that official’s sole discretion, withdraw the notice or transmit the response and request for hearing to the Office of Hearings and Appeals, which sets the date and the place for the hearing. The date of the hearing is at least 15 days after the designated department official receives the request. No liability shall be imposed on the institution prior to the hearing.

(c) *Limitations on participation.* The parties in any borrower defense and recovery proceeding are the Department and the institution(s) against which the Department seeks to recover losses caused to the Department as a result of borrower defense relief. Borrowers are not permitted to intervene or appear in this proceeding, either on their own behalf or on behalf of any purported group, except as witnesses put forth by either party. However, nothing in this section limits the rights available to borrowers under other regulations, including 34 CFR 685.206 and 685.222.

(d) *Effect on the borrower.* No proceeding under this subpart imposes liability on any borrower who has already obtained a discharge in an individual proceeding under 34 CFR 685.206(c) or 34 CFR 685.222(e). A borrower defense and recovery proceeding may determine whether and how much relief is due to, and whether and how much of a loan remains owing by, a borrower participating in a group

process proceeding as defined in 34 CFR 685.222(f) through (h).

(Authority: 20 U.S.C. 1087a *et seq.*, 1094)

■ 9. Revise newly redesignated § 668.88 to read as follows:

§ 668.88 Prehearing conference and motion practice.

(a) A hearing official may convene a prehearing conference if he or she thinks that the conference would be useful, or if the conference is requested by—

(1) The designated department official who brought a proceeding against an institution or third-party servicer under this subpart; or

(2) The institution or servicer, as applicable.

(b) The purpose of a prehearing conference is to allow the parties to settle or narrow the dispute.

(c) If the hearing official, the designated department official, and the institution, or servicer, as applicable, agree, a prehearing conference may consist of—

(1) A conference telephone call;

(2) An informal meeting; or

(3) The submission and exchange of written material.

(d) A non-dispositive motion shall be made, if at all, consistent with any procedures set forth by the hearing official. In the absence of such procedures, non-dispositive motions shall be permitted, and responses to such motions shall be permitted though not required.

(e)(1) A party may make a motion for summary disposition asserting that the undisputed facts, admissions, affidavits, stipulations, documentary evidence, matters as to which official notice may be taken, and any other evidentiary materials properly submitted in connection with a motion for summary disposition establish that—

(i) There is no genuine issue as to any material fact; and

(ii) The moving party is entitled to a decision in its favor as a matter of law.

(2) A motion for summary disposition must be accompanied by a statement of the material facts as to which the moving party contends there is no genuine issue. Such motion must be supported by evidence that the moving party contends support his or her position. The motion must be accompanied by a brief containing the points and authorities supporting the motion.

Any party may oppose such a motion by filing a response setting forth those material facts as to which he or she contends a genuine dispute exists. Such response must be supported by evidence

of the same type as may be submitted in support of a motion for summary disposition and a brief containing the points and authorities in support of the contention that summary disposition would be inappropriate.

(f) A motion under consideration by the Secretary or the hearing official shall not stay proceedings before the hearing official unless the Secretary or the hearing official, as appropriate, so orders.

(Authority: 20 U.S.C. 1094)

■ 10. Revise newly redesignated § 668.89 to read as follows:

§ 668.89 Hearing.

(a) A hearing is an orderly presentation of arguments and evidence conducted by a hearing official. At the discretion of the hearing official, any right to a hearing may be satisfied by one or more of the following: Summary disposition pursuant to § 668.88(e), with or without oral argument; an oral evidentiary hearing conducted in person, by telephone, by video conference, or any combination thereof; or a review limited to written evidence.

(b)(1) Notwithstanding any provision to the contrary, the hearing official sets the procedures to be used in the hearing, and may take steps to expedite the proceeding as appropriate.

(2) The formal rules of evidence and procedures applicable to proceedings in a court of law are not applicable.

However, discussions of settlement between the parties or the terms of settlement offers are not admissible to prove the validity or invalidity of any claim or defense.

(3)(i) The proponent of any factual proposition has the burden of proof with respect thereto.

(ii) The designated department official has the burden of persuasion in any fine, suspension, limitation, or termination proceeding under this subpart.

(iii) The designated department official has the burden of persuasion in a borrower defense and recovery action; however, for a borrower defense claim based on a substantial misrepresentation under § 682.222(d), the designated department official has the burden of persuasion regarding the substantial misrepresentation, and the institution has the burden of persuasion in establishing any offsetting value of the education under § 685.222(i)(2)(i).

(4) Discovery, as provided for under the Federal Rules of Civil Procedure, is not permitted.

(5) The hearing official accepts only evidence that is relevant and material to the proceeding and is not unduly repetitious.

(6) The hearing official may restrict the number of witnesses or exclude witnesses to avoid undue delay or presentation of cumulative evidence. Any witness permitted to appear may do so via telephonic, video, or other means, with the approval of the hearing official.

(7) Either party may call qualified expert witnesses. Each party will be limited to calling three expert witnesses, as a matter of right, including any rebuttal or surrebuttal witnesses. Additional expert witnesses shall be allowed only by order of the hearing official, granted only upon a showing of good cause.

(i) At a date set by the hearing official, each party shall serve the other with any report prepared by each of its expert witnesses. Each party shall serve the other party with a list of any rebuttal expert witnesses and a rebuttal report prepared by each such witness not later than 60 days after the deadline for service of expert reports, unless another date is set by the hearing official. A rebuttal report shall be limited to rebuttal of matters set forth in the expert report for which it is offered in rebuttal. If material outside the scope of fair rebuttal is presented, a party may file a motion not later than five days after the deadline for service of rebuttal reports, seeking appropriate relief with the hearing official, including striking all or part of the report, leave to submit a surrebuttal report by the party's own experts, or leave to call a surrebuttal witness and to submit a surrebuttal report by that witness.

(ii) No party may call an expert witness at the hearing unless the party has listed the expert and has provided reports as required by this section.

(iii) Each report shall be signed by the expert and contain a complete statement of all opinions to be expressed and the basis and reasons therefor; the data, materials, or other information considered by the witness in forming the opinions; any exhibits to be used as a summary of or support for the opinions; the qualifications of the witness, including a list of all publications authored or co-authored by the witness within the preceding ten years; the compensation to be paid for the study and testimony; and a listing of any other cases in which the witness has testified or sought to testify as an expert at trial or hearing, or by deposition, within the preceding four years. A rebuttal or surrebuttal report need not include any information already included in the initial report of the witness.

(8)(i) Except as provided in paragraph (b)(8)(ii) of this section, if an institution

has been required through compulsory process under section 490A of the HEA or other applicable law to submit to the United States or to the Department material regarding an express or an implied representation, the institution cannot thereafter, in any proceeding under this subpart in which it is alleged that the representation was false, erroneous, or misleading, and for any purpose relating to the defense of such allegation, introduce into the record, either directly or indirectly through references contained in documents or oral testimony, any material of any type that was required to be but was not timely submitted in response to that compulsory process.

(ii) The hearing official shall, upon motion at any stage, exclude all material that was required to be but was not timely submitted in response to a compulsory process described in paragraph (b)(8)(i) of this section, or any reference to such material, unless the institution demonstrates, and the hearing official finds, that by the exercise of due diligence the material could not have been timely submitted in response to the compulsory process, and the institution notified the Department or such other party that issued the order to produce, of the existence of the material immediately upon its discovery. The hearing official shall specify with particularity the evidence relied upon.

(9) When issues not raised in the notice of proposed action are tried without objection at the hearing, they will be treated in all respects as if they had been raised in the notice of proposed action, and no formal amendments are required.

(c) The hearing official makes a transcribed record of the proceeding and makes a copy of the record available to the designated Department official and to the institution or servicer.

(Authority: 20 U.S.C. 1094)

■ 11. Newly redesignated § 668.91 is amended by:

■ A. Redesignating paragraph (a)(2) as paragraph (a)(2)(i).

■ B. In newly redesignated paragraph (a)(2)(i) adding “or recovery” after “fine, limitation, suspension, or termination”.

■ C. Adding paragraph (a)(2)(ii).

■ D. Removing the second sentence in paragraph (a)(4).

■ E. Adding paragraph (c)(2)(x).

The additions read as follows:

§ 668.91 Initial and final decisions.

(a) * * *

(2)(i) * * *

(ii) In a borrower defense and recovery proceeding conducted in two

phases under § 668.87(a)(1)(iv)(B), the hearing official’s initial decision determines whether the institution is liable for the act or omission described in the notice of intent to recover, and the hearing official issues an initial decision on liability only.

* * * * *

(c) * * *

(2) * * *

(x) In a borrower defense and recovery proceeding conducted in two phases under § 668.87(a)(1)(iv)(B), if a party appeals an initial decision of the hearing official in the first phase, the Secretary may affirm, modify, or reverse the initial decision, or may remand the case to the hearing official for further proceedings consistent with the Secretary’s decision.

* * * * *

§ 668.96 [Amended]

■ 12. Newly redesignated § 668.96 is amended by:

■ A. In paragraph (a) removing the word “The” and adding, in its place, the words “In an action to fine an institution or servicer, or to limit, suspend, or terminate the participation of an institution or the eligibility of a servicer, the”.

■ B. In paragraph (b), after the words “The corrective action”, adding the words “under paragraph (a) of this section”.

■ C. In paragraph (c), after the word “decision”, adding the words “in any action under this subpart”.

§ 668.99 [Amended]

■ 13. In newly redesignated paragraph (c) of § 668.99, remove “§ 668.91(a)(4)” and add, in its place, “§ 668.92(a)(4)”.

[FR Doc. 2017–00972 Filed 1–18–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Parts 2 and 7

[Docket No. PTO–T–2016–0002]

RIN 0651–AD07

Changes in Requirements for Affidavits or Declarations of Use, Continued Use, or Excusable Nonuse in Trademark Cases

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: In order to assess and promote the accuracy and integrity of

the trademark register, the United States Patent and Trademark Office (USPTO or Office) amends its rules concerning the examination of affidavits or declarations of continued use or excusable nonuse filed pursuant to section 8 of the Trademark Act, or affidavits or declarations of use in commerce or excusable nonuse filed pursuant to section 71 of the Act. Specifically, under the regulations enacted herein, the USPTO may require the submission of information, exhibits, affidavits or declarations, and such additional specimens of use as may be reasonably necessary for the USPTO to ensure that the register accurately reflects marks that are in use in commerce in the United States for all the goods/services identified in the registrations, unless excusable nonuse is claimed in whole or in part. A register that does not accurately reflect marks in use in commerce in the United States for the goods/services identified in registrations imposes costs and burdens on the public. The amended rules will allow the USPTO to require additional proof of use to verify the accuracy of claims that a trademark is in use in commerce in connection with particular goods/services identified in the registration.

DATES: This rule is effective on February 17, 2017.

FOR FURTHER INFORMATION CONTACT:

Catherine Cain, Office of the Deputy Commissioner for Trademark Examination Policy, by email at TMFRNotices@uspto.gov, or by telephone at (571) 272–8946.

SUPPLEMENTARY INFORMATION:

Purpose: The USPTO revises the rules in parts 2 and 7 of title 37 of the Code of Federal Regulations to allow the USPTO, during the examination of affidavits or declarations of continued use or excusable nonuse filed pursuant to section 8 of the Trademark Act, 15 U.S.C. 1058, or affidavits or declarations of use in commerce or excusable nonuse filed pursuant to section 71 of the Trademark Act, 15 U.S.C. 1141k (section 8 or section 71 affidavits), to require the submission of such information, exhibits, affidavits or declarations, and such additional specimens of use as may be reasonably necessary for the USPTO to verify the accuracy of claims that a trademark is in use in commerce in connection with the goods/services listed in the registration.

This will benefit the public because it will facilitate the USPTO’s ability to assess and promote the integrity of the trademark register by encouraging accuracy in the identification of goods/services for which use in commerce or continued use is claimed. The accuracy

of the trademark register as a reflection of marks that are actually in use in commerce in the United States for the goods/services identified in the registrations listed therein serves an important purpose for the public. The public relies on the register to determine whether a chosen mark is available for use or registration. Where a party's search of the register discloses a potentially confusingly similar mark, that party may incur a variety of resulting costs and burdens, such as those associated with investigating the actual use of the disclosed mark to assess any conflict, proceedings to cancel the registration or oppose the application of the disclosed mark, civil litigation to resolve a dispute over the mark, or changing plans to avoid use of the party's chosen mark. If a registered mark is not actually in use in commerce in the United States, or is not in use in commerce in connection with all the goods/services identified in the registration, these costs and burdens may be incurred unnecessarily. An accurate and reliable trademark register helps avoid such needless costs and burdens.

The amended rules also facilitate the cancellation of registrations for marks that were never in use in commerce or are no longer in use, and for which acceptable claims of excusable nonuse were not submitted, in connection with the identified goods/services. The statutory requirements in sections 8 and 71 exist to enable the USPTO to clear the register of deadwood by cancelling, in whole or in part, registrations for marks that are not in use in commerce for all or some of the goods/services identified in the registration. The rules enacted herein further this statutory purpose.

Background

Post Registration Proof-of-Use Pilot Program: A final rule was published in the **Federal Register** on May 22, 2012 (77 FR 30197), in which the USPTO announced a two-year pilot program to assess and promote the accuracy and integrity of the trademark register. The USPTO randomly selected 500 registrations for which section 8 and section 71 affidavits were filed to participate in the pilot program to determine the actual use in commerce of the marks in connection with the goods/services identified in the registrations. As part of the pilot program, the selected trademark owners were required to submit proof of use of their marks for additional goods/services per class, in addition to the one specimen per class submitted with their affidavits, and to verify use of the additional

goods/services during the statutory filing period.

In 51% of the registrations selected for the pilot, the trademark owners failed to supply additional verified proof of use on specific goods/services for which use in commerce was initially claimed. Of this 51%, in 35% of the registrations, the owner requested that some goods/services that were initially claimed to be in use in commerce be deleted, and the remaining 16% of the registrations were cancelled because the trademark owners failed to respond to the requirements for additional proof or to other issues raised during examination of the section 8 or section 71 affidavit. Ultimately, the section 8 and section 71 affidavits were accepted for 84.4%, or 422 registrations, which included acceptances issued after goods/services queried under the pilot were deleted.

The status reports issued throughout the course of the pilot all supported the need for ongoing efforts aimed at ensuring the accuracy and integrity of the trademark register as to the actual use in commerce of marks in connection with the goods/services identified in the registrations. To that end, the USPTO held a roundtable discussion on December 12, 2014, for various stakeholder groups, requested written comments from interested parties to further explore the topic, and discussed the topic at several other outreach sessions. During the roundtable discussion and outreach sessions, one suggestion that received widespread support was to establish a permanent program similar to the proof-of-use pilot. The USPTO considered this recommendation in proposing the permanent program set forth in the notice of proposed rulemaking published in the **Federal Register** on June 22, 2016, at 81 FR 40589. As discussed below, the Office considered all public comments received during the comment period in the development of this final rule.

Proposed Rule: Comments and Responses

The USPTO published a proposed rule on June 22, 2016, soliciting comments on the proposed amendments. In response, the USPTO received comments from six organizations and eight individual commenters representing law firms, corporations, and individuals. The Office received comments both generally supporting and objecting to the proposed requirements. The commenters who supported the goal of promoting the integrity of the register by encouraging accuracy in the listing of

goods/services for which use in commerce is claimed agreed that the rules will facilitate the cancellation of registrations of marks that were never in use in commerce or are no longer in use. In addition, several of those commenters expressed suggestions or concerns regarding the audit program. Similar comments have been grouped together and summarized below, followed by the USPTO's responses. All comments are posted on the USPTO's Web site at <https://www.uspto.gov/trademark/trademark-updates-and-announcements/comments-changes-requirements-affidavits-or>.

Comment 1: One commenter suggested that costs imposed on trademark owners will likely be minimal because owners will only be randomly selected and not routinely or repeatedly subject to audits and another commenter noted that the information sought is within the knowledge of the trademark owner and should be simple to produce if there is indeed use. Another commenter stated that the proposed procedure would add an additional cost in terms of time and legal expense, but that the cost is generally offset by the public-policy benefit.

Response: The USPTO appreciates the commenters' support of the rule changes and concurs that the rule changes create minimal burdens on trademark owners. The USPTO also notes that as trademark owners are already required to ascertain whether a mark is currently in use in commerce with all the goods/services in connection with the filing of a section 8 or section 71 affidavit, any additional requirement to provide proof of such use with select goods/services should not be unduly burdensome or costly. Although approximately one-third of section 8 and section 71 affidavits are filed pro se, the USPTO assumes that an attorney is representing the registrant, and estimates it will take approximately one hour to comply.

Comment 2: One commenter noted that the proposed rule did not address the issue of the "abuse" encouraged by the Madrid Protocol system where there is no pre-registration use requirement for Madrid Protocol applications. Another commenter suggested that the proposed changes could be a model for changes to the process for affidavits or declarations of incontestability under section 15 of the Trademark Act, 15 U.S.C. 1065, by expanding the audit procedure to a percentage of section 15 affidavits. The commenter expressed concern that the cost of a faulty section 15 affidavit is high, given the ability of a registrant to use incontestability as leverage in disputes.

Response: The USPTO appreciates the commenters' concerns, but notes that the Madrid Protocol is an international treaty that became effective in the United States on November 2, 2003. Addressing any concerns related to the Madrid Protocol or its regulations is beyond the scope of this rulemaking, as is any expansion in the audit procedure to a percentage of section 15 affidavits.

Comment 3: One commenter requested that the USPTO consider some form of concession for registrants who are audited and successfully comply with audit requirements, such as an immediate fee reduction in the cost of a section 8 or section 71 affidavit or a future fee offset. Another commenter suggested that the USPTO offer registrants the option to elect out of the random audit by checking a box on the electronic form and voluntarily providing evidence of use for each good/service in a class. A third commenter recommended that the USPTO address abusive practices by: requiring specimens for all goods/services; requiring automatic audits of lengthy identifications of goods and services; allowing applicants whose mark is the subject of a likelihood-of-confusion refusal to petition the Office to audit a registration; providing an item-by-item checklist of all goods/services claimed and requiring registrants to specifically declare use for each good/service; shortening the initial period for filing a section 8 or section 71 affidavit; implementing a penalty system to incentivize renewal only for goods/services that are actually being used; and making more data available to the public concerning the marks on the register, the number of applications and renewals filed, and the number of refusals and amendments filed.

Response: The USPTO notes that although registrants are required to submit only one specimen of use in commerce per class with a section 8 or section 71 affidavit, they are not prevented from voluntarily providing evidence of use in commerce for each good/service listed in the registration. If a registrant does so, it would diminish the likelihood that additional proof of use would be required if the registration is selected for audit. However, any proposal to reduce the fees for section 8 or section 71 affidavits, to create a tiered fee structure, to implement a monetary penalty, to require specimens for all goods/services, or to allow a third party to petition the Office to audit a registration would require separate rulemakings. Moreover, shortening the initial filing period for a section 8 or section 71 affidavit would require Congressional action to amend the

Trademark Act. Even if the statute was amended, such proposals would also require substantial changes to the Trademark electronic filing system, as would modifying the forms to require, or allow the owner to elect to provide, proof of use for each good/service listed on the registration. Regarding the request to make data available to the public, the USPTO notes that information about application filings, active registrations, and new registrations by fiscal year is available on the USPTO Web site at <https://www.uspto.gov/dashboards/trademarks/main.dashxml>. The USPTO will consider making the other requested data available at a future date.

Comment 4: One commenter stated that cancelling the entire registration for failure to respond to an Office action is overly harsh if the specimen(s) originally submitted with the section 8 or section 71 affidavit are acceptable. In such cases, the commenter recommends that the USPTO cancel only those goods/services that are not supported by the specimen(s) submitted with the relevant affidavit.

Response: As in the pilot program, owners of the registrations selected will be afforded the usual post-registration response period to the Office action requiring additional information and are subject to the same consequences for failure to respond. In general, Office actions issued in relation to section 8 and section 71 affidavits are governed by the Trademark Act and rules. 15 U.S.C. 1058(c), (e), 1141k(c), (e); 37 CFR 2.163, 7.39. A response to a post-registration Office action must be filed within six months of the date of issuance of the Office action, or before the end of the filing period set forth in section 8(a) or section 71(a) of the Act, whichever is later. 37 CFR 2.163(b), 7.39(a). Failure to respond within the prescribed time periods results in cancellation of the registration, unless time remains in the grace period for filing a new affidavit. 37 CFR 2.163(c), 7.39(b). If no time remains in the grace period, trademark owners may file a petition to the Director under 37 CFR 2.146(a)(5) and 2.148 to waive 37 CFR 2.163(b) so that a late response to the Office action may be accepted. However, the Director will waive a rule only in an extraordinary situation, where justice requires, and no other party is injured. 37 CFR 2.146(a)(5), 2.148.

Comment 5: One commenter expressed concern that the proposed amendments were vague, unnecessarily open ended, and insufficiently described to properly assess the likely impact and effectiveness of the audit

program. Another commenter requested that the USPTO have further discussions with stakeholder groups prior to implementation of the program.

Response: The USPTO appreciates the commenters' concerns and notes that the expected impact and effectiveness of the audit program can be initially assessed in relation to the results of the pilot program, which supported the need for ongoing efforts aimed at ensuring the accuracy and integrity of the trademark register as to the actual use in commerce of marks in connection with the goods/services identified in the registrations. In addition, the widespread support among stakeholders to establish a permanent program is attributable to the results of the pilot program. An overview of the audit program enacted herein, which is similar to the pilot, is described in the section entitled Overview of the Audit Program of this final rule. As noted in that section, section 8 and section 71 affidavits in which the mark is registered for more than one good or service per class are subject to audit. The additional information or specimens required will be reviewed according to the generally accepted standards for use in commerce. The USPTO notes that there is a uniform standard for determining what constitutes an acceptable specimen both prior to and post registration and finds no basis to establish a different standard for use of the mark in commerce in the context of the audit program. The USPTO believes such a distinction would be a disservice to the public. Not only would a new standard for determining what constitutes acceptable use in commerce increase public confusion, but it would also call into question whether a mark is actually used with particular goods or services. The USPTO also intends to discuss with stakeholder groups the procedures that it will employ to carry out the program to obtain feedback regarding the procedures. These procedures will ultimately be available to the public and internal and external customers in the *Trademark Manual of Examining Procedure*.

Comment 6: Two commenters objected to any changes, as they believed the current rule is clear and the present practice is appropriate. One suggested that the existing rule is less susceptible to discriminatory application and that the proposed rule is not capable of being applied equally to all "applicants." The other commenter stated that it is not the role of the Office to police registrations and if a registrant is not using a mark in connection with all goods/services in

the registration, the registration may be challenged in a cancellation proceeding before the Trademark Trial and Appeal Board (TTAB).

Response: The USPTO appreciates the commenters' concerns regarding equal application of the rules, and notes that registrants, rather than applicants, would be subject to any requirements under the rules. The USPTO does not anticipate that the final rule will have a disproportionate impact upon any particular class of registrant and has determined that its objective of ensuring the accuracy and integrity of the register can be fairly reached by randomly selecting the registrations subject to audit based on the procedures discussed below. Any entity that has a registered trademark in which the mark is registered for more than one good or service per class could potentially be impacted by the rules.

The USPTO agrees that cancellation proceedings before the TTAB provide an avenue for third parties to seek removal of registrations for marks that are not in use in commerce for some or all of the goods/services identified in the registration. However, as discussed above, the accuracy of the trademark register as a reflection of marks that are actually in use in commerce in the United States for the goods/services identified in the registrations listed therein serves an important purpose for the public, which relies on the register to determine whether a chosen mark is available for use or registration. For example, when a party's search of the register discloses a potentially confusingly similar mark, that party may incur a variety of resulting costs and burdens, such as those associated with proceedings to cancel the registration. If a registered mark is not actually in use in commerce in the United States, or is not in use in commerce in connection with all the goods/services identified in the registration, the cost of undertaking a cancellation proceeding may be incurred unnecessarily. In addition, the results of the pilot audit program supported the need for ongoing efforts aimed at ensuring the accuracy and integrity of the trademark register as to the actual use in commerce of marks in connection with the goods/services identified in live registrations. Further, outreach to stakeholder groups and interested parties in the aftermath of the pilot yielded widespread support for establishing a permanent proof-of-use program similar to the pilot. Therefore, the USPTO believes that establishing a permanent program for auditing registrations that include multiple goods/services furthers the public

policy of ensuring the accuracy of the trademark register.

Overview of the Audit Program

The USPTO herein enacts a permanent audit program whereby it will conduct random audits of the combined total of section 8 and section 71 affidavits filed each year in which the mark is registered for more than one good or service per class. The USPTO anticipates that upon initial implementation it would conduct random audits of up to approximately 10% of such affidavits and may increase the percentage going forward, depending on results and as resources allow. As part of the review of the selected affidavits, in addition to the one specimen of use per class currently required, owners will be required to provide additional proof of use in the nature of information, exhibits, affidavits or declarations, and specimens showing use in commerce.

In a selected case, the USPTO will issue an Office action specifying the goods/services for which additional proof of use is required. Upon implementation, the USPTO anticipates requesting proof of use for two additional goods/services per class in the initial Office action. Thereafter, the owner may be required to submit proof of use in commerce for additional goods/services. If there is only one good/service in a class, additional proof of use will be required if the specimen submitted with the section 8 or section 71 affidavit would not also be acceptable to show actual use in commerce. The Office action will also advise trademark owners to delete those goods/services for which they are unable to provide the requested proof of use. It will further advise owners to delete all goods/services not in use in commerce because the Office may issue subsequent actions requiring proof of use on some, or all, remaining goods/services.

As in the pilot program, trademark owners will be afforded the usual response period to the Office action, that is, a response would be due within six months of the issuance date of the Office action, or before the end of the statutory filing period for the section 8 or section 71 affidavit, whichever is later. 37 CFR 2.163(b), 7.39(a). If the trademark owner responds, but is ultimately unable to provide the requested information, exhibits, affidavits or declarations, and specimens, the USPTO would deem the section 8 or section 71 affidavit unacceptable as to the goods/services to which the requirement pertained and will cancel such goods/services from the

registration. If no response to the Office action is filed within six months of the issuance date of the Office action, or before the end of the statutory filing period for the section 8 or section 71 affidavit, whichever is later, the USPTO will cancel the entire registration, unless time remains in the grace period under section 8(a)(3) or section 71(a)(3) of the Act. 15 U.S.C. 1058(a)(3), 1141k(a)(3); 37 CFR 2.163, 7.39. If time remains in the grace period, the owner may file a complete new section 8 or section 71 affidavit, with a new fee and grace-period surcharge. 37 CFR 2.161(d)(2), 7.36(b)(3). The USPTO further clarifies that trademark owners may also file a petition to the Director under 37 CFR 2.146(a)(5) and 2.148 to waive 37 CFR 2.163(b) so that a late response to an Office action may be accepted. However, the Director will waive a rule only in an extraordinary situation, where justice requires, and no other party is injured. 37 CFR 2.146(a)(5), 2.148.

Costs and Benefits: This rulemaking is not considered to be economically significant under Executive Order 12866 (Sept. 30, 1993).

Discussion of Proposed Regulatory Changes

The USPTO amends 37 CFR 2.161 and 7.37 to provide that the USPTO may require such information, exhibits, affidavits or declarations, and such additional specimens of use as may be reasonably necessary for the USPTO to assess and promote the accuracy and integrity of the register. The current rules mandate the submission of only one specimen per class in connection with a section 8 or section 71 affidavit unless additional information, exhibits, affidavits or declarations, or specimens are necessary for proper examination of the affidavit itself. 37 CFR 2.161(g), (h), 7.37(g), (h). This final rule will allow the USPTO to require additional proof of use of a mark not only to facilitate proper examination of a section 8 or section 71 affidavit, but also to verify the accuracy of claims that a trademark is in use on or in connection with the goods/services identified in the registration.

The USPTO revises § 2.161(h) to add the phrase "or for the Office to assess and promote the accuracy and integrity of the register" at the end of the paragraph.

The USPTO revises § 7.37(h) to add the phrase "or for the Office to assess and promote the accuracy and integrity of the register" at the end of the paragraph.

Rulemaking Requirements

Administrative Procedure Act: The changes in this rulemaking involve rules of agency practice and procedure, and/or interpretive rules. *See Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1204 (2015) (interpretive rules “advise the public of the agency’s construction of the statutes and rules which it administers”) (citation and internal quotation marks omitted); *Nat’l Org. of Veterans’ Advocates v. Sec’y of Veterans Affairs*, 260 F.3d 1365, 1375 (Fed. Cir. 2001) (rule that clarifies interpretation of a statute is interpretive); *Bachow Commc’ns Inc. v. FCC*, 237 F.3d 683, 690 (D.C. Cir. 2001) (rules governing an application process are procedural under the Administrative Procedure Act); *Inova Alexandria Hosp. v. Shalala*, 244 F.3d 342, 350 (4th Cir. 2001) (rules for handling appeals were procedural where they did not change the substantive standard for reviewing claims).

Accordingly, prior notice and opportunity for public comment for the changes in this rulemaking are not required pursuant to 5 U.S.C. 553(b) or (c), or any other law. *See Perez*, 135 S. Ct. at 1206 (notice-and-comment procedures are required neither when an agency “issue[s] an initial interpretive rule” nor “when it amends or repeals that interpretive rule”); *Cooper Techs. Co. v. Dudas*, 536 F.3d 1330, 1336–37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), does not require notice and comment rulemaking for “interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice,” quoting 5 U.S.C. 553(b)(A)). However, the USPTO has chosen to seek public comment before implementing the rule.

Final Regulatory Flexibility Analysis

The USPTO publishes this Final Regulatory Flexibility Analysis (FRFA) as required by the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) to examine the impact of the Office’s post-registration audit program on small entities. Under the RFA, whenever an agency is required by 5 U.S.C. 553 (or any other law) to publish a notice of proposed rulemaking (NPRM), the agency must prepare and make available for public comment a FRFA, unless the agency certifies under 5 U.S.C. 605(b) that the proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 603, 605. The USPTO published an Initial Flexibility Analysis (IRFA), along with the NPRM, on June 22, 2016 (81 FR 40589). The USPTO

received no comments from the public directly applicable to the IFRA, as stated below in Item 2.

Items 1–6 below discuss the six items specified in 5 U.S.C. 604(a)(1)–(6) to be addressed in a FRFA. Item 6 below discusses alternatives considered by the Office.

1. Succinct Statement of the Need for, and Objectives of, the Rule

The USPTO amends its rules to require any information, exhibits, affidavits or declarations, and such additional specimens deemed reasonably necessary to assess and promote the accuracy and integrity of the trademark register in connection with the examination of a section 8 or section 71 affidavit. Post registration affidavits under section 8 or section 71, and their accompanying specimens of use, demonstrate a registration owner’s continued use of its mark in commerce for the goods/services identified in the registration. The revisions enacted herein will facilitate the USPTO’s ability to ensure that the register accurately reflects marks that are in use in commerce that may be regulated by the U.S. Congress for the goods/services identified therein.

The objective of the rulemaking is to allow the USPTO to assess and promote the integrity of the trademark register. The Trademark Act gives the Director discretion regarding the number of specimens to require. 15 U.S.C. 1051(a)(1), (d)(1), 1058(b)(1)(C), 1141k(b)(1)(C). The current rules mandate the submission of only one specimen per class in connection with a section 8 or section 71 affidavit unless additional information, exhibits, affidavits or declarations, or specimens are necessary for proper examination of the affidavit itself. 37 CFR 2.161(g), (h), 7.37(g), (h). However, these rules do not currently allow the Office to require additional specimens or other information or exhibits in order to verify that the mark is in use on additional goods/services listed in the registration. The final rule will allow the USPTO to properly examine the nature and veracity of allegations of use made in connection with the submission of a section 8 or section 71 affidavit, and thereby assess and promote the integrity of the register by verifying that the register accurately reflects the goods/services for which use is claimed for a given registered mark.

2. A Statement of the Significant Issues Raised by the Public Comments in Response to the Initial Regulatory Flexibility Analysis, a Statement of the Assessment of the Agency of Such Issues, and a Statement of any Changes Made in the Proposed Rule as a Result of Such Comments

The USPTO did not receive any public comments in response to the IRFA. However, the Office received comments about the audit program in general, which are further discussed in the preamble.

3. The Response of the Agency to any Comments Filed by the Chief Counsel for Advocacy of the Small Business Administration in Response to the Proposed Rule, and a Detailed Statement of any Change Made to the Proposed Rule in the Final Rule as a Result of the Comments

The USPTO did not receive any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule.

4. Description of and an Estimate of the Number of Small Entities to Which the Rule Will Apply or an Explanation of Why No Such Estimate Is Available

The USPTO does not collect or maintain statistics in trademark cases on small- versus large-entity registrants, and this information would be required in order to estimate the number of small entities that would be affected by the final rule. However, the USPTO believes that the overall impact of the regulations enacted herein on registrants will be relatively minimal.

After registration, trademark owners must make periodic filings with the USPTO to maintain their registrations. A section 8 or section 71 affidavit is a sworn statement in which the registrant specifies the goods/services/collective membership organization for which the mark is in use in commerce and/or the goods/services/collective membership organization for which excusable nonuse is claimed. 15 U.S.C. 1058, 1141k. The purpose of the section 8 and section 71 affidavits is to facilitate the cancellation, by the Director, of registrations of marks no longer in use in connection with the goods/services/collective membership organization identified in the registrations. The final rule applies to any entity filing a section 8 or section 71 affidavit, but only a subset of trademark owners would be required to provide more than one specimen or additional information, exhibits, or specimens in connection with the audit. The USPTO is unable to

estimate the subset of trademark owners who are small entities that are impacted by the proposed rules. In Fiscal Year 2016, approximately 150,000 section 8 affidavits and 9,100 section 71 affidavits were filed.

5. Description of the Reporting, Recordkeeping, and Other Compliance Requirements of the Final Rule, Including an Estimate of the Classes of Small Entities Which Will Be Subject to the Requirement and the Type of Professional Skills Necessary for Preparation of the Report or Record

The final rule imposes no new recordkeeping requirements on trademark registrants.

Regarding compliance with this final rule, as an initial matter, the USPTO does not anticipate the rules to have a disproportionate impact upon any particular class of small or large entities. Any entity that has a registered trademark in which the mark is registered for more than one good or service per class could potentially be impacted by the final rule.

The USPTO enacts herein a permanent program where it would conduct random audits of section 8 and section 71 affidavits that are filed in which the mark is registered for more than one good or service per class. The USPTO anticipates that upon initial implementation it would conduct random audits of up to approximately 10% of such affidavits and may increase the percentage going forward, depending on results and as resources allow. In those post registration cases where an initial requirement for additional information, exhibits, affidavits or declarations, and specimens is issued in an Office action, although approximately one-third of section 8 and section 71 affidavits are filed pro se, the USPTO assumes that an attorney is representing the registrant, and estimates it will take approximately one hour to comply. To that end, the USPTO provides an online electronic form for responding to Office actions.

Similar to the submission necessary for the statutorily required section 8 and section 71 affidavits, a response to an Office action issued in connection with these affidavits will generally necessitate gathering and submitting one or more specimens of use and an accompanying declaration. Therefore, under the final rule, the type of fact gathering and review of the nature and extent of the use of the mark that underlies a section 8 or section 71 affidavit will already have occurred. Compliance with the requirements enacted herein will only necessitate gathering and submitting the additional

evidence to demonstrate and support what has previously been assessed.

Assuming the mark is in use as claimed, the compliance time involves the length of time to secure additional information, exhibits, affidavits or declarations, or specimens and accompanying declaration, plus any time it takes an attorney to communicate with the client in order to obtain what is required and make the necessary filing with the USPTO. As noted above, approximately one-third of section 8 and section 71 affidavits are filed pro se. Trademark owners selected for review are likely to have a shorter compliance time than what the USPTO has estimated, which assumes the involvement of an attorney. The final rule does not mandate the use of legal counsel.

6. Description of the Steps the Agency Has Taken To Minimize the Significant Economic Impact on Small Entities Consistent With the Stated Objectives of Applicable Statutes, Including a Statement of the Factual, Policy, and Legal Reasons for Selecting the Alternative Adopted in the Final Rule and Why Each One of the Other Significant Alternatives to the Rule Considered by the Agency Which Affect the Impact on Small Entities Was Rejected

The USPTO has considered whether and how it is appropriate to reduce any burden on small businesses through increased flexibility. The following alternatives were considered, but rejected, by the USPTO.

The USPTO considered an alternative where it would not require additional information, exhibits, affidavits or declarations, and specimens in connection with section 8 or section 71 affidavits, or where it would exempt small entities from such requirements. This alternative would have a lesser economic impact on small entities, but was rejected because it would not accomplish the stated objective of assessing and promoting the integrity of the trademark register by verifying that marks are in use for the goods/services identified in the registration. As noted above, the results of the post registration proof-of-use pilot supported the need for ongoing efforts aimed at assessing and promoting the accuracy and integrity of the register as to the actual use of marks in connection with the goods/services identified in the registrations. Subsequent outreach efforts revealed widespread support for continuing the pilot program on a permanent basis. Exempting small entities would prevent consideration of all section 8 and section 71 affidavits

and not achieve the stated objective of assessing and promoting the accuracy and integrity of the register.

The stated objective of the final rule also facilitates the cancellation of registrations for marks that are no longer in use or that were never used, and for which acceptable claims of excusable nonuse were not submitted, in connection with the identified goods/services. The statutory requirements in sections 8 and 71 exist to enable the USPTO to clear the register of deadwood by cancelling, in whole or in part, registrations for marks that are not in use for all or some of the goods/services identified in the registration. The final rule furthers this statutory purpose. Exempting small entities from possible scrutiny regarding use allegations would fail to address marks not used by them, thereby not achieving the objective.

The USPTO considered a second alternative that would extend the time period for compliance by small entities. However, this was rejected because there appears to be no reason that meeting the requirements of the final rule would be more time consuming for small entities. The USPTO's standard six-month time period for responding to Office actions allows sufficient time regardless of small-entity status.

Finally, the USPTO considered an alternative that would streamline or simplify the compliance mechanism for small entities, but it was deemed unnecessary given the ease of responding electronically to Office actions using the Trademark Electronic Application System Response to Post Registration Office Action form. Thus, under the final rule, compliance will be as streamlined and simplified as possible for all affected entities. Moreover, where the objective is to verify the accuracy of a claim of use in a section 8 or section 71 affidavit, the requirements for additional information, exhibits, affidavits or declarations, and specimens demonstrating the manner of use of the mark in connection with the specified goods/services are the least burdensome and most efficient means of achieving the objective of assessing and promoting the accuracy and integrity of the register by verifying allegations of use.

Use of performance rather than design standards is not applicable to the final rulemaking because the USPTO is not issuing any sort of standard. This final rule will require registrants to furnish evidence of use, rather than comply with a performance or design standard.

Executive Order 12866 (Regulatory Planning and Review): This rulemaking has been determined to be not

significant for purposes of Executive Order 12866 (Sept. 30, 1993).

Executive Order 13563 (Improving Regulation and Regulatory Review): The USPTO has complied with Executive Order 13563 (Jan. 18, 2011).

Specifically, the USPTO has, to the extent feasible and applicable: (1) Made a reasoned determination that the benefits justify the costs of the rule changes; (2) tailored the rules to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) provided the public with a meaningful opportunity to participate in the regulatory process, including soliciting the views of those likely affected prior to issuing a notice of proposed rulemaking, and provided on-line access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes, to the extent applicable.

Executive Order 13132 (Federalism): This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), prior to issuing any final rule, the USPTO will submit a report containing the final rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this notice are not expected to result in an annual effect on the economy of 100 million dollars or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this notice is not expected to result in a “major rule” as defined in 5 U.S.C. 804(2).

Unfunded Mandates Reform Act of 1995: The changes set forth in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local,

and tribal governments, in the aggregate, of 100 million dollars (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of 100 million dollars (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. *See* 2 U.S.C. 1501 *et seq.*

Paperwork Reduction Act: This rulemaking involves information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collection of information involved in this rulemaking has been reviewed and previously approved by OMB under control numbers 0651–0051 and 0651–0055.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects

37 CFR Part 2

Administrative practice and procedure, Trademarks.

37 CFR Part 7

Administrative practice and procedure, Trademarks, International registration.

For the reasons stated in the preamble and under the authority contained in 15 U.S.C. 1123 and 35 U.S.C. 2, as amended, the USPTO amends parts 2 and 7 of title 37 as follows:

PART 2—RULES OF PRACTICE IN TRADEMARK CASES

- 1. The authority citation for 37 CFR part 2 continues to read as follows:

Authority: 15 U.S.C. 1113, 15 U.S.C. 1123, 35 U.S.C. 2, Section 10 of Pub. L. 112–29, unless otherwise noted.

- 2. Amend § 2.161 by revising paragraph (h) to read as follows:

§ 2.161 Requirements for a complete affidavit or declaration of continued use or excusable nonuse.

* * * * *

(h) The Office may require the owner to furnish such information, exhibits, affidavits or declarations, and such additional specimens as may be reasonably necessary to the proper

examination of the affidavit or declaration under section 8 of the Act or for the Office to assess and promote the accuracy and integrity of the register.

* * * * *

PART 7—RULES OF PRACTICE IN FILINGS PURSUANT TO THE PROTOCOL RELATING TO THE MADRID AGREEMENT CONCERNING THE INTERNATIONAL REGISTRATION OF MARKS

- 3. The authority citation for 37 CFR part 7 continues to read as follows:

Authority: 15 U.S.C. 1123, 35 U.S.C. 2, unless otherwise noted.

- 4. Amend § 7.37 by revising paragraph (h) to read as follows:

§ 7.37 Requirements for a complete affidavit or declaration of use in commerce or excusable nonuse.

* * * * *

(h) The Office may require the holder to furnish such information, exhibits, affidavits or declarations, and such additional specimens as may be reasonably necessary to the proper examination of the affidavit or declaration under section 71 of the Act or for the Office to assess and promote the accuracy and integrity of the register.

* * * * *

Dated: January 5, 2017.

Russell Slifer,

Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office.

[FR Doc. 2017–00317 Filed 1–18–17; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 14

RIN 2900–AP51

Recognition of Tribal Organizations for Representation of VA Claimants

AGENCY: Department of Veterans Affairs.
ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its regulations concerning recognition of certain national, State, and regional or local organizations for purposes of VA claims representation. Specifically, this rulemaking allows the Secretary to recognize tribal organizations in a similar manner as the Secretary recognizes State organizations. The final rule allows a tribal organization that is

established and funded by one or more tribal governments to be recognized for the purpose of providing assistance on VA benefit claims. In addition, the final rule allows an employee of a tribal government to become accredited through a recognized State organization in a similar manner as a County Veterans' Service Officer (CVSO) may become accredited through a recognized State organization. The effect of this action is to address the needs of Native American populations who are geographically isolated from existing recognized Veterans Service Organizations (VSOs) or who may not be utilizing other recognized VSOs due to cultural barriers or lack of familiarity with those organizations.

DATES: *Effective Date:* This rule is effective February 21, 2017.

FOR FURTHER INFORMATION CONTACT: Dana Raffaelli, Staff Attorney, Benefits Law Group, Office of the General Counsel (022D), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461-7699. (This is not a toll free number.)

SUPPLEMENTARY INFORMATION: On July 20, 2016, VA issued a proposed rule to amend part 14 of title 38, Code of Federal Regulations, to provide for the recognition of tribal organizations that are established and funded by tribal governments so that representatives of the organizations may assist Native American veterans and their families in the preparation, presentation, and prosecution of their VA benefit claims. 81 FR 47087-47094. VA proposed to allow a tribal organization that is established and funded by one or more tribal governments to be recognized for the purpose of providing assistance on VA benefit claims. *Id.* In addition, VA proposed to allow an employee of a tribal government to become accredited through a recognized State organization in a similar manner as a CVSO may become accredited through a recognized State organization and to extend office space opportunities already granted to certain employees of State organizations to employees of tribal organizations. *Id.*

VA received 17 comments on the proposed rule. Overall, the comments were supportive of the proposed rule. A couple of commenters stated that they currently meet or will be able to meet the accreditation requirements for recognition as a tribal organization. The actual requests for recognition of specific tribal organizations are outside the scope of this rulemaking. However, VA invites all interested organizations or applicants to consider requesting recognition after this rulemaking takes effect. Please see VA's accreditation

Web site for more information on how to request recognition of an organization and how to apply to become accredited as a representative through a recognized organization or as an attorney or agent, <http://www.va.gov/ogc/accreditation.asp>. No change is warranted to this rulemaking based on these comments.

A few commenters misinterpreted the proposed rule as meaning that VA intended to propose that VA's recognition of a tribal organization would be tied to VA's recognition of the corresponding State organization. VA is not tying VA recognition of a tribal organization to a State. Recognition of a tribal organization will stand on its own. After a tribal organization becomes recognized by VA, that organization will be able to request to have its own representatives accredited under 38 CFR 14.629. Therefore, VA declines to make any changes based on these comments.

One commenter stated that there is no need to restrict a tribal government employee to being accredited by either a tribal organization or State organization. Although in the proposed rule, we focused much of our discussion on how a tribal government employee may be accredited through a tribal organization or a State organization, we do not intend for this rulemaking to limit the availability of other avenues to achieve VA accreditation. There are several ways that individuals, including tribal members, tribal government employees, and others who work within and serve tribal or Native American communities, may be accredited by VA to represent claimants. If an individual does not wish to be accredited through a tribal or State organization, the individual may seek accreditation through a National or Regional or Local organization or seek accreditation in his or her individual capacity as either an agent or an attorney under the standards set forth in § 14.629(b). Therefore, VA declines to make any changes based on this comment.

One commenter asked whether a tribal veterans' service representative who worked in multiple states would be required to get approval from all of the States in which they work. If the representative is accredited through the tribal organization and representing claimants on behalf of that organization, then the representative would not need to seek any additional accreditation through a State organization. If the representative is a tribal veterans service officer (TVSO) and the representative's sole accreditation status is through a State organization, the representative should confer with that State organization to see if the State has

placed any geographical limits on its accredited representatives. VA does not place any geographical or residency restrictions or limitations on State or tribal organizations as to who may be served by the organization. Therefore, no change is warranted to this rulemaking based on this comment.

A couple of commenters recommended that a tribal organization should have the ability to accredit representatives of State organizations through the tribal organization as well. A VA-recognized tribal organization is welcome to put forth any representatives of its choosing for VA accreditation so long as the organization is able to certify that the potential representative is of good character and reputation, has demonstrated an ability to represent claimants, and is a paid employee working no less than 1,000 hours annually. A recognized tribal organization may also recommend a potential representative for accreditation through the tribal organization by certifying that the individual is accredited and functioning as a representative of another recognized organization, this is commonly referred to as "cross-accreditation." See 38 CFR 14.627(j) and 14.629(a). Because we do not view this rulemaking as prohibiting State organization representatives from being accredited through a tribal organization as well, we do not believe that a change is warranted to this rulemaking based on these comments.

One commenter asked if it would be possible for a tribal government to have their employees accredited by a tribal organization and State organization concurrently. VA does not limit an accredited representative to one method of accreditation. Therefore, no change is warranted to this rulemaking based on this comment.

Several commenters appeared to interpret the proposed rule as limiting tribal organizations to representation of only veterans who are Native American and not their dependents or survivors who may not be Native American. It is not VA's intention to limit the type of claimants for VA benefits that any accredited organization, attorney, or agent may represent. The requirements for accreditation require an applying organization to state the number of veterans, survivors, and dependents that will be served by the organization. 38 CFR 14.628(d)(1)(ii)(D). VA makes no changes based on these comments.

Several commenters also expressed concern over the requirements for recognition in § 14.628(d). Specifically, the commenters expressed concern that many tribal organizations may not be

able to satisfy the requirement of having a primary purpose of serving veterans, the requirement of a substantial service commitment to veterans as shown either by a sizable organizational membership or by performance of veterans' services to a sizable number of veterans, or requirements concerning funding and training, to include providing the required supporting documentation. As stated in the proposed rule, VA must ensure that VA accredited organizations can provide long-term, competent representation and has found that the § 14.628(d) requirements further that objective. These requirements apply to all organizations seeking VA recognition. Exempting tribal organizations from meeting the § 14.628(d) requirements would not be consistent with the purpose of VA recognition to ensure that veterans are receiving qualified, competent representation on their VA benefit claims. VA has provided additional means to achieve VA recognition or accreditation for those tribal governments that may have difficulty establishing a tribal organization capable of meeting the § 14.628(d) requirements, to include the ability for one or more tribal governments to establish and fund a tribal organization and the ability of an employee of a tribal government to become accredited as a tribal veterans' service officer through a recognized State organization. Therefore, VA makes no changes based on these comments.

Several commenters requested that VA further define or quantify what would constitute adequate funding and a substantial service commitment to veterans either by showing a sizeable organizational membership or by showing performance of veterans' services to a sizeable number of veterans. VA's purpose is to ensure that VA claimants have responsible, qualified representation and the above noted requirements serve as an indicator that the organization is stable. VA makes these determinations on a case-by-case basis taking into consideration all of the evidence of record. VA's goal is to ensure that VA claimants have access to the representation that they may need, and in order to provide such access, VA needs flexibility to make accreditation determinations based on the totality of the circumstances. Therefore, VA declines to make any changes based on these comments.

Several commenters requested that funding be made available to establish tribal organizations. Section 5902, of title 38, United State Code, which is the law that authorizes VA to recognize organizations for the purpose of

providing assistance on VA benefit claims, does not provide for the funding of such organizations to train and maintain representatives. Pursuant to § 14.628(d)(iii)(B), organizations are not precluded from seeking and receiving other sources of State and Federal grant funding so long as the organization's funding is not subject to limitations imposed under any Federal grant or law which would prevent it from representing claimants before VA. Therefore, VA declines to make any changes based on these comments.

Several commenters suggested further outreach and collaboration. On March 3 and 10, 2016, respectively, VA issued letters to tribal leaders and a **Federal Register** notice, 81 FR 12626, seeking comment on VA's consideration of issuing a proposed rule that would amend part 14 of title 38, Code of Federal Regulations, to expressly provide for the recognition of tribal organizations so that representatives of the organizations may assist Native American claimants in the preparation, presentation, and prosecution of their VA benefit claims. Those interested in providing comment were given 30 days to respond. Based on requests from commenters, VA expanded the comment period an additional 15 days to April 26, 2016. VA received comments from 36 commenters. In the proposed rule, VA addressed the comments received from the tribal consultation and provided an additional 60-day comment period. 81 FR 47091–47093, July 20, 2016. Therefore, VA finds that it has complied with the notice and consultation requirements of the governing Executive Orders. *See* Exec. Order No. 13175, 65 FR 67249–67252, Nov. 9, 2000; Exec. Order 12866 sec. 6(a), 58 FR 51735, Sept. 30, 1993; Exec. Order 13563 sec. 2(b), 76 FR 3821, 3821–22, Jan. 18, 2011.

One commenter asked VA to include the veterans departments within the tribal governments as eligible for VA recognition. A Veterans Affairs office or department that is established and funded by a tribal government is included in the definition of tribal organization and may apply for recognition under the rule. Another commenter requested that tribal government be included in the definition of tribal organization. A tribal government would not fit the definition of a tribal organization because the primary purpose of a tribal government is generally much broader than serving the needs of Native American veterans. However, the definition of tribal organization allows for a tribal government to establish such an organization that will be for that specific

purpose. In this same way, VA recognizes State organizations rather than the State governments themselves. Therefore, no change to this rulemaking is warranted based on these comments.

Another commenter stated that, due to the geographic size of their tribal government, it would make sense for it to become its own regional council. If the commenter is asserting its intention to apply to become a VA accredited organization, VA welcomes all organizations to apply once this rulemaking becomes effective. No change is warranted to this rulemaking based on this comment.

One commenter recommended that, regarding tribal government approval for tribal organization representation, the approval be recognized with a single resolution or other document on behalf of member tribal nations. The commenter stated that obtaining resolutions from each nation would be administratively burdensome. Pursuant to § 14.628, the organization requesting VA accreditation must certify to VA that the organization meets the § 14.628(d) requirements for recognition. As long as VA receives certification from each tribal government approving the tribal organization, VA has no objection to the format of the certification being contained in a single resolution or document. An example may be that the establishment of the tribal organization is contained in one resolution and that resolution is signed, or certified, by all of the appropriate officials. VA makes no changes based on this comment.

One commenter asked that VA provide recognition for urban Indian organizations or urban Indian health programs. The comment is unclear on whether such an organization would be able to apply for VA recognition as a tribal organization. VA declines to add an additional organization category at this time. In addition to the amendments discussed in this rulemaking, an organization may still utilize other avenues to apply for VA recognition such as requesting VA recognition as a regional or local organization. To be recognized as a regional or local organization, an organization must meet the requirements of § 14.628(c) and (d).

The same commenter asked that employees of urban Indian organizations or urban Indian health programs be recognized as accredited representatives. An individual may apply for accreditation as a representative through a VA-recognized organization under standards set forth in § 14.629(a). Alternatively, an individual may also seek accreditation in an individual capacity as either an

agent or an attorney under the standards set forth in § 14.629(b). The commenter also asked that the requirement for tribal veterans' service officers to work 1,000 hours annually be eliminated or lowered. The same hour requirements apply to county veterans' service officers being recommended for accreditation by a State and will, under this rule, apply to tribal veterans' service officers being accredited by a State. As explained in the proposed rule, VA prescribed these criteria in order to ensure adequate training and fitness to serve as a VA accredited representative. VA declines to make any changes based on these comments.

One commenter asked VA to require culturally sensitive training for TVSOs. Section 14.628(d)(1)(v)(B) requires that a request for recognition of an organization include a plan for recruiting and training the organization's representatives. In addition, with regard to TVSOs, the organization's certifying official must certify that the TVSO is a paid employee of the tribal government working no less than 1,000 hours annually, has successfully completed a course of training and examination approved by VA, and that the TVSO will receive regular supervision or annual training to assure the TVSO continues to be qualified to represent claimants. 38 CFR 14.629(a)(2)(i)–(iii). The testing or training for TVSOs may include topics such as cultural sensitivity training at the discretion of the organization. VA declines to add a cultural sensitivity training requirement as we believe each organization would be the best judge of the need for cultural sensitivity training for its own representatives. In addition, such an addition would not be a logical outgrowth of the proposed rule. Therefore, VA makes no changes based on this comment.

One commenter stated that, with regard to the Paperwork Reduction Act (PRA) requirements, VA had underestimated the number of applicants/respondents that would apply to become an accredited tribal organization. However, the commenter did not provide a number of how many applicants/respondents they thought VA would receive. VA notified the Office of Management and Budget (OMB) of the commenter's concern and amended its PRA submission to double the number of applicants/respondents from 5 to 10 per year.

One commenter asked to what extent OMB was involved in the formulation of this rule. Executive Order 12866, 58 FR 51735, requires that OMB, specifically the Office of Information and Regulatory Affairs, review regulations before they

are submitted for publication in the **Federal Register**. VA submitted the proposed rule and required supporting documents prior to the publication of the proposed rule and will comply with the requirements of the Executive Order in issuing this final rule. No change to this rulemaking is warranted based on this comment.

One commenter asked to what extent VA believes that all States would support this rulemaking. VA has not received any adverse comments from States on this rulemaking. As previously stated, recognition of a tribal organization is not tied to a State organization. No change to this rulemaking is warranted based on this comment.

One commenter asked what support VA could provide to tribes that do not have enough veterans per capita to participate in the process outlined to coordinate their activities with States or county veterans' service organizations while respecting a tribe's sovereign authority. It is unclear whether the commenter is requesting that VA waive certain accreditation requirements. As previously discussed, VA cannot waive the requirements for accreditation for any organization. A tribe that is unable to establish an organization that is capable of meeting the requirements to be recognized as a tribal organization may be able to have its members apply to become accredited in their individual capacity as claims agents or attorneys or as representatives through another VA-recognized organization. VA makes no changes based on this comment.

One commenter said that educational benefits should be allowed to be used at tribal colleges and universities. This comment is outside the scope of this rulemaking. Therefore, no change is warranted based on this comment.

Finally, VA is correcting a grammatical error in proposed § 14.628(b)(2). In the third sentence, VA mistakenly referred to "tgovernment" when the correct reference should have been to "tribal government." VA is correcting this error in this rulemaking.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (at 44 U.S.C. 3507) requires that VA consider the impact of paperwork and other information collection burdens imposed on the public. Under 44 U.S.C. 3507(a), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid OMB control number. *See also* 5 CFR 1320.8(b)(3)(vi).

This final rule will impose the following new information collection

requirements. The collection of information in 38 CFR 14.628 requires organizations seeking VA accreditation under § 14.628 to submit certain documentation to certify that the organization meets the requirements for VA accreditation. Pursuant to § 14.628(d), an organization requesting recognition must have as a primary purpose serving veterans. In establishing that it meets this requirement, an organization requesting recognition shall submit a statement establishing the purpose of the organization and that veterans would benefit by recognition of the organization.

The organization must also demonstrate a substantial service commitment to veterans either by showing a sizable organizational membership or by showing performance of veterans' services to a sizable number of veterans. In establishing that it meets this requirement, an organization requesting recognition shall submit: The number of members and number of posts, chapters, or offices and their addresses; a copy of the articles of incorporation, constitution, charter, and bylaws of the organization, as appropriate; a description of the services performed or to be performed in connection with programs administered by VA, with an approximation of the number of veterans, survivors, and dependents served or to be served by the organization in each type of service designated; and a description of the type of services, if any, performed in connection with other Federal and State programs which are designed to assist former Armed Forces personnel and their dependents, with an approximation of the number of veterans, survivors, and dependents served by the organization under each program designated.

An organization requesting recognition must commit a significant portion of its assets to veterans' services and have adequate funding to properly perform those services. In establishing that it meets this requirement, an organization requesting recognition shall submit: A copy of the last financial statement of the organization indicating the amount of funds allocated for conducting particular veterans' services (VA may, in cases where it deems necessary, require an audited financial statement); and a statement indicating that use of the organization's funding is not subject to limitations imposed under any Federal grant or law which would prevent it from representing claimants before VA.

An organization requesting recognition must maintain a policy and capability of providing complete claims service to each claimant requesting representation or give written notice of any limitation in its claims service with advice concerning the availability of alternative sources of claims service. In establishing that it meets this requirement, an organization requesting recognition shall submit evidence of its capability to represent claimants before VA regional offices and before the Board of Veterans' Appeals. If an organization does not intend to represent claimants before the Board of Veterans' Appeals, the organization shall submit evidence of an association or agreement with a recognized service organization for the purpose of representation before the Board of Veterans' Appeals, or the proposed method of informing claimants of the limitations in service that can be provided, with advice concerning the availability of alternative sources of claims service. If an organization does not intend to represent each claimant requesting assistance, the organization shall submit a statement of its policy concerning the selection of claimants and the proposed method of informing claimants of this policy, with advice concerning the availability of alternative sources of claims service.

An organization requesting recognition must take affirmative action, including training and monitoring of accredited representatives, to ensure proper handling of claims. In establishing that it meets this requirement, an organization requesting recognition shall submit: A statement of the skills, training, and other qualifications of current paid or volunteer staff personnel for handling veterans' claims; and a plan for recruiting and training qualified claim representatives, including the number of hours of formal classroom instruction, the subjects to be taught, the period of on-the-job training, a schedule or timetable for training, the projected number of trainees for the first year, and the name(s) and qualifications of the individual(s) primarily responsible for the training.

In addition, the organization requesting recognition shall supply: A statement that neither the organization nor its accredited representatives will charge or accept a fee or gratuity for service to a claimant and that the organization will not represent to the public that VA recognition of the organization is for any purpose other than claimant representation; and the names, titles, and addresses of officers

and the official(s) authorized to certify representatives.

As required by the Paperwork Reduction Act of 1995 (at 44 U.S.C. 3507(d)), VA has submitted this information collection to OMB for its review. OMB approved these new information collection requirements associated with the final rule and assigned OMB control number 2900–0850.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. It does not require any action on the part of any entity but merely provides a new opportunity for tribal organizations to become recognized by VA for the purpose of assisting VA claimants in the preparation, presentation, and prosecution of claims for VA benefits. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the final regulatory flexibility analysis requirements of section 604.

Executive Order 13175

Executive Order 13175 provides that Federal agencies may not issue a regulation that has tribal implications, that imposes substantial direct compliance costs on tribal governments, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments or the Federal agency consults with tribal officials early in the process of developing the proposed regulation, develops and publishes in the **Federal Register** a tribal summary impact statement, and provides to the Director of OMB any written communications submitted to the agency by the tribal officials.

On March 3 and 10, 2016, respectively, VA issued letters to tribal leaders and a **Federal Register** notice, 81 FR 12626, seeking comment on VA's consideration of issuing a proposed rule that would amend part 14 of title 38, Code of Federal Regulations, to expressly provide for the recognition of tribal organizations so that representatives of the organizations may assist Native American claimants in the preparation, presentation, and prosecution of their VA benefit claims. Those interested in providing comment were given 30-days to respond. Based on requests from commenters, VA expanded the comment period an additional 15 days to April 26, 2016. VA received comments from a total of 37

commenters. VA addressed 36 of those comments in the proposed rule. 81 FR 47087, 47091–47093. During the drafting of the final rule, VA discovered one additional comment submitted in response to the tribal consultation. Therefore, VA is addressing the additional comment and republishing VA's responses to the other comments in this final rule.

One commenter asked if tribal organizations, since they are sovereign nations, would work with their local VA regional offices to include submitting claims through their respective regional offices. VA-recognized tribal organizations will be responsible for providing representation on behalf of their clients in the same manner as all other VA-recognized organizations, which often includes filing claims and evidence in support of their client's claims with the appropriate regional office. For TVSO's whose sole accreditation is through a State organization, VA defers to the State organization on their procedures for submitting claims and evidence to VA. No change is warranted to this rulemaking based on this comment.

The same commenter asked if tribal organizations will “commit to annual/routine training [for their] veterans service officers.” Part of the § 14.628(d) requirements is that an organization seeking accreditation must “[t]ake affirmative action, including training and monitoring of accredited representatives, to ensure proper handling of claims.” 38 CFR 14.628(d)(1)(v). When an organization applies for VA accreditation, the organization must include a plan for recruiting and training the organization's representatives. 38 CFR 14.628(d)(1)(v)(B). No change is warranted to this rulemaking based on this comment.

One commenter wrote that, currently, their tribal representatives are being accredited through their State as well as other national organizations and was curious as to the “road blocks” other tribal organizations were facing. This commenter did not provide any suggestions, and therefore, no change to this rulemaking is warranted.

Several commenters noted that currently Native American veterans face many roadblocks to obtaining representation. One commenter noted that geography, economic, and culture barriers prevent Native American veterans from utilizing currently available representation. These comments were offered in support of the rulemaking, and therefore, no change is warranted.

A few commenters misinterpreted the language provided in the consultation and notice as meaning that VA intended that VA's recognition of a tribal organization would be tied to VA's recognition of the corresponding State organization. One commenter stated that VA should recognize a tribal organization as "equal to" a State organization. VA is not tying VA recognition of a tribal organization to a State and is choosing not to make value judgements as to the importance of the recognition granted to State organizations and Tribal organizations. Recognition of a tribal organization will stand on its own. VA has chosen to use the term *similar* rather than the term *equal* in this rule because there are some differences in the requirements for VA recognition of a tribal organization and the requirements for State organizations. Specifically, the rule will allow a single tribal government, or multiple tribal governments to join together to establish and fund a tribal organization, but such allowance is not permitted for State governments.

A few commenters misinterpreted the language provided in the consultation and notice as limiting recognition of a tribal veterans' service officer through a State. One commenter asked for clarification on what type of employees would be eligible to become accredited by VA. The commenter stated that employees of a tribal nation as well as a tribal organization should be eligible. We agree, and the final rule allows for both avenues to attain VA accreditation depending on the tribal government's size, relationships with other tribal governments, relationships with States, and the needs of Native American veterans in their area. After a tribal organization becomes recognized by VA, that organization will be able to request to have its own representatives accredited under 38 CFR 14.629. In addition to recognizing tribal organizations and accredit their representatives, VA provides an additional means by which VA may recognize an employee of a tribal government as a tribal veterans' service officer through a State organization. This accreditation is akin to accreditation given to county veterans' service officers through State organizations and is only meant to provide an additional path to VA accreditation. The requirements for a tribal veterans' service officer to become accredited as a representative through a State organization be the same as the requirements for a county veterans' service officer. Therefore, VA makes no changes based on these comments.

One commenter asked what happens to the accreditation of a tribal organization if the Director is relinquished. It seems this comment stems from the misinterpretation previously discussed regarding the accreditation of a tribal organization and the corresponding State organization. The commenter also asked what happens if the State refuses to sponsor the replacement officer. As discussed above, once a tribal organization becomes recognized by VA, that organization can request to have its own representatives accredited under § 14.629. The tribal organization can file with VA to have a replacement officer accredited. Therefore, VA makes no changes based on this comment.

Several commenters also expressed concern over the requirements for recognition in § 14.628(d). Specifically, the commenters expressed concern that many tribal organizations may not be able to satisfy the primary purpose, size, funding, and training requirements, to include providing the required, supporting documentation. One commenter suggested that VA provide the funding for tribes "to engage in this work." Another commenter suggested including Indian Health Services for funding assistance. A few commenters expressed concern about the requirement that the organization must maintain a policy of either providing complete claims representation or provide "written notice of any limitation in its claims service with advice concerning the availability of alternative sources of claims service." 38 CFR 14.628(d)(1)(iv). One commenter seemed to believe VA was questioning the level of competence of tribal representatives. VA must ensure that VA accredited organizations can provide long-term, competent representation and has found that the § 14.628(d) requirements are protective of that mission. These requirements apply to all organizations seeking VA recognition. Exempting tribal organizations from meeting the § 14.628(d) requirements is not consistent with the purpose of VA recognition to ensure that veterans are receiving qualified, competent representation on their VA benefit claims. As previously discussed, VA has provided additional means to achieve VA recognition or accreditation for those tribal governments that may have difficulty establishing a tribal organization capable of meeting the § 14.628(d) requirements, to include the ability for one or more tribal governments to establish and fund a tribal organization and the ability of an

employee of a tribal government to become accredited as a tribal veterans' service officer through a recognized State organization. Therefore, VA makes no changes based on these comments.

One commenter suggested that VA grant accreditation to tribes through a Memorandum of Understanding and included their tribe's Memorandum of Understanding with their State. The commenter also questioned the role of VA in the accreditation and monitoring process. The laws governing VA accreditation are set out at 38 U.S.C. 5902 and 5904 and 38 CFR 14.626–14.637. These laws apply to all organizations, agents, and attorneys seeking VA accreditation. Pursuant to § 14.628, the organization requesting VA accreditation must certify to VA that the organization meets the § 14.628(d) requirements for recognition. Therefore, a Memorandum of Understanding between VA and a tribe is not sufficient for applying for VA accreditation. Furthermore, VA does monitor its accredited organizations, agents, and attorneys and handles disciplinary matters as they arise. Therefore, VA makes no changes based on this comment.

One commenter suggested that VA engage in additional consultation with Tribes that would be "interested in becoming recognized veterans[]" service organizations, but are unable to meet the requirements." In this rule, VA offers alternative avenues for VA recognition and accreditation for tribal governments that may not be capable of establishing an organization that can meet the VA recognition requirements in the rule on their own. VA declines to make any changes based on this comment.

One commenter also recommended that "VA enter into Memorandums of Understanding with [F]ederally-recognized tribes and tribal organizations for [v]eterans' [s]ervice [o]fficer training and service reimbursement, on individual bases." Another commenter objected to the fact that there was "no mention of funding to train and maintain such a position." Section 5902, of title 38, United States Code, which is the law that authorizes VA to recognize organizations for the purpose of providing assistance on VA benefit claims, does not provide for the funding of such organizations to train and maintain representatives. Pursuant to § 14.628(d)(iii)(B), organizations are not precluded from seeking and receiving other sources of State and Federal grant funding so long as the organization's funding is not subject to limitations imposed under any Federal grant or law which would prevent it from representing claimants before VA.

Therefore, VA declines to make any changes based on these comments.

One commenter wrote that VA “. . . should include [F]ederally-recognized tribes, not just tribal organizations funded by tribal governments, as an entity from which applications will be considered to be recognized for . . .” VA accreditation. Another commenter suggested adding “[F]ederally recognized tribes” or “[F]ederally recognized tribal governments” as part of the definition for tribal organizations. Another commenter suggested adding tribal communities. For the purposes of the regulations pertaining to the representation of VA claimants, VA defines a tribal government to mean “the Federally recognized governing body of any Indian tribe, band, nation, or other organized group or community. . . .” VA finds this definition to be inclusive of the comments, and therefore, no change is warranted.

One commenter suggested a legislative amendment to the definition of State in 38 U.S.C. 101(20) to include “[F]ederally recognized tribal governments.” Amending the statutory language is something that only Congress can accomplish. Since VA is defining the term “tribal government” in regulation and providing an avenue for VA recognition of a tribal organization separate from a State organization, VA does not find such a legislative amendment necessary. Therefore, no change is warranted based on this comment.

Several commenters wrote that “[s]pecial attention must be paid to what specifically is meant by a ‘[t]ribal [o]rganization’” and that VA should offer a clear definition of the term. The commenters did not offer any suggestions for such definition. As previously discussed, VA is defining this term for the purposes of this rulemaking. Therefore, VA does not make any changes based on this comment.

Several commenters asked VA to clarify whether tribal governments, including veterans departments within these governments, would be eligible for VA recognition. A Department of Veterans Affairs or a Veterans Affairs office that is established and funded by a tribal government is included in the definition of tribal organization. Therefore, no change to this rulemaking is warranted based on these comments.

One commenter asked that VA provide recognition for urban Indian organizations. The comment is unclear on whether such an organization would be able to apply for VA recognition as a tribal organization. VA declines to add

an additional organization category at this time. In addition to the amendments discussed in this rulemaking, an organization may still utilize other avenues to apply for VA recognition such as requesting VA recognition as a regional or local organization. To be recognized as a regional or local organization, an organization must meet the requirements of § 14.628(c) and (d).

Further, there are several ways that individuals, including tribal members, tribal government employees, and others who work within and serve tribal or Native American communities, may be accredited by VA to represent claimants. An individual may apply for accreditation as a representative through an existing VA-recognized organization under standards set forth in § 14.629(a). Alternatively, an individual may also seek accreditation in an individual capacity as either an agent or an attorney under the standards set forth in § 14.629(b). Therefore, VA declines to make any changes based on this comment.

A couple of commenters submitted statements certifying that their organization would meet the requirements for accreditation for a tribal organization. Applications for accreditation are outside the scope of this rulemaking. Therefore, no change is warranted based on these comments.

One commenter asked whether accredited tribal representatives would be granted access to software programs containing a veteran’s claims file information and whether that access would be on tribal grounds. This issue is outside the scope of this rulemaking. Therefore, no change is warranted based on this comment.

One commenter expressed support for VA recognizing tribal organizations in an equal manner as VA recognizes State organizations but suggested that VA authorize a field office close to tribal administration locations and fund one or two veterans service officer positions. The tribal consultation and this rulemaking are limited in scope to recognition for purposes of VA claims representation. The commenter’s suggestion of adding a field office is beyond the scope, and therefore, VA declines to make any changes based on this comment. VA also declines to make any changes to the commenter’s suggestion of funding job positions for veterans service officers. Part of the § 14.628(d) requirements is that an organization seeking accreditation must commit a significant portion of its assets to veterans’ services and have adequate funding to properly perform those services. 38 CFR 14.628(d)(1)(iii).

A few commenters expressed concern that the rulemaking is limiting VA recognition for the preparation, presentation, and prosecution of claims for VA benefits. One commenter seemed to think VA is depriving veterans from other title 38 benefits. The commenters did not specify what other accreditation they are seeking. As previously discussed, the relevant regulations in 38 CFR part 14 are to recognizing organizations and accrediting individuals to assist in the preparation, presentation, and prosecution of VA benefit claims. Pursuant to section 5902, VA accreditation may not be granted for any other purpose. This rulemaking in no way deprives any veteran of any title 38 benefits. Therefore, no change is warranted based on these comments.

One commenter suggested that office space opportunities should be available to tribal governments and organizations in the same manner as they are available to State organizations. As previously discussed, this rule will, under § 14.635, allow the Secretary to furnish office space and facilities, when available, to both State and tribal organization employees who are also accredited to national organizations for the purpose of assisting claimants in the preparation, presentation, and prosecution of claims for benefits. VA will be furnishing office space to tribal organizations in the same manner as it furnishes such space to State organizations. Therefore, no change is warranted based on this comment.

One commenter noted that VA should allow a tribal government employee to become accredited through an accredited body of their choice. VA in no way is limiting how a particular individual may apply to become an accredited VA representative. As previously discussed, VA is merely providing additional paths to VA accreditation than currently exist. Therefore, VA declines to make any changes to this rulemaking based on this comment.

Several commenters suggested further outreach and collaboration. One commenter suggested that VA form a tribal workgroup to allow representatives from tribal organizations to collaborate on implementing the new program. One commenter provided VA with their tribal consultation policy. Other commenters suggested that VA engage in additional consultation with experts in Indian law and hold an all-tribes call to gather additional input for this rulemaking. VA appreciates this information. As previously noted, VA extended the comment period for an additional 15 days to ensure that all interested parties had an appropriate

time to provide input. Therefore, VA finds that it has complied with the requirements of Executive Order 13175. VA also provided an additional 60-day comment period for the proposed rule.

One commenter asked for the projected implementation date of this rulemaking. The dates section of this final rule contains the effective date of the rulemaking.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action” requiring review by OMB, unless OMB waives such review, as “any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations or recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive Order.”

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866. VA’s impact analysis can be found as a supporting document at <http://www.regulations.gov>, usually within 48 hours after the rulemaking document is published. Additionally, a copy of this rulemaking and its impact analysis are available on VA’s Web site at <http://www.va.gov/orpm/>, by following the link for “VA Regulations Published From FY 2004 Through Fiscal Year to Date.”

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

There are no Catalog of Federal Domestic Assistance programs numbers and titles associated with this final rule.

List of Subjects in 38 CFR Part 14

Administrative practice and procedure, Claims, Courts, Foreign relations, Government employees, Lawyers, Legal services, Organization and functions (Government agencies), Reporting and recordkeeping requirements, Surety bonds, Trusts and trustees, Veterans.

For the reasons set out in the preamble, the Department of Veterans Affairs amends 38 CFR part 14 as follows:

PART 14—LEGAL SERVICES, GENERAL COUNSEL, AND MISCELLANEOUS CLAIMS

- 1. The authority citation for part 14 continues to read as follows:

Authority: 5 U.S.C. 301; 28 U.S.C. 2671–2680; 38 U.S.C. 501(a), 512, 515, 5502, 5901–5905; 28 CFR part 14, appendix to part 14, unless otherwise noted.

- 2. Amend § 14.627 by adding paragraph (r) to read as follows:

§ 14.627 Definitions.

* * * * *

(r) *Tribal government* means the Federally recognized governing body of any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or Regional or Village Corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act, which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

* * * * *

- 3. Amend § 14.628 by:

- a. Designating paragraph (b) as paragraph (b)(1) and adding paragraph (b)(2); and
- b. In the OMB approval parenthetical at the end of the section, removing “2900–0439” and adding, in its place, “2900–0850”.

The addition reads as follows:

§ 14.628 Recognition of organizations.

* * * * *

(b) * * *

(2) *Tribal organization*. For the purposes of 38 CFR 14.626 through 14.637, an organization that is a legally established organization that is primarily funded and controlled, sanctioned, or chartered by one or more tribal governments and that has a primary purpose of serving the needs of Native American veterans. Only one tribal organization may be recognized for each tribal government. If a tribal organization is created and funded by more than one tribal government, the approval of each tribal government must be obtained prior to applying for VA recognition. If one of the supporting tribal governments withdraws from the tribal organization, the tribal organization must notify VA of the withdrawal and certify that the tribal organization continues to meet the recognition requirements in paragraph (d) of this section.

* * * * *

§ 14.629 [Amended]

- 4. Amend § 14.629 by:

- a. In paragraph (a)(2) introductory text, removing “county veteran’s service officer” and adding in its place “county veterans’ service officer”;
- b. In paragraph (a)(2) introductory text, adding “or tribal veterans’ service officer” immediately following “county veterans’ service officer”; and
- c. In paragraph (a)(2)(i), adding “or tribal government” immediately following “county”.

§ 14.635 [Amended]

- 5. Amend § 14.635 by adding, in the introductory paragraph, “or tribal” immediately following “State”.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrisee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on January 11, 2017, for publication.

Dated: January 11, 2017.

Jeffrey Martin,

Office Program Manager, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

[FR Doc. 2017–00947 Filed 1–18–17; 8:45 am]

BILLING CODE 8320–01–P

**DEPARTMENT OF VETERANS
AFFAIRS****38 CFR Part 17****RIN 2900-AP94****Fertility Counseling and Treatment for
Certain Veterans and Spouses****AGENCY:** Department of Veterans Affairs.**ACTION:** Interim final rule.

SUMMARY: The Department of Veterans Affairs (VA) amends its regulation regarding fertility counseling and treatment available to certain veterans and spouses. VA currently provides certain infertility services other than in vitro fertilization (IVF) to veterans as part of the medical benefits package. IVF is the process of fertilization by manually fertilizing an egg, and then transferring the embryo to the uterus. This interim final rulemaking adds a new section authorizing IVF for a veteran with a service-connected disability that results in the inability of the veteran to procreate without the use of fertility treatment. In addition, we add a new section stating that VA may provide fertility counseling and treatment using assisted reproductive technologies (ART), including IVF, to a spouse of a veteran with a service-connected disability that results in the inability of the veteran to procreate without the use of fertility treatment. VA will provide ART treatment, including IVF, to these veterans and spouses as specified in the Continuing Appropriations and Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2017, and Zika Response and Preparedness Act to the extent such services are consistent with the services available to enrolled veterans under the medical benefits package.

DATES: *Effective Date:* This rule is effective on January 19, 2017.

Comment date: Comments must be received on or before March 20, 2017.

ADDRESSES: Written comments may be submitted by email through <http://www.regulations.gov>; by mail or hand-delivery to Director, Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; or by fax to (202) 273-9026. (This is not a toll-free number.) Comments should indicate that they are submitted in response to “RIN 2900AP94—Fertility Counseling and Treatment for Certain Veterans and Spouses.” Copies of comments received will be available for public inspection in the Office of Regulation Policy and

Management, Room 1068, between the hours of 8:00 a.m. and 4:30 p.m. Monday through Friday (except holidays). Please call (202) 461-4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Patricia M. Hayes, Ph.D., Chief Consultant, Women's Health Services, Patient Care Services, Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Ave. NW., Washington, DC 20420. (202) 461-0373. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Section 260 of the Continuing Appropriations and Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2017, and Zika Response and Preparedness Act (Public Law 114-223) states that VA may use appropriated funds available to VA for the Medical Services account to provide fertility counseling and treatment using assisted reproductive technology (ART) to a covered veteran or the spouse of a covered veteran, or adoption reimbursement to a covered veteran. This rulemaking expands the types of ART treatment available to certain veterans and makes fertility counseling and treatment including ART treatment available to spouses of those veterans, consistent with this statutory authority. Reimbursement of adoption expenses will be the subject of a separate rulemaking.

According to this law, Veterans who will receive this benefit are those with a service-connected disability that results in the inability of the veteran to procreate without the use of fertility treatment. The ART treatments referred to in this law are those relating to reproductive assistance provided to a member of the Armed Forces who incurs a serious injury or illness on active duty pursuant to title 10 of the United States Code (U.S.C.) section 1074(c)(4)(A), as described in a policy memorandum issued by the Assistant Secretary of Defense for Health Affairs on April 3, 2012, titled “Policy for Assisted Reproductive Services for the Benefit of Seriously or Severely Ill/Injured (Category II or III) Active Duty Service Members,” and the guidance issued to implement such policy, including any limitations on the amount of such benefits available to such a member. See Public Law 114-223, section 260(b)(2) and (3). The implementing guidance is contained in a document attached to the policy

memorandum. We will refer to the April 3, 2012, policy memorandum and guidance issued by the Department of Defense (DoD) to implement that policy collectively as DoD policy guidance. DoD has established a system for categorizing injured servicemembers for purposes of coordinating care. Those in Category II have a serious injury or illness, are unlikely to return to duty within a time specified by their Military Department, and may be medically separated from the military.

Servicemembers in Category III have a severe or catastrophic injury or illness, are highly unlikely to return to duty, and will most likely be medically separated from the military.

ART is defined at Public Law 114-223, section 260(b)(3) to mean the benefits relating to reproductive assistance in DoD policy guidance, including any limitations on the amount of such benefits in that policy. DoD policy guidance addresses assisted reproductive services available to servicemembers, providing specific guidance on the availability of IVF, as well as a wide range of services that VA considers as fertility treatment. Under this statute, VA is authorized to provide ART benefits, consistent with DoD policy guidance, to a veteran with a service-connected disability that results in the inability of the veteran to procreate without the use of fertility treatment, as well as the spouse of that veteran. The conference report accompanying this legislation makes clear that the implementing guidance developed by the Secretary shall not be materially different from, and in no way more expansive than, DoD's policy. Joint Explanatory Statement. 162 Congressional Record at S6011 (2016).

The Veterans' Health Care Eligibility Reform Act of 1996, Public Law 104-262, mandated that VA implement a national enrollment system to manage the delivery of healthcare services. A key component of managing delivery of healthcare services to eligible veterans is identifying the medical services provided by VA. The medical benefits package, defining the medical services provided to all enrolled veterans by VA, is found at 38 CFR 17.38. VA may provide services under the medical benefits package that are determined by appropriate healthcare professionals to be needed to promote, preserve, or restore the health of the individual and to be in accord with generally accepted standards of medical practice.

As part of the medical benefits package, VA provides many different types of fertility treatments and procedures to veterans. These include infertility counseling, laboratory blood

testing, surgical correction of structural pathology, reversal of a vasectomy or tubal ligation, medication, and various other diagnostic studies or treatments and procedures. This list is not all-inclusive. Most of the ART evaluation and treatment modalities offered by VA are consistent with DoD policy guidance. The exception is IVF. DoD offers IVF to servicemembers who have sustained serious or severe illness/injury while on active duty that led to the loss of their natural procreative ability, while IVF is excluded from VA's medical benefits package under § 17.38(c)(2). IVF is the process of fertilization by manually fertilizing an egg, and then transferring the embryo to the uterus. IVF is a common and medically accepted procedure for addressing infertility that cannot be overcome with other types of infertility treatment. Although we are not revising the medical benefits package itself, we are revising paragraph (c)(2) to add a note referencing the benefit available in § 17.380, as discussed below. We believe that this clarification will help veterans better understand the benefits available from VA.

Pursuant to Public Law 114–223 section 260, VA is adding new § 17.380 which states that IVF may be provided when clinically appropriate to a veteran who has a service-connected disability that results in the inability of the veteran to procreate without the use of fertility treatment, as well as a spouse of such veteran. Per 38 U.S.C. 101(2), the term veteran means a person who served in the active military, naval, or air service, and who was discharged or released therefrom under conditions other than dishonorable. Under this provision, IVF services available to such veterans are the same as those provided by DoD to a member of the Armed Forces who incurs a serious injury or illness on active duty pursuant to 10 U.S.C. 1074(c)(4)(A), as described in DoD policy guidance, including any limitations on the amount of such benefits available to such a member. For the purposes of this section, “a service-connected disability that results in the inability of the veteran to procreate without the use of fertility treatment” means, for a male veteran, a service-connected injury or illness that prevents the successful delivery of sperm to an egg; and, for a female veteran with ovarian function and a patent uterine cavity, a service-connected injury or illness that prevents the egg from being successfully fertilized by a sperm. This definition parallels requirements in DoD policy guidance for an active duty service member who is seriously or

severely ill/injured (Category II or III) to receive fertility counseling and treatment using ART. Public Law 114–223 provides appropriations for FY 2017. The benefits authorized under section 260 are thereby limited to FY2017. Paragraph (b) of § 17.380 states that the authority to provide IVF to covered veterans under this section expires September 30, 2017. If the authority is extended, we will amend this section accordingly.

In addition, VA adds a new § 17.412. This new section states that VA may provide fertility counseling and treatment using ART to a spouse of a veteran with a service-connected disability that results in the inability of the veteran to procreate without the use of fertility treatment to the extent such services are available to enrolled veterans under the medical benefits package. It also states that VA may provide IVF to a spouse of a veteran with a service-connected disability that results in the inability of the veteran to procreate without the use of fertility treatment. Such health care services may be provided when clinically appropriate and consistent with the benefits relating to reproductive assistance provided to a member of the Armed Forces who incurs a serious injury or illness on active duty as described in DoD policy guidance.

Paragraph (b) states that authority to provide fertility counseling and treatment including IVF to spouses of covered veterans under this section expires September 30, 2017. If the authority is extended we will amend this section accordingly.

DoD policy guidance addresses various issues including eligibility for ART, testing to predict fertility potential, infertility testing and treatment (including correction of the physical cause of infertility), provisions on the total number of IVF cycles that may be provided, and required processes and procedures. VA intends to issue policy and develop clinical guidelines consistent with DoD policy guidance.

Finally, we also revise the center heading immediately preceding § 17.410 to read “Hospital Care and Medical Services for Spouses and Families.” VA provides medical care to certain families of Camp Lejeune veterans under § 17.410, and the center heading referred to those services. The current rulemaking adds a new section immediately following § 17.410, and VA believes the center heading should be revised to avoid any confusion.

Administrative Procedure Act

In accordance with U.S.C. 553(b)(B) and (d)(3), the Secretary of Veterans Affairs has concluded that there is good cause to publish this rule as an interim final rule without prior opportunity for public comment and to publish this rule with an immediate effective date. As stated above, this rule makes IVF treatment available to certain veterans, and fertility counseling and treatment using ART to the spouses of those veterans. The Secretary finds that it is impracticable and contrary to the public interest to delay this rule for the purpose of soliciting advance public comment or to have a delayed effective date. This rulemaking will benefit those veterans and spouses most in need of ART services including IVF, and delay might cause a significant hardship for affected veterans and spouses. The Joint Theater Trauma Registry (JTTR) reflects the most common single cause of battle injuries is explosive devices (36.3%). Such trauma frequently results in genitourinary injury. For example, 1 in 5 warriors were evacuated from Operation Enduring Freedom (OEF) combat in October 2011 with a genitourinary injury. This increasingly common trauma can have catastrophic reproductive results. While the JTTR tracks combat trauma only for OEF and Operation Iraqi Freedom, genitourinary or spinal cord injury, or pelvic trauma related to combat injuries was also common in previous combat operations, and these injuries may make it impossible for affected veterans to procreate without the use of fertility treatment. In many cases ART, including IVF, is the only viable option for procreation. Further, since age is a factor in successful fertilization and completion of a pregnancy, rulemaking delay may result in some veterans or spouses losing fertility potential prior to a later effective date. In addition, this rulemaking will ensure that covered veterans leaving service at this time, and their spouses, will experience continuity of care when transferring from health care provided by DoD to that provided by VA, with no difference in the level or types of available ART. For the above reason, the Secretary issues this rule as an interim final rule. VA will consider and address comments that are received within 60 days of the date this interim final rule is published in the **Federal Register**.

Effect of Rulemaking

Title 38 of the Code of Federal Regulations, as revised by this final rulemaking, represents VA's implementation of its legal authority on

this subject. Other than future amendments to this regulation or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent VA guidance must be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

Paperwork Reduction Act

This interim final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this interim final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This interim final rule will directly affect only individuals and will not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Order 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action,” requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, as “any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of

recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive Order.”

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866. VA’s impact analysis can be found as a supporting document at <http://www.regulations.gov>, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA’s Web site at <http://www.va.gov/orpm/>, by following the link for “VA Regulations Published From FY 2004 Through Fiscal Year to Date.”

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This interim final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care; and 64.024, VA Homeless Providers Grant and Per Diem Program.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Government contracts, Grant programs—health, Grant programs—veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and Dental schools, Medical devices, Medical research,

Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Travel and transportation expenses, Veterans.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrisee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on December 23, 2016, for publication.

Janet Coleman,

Chief, Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

For the reasons set out in the preamble, VA amends 38 CFR part 17 as follows:

PART 17—MEDICAL

■ 1. The authority citation for part 17 is revised to read as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

Section 17.38 also issued under 38 U.S.C. 101, 501, 1701, 1705, 1710, 1710A, 1721, 1722, 1782, and 1786.

Sections 17.380 and 17.412 are also issued under sec. 260, Pub. L. 114–223, 130 Stat. 857.

Section 17.415 is also issued under 38 U.S.C. 7301, 7304, 7402, and 7403.

Sections 17.640 and 17.647 are also issued under sec. 4, Pub. L. 114–2, 129 Stat. 30.

Sections 17.641 through 17.646 are also issued under 38 U.S.C. 501(a) and sec. 4, Pub. L. 114–2, 129 Stat. 30.

■ 2. Amend § 17.38 by:

■ a. Revising paragraph (c)(2).

■ b. Removing the sectional authority citation.

The revision reads as follows:

§ 17.38 Medical benefits package.

* * * * *

(c) * * *

(2) In vitro fertilization. Note: See § 17.380.

* * * * *

■ 3. Add an undesignated center heading and § 17.380 to read as follows:

In Vitro Fertilization Treatment

§ 17.380 In vitro fertilization treatment.

(a)(1) In vitro fertilization may be provided when clinically appropriate to—

(i) A veteran who has a service-connected disability that results in the inability of the veteran to procreate without the use of fertility treatment; and,

(ii) The spouse of such veteran, as provided in § 17.412.

(2) For the purposes of this section, “a service-connected disability that results in the inability of the veteran to procreate without the use of fertility treatment” means, for a male veteran, a service-connected injury or illness that prevents the successful delivery of sperm to an egg; and, for a female veteran with ovarian function and a patent uterine cavity, a service-connected injury or illness that prevents the egg from being successfully fertilized by sperm.

(3) In vitro fertilization treatment will be provided under this section when clinically appropriate and to the same extent such treatment is provided to a member of the Armed Forces who incurs a serious injury or illness on active duty pursuant to 10 U.S.C. 1074(c)(4)(A), as described in the April 3, 2012, memorandum issued by the Assistant Secretary of Defense for Health Affairs on the subject of “Policy for Assisted Reproductive Services for the Benefit of Seriously or Severely Ill/Injured (Category II or III) Active Duty Service Members,” and the guidance issued by the Department of Defense to implement such policy, including any limitations on the amount of such benefits available to such a member.

(b) Authority to provide in vitro fertilization treatment to covered veterans under this section expires September 30, 2017.

■ 4. Revise the undesignated center heading immediately preceding § 17.410 to read as follows:

Hospital Care and Medical Services for Spouses and Families

■ 5. Add § 17.412 to read as follows:

§ 17.412 Fertility counseling and treatment for certain spouses.

(a)(1) VA may provide fertility counseling and treatment to a spouse of a veteran described in § 17.380 to the extent such services are available to a veteran under § 17.38, and consistent with the benefits relating to reproductive assistance provided to a member of the Armed Forces who incurs a serious injury or illness on active duty pursuant to 10 U.S.C. 1074(c)(4)(A), as described in the April 3, 2012, memorandum issued by the Assistant Secretary of Defense for Health Affairs on the subject of “Policy for Assisted Reproductive Services for the Benefit of Seriously or Severely Ill/Injured (Category II or III) Active Duty Service Members,” and the guidance issued by the Department of Defense to implement such policy, including any

limitations on the amount of such benefits available to such a member.

(2) VA may provide in vitro fertilization to a spouse of a veteran described in § 17.380 when clinically appropriate and consistent with the benefits relating to reproductive assistance provided to a member of the Armed Forces who incurs a serious injury or illness on active duty pursuant to 10 U.S.C. 1074(c)(4)(A), as described in the April 3, 2012, memorandum issued by the Assistant Secretary of Defense for Health Affairs on the subject of “Policy for Assisted Reproductive Services for the Benefit of Seriously or Severely Ill/Injured (Category II or III) Active Duty Service Members,” and the guidance issued by the Department of Defense to implement such policy, including any limitations on the amount of such benefits available to such a member.

(b) Authority to provide fertility counseling and treatment, including in vitro fertilization under this section, expires September 30, 2017.

[FR Doc. 2017–00280 Filed 1–18–17; 8:45 am]

BILLING CODE 8320–01–P

POSTAL SERVICE

39 CFR Part 233

Inspection Service Authority; Civil Monetary Penalty Inflation Adjustment

AGENCY: Postal Service.

ACTION: Interim final rule.

SUMMARY: This rule updates postal regulations to implement the annual inflation adjustments to civil monetary penalties that may be imposed under consumer protection and mailability provisions enforced by the Postal Service pursuant to the Deceptive Mail Prevention and Enforcement Act and the Postal Accountability and Enhancement Act. These adjustments are required under the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. This notice also includes the statutory civil monetary penalties subject to the 2015 Act.

DATES: *Effective date:* January 19, 2017.

FOR FURTHER INFORMATION CONTACT: Steven Sultan, (202) 268–7385.

SUPPLEMENTARY INFORMATION: The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (2015 Act), Public Law 114–74, 129 Stat. 584, amended the Federal Civil Penalties Inflation Adjustment Act of

1990 (1990 Act), Public Law 101–410, 104 Stat. 890 (28 U.S.C. 2461 note), to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. Section 3 of the 1990 Act specifically includes the Postal Service in the definition of “agency” subject to its provisions.

Beginning in 2017, the 2015 Act requires the Postal Service to make an annual adjustment for inflation to civil penalties that meet the definition of “civil monetary penalty” under the 1990 Act. The Postal Service must make the annual adjustment for inflation and publish the adjustment in the **Federal Register** by January 15. Each penalty will be adjusted as instructed by the Office of Management and Budget (OMB) based on the Consumer Price Index (CPI-U) from the most recent October. OMB has furnished detailed instructions regarding the annual adjustment for 2017 in memorandum M–17–11, *Implementation of the 2017 Annual Adjustment Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015* (December 16, 2016), https://www.whitehouse.gov/sites/default/files/omb/memoranda/2017/m-17-11_0.pdf. This year, OMB has advised that an adjustment multiplier of 1.01636 will be used. The new penalty amount must be rounded to the nearest dollar.

The 2015 Act allows the interim final rule and annual inflation adjustments to be published without prior public notice or opportunity for public comment.

Adjustments to Postal Service Civil Monetary Penalties

Civil monetary penalties may be assessed for postal offenses under sections 106 and 108 of the Deceptive Mail Prevention and Enforcement Act, Public Law 106–168, 113 Stat. 1811, 1814 (*see*, 39 U.S.C. 3012(a), (c)(1), (d), and 3017(g)(2), (h)(1)(A)); and section 1008 of the Postal Accountability and Enhancement Act, Public Law 109–435, 120 Stat. 3259–3261 (*see*, 39 U.S.C. 3018 (c)(1)(A)). The statutory civil monetary penalties subject to the 2015 Act and the amount of each penalty the annual adjustment for inflation are as follows:

39 U.S.C. 3012(a)—False Representations and Lottery Orders

Under 39 U.S.C. 3005(a)(1)–(3), the Postal Service may issue administrative orders prohibiting persons from using the mail to obtain money through false representations or lotteries. Persons who evade, attempt to evade, or fail to comply with an order to stop such prohibited practices may be liable to the United States for a civil penalty under

39 U.S.C. 3012(a). This section currently imposes a \$68,345 penalty for each mailing less than 50,000 pieces, \$136,689 for each mailing of 50,000 to 100,000 pieces, and \$13,669 for each additional 10,000 pieces above 100,000 not to exceed \$2,733,780. The new penalties will be as follows: \$69,463 for each mailing less than 50,000 pieces, \$138,925 for each mailing of 50,000 to 100,000 pieces, and \$13,893 for each additional 10,000 pieces above 100,000 not to exceed \$2,778,505.

39 U.S.C. 3012(c)(1)—False Representation and Lottery Penalties in Lieu of or as Part of an Order

In lieu of or as part of an order issued under 39 U.S.C. 3005(a)(1)–(3), the Postal Service may assess a civil penalty. Currently, the amount of this penalty, set in 39 U.S.C. 3012(c)(1), is \$34,172 for each mailing that is less than 50,000 pieces, \$68,345 for each mailing of 50,000 to 100,000 pieces, and an additional \$6,834 for each additional 10,000 pieces above 100,000 not to exceed \$1,366,890. The new penalties will be: \$34,731 for each mailing that is less than 50,000 pieces, \$69,463 for each mailing of 50,000 to 100,000 pieces, and an additional \$6,946 for each additional 10,000 pieces above 100,000 not to exceed \$1,389,252.

39 U.S.C. 3012(d)—Misleading References to the United States Government; Sweepstakes and Deceptive Mailings

Persons sending certain deceptive mail matter described in 39 U.S.C. 3001(h)–(k), including:

- Solicitations making false claims of Federal Government connection or approval;
- Certain solicitations for the purchase of a product or service that may be obtained without cost from the Federal Government;
- Solicitations containing improperly prepared “facsimile checks”; and
- Certain solicitations for “skill contests” and “sweepstakes” sent to individuals who, in accordance with 39 U.S.C. 3017(d), have requested that such materials not be mailed to them); may be liable to the United States for a civil penalty under 39 U.S.C. 3012(d). Currently, this penalty is not to exceed \$13,669 for each mailing. The new penalty will be \$13,893.

39 U.S.C. 3017(g)(2)—Commercial Use of Lists of Persons Electing Not To Receive Skill Contest or Sweepstakes Mailings

Under 39 U.S.C. 3017(g)(2), the Postal Service may impose a civil penalty against a person who provides

information for commercial use about individuals who, in accordance with 39 U.S.C. 3017(d), have elected not to receive certain sweepstakes and contest information. Currently, this civil penalty may not exceed \$2,733,780 per violation. The new penalty may not exceed \$2,778,505 per violation.

39 U.S.C. 3017(h)(1)(A)—Reckless Mailing of Skill Contest or Sweepstakes Matter

Currently, under 39 U.S.C. 3017(h)(1)(A), any promoter who recklessly mails nonmailable skill contest or sweepstakes matter may be liable to the United States in the amount of \$13,669 per violation for each mailing to an individual. The new penalty is \$13,893 per violation.

39 U.S.C. 3018(c)(1)(A)—Hazardous Material

Under 39 U.S.C. 3018(c)(1)(A), the Postal Service may impose a civil penalty payable into the Treasury of the United States on a person who knowingly mails nonmailable hazardous materials or fails to follow postal laws on mailing hazardous materials. Currently, this civil penalty is at least \$295, but not more than \$117,858 for each violation. The new penalty is at least \$300, but not more than \$119,786 for each violation.

List of Subjects in 39 CFR Part 233

Administrative practice and procedure, Banks, Banking, Credit, Crime, Infants and children, Law enforcement, Penalties, Privacy, Seizures and forfeitures.

For the reasons set out in this document, the Postal Service amends 39 CFR part 233 as follows:

PART 233—INSPECTION SERVICE AUTHORITY

- 1. The authority citation for 39 CFR part 233 continues to read as follows:

Authority: 39 U.S.C. 101, 102, 202, 204, 401, 402, 403, 404, 406, 410, 411, 1003, 3005, 3012, 3017, 3018; 12 U.S.C. 3401–3422; 18 U.S.C. 981, 983, 1956, 1957, 2254, 3061; 21 U.S.C. 881; Pub. L. 101–410, 104 Stat. 890; Omnibus Budget Reconciliation Act of 1996, sec. 662 (Pub. L. 104–208, 110 Stat. 3009–378); Pub. L. 106–168, 113 Stat. 1806; Pub. L. 114–74, 129 Stat. 584.

- 2. In § 233.12(a), remove “\$68,345” and add in its place “\$69,463”; remove “\$136,689” and add in its place “\$138,925”; remove “\$13,669” and add in its place “\$13,893”; remove “each piece above 100,000” and add in its place “each additional 10,000 pieces above 100,000”; remove “\$2,733,780” and add in its place “\$2,778,505”.

- 3. In § 233.12(b), remove “\$34,172” and add in its place “\$34,731”; remove “\$68,345” and add in its place “\$69,463”; remove “\$6,834” and add in its place “\$6,946”; remove “every” and add in its place “each”; remove “\$1,366,890” and add in its place “\$1,389,252”.

- 4. In § 233.12(c)(4), remove “\$13,669” and add in its place “\$13,893”.

- 5. In § 233.12(d), remove “\$2,733,780” and add in its place “\$2,778,505”.

- 6. In § 233.12(e), remove “\$13,669” and add in its place “\$13,893”.

- 7. In § 233.12(f), remove “\$295” and add in its place “\$300”; remove “\$117,858” and add in its place “\$119,786”.

Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2017–00204 Filed 1–18–17; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA–HQ–OPPT–2016–0207; FRL–9958–20]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances; Withdrawal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Partial withdrawal of direct final rule.

SUMMARY: EPA is withdrawing significant new use rules (SNURs) promulgated under the Toxic Substances Control Act (TSCA) for two chemical substances, which were the subject of premanufacture notices (PMNs). EPA published these SNURs using direct final rulemaking procedures, which requires EPA to take certain actions if a notice of intent to submit an adverse comment is received. EPA received notices of intent to submit adverse comments regarding the SNURs identified in this document. Therefore, the Agency is withdrawing the direct final rule SNURs identified in this document, as required under the direct final rulemaking procedures.

DATES: This document is effective January 19, 2017.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2016–0207, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency

Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Kenneth Moss, Chemical Control Division (7405M) Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: moss.kenneth@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave. Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

A list of potentially affected entities is provided in the **Federal Register** of November 17, 2015 (81 FR 1250) (FRL-9953-41). If you have questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

II. What direct final SNURs are being withdrawn?

In the **Federal Register** of November 17, 2015 (81 FR 1250), EPA issued direct final SNURs for the chemical substances that are identified in this document. These direct final SNURs were issued under the procedures in 40 CFR part 721, subpart D. Because the Agency received notices of intent to submit adverse comments, in accordance with § 721.160(c)(3)(ii), EPA is withdrawing the direct final SNURs issued for the following chemical substances, which were the subject of PMNs: bimodal mixture consisting of multi-walled carbon nanotubes and other classes of carbon nanotubes (generic), (PMN No. P-11-482); and carbon nanotubes (generic), (PMN No. P-15-54). EPA intends to publish proposed SNURs for the chemical substances identified in this document.

For further information regarding EPA's direct final rulemaking procedures for issuing SNURs, see 40 CFR part 721, subpart D, and the

Federal Register of July 27, 1989 (54 FR 31314).

III. Statutory and Executive Order Reviews

This action withdraws regulatory requirements that have not gone into effect and which contain no new or amended requirements. As such, the Agency has determined that this action will not have any adverse impacts, economic or otherwise. The statutory and Executive Order review requirements applicable to the direct final rule were discussed in the **Federal Register** of November 17, 2015 (81 FR 1250) (FRL-9953-41). Those review requirements do not apply to this action because it is a withdrawal and does not contain any new or amended requirements.

IV. Congressional Review Act (CRA)

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 9

Environmental protection, Reporting and recordkeeping requirements.

40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: January 9, 2017.

Maria J. Doa,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, 40 CFR chapter I is amended as follows:

PART 9—[AMENDED]

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300j-2, 300j-3, 300j-4, 300j-9, 1857 *et seq.*, 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

§ 9.1 [Amended]

■ 2. In the table in § 9.1, under the undesignated center heading

"Significant New Uses of Chemical Substances," remove the entries for §§ 721.10927 and 721.10942.

PART 721—[AMENDED]

■ 3. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

§ 721.10927 [Removed]

■ 4. Remove § 721.10927.

§ 721.10942 [Removed]

■ 5. Remove § 721.10942.

[FR Doc. 2017-00938 Filed 1-18-17; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. CDC-2015-0006]

42 CFR Part 73

RIN 0920-AA59

Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review of the List of Select Agents and Toxins and Enhanced Biosafety Requirements

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: In accordance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Response Act), the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) has reviewed the list of biological agents and toxins that have the potential to pose a severe threat to public health and safety. Following the review, HHS has decided: Not to finalize the proposed changes to the list of select agents and toxins at this time; to finalize provisions to address toxin permissible limits and the inactivation of select agents; to finalize specific provisions to the section of the regulations addressing biosafety; and to clarify regulatory language concerning security, training, incident response, and records. In a companion document published in this issue of the **Federal Register**, the U.S. Department of Agriculture (USDA) has made parallel regulatory changes.

DATES: Effective February 21, 2017.

FOR FURTHER INFORMATION CONTACT: Dr. Samuel S. Edwin, Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600

Clifton Road NE., MS-A46, Atlanta, Georgia 30329. Telephone: (404) 718-2000.

SUPPLEMENTARY INFORMATION: The preamble to this final rule is organized as follows:

- I. Executive Summary
- II. Changes to 42 CFR Part 73
 - A. Modifications to the List of HHS and Overlap Select Agents and Toxins
 - B. Responses to Other Proposed Changes
 - i. Definitions
 - ii. Inactivation of a Select Agent
 - iii. Toxins
 - iv. Exclusion Involving Patient Care
 - v. Exemptions for Select Agents and Toxins
 - vi. Registration
 - vii. Responsible Official
 - viii. Visitor Access to Select Agents and Toxins
 - ix. Security, Biosafety, and Incident Response Plans
 - x. Training
 - xi. Records
- III. Alternatives Considered
- IV. Required Regulatory Analyses
 - A. Executive Orders 12866 and 13563
 - B. The Regulatory Flexibility Act
 - C. Paperwork Reduction Act of 1995
 - D. E.O. 12988: Civil Justice Reform
 - E. E.O. 13132: Federalism
 - F. Plain Language Act of 2010
- V. References

I. Executive Summary

On February 27, 2015 we published an Advance Notice of Proposed Rulemaking (ANPRM) (80 FR 10656) that initiated the required biennial review and republication of the HHS list of select agents and toxins. The ANPRM solicited public comments regarding whether any biological agents and toxins should be added or removed from the HHS list of select agents and toxins based on the following criteria:

- (1) The effect on human health of exposure to the agent or toxin;
- (2) The degree of contagiousness of the agent or toxin, and the methods by which the agent or toxin is transferred to humans;
- (3) The availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or exposure to the toxin; and
- (4) Any other criteria, including the needs of children and other vulnerable populations that the commenter considered appropriate.

This notice also asked for public comment on whether HHS should remove the following agents from the HHS list of select agents and toxins: *Coxiella burnetii*, *Rickettsia prowazekii*, *Bacillus anthracis* Pasteur, *Brucella abortus*, *B. melitensis*, and *B. suis*.

On January 19, 2016, we published a Notice of Proposed Rulemaking (NPRM)

(81 FR 2805). The NPRM solicited public comments regarding whether any biological agents and toxins should be added or removed from the HHS list of select agents and toxins based on the same criteria used in ANPRM:

We also invited comments on the following:

(1) Methods that should be required to validate the rendering of a select agent non-viable or regulated nucleic acids that can produce infectious forms of any select agent virus as non-infectious;

(2) Proposed changes to the aggregate amount of toxin excluded from the requirements of the select agent regulations;

(3) Removal of Diacetoxyscirpenol (DAS) and T-2 from the list;

(4) Whether seven calendar days provides a sufficient amount of time for the entity to destroy or transfer a select agent or toxin after identification;

(5) Specific biosafety measures that should be required to prevent laboratory acquired infections (LAIs) or accidental release of the select agents and toxins from an entity into the community; and

(6) Alternative regulatory requirements that could be constructed such that a registered entity would know whether it had a theft or loss of a select agent or toxin without that registered entity first having “an accurate, current inventory for each select agent . . . held in long term storage.”

(7) Whether short, paralytic alpha-conotoxins containing the following amino acid sequence (X₁CCX₂PACGX₃X₄X₅X₆CX₇), *C. burnetii*, *R. prowazekii*, *B. anthracis* Pasteur, *B. abortus*, *B. melitensis*, and *B. suis* should be removed from the HHS list of select agents and toxins.

We received 22 public comments to the ANPRM and 35 public comments to the NPRM that addressed the composition of the HHS list of select agents and toxins. After carefully considering the technical input of subject matter experts, both within the Federal government and from public comments, and recommendations from Federal advisory groups, we have decided not to finalize the proposed changes to the list of select agents and toxins at this time. Upon further consideration, we may decide to finalize changes to the list at a future time.

This final rule makes the following changes to current regulations:

1. New provisions regarding the inactivation of select agents, specific biosafety requirements, and toxin requirements;
2. Other revisions to the regulations to clarify regulatory language concerning security, training, and records.

3. In addition, when HHS added *B. cereus* Biovar *anthracis* to the list of HHS select agents and toxins on September 14, 2016 by an interim final rule (81 FR 63138), we neglected to add the name of the agent to the immediate notification list for Tier 1 agents in sections 5 and 9 of the regulations. We are correcting that error in this final rule.

Costs of the Rule: The entities affected by this final rule include research and diagnostic facilities; Federal, State, and university laboratories; and private commercial and non-profit enterprises. The current regulations require registering for the possession, use, and transfer of select agents or toxins. In addition, the entity is currently required to ensure that the facility where the agent or toxin is housed has adequate biosafety and containment measures; that the physical security of the premises is adequate to prevent unauthorized access; that all individuals with approved access to select agents or toxins have the appropriate education, training, and/or experience to handle such agents or toxins; and that complete records concerning activities related to the select agents or toxins are maintained.

The HHS final rule will further reduce or minimize the risk of misuse of select agents and toxins that have the potential to pose a severe threat to human health. HHS recognizes that several of the required measures of the regulations may impose certain operational costs upon affected entities. Specifically, the rule will clarify that an entity must use a validated method to render a select agent non-viable or a regulated infectious nucleic acid sample non-infectious for future use. This means the method must be scientifically sound and produce consistent results each time it is used. Appropriate reporting and record keeping is required in order to mitigate threats to human health. In many cases, however, the affected entities already employ some or all of the required measures. Compliance costs actually incurred will therefore vary from one entity to the next.

While information on the specific changes that would need to occur at individual sites and the associated costs was not readily available during proposed rulemaking, some general observations regarding the potential costs were presented. These general cost observations can be found in the Regulatory Impact Analysis. Based on the current recordkeeping and reporting requirements, an additional 10 to 20 hours per year may be required by entities. At an imputed cost of \$33.40 per hour, this additional time

requirement per entity will total between \$334 and \$668 per year, or in total for all registered entities between \$80,000 and \$160,000.

Benefits: The objectives of the HHS final rule are to create a means of ensuring enhanced oversight in the transfer, storage, and use of select agents and toxins; clarify that an entity must use a validated method to render a select agent non-viable or a regulated

infectious nucleic acid sample non-infectious for future use; and require that entities in possession of such agents and toxins develop and implement effective means of biosafety, information security, and physical security. The overall benefit of the amended regulatory provisions will be a reduced likelihood of the accidental or intentional release of a select agent or

toxin; and the avoidance of human morbidity, mortality and the economic loss associated with such a release. The goal of the amended regulations is to enhance the protection of human health and safety.

II. Changes to 42 CFR Part 73

The table below describes the changes to the current regulation.

| Section No. | Section title | Change |
|-------------|--|---|
| 73.0 | Applicability and related requirements | No changes. |
| 73.1 | Definitions | Adds definitions: Validated inactivation procedure and viability testing protocol. |
| 73.2 | Purpose and scope | No changes. |
| 73.3 | HHS select agents and toxins | Clarifies language to include addition of <i>B. cereus</i> Biovar <i>anthracis</i> and adds new paragraphs. |
| 73.4 | Overlap select agents and toxins | Clarifies language to include addition of <i>B. cereus</i> Biovar <i>anthracis</i> and adds new paragraphs. |
| 73.5 | Exemptions for HHS select agents and toxins | Clarifies language; redesignates paragraph; and adds new paragraph. |
| 73.6 | Exemptions for overlap select agents and toxins | Clarifies language; redesignates paragraph; and adds new paragraph. |
| 73.7 | Registration and related security risk assessments | Redesignates paragraphs; adds new paragraph. |
| 73.8 | Denial, revocation, or suspension of registration | No changes. |
| 73.9 | Responsible Official | Clarifies language to include addition of <i>B. cereus</i> Biovar <i>anthracis</i> and adds new paragraphs. |
| 73.10 | Restricting access to select agents and toxins; security risk assessments. | Clarifies language. |
| 73.11 | Security | Clarifies language and adds new paragraph. |
| 73.12 | Biosafety | Clarifies language. |
| 73.13 | Restricted experiments | No changes. |
| 73.14 | Incident response | Clarifies language. |
| 73.15 | Training | Clarifies language and adds new paragraph. |
| 73.16 | Transfers | Clarifies language. |
| 73.17 | Records | Clarifies language and adds new paragraph. |
| 73.18 | Inspections | No changes. |
| 73.19 | Notification of theft, loss, or release | No changes. |
| 73.20 | Administrative review | No changes. |
| 73.21 | Civil money penalties | No changes. |

A. Modifications to the List of HHS and Overlap Select Agents and Toxins

We received 22 public comments to the ANPRM and 35 public comments to the NPRM that addressed the composition of the HHS list of select agents and toxins. After carefully considering the technical input of subject matter experts, both within the Federal government and from public comments, and recommendations from Federal advisory groups, we have decided not to finalize the proposed changes to the list of select agents and toxins at this time.

B. Responses to Other Proposed Changes

i. Definitions

It recently became clear that some inactivation protocols have failed to inactivate *B. anthracis* spores completely, as evidenced by inactivation failures that led to the inadvertent transfer of potentially live

B. anthracis samples by the Department of Defense in 2015. In response to this incident, new requirements were proposed to address the inactivation of select agents. We proposed adding definitions for the terms “inactivation” and “kill curve” to clarify the new inactivation provisions. As discussed below, we have removed the proposed requirement for a “kill curve,” and accordingly, we have also removed the proposed definition of “kill curve.”

To exclude a select agent or regulated nucleic acids that can produce infectious forms of any select agent virus from the requirements of the select agent regulations, an entity will need to subject the select agent or the nucleic acids to a validated inactivation procedure whose efficacy is confirmed through a viability testing protocol.

Commenters stated that additional definitions should be provided for “validated inactivation procedure,” “sterility testing protocol,” and “safety margin.” We agree with the commenters

and are defining the terms as described below. “Validated inactivation procedure” means “a procedure, whose efficacy is confirmed by data generated from a viability testing protocol, to render a select agent non-viable but allows the select agent to retain characteristics of interest for future use; or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use.”

Further, we have not included a separate definition for “inactivation” as it is now captured in the definition of “validated inactivation procedure.”

We have changed the proposed phrase “sterility testing protocol” to “viability testing protocol” and defined the latter as “a protocol to confirm the validated inactivation procedure by demonstrating the material is free of all viable select agent.” This change reflects the intent that the validated inactivation procedure, or the procedure for removal of viable select agents from material

containing select agents, must render the material non-viable (*i.e.*, unable to replicate). In addition, any nucleic acids that can produce infectious forms of any select agent virus must be rendered non-infectious for future use.

We are choosing to not define the term “safety margin” and have incorporated the concept of a performance standard instead.

The new definitions will help clarify the regulatory language found in 42 CFR 73.3, 73.4.

ii. Inactivation of a Select Agent

Historical inactivation failures by registered entities required us to focus on ways to increase the certainty that inactivated select agents intended for further use do not contain live agent. This is particularly important when the inactivation methods are tempered in order to avoid disrupting some of the physical characteristics of the agent. We proposed adding specific requirements to the exclusion sections of the regulations (42 CFR 73.3(d), 73.4(d)) to address the requirements for rendering select agents, nucleic acids that can produce infectious forms of any select agent virus, or extracts from select agents non-viable.

Sections 73.3(d)(2) (HHS select agents and toxins) and 73.4(d)(2) (Overlap select agents and toxins) both provide that a non-viable select agent is excluded from the requirements of the select agent regulations. We proposed that for a select agent to be non-viable or to render nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use, an entity must use a validated inactivation procedure. Commenters stated there is some confusion between inactivation validation requirements for moving materials to a lower containment level and inactivation validation requirements for waste disposal. We are clarifying that these provisions apply to a select agent that is inactivated for future use as a non-select agent and is not intended for material for waste disposal.

Many commenters stated that the focus on strengthening inactivation requirements was being driven by an incorrect public perception of recent procedural errors that occurred at federally run research laboratories. Without commenting on what is or might be the public's perception with regard to inactivation problems, we disagree with these comments because the focus on inactivation failures with select agents is based on the realization that past inactivation activities have proved to be inadequate.

We proposed that an entity would be required to develop a site-specific kill curve to identify conditions of inactivation for each select agent. Commenters stated that although the generation of kill curves is appropriate for inactivation procedures using heat, irradiation and filtration, it is not generally applicable to determining infectivity of nucleic acids. Commenters stated that for inactivation procedures where a “kill curve is not applicable, inactivation conditions are selected and then replicated to obtain 100% inactivation within a statistical certainty.”

We agree with the commenters and are withdrawing the proposal to require a kill curve and safety margin because these would not be applicable to all inactivation procedures. Further, the variety of agents and inactivation procedures makes it likely that prescriptive requirements would have unintended negative consequences on research. We are, nonetheless, finalizing requirements for a validated inactivation procedure and viability testing. We are requiring that for a select agent or regulated nucleic acid that can produce infectious forms of any select agent virus to be excluded from the requirements of the select agent regulations, an entity will be responsible for achieving a certain performance standard that is confirmed through a viability testing protocol. Surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactivation procedure. However, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains. Additional guidance regarding this performance standard has been developed and is available at www.selectagents.gov.

Many commenters asked HHS to state clearly if the standard for select agent inactivation is complete sterility (*i.e.*, not a single viable pathogen in the entire volume of an inactivated sample), a log reduction in viable pathogen titer, or the limit of detection of the assay. We agree that it is important to specify the intent of the performance standard. HHS recognizes the limits of detection of the viability testing procedures (related to the detection assay and the sampling of inactivated material) and expected run-to-run variation when following an inactivation procedure precisely precludes demonstrating full sterility of inactivated material. These sources of error must be considered when

establishing performance parameters for inactivation procedures. While complete sterility is not a feasible goal for material that is intended for further use, HHS expects that the risk of live agent in inactivated materials will be as low as realistically possible from both a safety and security perspective.

We proposed that entities subject representative samples of an inactivated select agent to a validated sterility testing protocol to ensure that the inactivation procedure has rendered the select agent non-viable. Commenters stated that it is not always practical to conduct validation on each sample that is inactivated. Often samples are in limited quantities and validation studies will leave very little or no sample for the experimental purpose. Commenters also stated that the requirement to subject representative samples to sterility testing using a validated protocol requires further clarification. Commenters stated that it is reasonable to require this type of testing when the inactivation procedure is first established and if any changes to the inactivation protocol are made. However, commenters stated that it cannot be reasonably done on each sample in laboratory research if the inactivation protocol has not changed. They stated that implementing such a requirement would waste specimens where limited volumes are available, would be costly in terms of technical time and resources, and is scientifically unjustified.

We agree with the commenters that the varied needs and conditions for inactivation preclude setting a specific standard for viability testing at this time. We have removed the proposed sterility testing requirement for select agents and nucleic acids that can produce infectious forms of any select agent virus and have incorporated this concept into the performance standard. The requirement to develop a validated inactivation procedure and subsequent validation data derived from viability testing will determine the extent of sampling required. This activity will provide the associated measures of uncertainty with the sampling protocol chosen.

We proposed adding exclusion requirements that extracts from a select agent could not be excluded from the requirements of the select agent regulations until an individual or entity met the following requirements: (1) Any extract is subjected to a process that removes all viable cells, spores, or virus particles; (2) any extract is subjected to a validated sterility testing protocol; (3) any viability of an extract that was subjected to a validated inactivation

protocol is reported to the Responsible Official (RO); and (4) any viability of a select agent or infectivity of regulated nucleic acids that can produce infectious forms of any select agent virus, previously assessed as inactive by their validated sterility testing protocol, is reported to APHIS or CDC.

Some commenters expressed concern with having to subject every extract from a select agent, such as nucleic acids, to sterility testing. We agree with the commenters and are replacing the term “extract” with “material containing a select agent” to clarify that the requirements apply to material containing a select agent such as serum or liquid culture where select agents are typically removed via filtration without a previous inactivation step. The term “extract” is commonly used in conjunction with nucleic acids extracted from a select agent. We are using the term “extract” in the final rule to reflect the application of two processing steps: An inactivation step to destroy the select agent (e.g., lysis of select agent) and then another step (such as filtration), to remove any remaining viable select agents. Extracts from a select agent (nucleic acids, antigens, lysates) would be subject to the performance standard for select agents in the new sections 3(d)(3) and 4(d)(3) of the select agent regulations that includes viability testing but does not necessarily require viability testing on every sample. The requirement to develop a validated inactivation procedure and subsequent validation data derived from viability testing will determine the extent of sampling required. However, material containing select agents, as opposed to extracts (e.g., nucleic acids, antigens, lysates), that is subjected to a process to remove all viable cells, spores, or virus particles would require viability testing on every sample prior to treating it as a non-select agent. The distinguishing feature between “material containing a select agent” and an extract from a select agent is that in the former the select agent will only be removed and in the latter the select agent will be destroyed before removal. The more stringent requirement for viability testing of all material containing a select agent where the select agent was removed is warranted because of the lack of select agent destruction which increases the risk of viable select agent remaining in the material.

We proposed that if there are strain-to-strain variations in resistance of a select agent to the inactivation procedure, then a specific kill curve must be developed for each strain that undergoes the inactivation procedure.

We received comments asking us to clarify language to specify under what circumstances strain-to-strain differences must be validated. Commenters also stated that this is an unnecessary use of resources especially when agents, based on their morphological characteristics, are susceptible to similar inactivating agents. Commenters suggested at a minimum the language should state that this requirement only applies when there are known strain-to-strain variations in resistance of a select agent to the inactivation procedure.

We agree with the commenters and added in the term “known” strain-to-strain variation and, as stated previously, have removed the kill curve requirement.

Commenters also inquired whether surrogate strains can be used to develop inactivation procedures. We agree with the commenters that surrogate strains known to possess equivalent properties with respect to inactivation as a select agent can be used to develop inactivation procedures. We have revised the requirement to include the provision that “Surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactivation procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.”

Commenters were concerned about performing viability testing on materials such as a single diagnostic sample that is determined to contain a select agent and where there is a limited amount of material with which to work. For example, consider an entity using a commercially available RNA extraction kit on a diagnostic sample to obtain RNA for sequencing, and the sample is identified to contain highly pathogenic avian influenza (HPAI). In this situation, the entire single sample would be used when trying to demonstrate that the inactivation procedure was effective. We agree with the commenters. As noted above, surrogate select agent strains that are known to possess equivalent properties with respect to inactivation as the select agent can be used to develop validated inactivation procedures. In this example, low pathogenic avian influenza (LPAI) could be used to validate the inactivation procedure for diagnostic samples that are identified as containing HPAI, if LPAI possesses equivalent properties with respect to inactivation as HPAI. In addition, we are clarifying that these

provisions do not apply to diagnostic samples until they are identified to contain a select agent and are inactivated for future use as a non-select agent.

Many commenters asked who would determine the validity of an inactivation protocol. The responsibility for this activity remains with the entity, which will allow for researchers to continue to develop new inactivation procedures. Entities retain the responsibility to evaluate their inactivation procedures, to include consideration of the biosafety and security risks posed by the inactivated material. The Federal Select Agent Program (FSAP) inspectors will verify that the entity has developed a validated inactivation procedure and may review validation data during an entity's inspection. We made no changes based on these comments.

Many commenters stated that the intent behind the annual review provisions was not clear. We agree with the commenters and modified the provisions to state that an entity “Review, and revise as necessary, each of the entity's validated inactivation procedures or viable agent removal method. The review must be conducted annually or after any change in Principal Investigator, change in the validated inactivation procedure or viable agent removal method, or failure of the validated inactivation procedure or viable agent removal method. The review must be documented and training must be conducted if there are any changes to the validated inactivation procedure, viable agent removal method, or viability testing protocol.” We made these changes because the annual review of an entity's validated inactivation procedures or viable agent removal method is key to a successful inactivation program. The annual review requirement does not necessarily involve revalidating inactivation procedures. This review could simply be the evaluation of the site-specific standard operating procedures for validated inactivation of select agents to ensure the inactivating conditions used and upper agent concentration limits found in validation data are consistent, and that entity staff are following the site-specific standard operating procedures for validated inactivation of select agents.

However, sometimes an entity will need to revalidate inactivation procedures during the annual review. For example, if the entity identifies that staff are not adhering to standard operating procedures for validated inactivation of select agents, or if the entity wants to deviate from the validated inactivation procedure, the

entity will need to revalidate the inactivation procedures during the annual review. Further, in this final rule, we have consolidated the review provisions into one provision, clarified that the reviews must be documented, and moved this provision into the requirements for the RO as they will be the individual responsible for these review activities.

Many commenters stated that the intent of the inactivation failure reporting requirements was not clear and reporting every inactivation failure to CDC or APHIS was burdensome. We agree with the commenters and have modified reporting requirements to require the RO to “Investigate to determine the reason for any failure of a validated inactivation procedure or any failure to remove viable agent from material. If the Responsible Official is unable to determine the cause of a deviation from a validated inactivation procedure or a viable agent removal method; or receives a report of any inactivation failure after the movement of material to another location, the Responsible Official must report immediately by telephone or email the inactivation failure or viable agent removal method failure to CDC or APHIS.” The intent of this modification is to create an environment at the entity where inactivation or select agent removal failures are investigated to determine the reason for the failure as opposed to merely re-subjecting the material to the inactivation or select agent removal method. It is the position of the FSAP that each failure represents either human error in conducting the validated procedure or an inadequate inactivation method or an inadequate select agent removal method if no human error can be discovered. Both situations demand careful attention by the entity to ensure training and/or reevaluation of the inactivation procedure in order to minimize the likelihood that the situation would reoccur in the future. The revised regulatory language only requires reporting of inactivation or select agent removal failures to FSAP when the RO cannot establish that the failure resulted from human error or when an entity receives a report of any inactivation failure after the movement of material to another location.

We also proposed that written records be kept for select agents that have been subjected to a procedure to render them non-viable, or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a procedure to render them incapable of producing infectious forms of any select agent virus. Some

commenters stated that the proposal was not clear how long these records must be kept and who is responsible for keeping these records. We made no changes based on these comments as these records are subject to the records retention requirement in section 17 of the select agent regulations and must be kept for three years by a registered individual or entity.

Some commenters asked about the conditions of submitting a waiver to the inactivation provisions of the select agent regulations. An entity may submit a request to FSAP to apply an alternative inactivation procedure. The entity is to provide justification regarding the alternative procedure including a description of what material is to be waived, the inactivation protocol and viability test to be used, validation data, and any other supporting information/references, such as scientific references. Accordingly, we revised the provision found in sections 3(d)(6) and 4(d)(6) to include information on how to apply for a waiver that reads “. . . To apply for such a determination a registered individual or entity must submit a written request and supporting scientific information to FSAP. A written decision granting or denying the request will be issued.” Additional guidance has been developed and is available at: www.selectagents.gov.

iii. Toxins

To ensure the language is consistent with the exclusion language found in 73.3(e) which describes the exclusion of toxins that have been modified to be *less* potent or toxic, we are making a technical change to the regulation and revising the terms “nonfunctional” toxin to “nontoxic” toxin and “functional form(s) of any of the toxins” to “toxic form(s) of any of the toxins.” This change is being made to clarify the intent of the regulations as the terms “nonfunctional” and “functional” are broad and have led to confusion. The intention behind the original provisions was to exclude toxins that can no longer exert their toxic effect and cause disease and regulate those that can. For example, Botulinum neurotoxin has three functional domains—binding domain, translocation domain and catalytic domain. Each functional domain solely can be manipulated such that the toxin is no longer toxic and does not cause diseases even though the other two domains may be functional.

Due Diligence

We are adding a more specific documentation requirement to the toxin exclusion provision found in section

73.3(d)(3)(i) of the select agent regulations to require the transferor of an unregulated amount of a select toxin to document the identity of the recipient and the legitimate need (*i.e.*, prophylactic, protective, bona fide research, or other peaceful purpose) claimed by the recipient. The name of the toxin and the total amount transferred must also be documented. Identity information of the person requesting and using the toxins must include the individual’s name, institution name, address, telephone number, and email address. We received one comment requesting to include language for transfers of toxins within an institution. We made no changes based on this comment because intra-entity transfers, where the sender and the recipient are covered by the same certificate of registration, are already addressed in section 17(3)(viii) of the regulations.

Toxin Permissible Limits

As proposed, we are increasing the toxin exclusion aggregate amounts. We received 10 comments supporting the increase in the toxin exclusion aggregate amounts. We received three general comments opposing the increase of the exclusion aggregate amounts and two additional comments opposing the increase of the ricin exclusion aggregate amount. One commenter stated that no changes were necessary. Another commenter had concerns regarding whether the risk assessment scenarios were relevant to the goal of reducing any significant harm able to be caused by illegitimate use of any lethal amounts of toxin. We are making no changes based on these comments.

DHS developed toxin parameters and attack scenarios for potential inhalation and ingestion exposures to select toxins to protect the homeland against the potential release of weaponized biological toxins. The DHS group analyzed a range of release sizes (in mg) for each select toxin in order to estimate the number of people that would be exposed to each toxin amount by ingestion of milk (using published TD[50] or LD[50]) and/or indoor inhalation (using published LD[50]). Revised toxin exclusion aggregate amounts were proposed based on the data generated by the models to expose <10 or <100 people by inhalation or ingestion to the LD[50] or TD[50] levels of toxin. A commenter stated that (1) the scenarios proposed appear to consider a high-consequence event or exposure to a given toxin and that the interpretation of what constitutes a high-consequence event or exposure is impacted not only in the number of people affected but in

the attention afforded by news media and the public and (2) a revision of these exclusion limits should also consider amounts that would be sufficient for research purposes. We are making no changes based on these comments because we do not believe the impact the news media may have if an exposure occurs is an appropriate consideration for the listing of a biological agent or toxin. Further, the consideration of amounts sufficient for research purposes is a subjective assessment as smaller academic laboratories have differing needs than an entity that is developing detection assays. The comments specific to ricin raised concerns that the increased exclusion aggregate amounts would increase the risk of (1) exposure to laboratory workers and (2) that individuals would have access to greater amounts of material to use for nefarious purposes. We are making no changes based on these comments. We do not agree that the increased permissible limits will increase the risk of laboratory worker exposure. The new proposed exclusion amount is less than an oral lethal dose for a single person weighing more than 50 kg, based on 20 mg/kg-body weight (Ref. 1), thus a single fatality would require consuming more than all of the ricin in the laboratory. Ricin does display a higher toxicity when administered intravenously or by inhalation, but these two routes of exposure require either injection or manipulation to generate particles capable of reaching the lower respiratory tract, respectively, two processes not likely to occur accidentally. Also, entities that produce ricin typically do so in liquid, as opposed to lyophilized powder formulations, thus decreasing the risk of ingestion or aerosol exposure. Additionally, the increased exclusion aggregate amounts would allow entities to more efficiently produce and store ricin preparations which are typically frozen in aliquots until the need to use the material arises. Finally, while increasing the permissible limits allows individuals with nefarious purposes access to greater amounts of toxin, we do not believe access to the revised amounts poses a severe threat to public health and safety based on the reasons stated above.

Toxins: Exclusion of an HHS Select Toxin Identified in an Original Food Samples and Clinical Samples

As proposed, we are excluding from the requirements of the regulations a select toxin identified in an original food sample and clinical samples. Original food samples and clinical

samples are those specimens that are submitted to laboratories for diagnosis or verification purposes to identify or verify a biological agent or toxin. For example, an original food sample could be a container of potato salad or juice. An original clinical sample could be serum or stool from a patient. Laboratories that test food and clinical samples for the presence of toxins generally do not know the level of toxin in a sample and do not extract and purify a toxin as part of their studies. Therefore, our proposal to exclude select toxin identified in an original food sample or clinical sample identified is consistent with the rationale for the current exclusion for animals exposed to toxins (42 CFR 73.3(d)(4)). This exclusion was based on recommendations by toxin subject matter experts. We received one comment that supported this exclusion.

Exclusion of Botulinum Neurotoxin Produced as a Byproduct

In the NPRM, we proposed to exclude all toxins that are only produced as a byproduct of a study of the toxin producing host organism so long as the toxin had not been intentionally collected, purified, or otherwise extracted, and the material containing the toxin was inactivated and properly disposed of within 30 days of the initiation of the culture. Based on the input from subject matter experts, the final regulatory language narrows the exception to only Botulinum neurotoxin produced as a byproduct in the study of Botulinum neurotoxin producing species of *Clostridium*. Work with that organism is already regulated, thus providing regulatory oversight of the material during the 30 day time frame, as opposed to an agent like *Staphylococcus aureus*, the organism that produces *Staphylococcal* enterotoxins, which is not regulated. One commenter stated that clarification was needed in the “exclusion of toxin produced as a by-product” and inquired whether this provision applies to material held in long term storage or cell lysates or culture supernatants kept for diagnostic or research purposes other than toxin work. Since the situations described by the commenter referred to material held in long term storage (longer than 30 days) this exclusion would not apply.

iv. Exclusion Involving Patient Care

To clarify how the select agent regulations apply to activities associated with the diagnosis and care for individuals infected with a select agent, we proposed that waste generated during the delivery of patient care is not

considered regulated under the select agent regulations. One commenter recommended that we define patient care as part of the diagnosis definition. Specifically, the commenter suggested we define diagnosis as “the analysis of specimens for the purpose of identifying or confirming the presence or characteristics of a select agent or toxin provided that such analysis is associated with the determination or provision of patient treatment in a patient care setting, or directly related to protecting the public health or safety, animal health or animal products, or plant health or plant products. Clinical or diagnostic specimen retention times as required for patient treatment are included within the determination of the point in time when patient care has concluded.” Another commenter stated “the challenges of differentiating between patient care and experimental research when treating infectious diseases are complex and nuanced and any effort to introduce regulation of medical care involving select agents and toxins has the potential to introduce inconsistencies and confusion.” The proposed exclusion language in the NPRM was “Waste generated during the delivery of patient care from a patient infected with a select agent that is decontaminated with a validated method within seven calendar days of the conclusion of patient care.” We revised the proposed language based on the two comments to state: “Waste generated during the delivery of patient care by health care professionals from a patient diagnosed with an illness or condition associated with a select agent, where such waste is, within seven days of the conclusion of patient care, decontaminated, or transferred for destruction in compliance with state and Federal regulations.”

We revised the proposed exemption language in 42 CFR 73.5(a)(3), and 42 CFR 73.6(a)(3) to provide that, unless otherwise directed by the HHS Secretary or APHIS Administrator, as appropriate, “the clinical or diagnostic specimens collected from a patient infected with a select agent are transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process within seven days after delivery of patient care by health care professionals has concluded.”

For specimens generated from the patient, the specimens are not subject to the select agent regulations for only the period that they are directly associated with the diagnosis. In accordance with sections five and six of the select agent regulations, within seven calendar days after identification, a specimen is subject to the select agent regulations

and must be transferred in accordance with section 73.16 or destroyed on-site by a recognized sterilization or inactivation process. Since the material would be excluded from the regulations, there would be no requirement to document the transfer or destructions. A specimen must be secured against theft, loss, or release during the period between identification and transfer or destruction, and any theft, loss, or release of the specimen must be reported. All specimens generated from the patient and kept more than seven days after acute patient care concludes would be subject to the select agent regulations.

v. Exemptions for Select Agents and Toxins

Informing Specimen Provider

Since a registered or reference laboratory typically confirms the identification of a select agent or toxin for public health and agriculture, we proposed to require that a registered or reference laboratory inform the specimen provider of the identification as a condition for a clinical or diagnostic laboratory to maintain their exemption under 42 CFR 73.5(a), and 42 CFR 73.6(a). Two commenters stated they did not believe basic good practices require regulations. We made no changes based on these comments because this provision will ensure that the reference laboratory notifies the specimen provider of the identification of the select agent or toxin. It is important that the specimen provider is aware that they are in possession of the agent or toxin and must meet the requirements outlined in 42 CFR 73.5, 73.6 (e.g., cannot maintain possession of the select agent or toxin, must destroy or get approval for a transfer, and report a theft, loss, or release).

Identification of Toxin

In the current select agent regulations, in order for clinical or diagnostic laboratories to maintain their exemption under 42 CFR 73.5(a), and 42 CFR 73.6(a), the clinical or diagnostic laboratory must, either immediately or within seven calendar days, report the identification of a select agent or toxin to APHIS or CDC unless directed otherwise by HHS Secretary or APHIS Administrator. In the NPRM, we proposed to amend the language in 42 CFR 73.5(a), and 42 CFR 73.6(a) to state: "Unless directed otherwise by the Secretary, within seven calendar days after identification of the select agent or toxin (except for Botulinum neurotoxin (BoNT) and/or Staphylococcal enterotoxins (Subtypes A–E)), or within

30 calendar days after identification of Botulinum neurotoxin and/or Staphylococcal enterotoxin (Subtypes A–E), the select agent or toxin is transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process." We sought comments concerning (1) the extension of the exemption time period to 30 days for BoNT and Staphylococcal enterotoxin (Subtypes A–E) to allow clinical and diagnostic laboratories sufficient time to complete their investigations without having to transfer or destroy the sample, and (2) whether seven calendar days provided sufficient amount of time for the entity to destroy or transfer other select agents or toxins after identification. We received one comment to extend the amount of time for other select agents or toxins to 10 calendar days since destruction may not occur on-site, therefore allowing the secure transport to the ultimate site of disposition. We made no changes to adjust the seven calendar day requirement for agents or toxins other than BoNT and Staphylococcal enterotoxin (Subtypes A–E) because the other agents or toxins do not involve the identification of both agent and toxin as part of diagnosis. Therefore, these situations are not as complicated and do not warrant additional time for reporting identification.

vi. Registration

We are codifying in regulation the current FSAP policy that an entity is required to meet all of the regulatory requirements for those select agents and toxins listed on an entity's registration regardless of whether the select agent or toxin is in the actual possession of an entity, and without regard to the actual amounts of toxins in the possession of an entity. We received no comments regarding this proposal and have made no changes to the language in the proposed rule.

vii. Responsible Official

Section 73.9(a)(6) of the select agent regulations currently states that the RO must ensure that an annual inspection is conducted for each laboratory where select agents and toxins are stored or used. This requirement also provides that the results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected. We proposed adding a requirement that the RO must also document the corrective actions taken by the entity to address any identified deficiencies. We received one comment that supported this proposed requirement and are finalizing the requirement as proposed.

HHS or USDA Office of the Inspector General Hotline

In its December 2014 report, the Federal Experts Security Advisory Panel (FESAP) recommended adding a specific regulatory requirement addressing how individuals are informed of the availability of procedures for accessing the HHS or USDA Office of Inspector General Hotlines to anonymously report a safety or security concern. In response to that recommendation, we proposed adding a requirement that the RO must ensure that individuals at their entity are provided the contact information of the HHS Office of Inspector General Hotline and USDA Office of Inspector General Hotline so that an individual is able to anonymously report a biosafety or security concern related to select agents and toxins. We received no comments regarding this proposed addition and are finalizing the requirement as proposed.

viii. Visitor Access to Select Agents and Toxins

Section 73.10(e) of the select agent regulations currently provides that a person with a valid approval from the HHS Secretary or APHIS Administrator to have access to select agents and toxins may request, through his or her RO, that the HHS Secretary or APHIS Administrator provide their approved access status to another registered individual or entity for a specified period of time. This allows a person with approved access at a registered entity to have approved access to a select agent at another registered entity. To ensure that the RO of the entity hosting such a visitor is aware if a visiting individual loses access approval to select agents and toxins, we added a requirement that the RO at the home entity must immediately notify the RO of the visiting entity if a person's access to select agents or toxins has been terminated. We received one comment that supported this addition to the regulations and are finalizing the requirement as proposed.

ix. Security, Biosafety, and Incident Response Plans

The select agent regulations require a registered entity to develop and implement a number of plans in order to ensure the safety and security of the select agents and toxins they handle. These are:

- A security plan that provides for measures sufficient to safeguard a select agent or toxin against unauthorized access, theft, loss, or release (42 CFR 73.11);

- A biosafety plan that provides for measures sufficient to contain a select agent or toxin (42 CFR 73.12); and
- An incident response plan that provides for measures that the registered entity will implement in the event of theft, loss, or release of a select agent or toxin; inventory discrepancies; security breaches (including information systems); severe weather and other natural disasters; workplace violence; bomb threats and suspicious packages; and emergencies such as fire, gas leak, explosion, power outage, or others. (42 CFR 73.14).

The select agent regulations require that drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plans, and that the plans must be reviewed and revised, as necessary, after any drill or exercise, and after any incident. We proposed to require that these drills or exercises be documented to include how the drill or exercise tested and evaluated the plan, any problems identified and corrective actions that were taken, and the names of the individuals who participated in the drill or exercise. Three commenters stated that there was no need to codify the documentation of how a drill or exercise evaluated a plan and corrective actions in regulations because they believed this requirement is already being documented. We are making no changes based on the comments because this requirement will provide a more thorough accounting of required activities via testing and entity-directed improvements.

Another commenter requested clarification regarding the recording of the names of individuals who participate in drills or exercises. The commenter believed the requirement should be limited to registered entity personnel and not include first responders or other non-entity participants, but list only the participating external agencies (e.g., emergency management, emergency medical services, or fire department). We agreed with the commenter and have amended the proposed regulatory language to clarify that an entity only needs to document the names of individuals at the registered entity. An entity may choose to list the external agencies who participated in the drill or exercise.

Similar to the existing requirement for the security plan, we proposed to add a requirement that the biosafety and incident response plans be submitted for initial registration, renewal of registration, or when requested by FSAP. We received two comments regarding these proposals which

supported this requirement. However, one commenter questioned the need for additional requirements as this is already done routinely. While we agreed with the commenter that some, or even most, entities already provide the plans routinely, we are making no changes to the proposed language so that all entities will be required to submit their biosafety and incidence response plans, consistent with the existing requirement for the security plan.

Security

We proposed amending the requirement that a security plan contain a description of how the entity authorizes the means of entry into areas where select agents or toxins are stored or used, to add a requirement that the security plan must include a description of centralized access control management systems (e.g., keycards) and/or key management (e.g., mechanical keys). We proposed this requirement because during our inspections of registered entities we have observed that the central access control management system in some instances is controlled, either on- or off-site, by individuals who (1) have not received access approval from HHS Secretary or APHIS Administrator, and (2) have the ability to assign people access or override access controls without the knowledge of the entity's RO. Three commenters suggested that access management processes are sensitive and a greater security risk may result from having too detailed information available in a single document. One commenter recommended we include a definition of what an access control system is and what components need to be included in the security plan. After considering the comments and reconsidering the purpose of the proposed language, we are not finalizing the proposed revision. Our concerns about unauthorized persons either having access or granting access without the knowledge of the entity RO can be addressed by the current provisions found in subsections (c)(1) and (c)(2) of section 11 (security) of the select agent regulations, which make the RO responsible to ensure access controls, irrespective of the type of security system in place.

Paragraphs (d)(7)(i) through (d)(7)(v) of section 11 (security) of the select agent regulations encompass a list of events that individuals with access approval from the HHS Secretary or the APHIS Administrator must immediately report to the RO. We proposed to add a new requirement that the RO must be notified of any loss of computer, hard drive, or other data storage device

containing information that could be used to gain access to select agents or toxins. We received one comment requesting clarification on the time frame for notification. We made no changes based on the comment since the regulations under subsection (d) already provide that notification must be immediate. The notification will facilitate notification of the Federal Bureau of Investigation (FBI) if deemed necessary by the RO as the loss of such equipment may be criminal in nature.

Biosafety

We proposed amending the regulatory language in section 73.12 of the select agent regulations to update the name change of the National Institutes of Health (NIH) "Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules" (Ref. 2). We received no comments and are finalizing this change as proposed.

The biosafety section of the select agent regulations contains a reference to the Occupational Safety and Health Administration (OSHA) regulations found in 29 CFR 1910.1200 and 1910.1450. These sections provide specific requirements for handling hazardous chemicals in the laboratories. These regulations also provide recommendations for safely working with chemicals including toxins and give non-mandatory recommendations for prudent practices in laboratories handling chemical hazards. Since the current edition of the CDC/NIH "Biosafety in Microbiological and Biomedical Laboratories" Appendix I (Ref. 3) now provides guidelines for work with toxins of biological origin, we proposed removal of the reference to these OSHA regulations. We note, however, that regulated entities are still required to meet the OSHA regulatory requirements where applicable. We received no comments and are finalizing this change as proposed.

In the NPRM, we proposed adding the requirement that "biosafety and containment procedures specific to each registered laboratory must be available to each individual working in that laboratory." We proposed adding this language to ensure that laboratory personnel working with select agents and toxins have access to relevant biosafety information and are therefore aware of the risks associated with these agents. One commenter requested clarification regarding the term "laboratory" and whether the term referred to a single room or a building or to a group of rooms (e.g., laboratory, animal room, necropsy) used by a Principal Investigator for a research project. The commenter also requested

clarification on the language “must be available to each individual working in the laboratory” and whether this implied that there must be a specific biosafety manual for each room. We also received three comments that questioned the need for a new requirement since the commenters believe a laboratory-specific biosafety manual was already accessible to individuals. We are not adding the proposed provision to the regulations because upon further reflection we agree with the commenters that individuals already have access to their biosafety plan.

In the NPRM, we proposed adding specific provisions to the biosafety section that would require (1) a written risk assessment for each registered select agent or toxin; (2) written safety procedures to protect entity personnel, the public, and the environment from exposure to the select agent or toxin; (3) written decontamination procedures; and (4) written waste management procedures. We received 13 comments that stated that “risk assessments” should be defined and the proposed requirement of having these for each procedure involving a select agent or toxin that addresses the hazards associated with the agent or toxin must be clarified because risk assessments are completed through institutional review committees by collaborative processes with Principal Investigators and biosafety professionals. One commenter stated that a risk assessment was always a requirement. We agree with the commenters that “risk assessment for each procedure” should not be required and agreed that having a risk assessment was already addressed in the regulations as outlined in Section 12(a) that “An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use.” However, we have clarified in the final regulatory language found in section 12(a)(1) of the select agent regulations that the biosafety plan include “the hazardous characteristics of each agent or toxin listed on the entity’s registration and the biosafety risk associated with laboratory procedures related to the select agent or toxin.”

The majority of the commenters stated that the approach outlined in the NPRM discussion of section 12(a) would lead to decreased compliance and an increase in paperwork burden. One commenter stated that many biosafety plans are already upwards of 50 pages, and increasing the length further may greatly decrease the likelihood that

researchers will continue to read these plans and use them as a resource. Another commenter stated that regulatory language should be omitted to prevent creating a redundant process such as those provisions already covered under training and incident response. We agree with commenters and have removed the training and incident response language that was noted in the NPRM because these provisions are already covered by other sections in the regulations (*i.e.*, incident response and training sections). We combined other provisions to reduce the seven provisions listed in the NPRM to four provisions in the final rule.

One commenter stated we should consider requiring the adoption of shared algorithms developed by the American Society for Microbiology (ASM) for use by clinical laboratories. These algorithms are presented as frequently asked questions (FAQs) from ASM to assist laboratories. We made no changes based on this comment because FSAP already provides FAQs to assist entities with meeting the biosafety requirements of the regulations.

Another commenter recommended that we also offer the suggestion that entities consider implementing programs whereby personnel are required to work with another trained person (*i.e.*, a “buddy” system or dual authentication) as an appropriate and effective proactive method for the prevention of laboratory acquired infections and accidental releases of select agents. We made no changes based on this comment as it is essential for entities to develop their own biosafety initiatives to meet their own needs. The commenter continued that many of these issues come down to the culture of safety in an entity, and adherence to established protocols and training. The commenters wanted the regulatory provisions to reflect an improved safety culture. Two commenters requested that we consider leaving the current provisions in place and develop guidance to assist entities that would include risk assessment, use of safety equipment, personal protective equipment, containment devices, and occupational health consideration.

Another commenter stated that the new section appears redundant with the risk assessment(s) performed during review of work registrations by an Institutional Biosafety Committee. We agree with the commenters that the provisions focus on the hazards and risks associated with the select agents and toxins and the safety practices put in place by the entity to protect entity personnel, the public, and the environment. We have revised the proposed language to state

that the biosafety plan must include the provisions found in section 12(a) of the select agent regulations (see § 73.12(a)(1)–(4)). To address the commenters’ suggestion that FSAP develop a guidance document regarding biosafety, additional guidance has been developed and is available at: <http://www.selectagents.gov>.

x. Training

We proposed to amend section 15 of the select agent regulations to require that training be completed within 12 months of that individual’s anniversary of receiving access approval from the HHS Secretary or the APHIS Administrator, or prior to his or her entry into an area where any select agents and toxins are used or stored, whichever occurs first. This change is necessary in order to ensure that individuals at registered entities receive timely training. We received no specific comments regarding this proposed change. However, seven commenters stated that we should include a description of the level of training necessary for personnel in varying positions with highly disparate job duties and responsibilities. The commenters requested that we clarify that the required training will be conducted at a level appropriate to the registered person’s role and level of access to select agents. We made no changes based on this comment because the current regulatory language is clear that “the training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins.” The training for the individuals should be determined by the entity based on at the level of which the individual will have access to select agents or toxins. The training that each person receives should be designed to ensure that they can carry out their responsibilities without causing harm to themselves, or to their fellow co-workers, or to the public. We did clarify the regulatory language regarding training for an individual who must be escorted to specify that their training must be accomplished prior to the individual’s entry into a registered area.

One commenter also asked that we consider making “training a pre-requisite for access to select agents and toxins, and not a requirement for just being FSAP approved.” The regulations in 42 CFR 73.15(a)(1) already requires that each approved individual receive information and training on biosafety, security (including security awareness), and incident response before that individual has access to any select agents and toxins. The same commenter

asked that we clearly specify the requirements for both initial and annual training. While we made no changes to our regulatory language based on this comment, the document, "Guidance for Meeting the Training Requirements of the Select Agent Regulations," found at <http://www.selectagents.gov/guidance-training.html>, has been amended to provide further detail and assistance regarding the content of initial and annual training. The same commenter stated that in two instances an employee's annual training deadline occurred in the middle of an extended medical leave during which it was not possible to complete the training, and the entity had to choose to either let the training become overdue, or to remove the individual from the registration and completely start over with the security risk assessment (SRA) approval process once the individual was back to work. The commenter stated that "SRA approved personnel could commonly be on other types of extended leave such as maternity leave, or on sabbatical doing research at another institution but still employed and SRA approved at their home institution." While we made no changes to our regulatory language based on this comment, we have updated our guidance, "Guidance for Meeting the Training Requirements of the Select Agent Regulations," which is available at www.selectagents.gov, to include information on how to deal with situations regarding individuals that have extended absences from the laboratory.

xi. Records

Based on our inspections of registered entities, we observed that not all entities maintain records of the final disposition of select agents when consumed or destroyed, and this impedes validation of inventory holdings. Section 73.17 of the select agent regulations currently does not include a requirement for documenting the final disposition of a select agent. To ensure the proper tracking of a select agent from acquisition to final disposition, we are adding a requirement for entity records to include the final disposition (including destruction) for each select agent that has been held in long-term storage. One commenter expressed concern that a requirement for a record of destruction of select agents would place an undue burden on investigators and recommended that this requirement be excluded from the final rule. However, the commenter did agree that an entity should be required to maintain a current and accurate inventory of all select agents in their possession and document when an agent is no longer in

their possession. We agree with the commenter that final disposition needs to be part of the entity's recordkeeping requirement. We disagree with the commenter that this will place undue burden on investigators because this information can be included with an entity's existing recordkeeping system (e.g., inventory spreadsheet). Therefore, to clarify the regulatory language, we have revised the proposed regulatory language to provide that the record will need to include "the select agent used, purpose of use, and, when applicable, final disposition."

Section 73.17 of the select agent regulations currently states that records and databases need to be accurate. To ensure that the accuracy of handwritten records can be verified, we proposed to clarify that a handwritten record must be legible (*i.e.*, capable of being read). We received one comment requesting that we define the term "legible handwritten records." We made no changes based on this comment because we are using the term "legible" in its ordinary meaning.

We proposed to expand the scope of records required to be maintained to include any records that contain information related to the requirements of the regulations. We received five comments that expressed concerns about the information being kept in laboratory notes. The commenters stated that the information is "proprietary in nature," contains intellectual property information and should not be required to be provided to FSAP inspectors. We understand the concerns of the commenters and clarified the language to indicate that it is only information related to requirements of the select agent regulations that must be produced on request. Such information may be found in the biocontainment certifications, laboratory notebooks, institutional biosafety and/or animal use committee minutes and approved protocols, and records associated with occupational health and suitability programs. Accordingly, we will only review relevant portions of any laboratory notebooks or documents, and only if they contain information related to any requirements of the regulations under sections 73.5, 73.7, 73.9, 73.11, 73.12, 73.14, 73.15, 73.16, 73.17, and 73.19 of the select agent regulations. Two commenters stated that certain records are "protected under the HIPAA Privacy Rule." FSAP would expect any information provided to FSAP regarding an individual's health would be provided in accord with the HIPAA Privacy Rule, including the use and disclosure of protected health information to public health authorities

authorized by law to collect or receive such information for preventing or controlling disease, injury, or disability.

Records for Long-Term Storage

In the NPRM we also solicited information and ideas as to how a regulatory requirement could be constructed such that a registered entity would know whether a select agent or toxin had been lost or stolen, without that registered entity first having "an accurate, current inventory for each select agent . . . held in long-term storage." In addition, we requested ideas as to how the current regulations could be amended to address the threat of the theft of a select agent from a container held in long-term storage. We received three comments that addressed this request. One commenter suggested that FSAP inspectors review the record of select agents held in long-term storage and accept the attestation of the responsible investigators of their accuracy. Another commenter stated we should continue with FSAP's current select agent practices to allow for these stocks to be maintained in tamper-evident containers (e.g., security ties on freezer boxes) so that vials are not individually removed, thawed, and measured. The third commenter recommended dual authentication coupled with required entity inventory reviews. We appreciate the comments and will continue to consider how the recognition of theft and loss might be addressed through alternative approaches.

III. Alternatives Considered

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires HHS and USDA to review and republish the list of select agents and toxins every two years. In drafting this final rule, we considered the action proposed in the NPRM of removing the six select agents and one toxin where its costs and benefits were discussed. If those policies were adopted, it would result in savings ranging from approximately \$15,300 for a small commercial BSL-3 laboratory to approximately \$165,000 for a larger university with BSL-2/3 laboratories for laboratories no longer regulated. Based on the review of FSAP database, approximately eleven small entities would no longer be regulated and would not be required to register with FSAP. If the entities withdrew their registration, it would result in an estimated saving of \$168,300 annually. On the other hand, this policy could increase the likelihood of entities working with these removed select agents and toxin not having the

appropriate biosafety and security provisions in place to prevent an accidental or intentional release of a select agent or toxin. The intentional release could adversely affect the public health and safety. Recent events concerning the accidental transfer of select agents that had not been fully inactivated, leading to the inadvertent release of select agents, caused us to also look at provisions in this regulation. After carefully considering the technical input of subject matter experts, both within the Federal government and from public comments, and recommendations from Federal advisory groups, we have decided not to finalize the proposed changes to the list of select agents and toxins at this time.

IV. Required Regulatory Analyses

A. Executive Orders 12866 and 13563

Under Executive Order (E.O.) 12866, Regulatory Planning and Review (58 FR 51735, October 4, 1993), CDC is required to determine whether this regulatory action would be “significant” and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Orders (E.O.). E.O. 12866 defines “significant regulatory action” as any regulatory action that is likely to result in a rule that may:

- Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities;
- Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients; or,
- Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in E.O. 12866.

E.O. 13563, Improving Regulation and Regulatory Review, (76 FR 3821, January 21, 2011), updates some of the provisions of E.O. 12866 in order to promote more streamlined regulatory actions. This E.O. charges, in part, that, while protecting “public health, welfare, safety, and our environment” that regulations must also “promote predictability and reduce uncertainty” in order to promote economic growth. Further, regulations must be written in plain language and be easy to understand.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by E.O. 12866, and a final regulatory flexibility analysis (See Section III.B. of this Preamble) that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available in the docket at www.regulations.gov or at www.selectagents.gov.

We have determined that this final rule is significant for the purposes of Executive Order 12866 and, therefore, this final rule has been reviewed by OMB.

Summary of the Regulatory Impact Analysis

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107–188) provides for the regulation of certain biological agents and toxins that have the potential to pose a severe threat to human, animal, or plant health, or to animal or plant products. APHIS and CDC have primary responsibility for implementing the provisions of the Act within the Department of Agriculture and the Department of Health and Human Services, respectively. Within APHIS, Veterinary Services (VS) select agents and toxins are those that have been determined to have the potential to pose a severe threat to animal health or animal products, and Plant Protection and Quarantine (PPQ) select agents and toxins are those that have been determined to have the potential to pose a severe threat to plant health or plant products. HHS select agents and toxins are those that have been determined to have the potential to pose a severe threat to human health. APHIS and CDC coordinate regulatory activities for overlap select agents and toxins that have been determined to pose a severe threat to human and animal health or products.

Sections 201 and 212(a)(2) of the Act require a biennial review and republication of the select agent and toxin list, with revisions as appropriate in accordance with this law. These final rules will implement the recommendations of the fourth biennial review of select agent regulations and have finalized changes that will increase their usability as well as provide for enhanced program oversight. These amendments include new provisions regarding the inactivation of select agents, specific biosafety and toxin requirements and clarification of

regulatory language concerning security, training, and records.

The final rule will require that entities develop validated inactivation procedures for select agents or regulated infectious nucleic acid and maintain written records of having done so. Costs of complying with this amendment are expected to be modest.

Currently, there are 286 entities registered with APHIS and CDC including 91 academic, 53 commercial, 81 State government, 45 Federal government, and 16 private (non-profit) institutions, most of which are considered to be small entities. Based on current record keeping and reporting requirements, an additional 10 to 20 hours per year may be required for maintaining records associated with select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agents. At an imputed cost of \$33.40 per hour (GS–12, step 2), this additional time requirement per entity will cost between \$334 and \$668 per year, or in total for all registered entities between \$80,000 and \$160,000. The final rule will not have a significant economic impact on a substantial number of small entities. Costs associated with this rule do not include costs related to training, overhead, updates to facilities, etc. We assume in this rule that all costs associated with such factors for entities performing inactivation procedures have already been incurred prior to rulemaking.

The benefits of strengthened safeguards against the unintentional or deliberate release of a select agent or toxin greatly exceed compliance costs of the rules. As an example of losses that can occur, the October 2001 anthrax attacks caused five fatalities and 17 illnesses, disrupted business and government activities (including \$2 billion in lost revenues for the Postal Service), and required more than \$23 million to decontaminate one Senate office building and \$3 billion to decontaminate postal facilities and procure mail-sanitizing equipment. Deliberate introduction greatly increases the probability of a select agent becoming established and causing wide-ranging and devastating impacts to the economy, other disruptions to society, and diminished confidence in public and private institutions.

The amended regulations will enhance the protection of human, animal, and plant health and safety. The final rules will reduce likelihood of the accidental or intentional release of a

select agent or toxin. Benefits of the rules will derive from the greater probability that a release will be prevented from occurring.

B. The Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA)

We have examined the impacts of the proposed rule under RFA (5 U.S.C. 601–612). Unless we certify that the proposed rule is not expected to have a significant economic impact on a substantial number of small entities, RFA, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. We certify that this proposed rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA because these registered entities are already required to comply with the select agent regulations. The small entities would only incur some costs if they are performing inactivation procedures and are not maintaining records. The additional costs that may be incurred are small in comparison to the long-term benefits of additional protection against the release of select agents and toxins that would result in devastating effects to the economy.

This regulatory action is not a major rule as defined by Sec. 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This proposed rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in cost or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

C. Paperwork Reduction Act of 1995

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), CDC has determined that the Paperwork Reduction Act does apply to information collection and recordkeeping requirements included in this rule. We note that the information collection and recordkeeping requirements are already approved by the Office of Management and Budget (OMB) under OMB Control Number 0920–0576 (Possession, Use, and Transfer of Select Agents and Toxins (42 CFR 73), Expiration 12/31/2018).

D. E.O. 12988: Civil Justice Reform

This rule has been reviewed under E.O. 12988, Civil Justice Reform. Once the final rule is in effect, CDC notes that: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) No retroactive effect will be given to this rule; and (3) Administrative proceedings will not be required before parties may file suit in court challenging this rule.

E. E.O. 13132: Federalism

HHS/CDC has reviewed this final rule in accordance with E.O. 13132 regarding Federalism, and has determined that it does not have “federalism implications.” The rule does not “have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.”

F. Plain Language Act of 2010

Under the Plain Language Act of 2010 (Pub. L. 111–274, October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. HHS/CDC has attempted to use plain language in promulgating this rule consistent with the Federal Plain Writing Act guidelines.

V. References

1. D.R. Franz and N.K. Jaax (1997). Defense Against Toxin Weapons (Chapter 30). In *Textbook of Military Medicine: Medical Aspects of Chemical and Biological Warfare*, Borden Institute, Walter Reed Army Medical Center, Washington, DC. 631–642.
2. U.S. Department of Health and Human Services, National Institutes of Health. (2013). *NIH Guidelines for Research Involving Recombinant Or Synthetic Nucleic Acid Molecules (NIH Guidelines)*. Retrieved from http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html.
3. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health. (2009). *Biosafety in Microbiological and Biomedical Laboratories (BMBL)* 5th Edition. Retrieved from <http://www.cdc.gov/biosafety/publications/bmbl5/index.htm>.

List of Subjects in 42 CFR Part 73

Biologics, Packaging and containers, Penalties, Reporting and recordkeeping requirements, and Transportation.

For the reasons discussed in the preamble, we amend 42 CFR part 73 as follows:

PART 73—SELECT AGENTS AND TOXINS

- 1. The authority citation for part 73 continues to read as follows:

Authority: 42 U.S.C. 262a; sections 201–204, 221 and 231 of Title II of Public Law 107–188, 116 Stat 637 (42 U.S.C. 262a).

- 2. Section 73.1 is amended by adding in alphabetical order, definitions of *validated inactivation procedure* and *viability testing protocol* to read as set forth below.

§ 73.1 Definitions.

* * * * *

Validated inactivation procedure means a procedure, whose efficacy is confirmed by data generated from a viability testing protocol, to render a select agent non-viable but allows the select agent to retain characteristics of interest for future use; or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use.

* * * * *

Viability testing protocol means a protocol to confirm the validated inactivation procedure by demonstrating the material is free of all viable select agent.

* * * * *

- 3. Section 73.3 is amended as follows:
- a. By revising paragraph (b).
- b. By removing “functional” and adding in its place “toxic” in paragraph (c)(2).
- c. By revising paragraph (d)(2).
- d. By redesignating paragraph (d)(3) as (d)(7) and revising redesignated paragraphs (d)(7) introductory text and (d)(7)(i).
- e. By redesignating paragraph (d)(4) as paragraph (d)(8).
- f. By redesignating paragraph (d)(5) as paragraph (d)(12).
- g. By adding new paragraphs (d)(3), (d)(4), (d)(5), (d)(6), (d)(9), (d)(10) and (d)(11).
- h. By adding paragraph (e)(3).
- i. By adding “*Bacillus cereus* Biovar *anthracis*,” before “*Botulinum neurotoxins*” in paragraph (f)(3)(i).

The additions and revisions read as follows:

§ 73.3 HHS select agents and toxins.

* * * * *

- (b) HHS select agents and toxins:

Abrin

Bacillus cereus Biovar *anthracis**

*Botulinum neurotoxins**

*Botulinum neurotoxin producing species of Clostridium**

Conotoxins (Short, paralytic alpha conotoxins containing the following

amino acid sequence
 $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)¹
Coxiella burnetii
 Crimean-Congo hemorrhagic fever virus
 Diacetoxyscirpenol
 Eastern equine encephalitis virus
 Ebola virus*
*Francisella tularensis**
 Lassa fever virus
 Lujo virus
 Marburg virus*
 Monkeypox virus
 Reconstructed replication competent
 forms of the 1918 pandemic influenza
 virus containing any portion of the
 coding regions of all eight gene
 segments (Reconstructed 1918
 influenza virus)
 Ricin
Rickettsia prowazekii
 SARS coronavirus (SARS-CoV)
 Saxitoxin
 South American hemorrhagic fever
 viruses:
 Chapare
 Guanarito
 Junin
 Machupo
 Sabia
 Staphylococcal enterotoxins (subtypes
 A–E)
 T–2 toxin
 Tetrodotoxin
 Tick-borne encephalitis virus
 Far Eastern subtype
 Siberian subtype
 Kyasanur Forest disease virus
 Omsk haemorrhagic fever virus
 Variola major virus (Smallpox virus)*
 Variola minor virus (Alastrim)*
*Yersinia pestis**

* * * * *

(d) * * *

(2) Non-viable HHS select agents or
 nontoxic HHS toxins.

(3) A select agent or toxin that has
 been subjected to decontamination or a
 destruction procedure when intended
 for waste disposal.

(4) A select agent or regulated nucleic
 acids that can produce infectious forms
 of any select agent virus that has been
 subjected to a validated inactivation

procedure that is confirmed through a
 viability testing protocol. Surrogate
 strains that are known to possess
 equivalent properties with respect to
 inactivation can be used to validate an
 inactivation procedure; however, if
 there are known strain-to-strain
 variations in the resistance of a select
 agent to an inactivation procedure, then
 an inactivation procedure validated on
 a lesser resistant strain must also be
 validated on the more resistant strains.

(5) Material containing a select agent
 that is subjected to a procedure that
 removes all viable select agent cells,
 spores, or virus particles if the material
 is subjected to a viability testing
 protocol to ensure that the removal
 method has rendered the material free of
 all viable select agent.

(6) A select agent or regulated nucleic
 acids that can produce infectious forms
 of any select agent virus not subjected
 to a validated inactivation procedure or
 material containing a select agent not
 subjected to a procedure that removes
 all viable select agent cells, spores, or
 virus particles if the material is
 determined by the HHS Secretary to be
 effectively inactivated or effectively
 removed. To apply for a determination
 an individual or entity must submit a
 written request and supporting
 scientific information to CDC. A written
 decision granting or denying the request
 will be issued.

(7) Except as required in § 73.16(l),
 the aggregate amount of the toxin under
 the control of a principal investigator,
 treating physician or veterinarian, or
 commercial manufacturer or distributor
 does not, at any time, exceed the
 following amounts: 1000 mg of Abrin; 1
 mg of Botulinum neurotoxins; 100 mg of
 Conotoxins (Short, paralytic alpha
 conotoxins containing the following
 amino acid sequence
 $X_1CCX_2PACGX_3X_4X_5X_6CX_7$); 10,000 mg
 of Diacetoxyscirpenol; 1000 mg of Ricin;
 500 mg of Saxitoxin; 100 mg of
 Staphylococcal enterotoxins (subtypes
 A–E); 10,000 mg of T–2 toxin; or 500 mg
 of Tetrodotoxin. Provided that,

(i) The toxin is transferred only after
 the transferor uses due diligence and
 documents the identification of the
 recipient and the legitimate need (e.g.,
 prophylactic, protective, bona fide
 research, or other peaceful purpose)
 claimed by the recipient to use such
 toxin. Information to be documented
 includes, but is not limited to, the
 recipient identity information,
 including the recipient's name,
 institution name, address, telephone
 number and email address; name of the
 toxin and the total amount transferred;
 and the legitimate need claimed by the
 recipient. Notwithstanding the

provisions of paragraph (d) of this
 section, the HHS Secretary retains the
 authority to, without prior notification,
 inspect and copy or request the
 submission of the due diligence
 documentation to the CDC.

* * * * *

(9) An HHS select toxin identified in
 an original food sample or clinical
 sample.

(10) For those laboratories that are not
 exempt under § 73.5(a) and § 73.6(a),
 Botulinum neurotoxin that is produced
 as a byproduct in the study of
 Botulinum neurotoxin producing
 species of *Clostridium* so long as the
 toxin has not been intentionally
 cultivated, collected, purified, or
 otherwise extracted, and the material
 containing the toxin is rendered non-
 toxic and disposed of within 30 days of
 the initiation of the culture.

(11) Waste generated during the
 delivery of patient care by health care
 professionals from a patient diagnosed
 with an illness or condition associated
 with a select agent, where that waste is
 decontaminated or transferred for
 destruction by complying with state and
 Federal regulations within seven
 calendar days of the conclusion of
 patient care.

(e) * * *

(3) An individual or entity may make
 a written request to the HHS Secretary
 for reconsideration of a decision
 denying an application for the exclusion
 of an attenuated strain of a select agent
 or a select toxin modified to be less
 potent or toxic. The written request for
 reconsideration must state the facts and
 reasoning upon which the individual or
 entity relies to show the decision was
 incorrect. The HHS Secretary will grant
 or deny the request for reconsideration
 as promptly as circumstances allow and
 will state, in writing, the reasons for the
 decision.

* * * * *

■ 4. Section 73.4 is amended as follows:

■ a. By revising paragraph (b).

■ b. By removing “functional” and
 adding in its place “toxic” in paragraph
 (c)(2).

■ c. By revising paragraph (d)(2).

■ d. By redesignating paragraph (d)(3) as
 (d)(9).

■ e. By adding new paragraphs (d)(3),
 (d)(4), (d)(5), (d)(6), (d)(7) and (d)(8).

■ f. By adding paragraph (e)(3).

The revision and additions read as
 follows:

§ 73.4 Overlap select agents and toxins.

* * * * *

(b) Overlap select agents and toxins:

Bacillus anthracis *

Bacillus anthracis Pasteur strain

¹ C = Cysteine residues are all present as
 disulfides, with the 1st and 3rd Cysteine, and the
 2nd and 4th Cysteine forming specific disulfide
 bridges; The consensus sequence includes known
 toxins α -MI and α -GI (shown above) as well as α -
 GIA, Ac1.1a, α -CnIA, α -CnIB; X1 = any amino
 acid(s) or Des-X; X2 = Asparagine or Histidine; P
 = Proline; A = Alanine; G = Glycine; X3 = Arginine
 or Lysine; X4 = Asparagine, Histidine, Lysine,
 Arginine, Tyrosine, Phenylalanine or Tryptophan;
 X5 = Tyrosine, Phenylalanine, or Tryptophan; X6
 = Serine, Threonine, Glutamate, Aspartate,
 Glutamine, or Asparagine; X7 = Any amino acid(s)
 or Des X and; “Des X” = “an amino acid does not
 have to be present at this position.” For example
 if a peptide sequence were XCCHPA then the
 related peptide CCHPA would be designated as Des-
 X.

Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei *
Burkholderia pseudomallei *
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan equine encephalitis virus

* * * *

(d) * * *

(2) Non-viable overlap select agents or nontoxic overlap toxins.

(3) A select agent or toxin that has been subjected to decontamination or a destruction procedure when intended for waste disposal.

(4) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol. Surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactivation procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.

(5) Material containing a select agent that is subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is subjected to a viability testing protocol to ensure that the removal method has rendered the material free of all viable select agent.

(6) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus not subjected to a validated inactivation procedure or material containing a select agent not subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is determined by the HHS Secretary or Administrator to be effectively inactivated or effectively removed. To apply for a determination an individual or entity must submit a written request and supporting scientific information to CDC or APHIS. A written decision granting or denying the request will be issued.

(7) An overlap select toxin identified in an original food sample or clinical sample.

(8) Waste generated during the delivery of patient care by health care professionals from a patient diagnosed with an illness or condition associated with a select agent, where that waste is decontaminated or transferred for destruction by complying with state and

Federal regulations within seven calendar days of the conclusion of patient care.

* * * *

(e) * * *

(3) An individual or entity may make a written request to the HHS Secretary or Administrator for reconsideration of a decision denying an application for the exclusion of an attenuated strain of a select agent or a select toxin modified to be less potent or toxic. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The HHS Secretary or Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

* * * *

■ 5. Section 73.5 is amended as follows:

■ a. By revising paragraph (a)(1).

■ b. By redesignating paragraph (a)(3) as paragraph (a)(4) and revising newly redesignated paragraph (a)(4).

■ c. By adding new paragraph (a)(3).

■ d. By adding “*Bacillus cereus* Biovar *anthracis*,” before “*Botulinum neurotoxins*” in paragraph (a)(3)(i).

The revisions and addition read as follows:

§ 73.5 Exemptions for HHS select agents and toxins.

(a) * * *

(1) Unless directed otherwise by the HHS Secretary, within seven calendar days after identification of the select agent or toxin (except for *Botulinum neurotoxin* and/or *Staphylococcal enterotoxin* (Subtypes A–E)), or within 30 calendar days after identification of *Botulinum neurotoxin* and/or *Staphylococcal enterotoxin* (Subtypes A–E), the select agent or toxin is transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process,

* * * *

(3) Unless otherwise directed by the HHS Secretary, the clinical or diagnostic specimens collected from a patient infected with a select agent are transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process within seven calendar days after delivery of patient care by health care professionals has concluded, and

(4) The identification of the agent or toxin is reported to CDC or APHIS, the specimen provider, and to other appropriate authorities when required by Federal, State, or local law by telephone, facsimile, or email. This report must be followed by submission

of APHIS/CDC Form 4 to APHIS or CDC within seven calendar days after identification.

* * * *

■ 6. Section 73.6 is amended as follows:

■ a. By redesignating paragraph (a)(3) as paragraph (a)(4) and revising newly redesignated paragraph (a)(4).

■ b. By adding new paragraph (a)(3).

The revision and addition read as follows:

§ 73.6 Exemptions for overlap select agents and toxins.

(a) * * *

(3) Unless otherwise directed by the HHS Secretary or Administrator, the clinical or diagnostic specimens collected from a patient infected with a select agent are transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process within seven calendar days after delivery of patient care by health care professionals has concluded, and

(4) The identification of the agent or toxin is reported to CDC or APHIS, the specimen provider, and to other appropriate authorities when required by Federal, State, or local law by telephone, facsimile, or email. This report must be followed by submission of APHIS/CDC Form 4 to APHIS or CDC within seven calendar days after identification.

* * * *

■ 7. Section 73.7 is amended as follows:

■ a. By redesignating paragraphs (b) through (k) as paragraphs (c) through (l), respectively.

■ b. By adding a new paragraph (b) to read as follows:

§ 73.7 Registration and related security risk assessments.

* * * *

(b) As a condition of registration, each entity is required to be in compliance with the requirements of this part for select agents and toxins listed on the registration regardless of whether the entity is in actual possession of the select agent or toxin. With regard to toxins, the entity registered for possession, use or transfer of a toxin must be in compliance with the requirements of this part regardless of the amount of toxin currently in its possession.

* * * *

■ 8. Section 73.9 is amended as follows:

■ a. In paragraph (a)(6) by removing “laboratory” and adding in its place “registered space” and adding “and the corrections documented” after “corrected” at the end of the sentence.

■ b. By adding paragraphs (a)(7), (a)(8) and (a)(9) to read as set forth below.

■ c. By adding “*Bacillus cereus* Biovar *anthracis*,” after “*Bacillus anthracis*,” in paragraph (c)(1).

§ 73.9 Responsible Official.

(a) * * *

(7) Ensure that individuals are provided the contact information for the HHS Office of Inspector General Hotline and the USDA Office of Inspector General Hotline so that they may anonymously report any biosafety or security concerns related to select agents and toxins.

(8) Investigate to determine the reason for any failure of a validated inactivation procedure or any failure to remove viable select agent from material. If the Responsible Official is unable to determine the cause of a deviation from a validated inactivation procedure or a viable select agent removal method; or receives a report of any inactivation failure after the movement of material to another location, the Responsible Official must report immediately by telephone or email the inactivation or viable agent removal method failure to CDC or APHIS.

(9) Review, and revise as necessary, each of the entity's validated inactivation procedures or viable select agent removal methods. The review must be conducted annually or after any change in Principal Investigator, change in the validated inactivation procedure or viable select agent removal method, or failure of the validated inactivation procedure or viable select agent removal method. The review must be documented and training must be conducted if there are any changes to the validated inactivation procedure, viable select agent removal method, or viability testing protocol.

* * * * *

■ 9. Section 73.10 is amended as follows:

■ a. By a sentence to the end of paragraph (e) to read as follows:

§ 73.10 Restricting access to select agents and toxins; security risk assessments.

* * * * *

(e) * * * A Responsible Official must immediately notify the Responsible Official of the visited entity if the person's access to select agents and toxins has been terminated.

* * * * *

■ 10. Section 73.11 is amended as follows:

■ a. In paragraph (c)(5) by adding “keycards,” between “keys,” and “passwords” and removing “numbers” and adding in its place “permissions”.

■ b. By adding paragraph (d)(7)(vi).

■ c. By adding a sentence to the end of paragraph (h).

The additions read as follows:

§ 73.11 Security.

* * * * *

(d) * * *

(7) * * *

(vi) Any loss of computer, hard drive or other data storage device containing information that could be used to gain access to select agents or toxins.

* * * * *

(h) * * * Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.

■ 11. Section 73.12 is amended as follows:

■ a. By revising paragraph (a).

■ b. By removing paragraph (c)(2), redesignating paragraph (c)(3) as (c)(2), and in newly redesignated paragraph (c)(2), removing “NIH Guidelines for Research Involving Recombinant DNA Molecules” and adding in its place “NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules”.

■ c. By adding a new sentence to the end of paragraph (e).

The revision and addition read as follows:

§ 73.12 Biosafety.

(a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested. The biosafety plan must include the following provisions:

(1) The hazardous characteristics of each agent or toxin listed on the entity's registration and the biosafety risk associated with laboratory procedures related to the select agent or toxin;

(2) Safeguards in place with associated work practices to protect entity personnel, the public, and the environment from exposure to the select agent or toxin including, but not limited to: Personal protective equipment and other safety equipment; containment equipment including, but not limited to,

biological safety cabinets, animal caging systems, and centrifuge safety containers; and engineering controls and other facility safeguards;

(3) Written procedures for each validated method used for disinfection, decontamination or destruction, as appropriate, of all contaminated or presumptively contaminated materials including, but not limited to: Cultures and other materials related to the propagation of select agents or toxins, items related to the analysis of select agents and toxins, personal protective equipment, animal caging systems and bedding (if applicable), animal carcasses or extracted tissues and fluids (if applicable), laboratory surfaces and equipment, and effluent material; and

(4) Procedures for the handling of select agents and toxins in the same spaces with non-select agents and toxins to prevent unintentional contamination.

* * * * *

(e) * * * Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.

■ 12. Section 73.14 is amended as follows:

■ a. By adding a new sentence to the end of paragraph (a).

■ b. By adding a new sentence to the end of paragraph (f).

The additions read as follows:

§ 73.14 Incident response.

(a) * * * The current incident response plan must be submitted for initial registration, renewal of registration, or when requested.

* * * * *

(f) * * * Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.

■ 13. Section 73.15 is amended as follows:

■ a. Revising paragraph (a) to read as set forth below.

■ b. By adding paragraph (e) to read as set forth below.

§ 73.15 Training.

(a) An individual or entity required to register under this part must provide information and training on biocontainment, biosafety, security (including security awareness), and incident response to:

(1) Each individual with access approval from the HHS Secretary or

Administrator. The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins. The training must be accomplished prior to the individual's entry into an area where a select agent is handled or stored, or within 12 months of the date the individual was approved by the HHS Secretary or the Administrator for access, whichever is earlier.

(2) Each individual not approved for access to select agents and toxins by the HHS Secretary or Administrator before that individual enters areas under escort where select agents or toxins are handled or stored (*e.g.*, laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored. The training must be accomplished prior to the individual's entry into where select agents or toxins are handled or stored (*e.g.*, laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.).

(e) The Responsible Official must ensure and document that individuals are provided the contact information of the HHS Office of Inspector General Hotline and the USDA Office of Inspector General Hotline so that they may anonymously report any safety or security concerns related to select agents and toxins.

■ 14. Section 73.16 is amended by revising paragraph (l)(1) to read as follows:

§ 73.16 Transfers.

(l) * * *

(1) Transfer the amounts only after the transferor uses due diligence and documents that the recipient has a legitimate need (*e.g.*, prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such toxins. Information to be documented includes, but is not limited, to the recipient information, toxin and amount transferred, and declaration that the recipient has legitimate purpose to store and use such toxins.

■ 15. Section 73.17 is amended as follows:

■ a. In paragraphs (a)(1)(iii) and (a)(3)(v) by adding "or other storage container" after "freezer".

■ b. By revising paragraph (a)(1)(v).

■ c. By adding paragraph (a)(8).

■ d. By revising paragraph (b).

■ e. By revising paragraph (c).

The revision and additions read as follows:

§ 73.17 Records.

(a) * * *

(1) * * *

(v) The select agent used, purpose of use, and, when applicable, final disposition,

* * * * *

(8) For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent:

(i) A written description of the validated inactivation procedure or viable select agent removal method used, including validation data;

(ii) A written description of the viability testing protocol used;

(iii) A written description of the investigation conducted by the entity Responsible Official involving an inactivation or viable select agent removal failure and the corrective actions taken;

(iv) The name of each individual performing the validated inactivation or viable select agent removal method;

(v) The date(s) the validated inactivation or viable select agent removal method was completed;

(vi) The location where the validated inactivation or viable select agent removal method was performed; and

(vii) A certificate, signed by the Principal Investigator, that includes the date of inactivation or viable select agent removal, the validated inactivation or viable select agent removal method used, and the name of the Principal Investigator. A copy of the certificate must accompany any transfer of inactivated or select agent removed material.

* * * * *

(b) The individual or entity must implement a system to ensure that all records and data bases created under this part are accurate and legible, have controlled access, and authenticity may be verified.

(c) The individual or entity must promptly produce upon request any information that is related to the requirements of this part but is not otherwise contained in a record required to be kept by this section. The location of such information may include, but is not limited to, biocontainment certifications,

laboratory notebooks, institutional biosafety and/or animal use committee minutes and approved protocols, and records associated with occupational health and suitability programs. All records created under this part must be maintained for 3 years.

Dated: January 9, 2017.

Sylvia M. Burwell,
Secretary.

[FR Doc. 2017-00726 Filed 1-18-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

RIN 0906-AB01

National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Final rule.

SUMMARY: On July 29, 2015, the Secretary of Health and Human Services (the Secretary) published in the **Federal Register** a Notice of Proposed Rulemaking (NPRM) to amend the regulations governing the National Vaccine Injury Compensation Program (VICP or program) by proposing revisions to the Vaccine Injury Table (Table). The Secretary based the Table revisions primarily on the 2012 Institute of Medicine (IOM) report, "Adverse Effects of Vaccines: Evidence and Causality," the work of nine HHS workgroups who reviewed the IOM findings, and consideration of the Advisory Commission on Childhood Vaccines' (ACCV) recommendations. The Secretary amends the Table through the changes in this final rule. These changes will apply only to petitions for compensation under the VICP filed after this final rule becomes effective.

DATE: This rule is effective February 21, 2017.

FOR FURTHER INFORMATION CONTACT: Dr. Narayan Nair, Acting Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, 5600 Fishers Lane, Room 8N146B, Rockville, MD 20857, or by telephone (855) 266-2427. This is a toll-free number.

SUPPLEMENTARY INFORMATION:

I. Background

The National Childhood Vaccine Injury Act of 1986, title III of Public Law 99-660 (42 U.S.C. 300aa-10 *et seq.*), established the VICP, a Federal

compensation program for persons thought to be injured by vaccines. The statute governing the VICP has been amended several times since 1986 and is hereinafter referred to as “the Act.” Petitions for compensation under the VICP are filed in the United States Court of Federal Claims (Court), with a copy served on the Secretary, who is designated as the “Respondent.” The Court, acting through judicial officers called Special Masters, makes decisions as to eligibility for, and the amount of, compensation.

To gain entitlement to compensation under this program, a petitioner must establish that a vaccine-related injury or death has occurred, either by proving that a vaccine actually caused or significantly aggravated an injury (causation-in-fact) or by demonstrating the occurrence of what is referred to as a “Table Injury.” That is, a petitioner may show that the vaccine recipient suffered an injury of the type enumerated in the regulations at 42 CFR 100.3—the “Vaccine Injury Table”—corresponding to the vaccination in question and that the onset of such injury took place within a time period also specified in the Table. If so, the injury is presumed to have been caused by the vaccination and the petitioner is entitled to compensation (assuming that other requirements are satisfied) unless the Respondent affirmatively shows that the injury was caused by some factor other than the vaccination (*see* 42 U.S.C. 300aa–11(c)(1)(C)(i), 300aa–13(a)(1)(B)), and 300aa–14(a)).

In prior Table revisions, the Secretary determined that the appropriate framework for making changes to the Table is to make specific findings as to the illnesses or conditions that can reasonably be determined, in some circumstances, to be caused or significantly aggravated by the vaccines under review and the circumstances under which such causation or aggravation can reasonably be determined to occur. The Secretary continues this approach through the use of the 2012 IOM report, the work of the nine workgroups who reviewed the IOM findings, and consideration of the ACCV’s recommendations. After consultation with the ACCV, the Secretary may modify the Table by promulgating regulations, with notice and opportunity for a public hearing and at least 180 days of public comment. *See* 42 U.S.C. 300aa–14(c) and (d).

II. Summary of the Final Rule

After the IOM released its 2012 report, 9 HHS workgroups comprising HRSA and Centers for Disease Control and

Prevention (CDC) medical staff reviewed IOM’s conclusions for 158 vaccine-adverse events, as well as any newly published scientific literature not contained in the report, and developed a set of proposed changes to the Table and its definitional counterpart, the Qualifications and Aids to Interpretation (QAI). For the vast majority of the vaccine-adverse event pairs reviewed (135), the IOM determined that the evidence was inadequate to accept or reject a causal relationship. Considering the remaining IOM conclusions and the ACCV Guiding Principles, the Secretary in this final rule is adopting certain additions or changes to the Table where the scientific evidence either convincingly supports or favors acceptance of a causal relationship between certain conditions and covered vaccines, which are unchanged from the proposed rule. As required by the Act, the changes in the proposed rule were presented to the ACCV, which reviewed and concurred with the Table changes set forth in this final rule.

Additionally, the Secretary, following the recommendation of the ACCV, is finalizing the Table change, as proposed, to add the injury of Guillain-Barré Syndrome (GBS) for seasonal influenza vaccinations, which is consistent with the approach taken in the Countermeasures Injury Compensation Program (CICP). Studies have demonstrated a causal association between the monovalent 2009 H1N1 vaccine and the 1976 swine flu vaccine and GBS. These causal associations were the basis of the 2015 decision by the Secretary in the CICP Pandemic Influenza A Countermeasures Injury Table Final Rule (80 FR 47411) to include GBS as an injury associated with the 2009 H1N1 influenza. With respect to that vaccine, the Secretary found that there was compelling, reliable, and valid medical and scientific evidence of an association between the 2009 H1N1 vaccine and GBS, which is required to add an injury to the CICP’s Injury Table. To date, the H1N1 antigen has been included in all seasonal influenza vaccines beginning with the 2010–2011 flu season. HHS notes that seasonal influenza vaccine formulations, unlike other vaccines, include multiple antigens that change from year-to-year, and enhanced surveillance activities to detect the incidence of GBS that occurred during the 2009 H1N1 pandemic may not occur with each virus strain change. In light of this information and other information as discussed in the proposed rule, the ACCV recommended

that the Secretary add GBS consistent with one of its Guiding Principles: That where there is credible evidence to both support and reject a change to the Table, the change should, whenever possible, be made to the benefit of petitioners.

In addition, in the final rule, the Secretary adopts the proposed rule’s new paragraph (b), *Provision that applies to all vaccines listed*. To streamline the Table, this paragraph includes any acute complication or sequela, including death, of the illness, disability, injury, or condition listed, as a Table injury (absent an exclusion as set forth under the QAI) rather than adding the provision to every line of the Table. To further streamline the Table, the Secretary deleted redundant wording in the various definitions, particularly with regard to any references to the presumption of causation, and the importance of the entire medical record. These elements have been included in paragraph (b) and are unchanged from the proposed rule. Finally, in this final rule, the Secretary adopts changes in the proposed rule that simplify and expand applicability of a provision that previously applied only to an encephalopathy. This provision, which indicates that idiopathic conditions do not rebut the Table presumption, now applies (through inclusion in paragraph (b)), to all injuries, while continuing to apply to an encephalopathy.

In this final rule, in addition to the changes described in the proposed rule, the Secretary has made the following non-substantive changes to the proposed rule for purposes of clarity:

- a. Added headings to (c)(2)(ii) and (c)(3)(ii).
- b. Moved text from the end of paragraph (c)(3)(ii)(C) to create a new (c)(3)(ii)(D).
- c. Changed paragraphs (c)(11) and (12) by revising the sentence regarding organs other than the skin by adding “the” before “disease”, inserting “and” after “organ”, and moving “, not just mildly abnormal laboratory values” to the end of the sentence.
- d. Revised paragraph (c)(15)(i) by changing “nine weeks” to “9 weeks”.
- e. Changed paragraph (e)(1) (“Coverage Provisions”) for purpose of clarity and consistency with 42 U.S.C. 300aa–14(c)(4) by adding “only” before “to petitions for compensation.”

The modified Table applies only to petitions filed under the VICP after the effective date of this final rule. Also, petitions must be filed within the applicable statute of limitations. The general statute of limitations applicable to petitions filed under the VICP, set forth in 42 U.S.C. 300aa–16(a),

continues to apply. However, the statute identifies a specific exception to this statute of limitations that applies when the effect of a revision to the Table makes a previously ineligible person eligible to receive compensation or when an eligible person's likelihood of obtaining compensation significantly increases. Under this exception, an individual who may be eligible to file a petition based on the revised Table may file the petition for compensation not later than 2 years after the effective date of the revision if the alleged injury or death occurred not more than 8 years before the effective date of the revision of the Table (42 U.S.C. 300aa-16(b)). This is true even if such individual previously filed a petition for compensation, and is thus an exception to the "one petition per injury" limitation of 42 U.S.C. 300aa-11(b)(2).

For any vaccine-adverse event pairs for which future scientific evidence develops to support a finding of a causal relationship, the Secretary will consider future rulemaking to revise the Table accordingly.

III. Comments and Responses

The NPRM provided a 180-day comment period that resulted in the receipt of 14 written comments—13 from individuals and one from a national organization. In addition, a public hearing on the proposed rule was held on January 14, 2016, during which a representative from the above mentioned national organization presented comments. The organization's oral comments were an expansion of the organization's previously submitted written comments. The Secretary carefully considered all received comments in the development of this final rule. Below is a summary of the comments and the Secretary's responses:

Comment: One commenter suggested that vaccines are unsafe, disagreed with the process for predicting vaccine harm to humans, and disagreed with the makeup of the "group assembled to force changes in this Table," calling it a biased group.

Response: The United States has a long-standing vaccine safety program that closely monitors the safety of vaccines on an ongoing basis. Before vaccines are approved by the Food and Drug Administration (FDA), they are tested and studied extensively by scientists to help ensure they are safe and effective. After vaccines are approved, a critical part of the vaccine safety program is that the Centers for Disease Control and Prevention (CDC)'s Immunization Safety Office (ISO) and FDA monitor for possible vaccine side

effects and conduct studies to determine whether health problems are caused by vaccines. CDC's ISO data show that the current U.S. vaccine supply is the safest in history.¹ Also, regulating clinical research and reviewing the safety of vaccines are responsibilities of the FDA, not the VICP, and changes in vaccine research and how vaccines are studied and tested are beyond the scope of this final rule.

As previously indicated, the Table revisions were based primarily on the 2012 IOM report which was developed after the IOM committee conducted a comprehensive review of the scientific literature on vaccines and adverse events. The committee charged with undertaking this review consisted of 16 members with expertise in the following fields: Pediatrics, internal medicine, neurology, immunology, immunotoxicology, neurobiology, rheumatology, epidemiology, biostatistics, and law. The members of the review committee were subject to stringent conflict of interest criteria by the IOM. In addition, the proposed Table changes were developed by HHS workgroups and reviewed by the ACCV, the membership of which, by statute, reflects a variety of stakeholders with different perspectives.

Comment: A commenter suggested that shoulder injury related to vaccine administration (SIRVA) as defined in the QAI is too restrictive because the recipient's pain and reduced range of motion must be limited to the shoulder in which the intramuscular vaccine was administered. The commenter stated that such language was an artificial and unnecessary qualification, and expressed concern that recipients who have other symptoms, such as shoulder pain radiating to the neck or upper back, will not have the benefits of a Table injury. The commenter suggested that the QAI be expanded to include the shoulder and parts of the body attributed to that injury.

Response: SIRVA is a musculoskeletal condition caused by injection of a vaccine intended for intramuscular administration into the shoulder, and, as its name suggests, the condition is localized to the shoulder in which the vaccine was administered. In other words, pain in the neck or back without an injury to the shoulder in which an individual received a vaccine would not be considered SIRVA. Shoulder injuries that are not caused by injection occur frequently in the population. Thus, it is important to have a definition of SIRVA that is clearly associated with vaccine

injection. The portion of the QAI limiting the pain and reduced range of motion to the shoulder in which the vaccine was administered is necessary to accurately reflect the vaccine-associated condition.

Comment: A commenter recommends revising the statute of limitations for filing complex cases, with additional consideration given to the aggravation of preexisting conditions not active until post vaccine(s).

Response: Revision of the statute of limitations would require a statutory amendment and thus is not within the scope of this final rule.

Comment: A commenter stated that there is a problem with the VICP's 3-year statute of limitations for filing a claim and the military's 5-year program titled, Temporary Disabled Retirement Listing (TDRL), where active duty military personnel injured by vaccines are placed. The commenter stated that the rules need to be amended and/or waivers granted to military personnel who are severely injured by vaccines so they can seek compensation for damages.

Response: Amending the Act's statute of limitations is not within the scope of this final rule.

Comment: A commenter recommended the addition of SIRVA to the vaccine court [sic]. The commenter also indicated a belief that SIRVA is due to lack of education on proper injection technique. The commenter further stated that the CDC should make SIRVA, which the commenter believes is 100 percent preventable, a priority.

Response: This final rule will add SIRVA as an injury associated with certain vaccines on the Table. In the VICP, claims are adjudicated by special masters in the Court. SIRVA prevention activities are not within the scope of this final rule.

Comment: A commenter recommended that the VICP transfer a fraction of its compensation responsibilities to pharmaceutical companies, which would incentivize these companies to develop safer vaccines to avoid claim compensation.

Response: The source of funding for the VICP is the Vaccine Injury Compensation Trust Fund (Trust Fund). The Trust Fund is funded by an excise tax on each dose of vaccines recommended by the CDC for routine administration to children. To the extent that the commenter is proposing a change to the funding mechanism for the VICP, effectuating such a change is beyond the scope of this final rule.

Comment: A commenter agreed with the Secretary's proposal that SIRVA injuries be added to the Table for the

¹ <http://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html>

measles, mumps, and rubella (MMR) and varicella vaccines that are currently administered only by percutaneous injection in case an intramuscular injection is available in the future. The commenter suggested that the Table make clear that SIRVA only pertains to intramuscular injection so there is no confusion with respect to vaccines administered using a different method. The commenter also suggested that syncope be added as an injury for vaccines that are administered by jet injectors. The commenter expressed support for the revision of the Table based on new medical findings and for the organizational changes to paragraph (b) of the Table.

Response: The Secretary agrees that SIRVA should be an injury listed on the Table for potential future formulations of MMR and varicella vaccines that are administered by intramuscular injection, and, therefore, has added SIRVA to the Table for those vaccines despite the fact that currently there are no MMR or varicella vaccines that are administered by intramuscular injection. As such, if an intramuscular formulation of those vaccines is developed in the future, the Table will not need to be amended to allow petitioners to potentially meet the definition for SIRVA in the QAI with respect to those vaccines. The QAI specifically states that SIRVA is a condition related to “administration of a vaccine intended for intramuscular administration in the upper arm.” Thus, the Secretary believes it is clear that to meet the definition of SIRVA in the QAI, the vaccine administered must be one intended for intramuscular injection in the upper arm.

The Secretary is not aware of any reliable and persuasive evidence demonstrating that syncope occurs following administration of a vaccine via a needleless jet device. While it may be plausible for syncope to occur with this route of administration, given the lack of evidence of syncope following administration of a vaccine via a needleless jet device, the Secretary will not include syncope as a Table injury for vaccines that are administered by a needleless jet device at this time. However, this does not preclude a claim alleging syncope after the administration of a vaccine via needleless jet device from being filed with the program as a non-Table injury.

Comment: One commenter opposed the revision of the Vaccine Injury Table’s QAI for encephalopathy, stating that it is not based on sound science and that it creates a restrictive and exclusionary guideline that unfairly discriminates against children and

adults born with certain genes or pre-existing conditions (which may be triggered or significantly aggravated following vaccination). The commenter further contends that due to lack of knowledge about biological mechanisms and high risk factors for vaccine injury, the proposed changes are without ethical, scientific, or legal justification.

Response: The Secretary respectfully disagrees with the comment that the revised definition for encephalopathy and the new definition for encephalitis in the QAI are not based on firm science. The previous definition of encephalopathy in the QAI was imprecise and did not include the comprehensive criteria used by medical providers, particularly specialists, to diagnose encephalopathy or encephalitis. In addition, the previous QAI did not include any definition for encephalitis, and, therefore, new and more accurate criteria and definitions were necessary. To develop precise definitions for the QAI, an extensive literature search was conducted for reliable, reputable, evidence-based criteria consistently used by medical specialists in the fields of infectious disease and neurology. The Secretary also evaluated information from organizations and publications to formulate definitions, including those responsible for publishing case definitions for the Vaccine Adverse Event Reporting System (2002) and other significant guidelines.

The commenter also stated that the proposed revisions create a restrictive and exclusionary guideline, unfairly discriminating against children and adults born with certain genes or pre-existing conditions which may be triggered or significantly aggravated following vaccination. The Secretary understands these concerns and agrees that individuals should not be disqualified from potentially receiving VICP compensation due to biodiversity and individual susceptibilities. Certain individuals may not meet the QAI definition, as it is impossible to develop a scientifically sound definition that allows for inclusion of every circumstance, particularly those that may arise when unique and sometimes complex pre-vaccination medical conditions exist.² However, individuals who do not meet the Table criteria are not precluded from filing a petition, and may be found entitled to receive compensation if they demonstrate that their condition was caused or significantly aggravated by a covered vaccine.

Comment: One commenter also noted that, historically, acute and chronic encephalopathy have been acknowledged as a serious complication of pertussis, measles and measles containing vaccines, and have been reported following receipt of other vaccines.

Response: With regard to this comment, it is important to note that the initial Table and QAI set forth in the 1986 Act reflected Congress’s initial determination of vaccine-related injuries for whole cell diphtheria, tetanus, and pertussis (DTwP) vaccine, which is no longer used. Additionally, modifications to the Table and QAI by the Secretary in 1995 were based on scientific findings—the National Childhood Encephalopathy Study and its 10-year follow-up study—related to DTaP vaccine. The IOM committee’s conclusions in both 1991 and 1994 were mixed regarding the statistically significant findings of encephalopathy in these studies. After reviewing the evidence, the National Vaccine Advisory Committee (NVAC) voted to remove encephalopathy from the Table. However, in the end, the Secretary, for both scientific and policy reasons, and with support of the ACCV, retained the condition on the Table, but clarified the definition of encephalopathy to make it more clinically precise.

While the initial Table and QAI were based on studies using DTwP vaccine, the acellular (aP) diphtheria, tetanus, and pertussis (DTaP) vaccine has been the primary formulation used in the United States since 1997 when it was recommended for routine use in children younger than 7 years of age. Current DTaP vaccines were developed because of concerns of reactogenicity with whole cell pertussis.

To date, no adequate scientific study has been published that demonstrates a causal relationship between either acellular pertussis vaccines or MMR vaccines and encephalopathy or encephalitis. As a result, in its most recent evaluation of adverse events after vaccines (2012), the IOM found that the evidence was inadequate to accept or reject a causal association between either acellular pertussis containing vaccines or MMR vaccines and encephalopathy or encephalitis. Of the large scale studies that have been conducted on DTaP, none have shown an increased risk of encephalopathy or encephalitis after receiving the DTaP vaccine. Furthermore, these studies have demonstrated a significant reduction in the number of common adverse events with acellular pertussis, such as crying and fevers, and less common ones, such as febrile seizures.

² 2012 IOM Report, pp. 52, and 82–84.

With regard to the MMR vaccine, because natural infection of measles, mumps and/or rubella virus is thought to lead to neurologic illness by damaging neurons through direct viral infection and/or reactivation, it is theorized that the same mechanisms may be responsible for vaccine-associated encephalopathy and encephalitis. However, of the studies examined and described by the IOM in its 2012 report, none identified causality between the MMR vaccine and encephalopathy or encephalitis. Similarly, the IOM concluded that the mechanistic evidence for an association is weak, based on knowledge about natural infection and only a few case reports. Accordingly, the Secretary does not agree that brain inflammation or acute and chronic encephalopathy have been acknowledged as a serious complication of either the DTaP or MMR vaccines. However, for the reasons discussed in the NPRM, the Secretary chose to retain these conditions in the revisions to the Table and QAI.

Comment: One commenter, when conveying views on acute encephalopathy as “one of the most serious complications of vaccination . . .” also referenced both encephalitis and encephalomyelitis in the discussion.

Response: The Secretary would like to clarify that encephalitis and encephalomyelitis (which is referred to as acute disseminated encephalomyelitis or ADEM) are distinct conditions. While they share some clinical characteristics, ADEM is a demyelinating condition with distinct differences from other types of encephalitis, as demonstrated on brain magnetic resonance imaging (MRI). The type of encephalitis that was initially attributed to DTWP was not described as demyelinating. Although early ADEM may have laboratory and clinical characteristics similar to acute encephalitis, findings on an MRI are distinct, with only ADEM displaying evidence of acute demyelination. For scientific accuracy, we have excluded ADEM from the Table definition of encephalitis.

Comment: One commenter, while applauding the expansion of the Vaccine Injury Table and agreeing with the IOM’s recommendations, stated that the Table remains wholly inadequate to properly address “the widespread epidemic of vaccine adverse events.” The commenter stated that the reason for this is that science has been corrupted by commercial interests, by financial ties between industry, regulators, and academic institutions

and that health care delivery has been compromised by financial ties between industry, physicians, and their trade publications.

Response: The Secretary believes that the revisions to the Table and QAI increase clarity and scientific accuracy regarding those injuries that will be afforded the Table’s presumption of vaccine causation. As previously indicated, the revisions to the Table and QAI were based primarily on the 2012 IOM report which was developed after the IOM committee conducted a comprehensive review of the scientific literature on vaccines and adverse events. The committee charged with undertaking this review consisted of 16 members with expertise in the following fields: pediatrics, internal medicine, neurology, immunology, immunotoxicology, neurobiology, rheumatology, epidemiology, biostatistics, and law. The members of the review committee were subject to stringent conflict of interest criteria by the IOM. In addition, the proposed Table changes were developed by HHS workgroups and reviewed by the ACCV, the membership of which, by statute, reflects a variety of stakeholders with different perspectives.

Comment: One commenter stated that the Secretary should not make changes to the Vaccine Injury Table that would make it more difficult for “victims” to be compensated.

Response: The Secretary believes that the revisions to the Table and QAI set forth in this final rule, such as the addition of injuries, will make it easier for petitioners alleging injuries that meet the criteria in the Table and QAI to receive the Table’s presumption of causation (which relieves them of having to prove that the vaccine actually caused or significantly aggravated the injury). This will make it easier for such petitioners to receive compensation under the VICP.

Comment: One commenter asked that additional consideration be given to the human papillomavirus (HPV) vaccination as a cause of postural orthostatic tachycardia syndrome (POTS), a condition where individuals can experience fainting and lightheadedness. The commenter also stated that the “review period” should be indefinite for the HPV vaccine.

Response: Like all vaccines used in the United States, HPV vaccines are required to go through years of safety testing before they are approved by the FDA. After they are approved and made available to the public, CDC and FDA continue to evaluate vaccines to ensure their safety. To date, there is no medical or scientific evidence that the HPV

vaccine causes POTS and safety monitoring has not shown any other problems. Extending the review period for alleged injuries due to the HPV vaccine would require a statutory amendment to the Act’s statute of limitations which is not within the scope of the final rule.

Comment: A commenter requested that food allergies be added to the Table asserting that food proteins that are present in vaccines cause the development of food allergies. The commenter also requested removal of the time limit that compensation is not provided for injuries or death that occurred more than “8 years before the effective date of the revision of the Table” because the commenter believes that “food proteins in vaccines have been causing injury for decades.”

Response: The Secretary does not agree that food allergies should be added to the Table as injuries. HHS conducted a literature search of the major medical databases for any articles linking the development of food allergies to vaccinations (81 FR 17423, March 29, 2016). Despite an extensive search, HHS found no published research addressing any linkages or potential causality between vaccinations covered by VICP and the development of food allergies in any population. In addition, revision of the Act’s statute of limitations would require a statutory amendment and thus is not within the scope of this final rule.

Comment: One commenter suggested that autism spectrum disorders be added to the Vaccine Injury Table. The commenter also requested removal of the time limit that compensation not be provided for injuries or death that occurred more than “8 years before the effective date of the revision of the Table” because the commenter believes that “bovine milk contaminated vaccines have been causing injury for decades.”

Response: The Secretary does not agree that autism spectrum disorders should be added as an injury to the Table. The 2012 IOM report found that the epidemiologic and mechanistic evidence favored rejection of a causal relationship between the MMR vaccine and autism. Moreover, in opinions that were upheld on appeal to the U.S. Court of Appeals for the Federal Circuit, special masters of the U.S. Court of Federal Claims held that the MMR, whether administered alone or in conjunction with thimerosal-containing vaccines, is not a causal factor in the development of autism or autism spectrum disorders. In addition, revision of the Act’s statute of limitations would require a statutory

amendment and thus is not within the purview of this final rule.

Comment: One commenter stated that thimerosal (a preservative added to vaccines) causes nerve damage.

Response: The Secretary disagrees with the comment that thimerosal in vaccines causes nerve damage to immunized individuals. Currently, no childhood vaccines used in the U.S. include thimerosal as a preservative, except for some formulations of influenza vaccine in multi-dose vials. When exposure to thimerosal occurs through vaccination, it is at a very low dose, which is readily eliminated from the body. Thimerosal has been used safely in vaccines since the 1930s. According to the CDC, scientists have been studying the use of thimerosal in vaccines for many years. They have not found any evidence that thimerosal causes any harm. Thimerosal use in medical products has a record of being very safe. Data from many studies show no evidence of harm caused by low doses of thimerosal in vaccines.³

Economic and Regulatory Impact

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that provide the

greatest net benefits (including potential economic, environmental, public health, safety, distributive, and equity effects). In addition, under the Regulatory Flexibility Act, if a rule has a significant economic effect on a substantial number of small entities the Secretary must specifically consider the economic effect of a rule on small entities and analyze regulatory options that could lessen the impact of the rule.

Executive Order 12866 requires that all regulations reflect consideration of alternatives, costs, benefits, incentives, equity, and available information. Regulations must meet certain standards, such as avoiding an unnecessary burden. Regulations that are “significant” because of cost, adverse effects on the economy, inconsistency with other agency actions, effects on the budget, or novel legal or policy issues require special analysis.

The Secretary has determined that no resources are required to implement the requirements in this rule. Compensation will be made in the same manner. This final rule only lessens the burden of proof for potential petitioners. Therefore, in accordance with the Regulatory Flexibility Act of 1980 (RFA), and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, the Secretary certifies that this rule will not have a significant impact on a substantial number of small entities.

The Secretary has also determined that this final rule does not meet the criteria for a major rule as defined by Executive Order 12866 and would have no major effect on the economy or Federal expenditures. We have determined that the final rule is not a “major rule” within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. 801. Similarly, it will not have effects on State, local, and tribal governments and on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995.

The provisions of this rule do not, on the basis of family well-being, affect the following family elements: Family safety; family stability; marital commitment; parental rights in the education, nurture and supervision of their children; family functioning; disposable income or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of 1999.

This rule is not being treated as a “significant regulatory action” as defined under section 3(f) of Executive

Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget.

As stated above, this final rule will modify the Vaccine Injury Table and its Qualifications and Aids to Interpretation based on legal authority.

Impact of the New Rule

This final rule will have the effect of making it easier for future petitioners alleging injuries that meet the criteria in the Vaccine Injury Table to receive the Table’s presumption of causation (which relieves them of having to prove that the vaccine actually caused or significantly aggravated the injury).

Paperwork Reduction Act of 1995

This final rule has no information collection requirements.

Dated: January 6, 2017.

James Macrae,

Acting Administrator, Health Resources and Services Administration.

Approved: January 9, 2017.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

List of Subjects in 42 CFR Part 100

Biologics, Health insurance, Immunization.

National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table

Therefore, for the reasons stated in the preamble, the Department of Health and Human Services amends 42 CFR part 100 as follows:

PART 100—VACCINE INJURY COMPENSATION

■ 1. The authority citation for 42 CFR part 100 continues to read as follows:

Authority: Secs. 312 and 313 of Public Law 99–660 (42 U.S.C. 300aa–1 note); 42 U.S.C. 300aa–10 to 300aa–34; 26 U.S.C. 4132(a); and sec. 13632(a)(3) of Public Law 103–66.

■ 2. Revise § 100.3 to read as follows:

§ 100.3 Vaccine injury table.

(a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Public Law 99–660, 100 Stat. 3779 (42 U.S.C. 300aa–1 note) and section 2114(c) of the Public Health Service Act, as amended (PHS Act) (42 U.S.C. 300aa–14(c)), the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such

³ Following are referenced thimerosal studies:

1. Thimerosal Exposure in Infants and Developmental Disorders: A Retrospective Cohort Study in the United Kingdom Does Not Support a Causal Association by Nick Andrews et al. *Pediatrics*. September 2004. Vol 114: pp. 584–591. <http://pediatrics.aappublications.org/cgi/content/full/114/3/584>.

2. Pervasive Developmental Disorders in Montreal, Quebec, Canada: Prevalence and Links with Immunizations by Eric Frombonne et al. *Pediatrics*. July 2006. Vol 118: e139–e150. <http://pediatrics.aappublications.org/cgi/content/full/118/1/e139>.

3. Association between Thimerosal-Containing Vaccine and Autism by Anders Hviid et al. *Journal of the American Medical Association*. October 2003. Vol 290: pp. 1763–1766. <http://jama.ama-assn.org/cgi/content/full/290/13/1763>.

4. Immunization Safety Review: Vaccines and Autism. Institute of Medicine. The National Academies Press: 2004. <http://www.iom.edu/Reports/2004/Immunization-SafetyReview-Vaccines-and-Autism.aspx>.

5. Prenatal and Infant Exposure to Thimerosal from Vaccines and Immunoglobulins and Risk of Autism by Cristofer Price et al. *Pediatrics*. September 2010. Vol 126: pp. 656–664. <http://pediatrics.aappublications.org/cgi/reprint/peds.20100309v1>.

6. Continuing Increases in Autism Reported to California’s Developmental Services System by Robert Schechter et al. *Archives of General Psychiatry*. January 2008. Vol 65: pp. 19–24. <http://archpsyc.ama-assn.org/cgi/content/full/65/1/19>.

7. Early Thimerosal Exposure and Neuropsychological Outcomes at 7 to 10 Years by William Thompson et al. *The New England Journal of Medicine*. September 2007. Vol 357: pages 1281–1292. <http://www.nejm.org/doi/pdf/10.1056/NEJMoa071434>.

injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program. Paragraph (b) of this section sets forth additional provisions that are

not separately listed in this Table but that constitute part of it. Paragraph (c) of this section sets forth the qualifications and aids to interpretation for the terms used in the Table. Conditions and injuries that do not meet

the terms of the qualifications and aids to interpretation are not within the Table. Paragraph (d) of this section sets forth a glossary of terms used in paragraph (c).

VACCINE INJURY TABLE

| Vaccine | Illness, disability, injury or condition covered | Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration |
|---|--|--|
| I. Vaccines containing tetanus toxoid (<i>e.g.</i> , DTaP, DTP, DT, Td, or TT). | A. Anaphylaxis | ≤4 hours. |
| | B. Brachial Neuritis | 2–28 days (not less than 2 days and not more than 28 days). |
| | C. Shoulder Injury Related to Vaccine Administration. | ≤48 hours. |
| | D. Vasovagal syncope | ≤1 hour. |
| II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (<i>e.g.</i> , DTP, DTaP, P, DTP-Hib). | A. Anaphylaxis | ≤4 hours. |
| | B. Encephalopathy or encephalitis | ≤72 hours. |
| | C. Shoulder Injury Related to Vaccine Administration. | ≤48 hours. |
| | D. Vasovagal syncope | ≤1 hour. |
| III. Vaccines containing measles, mumps, and rubella virus or any of its components (<i>e.g.</i> , MMR, MM, MMRV). | A. Anaphylaxis | ≤4 hours. |
| | B. Encephalopathy or encephalitis | 5–15 days (not less than 5 days and not more than 15 days). |
| | C. Shoulder Injury Related to Vaccine Administration. | ≤48 hours. |
| | D. Vasovagal syncope | ≤1 hour. |
| IV. Vaccines containing rubella virus (<i>e.g.</i> , MMR, MMRV). | A. Chronic arthritis | 7–42 days (not less than 7 days and not more than 42 days). |
| V. Vaccines containing measles virus (<i>e.g.</i> , MMR, MM, MMRV). | A. Thrombocytopenic purpura | 7–30 days (not less than 7 days and not more than 30 days). |
| | B. Vaccine-Strain Measles Viral Disease in an immunodeficient recipient. —Vaccine-strain virus identified | Not applicable. |
| | —If strain determination is not done or if laboratory testing is inconclusive. | ≤12 months. |
| VI. Vaccines containing polio live virus (OPV) .. | A. Paralytic Polio. —in a non-immunodeficient recipient | ≤30 days. |
| | —in an immunodeficient recipient | ≤6 months. |
| | —in a vaccine associated community case | Not applicable. |
| | B. Vaccine-Strain Polio Viral Infection. —in a non-immunodeficient recipient | ≤30 days. |
| | —in an immunodeficient recipient | ≤6 months. |
| | —in a vaccine associated community case | Not applicable. |
| VII. Vaccines containing polio inactivated virus (<i>e.g.</i> , IPV). | A. Anaphylaxis | ≤4 hours. |
| | B. Shoulder Injury Related to Vaccine Administration. | ≤48 hours. |
| | C. Vasovagal syncope | ≤1 hour. |
| VIII. Hepatitis B vaccines | A. Anaphylaxis | ≤4 hours. |
| | B. Shoulder Injury Related to Vaccine Administration. | ≤48 hours. |
| | C. Vasovagal syncope | ≤1 hour. |
| IX. Haemophilus influenzae type b (Hib) vaccines. | A. Shoulder Injury Related to Vaccine Administration. | ≤48 hours. |
| | B. Vasovagal syncope | ≤1 hour. |
| X. Varicella vaccines | A. Anaphylaxis | ≤4 hours. |
| | B. Disseminated varicella vaccine-strain viral disease. —Vaccine-strain virus identified | Not applicable. |
| | —If strain determination is not done or if laboratory testing is inconclusive. | 7–42 days (not less than 7 days and not more than 42 days). |
| | C. Varicella vaccine-strain viral reactivation | Not applicable. |
| | D. Shoulder Injury Related to Vaccine Administration. | ≤48 hours. |
| | E. Vasovagal syncope | ≤1 hour. |
| XI. Rotavirus vaccines | A. Intussusception | 1–21 days (not less than 1 day and not more than 21 days). |
| XII. Pneumococcal conjugate vaccines | A. Shoulder Injury Related to Vaccine Administration. | ≤48 hours. |

VACCINE INJURY TABLE—Continued

| Vaccine | Illness, disability, injury or condition covered | Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration |
|---|---|--|
| XIII. Hepatitis A vaccines | B. Vasovagal syncope | ≤1 hour. |
| | A. Shoulder Injury Related to Vaccine Administration. | ≤48 hours. |
| XIV. Seasonal influenza vaccines | B. Vasovagal syncope | ≤1 hour. |
| | A. Anaphylaxis | ≤4 hours. |
| | B. Shoulder Injury Related to Vaccine Administration. | ≤48 hours. |
| | C. Vasovagal syncope | ≤1 hour. |
| | D. Guillain-Barré Syndrome | 3–42 days (not less than 3 days and not more than 42 days). |
| XV. Meningococcal vaccines | A. Anaphylaxis | ≤4 hours. |
| | B. Shoulder Injury Related to Vaccine Administration. | ≤48 hours. |
| | C. Vasovagal syncope | ≤1 hour. |
| XVI. Human papillomavirus (HPV) vaccines | A. Anaphylaxis | ≤4 hours. |
| | B. Shoulder Injury Related to Vaccine Administration. | ≤48 hours. |
| | C. Vasovagal syncope | ≤1 hour. |
| XVII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage. | A. Shoulder Injury Related to Vaccine Administration. | ≤48 hours. |
| | B. Vasovagal syncope | ≤1 hour. |

(b) *Provisions that apply to all conditions listed.* (1) Any acute complication or sequela, including death, of the illness, disability, injury, or condition listed in paragraph (a) of this section (and defined in paragraphs (c) and (d) of this section) qualifies as a Table injury under paragraph (a) except when the definition in paragraph (c) requires exclusion.

(2) In determining whether or not an injury is a condition set forth in paragraph (a) of this section, the Court shall consider the entire medical record.

(3) An idiopathic condition that meets the definition of an illness, disability, injury, or condition set forth in paragraph (c) of this section shall be considered to be a condition set forth in paragraph (a) of this section.

(c) *Qualifications and aids to interpretation.* The following qualifications and aids to interpretation shall apply to, define and describe the scope of, and be read in conjunction with paragraphs (a), (b), and (d) of this section:

(1) *Anaphylaxis.* Anaphylaxis is an acute, severe, and potentially lethal systemic reaction that occurs as a single discrete event with simultaneous involvement of two or more organ systems. Most cases resolve without sequela. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse.

Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. There are no specific pathological findings to confirm a diagnosis of anaphylaxis.

(2) *Encephalopathy.* A vaccine recipient shall be considered to have suffered an encephalopathy if an injury meeting the description below of an acute encephalopathy occurs within the applicable time period and results in a chronic encephalopathy, as described in paragraph (d) of this section.

(i) *Acute encephalopathy.* (A) For children less than 18 months of age who present:

(1) Without a seizure, an acute encephalopathy is indicated by a significantly decreased level of consciousness that lasts at least 24 hours.

(2) Following a seizure, an acute encephalopathy is demonstrated by a significantly decreased level of consciousness that lasts at least 24 hours and cannot be attributed to a postictal state—from a seizure or a medication.

(B) For adults and children 18 months of age or older, an acute encephalopathy is one that persists at least 24 hours and is characterized by at least two of the following:

(1) A significant change in mental status that is not medication related

(such as a confusional state, delirium, or psychosis);

(2) A significantly decreased level of consciousness which is independent of a seizure and cannot be attributed to the effects of medication; and

(3) A seizure associated with loss of consciousness.

(C) The following clinical features in themselves do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, poor feeding, persistent inconsolable crying, bulging fontanelle, or symptoms of dementia.

(D) Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy and in the absence of other evidence of an acute encephalopathy seizures shall not be viewed as the first symptom or manifestation of an acute encephalopathy.

(ii) *Exclusionary criteria for encephalopathy.* Regardless of whether or not the specific cause of the underlying condition, systemic disease, or acute event (including an infectious organism) is known, an encephalopathy shall not be considered to be a condition set forth in the Table if it is shown that the encephalopathy was caused by:

(A) An underlying condition or systemic disease shown to be unrelated to the vaccine (such as malignancy, structural lesion, psychiatric illness, dementia, genetic disorder, prenatal or

perinatal central nervous system (CNS) injury); or

(B) An acute event shown to be unrelated to the vaccine such as a head trauma, stroke, transient ischemic attack, complicated migraine, drug use (illicit or prescribed) or an infectious disease.

(3) *Encephalitis*. A vaccine recipient shall be considered to have suffered encephalitis if an injury meeting the description below of acute encephalitis occurs within the applicable time period and results in a chronic encephalopathy, as described in paragraph (d) of this section.

(i) *Acute encephalitis*. Encephalitis is indicated by evidence of neurologic dysfunction, as described in paragraph (c)(3)(i)(A) of this section, plus evidence of an inflammatory process in the brain, as described in paragraph (c)(3)(i)(B) of this section.

(A) Evidence of neurologic dysfunction consists of either:

(1) One of the following neurologic findings referable to the CNS: Focal cortical signs (such as aphasia, alexia, agraphia, cortical blindness); cranial nerve abnormalities; visual field defects; abnormal presence of primitive reflexes (such as Babinski's sign or sucking reflex); or cerebellar dysfunction (such as ataxia, dysmetria, or nystagmus); or

(2) An acute encephalopathy as set forth in paragraph (c)(2)(i) of this section.

(B) Evidence of an inflammatory process in the brain (central nervous system or CNS inflammation) must include cerebrospinal fluid (CSF) pleocytosis (>5 white blood cells (WBC)/mm³ in children >2 months of age and adults; >15 WBC/mm³ in children <2 months of age); or at least two of the following:

(1) Fever (temperature ≥ 100.4 degrees Fahrenheit);

(2) Electroencephalogram findings consistent with encephalitis, such as diffuse or multifocal nonspecific background slowing and periodic discharges; or

(3) Neuroimaging findings consistent with encephalitis, which include, but are not limited to brain/spine magnetic resonance imaging (MRI) displaying diffuse or multifocal areas of hyperintense signal on T2-weighted, diffusion-weighted image, or fluid-attenuation inversion recovery sequences.

(ii) *Exclusionary criteria for encephalitis*. Regardless of whether or not the specific cause of the underlying condition, systemic disease, or acute event (including an infectious organism) is known, encephalitis shall not be considered to be a condition set forth in

the Table if it is shown that the encephalitis was caused by:

(A) An underlying malignancy that led to a paraneoplastic encephalitis;

(B) An infectious disease associated with encephalitis, including a bacterial, parasitic, fungal or viral illness (such as herpes viruses, adenovirus, enterovirus, West Nile Virus, or human immunodeficiency virus), which may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing; or

(C) Acute disseminated encephalomyelitis (ADEM). Although early ADEM may have laboratory and clinical characteristics similar to acute encephalitis, findings on MRI are distinct with ADEM displaying evidence of acute demyelination (scattered, focal, or multifocal areas of inflammation and demyelination within cerebral subcortical and deep cortical white matter; gray matter involvement may also be seen but is a minor component); or

(D) Other conditions or abnormalities that would explain the vaccine recipient's symptoms.

(4) *Intussusception*. (i) For purposes of paragraph (a) of this section, intussusception means the invagination of a segment of intestine into the next segment of intestine, resulting in bowel obstruction, diminished arterial blood supply, and blockage of the venous blood flow. This is characterized by a sudden onset of abdominal pain that may be manifested by anguished crying, irritability, vomiting, abdominal swelling, and/or passing of stools mixed with blood and mucus.

(ii) For purposes of paragraph (a) of this section, the following shall not be considered to be a Table intussusception:

(A) Onset that occurs with or after the third dose of a vaccine containing rotavirus;

(B) Onset within 14 days after an infectious disease associated with intussusception, including viral disease (such as those secondary to non-enteric or enteric adenovirus, or other enteric viruses such as Enterovirus), enteric bacteria (such as *Campylobacter jejuni*), or enteric parasites (such as *Ascaris lumbricoides*), which may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing;

(C) Onset in a person with a preexisting condition identified as the lead point for intussusception such as intestinal masses and cystic structures (such as polyps, tumors, Meckel's diverticulum, lymphoma, or duplication cysts);

(D) Onset in a person with abnormalities of the bowel, including congenital anatomic abnormalities, anatomic changes after abdominal surgery, and other anatomic bowel abnormalities caused by mucosal hemorrhage, trauma, or abnormal intestinal blood vessels (such as Henoch Schölein purpura, hematoma, or hemangioma); or

(E) Onset in a person with underlying conditions or systemic diseases associated with intussusception (such as cystic fibrosis, celiac disease, or Kawasaki disease).

(5) *Chronic arthritis*. Chronic arthritis is defined as persistent joint swelling with at least two additional manifestations of warmth, tenderness, pain with movement, or limited range of motion, lasting for at least 6 months.

(i) Chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:

(A) Medical documentation recorded within 30 days after the onset of objective signs of acute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination; and

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination; and

(C) Medical documentation of an antibody response to the rubella virus.

(ii) The following shall not be considered as chronic arthritis:

Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile idiopathic arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/dermatomyositis, fibromyalgia, necrotizing vasculitis and vasculopathies and Sjögren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction), metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders, and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's Syndrome, blood disorders, or arthralgia (joint pain), or joint stiffness without swelling.

(6) *Brachial neuritis*. This term is defined as dysfunction limited to the upper extremity nerve plexus (*i.e.*, its trunks, divisions, or cords). A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is

typically followed in days or weeks by weakness in the affected upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. Atrophy of the affected muscles may occur. The neuritis, or plexopathy, may be present on the same side or on the side opposite the injection. It is sometimes bilateral, affecting both upper extremities. A vaccine recipient shall be considered to have suffered brachial neuritis as a Table injury if such recipient manifests all of the following:

- (i) Pain in the affected arm and shoulder is a presenting symptom and occurs within the specified time-frame;
- (ii) Weakness;

(A) Clinical diagnosis in the absence of nerve conduction and electromyographic studies requires weakness in muscles supplied by more than one peripheral nerve.

(B) Nerve conduction studies (NCS) and electromyographic (EMG) studies localizing the injury to the brachial plexus are required before the diagnosis can be made if weakness is limited to muscles supplied by a single peripheral nerve.

(iii) Motor, sensory, and reflex findings on physical examination and the results of NCS and EMG studies, if performed, must be consistent in confirming that dysfunction is attributable to the brachial plexus; and

(iv) No other condition or abnormality is present that would explain the vaccine recipient's symptoms.

(7) *Thrombocytopenic purpura*. This term is defined by the presence of clinical manifestations, such as petechiae, significant bruising, or spontaneous bleeding, and by a serum platelet count less than 50,000/mm³ with normal red and white blood cell indices. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with other causes such as hypersplenism, autoimmune disorders (including alloantibodies from previous transfusions) myelodysplasias, lymphoproliferative disorders, congenital thrombocytopenia or hemolytic uremic syndrome. Thrombocytopenic purpura does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura that are mediated, for example, by viral or fungal infections, toxins or drugs. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with disseminated intravascular coagulation, as observed with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr

virus, cytomegalovirus, hepatitis A and B, human immunodeficiency virus, adenovirus, and dengue virus. An antecedent viral infection may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing. However, if culture or serologic testing is performed, and the viral illness is attributed to the vaccine-strain measles virus, the presumption of causation will remain in effect. Bone marrow examination, if performed, must reveal a normal or an increased number of megakaryocytes in an otherwise normal marrow.

(8) *Vaccine-strain measles viral disease*. This term is defined as a measles illness that involves the skin and/or another organ (such as the brain or lungs). Measles virus must be isolated from the affected organ or histopathologic findings characteristic for the disease must be present. Measles viral strain determination may be performed by methods such as polymerase chain reaction test and vaccine-specific monoclonal antibody. If strain determination reveals wild-type measles virus or another, non-vaccine-strain virus, the disease shall not be considered to be a condition set forth in the Table. If strain determination is not done or if the strain cannot be identified, onset of illness in any organ must occur within 12 months after vaccination.

(9) *Vaccine-strain polio viral infection*. This term is defined as a disease caused by poliovirus that is isolated from the affected tissue and should be determined to be the vaccine-strain by oligonucleotide or polymerase chain reaction. Isolation of poliovirus from the stool is not sufficient to establish a tissue specific infection or disease caused by vaccine-strain poliovirus.

(10) *Shoulder injury related to vaccine administration (SIRVA)*. SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even

if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

(i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;

(ii) Pain occurs within the specified time-frame;

(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

(11) *Disseminated varicella vaccine-strain viral disease*. Disseminated varicella vaccine-strain viral disease is defined as a varicella illness that involves the skin beyond the dermatome in which the vaccination was given and/or disease caused by vaccine-strain varicella in another organ. For organs other than the skin, the disease must be demonstrated in the involved organ and not just through mildly abnormal laboratory values. If there is involvement of an organ beyond the skin, and no virus was identified in that organ, the involvement of all organs must occur as part of the same, discrete illness. If strain determination reveals wild-type varicella virus or another, non-vaccine-strain virus, the viral disease shall not be considered to be a condition set forth in the Table. If strain determination is not done or if the strain cannot be identified, onset of illness in any organ must occur 7–42 days after vaccination.

(12) *Varicella vaccine-strain viral reactivation disease*. Varicella vaccine-strain viral reactivation disease is defined as the presence of the rash of herpes zoster with or without concurrent disease in an organ other than the skin. Zoster, or shingles, is a painful, unilateral, pruritic rash appearing in one or more sensory dermatomes. For organs other than the skin, the disease must be demonstrated in the involved organ and not just through mildly abnormal laboratory values. There must be laboratory confirmation that the vaccine-strain of the varicella virus is present in the skin or in any other involved organ, for example by oligonucleotide or polymerase chain reaction. If strain determination reveals wild-type

varicella virus or another, non-vaccine-strain virus, the viral disease shall not be considered to be a condition set forth in the Table.

(13) *Vasovagal syncope*. Vasovagal syncope (also sometimes called neurocardiogenic syncope) means loss of consciousness (fainting) and postural tone caused by a transient decrease in blood flow to the brain occurring after the administration of an injected vaccine. Vasovagal syncope is usually a benign condition but may result in falling and injury with significant sequela. Vasovagal syncope may be preceded by symptoms such as nausea, lightheadedness, diaphoresis, and/or pallor. Vasovagal syncope may be associated with transient seizure-like activity, but recovery of orientation and consciousness generally occurs simultaneously with vasovagal syncope. Loss of consciousness resulting from the following conditions will not be considered vasovagal syncope: organic heart disease, cardiac arrhythmias, transient ischemic attacks, hyperventilation, metabolic conditions, neurological conditions, and seizures. Episodes of recurrent syncope occurring after the applicable time period are not considered to be sequela of an episode of syncope meeting the Table requirements.

(14) *Immunodeficient recipient*. Immunodeficient recipient is defined as an individual with an identified defect in the immunological system which impairs the body's ability to fight infections. The identified defect may be due to an inherited disorder (such as severe combined immunodeficiency resulting in absent T lymphocytes), or an acquired disorder (such as acquired immunodeficiency syndrome resulting from decreased CD4 cell counts). The identified defect must be demonstrated in the medical records, either preceding or postdating vaccination.

(15) *Guillain-Barré Syndrome (GBS)*. (i) GBS is an acute monophasic peripheral neuropathy that encompasses a spectrum of four clinicopathological subtypes described below. For each subtype of GBS, the interval between the first appearance of symptoms and the nadir of weakness is between 12 hours and 28 days. This is followed in all subtypes by a clinical plateau with stabilization at the nadir of symptoms, or subsequent improvement without significant relapse. Death may occur without a clinical plateau. Treatment related fluctuations in all subtypes of GBS can occur within 9 weeks of GBS symptom onset and recurrence of symptoms after this time-frame would not be consistent with GBS.

(ii) The most common subtype in North America and Europe, comprising more than 90 percent of cases, is acute inflammatory demyelinating polyneuropathy (AIDP), which has the pathologic and electrodiagnostic features of focal demyelination of motor and sensory peripheral nerves and nerve roots. Another subtype called acute motor axonal neuropathy (AMAN) is generally seen in other parts of the world and is predominated by axonal damage that primarily affects motor nerves. AMAN lacks features of demyelination. Another less common subtype of GBS includes acute motor and sensory neuropathy (AMSAN), which is an axonal form of GBS that is similar to AMAN, but also affects the sensory nerves and roots. AIDP, AMAN, and AMSAN are typically characterized by symmetric motor flaccid weakness, sensory abnormalities, and/or autonomic dysfunction caused by autoimmune damage to peripheral nerves and nerve roots. The diagnosis of AIDP, AMAN, and AMSAN requires:

- (A) Bilateral flaccid limb weakness and decreased or absent deep tendon reflexes in weak limbs;
- (B) A monophasic illness pattern;
- (C) An interval between onset and nadir of weakness between 12 hours and 28 days;
- (D) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse; however, death may occur without a clinical plateau); and,
- (E) The absence of an identified more likely alternative diagnosis.

(iii) Fisher Syndrome (FS), also known as Miller Fisher Syndrome, is a subtype of GBS characterized by ataxia, areflexia, and ophthalmoplegia, and overlap between FS and AIDP may be seen with limb weakness. The diagnosis of FS requires:

- (A) Bilateral ophthalmoparesis;
- (B) Bilateral reduced or absent tendon reflexes;
- (C) Ataxia;
- (D) The absence of limb weakness (the presence of limb weakness suggests a diagnosis of AIDP, AMAN, or AMSAN);
- (E) A monophasic illness pattern;
- (F) An interval between onset and nadir of weakness between 12 hours and 28 days;
- (G) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse; however, death may occur without a clinical plateau);
- (H) No alteration in consciousness;
- (I) No corticospinal tract signs; and
- (J) The absence of an identified more likely alternative diagnosis.

(iv) Evidence that is supportive, but not required, of a diagnosis of all subtypes of GBS includes electrophysiologic findings consistent with GBS or an elevation of cerebral spinal fluid (CSF) protein with a total CSF white blood cell count below 50 cells per microliter. Both CSF and electrophysiologic studies are frequently normal in the first week of illness in otherwise typical cases of GBS.

(v) To qualify as any subtype of GBS, there must not be a more likely alternative diagnosis for the weakness.

(vi) Exclusionary criteria for the diagnosis of all subtypes of GBS include the ultimate diagnosis of any of the following conditions: chronic immune demyelinating polyradiculopathy (CIDP), carcinomatous meningitis, brain stem encephalitis (other than Bickerstaff brainstem encephalitis), myelitis, spinal cord infarct, spinal cord compression, anterior horn cell diseases such as polio or West Nile virus infection, subacute inflammatory demyelinating polyradiculoneuropathy, multiple sclerosis, cauda equina compression, metabolic conditions such as hypermagnesemia or hypophosphatemia, tick paralysis, heavy metal toxicity (such as arsenic, gold, or thallium), drug-induced neuropathy (such as vincristine, platinum compounds, or nitrofurantoin), porphyria, critical illness neuropathy, vasculitis, diphtheria, myasthenia gravis, organophosphate poisoning, botulism, critical illness myopathy, polymyositis, dermatomyositis, hypokalemia, or hyperkalemia. The above list is not exhaustive.

(d) *Glossary for purposes of paragraph (c) of this section—*(1) *Chronic encephalopathy*. (i) A chronic encephalopathy occurs when a change in mental or neurologic status, first manifested during the applicable Table time period as an acute encephalopathy or encephalitis, persists for at least 6 months from the first symptom or manifestation of onset or of significant aggravation of an acute encephalopathy or encephalitis.

(ii) Individuals who return to their baseline neurologic state, as confirmed by clinical findings, within less than 6 months from the first symptom or manifestation of onset or of significant aggravation of an acute encephalopathy or encephalitis shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy or encephalitis.

(2) *Injected* refers to the intramuscular, intradermal, or

subcutaneous needle administration of a vaccine.

(3) *Sequelae* means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.

(4) *Significantly decreased level of consciousness* is indicated by the presence of one or more of the following clinical signs:

(i) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(ii) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(iii) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(5) *Seizure* includes myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures, but not absence (petit mal), or pseudo seizures. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.

(e) *Coverage provisions.* (1) Except as provided in paragraph (e)(2), (3), (4), (5), (6), (7), or (8) of this section, this section applies only to petitions for compensation under the program filed with the United States Court of Federal Claims on or after February 21, 2017.

(2) Hepatitis B, Hib, and varicella vaccines (Items VIII, IX, and X of the Table) are included in the Table as of August 6, 1997.

(3) Rotavirus vaccines (Item XI of the Table) are included in the Table as of October 22, 1998.

(4) Pneumococcal conjugate vaccines (Item XII of the Table) are included in the Table as of December 18, 1999.

(5) Hepatitis A vaccines (Item XIII of the Table) are included on the Table as of December 1, 2004.

(6) Trivalent influenza vaccines (Included in item XIV of the Table) are included on the Table as of July 1, 2005. All other seasonal influenza vaccines (Item XIV of the Table) are included on the Table as of November 12, 2013.

(7) Meningococcal vaccines and human papillomavirus vaccines (Items XV and XVI of the Table) are included on the Table as of February 1, 2007.

(8) Other new vaccines (Item XVII of the Table) will be included in the Table

as of the effective date of a tax enacted to provide funds for compensation paid with respect to such vaccines. An amendment to this section will be published in the **Federal Register** to announce the effective date of such a tax.

[FR Doc. 2017-00701 Filed 1-18-17; 8:45 am]

BILLING CODE 4160-15-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 3160

[17X.LLWO310000.L13100000.PP0000]

RIN 1004-AE49

Onshore Oil and Gas Operations—Annual Civil Penalties Inflation Adjustments

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rule.

SUMMARY: This rule adjusts the level of civil monetary penalties contained in the Bureau of Land Management's regulations governing onshore oil and gas operations as required by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the "Act"). The adjustments made by this final rule constitute the annual inflation adjustments contemplated by the Act, and are consistent with applicable Office of Management and Budget (OMB) guidance.

DATES: This rule is effective on January 19, 2017.

FOR FURTHER INFORMATION CONTACT: Steven Wells, Division Chief, Fluid Minerals Division, 202-912-7143, for information regarding the BLM's Fluid Minerals Program. For questions relating to regulatory process issues, please contact Jennifer Noe, Division of Regulatory Affairs, at 202-912-7442. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339, 24 hours a day, 7 days a week to contact the above individuals.

SUPPLEMENTARY INFORMATION:

I. Background

II. Calculation of Adjustment

III. Procedural Requirements

- A. Regulatory Planning and Review (E.O. 12866 and 13563)
- B. Regulatory Flexibility Act
- C. Small Business Regulatory Enforcement Fairness Act
- D. Unfunded Mandates Reform Act
- E. Takings (E.O. 12630)
- F. Federalism (E.O. 13132)
- G. Civil Justice Reform (E.O. 12988)
- H. Consultation with Indian Tribes (E.O. 13175 and Departmental Policy)
- I. Paperwork Reduction Act
- J. National Environmental Policy Act
- K. Effects on the Energy Supply (E.O. 13211)
- L. Administrative Procedure Act

I. Background

On November 2, 2015, the President signed the Act into law (Sec. 701 of Pub. L. 114-74). The Act requires agencies to:

1. Adjust the level of civil monetary penalties with an initial "catch-up" adjustment through an interim final rulemaking in 2016;

2. Make subsequent annual adjustments for inflation beginning in 2017; and

3. Report annually in Agency Financial Reports on these inflation adjustments.

In July 2016, the BLM issued an interim final rule that adjusted the level of civil monetary penalties with the initial "catch-up" adjustment, which is reflected in the table below in the "Previous Penalty" column.

With this final rule, the BLM is adjusting civil monetary penalties for inflation. The adjustments made by this rule are consistent with the requirements of the Act and OMB guidance.

The purpose of these adjustments is to maintain the deterrent effect of civil penalties found in existing regulations, in order to further the policy goals of the underlying statutes. The BLM has reviewed its existing regulations and determined that only the civil monetary penalties found at 43 CFR 3163.2 are subject to the Act's requirements.

The adjustments made by this final rule constitute the first annual adjustment contemplated by the Act, and include the following changes to the penalties:

| CFR Citation | Description of the penalty | Previous penalty | Adjusted penalty |
|---------------------|--|------------------|------------------|
| 43 CFR 3163.2(a) | Failure to comply | \$1,031 | \$1,048 |
| 43 CFR 3163.2(b) | If corrective action is not taken | 10,314 | 10,483 |
| 43 CFR 3163.2(d) | If transporter fails to permit inspection for documentation | 1,031 | 1,048 |
| 43 CFR 3163.2(e) | Failure to permit inspection, failure to notify | 20,628 | 20,965 |
| 43 CFR 3163.2(f) | False or inaccurate documents; unlawful transfer or purchase | 51,570 | 52,414 |
| 43 CFR 3163.2(g)(1) | Initial penalty under 43 CFR 3163.2(a) for a major violation | 1,031 | 1,048 |
| 43 CFR 3163.2(g)(1) | Maximum penalty under 43 CFR 3163.2(a) for a major violation | 2,063 | 2,097 |

| CFR Citation | Description of the penalty | Previous penalty | Adjusted penalty |
|--------------------------------|--|------------------|------------------|
| 43 CFR 3163.2(g)(1) | Initial penalty under 43 CFR 3163.2(b) for a major violation | 10,314 | 10,483 |
| 43 CFR 3163.2(g)(1) | Maximum penalty under 43 CFR 3163.2(b) for a major violation | 20,628 | 20,965 |
| 43 CFR 3163.2(g)(1) | Penalty under 43 CFR 3163.2(d) for a major violation | 1,031 | 1,048 |
| 43 CFR 3163.2(g)(1) | Penalty under 43 CFR 3163.2(e) for a major violation | 20,628 | 20,965 |
| 43 CFR 3163.2(g)(1) | Penalty under 43 CFR 3163.2(f) for a major violation | 51,570 | 52,414 |
| 43 CFR 3163.2(g)(2)(iii) | Initial penalty under 43 CFR 3163.2(a) for a minor violation | 103 | 105 |
| 43 CFR 3163.2(g)(2)(iii) | Initial penalty under 43 CFR 3163.2(b) for a minor violation | 1,031 | 1,048 |
| 43 CFR 3163.2(g)(2)(iii) | Maximum penalty under 43 CFR 3163.2(a) for a minor violation | 206 | 209 |
| 43 CFR 3163.2(g)(2)(iii) | Maximum penalty under 43 CFR 3163.2(b) for a minor violation | 2,063 | 2,097 |

II. Calculation of Adjustment

OMB issued guidance on calculating the annual adjustment for 2017 in accordance with the Act. See December 16, 2016, Memorandum for the Heads of Executive Departments and Agencies, from Shaun Donovan, Director, Office of Management and Budget, re:

Implementation of the 2017 annual adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act

Improvements Act of 2015. Under this guidance, the Department of the Interior has identified applicable civil monetary penalties and calculated the annual adjustment. A civil monetary penalty is any assessment with a dollar amount that is levied for a violation of a Federal civil statute or regulation, and is assessed or enforceable through a civil action in Federal court or an administrative proceeding. A civil monetary penalty does not include a penalty levied for violation of a criminal statute, or fees for services, licenses, permits, or other regulatory review. The calculated annual inflation adjustments are based on the percent change between the October CPI-U preceding the date of the adjustment, and the prior year's October CPI-U. In this case, October 2016 CPI-U (241.729)/October 2015 CPI-U (237.838) = 1.01636.

III. Procedural Requirements

A. Regulatory Planning and Review (E.O. 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is not significant. Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility

and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science, and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires an agency to prepare a regulatory flexibility analysis for rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which an agency is required to first publish a proposed rule. See 5 U.S.C. 603(a) and 604(a). The Act requires agencies to adjust civil penalties annually for inflation through a final rule (see § 4(b)(2) of the Act). Because the final rule in this case does not include publication of a proposed rule, the RFA does not apply to this final rule.

C. Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

(a) Does not have an annual effect on the economy of \$100 million or more.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

This rule will potentially affect individuals and companies who hold leases on Federal or Indian lands. The BLM believes that the vast majority of potentially affected entities will be small businesses as defined by the Small Business Administration.

However, the BLM does not believe the rule will pose a significant economic impact on the industry, including any small entities, for two reasons. First, any lessee can avoid being assessed civil penalties by operating in compliance with BLM rules and regulations.

Second, payments for penalties adjusted as a result of this rule will be negligible compared with the \$23 billion worth of crude oil and natural gas produced from Federal and Indian leases in FY 2015.

D. Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or tribal governments, or the private sector of more than \$100 million per year. The rule does not have a significant or unique effect on State, local, or tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

E. Takings (E.O. 12630)

This rule does not effect a taking of private property or otherwise have takings implications under Executive Order 12630. A takings implication assessment is not required.

F. Federalism (E.O. 13132)

Under the criteria in section 1 of Executive Order 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. A federalism summary impact statement is not required.

G. Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of Executive Order 12988. Specifically, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

H. Consultation With Indian Tribes (E.O. 13175 and Departmental policy)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian tribes through a commitment to consultation with Indian tribes and recognition of their right to self-governance and tribal sovereignty. We have evaluated this rule under the Department's consultation policy and under the criteria in Executive Order 13175 and have determined that it has no substantial direct effects on federally recognized Indian tribes and that consultation under the Department's tribal consultation policy is not required.

I. Paperwork Reduction Act

This rule does not contain information collection requirements, and a submission to OMB under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) is not required. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number.

J. National Environmental Policy Act

A detailed statement under the National Environmental Policy Act of 1969 (NEPA) is not required because the rule is covered by a categorical exclusion. This rule is excluded from the requirement to prepare a detailed statement because it is a regulation of an administrative nature. (For further information see 43 CFR 46.210(i).) We have also determined that the rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA.

K. Effects on the Energy Supply (E.O. 13211)

This rule is not a significant energy action under the definition in Executive Order 13211. Therefore, a Statement of Energy Effects is not required.

L. Administrative Procedure Act

The BLM is promulgating this rule as a final rule because the Act expressly directs us to do so. In accordance with the Act, agencies must adjust civil monetary penalties notwithstanding Section 553 of the Administrative Procedure Act (APA) (see § 4(b)(2) of the Act). This means that the notice and opportunity to comment procedures of the APA do not apply and are not required for agencies to issue regulations implementing the annual adjustment. In addition, since the Act does not give the BLM any discretion to vary the amount of the annual inflation

adjustment for any given penalty to reflect any views or suggestions provided by commenters, it would serve no purpose to provide an opportunity for public comment on this rule.

List of Subjects 43 CFR Part 3160

Administrative practice and procedure; Government contracts; Indians-lands; Mineral royalties; Oil and gas exploration; Penalties; Public lands-mineral resources; Reporting and recordkeeping requirements.

For the reasons given in the preamble, the BLM amends Chapter II of Title 43 of the Code of Federal Regulations as follows:

PART 3160—ONSHORE OIL AND GAS OPERATIONS

■ 1. The authority citation for part 3160 is revised to read as follows:

Authority: 25 U.S.C. 396d and 2107; 30 U.S.C. 189, 306, 359, and 1751; 43 U.S.C. 1732(b), 1733, 1740; and Sec. 107, Pub. L. 114–74, 129 Stat. 599, unless otherwise noted.

Subpart 3163—Noncompliance, Assessments, and Penalties

§ 3163.2 [Amended]

■ 2. In § 3163.2:

■ a. In paragraph (a), remove “\$1,031” and add in its place “\$1,048”.

■ b. In paragraph (b), remove “\$10,314” and add in its place “\$10,483”.

■ c. In paragraph (d), remove “\$1,031” and add in its place “\$1,048”.

■ d. In paragraph (e) introductory text, remove “\$20,628” and add in its place “\$20,965”.

■ e. In paragraph (f) introductory text, remove “\$51,570” and add in its place “\$52,414”.

■ f. In paragraph (g)(1), remove “\$1,031” each place that it occurs and add in its place “\$1,048”; remove “\$10,314” and add in its place “\$10,483”; remove “\$2,063” and add in its place “\$2,097”; remove “\$20,628” each place that it occurs and add in its place “\$20,965”; remove “\$51,570” and add in its place “\$52,414”.

■ g. In paragraph (g)(2)(iii), remove “\$103” and add in its place “\$105”; remove “\$1,031” and add in its place “\$1,048”; remove “\$206” and add in its place “\$209”; remove “\$2,063” and add in its place “\$2,097”.

Dated: January 10, 2017.

Amanda C. Leiter,

Acting Assistant Secretary, Land and Minerals Management.

[FR Doc. 2017–00727 Filed 1–18–17; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 11

[Docket No. FWS–HQ–LE–2017–0001; FF09L00200–FX–LE18110900000]

RIN 1018–BB97

Civil Penalties; 2017 Inflation Adjustments for Civil Monetary Penalties

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: The U.S. Fish and Wildlife Service (Service or we) is issuing this final rule, in accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Inflation Adjustment Act) and Office of Management and Budget (OMB) guidance, to adjust for inflation the statutory civil monetary penalties that may be assessed for violations of Service-administered statutes and their implementing regulations. We are required to adjust civil monetary penalties annually for inflation according to a formula specified in the Inflation Adjustment Act. This rule replaces the previously issued amounts with the updated amounts after using the 2017 inflation adjustment multiplier provided in the OMB guidance.

DATES: This rule is effective January 19, 2017.

ADDRESSES: This rule may be found on the internet at www.regulations.gov in Docket No. FWS–HQ–LE–2017–0001. The previous rulemaking action related to this rule and described below in **SUPPLEMENTARY INFORMATION** may be found at www.regulations.gov in Docket No. FWS–HQ–LE–2016–0045.

FOR FURTHER INFORMATION CONTACT: Paul Beiriger, Special Agent in Charge, Branch of Investigations, U.S. Fish and Wildlife Service, Office of Law Enforcement, (703) 358–1949.

SUPPLEMENTARY INFORMATION:

Background

The regulations in title 50 of the Code of Federal Regulations at 50 CFR part 11 provide uniform rules and procedures for the assessment of civil penalties resulting from violations of certain laws and regulations enforced by the Service.

On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (sec. 701 of Pub. L. 114–74) (Inflation Adjustment Act). The Inflation Adjustment Act requires Federal agencies to adjust the

level of civil monetary penalties with an initial “catch up” adjustment through rulemaking and then make subsequent annual adjustments for inflation. The purpose of these adjustments is to maintain the deterrent effect of civil penalties and to further the policy goals of the underlying statutes.

Under section 4 of the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461 note, as amended by the Inflation Adjustment Act, Pub. L. 114–74, 129 Stat. 584 (2015), each Federal agency is required to issue regulations adjusting for inflation the statutory civil monetary penalties (civil penalties) that can be imposed under the laws administered by that agency. The Inflation Adjustment Act provided for an initial “catch up adjustment” to take effect no later than August 1, 2016, followed by subsequent adjustments to be made no later than January 15 every year thereafter. This final rule adjusts the civil penalty amounts that may be imposed pursuant to each statutory provision beginning on the date specified above in DATES.

On June 28, 2016, the Service published in the **Federal Register** an interim rule that revised 50 CFR part 11 (81 FR 41862). We did not receive any comments on the interim rule during the public comment period provided. Therefore, the interim rule became effective on July 28, 2016, as specified in that rule. The Service subsequently published a final rule on December 23, 2016, adopting the interim rule as final (81 FR 94274). The current rule adjusts the civil monetary penalty amounts that were listed in the June 28, 2016, interim rule and subsequently codified in 50 CFR 11.33 by using the inflation multiplier provided to all Federal agencies by OMB (see below).

OMB issued a memorandum, M–17–11, entitled “Implementation of the 2017 annual adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015,” which provides the cost-of-living adjustment multiplier for 2017: 1.01636. Therefore, we multiplied each penalty in the table published in the interim rule on June 28, 2016 (81 FR 41862), by

1.01636 to obtain the 2017 annual adjustment. The new amounts are reflected in the table in the rule portion of this document and replace the current amounts in 50 CFR 11.33.

Required Determinations

In this final rule, we are affirming our required determinations made in the June 28, 2016, interim rule (81 FR 41862); for descriptions of our actions to ensure compliance with the following statutes and Executive Orders, see that rule:

National Environmental Policy Act (42 U.S.C. 4321 *et seq.*);
Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 804(2));
Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*);
Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*); and
Executive Orders 12630, 12866, 12988, 13132, 13175, 13211, and 13563.

Administrative Procedure Act

As stated above, under section 4 of the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461 note, as amended by the Inflation Adjustment Act, Pub. L. 114–74, 129 Stat. 584 (2015), each Federal agency is required to issue regulations adjusting for inflation the statutory civil monetary penalties that can be imposed under the laws administered by that agency. The Inflation Adjustment Act provided for an initial “catch up adjustment” to take effect no later than August 1, 2016, followed by subsequent adjustments to be made no later than January 15 every year thereafter. This final rule adjusts the civil penalty amounts that may be imposed pursuant to each statutory provision beginning on the effective date of this rule. To comply with the Inflation Adjustment Act, we are issuing these regulations as a final rule.

Section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule

without providing notice and an opportunity for prior public comment. The Service finds that providing for public comment before issuing this rule is unnecessary as this rulemaking is a nondiscretionary action. The Service is required to publish this rule in order to update the civil penalty amounts by the specified formula described above. The Service has no discretion to vary the amount of the adjustment to reflect any views or suggestions provided by commenters. Accordingly, it would serve no purpose to provide an opportunity for public comment prior to publication of this rule. Since this update to the June 28, 2016, interim rule (81 FR 41862) is merely ministerial, we find that pre-publication notice and public comment with respect to the revisions set forth in this rule is unnecessary. We also believe that we have good cause under 5 U.S.C. 553(d) to make this rule effective upon publication to meet the statutory deadline imposed by the Inflation Adjustment Act.

List of Subjects in 50 CFR Part 11

Administrative practice and procedure, Exports, Fish, Imports, Penalties, Plants, Transportation, Wildlife.

Regulation Promulgation

For the reasons described above, we amend part 11, subchapter B of chapter I, title 50 of the Code of Federal Regulations as set forth below.

PART 11—CIVIL PROCEDURES

■ 1. The authority citation for part 11 continues to read as follows:

Authority: 16 U.S.C. 470aa–470mm, 470aaa–470aaa-11, 668–668d, 1361–1384, 1401–1407, 1531–1544, 3371–3378, 4201–4245, 4901–4916, 5201–5207, 5301–5306; 18 U.S.C. 42–43; 25 U.S.C. 3001–3013; and Sec. 107, Pub. L. 114–74, 129 Stat. 599, unless otherwise noted.

■ 2. Revise the table in § 11.33 to read as follows:

§ 11.33 Adjustments to penalties.

* * * * *

| Law | Citation | Type of violation | Maximum civil monetary penalty |
|---|----------------------------|---|--------------------------------|
| (a) African Elephant Conservation Act .. | 16 U.S.C. 4224(b) | Any violation | \$10,055 |
| (b) Bald and Golden Eagle Protection Act. | 16 U.S.C. 668(b) | Any violation | 12,705 |
| (c) Endangered Species Act of 1973 | 16 U.S.C. 1540(a)(1) | (1) Knowing violation of section 1538 ... | 50,276 |
| | | (2) Other knowing violation | 24,132 |
| | | (3) Any other violation | 1,270 |
| (d) Lacey Act Amendments of 1981 | 16 U.S.C. 3373(a) | (1) Violations referred to in 16 U.S.C. 3373(a)(1). | 25,409 |

| Law | Citation | Type of violation | Maximum civil monetary penalty |
|--|-----------------------------|--|--------------------------------|
| (e) Marine Mammal Protection Act of 1972. | 16 U.S.C. 1375 | (2) Violations referred to in 16 U.S.C. 3373(a)(2). Any violation | 635 25,409 |
| (f) Recreational Hunting Safety Act of 1994. | 16 U.S.C. 5202(b) | (1) Violation involving use of force or violence or threatened use of force or violence. (2) Any other violation | 16,169 8,084 |
| (g) Rhinoceros and Tiger Conservation Act of 1998. | 16 U.S.C. 5305a(b)(2) | Any violation | 17,688 |
| (h) Wild Bird Conservation Act | 16 U.S.C. 4912(a)(1) | (1) Violation of section 4910(a)(1), section 4910(a)(2), or any permit issued under section 4911. (2) Violation of section 4910(a)(3) | 42,618 20,456 |
| | | (3) Any other violation | 853 |

Dated: January 10, 2017.

Michael J. Bean,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2017-00889 Filed 1-18-17; 8:45 am]

BILLING CODE 4333-15-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 223

[Docket No. 150211138-7024-02]

RIN 0648-XD771

Endangered and Threatened Wildlife and Plants; Final Rule To List Two Guitarfishes as Threatened Under the Endangered Species Act

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: We, NMFS, issue a final rule to list two foreign marine guitarfish species under the Endangered Species Act (ESA). We considered comments submitted on the proposed listing rule and have determined that the blackchin guitarfish (*Rhinobatos cemiculus*) and common guitarfish (*Rhinobatos rhinobatos*) warrant listing as threatened species. We will not designate critical habitat for either of these species because the geographical areas occupied by these species are entirely outside U.S. jurisdiction, and we have not identified any unoccupied areas within U.S. jurisdiction that are currently essential to the conservation of either of these species.

DATES: This final rule is effective February 21, 2017.

ADDRESSES: Chief, Endangered Species Division, NMFS Office of Protected Resources (F/PR3), 1315 East West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Brendan Newell or Marta Nammack NMFS, Office of Protected Resources (OPR), (301) 427-8403.

SUPPLEMENTARY INFORMATION:

Background

On July 15, 2013, we received a petition from WildEarth Guardians to list 81 marine species or subpopulations as threatened or endangered under the ESA. This petition included species from many different taxonomic groups, and we prepared our 90-day findings in batches by taxonomic group. We found that the petitioned actions may be warranted for 24 of the species and 3 of the subpopulations and announced the initiation of status reviews for each of the 24 species and 3 subpopulations (78 FR 63941, October 25, 2013; 78 FR 66675, November 6, 2013; 78 FR 69376, November 19, 2013; 79 FR 9880, February 21, 2014; and 79 FR 10104, February 24, 2014). On September 19, 2016, we published a proposed rule to list the blackchin guitarfish (*Rhinobatos cemiculus*) and the common guitarfish (*Rhinobatos rhinobatos*) as threatened species (81 FR 64094). We requested public comment on information in the draft status review and proposed rule, and the comment period was open through November 18, 2016. This final rule provides a discussion of the information we received during the public comment period and our final determination on the petition to list the blackchin guitarfish and the common guitarfish under the ESA. The status of the findings and relevant **Federal Register** notices for the other 22 species and 3 subpopulations can be found on our Web site at www.nmfs.noaa.gov/pr/species/petition81.htm.

Listing Species Under the Endangered Species Act

We are responsible for determining whether species are threatened or endangered under the ESA (16 U.S.C. 1531 *et seq.*). To make this determination, we consider first whether a group of organisms constitutes a “species” under the ESA, then whether the status of the species qualifies it for listing as either threatened or endangered. Section 3 of the ESA defines a “species” to include “any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature.”

Section 3 of the ESA defines an endangered species as “any species which is in danger of extinction throughout all or a significant portion of its range” and a threatened species as one “which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.” We interpret an “endangered species” to be one that is presently in danger of extinction. A “threatened species,” on the other hand, is not presently in danger of extinction, but is likely to become so in the foreseeable future (that is, at a later time). In other words, the primary statutory difference between a threatened and endangered species is the timing of when a species may be in danger of extinction, either presently (endangered) or in the foreseeable future (threatened).

When we consider whether a species might qualify as threatened under the ESA, we must consider the meaning of the term “foreseeable future.” It is appropriate to interpret “foreseeable future” as the horizon over which predictions about the conservation status of the species can be reasonably relied upon. The foreseeable future

considers the life history of the species, habitat characteristics, availability of data, particular threats, ability to predict threats, and the reliability to forecast the effects of these threats and future events on the status of the species under consideration. Because a species may be susceptible to a variety of threats for which different data are available, or which operate across different time scales, the foreseeable future is not necessarily reducible to a particular number of years.

Section 4(a)(1) of the ESA requires us to determine whether any species is endangered or threatened due to any of the following factors: The present or threatened destruction, modification, or curtailment of its habitat or range; overutilization for commercial, recreational, scientific, or educational purposes; disease or predation; the inadequacy of existing regulatory mechanisms; or other natural or manmade factors affecting its continued existence. Under section 4(b)(1)(A), we are also required to make listing determinations based solely on the best scientific and commercial data available, after conducting a review of the species' status and after taking into account efforts being made by any state or foreign nation to protect the species.

In making a listing determination, we first determine whether a petitioned species meets the ESA definition of a "species." Next, using the best available information gathered during the status review for the species, we complete a status and extinction risk assessment. In assessing extinction risk for these two guitarfishes, we considered the demographic viability factors developed by McElhany *et al.* (2000). The approach of considering demographic risk factors to help frame the consideration of extinction risk has been used in many of our status reviews, including for Pacific salmonids, Pacific hake, walleye pollock, Pacific cod, Puget Sound rockfishes, Pacific herring, scalloped hammerhead sharks, and black abalone (see www.nmfs.noaa.gov/pr/species/ for links to these reviews). In this approach, the collective condition of individual populations is considered at the species level according to four viable population descriptors: abundance, growth rate/productivity, spatial structure/connectivity, and diversity. These viable population descriptors reflect concepts that are well-founded in conservation biology and that individually and collectively provide strong indicators of extinction risk (NMFS 2015).

We then assess efforts being made to protect the species to determine if these conservation efforts are adequate to

mitigate the existing threats. Section 4(b)(1)(A) of the ESA requires the Secretary, when making a listing determination for a species, to take into consideration those efforts, if any, being made by any State or foreign nation to protect the species.

Summary of Comments

In response to our request for comments on the proposed rule, we received five comment letters. Two comment letters were from foreign governments and clarified information about their relevant regulations. One comment letter was from an environmental nonprofit organization supporting our proposed listing decision. Two comment letters were submitted anonymously, each challenging a number of our statements or conclusions in the status review or proposed rule, generally without providing references or evidence that would allow us to investigate further. One commenter also provided some editorial comments, which were incorporated in the status review as appropriate. Summaries of issues raised by the public comments received and our responses are provided below, with references where appropriate.

Comment 1: One commenter pointed out that *R. cemiculus* is also referred to in some of the literature by the taxonomic synonym *Glaucostegus cemiculus*.

Response: The fact that *Glaucostegus cemiculus* is a synonym for *R. cemiculus* has been added to the *Taxonomy and Distinctive Characteristics* section of the status review. Although we did not include this synonym in the draft status review this did not impact the development of the status review or proposed rule. We were aware of this synonym and searched for publications related to this species using both *Rhinobatos cemiculus* and *Glaucostegus cemiculus* while gathering information for the status review.

Comment 2: One commenter disagreed with our description of the smallest reported length for a fish in a study as the "minimum total length (TL)," stating that minimum TL is always 0 mm for all animals.

Response: The word *minimum* was used while discussing the smallest lengths ever reported for juveniles of each species. We did not intend to imply that the reported lengths were the smallest possible lengths that the animals could be. We have revised the status review to clarify this point.

Comment 3: One commenter noted that we did not include the *k* value for *R. rhinobatos* reported in Ismen *et al.*

(2007) in the discussion about growth rates.

Response: The *k* value from Ismen *et al.* (2007) has been added to the discussion in the *Reproduction and Growth* section of the status review.

Comment 4: One commenter claimed our analysis is biased because we discuss "conflict" in the literature regarding conclusions researchers have reached about the two guitarfish species' reproductive potential and growth rates. This commenter stated that these different conclusions reached by researchers are not conflicting conclusions but are evidence of intraspecific variation, which could be evidence of population structure. The same party made multiple other comments about regional variations in morphology and biology indicating population structure. An additional commenter also claimed that there is more evidence for population structuring in these guitarfishes than three ESA-listed species of angelshark, *Squatina aculeata*, *S. oculata*, and *S. squatina*. These three *Squatina* species were listed as endangered on August 1, 2016 (81 FR 50394). This commenter provided no references to validate this claim.

Response: We disagree with the commenter's implication that noting conflicting conclusions from different authors about a species' life history implies bias. We acknowledge that variations in biology in different portions of a species' range could imply population structure. However, Lteif (2015) attributed these variations to environmental differences throughout each species' range (*e.g.*, food availability and water temperatures) or the relatively small amount of data on the species and differences in sampling approach. ICES (2010) stated that the relationships between the Mediterranean and Atlantic stocks of *R. cemiculus* and *R. rhinobatos* are unclear. We found no other discussions of population structure in the available information. Given the lack of information, we could not reach conclusions about population structure. Our status review presents the best available information and notes where authors have reached different conclusions to accurately represent the available information.

Comment 5: One commenter asserted that the discussion in the status review of both species' preference for warmer waters is moot because the only temperature data provided in the document is sea surface temperature data, and as both species are demersal, they live below the thermocline. This commenter also asserted that, in our

discussion about the threat of climate change in the status review, we failed to address specifically how changing bottom temperatures will affect the species.

Response: According to the best available scientific information, both of the guitarfishes are demersal species that typically occur up to a maximum depth of 100m and spend at least a portion of their lives in shallow waters. The only information we found regarding how these species interact with water temperature is that both species prefer warmer, subtropical waters (Capape and Zaouali 1994; Corsini-Foka 2009; Edelist 2014). The discussion in the status review is about the role that temperature likely plays in restricting many Mediterranean species to biogeographic ranges. While we consider this information relevant to understanding both guitarfish species' habitat and distribution, we explicitly acknowledged in the draft status review that we found no information on how any particular isotherm affects the distribution and abundance of these guitarfish species. We found no discussion in the scientific literature regarding how these species interact with thermoclines, the depths of which likely vary seasonally and regionally given the wide distribution of these species (Coll *et al.*, 2010). Specifically regarding climate change, Akyol and Capapé (2014) and Rafrafi-Nouira *et al.* (2015) both attributed shifts in *R. cemiculus* distribution to warming waters but did not discuss bottom temperatures or thermoclines. No references were provided by the commenter to explain how both species interact with thermoclines or invalidate our interpretation that sea surface and mixed layer temperature is likely relevant to the distribution of these subtropical species.

Comment 6: One commenter asserted that our assumption that both guitarfish species are likely mirroring the trend of decreasing elasmobranch and batoid (rays, skates, guitarfishes, etc.) landings in southern Tunisia, where the best available information shows that both guitarfish species made up a high proportion of the total elasmobranch catch in the longline and gillnet fisheries over a 2-year period, is flawed, because, "A high percentage of one species in a catch at one time says nothing about the trend of that species over time as different species can be targeted or caught with different methods or have different population structures and sources and sinks."

Response: We agree that a high percentage of one species in a catch at one time does not indicate a trend.

However, the data in question were collected across two different fisheries (longline and gillnet) and in each case the data were collected over multiple months in both 2007 and 2008 years (Echwiki *et al.*, 2013; Echwiki *et al.*, 2012). Echwiki *et al.* (2013) and Echwiki *et al.* (2012) discuss their results in the context of the trends in elasmobranch abundance declines in the region. An additional citation (Bradaï *et al.*, 2006) has been added to the status review and provides further indication that both species have been and are commonly targeted and landed in southern Tunisia. Given the high proportion of these guitarfish species in the studied artisanal fisheries catches, and the fact that these species are known to be commonly targeted and landed in southern Tunisia, it is likely that the abundance trends for these species are similar to the overall trend of declining elasmobranch catches in southern Tunisia.

Comment 7: One commenter made several comments that there is no evidence that *R. rhinobatos* and *R. cemiculus* were likely historically rare throughout most of the northwestern Mediterranean relative to other portions of its range (e.g., the southern and eastern Mediterranean). The same commenter challenged our conclusion that both species have likely always been rare in all parts of their Atlantic ranges north of the Strait of Gibraltar. This commenter asserted that we failed to include museum records and anthropological literature, but the commenter did not provide any references.

Response: Our interpretation of the best available information is that *R. rhinobatos* and *R. cemiculus* were present, but likely uncommon or rare throughout most of the northwestern Mediterranean (including the waters off Spain, the seas around Italy, and, in the case of *R. rhinobatos*, the waters of France), with the exception of the waters around Sicily and the Balearic Islands. This interpretation is consistent with the conclusions reached in the best available scientific literature (Akyol and Capapé 2014; Capapé *et al.*, 2006; Capapé *et al.*, 1975; Dulpiu *et al.*, 2005; Psomadakis *et al.*, 2009). In the parts of their Atlantic ranges north of the Strait of Gibraltar, as stated in the status review, we found information that indicates both species have been rare for at least the last 45 years (ICES 2016), and no information that indicates either species was common at any time in what is known to be the northern extent of their ranges.

To reach these conclusions we searched for data and publications

related to both species, and guitarfishes in general, in all of the countries and seas that are considered part of either species' historical range. In the status review, we considered and incorporated the best available information, which included peer reviewed scientific articles, regional checklists of ichthyofauna, studies of fishers' knowledge, reports from conservation organizations (e.g., IUCN), and museum records. We also used relevant data from long term datasets such as trawl surveys and regional fisheries databases, including the MEDITS survey program (International bottom trawl survey in the Mediterranean) and the International Council for the Exploration of the Sea (ICES) DATRAS (Baino *et al.*, 2001; Bertrand *et al.*, 2000, ICES 2016). The only publications that we found that concluded that both species were common throughout the northwestern Mediterranean were the IUCN assessments of both species (Notarbartolo di Sciara *et al.*, 2007a; Notarbartolo di Sciara *et al.*, 2007b) and ICES (2010). All three of these reports specifically discuss and provide references for both species once being common off the Balearic Islands and Sicily, which make up a small amount of the overall area of the northwestern Mediterranean. No references were cited in these three reports to provide evidence that *R. rhinobatos* or *R. cemiculus* were common in the remaining area of the northwestern Mediterranean.

Comment 8: One commenter noted the lack of explanation about what we mean by "available literature."

Response: A summary of how we compiled the information used in the status review was added to the second paragraph of the *Scope and Intent of Present Document* section of the status review.

Comment 9: Regarding the *Overutilization for Commercial, Recreational, Scientific, or Educational Purposes* section of the status review, one commenter stated: "Generally in this section you misunderstand the difference between science and fisheries data. Scientifically gathered data is preferable and you are required to use the best available SCIENCE. Fisheries catch and landing data are not the best possible type of data, are not scientifically gathered and have serious flaws which you ignore entirely."

Response: The commenter incorrectly restricts the information we are required to use. ESA Section 4(b)(1)(A) states: "The Secretary shall make determinations required by [Section 4](a)(1) solely on the basis of the best scientific and commercial data available

to him . . .” There is a paucity of scientific studies on both species range wide, including the almost complete lack of fisheries independent population data, a fact that is well documented in the status review and proposed rule. We agree that additional scientifically gathered data would greatly enhance our ability to accurately understand the status of both species. However, when analyzing the threat of commercial fisheries to these guitarfishes, fisheries data are relevant and valuable. Therefore, this information must be considered as a source of “best scientific and commercial data available,” regardless of flaws with these data, which are acknowledged and discussed throughout the status review.

Comment 10: Also regarding the discussion of commercial overutilization in the *Overutilization for Commercial, Recreational, Scientific, or Educational Purposes* section of the status review, one commenter asks: “why is only bycatch considered?”

Response: All types of interactions with commercial and artisanal fisheries are considered and described in the status review, including bycatch from industrial and artisanal fishing and targeted fishing of both guitarfish species by artisanal fishers using gillnets, longlines, and beach based lines. The commenter may have missed the information by focusing on only one part of the discussion within the section.

Comment 11: Regarding the passage in the status review: “At the time of the 2007 publication of the IUCN report *Overview of the Conservation Status of Cartilaginous Fishes (Chondrichthyans) in the Mediterranean Sea*,” by Cavanagh and Gibson (2007) there were six Mediterranean elasmobranchs affected by target fisheries . . . It is unclear if *R. rhinobatos* and *R. cemiculus* were two of the six targeted species referenced in this report”, one commenter asked how it can be unclear if the two *Rhinobatos* species were not part of the six species referred to in Cavanagh and Gibson (2007).

Response: Cavanagh and Gibson (2007) did not discuss which elasmobranch species or groups were part of past or present targeted fisheries, except for using angelsharks (*Squatina spp.*) as an example of species that had become so rare they were no longer targeted. Therefore, it was not possible to determine which six Mediterranean elasmobranch species were considered to be affected by targeted fisheries by Cavanagh and Gibson (2007).

Comment 12: One commenter stated that the discussion of elasmobranch landing trends in Egyptian fisheries in

the status review is contradictory because it claims both increased and decreased landings in Egyptian fisheries.

Response: In Egypt, an increase in effort across fisheries led to a decrease in overall fisheries landings, but an increase in the landings of, and demand for, elasmobranchs, which had previously been discarded. The commenter appears to have misunderstood the discussion in the status review. Elasmobranch landings increased because the landings of preferred, non-elasmobranch targets were decreasing. Thus, elasmobranchs, which were always caught but previously discarded, have been landed at a higher rate by fishers to offset the decreasing availability of other species.

Comment 13: Regarding the discussion in the status review of the development of the shark (and other shark-like elasmobranchs) fin industry in the Atlantic, one commenter stated, “you claim a need for increased effort CAUSES a need to maximize profits. This is quite [a] twist on economic theory which usually has causation go from the desire for profit as the starting point causing need for more effort . . .”

Response: This conclusion was reached by Diop and Dossa (2011) who provide the most comprehensive report on shark fishing in West Africa available. As explained in the status review, as fisheries in easily accessible areas became overexploited, fishers had to travel farther to find fish. This increased effort raised their cost of doing business (e.g., fuel costs). Because storage capacity is limited on fishing vessels, and shark fins are more valuable than other products that would take up more space, shrinking profit margins that resulted from the need to increase effort contributed to the unsustainable shift to retaining a larger percentage of the highest value products (i.e., shark fins from many sharks) rather than utilizing the entire shark or less valuable species.

Comment 14: One commenter stated that while we noted in the status review that large sharks, such as dusky sharks, are predators of *Rhinobatos* spp., we failed to discuss how the decline of dusky sharks would impact *R. cemiculus* and *R. rhinobatos*.

Response: Based on our analysis, predation is not posing a threat to either guitarfish species and, with the exception of one sentence in Camhi *et al.* (2005), we found no additional information regarding predation on guitarfishes by any shark species. Additionally, dusky sharks were an example of a large shark that preys on

these species, but not the only shark species to do so.

Comment 15: One commenter stated that in the *Commercial Overutilization in the Atlantic* section of the status review “you claim *Rhinobatos* is found in the highest numbers but you fail to say compared to what or part of what grouping.”

Response: The sentence the commenter is referring to is a quote provided in a series of quotes of the qualitative descriptions of elasmobranch fisheries in West African nations by Diop and Dossa (2011). In all cases, Diop and Dossa (2011) were discussing landing of guitarfishes relative to other elasmobranchs. Additional text has been added to the *Commercial Overutilization in the Atlantic* section to clarify this point.

Comment 16: One commenter pointed out the recent evidence suggesting a decline in the demand for shark fins.

Response: A paragraph further discussing trends in demand for shark fins and meat, as well as the uncertainty related to how these shifts in demand are impacting both guitarfish species, has been added to the *Commercial Overutilization in the Atlantic* section of the status review.

Comment 17: One commenter stated that we are required to consider the interaction of the ESA Section 4 (a)(1) factors but failed to do so.

Response: The commenter is correct that we are required to consider the interaction between the ESA 4(a)(1) factors, and we did so. We present a discussion of the interactions among the threats and each species’ demographic risks in the *Extinction Risk Analysis* sections of the status review for each species. However, because data on both species and their threats are generally lacking, a more detailed analysis of the interactions among the threat factors was not possible.

Comment 18: One commenter stated that we incorrectly limited our analysis to present and future threats only and that we should have also considered past threats.

Response: The ESA and the section 4 regulations require that we list a species if the species is endangered or threatened because of any of the five factors in ESA section 4 (a)(1). Included in our risk analysis is an assessment of the manifestation of past threats that have contributed to the species’ current status.

Comment 19: One commenter stated, “Foreseeable future discussion is confounded and you just assert your timeline, you provide no evidence it is the best available. Assertions really aren’t [sic] facts.”

Response: As discussed in *Box 2: Defining Foreseeable Future* in the status review, the foreseeable future for both guitarfish species (15–20 years) is based on these species' life histories and the main threats each species faces. Given the relatively low productivity of these species, it will likely take more than one generation for these species to recover. 15–20 years corresponds to approximately three generations of *R. cemiculus*, which likely reproduces at a slower rate than *R. rhinobatos*. 15–20 years is also a reasonable period of time to project the continued threats of overutilization and inadequacy of existing regulations. Many of the regulations that protect these species have recently been adopted and are inadequately enforced. Given both species' reproductive life history traits, 15–20 years is a reasonable amount of time to foresee continued decline of both species should these regulations continue to be inadequate, which seems likely at this time. The commenter provided no information to invalidate any or all of the justification for our definition.

Comment 20: One commenter pointed out that in our discussion of the increase in abundance of *R. rhinobatos* in the Tunis Northern and Southern Lagoon after restoration, we did not discuss the possibility that individuals could be migrating into the area without an increase in the overall population.

Response: A sentence acknowledging that it is unknown if the increase of *R. rhinobatos* in the Tunis Lagoons is the result of an increasing population or simply individuals migrating into what has become suitable habitat has been added to the *Demographic Risk Analysis* section of the status review.

Comment 21: One commenter stated that we missed the following references: Ali *et al.* (2008), Ambrose (2004), Bauchot (1987), Faruggia, Feretti, Lloris, and Rucabado (1998), McEachran and Capape (1984), Seck *et al.* (2004), Valadou (2003), and Whitehead *et al.* (1984).

Response: In response to this comment, we conducted a search for the references listed that we were unaware of, which were Ambrose (2004), Valadou (2003), and Faruggia *et al.* (1998). Only an abstract for Ambrose. (2004) was available online, which contained no information about guitarfishes. Because we were not able to review this publication we have not included it in this analysis. We requested but have not received a copy of Valadou (2003), which is a master's dissertation that we cannot access online. We were also unable to find

Faruggia *et al.* (1998) based on the information provided.

We were already aware of Seck *et al.* (2004), Ali *et al.* (2008), Bauchot (1987), McEachran and Capape (1984), and Whitehead *et al.* (1984). Seck *et al.* (2004) was used and cited in our draft status review and proposed rule. Ali *et al.* (2008) was not available online or through interlibrary loan during the development of the status review, proposed rule, and final rule, and we reached out to one of the authors regarding this and another publication but have not received a response. Because this comment was submitted anonymously, we also could not contact the commenter with a request for a copy of this or other references. Bauchot (1987), McEachran and Capape (1984), and Whitehead *et al.* (1984) are identification guides that provide basic taxonomic and life history information consistent with information already included in the status review. Thus, these references provided no additional information that would affect our status review.

Comment 22: One comment letter asserted that our decision to list *R. rhinobatos* and *R. cemiculus* as threatened is arbitrary and capricious because the commenter believes that both guitarfish species are “in at least as bad a condition” as three species of angelshark, *Squatina aculeata*, *S. oculata*, and *S. squatina*, which are listed as endangered under the ESA (81 FR 50394). This commenter provided the following reasons for this opinion: (1) These five species are all demersal elasmobranchs that share similar ranges, thus they face similar spatial threats; (2) The maximum depth that the guitarfishes occur in (100m) is shallower than the angelsharks' maximum depth (550m), thus the guitarfishes must be easier for humans to catch, increasing their vulnerability; (3) Guitarfishes have a faster reproductive cycle, smaller litter size, later age at maturity, and likely longer life span than the angelsharks, which makes the guitarfishes less resilient to overexploitation; (4) The guitarfishes, but not the angelsharks, are known to have an inshore migration for reproduction, putting the guitarfishes at a greater risk from human threats; (5) There is more evidence of population structuring for the guitarfishes than the angelsharks, resulting in smaller, isolated, less resilient populations; (6) There is higher commercial demand and fewer conservation efforts for the guitarfishes than the angelsharks; (7) Abundance data, including data from the Canary Islands and the northwest Mediterranean, support a worse status

for the guitarfishes than the angelsharks, and; (8) The guitarfishes were likely in demand and serially exploited even earlier than the angelsharks.

Response: While we acknowledge that all five species share some similarities in biology, ecology, and threats, we do not base decisions on whether or not one species should be listed as threatened or endangered solely on similarities in life history traits or circumstances with other listed species. We assess each species individually based on the best scientific and commercial information available, considering both the demographic risks facing the species as well as current and future threats that may affect the species' status. Data on all five species are lacking, but the best available information shows that all three angelsharks are extremely rare throughout most of their ranges, with evidence of declines in abundance and subsequent extirpations and range curtailment, while both guitarfishes are likely still somewhat abundant in relatively larger portions of their ranges, such as within portions of the southern and eastern Mediterranean and West Africa (Echwiki *et al.*, 2012; Golani 2006; Ismen *et al.*, 2007, Lteif 2015, M. Ducrocq, Parcs Gabon, pers. comm. to J. Shultz, NMFS, 21 June, 2016; Miller 2016, Saad *et al.*, 2006).

To specifically address some of the commenter's points about guitarfish, regarding point (6), while both the guitarfish and the angelsharks face threats from commercial fishing, it is not appropriate to directly compare the fishing related threats these species face. For example, the fin trade has contributed to the decline of the guitarfishes but is not a direct threat to the angelsharks, while historical commercial fishing pressure on angelsharks has already made these species so rare that they can no longer support fisheries in most areas. Regarding points (5) and (7), the commenter provided no references to verify the assertions about the two guitarfishes' population structures or abundance throughout their respective ranges or the presence of guitarfish in the Canary Islands, so we are unable to determine the validity of any data upon which the commenter based these assertions. As such, without any new information to consider, we maintain our previous conclusion in the proposed rule that the two guitarfish species are likely to be in danger of extinction in the foreseeable future throughout their ranges and, thus, are threatened species under the ESA.

Additionally, we also wish to clarify some of the information presented for

angelsharks, particularly in response to the commenter's points in (2) and (4). We note that while *S. aculeata* and *S. oculata* have maximum depths of up to 500 m and 560 m, respectively, *S. aculeata* can be found in depths as shallow as 30 m and *S. oculata* is more commonly found in depths between 50 m and 100 m. *Squatina squatina* is generally found in shallower water, from inshore areas out to the continental shelf in depths of 5 m to 150 m. This species is also thought to conduct inshore migrations in the summer, with reports of beachgoers being bitten by small (likely juvenile) angelsharks (suggesting inshore migration for reproduction). This information on these species, as well as additional information on the threats and status of the three angelsharks, can be found in the proposed (80 FR 40969; July 14, 2015) and final rules (81 FR 50394; August 1, 2016) listing these species under the ESA, as well as the status review for these three species (Miller 2016), available on our Web site at www.nmfs.noaa.gov/pr/species/petition81.htm.

Comment 23: The Embassy of Greece, through the Hellenic Ministry of Rural Development and Food, commented that Greece meets its obligations arising from international conventions, such as the Barcelona Convention, and is a party to the General Fisheries Commission of the Mediterranean (GFCM), the regional fisheries management organization whose convention area includes Mediterranean waters and the Black Sea. The measures adopted by the GFCM are incorporated into European Law. The Ministry specifically highlighted GFCM recommendation GFCM/36/3012/3, which prohibits those elasmobranchs on Annex II of the Specially Protected Areas and Biological Diversity (SPA/BD) Protocol to the Barcelona Convention (which includes both guitarfish species) from being retained on board, transhipped, landed, transferred, stored, sold or displayed, or offered for sale. The Ministry noted that the species must be released, as far as possible, unharmed and alive, and that there is an obligation for owners of fishing vessels to record information related to fishing activities, including capture data, incidental catch, and releases and/or discards of species. The Ministry recently adopted and released Circular No. 4531/83795/20-07-2016 to inform all stakeholders of the provisions of the above protection measures.

Response: We thank the Hellenic Ministry of Rural Development and Food for the comments and have updated the status review accordingly. We note that while these regulations

will likely, to some extent, reduce the fishing related mortality to both guitarfish species, it does not appear that either species is common in Greek waters. Therefore we conclude that these regulatory mechanisms are unlikely to significantly decrease both *Rhinobatos* species' risks of extinction.

Comment 24: The Lebanese Ministry of Agriculture, through the Embassy of Lebanon, commented that fishing both *Rhinobatos* species is prohibited in Lebanon by decision number 1045/1 issued on November 25, 2014, based on GFCM recommendation GFCM/36/3012/3. Based on this decision, they welcomed our proposal to list both guitarfishes species as threatened under the ESA.

Response: We thank the Lebanese Ministry of Agriculture for the comments and have updated the status review accordingly. We note that the information available to us (Lteif 2015) indicates that regulations related to these guitarfish species are not adequately enforced. However, we note that these conclusions were reached based on data that were collected up until approximately the time that decision number 1045/1 was issued, so the enforcement of relevant regulations may now be effective. Given the uncertainty regarding the enforcement of these regulations, and the relatively small portion of both species' ranges that occur in Lebanese waters, we conclude that these regulatory mechanisms are unlikely to significantly decrease both *Rhinobatos* species' risks of extinction range wide.

Comment 25: One commenter noted that in the *Inadequacy of Existing Regulations* section of the status review we did not mention relevant Turkish laws, species specific laws for *Rhinobatos* species in Banc d'Arguin National Park (Mauritania), and a ban on finning in Nigeria.

Response: The commenter provided no references regarding any of these regulations. We found no information about Turkish laws relevant to guitarfishes or sharks and rays in general and the General Fisheries Commission for the Mediterranean National Legislation Database (available at: <http://nationallegislation.gfcmsecretariat.org>) lists no such relevant law. However, some additional information about general fisheries management efforts in Turkey, including vessel registrations, gear restrictions, and seasonal area closures has been added to the *Regulatory Mechanisms in the Mediterranean* section of the status review. Because these management efforts are not specific to guitarfish, and we have no

information on how these efforts affect guitarfish in Turkey, this new information does not change our conclusion that current regulations are inadequate to protect either species.

As discussed in the status review, fishing for all shark species, including guitarfishes, has been banned since 2003 in Banc d'Arguin National Park. Additional information on regulatory efforts from 1998 to 2003 has been added to the *Regulatory Mechanisms in the Atlantic* section of the status review. This information provides context for how the current protective regulations were developed in Banc d'Arguin, which are currently adequately protecting both species in this small portion of their ranges, a fact that was acknowledged in the draft status review.

The fact that Nigeria prohibits the dumping of shark carcasses at sea has also been added to the *Regulatory Mechanisms in the Atlantic* section. While this information augments our knowledge of regulations that may affect these species, we found no information on how this regulation is enforced and very little information on guitarfish in Nigeria in general. Thus, it does not change our conclusion that current regulations are inadequate to protect either species.

Comment 26: One commenter strongly supported our proposed rule and encouraged us to finalize the our listing decision in a timely manner, incorporate comments and suggestions submitted during the comment period, and incorporate a full analysis of all the factors under section 4(a)(1) of the ESA.

Response: We appreciate this comment. We have incorporated all substantive comments received into the status review and this final rule and fully analyzed the ESA section 4(a)(1) factors using the best available scientific and commercial information.

Summary of Changes From the Proposed Listing Rule

We reviewed, and incorporated as appropriate, scientific data from references that were not previously included in the draft status review (Newell 2016) and proposed rule (81 FR 64094; September 19, 2016). We included the following references and communications, which, together with previously cited references, represent the best available scientific and commercial data on *R. cemiculus* and *R. rhinobatos*: Ambrose *et al.* (2005), Atweberhan *et al.* (2012), Carla Jazzar, Embassy of Lebanon, pers. comm. to D. Wieting, NMFS (7 December, 2016), Caverivière and Andriamirado (1997), Coll (2010), D. Berces, University of Florida, pers. comm. to B. Newell,

NMFS, (14 November, 2016), Farrugio *et al.* (1993), Hellenic Ministry of Rural Development pers. comm. (2016), HSI (2016), ICES (2010), and OECD (undated). However, the information not previously included in the draft status review or proposed rule does not present significant new findings that change either of our proposed listing determinations. The updated status review (Newell 2016) is available at: www.nmfs.noaa.gov/pr/species/petition81.htm.

Status Review

The status review for both guitarfish species was conducted by a NMFS biologist in the Office of Protected Resources. In order to complete the status review, we compiled information on the species' biology, ecology, life history, threats, and conservation status from information contained in the petition, our files, a comprehensive literature search, and consultation with experts. Prior to publication of the proposed rule, the status review was subjected to peer review. Peer reviewer comments are available at www.cio.noaa.gov/services_programs/prplans/PRsummaries.html. This status review provides a thorough discussion of the life history, demographic risks, and threats to the two guitarfish species. We considered all identified threats, both individually and cumulatively, to determine whether these guitarfish species respond in a way that causes actual impacts at the species level. The collective condition of individual populations was also considered at the species level, according to the four viable population descriptors discussed above.

Summary of Factors Affecting the Two Guitarfish Species

We considered whether any one or a combination of the five threat factors specified in section 4(a)(1) of the ESA contribute to the extinction risk of these species. The comments that we received on the proposed rule and the additional information that became available since the publication of the proposed rule did not change our conclusions regarding any of the section 4(a)(1) factors or their interactions for these species. Therefore, we incorporate herein all information, discussion, and conclusions on the summary of factors affecting the two guitarfish species in the status review (Newell 2016) and proposed rule (81 FR 64094; September 19, 2016).

Extinction Risk

None of the information we received from public comment on the proposed rule affected our extinction risk

evaluations of these two guitarfish species. Therefore, we incorporate herein all information, discussion, and conclusions, with the minor updates noted above, on the extinction risk of the two guitarfish species in the status review (Newell 2016) and proposed rule (81 FR 64094; September 19, 2016).

Protective Efforts

As part of our evaluation of the status of the guitarfishes, we considered conservation efforts to protect each species and evaluated whether these conservation efforts are adequate to mitigate the existing threats to the point where extinction risk is significantly lowered and the species' status is improved. None of the information we received from public comment on the proposed rule affected our conclusions regarding conservation efforts to protect the two guitarfish species. We incorporate herein all information, discussion, and conclusions on the protective efforts for both guitarfish species in the status review (Newell 2016) and proposed rule (81 FR 64094; September 19, 2016).

Final Determination

There is significant uncertainty regarding the status of the current populations of both *R. rhinobatos* and *R. cemiculus*, but both species may still be relatively common, although very likely below their historical population levels, in Tunisia, Israel, Lebanon, Syria, and southeastern Turkey. Based on this information, and the best available scientific and commercial information, as summarized here, in the proposed rule (81 FR 64094; September 19, 2016), and in Newell (2016), we find that neither *Rhinobatos* species is currently at high risk of extinction throughout their ranges. However, both species are at moderate risk of extinction. We assessed the ESA section 4(a)(1) factors and conclude that *R. rhinobatos* and *R. cemiculus* face ongoing threats of overutilization by fisheries and inadequate existing regulatory mechanisms throughout their ranges. Both species have also suffered a curtailment of a large portion of their historical ranges. These species' natural biological vulnerability to overexploitation and present demographic risks (declining abundance, decreasing size of reproductive individuals, and low productivity) are currently exacerbating the negative effects of these threats. Further, ongoing conservation efforts are not adequate to improve the status of these species. Thus, both species likely to become endangered throughout their ranges in the foreseeable future (15–20

years). Therefore, we are listing both species as threatened under the ESA.

Effects of Listing

Conservation measures provided for species listed as threatened under the ESA include recovery actions (16 U.S.C. 1533(f)); Federal agency requirements to consult with NMFS under section 7 of the ESA to ensure their actions do not jeopardize the species or result in adverse modification or destruction of critical habitat should it be designated (16 U.S.C. 1536); designation of critical habitat if prudent and determinable (16 U.S.C. 1533(a)(3)(A)); and prohibitions on taking (16 U.S.C. 1538) through a rule promulgated under section 4(d). In addition, recognition of the species' plight through listing promotes conservation actions by Federal and State agencies, foreign entities, private groups, and individuals.

Identifying Section 7 Consultation Requirements

Section 7(a)(2) (16 U.S.C. 1536(a)(2)) of the ESA and NMFS/USFWS regulations require Federal agencies to consult with us to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of listed species or destroy or adversely modify critical habitat. It is unlikely that the listing of these species under the ESA will increase the number of section 7 consultations, because these species occur entirely outside of the United States and are unlikely to be affected by Federal actions.

Critical Habitat

Critical habitat is defined in section 3 of the ESA (16 U.S.C. 1532(5)) as: (1) The specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the ESA, on which are found those physical or biological features (a) essential to the conservation of the species and (b) that may require special management considerations or protection; and (2) specific areas outside the geographical area occupied by a species at the time it is listed upon a determination that such areas are essential for the conservation of the species. Section 4(a)(3)(A) of the ESA (16 U.S.C. 1533(a)(3)(A)) requires that, to the extent prudent and determinable, critical habitat be designated concurrently with the listing of a species. However, critical habitat shall not be designated in foreign countries or other areas outside U.S. jurisdiction (50 CFR 424.12 (g)).

The best available scientific and commercial data as discussed above identify the geographical areas occupied

by *R. rhinobatos* and *R. cemiculus* as being entirely outside U.S. jurisdiction, so we cannot designate occupied critical habitat for these species. We can designate critical habitat in areas in the United States currently unoccupied by the species if the area(s) are determined by the Secretary to be essential for the conservation of the species. The best available scientific and commercial information on these species does not indicate that U.S. waters provide any specific essential biological function for either of the *Rhinobatos* species. Therefore, based on the available information, we are not designating critical habitat for *R. cemiculus* or *R. rhinobatos*.

Identification of Those Activities That Would Constitute a Violation of Section 9 of the ESA

On July 1, 1994, NMFS and FWS published a policy (59 FR 34272) that requires NMFS to identify, to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the ESA. Because we are listing *R. rhinobatos* and *R. cemiculus* as threatened, no prohibitions of section 9(a)(1) of the ESA will apply to these species.

Protective Regulations Under Section 4(d) of the ESA

We are listing *R. rhinobatos* and *R. cemiculus* as threatened under the ESA. In the case of threatened species, ESA section 4(d) leaves it to the Secretary's discretion whether, and to what extent, to extend the section 9(a) "take" prohibitions to the species, and authorizes us to issue regulations necessary and advisable for the conservation of the species. Thus, we have flexibility under section 4(d) to tailor protective regulations, taking into

account the effectiveness of available conservation measures. The section 4(d) protective regulations may prohibit, with respect to threatened species, some or all of the acts which section 9(a) of the ESA prohibits with respect to endangered species. These section 9(a) prohibitions apply to all individuals, organizations, and agencies subject to U.S. jurisdiction. Because neither species has ever occupied U.S. waters, and the United States has no known commercial or management interest in either species, we are not applying any section 9(a) prohibitions to either species at this time.

References

A complete list of references used in this final rule is available upon request (see **ADDRESSES**).

Classification

National Environmental Policy Act

The 1982 amendments to the ESA, in section 4(b)(1)(A), restrict the information that may be considered when assessing species for listing. Based on this limitation of criteria for a listing decision and the opinion in *Pacific Legal Foundation v. Andrus*, 675 F. 2d 825 (6th Cir. 1981), we have concluded that ESA listing actions are not subject to the environmental assessment requirements of the National Environmental Policy Act (NEPA).

Executive Order 12866, Regulatory Flexibility Act, and Paperwork Reduction Act

As noted in the Conference Report on the 1982 amendments to the ESA, economic impacts cannot be considered when assessing the status of a species. Therefore, the economic analysis requirements of the Regulatory Flexibility Act are not applicable to the

listing process. In addition, this final rule is exempt from review under Executive Order 12866. This final rule does not contain a collection-of-information requirement for the purposes of the Paperwork Reduction Act.

Executive Order 13132, Federalism

In accordance with E.O. 13132, we determined that this final rule does not have significant federalism effects and that a federalism assessment is not required.

List of Subjects in 50 CFR Part 223

Endangered and threatened species, Exports, Imports, Transportation.

Dated: January 10, 2017.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 223 is amended as follows:

PART 223—THREATENED MARINE AND ANADROMOUS SPECIES

■ 1. The authority citation for part 223 continues to read as follows:

Authority: 16 U.S.C. 1531–1543; subpart B, § 223.201–202 also issued under 16 U.S.C. 1361 *et seq.*; 16 U.S.C. 5503(d) for § 223.206(d)(9).

■ 2. In § 223.102, paragraph (e) add new entries for "Guitarfish, blackchin" and "Guitarfish, common", in alphabetical order by common name under the "Fishes" table subheading to read as follows:

§ 223.102 Enumeration of threatened marine and anadromous species.

* * * * *

(e) * * *

| Species ¹ | | Description of listed entity | Citation(s) for listing determination(s) | Critical habitat | ESA rules |
|-----------------------|-----------------------------------|------------------------------|---|------------------|-----------|
| Common name | Scientific name | | | | |
| * | * | * | * | * | |
| Fishes | | | | | |
| * | * | * | * | * | |
| Guitarfish, blackchin | <i>Rhinobatos cemiculus</i> ... | Entire species | 82 FR [Insert FEDERAL REGISTER page where the document begins], January 19, 2017. | NA | NA. |
| Guitarfish, common | <i>Rhinobatos rhinobatos</i> | Entire species | 82 FR [Insert FEDERAL REGISTER page where the document begins], January 19, 2017. | NA | NA. |
| * | * | * | * | * | |

¹ Species includes taxonomic species, subspecies, distinct population segments (DPSs) (for a policy statement, see 61 FR 4722, February 7, 1996), and evolutionarily significant units (ESUs) (for a policy statement, see 56 FR 58612, November 20, 1991).

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[FR Doc. 2017-00680 Filed 1-18-17; 8:45 am]

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DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 600**

[Docket No. 1512-01999-6969-02]

RIN 0648-BF51

Standardized Bycatch Reporting Methodology

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: This final rule interprets and provides guidance on the requirement of the Magnuson-Stevens Fishery Conservation and Management Act (MSA) that all fishery management plans (FMPs), with respect to any fishery, establish a standardized reporting methodology to assess the amount and type of bycatch occurring in a fishery. The final rule establishes requirements and provides guidance to regional fishery management councils and the Secretary of Commerce regarding the development, documentation, and review of such methodologies, commonly referred to as Standardized Bycatch Reporting Methodologies (SBRMs).

DATES: Effective February 21, 2017.

ADDRESSES: Copies of the Categorical Exclusion/Regulatory Impact Review (RIR)/Final Regulatory Flexibility Act Analysis (FRFAA) prepared for this action can be obtained from: Karen Abrams, National Marine Fisheries Service, 1315 East West Highway, Room 13461, Silver Spring, MD 20910. An electronic copy of the CE/RIR/RFAA documents as well as copies of public comments received can be viewed at the Federal e-rulemaking portal: <http://www.regulations.gov/> (Docket ID: NOAA-NMFS-2012-0092).

FOR FURTHER INFORMATION CONTACT: Karen Abrams, 301-427-8508, or by email: karen.abrams@noaa.gov.

SUPPLEMENTARY INFORMATION:**Background**

Section 303(a)(11) of the Magnuson-Stevens Fishery Conservation and Management Act (MSA) requires that any fishery management plan (FMP) prepared by a regional fishery management council (Council) or the

Secretary of Commerce with respect to any fishery establish a standardized reporting methodology to assess the amount and type of bycatch occurring in the fishery, and include conservation and management measures that, to the extent practicable, minimize bycatch and bycatch mortality (16 U.S.C. 1853(a)(11)). *See also* 16 U.S.C. 1854(c) and (g) (authorizing Secretarial FMPs). Hereafter, “Council” includes the Secretary of Commerce as applicable when preparing FMPs or amendments under 16 U.S.C. 1854(c) and (g). *See* 50 CFR 600.305(d). This standardized reporting methodology is commonly referred to as a “Standardized Bycatch Reporting Methodology” (SBRM). This final rule, which is promulgated pursuant to 16 U.S.C. 1855(d), sets forth NMFS’ interpretation of section 303(a)(11) and establishes national requirements and guidance for developing, documenting, and reviewing SBRMs. A proposed rule for this action was published on February 25, 2016 (81 FR 9413), with public comments accepted through April 25, 2016.

Section 303(a)(11) was added to the MSA by the Sustainable Fisheries Act of 1996 (SFA). The MSA does not define “standardized reporting methodology” or any of the words contained within the phrase. Similar to section 303(a)(11), National Standard 9 (NS9) (16 U.S.C. 1851(a)(9)) requires that conservation and management measures “shall, to the extent practicable, (A) minimize bycatch and (B) to the extent bycatch cannot be avoided, minimize the mortality of such bycatch.” However, NS9 does not address SBRM.

Prior to this rulemaking, NMFS never issued regulations that set forth the basic requirements of the SBRM provision. To implement the 1996 SFA Amendments, NMFS developed NS9 guidelines in 1998, and amended these guidelines in 2008. *See* 50 CFR 600.350. The guidelines provide several clarifications about bycatch requirements under the MSA, but do not interpret the SBRM requirement. In 2004, NMFS published *Evaluating Bycatch: A National Approach to Standardized Bycatch Monitoring Programs* (NOAA Technical Memorandum NMFS-F/SPO-66, October 2004, hereafter referred to as *Evaluating Bycatch*), a report that was prepared by the agency’s National Working Group on Bycatch (available at http://www.nmfs.noaa.gov/by_catch/SPO_final_rev_12204.pdf). The report did not provide, or purport to provide, the agency’s interpretation of the basic requirements of complying with MSA section 303(a)(11). *See Evaluating*

Bycatch at Chapters 3, 4, and 5 and Appendix 5 (discussing regional bycatch and fisheries issues, reporting/monitoring measures, and precision goals for bycatch estimates, but noting that goals “may in some instances exceed minimum statutory requirements”).

Additional background information—including NMFS’ rationale for developing this rule, statutory and historical background, and the purpose and scope of the rule—can be found in the proposed rule that published on February 25, 2016 (81 FR 9413). Copies are available from NMFS (*see ADDRESSES*), or can be viewed electronically at the Federal E-Rulemaking portal for this action: <http://www.regulations.gov>.

Separate from this rulemaking, which solely addresses reporting methodologies for bycatch as defined under the MSA, NMFS has engaged in a broad range of activities since the 1970s to address its bycatch-related responsibilities under the MSA, the Marine Mammal Protection Act (MMPA), the Endangered Species Act (ESA), and other relevant statutes and international agreements. More specifically, NMFS, the Councils, and multiple partners have implemented management measures to minimize bycatch and bycatch mortality in fisheries (e.g., time and area closures); developed and/or researched bycatch reduction technologies for fishing gear (e.g., turtle excluder devices and circle hooks); convened multi-stakeholder take reduction teams to address marine mammal bycatch; supported national research programs, such as the Bycatch Reduction Engineering Program; promoted the adoption of bycatch reduction measures in international regional fishery management organizations; and published a series of biennial National Bycatch Reports and Updates since 2011 that provide a historical summary of fishery- and species-specific bycatch estimates on an annual basis for major U.S. fisheries around the country, to cite a few examples. NMFS also has a database from which members of the public can query bycatch estimates from the National Bycatch Reports and Updates. *See* <http://www.st.nmfs.noaa.gov/observer-home/first-edition-update-1>. To build on its bycatch efforts, this year in February 2016, NMFS issued for public comment a draft *National Bycatch Reduction Strategy* that aims to coordinate NMFS’ efforts to address bycatch under the various mandates it is charged with carrying out to further advance its work in addressing bycatch both domestically and internationally.

NMFS received numerous public comments on the draft strategy and is working to address those comments and finalize the strategy. For more information on NMFS' 40 year commitment to addressing bycatch, *see* <http://noaa.maps.arcgis.com/apps/MapSeries/index.html?appid=e5d4037090054fa2843a6ab522c9b73b>.

I. Overview of the Major Aspects of the Final Rule

Section 600.1600 explains the purpose and scope of an SBRM and § 600.1610 clarifies the requirements for establishing and reviewing SBRMs. The rule requires that an FMP identify the required procedure or procedures that constitute the SBRM for the fishery. The rule also requires that the FMP, or fisheries research plan authorized under 16 U.S.C. 1862, explain how the SBRM meets the purpose described under § 600.1600, based on an analysis of (1) the characteristics of the bycatch occurring in the fishery, (2) the feasibility of the methodology from cost, technical and operational perspectives, (3) the uncertainty of the data resulting from the methodology, and (4) how the data resulting from the methodology are used to assess the amount and type of bycatch occurring in the fishery. Finally, the rule provides that a Council should give guidance to NMFS on how to adjust the implementation of the SBRM consistent with the FMP, and requires periodic reviews of SBRMs.

Below is further explanation of the major aspects of the final rule. In addition to streamlining the final rule to improve clarity and organization, NMFS has made several changes in the final rule to respond to public comments. The changes are discussed below and in sections II (Response to Comments) and III (Changes from Proposed Action) of this preamble.

A. Scope of Rule

Establishing an SBRM is a requirement of the MSA. Therefore, this rule is based on the MSA's definition of "bycatch," which includes fish which are harvested in a fishery, but which are not sold or kept for personal use, and includes economic discards and regulatory discards. Such term does not include fish released alive under a recreational catch and release fishery management program. 16 U.S.C. 1802(2). NMFS' NS9 guidelines clarify that "[a] catch-and-release fishery management program is one in which the retention of a particular species is prohibited. In such a program, those fish released alive would not be considered bycatch." 50 CFR 600.350(c)(2). NMFS received several comments on the rule's

definition of "bycatch." To clarify its intent to rely on the MSA's definition of "bycatch," NMFS has revised the final rule at § 600.1605(b) to add reference to the MSA definition. Summaries of the comments received on the definition of bycatch and NMFS' responses may be found in section II (Response to Comments) of this preamble.

B. Purpose of an SBRM

Based on the statutory language of section 303(a)(11) of the MSA, the final rule clarifies in § 600.1600 that the purpose of an SBRM is to collect, record, and report bycatch data in a fishery that, in conjunction with other information, are used to assess the amount and type of bycatch occurring in the fishery and inform the development of conservation and management measures that, to the extent practicable, minimize bycatch and bycatch mortality. Consistent with this purpose, § 600.1605(a) defines "standardized reporting methodology" with reference to procedures used to collect, record, and report bycatch data in a fishery. Section 600.1605(a) clarifies that bycatch assessment procedures are not part of an SBRM, and thus do not need to be described as part of the methodology in an FMP. A Council may include such a description if it so chooses and could provide this description by incorporating by reference information from a Stock Assessment and Fishery Evaluation (SAFE) report or other documents.

As explained in the proposed rule (*see* 81 FR 9413 at 9414–9415), activities to collect, record, and report bycatch data in a fishery are connected to, but distinct from, the methods used to assess bycatch and the development of measures to minimize bycatch or bycatch mortality. NMFS received numerous comments on the linkage between bycatch data collection and bycatch assessment. Having carefully considered public comment on this issue, NMFS has decided to maintain the distinction between data collection and bycatch assessment in the final rule. NMFS continues to believe that it is important to be clear about the key policy choices and objectives associated with establishing an SBRM, and not confuse those choices with statistical and technical approaches for estimating bycatch that are inherently scientific and data dependent, or with the policy choices associated with developing measures to minimize bycatch or bycatch mortality. *See* "Activities Associated with an SBRM" in the proposed rule and "Distinction Between Data Collection and Data Assessment" in section II of this preamble for further

information and explanation of this issue.

While recognizing the distinction between data collection and bycatch assessment, NMFS affirms the important linkage between these activities. To reinforce this link, NMFS has revised § 600.1610(a)(2)(iv) to require a Council to address how the data resulting from an SBRM are used to assess the amount and type of bycatch in the fishery and to consult with its Science and Statistical Committee (SSC) and/or regional NMFS science centers on SBRM design considerations (*e.g.*, data elements, sampling designs, sample sizes, and reporting frequency). NMFS also cross-references this requirement in § 600.1600. *See* section I. E. 4. *Data Use* of this preamble for further explanation.

C. Meaning of "Standardized"

Section 303(a)(11) requires that "Any fishery management plan . . . with respect to any fishery, shall . . . establish a standardized reporting methodology to assess the amount and type of bycatch occurring in the fishery." 16 U.S.C. 1853(a)(11). Section 303(a)(11) does not require regional or national standardization; rather, the requirement to establish a standardized reporting methodology applies to each FMP with respect to any fishery managed under it. Consistent with the statutory language, this rule defines "standardized reporting methodology" as an established, consistent procedure or procedures used to collect, record, and report bycatch data in a fishery, which may vary from one fishery to another. *See* 600.1605(a) (emphasis added).

A Council establishes the SBRM based on the requirements outlined in this rule and the purpose of an SBRM (*see* § 600.1600). The definition of "standardized reporting methodology" envisions that a Council may include more than one data collection, recording, and reporting procedure in its SBRM. As acknowledged in § 600.1610(a)(2)(i), the amount and type of bycatch occurring in a fishery may vary based on different fishing activities and operations (*e.g.*, gear types used, how gear is deployed, gear selectivity, fishing effort, fishing locations). In light of the above, a Council could decide that a combination of procedures is appropriate for a fishery. In such a case, the FMP must still identify what the established, consistent procedures are for the fishery. For example, in a fishery in which vessels use trawl nets and gill nets, a Council could determine that different procedures are appropriate for the different gear types. The Council would then be required to identify the

required, consistent procedures for both gear types in the FMP. *See* section I. E. 1. and the response to comment 9 in section II of this preamble for further explanation.

D. FMP Contents

Section 600.1610(a)(1) requires every FMP to identify the required procedure or procedures that constitute the SBRM for the fishery. Such procedures may include, but are not limited to, observer programs, electronic monitoring and reporting technologies, and self-reported mechanisms. This rule does not prescribe the use of particular procedures.

Section 600.1610(a)(1) also requires Councils to explain in an FMP, or a fishery research plan authorized under 16 U.S.C. 1862, how the SBRM meets the purpose described in § 600.1600, based on an analysis of requirements (set forth in § 600.1610(a)(2) and described below). The FMP, or fishery research plan under 16 U.S.C. 1862, may reference analyses and information in other FMPs, FMP amendments, SAFE reports, or other documents. Consistent with current practices, the rule encourages Councils to work together and collaborate on SBRMs for fisheries that operate across multiple jurisdictions, as appropriate.

NMFS amended the final rule to refer to 16 U.S.C. 1862, a provision that authorizes the North Pacific Fishery Management Council to prepare a fisheries research plan for any fishery under its jurisdiction (except salmon) that requires observers and establishes a system of fees to pay for the costs of implementing the plan. The North Pacific Council has established a fisheries research plan that requires an observer program as authorized under 16 U.S.C. 1862, and the program constitutes the SBRM for the fisheries covered thereunder. Given that, this rule allows the North Pacific Council to explain in its fisheries research plan how the SBRM for those fisheries meets the statutory purpose of an SBRM.

Finally, § 600.1610(a)(1) explains that, in addition to proposing regulations necessary to implement the standardized reporting methodology, a Council should provide in an FMP, or a fishery research plan authorized under 16 U.S.C. 1862, guidance to NMFS on how to adjust implementation of the methodology consistent with the FMP. That section cites to the National Standard 6 guidelines (50 CFR 600.335), which provide guidance on taking variations and contingencies into account. NMFS notes that, to the extent that adjustments are needed to an SBRM beyond what is established in an FMP,

an FMP amendment would be required. This text in § 600.1610(a)(1) replaces § 600.1610(c) (adaptable implementation) because public comments expressed confusion over that proposed provision. NMFS reiterates that every FMP must establish an SBRM. NMFS did not intend to imply otherwise in the proposed § 600.1610(c) (at 81 FR 9413, February 25, 2016). Rather, NMFS' intent in the proposed § 600.1610(c) (at 81 FR 9413, February 25, 2016), and now in § 600.1610(a)(1), is to recognize that fisheries management occurs in a highly variable environment and there are numerous biological, social, and economic variables that may affect the operational aspects of implementing data collection and reporting programs that constitute an SBRM. In light of this, NMFS strongly recommends that Councils provide direction, as needed, to NMFS about how to adjust the implementation of an SBRM consistent with the FMP. NMFS believes that its approach in § 600.1610(a) will promote efficiency and transparency by encouraging a Council to consider implementation and operational issues up-front during the development of an SBRM. *See* response to comment 29 and 48 for further explanation.

E. Fishery-Specific Analysis

MSA section 303(a)(11) requires that FMPs establish SBRMs, but beyond the fact that an SBRM must meet its statutory purpose, section 303(a)(11) provides no other guidance on the considerations that should go into developing an SBRM. Therefore, NMFS has discretion to interpret section 303(a)(11) and establish reasonable considerations and requirements. Based on NMFS' experience with implementing section 303(a)(11), and taking into consideration public comment on the proposed rule, this final rule requires that all Councils conduct a fishery-specific analysis that addresses the following when establishing or reviewing an SBRM: (1) The characteristics of the bycatch occurring in the fishery, (2) the feasibility of the methodology from cost, technical and operational perspectives, (3) the uncertainty of the data resulting from the methodology, and (4) how the data resulting from the methodology are used to assess the amount and type of bycatch occurring in the fishery. The first and second requirements were included in the proposed rule and have been revised minimally in response to comments. With respect to the third and fourth requirements, NMFS has, in response to public comments, clarified and elaborated upon the proposed

requirement that a Council address "the quality of the data associated with the methodology" (*see* proposed § 600.1610(a)(2)(i) at 81 FR 9413, February 25, 2016). Below is further explanation of these four requirements.

In response to comments, NMFS has removed text that required consideration of the conservation and management objectives regarding bycatch in the fishery (*see* proposed § 600.1610(a)(2)(i) at 81 FR 9413, February 25, 2016), and text stating that a Council may consider the overall magnitude and/or economic impact of the fishery (*see* proposed § 600.1610(a)(2)(i) at 81 FR 9413, February 25, 2016). The reasons for these changes are provided in the responses to comments 44 and 46.

1. Characteristics of Bycatch in the Fishery

Section 600.1610(a)(2)(i) provides that a Council must address information about the characteristics of bycatch in the fishery when available, including, but not limited to, the amount of bycatch occurring in the fishery, the importance of bycatch in estimating the fishing mortality of fish stocks, and the effect of bycatch on ecosystems. Section 600.1610(a)(2)(i) recognizes that the amount and type of bycatch occurring in the fishery may vary based on different fishing activities and operations. Bycatch can be affected by several aspects of a fishery, including gear types used, how gear is deployed, gear selectivity, fishing effort, fishing locations, and existing management measures. A Council may consider these operational aspects when selecting the collection, monitoring, and reporting procedures that constitute the SBRM for a fishery.

2. Feasibility

Section 600.1610(a)(2)(ii) requires that the implementation of an SBRM be feasible from cost, technical, and operational perspectives. Data collection, reporting, and recording procedures can be expensive, logistically challenging to design and implement, involve new and cutting-edge technologies, and necessitate the consideration of the safety of human life at sea. Having carefully considered public comments, NMFS continues to believe that it is reasonable and appropriate for a Council to analyze issues of feasibility when establishing or reviewing an SBRM and to ultimately choose a methodology that is in fact feasible (*i.e.*, capable of being implemented) from cost, technical, and operational perspectives. If a Council proposes an FMP or FMP amendment

with an SBRM that is not feasible, NMFS may disapprove or partially disapprove the FMP amendment. In response to public comments, NMFS clarifies in the final rule that feasibility concerns do not exempt an FMP from the requirement to establish an SBRM. NMFS reiterates that the requirement to establish an SBRM is a statutory requirement applicable to all FMPs.

Proposed § 600.1610(a)(2)(i) at 81 FR 9413, February 25, 2016, would have required SBRMs to be designed to be implemented with available funding. In response to comments, NMFS has deleted this provision. *See* section II (the responses to comments on “Consideration of Feasibility, Costs, and Funding”) of this preamble. Instead, NMFS explicitly acknowledges in § 600.1610(a)(2)(ii) that costs and funding may vary from year to year, and requires a Council to address how implementation of the SBRM may be adjusted while continuing to meet the purpose described under § 600.1600. If a Council chooses to establish an SBRM that may be adjusted in response to changes in costs or funding, the Council should provide guidance to NMFS on how to adjust the implementation of the SBRM consistent with the FMP, as provided in § 600.1610(a)(1) (*see* section I. D. of this preamble).

As an example, NMFS notes that the resources available for observer programs may vary from year to year. To address this variability in resources, the North Pacific Council uses an Annual Deployment Plan, a component of its fisheries research plan authorized under 16 U.S.C. 1862, to describe how NMFS and the Council will annually deploy observers given changes in funding, costs, and effort consistent with the FMP. As another example, in New England and the Mid Atlantic, if the available funding is insufficient to meet the SBRM performance standard, the SBRM Omnibus Amendment for New England and Mid-Atlantic fisheries (80 FR 37182, June 30, 2015) (currently the subject of litigation) establishes a non-discretionary formulaic process for prioritizing how the available observer sea-days would be allocated to maximize the effectiveness of the SBRM. NMFS reiterates that, regardless of resource constraints, all FMPs must establish an SBRM that meets the purpose described in § 600.1600.

3. Data Uncertainty

Section 600.1610(a)(2)(iii) requires Councils to address the uncertainty of the data resulting from the SBRM. This section also requires that an SBRM be designed so that the uncertainty associated with the resulting bycatch

data can be described, quantitatively or qualitatively. Eliminating data uncertainty is not an end in itself, but the rule recognizes that Councils should seek to minimize uncertainty in the resulting data, recognizing that different degrees of uncertainty may be appropriate for different fisheries.

4. NMFS received numerous public comments requesting that the final rule include specific standards for accuracy, precision, or statistical reliability of bycatch estimates and data. *See* section II for comments and responses related to “Consideration of Quality and Use of Data.” After considering public comments and consulting with agency scientists, NMFS does not believe it is appropriate to establish accuracy, precision, or reliability standards for bycatch data or estimates to be applied across all fisheries. As explained in “Purpose of an SBRM” above, bycatch assessment or estimation is not considered part of an SBRM under this rule. Moreover, as explained in the responses to comments, the specific characteristics of each fishery and its bycatch vary widely from region to region and from fishery to fishery. For example, during development of this rule, agency scientists noted that bycatch estimates for species with low encounter rates will have lower precision than commonly encountered bycatch species. Establishing bycatch data or estimation standards across all fisheries could result in an overly intensive sampling effort that may not be needed for bycatch assessment or management purposes, would not be feasible, and would be an inefficient use of agency resources. Instead, this rule requires that Councils address the uncertainty of the data resulting from an SBRM and design an SBRM so that the uncertainty associated with the resulting bycatch data can be described, quantitatively or qualitatively. As reflected in § 600.1600, there may be other relevant sources of data beyond the data provided by an SBRM that are used to develop bycatch estimates for the fishery (*e.g.*, fishing effort, fishery independent data, commercial landings data). Understanding the quality of data resulting from an SBRM and other sources is important in the assessment of bycatch and will assist Councils in developing conservation and management measures that, to the extent practicable, minimize bycatch, and minimize the mortality of bycatch. For example, a Council may choose to adopt measures that are more conservative in instances where bycatch data is a large component of fishing

mortality and is highly uncertain. *Data Use*

Section 600.1610(a)(2)(iv) requires a Council to address how the data resulting from an SBRM are used to assess the amount and type of bycatch occurring in the fishery. As explained in the “Purpose of the SBRM” section above, this provision was added in part to clarify and reinforce the link between an SBRM and the assessment of bycatch data. Section 600.1605(a) clarifies that, although bycatch assessment is not part of the SBRM, bycatch assessment must be considered as described in this provision. *See* responses to comments 16 and 25 (explaining the role of NMFS science centers in providing scientific information and analyses and how catch and landings information is made available).

Section 600.1610(a)(2)(iv) also incorporates the consultation provision of the proposed rule’s § 600.1610(b) (81 FR 9413, February 25, 2016). NMFS received comments during the public comment period asking the agency to clarify the consultation process. In response to comments (*see* “Consideration of Quality and Use of Data” in section II of this preamble), NMFS clarifies in the final rule that, related to its consideration of data use, a Council must consult with its SSC and/or the regional NMFS science center on reporting methodology design considerations such as data elements, sampling designs, sample sizes, and reporting frequency. Information provided through the consultation process will enable a Council to develop an SBRM that incorporates scientific input and that will provide data that can be used, in conjunction with other relevant sources of data, to assess the amount and type of bycatch occurring in the fishery.

Finally, § 600.1610(a)(2)(iv) requires Councils to consider the scientific methods and techniques available to collect, record, and report bycatch data that could improve the quality of bycatch estimates. As bycatch data collection technologies improve, NMFS anticipates that a Council will consider those technological advances when establishing and reviewing SBRMs in accordance with the review timeline specified in § 600.1610(b). *See* response to comment 47.

F. Review of FMPs

Section 600.1610(b) states that all FMPs must be consistent with this rule within 5 years of its effective date. To verify consistency with this rule, Councils, in coordination with NMFS, must conduct a review of their existing SBRMs. The review should provide

information sufficient for NMFS to determine whether an FMP needs to be amended. The review should be documented, but does not need to be contained in an FMP.

There are several potential outcomes of the review. NMFS could determine that there are FMPs with existing SBRMs that are consistent with this rule, in which case no FMP amendments would be necessary. Other FMPs may describe SBRMs more expansively than the definition in this final rule. For example, they may contain components that are consistent with this rule, along with additional components that are not precluded by this rule, but are not minimally required. Those FMPs also may not require further amendments if NMFS determines they are consistent with this rule. Still other FMPs may describe procedures or activities that comprise an SBRM, but do not explain them in a manner consistent with this rule. In such cases, changes to an FMP, or a fisheries research plan, may be warranted. Consistent with current practices, NMFS encourages Councils to work together and collaborate on SBRM reviews and potential FMP amendments for fisheries that operate across multiple jurisdictions, as appropriate.

After the initial review, Councils, in coordination with NMFS, should periodically review SBRMs to verify continued compliance with the MSA and this rule. Such a review should be conducted at least once every 5 years. Section 600.1610(b) is consistent with the review and improvement of data collection methods, data sources, and applications described under the NS9 guidelines at 50 CFR 600.350(d)(1).

II. Response to Comments

NMFS solicited public comments on the proposed rule for 60 days (February 25 through April 25, 2016), and during that time made presentations to four of the eight Councils and the Highly Migratory Species Advisory Panel. NMFS received 25 substantive comment letters on the proposed rule during the public comment period. Of those, six were form letters that had 65,961 signatures, and 1,382 of those signatories provided individualized add-on comments. The other 19 substantive comment letters were from non-governmental organizations, industry groups/commissions, Councils, and individuals. Summaries of the substantive comments that we received concerning the proposed rule, and our responses to all of the significant issues they raise, are provided below. Comments of a similar nature were grouped together where appropriate.

Need and Effect

Comment 1: Several commenters noted a need for clarification as to whether the proposed rule establishes national requirements or guidance. Some commenters stated that the preamble to the proposed rule stated that the rule is intended to “establish national requirements and guidance,” but in fact it provides broad guidelines and few mandatory requirements. Another commenter requested clarification as to whether the proposed rule constitutes guidance to the Councils versus regulatory requirements upon the Councils.

Response: This rule sets forth NMFS’ interpretation of the SBRM provision under MSA section 303(a)(11) (16 U.S.C. 1853(a)(11)) and requirements for establishing and reviewing SBRMs consistent with that interpretation. Many provisions of the rule are mandatory. The rule does not, however, prescribe specific details on the types of data collection and reporting procedures needed for each fishery. Instead, the rule requires Councils to undertake a fishery-specific analysis of the SBRM appropriate for the fishery and establish an SBRM that meets the purpose described in § 600.1600.

Comment 2: One commenter suggested that, in order to allow for the most flexible and effective SBRM process, the agency should issue these SBRM provisions as guidance, rather than a rule.

Response: As explained in the preamble to the proposed rule, NMFS has never issued regulations that set forth the basic requirements of MSA section 303(a)(11). In the absence of a national SBRM regulation, Councils have taken varying approaches to interpreting the provision, with some adopting the recommendations in *Evaluating Bycatch* and others interpreting the requirement in a different way. Litigation has also influenced the development of SBRMs in some regions. In light of the varying existing approaches, NMFS believes that an analysis and articulation of the basic requirements of section 303(a)(11) through a rulemaking is necessary in order to achieve greater consistency in establishing, documenting, and reviewing SBRMs. Public comment received on the proposed rule has greatly assisted NMFS in evaluating different approaches to interpreting the SBRM provision and developing this final rule. With regard to flexibility, this rule recognizes the diversity of fisheries across the country by allowing for a fishery-specific evaluation of the type of SBRM that is appropriate for a fishery,

consistent with the requirements of the MSA and this rule.

Comment 3: One commenter stated that the preamble to the proposed rule did not cite a recent North Pacific case that affirmed that the Alaska Region’s catch accounting system (CAS) is an SBRM. In light of that case, the commenter requested that the agency consider excluding fisheries under the jurisdiction of the North Pacific Fishery Management Council (NPFMC) from requirements of this rule.

Response: NMFS has prevailed in several SBRM lawsuits, including *The Boat Co. v. Pritzker*, No. 3:12-cv-0250-HRH, (D. Alaska Aug. 6, 2014), the North Pacific case mentioned by the commenter. However, as explained in response to comment 2, NMFS believes that it is important to have a national rulemaking applicable to all FMPs. NMFS recognizes that there is a North Pacific-specific observer provision under section 313 of the MSA, 16 U.S.C. 1862, that provides for use of a fisheries research plan. NMFS has revised this final rule in § 600.1610 to account for this provision.

Definition of Bycatch

Comment 4: A commenter requested clarification on the distinction between bycatch and discards.

Response: The distinction between bycatch and discards is clearly laid out in MSA’s definitions section and in NMFS’ NS9 guidelines. The MSA defines bycatch as fish which are harvested in a fishery, but which are not sold or kept for personal use, and includes economic discards and regulatory discards. Such term does not include fish released alive under a recreational catch and release fishery management program. 16 U.S.C. 1802(2). The MSA defines “economic discards” as fish which are the target of a fishery, but which are not retained because of an undesirable size, sex, or quality, or other economic reasons (16 U.S.C. 1802(9)), and the term “regulatory discards” as fish harvested in a fishery which fishermen are required by regulation to discard whenever caught, or are required by regulation to retain but not sell (16 U.S.C. 1802(38)). As explained in NMFS’ NS9 guidelines, “[b]ycatch includes the discard of whole fish at sea or elsewhere, including economic discards and regulatory discards. . . .” 50 CFR 600.350(c)(1).

Comment 5: One commenter recommended that the regulatory text be revised to more clearly indicate that bycatch does not include incidental catch of seabirds or marine mammals. Other commenters recommended

expanding the scope of the rule to provide guidance on the reporting of all types of bycatch, including marine mammals and seabirds. With regard to marine mammal bycatch, one commenter noted that a lack of guidance could lead to ineffective monitoring if Council actions are not integrated with efforts by the relevant take reduction teams.

Response: The requirement to establish an SBRM is a requirement of the MSA. Thus, this rule—which interprets the SBRM provision—is based on the MSA’s definitions of “bycatch” and “fish.” These definitions exclude marine mammals and birds. See 16 U.S.C. 1802(2) and (12). In response to comment, NMFS has revised the final rule at § 600.1605(b) to add references to the MSA definitions.

This rule does not preclude Councils from developing programs to collect, record, and report information about marine mammal mortality and injury and seabird interactions or unintentional mortality; however, the MSA does not require Councils to do so to be in compliance with the requirements of section 303(a)(11). Marine mammals are protected under the Marine Mammal Protection Act, 16 U.S.C. 1361 *et seq.*, which NMFS administers. NMFS is committed to working with the Councils and Take Reduction Teams (TRTs) to reduce bycatch of marine mammals. TRTs provide recommendations to NMFS on measures to reduce marine mammal mortalities and serious injuries in commercial fisheries. NMFS uses these recommendations to develop and implement take reduction plans. TRTs also provide input to NMFS on evaluating the effectiveness of these take reduction plans; such input often includes discussion and recommendations for observer coverage levels to monitor marine mammal bycatch. In previous years, NMFS has augmented observer coverage in specific fisheries to monitor marine mammal bycatch. As such, any marine mammal monitoring will be closely coordinated with monitoring required by an SBRM.

Comment 6: A commenter noted that NMFS’ U.S. National Bycatch Report, which reports on all bycatch, defines bycatch broadly as “discarded catch of any living marine resource plus unobserved mortality due to a direct encounter with fishing gear.” The commenter stated that NMFS needs better data for the report, so the rule should define bycatch in a similar way.

Response: NMFS is not changing the definition of bycatch in the final rule for the reasons explained in the response to comment 5. NMFS notes that the

National Bycatch Report is not a requirement under the MSA or other law. Since 2011, NMFS has issued the National Bycatch Report and its Updates to inform the public about bycatch and provide a cross-program perspective to inform agency priorities and planning related to bycatch mandates under the MMPA, ESA, MSA, and other statutes and international agreements. Given the varying definitions of bycatch under these authorities, the National Bycatch Report and its Updates use a broader definition of bycatch than the MSA; they include information about fish, as well as marine mammal and seabird interactions. Therefore, in preparing the National Bycatch Report and its Updates, NMFS compiles information from numerous sources, including, but not limited to, observer data, logbooks, vessel trip reports, dealer reports, landing receipts, surveys, and stock assessments; these documents do not rely solely on data provided by SBRMs. The more narrow definition of bycatch in the MSA, and the resulting scope of this final rule, will not hinder future versions of the National Bycatch Report.

NMFS also notes that the National Bycatch Report and its Updates provide a compilation of bycatch information and national and regional overviews to document bycatch in fisheries over time. They are not, however, used for day-to-day management of fisheries. The 2011 First Edition of the Report used data available in 2005, Update 1 (2013) used 2010 data, and Update 2 (2016) used 2011–2013 data. U.S. National Bycatch Report, First Edition Update 2 (February 2016) at p. 9 (*see* http://www.st.nmfs.noaa.gov/Assets/Observer-Program/bycatch-report-update-2/NBR%20First%20Edition%20Update%202_Final.pdf). NMFS has created a custom database that allows members of the public to query bycatch estimates that have been published in the National Bycatch Report Updates. Members of the public can access the database at <http://www.st.nmfs.noaa.gov/observer-home/first-edition-update-1>.

Comment 7: Several commenters submitted comments on the definition of bycatch with respect to recreational fishing. One commenter suggested that fish released alive under recreational fishing be included as bycatch to be monitored as part of an SBRM. The commenter stated that recreational fishing can be a large component of the total catch. Further, recreational bycatch can be a significant source of mortality, and in some cases, exceeds the amount of fish caught and kept. Another commenter requested that the rule include an exemption for “catch and

release” fishing and asked whether “no possession” implies that encounters are “catch and release.”

Response: NMFS does not agree with the suggestion to broaden the definition of bycatch in this rule to cover all fish released alive under recreational fishing. “[F]ish released alive under a recreational catch and release fishery management program” are excluded from the MSA definition of bycatch. 16 U.S.C. 1802(2). NMFS’ NS9 guidelines clarify that “[a] catch-and-release fishery management program is one in which the retention of a particular species is prohibited. In such a program, those fish released alive would not be considered bycatch.” 50 CFR 600.350(c)(2).

NMFS agrees that release mortality is an important issue, and the agency has taken steps to understand and address this issue. In August 2014, NMFS published a Technical Memorandum entitled *Fisheries Release Mortality*, which summarized NMFS-funded fish release mortality research over the past 15 years, identified release mortality data gaps, compiled mortality estimates used by NMFS, and identified criteria to help scientists and managers focus release mortality resources (NOAA Technical Memorandum NMFS–F/SPO–142, July 2014). In February 2016, NMFS released an Action Plan for Fish Release Mortality Science, which identifies national goals and objectives for estimating and reducing discard and release mortality for fish in commercial and recreational fisheries (<https://www.st.nmfs.noaa.gov/ecosystems/bycatch/discard-and-release-mortality>). NMFS directs commenters to these documents for further information regarding the agency’s efforts to address and evaluate release mortality in both commercial and recreational fisheries.

Interpretation of “Standardized”

Comment 8: Several commenters stated that NMFS’ proposed definition of “standardized reporting methodology” in § 600.1605(a) is contrary to Congress’ intent and the ordinary meaning of the word “standardized.” Commenters asserted that the MSA requires that SBRMs be standardized at the national, regional, or ecosystem level. In general, many of these commenters expressed concern that without regional, ecosystem, or national standardization, it will be difficult or impossible to assess the bycatch of species between fisheries or within multispecies fisheries; compare or combine data across fisheries or regions; understand ecosystem, regional, or national bycatch trends; or minimize bycatch. One commenter recommended

standardization according to gear type, specifically, reporting of bycatch by gear as a ratio of bycatch per unit effort to catch per unit effort (BPUE: CPUE). One commenter agreed that the proposed definition reflects the statutory language, but urged NMFS to direct managers to consider monitoring fish caught as bycatch that are managed in separate FMPs and by different management entities. One commenter also noted that the rule should be revised in light of NMFS' acknowledgment in the 2011 U.S. National Bycatch Report that it is difficult to compare or combine bycatch data across fisheries or regions due to differences in bycatch data, including the quantity and quality of data and reporting in pounds vs. individuals.

Response: NMFS is not changing its fishery-level approach to standardization in the final rule. The rule at § 600.1605(a) defines "standardized reporting methodology" with reference to a fishery, consistent with MSA section 303(a)(11). That section requires that "Any fishery management plan . . . with respect to any fishery, shall . . . establish a standardized reporting methodology to assess the amount and type of bycatch occurring in the fishery." 16 U.S.C. 1853(a)(11). The characteristics of bycatch in a fishery vary based on the fishing activity and operations. Therefore, requiring that SBRMs be standardized at the regional or national level would constrain the ability to tailor bycatch data programs to the needs of specific fisheries. However, consistent with current practices, the final rule encourages Councils to work together and collaborate on SBRMs for fisheries that operate across multiple jurisdictions, as appropriate.

NMFS does not agree that this rule will make it more difficult to assess the bycatch of species between fisheries or within multispecies fisheries; compare or combine data across fisheries or regions; understand ecosystem, regional, or national bycatch trends; or minimize bycatch. Unit conversion is a standard approach to dealing with data disparities. The agency routinely compiles data from varied sources and uses mathematical conversions and analytical tools to understand the data at the necessary scale.

With regard to gear type, as discussed in the preamble (*see* section I. C.), a Council may determine that different collection, recording, and reporting procedures are appropriate within a fishery for different gear types. However, because different fishing activities and operations (including but not limited to gear type) may affect the

amount and type of bycatch that occurs in a fishery and thus the types of reporting procedures that may be needed in a fishery, NMFS does not agree that SBRMs across a region or the country must be standardized by gear type. Furthermore, NMFS is not making changes to the rule in response to the suggestion to report bycatch by gear as a ratio of bycatch per unit effort to catch per unit effort (BPUE: CPUE). This suggestion pertains to how data might be displayed or synthesized when assessing the amount and type of bycatch. As explained previously, this rule pertains to the requirements for the collection, recording and reporting of bycatch data.

With respect to the National Bycatch Report, NMFS reiterates that the Report is not required under the MSA. Nevertheless, since 2011, NMFS has issued a National Bycatch Report and its Updates that provide a national- and regional-level look at bycatch. *See* response to comments 6 and 26 for further information on the National Bycatch Report. For the Second Edition of the National Bycatch Report (to be published in late 2017), NMFS is working to develop length-weight conversion factors for use in the Report. The use of conversion factors is not new; for example, NMFS has used such conversion factors in the pelagic longline fisheries based in Hawaii and American Samoa (<https://pifsc-www.irc.noaa.gov/library/pubs/DR-16-004.pdf>). Unit conversion and mathematical analysis is a standard approach to dealing with data disparities.

Comment 9: One commenter asserted that the inclusion of "subset of a fishery" in § 600.1605(a) is inconsistent with the MSA. Another commenter asked what a sub-"set" is, noting that it might be difficult in some fisheries to define a "set" and that, for many fisheries, collecting data at the "set" level would be extremely burdensome. The commenter expressed concern that fine-scale data collection might encourage inaccuracies and non-compliance with reporting requirements.

Response: The intent of the proposed rule's § 600.1605(a) (81 FR 9413, February 25, 2016) was to acknowledge that different fishing activities and operations can affect the amount and type of bycatch that occurs, and thus the types of reporting procedures that may be needed. Bycatch can be affected by, among other things, the gear types used, how gear is deployed, gear selectivity, fishing effort, fishing locations, and existing management measures. In response to this comment, NMFS has

amended § 600.1610(a)(2)(ii) to recognize that the amount and type of bycatch occurring in a fishery may vary based on different fishing operations. NMFS has also removed "subset" and refers simply to "fishery" in § 600.1605(a), to reflect the language of MSA section 303(a)(11). NMFS notes that the MSA's definitions of "fishery" and "stock of fish" are broad. *See* 16 U.S.C. 1802(13) (defining "fishery" as one or more stocks of fish which can be treated as a unit for purposes of conservation and management and which are identified on the basis of geographical, scientific, technical, recreational, and economic characteristics; and . . . any fishing for such stocks), and 16 U.S.C. 1802(42) (defining a "stock of fish" as a species, subspecies, geographical grouping, or other category of fish capable of management as a unit). Given the broad definition of "fishery" and the purpose of an SBRM, NMFS continues to believe that a Council, when developing an SBRM, may take into consideration different fishing activities and operations. For example, if there is fishing for a stock using trawl nets and gill nets, a Council may determine that different data collection, recording, and reporting procedures are appropriate for the two gear types. In such case, the FMP must identify what the established, consistent procedures are for both gear types. *See also* section I. C.

Comment 10: One commenter noted that in the Greater Atlantic Region, the current SBRM is designed by "fishing modes," which, in some cases, may not meet the statute's definition of a "fishery." The commenter recommended that it be made clear that this approach meets the requirements of the statute.

Response: NMFS is not making revisions to the final rule in response to this comment. NMFS approved the SBRM Omnibus Amendment for New England and Mid-Atlantic fisheries in June 2015, after reviewing the amendment for consistency with the MSA and other applicable law. Moreover, the SBRM Omnibus Amendment is currently the subject of litigation.

Comment 11: NMFS received comments that the lack of standardization in the proposed rule conflicts with the requirements of National Standard 3 (NS3).

Response: This rule is consistent with NS3, which requires, to the extent practicable, an individual stock of fish shall be managed as a unit throughout its range, and interrelated stocks of fish shall be managed as a unit or in close coordination. 16 U.S.C. 1851(a)(3). The

NS3 guidelines provide guidance for interpreting a “management unit” in the context of a “fishery.” See 50 CFR 600.320(d) (defining management unit as “a fishery or that portion of a fishery identified in an FMP as relevant to the FMP’s management objectives”) and (d)(1) (explaining that “choice of a management unit depends on the focus of the FMP’s objectives, and may be organized around biological, geographic, economic, technical, social, or ecological perspectives”). As explained in response to comment 8, this final rule defines standardized reporting methodology with regard to a “fishery.” Thus, NMFS does not see any conflict between the two provisions. To the extent there is any conflict, NMFS notes that NS3 contains the qualifier, “to the extent practicable.”

Comment 12: One commenter recommended establishing minimum standards for federal bycatch reporting and offered to work with NMFS to define these standards and identify what can be done to help those Councils whose fisheries do not meet the minimum standards.

Response: This final rule establishes minimum standards for the collection, recording, and reporting of bycatch data under MSA section 303(a)(11). NMFS looks forward to working with all Councils as they review their FMPs under this final rule.

Purpose of a Standardized Reporting Methodology

Comment 13: Many commenters stated that the proposed rule’s § 600.1605(a) (81 FR 9413, February 25, 2016) is flawed because it defines standardized reporting methodology only with regard to collection, recording, and reporting of bycatch data, and not the assessment or analysis of that data. Several commenters asserted that this approach is contrary to the plain language of the MSA and Congressional intent, and that courts have found that bycatch assessment is a required component of SBRM.

Response: NMFS disagrees that an assessment methodology is a required part of SBRM, but agrees that an SBRM needs to meet its intended purpose, which includes collecting data that can be used to assess the amount and type of bycatch in a fishery. The proposed rule acknowledged this nexus between the SBRM and the assessment of bycatch. To reinforce this link, NMFS has added to § 600.1600 explanatory language from the proposed rule preamble stating that the purpose of an SBRM is to collect, record, and report bycatch data in a fishery that, in conjunction with other relevant sources

of information, are used to assess the amount and type of bycatch occurring in a fishery and to inform the development of conservation and management measures that, to the extent practicable, minimize bycatch and bycatch mortality. In addition, NMFS has added a new paragraph (iv) to § 600.1610(a)(2) that requires a Council to address how the data resulting from an SBRM are used to assess the amount and type of bycatch in the fishery, and requires the Council to consult with its SSC and/or regional NMFS science centers on SBRM design considerations (e.g., data elements, sampling designs, sample sizes, and reporting frequency). NMFS believes this approach is consistent with the plain language of section 303(a)(11) of the MSA, which requires that an FMP establish a standardized reporting methodology to assess the amount and type of bycatch occurring in the fishery, and include conservation and management measures that minimize bycatch and bycatch mortality to the extent practicable. 16 U.S.C.

1853(a)(11). Section 303(a)(11) requires a reporting methodology, not an *assessment* methodology. Other section 303(a) provisions explicitly require that assessments be included in an FMP, but this is not the case for section 303(a)(11). See e.g., 16 U.S.C. 1853(a)(3) (requiring FMP to assess and specify the present and probable future condition of, and the maximum sustainable yield and optimum yield from, the fishery), and 16 U.S.C. 1853(a)(4) (requiring that FMPs assess and specify . . . the capacity and extent to which fishing vessels of the United States, on an annual basis, will harvest the optimum yield . . .). NMFS disagrees that its interpretation is contrary to Congressional intent. In support of their comments, commenters cited Senate Report 104–276, which states that the Sustainable Fisheries Act (S. 39) “would mandate the assessment of bycatch level in each fishery” (S. Rep. No. 104–276, at 99 (1996)). This report discussed a version of a Senate bill that was reported out of committee on May 23, 1996, which would have required that FMPs “assess the amount and type of bycatch occurring in the fishery.” That text was not enacted.

NMFS recognizes that some district courts have described the SBRM requirement as a bycatch assessment methodology or have asserted that section 303(a)(11) requires the assessment of bycatch in the fishery. See, e.g., *Oceana v. Locke*, 831 F.Supp.2d 95 (D.D.C. 2011); *Pac. Marine Conservation Council v. Evans*, 200 F. Supp.2d 1194 (N.D. Cal. 2002). NMFS

considered this case law in developing the proposed rule. After taking public comment into consideration, and reconsidering relevant case law, NMFS continues to believe that the approach taken in this final rule is appropriate and consistent with the MSA, for the reasons explained above. To the extent that courts have described the SBRM provision as an “assessment methodology,” NMFS notes that the cases did not engage in a comprehensive review of the statutory construction of the SBRM provision. Reading section 303(a)(11) in context with other provisions of the MSA, NMFS believes that the final rule’s definition of “standardized reporting methodology,” which does not include assessment methods, is consistent with the MSA.

Comment 14: Several commenters asserted that data collection and assessment are inextricably linked. Where, how, how much, and what type of data is collected determines how those data may be analyzed and used to come up with bycatch estimates. If the design of an SBRM is disconnected from the needs of the bycatch assessment process, there will be a waste of resources and effort, and scientists and managers will not have reliable data they need to get an accurate accounting of bycatch, reduce uncertainty in the assessment of species, and better manage the fishery to minimize bycatch. Other commenters agreed that fishery managers must consider data methodologies in tandem with assessment methodologies to make sure that data will actually be usable to “assess the amount and type of bycatch occurring in a fishery.”

Response: NMFS affirms that an SBRM must meet its statutory purpose, which includes collecting data that can be used to assess the amount and type of bycatch occurring in a fishery. The final rule does not delink data collection and assessment. Rather, as explained in response to comment 13, NMFS has revised the final rule to reinforce this nexus.

Estimating or assessing bycatch often requires a variety of highly technical data that can vary based on fishery, region of the country, and type of bycatch involved. Relevant data may come from observer program databases, logbooks, commercial landings databases, the NMFS Marine Recreational Information Program database, or other sources. As explained in the preamble of the proposed rule (81 FR 9413, February 25, 2016), a variety of different models or approaches may be used to synthesize these data to assess, evaluate, or estimate bycatch. Given that the assessment/estimating of

bycatch is a scientific matter, and science is a dynamic process with new findings constantly advancing the state of knowledge (see National Standard 2 guidelines, 50 CFR 600.315(a)(5)), NMFS does not believe that an FMP—which is a management and policy document that can take a long time to amend—must specify the approaches and methods that scientists must use to make such assessments or estimations. If a Council wants to include such methods in its SBRM, the Council may do so, but is not required to.

Uncertainty in data is a reality of fisheries management. See NS9 guidelines, 50 CFR 600.350(d)(2) (stating that due to limitations in available information, fishery managers “may not be able to generate precise estimates of bycatch and bycatch mortality of other effects” for management alternatives). NMFS’ National Standard 2 guidelines provide that mandatory measures not be delayed due to incomplete data, but management decisions should recognize the risks associated with the sources of uncertainty and gaps in the scientific information. *Id.* § 600.315(a)(2), (a)(6)(v). Consistent with these guidelines, and in response to comments, NMFS has revised the proposed rule regulatory text by adding language to § 600.1610(a)(2) in a new paragraph (iii) to require a Council to address uncertainty and design an SBRM so that uncertainty associated with the resulting bycatch data reported to the Secretary can be described, quantitatively or qualitatively. NMFS clarifies in that subsection that Councils should seek to minimize uncertainty in the resulting data, recognizing that different degrees of data uncertainty may be appropriate for different fisheries. See comment and response 31, *infra*, discussing data quality issues.

Comment 15: Several commenters asserted that NMFS must not step away from prior guidance in *Evaluating Bycatch* that “the combination of data collection and analyses that is used to estimate bycatch in a fishery constitutes the SBRM for that fishery.”

Response: NMFS acknowledged in the notice of proposed rulemaking that Appendix 5 of *Evaluating Bycatch* describes SBRM as the combination of data collection and analyses that is used to estimate bycatch in a fishery. However, as previously noted, *Evaluating Bycatch* is a technical memorandum; neither the memorandum nor its appendices established binding policy or agency interpretation of MSA section 303(a)(11). NMFS is issuing this rule to set forth its interpretation of section

303(a)(11). In developing this rule, NMFS undertook a comprehensive evaluation of section 303(a)(11), including the language of the provision and its context in the overall statutory scheme for fisheries management established by Congress in the MSA. See “Purpose of an SBRM” above, responses to comments 13 through 17, and “Activities Associated with an SBRM” in the proposed rule (discussing distinction between data collection/reporting and assessment) (81 FR 9413, February 25, 2016). NMFS believes that it is important to be clear about the key policy choices and objectives associated with establishing a reporting methodology, and not confuse those choices with statistical and technical approaches for estimating bycatch that are inherently scientific and data dependent, or with the policy choices associated with developing measures to minimize bycatch or bycatch mortality. After careful analysis and consideration of public comments, NMFS has decided not to retain the approach from *Evaluating Bycatch*.

Comment 16: One commenter states that, assuming the agency’s proposed rule for SBRM was in place, Councils and scientists would now have no guidance for how to actually assess bycatch. There is no guidance provided, and none promised, on how to model the amount, type, and scope of bycatch with the (likely) piecemeal and uneven data provided by SBRMs.

Response: NMFS relies on expertise from six regional science centers to provide scientific information and analyses for fishery management. Providing guidance in this rule on how to assess bycatch is inappropriate and unnecessary given the dynamic nature of science and existing guidance and scientific processes. Notably, National Standard 2 (NS2), 16 U.S.C. 1851(a)(2), requires that conservation and management measures be based on the best scientific information available, and NMFS has provided guidance on NS2 at 50 CFR 600.315.

Best scientific information available includes, but is not limited to, models, data, analyses, and scientific assessments, and new scientific findings constantly advance the state of knowledge. *Id.* § 600.315(a)(4)–(5). As explained in the NS2 guidelines, scientific information is not conducted in a vacuum, but is subject to peer review, consistent with the guidelines and the Office of Management and Budget Final Information Quality Bulletin for Peer Review. *Id.* § 600.315(a)(6)(vii). Moreover, each Council has a Scientific and Statistical Committee that is responsible for

providing the Council with ongoing scientific advice. *Id.* § 600.315(c) and 16 U.S.C. 1852(g)(1).

Comment 17: One commenter supports the clarification that the SBRM consists of the data collection and reporting programs, and is distinct from the methods used to assess bycatch and the measures to minimize bycatch. The proposed rule preamble indicated that a Council may include other elements (such as the analytic approach used to assess bycatch), and the commenter suggested adding this point to the regulatory text.

Response: NMFS thanks the commenter for expressing support for its approach. However, NMFS does not believe that changes to the regulatory text are necessary. As explained in the proposed rule preamble (81 FR 9413, February 25, 2016), this rule describes the basic requirements of the SBRM provision of section 303(a)(11) of the MSA. A Council may, but is not required to, add other relevant information to its FMP beyond the basic requirements of this rule.

Comment 18: One commenter stated that the underlying purpose of an SBRM might affect its design, as data provided by these programs can be used a number of different ways, and the design needs to be appropriate for these uses. For example, the design of an SBRM may be very different if it is primarily used to support stock assessments rather than fishery management decisions. In the former case, an argument could be made that the responsible science center should have extensive input in its development. On the other hand, if intended primarily to address the requirements placed on managers to minimize bycatch to the extent practicable, the Council’s needs should have more weight. The proposed rule should suggest a clear discussion in the SBRM about how its design addresses the needs of scientists and managers.

Response: The rule requires that an FMP, or a fishery research plan authorized under 16 U.S.C. 1862, explain how an SBRM meets the purpose described in § 600.1600, based on an analysis of requirements in § 600.1610(a)(2). The purpose of SBRM is two-fold: Provide data that, in conjunction with other relevant sources of information, are used to assess the amount and type of bycatch occurring in a fishery and for informing the development of conservation and management measures to minimize bycatch. Given this purpose, § 600.1610(a)(2) requires a Council to address the characteristics of bycatch in the fishery, the feasibility of the SBRM, data uncertainty, and data use. NMFS

acknowledges in the final rule that different SBRMs may be appropriate for different fisheries due to the inherent variability among fisheries. Scientific input is an important aspect of developing an SBRM, thus § 600.1610(a)(2)(iv) requires a Council to consult with its SSC and/or regional NMFS science center on SBRM design considerations.

Comment 19: One commenter asserted that the SBRM rule should follow a precautionary, ecosystem-based approach that can be applied uniformly to all fisheries to count, cap and control bycatch.

Response: For the reasons explained in responses to comments 1, 2, 8 and other comments, this final rule takes a fishery-specific approach to establishing SBRMs. NMFS believes that this rule will ensure the standardized collection, recording, and reporting of bycatch data for each fishery. A uniform approach to count, cap, and control bycatch across all fisheries is not required under the MSA, and is not practical or cost effective, given the variability in fishery characteristics. *See* response to comment 8 for further explanation. NMFS believes that this rule is consistent with and complementary to the agency's policy for ecosystem-based fisheries management. NMFS strongly supports implementation of Ecosystem-Based Fisheries Management (EBFM) to better inform and enable decisions regarding trade-offs among and between fisheries (commercial, recreational, and subsistence), aquaculture, protected species, biodiversity, and habitats. Recognizing the interconnectedness of these ecosystem components will help maintain resilient and productive ecosystems (including human communities), even as they respond to climate, habitat, ecological, and other environmental changes. *See* <http://www.st.nmfs.noaa.gov/Assets/ecosystems/ebfm/Final-EBFM-Policy-PDS-Review-5.20.2016-final-for-PDS.pdf>. This rule is consistent with the EBFM policy statement because it provides for a national approach to establishing and reviewing SBRMs and will improve NMFS' understanding of the impacts of a fishery on non-target stocks. Such information will help NMFS and the Councils consider the ecosystem-level trade-offs that are a key component of EBFM.

Comment 20: One commenter stated that in order for data to be "useful" (*see* proposed § 600.1610(a)(1)(i) at 81 FR 9413, February 25, 2016), clear criteria must be set so that standardized bycatch data can be fed into the calculation of annual catch limits (ACL) and fully considered in the implementation of

accountability measures (AM). Bycatch must be accurately assessed because it counts against a stock's catch limit. Bycatch must be monitored to comply with both the SBRM provision in MSA section 303(a)(11) and ACL/AM requirements in MSA section 303(a)(15).

Response: NMFS has deleted the term "useful" and revised the final rule to require that Councils address data use and data uncertainty when establishing or reviewing an SBRM. *See e.g.*, responses to comments 13 and 31 through 33. Data resulting from SBRMs may be used to inform management decisions beyond bycatch-related ones, and NS2 provides the standard for data used to inform such decisions: Conservation and management measures shall be based on the "best scientific information available." 16 U.S.C. 1851(a)(2). For the reasons explained in responses to comments 31 through 33, NMFS is not establishing national standards for accuracy of data or estimates in this final rule.

NMFS notes that SBRMs (16 U.S.C. 1853(a)(11)) and ACLs/AMs (16 U.S.C. 1853(a)(15)) are separate statutory requirements, which should not be conflated. *See Oceana v. Locke*, 831 F.Supp.2d 95 (D.D.C. 2011). Detailed guidance on establishing ACL/AM mechanisms is provided in the National Standard 1 (NS1) guidelines (50 CFR 600.310). To the extent that data from an SBRM are used in specifying ACLs, this final rule complements the NS1 guidelines. The NS1 guidelines state that the "acceptable biological catch" accounts for scientific uncertainty in the estimate of the overfishing limit for a stock or stock complex. 50 CFR 600.310(f)(2)(ii). Section 600.1610(a)(2)(iii) also addresses uncertainty, requiring that an SBRM be designed so that uncertainty associated with the resulting data can be described quantitatively or qualitatively. This is consistent with the NS2 guidelines (50 CFR 600.315), which provide guidance on uncertainty and issues related to use of the best scientific information available. Moreover, the NS1 guidelines refer to mortality of fish that are discarded (50 CFR 600.310(f)(2)(i)), and § 600.1610(a)(2)(i) of this final rule requires that, when developing an SBRM, a Council must address, among other things, "the importance of bycatch in estimating the fishing mortality of fish stocks."

Types of Data Collection, Recording, and Reporting Procedures

Comment 21: One commenter recommended eliminating the "self-reported mechanisms" option provided for in the proposed rule's § 600.1610(a)

(81 FR 9413, February 25, 2016) to help eliminate bias in data collection.

Response: NMFS does not agree with this comment; self-reported mechanisms are important to include as a potential reporting procedure because they are cost effective, feasible, and already available and appropriate for use in various fisheries to report bycatch data. Self-reported mechanisms (such as logbooks that include bycatch reporting) usually are required of all fishery participants, and therefore represent a near-census of the fishery. The costs of logbook programs are typically low, and, concerns regarding safety are limited to concerns that already exist with fishing operations, which are substantial for fishermen but basically nonexistent for those processing logbooks. However, NMFS recognizes that an SBRM based solely on logbooks will not be appropriate for all fisheries. That is why the rule requires Councils to undertake a fishery-specific analysis of SBRMs. Further, the rule requires that an SBRM be designed so that the uncertainty associated with the data resulting from the SBRM can be described. Management decisions should recognize the risks associated with that uncertainty. *See* National Standard 2 guidelines, 50 CFR 600.315.

Comment 22: Many commenters recommended reporting bycatch data and estimates in a manner that is useful for stakeholders, managers, and scientists.

Response: NMFS agrees with this comment. The final rule states that the purpose of an SBRM is to collect, record, and report bycatch data that, in conjunction with other relevant sources of information, can be used to assess bycatch and inform the development of conservation and management measures. Any SBRM established by a Council must achieve this purpose, thereby ensuring that bycatch data resulting from an SBRM will be useful for stakeholders, managers, and scientists.

Comment 23: Several commenters recommended requiring observer programs and/or electronic monitoring to promote the collection of accurate data and mitigate against data collection bias. One commenter stated other agency documents have recognized the benefits of observers for quantifying and estimating bycatch. However, the proposed rule does not require trained observers.

Response: NMFS disagrees that the rule should require the implementation of observer or electronic monitoring programs. Observer and electronic monitoring programs are not the only ways to collect, record, and report

bycatch, and the MSA does not require their inclusion in every SBRM. *See* 16 U.S.C. 1853(a)(11), (b)(8). NMFS recognizes that observer programs are used in many fisheries for collecting bycatch data. However, observer programs are costly and logistically challenging, and such programs may not be needed in all fisheries. Requiring every SBRM to include an observer program would not be an efficient use of resources. Further, it is NMFS' policy to encourage the consideration of electronic technologies to complement and/or improve existing fishery-dependent data collection programs to achieve the most cost-effective and sustainable approach that ensures alignment of management goals, data needs, funding sources and regulations. *See* NMFS Policy Directive 30–133, Policy on Electronic Technologies and Fishery-Dependent Data Collection (May 3, 2013). However, the adoption of new technologies raises numerous fishery-specific technical, legal, and policy issues, and, as with observer programs, electronic monitoring programs may not be needed or feasible in a particular fishery. Recognizing the diversity of fisheries across the country, this rule requires Councils to undertake a fishery-specific evaluation to determine the SBRM appropriate to a fishery, while still achieving the purpose of an SBRM as described in § 600.1600.

Comment 24: A commenter requested that intercept surveys be explicitly mentioned in § 600.1610(a) as an example of a self-reported mechanism.

Response: The types of self-reported mechanisms identified in § 600.1610(a)(1) are examples; this list is not exhaustive or limiting. NMFS agrees that intercept surveys are a type of self-reported mechanism, along with others, that could be included in an SBRM.

Comment 25: A commenter requested written reports for the Councils (and the public) from NMFS each year that minimally report by species and sector how many fish were landed and how many were released. To track Council progress towards minimizing bycatch, the commenter suggested a report in December on the first 6 months of the year and a final report in June showing landings and released fish by sector by species for the previous year. The commenter also requested that preliminary bycatch information by sector be provided at each Council meeting when landings information is presented.

Response: Catch and landings data and estimates/assessments are available through a variety of means, including, but not limited to, stock assessments

and other scientific documents and reports, SAFE reports, annual Fisheries of the United States reports, the National Bycatch Reports and national reports to international committees. Landings data can be accessed online using NMFS' species information system at <https://www.st.nmfs.noaa.gov/sisPortal/sisPortalMain.jsp>.

Comment 26: One commenter stated that locating specific data and metadata about bycatch is an ongoing issue because various data are reported in disparate reports. The commenter suggested including a provision to require the movement to housing of data in a single source (such as a data warehouse) to improve standardizing, documenting, and accessing data.

Response: Since 2011, NMFS has published a series of National Bycatch Reports and Updates that provide information on fishery- and species-specific bycatch estimates for major U.S. fisheries around the country. Some of the estimates contained in the National Bycatch Reports and Updates are also published in other NMFS documents such as its marine mammal stock assessment reports. Additionally as stated in response to comment 6 and 25, NMFS has created a custom database that allows members of the public to query bycatch estimates that were published in the National Bycatch Report Updates. (Members of the public can access the database here: <http://www.st.nmfs.noaa.gov/observer-home/first-edition-update-1>). *See* responses to comments 8 and 9 for an explanation as to why section 303(a)(11) and this rule do not require data collection to be standardized at the national level.

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Comment 27: One commenter stated that the required factors for SBRMs (proposed § 600.1610(a)(2)(i), (ii) at 81 FR 9413, February 25, 2016) are minimal and lack specificity. Details of establishing and reviewing SBRMs are left to Councils, and NMFS has no enforcement mechanism to ensure SBRMs are established and no option to take over if a Council fails to establish an SBRM. NMFS should revise the rule to make SBRMs mandatory. In addition, the rule should prescribe and detail each aspect of bycatch data collection and assessment to allow uniformity of information that can be aggregated and compared, ideally not only nationally but also internationally.

Response: The requirement to establish an SBRM is mandatory under MSA section 303(a)(11). Section 600.1600 and the proposed rule preamble (81 FR 9413, February 25, 2016) explicitly state that this is an

MSA requirement. In response to public comments, NMFS has included in the final rule revisions that clarify the requirements (initially referred to as "factors" in the proposed rule) for establishing and reviewing an SBRM. Section 600.1610(a)(1) provides that an FMP, or a fishery research plan as authorized under 16 U.S.C. 1862, must explain how the methodology meets the purpose described in § 600.1600, based on an analysis of the requirements set forth in § 600.1610(a)(2): Characteristics of bycatch, feasibility, data uncertainty, and data use. NMFS disagrees that methodology needs to be standardized at a national or international level. *See* comments and responses 1, 2, 8, and 9. With regard to data assessment, this rule requires a Council to address data use and data uncertainty and to consult with its SSC and/or NMFS science centers. *See* comments and responses 16, and 31 through 33. NMFS does not believe more prescriptive text is needed regarding data collection and assessment.

Under the MSA, Councils are in the first instance responsible for developing FMPs and addressing mandatory FMP requirements, including SBRMs. NMFS has a seat on each Council. NMFS will use its regular procedures for approval of FMPs and FMP amendments to ensure that FMPs and their implementing regulations are consistent with the MSA and other applicable laws. NMFS notes that MSA section 304(c) specifically addresses when NMFS may prepare an FMP.

Comment 28: NMFS received comments stating that its proposed regulations regarding the contents of FMPs and the factors that a Council must consider in establishing or reviewing an SBRM are too prescriptive. One commenter recommended revising the regulatory text of § 600.1610 in several places to clearly reflect that the objective of this proposed rule is to provide guidance to the Councils on the implementation of SBRMs. The commenter recommended changes to the regulatory text to provide greater flexibility.

Response: As explained previously, the purpose of this rule is to set forth the basic requirements of MSA section 303(a)(11). *See* comments and responses 1 and 2 (explaining the effect and need for rule). NMFS does not believe the rule is overly prescriptive, as it takes a fishery-specific approach, and does not prescribe specific details on the methodology needed for each fishery.

Comment 29: A commenter stated that § 600.1610(a)(1) should be revised to allow Councils to include a more detailed description of the SBRM in

other documents than the FMP. For example, the North Pacific Fishery Management Council and NMFS use an Annual Deployment Plan (ADP) process to determine the scientific sampling plan and method for assigning observers to vessels and processing plants. This can change from year to year. Under proposed § 600.1610(a)(1) at 81 FR 9413, February 25, 2016, it appears that an FMP would need to include a specific reference to the ADP process (which it already does), or to provisions for a specific annual ADP, which would be outdated almost immediately upon approval of the FMP amendment. This is not necessary and is directly counter to the overall objective of this proposed rule, which is to provide the public with greater clarity about the provisions of an SBRM.

Response: Each FMP must identify the required procedure or procedures that constitute the SBRM for a fishery. See § 600.1610(a)(1). In addition, an FMP, or fishery research plan as authorized under 16 U.S.C. 1862, must explain how an SBRM meets the purpose described in § 600.1600, based on an analysis of four requirements under § 600.1610(a)(2). The rule provides that the FMP or fisheries research plan may reference analyses and information in other documents. NMFS has also revised § 600.1610(a)(1) to state that, in addition to any proposed implementing regulations, a Council should also provide in its FMP, or fishery research plan authorized under 16 U.S.C. 1862, guidance to NMFS on how to adjust implementation of an SBRM consistent with the FMP. In the North Pacific, the ADP referenced by the commenter is a component of the fishery research plan, thus NMFS and the Council may continue to use the ADP to determine annually the scientific sampling plan and method for assigning observers to vessels and processing plants, consistent with the fisheries research plan and FMP. See comment and response 48 for additional explanation.

Consideration of Quality and Use of Data

Comment 30: One commenter expressed support for the requirement for Councils to consider data quality.

Response: NMFS appreciates the support regarding the consideration of data quality. In the final rule, NMFS has elaborated on the concept of data quality by requiring Councils to address both the uncertainty of the data and the use of the data resulting from the SBRM. See comments and responses on “Purpose of a Standardized Reporting

Methodology” and comments and responses 31 through 36.

Comment 31: Several commenters asserted that the rule must incorporate standards for precision and accuracy, or should provide guidance that SBRMs produce statistically accurate, precise, and/or reliable estimates of bycatch. Another commenter stated that while the MSA does not specify a specific level of accuracy or precision, it does require that SBRMs produce data that are accurate and reliable enough to satisfy the statutory requirement to develop measures to minimize bycatch and bycatch mortality. Commenters cited several court decisions regarding SBRMs and accuracy or reliability of data. Some commenters also asserted that the proposed rule would result in data that is contrary to the agency’s guidelines for National Standard 2 (NS2).

Response: NMFS agrees that an SBRM must meet its statutory purpose. See response to comment 13 for further explanation. To that end, the final rule requires Councils to explain how a chosen SBRM meets its statutory purpose, based on an analysis of the characteristics of bycatch in the fishery, the feasibility of the SBRM, the uncertainty of the data associated with an SBRM, and the use of the data resulting from an SBRM. See comments and responses 32 through 36 for further discussion related to data use and uncertainty considerations.

In this final rule, however, NMFS is not establishing national standards for precision, accuracy, or reliability of bycatch estimates or data. NMFS clarifies in this rule that Councils should seek to minimize uncertainty in the resulting data, recognizing that different degrees of data uncertainty may be appropriate for different fisheries. However, the specific characteristics of each fishery and its bycatch vary widely from region to region and from fishery to fishery. NMFS believes that it is important for Councils to address the characteristics of bycatch in a particular fishery and also address data use, data uncertainty, and feasibility considerations in the context of that fishery. To ensure robust scientific advice in establishing or reviewing SBRMs, § 600.1610(a)(2)(iv) requires a Council to consult with its SSC and/or regional NMFS science centers on reporting methodology design considerations, such as data elements, sampling designs, sample sizes and reporting frequency, all of which contribute to the level of data quality.

The SBRM provision in section 303(a)(11) of the MSA does not specify

reliability, accuracy, precision, or other qualifiers regarding bycatch data or estimates. NMFS recognizes that some courts have addressed bycatch estimates or the quality of data in the context of particular FMPs or amendments. See, e.g., *NRDC v. Evans*, 168 F.Supp.2d 1149, 1154 (N.D. Cal. 2001) (finding that NMFS failed to address the SBRM requirement and its “duty to obtain accurate bycatch data”); and *Oceana v. Evans*, 384 F.Supp.2d 203, 234–235 (D.D.C. 2005) (finding that NMFS failed to analyze what type of program would “succeed in producing the statistically reliable estimates of bycatch needed to better manage the fishery” and to address an accuracy concern in a scientific study). However, these opinions were based on the specific FMPs before the courts, and did not engage in comprehensive analysis of the statutory construction of the SBRM provision. NMFS believes that the approach in the final rule is consistent with MSA section 303(a)(11) and will ensure that SBRMs achieve the statutory purpose for SBRMs (§ 600.1600), while allowing Councils to address the unique circumstances of particular fisheries.

NMFS disagrees that the rule would result in data that is contrary to the NS2 guidelines. NS2 requires that conservation and management measures be based on the best scientific information available. 16 U.S.C. 1851(a)(2). It does not require NMFS to produce statistically reliable data or data that achieves a particular level of precision for the bycatch estimates. In fact, the NS2 guidelines recognize that there may be data limitations in different fisheries. See 50 CFR 600.315(a)(3) (noting that “data-poor” fisheries may require use of simpler assessment methods and greater use of proxies for quantities that cannot be directly estimated). Consistent with the NS2 guidelines at § 600.315(a)(2) and § 600.315(a)(6)(v), and in response to comments, NMFS has revised § 600.1610(a)(2) by adding a new paragraph (iii) that requires a Council to address uncertainty and to design SBRMs so that uncertainty associated with the resulting bycatch data reported to the Secretary can be described quantitatively or qualitatively.

Comment 32: Many commenters stated that the SBRM rule will result in poor data and, as a result, managers will not be able to sustainably manage fisheries. Commenters asserted that an accurate accounting of bycatch in fisheries is critical to fulfilling the requirements of the MSA to account for all sources of mortality in fisheries management, prevent overfishing, rebuild overfished stocks, and minimize

the amount of bycatch and mortality of unavoidable bycatch.

Response: NMFS disagrees that the rule will adversely affect data collection and fishery management efforts. The rule reinforces that an SBRM must meet its statutory purpose and sets forth requirements for establishing and reviewing SBRMs. For example, the rule includes a requirement that Councils address the uncertainty of the data resulting from an SBRM and that Councils design an SBRM so that the uncertainty of the data can be described. The rule clarifies that Councils should seek to minimize uncertainty in the resulting data, recognizing that different degrees of data uncertainty may be appropriate for different fisheries. The rule also includes a requirement that Councils address how the data resulting from the SBRM are used and consult with their SSCs and/or the regional science centers on SBRM design considerations. NMFS believes that the rule's requirements, along with periodic review of SBRMs, will ensure that SBRMs produce bycatch data that, along with other sources of data, can be used to assess and estimate bycatch and inform the development of conservation and management measures.

The NS2 and NS9 guidelines acknowledge that all scientific data come with a level of uncertainty. *See* response to comment 31 (discussing 50 CFR 600.350(d)(2), § 600.315(a)(2), and § 600.315(a)(6)(v)). As the NS2 guidelines note, science is a dynamic process and new scientific findings constantly advance the state of knowledge. *Id.* § 600.315(a)(5) (stating that best scientific information is, therefore, not static and ideally entails developing and following a research plan). The key thing is to account for uncertainty when considering fishery management decisions. *See e.g.*, 50 CFR 600.315(a)(2) and § 600.315(a)(6)(v) (providing for acknowledgment of uncertainties in scientific information used to inform decision making); and § 600.310(f)(1)(vi) and § 600.310(f)(2)(i) (describing under NS1 guidelines sources of scientific uncertainty and requiring that acceptable biological catch control rule account for scientific uncertainty and the Council's risk policy). NMFS notes that the requirement to establish an SBRM (16 U.S.C. 1853(a)(11)) is a separate statutory requirement from annual catch limits and other overfishing provisions (16 U.S.C. 1853(a)(15) and 1851(a)(1)) and from rebuilding provisions (16 U.S.C. 1854(e)). These various provisions should not be conflated.

Comment 33: One commenter stated that without any guidance on the level

of accuracy and precision of the data, it is unclear to what extent the data will be "useful" in assessing bycatch to inform management decisions. The commenter stated that the rule itself does not need to specify what constitutes "useful," but it should recommend a clear process, like SSC consultation, that will define "useful." Another commenter stated that NMFS should clarify the language in § 600.1610(b) requiring consultation with a council's SSC, advisory panels, and the NOAA science centers to ensure that bycatch estimation can be appropriately considered with respect to establishing a reporting methodology. Another commenter stated that SBRMs should be designed based on the best scientific statistical and sampling methods available to collect and analyze that data.

Response: In response to comments, NMFS has deleted reference to "data that are useful" in the final rule. Instead, NMFS specifies that an SBRM must meet its statutory purpose set forth in § 600.1600, and requires under § 600.1610(a)(2)(iv) consultation with the SSC and NOAA science centers. Specifically, NMFS has revised the final rule to require in § 600.1610(a)(2)(iv) that a Council consult with its SSC and the NOAA science centers on methodology design considerations such as data elements, sampling designs, sample sizes, reporting frequency, and the scientific methods and techniques available to collect, record, and report bycatch data that could improve the quality of the bycatch estimates. Information provided through the consultation process will enable a Council to develop an SBRM that incorporates scientific input and that will provide data that can be used to assess the amount and type of bycatch occurring in the fishery.

Comment 34: Some commenters expressed support for *Evaluating Bycatch*, which recommended the use of at-sea observers and observational technologies, a statistically valid sampling design, a goal to achieve levels of precision of 20 to 30 percent coefficient of variation (CV), models for combining data to assess bycatch, and adherence to data collection and estimation standards. One commenter asserted that, without further study, NMFS cannot step away from the recommendations in *Evaluating Bycatch*. The commenter stated that the memorandum may represent the "best available science" and, if so, NMFS must rely upon it and incorporate it in this rule.

Response: NMFS disagrees that *Evaluating Bycatch* should be

incorporated into this rule: It was not developed as the agency's interpretation of MSA section 303(a)(11), and it conflates the establishment of a reporting methodology with methods to assess/estimate bycatch. However, NMFS closely reviewed *Evaluating Bycatch* when developing this rule and drew upon concepts and approaches from that report. For example, the report noted that the choice of which monitoring methods are used in a particular fishery is based on consideration of a range of factors, *e.g.*, quality of data, credibility, timeliness, cost, safety. *See Evaluating Bycatch* at 23. With regard to estimates of bycatch from observer data, the report provides CV recommendations, but lists numerous caveats for using precision goals in the context of bycatch reporting/monitoring programs. *See id.* at 103 (noting that there may be circumstances where meeting precision goals for bycatch estimates would not be an efficient use of public resources, funding and logistical constraints may prevent attainment of goals, etc.). NMFS also notes that this rule takes a fishery-specific approach and requires Councils to address bycatch characteristics, data quality, data use, and feasibility, which are considerations reflected in *Evaluating Bycatch*.

Evaluating Bycatch continues to be available as a resource; it contains information that may be helpful when developing SBRMs, such as discussion of regional bycatch and fisheries issues, the advantages and disadvantages of different reporting/monitoring measures, and precision goals for bycatch estimates. However, the report is from 2004, so it would be important for a Council to consider whether more updated information is available when establishing or reviewing an SBRM.

Comment 35: Adequate monitoring of bycatch of fish as well as other living marine resources should be required in the proposed rule. The 2005 report entitled, "How Much Observer Coverage is Enough to Adequately Estimate Bycatch?" should be reviewed carefully to assist the Fisheries Service in developing standardized criteria for bycatch monitoring.

Response: In developing this final rule, NMFS considered the Babcock and Pikitch report, "How Much Observer Coverage is Enough to Adequately Estimate Bycatch?" NMFS is very familiar with this report, as NMFS has addressed the report in past litigation over SBRMs. As explained in the response to comment 13, assessing and estimating bycatch is not included in the definition of an SBRM. However, the rule requires, among other things,

consideration of data uncertainty and data use in developing and reviewing SBRMs. The Babcock and Pikitch report is one source among many sources of information available to Councils and NMFS when developing and reviewing SBRMs.

NMFS notes that the report focuses on the use of observers for collecting, recording, and reporting bycatch data. The MSA provides that observers may be used, but are not required to be used, for data collection. *See* 16 U.S.C. 1853(b)(8) (providing for observers as a discretionary FMP measure). The report acknowledges that there is a range of observer coverages that may be more or less appropriate for a fishery. The report also notes that determining the appropriate level of sampling effort is an iterative process. This final rule similarly acknowledges that different SBRMs will be appropriate for different fisheries, and provides for scientific input into development of SBRMs and periodic review of SBRMs.

Comment 36: One commenter stated that NMFS should conduct scientific studies on accuracy/bias, precision, management uncertainty, and electronic monitoring advances to determine how to set standardized criteria for bycatch monitoring and reporting.

Response: NMFS strives to continually improve the science underlying its fishery management programs. Pursuant to 16 U.S.C. 1881c, NMFS prepares, in cooperation with the Councils and states, a strategic plan for fisheries research. The NMFS Office of Science and Technology's 2013 Strategic Plan identifies a variety of activities to improve data collection and data assessments for a variety of purposes, including bycatch analyses. *See* <https://www.st.nmfs.noaa.gov/Assets/Strategic-Plans/ST%20Strategic%20Science%20Plan%20%202013.pdf>. NMFS recently initiated a review and update of this plan. Furthermore, in February 2016, NMFS released a draft *National Bycatch Reduction Strategy* (draft Strategy). *See* http://www.nmfs.noaa.gov/sfa/fisheries_eco/bycatch/docs/national-bycatch-strategy-2-23-16-web.pdf. The first objective of the draft Strategy is to strengthen monitoring and data collection programs through cost-effective use of new and existing tools (e.g., observers, logbooks, and electronic technologies) to collect bycatch data that inform agency bycatch priorities. NMFS received multiple public comments on the draft Strategy and is now working to finalize it and develop action plans. Once the strategy is finalized, NMFS plans to develop regional and national action plans in coordination with

stakeholders to identify specific actions that reflect regionally specific bycatch priorities, including research and monitoring priorities. Another example of NMFS' commitment to continually improving our data collection programs is NMFS' Policy on electronic technologies and fishery-dependent data collection programs. *See* NMFS Policy Directive 30–133, Policy on Electronic Technologies and Fishery-Dependent Data Collection (<http://www.nmfs.noaa.gov/op/pds/documents/30/30-133.pdf>). This policy provides guidance on the adoption of electronic technology solutions in fishery dependent data collection programs. Electronic technologies include the use of vessel monitoring systems, electronic logbooks, video cameras for electronic monitoring, and other technologies.

To the extent the commenter is recommending studies to support development of national, uniform bycatch reporting requirements, NMFS disagrees with the recommendation, as this rule takes a fishery-specific approach to the SBRM requirement. *See* the responses to comments 8 through 12.

Consideration of Feasibility, Costs, and Funding

Comment 37: Several commenters stated that the SBRM provision of section 303(a)(11) does not say that an FMP must include SBRM if it is “feasible” or “practicable”; the statute requires FMPs to establish SBRM without any qualifying condition. Commenters assert that the provisions of the proposed rule relating to feasibility, including consideration of costs and funding, are contrary to the plain language of the statute. Commenters also cite *Oceana v. Locke*, 670 F. 3d 1238 (D.C. Cir. 2011), for the proposition that the MSA requires NMFS to establish SBRM without regard to any consideration of practicability (i.e., costs or funding). Commenters also argue that NMFS may not import a “practicable” standard from National Standard 7 (NS7), and may not use reducing costs as an excuse to implement weakened management measures that will not achieve the MSA's primary conservation requirements.

Response: NMFS agrees that the requirement to establish a standardized reporting methodology is mandatory for all FMPs. However, NMFS disagrees that the MSA precludes consideration of feasibility from cost, technical, and operational perspectives when establishing such a methodology. Beyond the fact that an SBRM must

meet its statutory purpose, section 303(a)(11) does not specify *any* considerations for establishing a standardized reporting methodology; therefore, NMFS has discretion to interpret the MSA and establish reasonable considerations and requirements. Data collection, reporting, and recording programs can be expensive, logistically challenging to design and implement, involve new and cutting-edge technologies, and necessitate the consideration of the safety of human life at sea. Therefore, it is reasonable and appropriate for a Council to analyze issues of feasibility when establishing or reviewing an SBRM and to ultimately choose a methodology that is in fact feasible (i.e., capable of being implemented) from cost, technical, and operational perspectives. *See* response to comment 38 (describing budget and funding challenges).

Contrary to commenters' assertion, *Oceana v. Locke*, 670 F. 3d 1238 (D.C. Cir. 2011), does not preclude consideration of costs. In that case, the court noted that the second clause of section 303(a)(11) (regarding bycatch minimization measures) includes the phrase “to the extent practicable,” but that phrase does not appear in the first clause that requires establishing SBRMs. *Oceana v. Locke* held that costs and funding are not an excuse to forego establishing SBRMs. Consistent with the opinion, NMFS has revised § 600.1610(a)(2)(ii) in this rule to state explicitly that feasibility concerns do not exempt an FMP from the requirement to establish SBRM. NMFS disagrees that the opinion prohibits *any* consideration of costs or funding.

Commenters assert that NMFS cannot consider NS7 (conservation and management measures shall, where practicable, minimize costs and avoid unnecessary duplication) in interpreting section 303(a)(11) because they are separate statutory provisions. MSA sections 301 (National Standards) and 303 (FMP Contents) are separate provisions, but NMFS disagrees that the agency may not consider them both in developing this rule. FMPs must comply with mandatory FMP requirements under section 303(a)—such as the SBRM provision—and also the National Standards under section 301. *See* 16 U.S.C. 1853(a) and 16 U.S.C. 1851(a). In addition, it is important to consider the SBRM provision in the context of the statute as a whole.

Commenters further argue that even if it is permissible to consider NS7, NS7 requires that costs be minimized “where practicable, not absolutely,” citing *Connecticut v. Daley*, 53 F.Supp.2d 147,

172–73 (D. Conn. 1999). This rule requires that an SBRM be feasible from cost and other perspectives, not that costs be minimized absolutely. Commenters also cite *N. Carolina Fisheries Ass'n, Inc. v. Gutierrez*, 518 F.Supp.2d 62, 91–92 (D.D.C. 2007), for the proposition that Congress intended that “a focus on the economic consequences of regulations not subordinate th[e] principal [conservation] goal of the MSA.” NMFS notes that the cited language did not address NS7, as commenters assert, but NS8. NS8 requires, in relevant part, that FMP measures “shall, consistent with the conservation requirements of this Act (including the prevention of overfishing and rebuilding of overfished stocks), take into account the importance of fishery resources to fishing communities” and “to the extent practicable, minimize adverse economic impacts on such communities” 16 U.S.C. 1851(a)(8). Whether an SBRM can be implemented from cost and other perspectives is different than an analysis of economic impacts on communities. Moreover, NS8 makes explicit reference to MSA conservation requirements, whereas NS7 does not. In any event, as explained above, this rule does not allow a Council to forego establishing an SBRM based on high costs or low funding.

Comment 38: NMFS received several comments on the requirement in the proposed rule that all SBRMs must be designed to be implemented within available funding. Some commenters supported the requirement, some asked for clarification, and some opposed the requirement. One commenter requested that NMFS clarify that if funds are not available from current funding sources, then there is no requirement to implement the SBRM. One commenter noted that future funding for monitoring programs is unknown, so it is not clear how a Council can be expected to address “feasibility” when designing an SBRM or how it can design an SBRM to be implemented within available funding. The commenter suggested a more thorough discussion of how a Council is supposed to design a program for an uncertain funding amount. Other commenters asserted that NMFS controls the availability for funding for SBRMs. These commenters stated that the proposed rule therefore would allow the agency to disapprove the establishment of an SBRM based on a self-imposed funding problem.

Response: SBRMs are mandated by statute, and NMFS has revised § 600.1610(a)(2)(ii) to state explicitly that feasibility concerns do not exempt an FMP from this statutory mandate. In

response to public comment, NMFS has deleted reference to designing an SBRM to be “implemented with available funding,” but has retained the requirement that an SBRM must be feasible from cost, technical, and operational perspectives. For example, although an increase in observer coverage levels in a certain fishery may reduce the uncertainty of the data resulting from the SBRM, such an increase may not be feasible from a cost or safety standpoint or may result in only an incremental improvement in data quality. Under this rule, Councils would evaluate whether such an increase is justified in light of the purpose of the methodology and feasibility and other requirements under § 600.1610(a)(2).

NMFS is charged with fulfilling a wide range of requirements under the MSA, MMPA, ESA, and other statutes. These mandates include, but are not limited to, ending overfishing and rebuilding fish stocks, protecting and recovering threatened and endangered species, reducing bycatch, enforcing laws and regulations, and combating illegal, unreported, and unregulated fishing internationally. Addressing all of these mandates and requirements is a challenging undertaking for NMFS, particularly in light of increasing legal mandates and budget constraints.

When Congress establishes a program or activity, it must decide how to finance it. Typically programs and activities are financed by appropriating funds from the U.S. Treasury. NMFS requests Congressional appropriations through the President’s budget request to support statutory and regulatory requirements. Through this annual appropriations process, funding is provided for NMFS’ many mandates. In addition to providing the necessary funds, a congressional appropriation establishes a maximum authorized program level, meaning that an agency cannot, absent specific statutory authorization, operate beyond the level that can be paid for by its appropriations. 72 Comp. Gen. 164, 165 (1993). In light of these considerations, and given that procedures to collect, report, and record bycatch data can be extremely costly, NMFS believes that it is important to require that SBRMs be feasible from cost as well as other perspectives.

NMFS acknowledges that Congressional appropriations may change over time, and appropriated funds may, consistent with federal appropriations law, be allocated to implement various statutory mandates and to respond to changes in conditions and priorities across the country.

However, even though it may not be possible to anticipate future funding levels for procedures to collect, record, and report bycatch with complete certainty, the Councils would not be developing SBRMs in a vacuum. NMFS has a seat on each Council, and meets regularly with the Council Coordination Committee. The Councils and NMFS are able to consider the trends in costs and in appropriations levels in recent years. For example, NMFS notes that funding for observer programs has been relatively stable over the past two years, with approximately \$43.7 million appropriated by Congress for observer programs in FY 2015 and FY 2016.

Comment 39: One commenter stated that SBRMs should be functional at a variety of funding levels. If funding is insufficient for monitoring a particular management regime, then the regime should be made more precautionary (e.g., bigger buffers), rather than foregoing SBRMs or moving forward with inadequate funding. The commenter states that ACLs, AMs, and SBRMs are all key, interconnected components of a sustainable fishery. If the FMP design is demanding, then the SBRM must be too. If there is insufficient funding, the FMP design and the SBRM both need to be scaled back. NMFS should give guidance about how to revise FMP components to balance the level of an SBRM that is feasible.

Response: NMFS agrees that an SBRM should be functional at varying funding levels. Section 600.1610(a)(2)(ii) explicitly acknowledges that funding may vary from year to year, and requires a Council to address how implementation of the methodology may be adjusted while continuing to meet the purpose described under § 600.1600. NMFS believes this consideration is important, given the potential variability in funding levels, the desire for timely and efficient SBRM implementation, and the fact that FMP amendments can take a long time to develop and implement. This consideration is particularly important when developing SBRMs that have data collection procedures that may be more susceptible to changes in funding (e.g., observer programs). NMFS notes that the SBRM provision under MSA section 303(a)(11) is not couched in terms of an annual requirement as is the case with ACLs. Even if a funding shortfall in a particular year affects the implementation of an SBRM that does not necessarily mean that the SBRM is failing to meet its purpose or that it needs to be amended.

Data resulting from SBRMs may be used to inform management decisions

beyond bycatch-related ones, but, as explained in response to comment 20, SBRMs and ACLs/AMs are separate statutory requirements that should not be conflated. NMFS does not believe that further guidance is needed regarding buffers, given existing guidance related to scientific and other uncertainties. The NS1 guidelines, 50 CFR 600.310, describe how the Councils should consider uncertainty when specifying ACLs and AMs. The NS2 guidelines, 50 CFR 600.315, provide guidance on using data that is uncertain in management decisions. In addition, the NS6 guidelines, 50 CFR 600.335, address how to take into account variations in fisheries (e.g., biological and economic uncertainties and uncertainties from changes in fishing practices).

Comment 40: One commenter requested that NMFS clarify in the proposed rule's § 600.1610(a)(2)(ii) (81 FR 9413, February 25, 2016) who would be doing the assessment that a methodology is feasible from cost, technical, and operational perspectives.

Response: NMFS has clarified § 600.1610(a)(2) to state that the Councils are required to address feasibility and comply with other requirements of the section. Section 600.1605(b) defines "Council" in the same manner as in 50 CFR 600.305. Therefore, the word "Council" includes the Regional Fishery Management Councils and the Secretary of Commerce, as applicable. Per MSA section 304(a), NMFS approves, disapproves, or partially approves Council-developed FMPs and FMP amendments for consistency with the MSA and other applicable law. 16 U.S.C. 1854(a).

Comment 41: Two comments were related to the costs, including industry costs, associated with observer programs and electronic monitoring. One commenter stated that industry should not be required to pay for observer coverage. One commenter asked about the costs to monitor groundfish, and noted that there are some legal questions to address before electronic monitoring can be implemented.

Response: NMFS recognizes that electronic monitoring and observer programs can be costly and logistically challenging to implement. However, a discussion of the particular costs and challenges associated with monitoring programs in specific fisheries is beyond the scope of this rule.

Comment 42: One commenter stated that NMFS cannot justify to Congress the need for more funds related to bycatch data collection if the agency prevents Councils from designing good

SBRMS, and, therefore, from assessing data needs and identifying capacity shortfalls.

Response: With respect to the quality and use of the data resulting from SBRMs, please see responses to comments 30 through 36. With respect to budget requests, NMFS works with the Department of Commerce and the Office of Management and Budget (OMB) to request Congressional appropriations through the President's budget to Congress each fiscal year in accordance with relevant laws, regulations, and administrative procedures. NMFS uses information about bycatch research and data collection needs contained in a variety of reports and strategic planning processes to inform this budget planning and formulation process (e.g., the strategic plan for fisheries research required by 16 U.S.C. 1881c of the MSA, National Observer Program strategic reviews and annual reports, SAFE reports, and numerous other documents). However, the development of NMFS-related funding requests contained in the President's yearly budget submission to Congress is beyond the scope of this rule.

Characteristics of Bycatch and Other Considerations

Comment 43: Several commenters expressed support for the requirement for Councils to consider characteristics of bycatch in the fishery. One commenter noted that this requirement is more useful and important when establishing conservation and management measures. The commenter recommends that this sentence be moved to 50 CFR 600.1610(a)(2)(ii) as additional factors that the Councils may consider. Another commenter asserted that SBRMs should be designed to provide more certain bycatch data in fisheries where discard mortality is identified as an important source of fishing mortality.

Response: This rule requires Councils to undertake a fishery-specific analysis to establish an SBRM that meets the purpose described in § 600.1600 of this final rule. To perform such an analysis, NMFS believes that the specific characteristics of bycatch in that fishery need to be addressed. See response to comment 9 and section I.C. (discussing consideration of different fishing activities and operations).

NMFS agrees that considering the importance of bycatch as part of fishing mortality is an important consideration when establishing or reviewing SBRMs. More specifically, § 600.1610(a)(2)(i) provides that a Council must address information about the characteristics of

bycatch in the fishery when available, including, but not limited to, the amount of bycatch occurring in the fishery, the importance of bycatch in estimating the fishing mortality of fish stocks, and the effect of bycatch on ecosystems. NMFS believes that a fishery-specific evaluation of bycatch as stated above, in conjunction with considerations of feasibility, data use, and data uncertainty will result in an SBRM that meets the purpose as described in § 600.1600.

Comment 44: Some commenters stated that NMFS does not have discretion to decide not to require or establish an adequate SBRM, due to financial constraints or any other factors, such as the "overall magnitude and/or economic impact of the fishery."

Response: As explained in response to comment 38, section 303(a)(11) of the MSA requires all FMPs to establish an SBRM, and NMFS has revised § 600.1610(a)(2)(ii) to state that feasibility concerns (which include costs and funding) do not exempt an FMP from this mandate. NMFS has removed the text about considering the overall magnitude and/or economic impact of the fishery from the final rule, because NMFS believes that it is not necessary given existing guidance for NS7 and National Standard 8.

Comment 45: One commenter suggested the incorporation of guidance to ensure the proper identification of bycatch species to reduce misidentification errors. The commenter also suggested including consideration of the status of bycatch species.

Response: Incorporating guidance for proper identification of bycatch species is beyond the scope of this rule. NMFS has created numerous species identification guides, some of which include information about the bycatch species' management status. For example, a NMFS shark identification guide for the recreational fishery of the U.S. Atlantic and Gulf of Mexico specifies which shark species are prohibited and must be released (see http://www.nmfs.noaa.gov/sfa/hms/species/sharks/rec_shark_id_placard.pdf). NMFS also has created a guide to help Alaska fishery observers identify coral species that may occur as bycatch (see http://www.afsc.noaa.gov/FMA/PDF_DOCS/Coral_Tutorial_2014.pdf). NMFS believes this guidance is more appropriately accomplished through these identification guides.

Comment 46: Several commenters commented on the proposed rule's § 600.1610(a)(2)(i) (81 FR 9413, February 25, 2016), which would require Councils to consider the conservation and management

objectives regarding bycatch in the fishery. One commenter asked whether this was intended to address something different than the bycatch provisions in MSA section 303(a). One commenter suggested clarifying that this does not establish a requirement that each FMP identify specific bycatch objectives beyond those required in section 303(a)(11).

Response: The intent of proposed § 600.1610(a)(2)(i) (81 FR 9413, February 25, 2016) was to provide for a fishery-specific analysis when establishing an SBRM. To clarify that this rule is not requiring Councils to identify specific bycatch objectives beyond those required by section 303(a)(11) and NS9, NMFS has removed reference to “conservation and management objectives regarding bycatch.” Further, NMFS believes that it is not necessary to state this as a requirement in § 600.1610(a)(2), because all SBRMs must meet the purpose described in § 600.1600, which includes reference to “inform[ing] the development of conservation and management measures that, to the extent practicable, minimize bycatch and bycatch mortality.”

Comment 47: One commenter stated that SBRMs can and should describe the methodology by which bycatch data will be incrementally improved with new efficiencies, techniques, and funding.

Response: NMFS disagrees with this comment as this rule, existing National Standard guidelines, and NMFS strategic plans already provide sufficient direction on improving bycatch data. This rule includes a provision for Councils to review SBRMs at least every 5 years, and in § 600.1610(a)(2)(iv), requires Councils to consider scientific methods and techniques available to collect, record and report bycatch data that could improve the quality of bycatch estimates. In addition, the NS 9 guidelines provide guidance on improving data collection methods, data sources, and applications of data for each fishery to determine the amount, type, disposition, and other characteristics of bycatch and bycatch mortality in each fishery for purposes of NS9 and MSA sections 303(a)(11) and 303(a)(12). 50 CFR 600.350(d)(1). NMFS notes that it also has ongoing initiatives to address bycatch and to strengthen monitoring programs. *See* response to comment 36 for further explanation of these initiatives.

Adaptable Implementation

Comment 48: NMFS received mixed comments on the adaptable

implementation provision (proposed § 600.1610(c) at 81 FR 9413, February 25, 2016). Some expressed support for it as it provides flexibility during implementation and others recommended changes to or elimination of the provision. One commenter indicated that the provision would support a Council's efforts to look at ways to increase and improve methodologies for data collection practices. One commenter stated that, before operational adjustments are made, managers should ensure that they can effectively collect and report data consistently across jurisdictions to inform the management of bycatch species. Another commenter stated that this provision frustrates congressional intent to have national-level standardization, and also allows for non-transparent processes to adjust SBRMs. The commenter asserted that changes to an SBRM must be made through an FMP amendment to safeguard public participation and ensure that impacts will be more fully considered. One commenter requested deleting § 600.1610(c), as it would severely limit a Council's ability to develop effective SBRMs and change SBRMs based on fishery characteristics in the future.

Response: Fisheries management occurs in a highly variable environment, and from year to year, there can be changes in available funding, equipment, methods for recording and transmitting data, fishing activity, and other changes. NMFS' intent in proposing § 600.1610(c) was to emphasize that, when developing an SBRM, it is important to consider implementation and operational issues that might arise. *See* 50 CFR 600.335(b) (noting in National Standard 6 guidelines that a regime “must be flexible enough to allow timely response to resource, industry, and other national and regional needs”). NMFS, Councils, and stakeholders all have an interest in smooth implementation of SBRMs, and FMPs can take a long time to amend. In response to public comments and to clarify its intent, NMFS has deleted proposed § 600.1610(c) at 81 FR 9413, February 25, 2016. Instead, § 600.1610(a)(1) clarifies that in addition to proposing regulations necessary to implement the SBRM, a Council should also provide in its FMP, or in a fishery research plan authorized under 16 U.S.C. 1862, guidance to NMFS on how to adjust implementation of an SBRM, consistent with the FMP. *See* National Standard 6 guidelines, 50 CFR 600.335. This text refers to adjustments “consistent with the FMP.” To the

extent that changes would be needed to an SBRM beyond what the FMP established, an FMP amendment would be needed. NMFS believes that this approach will encourage transparency. The rule requires a Council to address implementation and operational issues up-front during the development of an SBRM and encourages a Council to provide guidance to NMFS on SBRM implementation.

Consistent with the SBRM established in an FMP, a Council could provide for adjustments in how an SBRM is implemented through regulations (*see, e.g.,* SBRM Omnibus Amendment (80 FR 37182, June 30, 2015)). Councils may also provide other guidance to NMFS via non-regulatory mechanisms. As an example, the North Pacific Groundfish FMP uses an Annual Deployment Plan (ADP) to address practical and operational implementation issues. *See* comment and response 29 for further explanation of the ADP. When a Council is considering whether to provide for regulations and/or other guidance to implement an SBRM, some questions that may be helpful include: What are the implementation and operational issues that might arise (*see e.g.,* variations and uncertainties described in NS6 guidelines); what type of adjustments or guidance might be helpful to address these issues; would certain adjustments result in an SBRM not meeting its purpose (*see* § 600.1600); and what would happen if there is an unexpected funding shortfall. NMFS disagrees that SBRMs need to be standardized at a national level in order to have data to inform management decisions. *See* comments and responses 13 (explaining purpose of SBRMs and consideration of data use and quality) and 8 (explaining interpretation of “standardized”).

Comment 49: One commenter stated that allowing adjustments to the bycatch methodology to be based on factors such as funding, management contingencies, or scientific priorities could be interpreted to authorize the type of budgetary exemption from SBRM requirements that has been found contrary to the MSA, citing *Oceana v. Locke*, 670 F.3d 1238 (D.C. Cir. 2011).

Response: As explained in responses to comments 37 and 38, MSA section 303(a)(11) requires that all FMPs establish an SBRM, and NMFS has clarified in § 600.1610(a)(2)(ii) that “feasibility concerns do not exempt an FMP from the requirement to establish a standardized reporting methodology.” NMFS disagrees that *Oceana v. Locke* precludes a Council from considering implementation and operational issues and trying to plan for them. *See*

response to comment 37 for further discussion of the court case. Section 600.1610(a)(1) provides that a Council must explain how an SBRM, which may include an implementation adjustment mechanism, meets the statutory purpose of an SBRM (*see* § 600.1600), based on an analysis of the requirements in § 600.1610(a)(2) (characteristics of bycatch, feasibility, data quality and data use).

Review of FMPs

Comment 50: Some commenters stated that the Sustainable Fisheries Act of 1996 (SFA) required the agency to establish SBRM regulations by 1998, thus the 5 year review period would unreasonably delay SBRM implementation to 21 years after it was required by Congress.

Response: NMFS disagrees with these comments. Section 108(a) of the SFA added several provisions to section 303(a) of the MSA, including section 303(a)(11). (*See* Pub. L. 104–297, 110 Stat. 3559, sec. 108 (Oct. 11, 1996)). Section 108(b) of the SFA required that each Council submit to the Secretary of Commerce amendments to each FMP to comply with the amendments made in section 108(a) not later than 24 months after the date of enactment. *Id.* The Act did not require NMFS to promulgate a national SBRM rulemaking. As explained in the preamble to the proposed rule, NMFS is promulgating this rule pursuant to section 305(d) of the MSA (16 U.S.C. 1855(d)) to clarify NMFS' interpretation of the SBRM provision and provide for periodic review of SBRMs.

Comment 51: NMFS received several comments on the 5-year timeline for reviewing FMPs for consistency with the rule. One commenter supported the timeline, but given concerns about workload for the Councils, recommended extending subsequent SBRM reviews to 10 years or on an as needed basis. Another commenter noted that if a Council is provided with updated estimates of bycatch at each Council meeting along with the estimates of recreational and commercial landings, the ability to monitor bycatch on an ongoing basis will also reduce the need for a comprehensive review from 5 to 10 years. Another commenter recommended that a review be conducted after 5 years of data are available, rather than 5 years after implementation.

Response: Data collection and reporting methods, conservation and management issues, and bycatch characteristics may change considerably in a 5-year timeframe. Therefore, NMFS

believes that review in 5 years (and not a longer period) is appropriate. NMFS notes that there are several other FMP review processes that are on 3 to 5 year review timeframes. These include catch share programs, essential fish habitat, scientific research and other reviews. From an efficiency and resource standpoint, Councils may want to consider conducting SBRM reviews in conjunction with other ongoing FMP reviews as much as possible. Further, this provision is consistent with the NS9 guidelines, which refer to the review and improvement of data collection methods, data sources, and applications. 50 CFR 600.350(d)(1).

Comment 52: One commenter urged NMFS to seriously consider the potential negative implications, including unnecessary workload, of the rule on regions which are already in compliance with MSA requirements. Section 600.1610(a)(1) should be modified so that it makes clear that the first step would be for the Councils to review their FMPs to determine if their FMPs provide a clear description of the SBRM, and only if the Council determines it does not, should additional modifications be made in either the FMP or through other reference documents. The provision requiring that all FMPs must be consistent with the rule within 5 years is not necessary if Councils have reviewed their FMPs and determined that their FMPs do not need to be modified.

Response: The proposed rule provided Councils with a 5-year time frame to review and, if necessary, amend their existing FMPs for consistency with the rule. NMFS continues to believe that there is a need for this review. However, the final rule clarifies that a Council does not need to amend an FMP if NMFS determines that it is consistent with this rule.

Other Comments

Comment 53: Some commenters requested that NMFS extend the comment period for the proposed rule an additional 60 days.

Response: NMFS believes that the 60-day comment period provided the public with a meaningful opportunity to comment on the proposed rule, and therefore, declined to extend this period. Considering the nature and scope of the proposed rule, NMFS believes that 60 days was an adequate timeframe for interested persons to understand the issues raised and submit to the agency written comments with information and arguments relevant to those issues. Furthermore, several Councils are actively working on SBRM-

related issues and would benefit from the guidance and interpretation that this rule would provide. If, as a result of reviewing their FMPs for consistency with the MSA and this rule, Councils amend their FMPs, the public will have another opportunity to comment on any specific actions proposed by a Council.

Comment 54: Given the critical nature of bycatch data collection, one commenter urged the agency to provide resources to improve collection, recording, and reporting of bycatch as soon as possible.

Response: NMFS has made SBRM data collection programs a priority. NMFS continually seeks to improve data collection, recording, and reporting through a variety of mechanisms. *See* response to Comment 47 for more information.

Comment 55: Commenters stated that the proposed rule would undermine the following agency and Council efforts to improve fisheries data, modernize data collection programs, and integrate ecosystem considerations into fisheries management: Ecosystem-Based Fishery Management Policy, National Bycatch Reduction Strategy, Action Plan for Fish Release Mortality Science, Regional Electronic Monitoring and Reporting Implementation Plans, and MRIP Implementation Plan. Commenters also asserted that the proposed rule would prevent the agency from implementing hard caps and performance objectives in the West Coast drift gillnet fishery and would facilitate the further collapse of the New England groundfish fishery.

Response: NMFS disagrees that this rule would negatively affect ongoing efforts to improve fisheries data, modernize data collection, and implement ecosystem based fisheries management. This rule interprets basic requirements of the SBRM provision and does not prescribe or otherwise change ongoing policy and science initiatives. Because the rule interprets the basic requirements for establishing SBRMs, NMFS also disagrees with the comment that suggests the rule would prevent the establishment of hard caps in the West Coast drift gillnet fishery or undermine the New England groundfish fishery. The commenter presumes that this rule will diminish the quality of bycatch data and thus the assessment of bycatch and the Council's ability to adopt management measures to address bycatch. NMFS addresses this concern in responses to comments regarding the "need and effect" and "distinction between data collection and assessment".

Comment 56: One commenter stated that bycatch is a significant issue in recreational and commercial fisheries in

the Southeast, citing red snapper and red grouper as examples. The commenter stated that sufficient SBRMs in the fishermen logbooks and observer coverage would provide much more certain data leading to a more robust assessment used for management.

Response: NMFS notes that an SBRM is a requirement of an FMP and that Councils do not establish SBRMs “in the fishermen logbooks and observer coverage.” To the extent that this commenter is recommending specific changes to the SBRMs in particular fisheries (e.g., red snapper and red grouper), this comment is beyond the scope of this rulemaking. The purpose of this rule is to describe the minimum requirements for establishing an SBRM. The specific SBRMs for each fishery are established through individual FMPs and the Council process as guided by the MSA and this rule. This rule requires that all FMPs be consistent with this rule within 5 years of the effective date of this rule. As individual FMPs are reviewed by the Councils, stakeholders will have additional opportunities to provide input on fishery and regional-specific issues associated with particular SBRMs.

Comment 57: One commenter stated that it is unclear if the Pacific Islands, the Southeast and Southwest have implemented SBRM. The Caribbean Fishery Management Council does not appear to have established SBRMs at all. For example, there is no mention of SBRM in FMPs for Queen Conch, Reef Fish, Spiny Lobster, or Corals and Reef Associated Plants and Invertebrates.

Response: All FMPs have established SBRMs consistent with the MSA and implement them through different mechanisms. NMFS acknowledges that the documentation and explanation in FMPs for SBRMs varies considerably. This rule, by clarifying the basic requirements for establishing SBRMs, will strengthen existing SBRMs and ensure greater transparency as Councils review and potentially update their FMPs for consistency with this rule.

Comment 58: NMFS received comments disagreeing with the agency’s decision to not prepare an environmental impact assessment (EIS) or environmental assessment (EA). The commenters stated that a categorical exclusion under the National Environmental Policy Act (NEPA) is not appropriate.

Response: NMFS believes a categorical exclusion is appropriate for this action. Under sections 5.05 and 6.03c.3(i) of NOAA’s Administrative Order (NAO) 216–6, as preserved by NAO 216–6A, “Compliance with the National Environmental Policy Act,

Executive Orders 12114, Environmental Effects Abroad of Major Federal Actions; 11988 and 13690, Floodplain Management; and 11990, Protection of Wetlands,” the following types of actions may be categorically excluded from the requirement to prepare an EA or EIS: “. . . policy directives, regulations and guidelines of an administrative, financial, legal, technical or procedural nature, or the environmental effects of which are too broad, speculative or conjectural to lend themselves to meaningful analysis and will be subject later to the NEPA process, either collectively or case-by-case . . .” In this instance, a categorical exclusion is appropriate for this action because NMFS cannot meaningfully analyze potential environmental, economic, and social impacts at this stage. This rule provides guidance on establishing and reviewing SBRMs. While the rule explains how the development, documentation, and review of SBRMs should be addressed, the rule does not mandate specific conservation or management measures for any fishery. There is considerable diversity in federally managed fisheries and FMPs, and the Councils and NMFS have discretion to develop different conservation and management alternatives consistent with the MSA and other law. It is not clear what Councils will or will not do in response to this rule. Thus, it is not possible to predict any concrete impacts on the human environment without the necessary intervening actions of the Councils (e.g., consideration of SBRMs for specific fisheries). Any analysis of potential impacts would be speculative at best.

None of the exceptions for Categorical Exclusions provided by section 5.05c of NAO 216–6 apply. While there is controversy concerning the SBRM rule, the controversy is primarily related to different views on how section 303(a)(11) of the MSA should be interpreted. The rule would not, in itself, have uncertain environmental impacts, unique or unknown risks, or result in cumulatively significant impacts on a fishery, protected species, or habitat, as it does not prescribe specific outcomes for FMPs. When a given Council or the Secretary prepares and submits a new FMP or FMP amendment or other regulatory action, at that time, biological, economic, and social impacts of the amendment/action would be subject to NEPA analysis.

Comment 59: NMFS received one comment stating that the agency should not proceed unless a Regulatory Impact Review as required by E.O. 12866 has been conducted and the public has an

opportunity to review and comment on that analysis. The commenter noted that the rule will require significant agency and Council resources.

Response: NMFS conducted a draft Regulatory Impact Review and determined the rule is not significant for the purposes of Executive Order 12866. Additionally, the Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that the proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. These conclusions were stated in the “Classification” section of the proposed rule proposed at 81 FR 9413, February 25, 2016. NMFS prepared a final Regulatory Impact Review before issuing this rule. That review analyzed the impact of this rule on the agency, the Councils, and small entities, and is summarized in the “Classification” section of this preamble.

III. Changes From Proposed Rule

In the first sentence of § 600.1600, “with respect to any fishery” was added after “fishery management plan” to reflect the text of section 303(a) of the MSA. The second sentence of § 600.1600 was revised in response to public comment to clarify the purpose of a standardized reporting methodology.

In § 600.1605(a), NMFS made minor changes to the definition of “standardized reporting methodology.” First, in response to public comment, NMFS removed “subset of a fishery” from the definition. Second, NMFS combined the first and second sentences of the proposed definition. Third, NMFS added a sentence to the end of the definition to clarify the link between an SBRM and the assessment of bycatch.

Section 600.1605(b) was revised to add reference to the MSA’s definitions of “bycatch” and “fishery” in 16 U.S.C. 1802. Other minor revisions were made to the citations in § 600.1605(b).

In § 600.1610(a)(1), the first sentence was revised to clarify the information that must be identified in an FMP. The first part of the second sentence of the paragraph was modified for clarity. Instead of “The description must state the required bycatch data collection, recording, and reporting procedures for each fishery, which may include . . .”, the second sentence of § 600.1610(a)(1) now begins: “The required procedures may include . . .”

In response to comments and to make clear that an SBRM must achieve its statutory purpose, the third sentence of § 600.1610(a)(1) now requires a Council

to explain “how an SBRM meets the purpose described in 50 CFR 600.1600, based on an analysis of the requirements under § 600.1610(a)(2),” in place of the proposed rule’s requirement that a Council explain “why the methodology is appropriate for the fishery.” The third sentence requires that this explanation be contained in an FMP or a fishery research plan authorized under 16 U.S.C. 1862, a North Pacific-specific provision of the MSA.

Consistent with current practices, § 600.1610(a)(1) states that Councils should work together and collaborate on standardized reporting methodologies for fisheries that operate across multiple jurisdictions, as appropriate.

Also in § 600.1610(a)(1), NMFS clarifies that in addition to proposing regulations necessary to implement the standardized reporting methodology, a Council should also provide in its FMP, or a fishery research plan authorized under 16 U.S.C. 1862, guidance to NMFS on how to adjust implementation of a standardized reporting methodology, consistent with the FMP. See National Standard 6 guidelines, 50 CFR 600.335. This text replaces § 600.1610(c) of the proposed rule, which described an adaptable implementation process for SBRMs. NMFS removed § 600.1610(c) and added the new sentence in § 600.1610(a)(1) in response to public comments expressing confusion over the process described in proposed rule’s § 600.1610(c) (81 FR 9413, February 25, 2016).

In § 600.1610(a)(2), NMFS clarified what a Council is required to address when establishing or reviewing an SBRM. Also in § 600.1610(a)(2), NMFS broke out the “required factors” and “additional factors” of the proposed rule’s paragraphs (a)(2)(i) and (a)(2)(ii) into four subparagraphs to improve the organization and clarity of the paragraph.

In § 600.1610(a)(2)(i), NMFS deleted the requirement that “[d]ata resulting from the methodology must be useful, in conjunction with other sources of data, in meeting the purpose described in § 600.1600 and fishery-specific bycatch objectives.” This requirement is no longer necessary because, as detailed above, § 600.1610(a)(1) requires that all SBRMs meet the purpose described in § 600.1600. NMFS also deleted the requirement that Councils “consider the conservation and management objectives regarding bycatch in the fishery” proposed in § 600.1610(a)(2) in response to public comment expressing confusion about this provision. NMFS believes that it is not necessary to state this as a requirement in § 600.1610(a)(2) because all SBRMs must meet the

purpose described in § 600.1600, which includes reference to “inform[ing] the development of conservation and management measures that, to the extent practicable, minimize bycatch and bycatch mortality.”

In § 600.1610(a)(2)(i), NMFS created a distinct subparagraph for the requirement that all Councils address information about the characteristics of bycatch in the fishery. The proposed rule required Councils to “consider information about the characteristics of bycatch in the fishery, when available, such as the amount of bycatch occurring in the fishery, the importance of bycatch in estimating the total mortality of fish stocks, and the importance of bycatch to related ecosystems.” In the final rule, NMFS changed “such as” to “including but not limited to” to clarify that Councils must address all three types of information, where such information is available. In the same sentence, NMFS replaced “total mortality” with “fishing mortality” because bycatch mortality is part of fishing mortality (*i.e.*, fish dying due to fishing activity) and not a component of natural mortality which is part of total mortality. For purposes of clarity, NMFS also changed “the importance of bycatch to related ecosystems” to “the effect of bycatch on ecosystems.” NMFS also added text in § 600.1610(a)(2)(i) to acknowledge that the amount and type of bycatch occurring in a fishery “may vary based on the operations of the fishery.”

In response to public comment, NMFS removed text from § 600.1610(a)(2)(ii) stating that “a Council may also consider the overall magnitude and/or economic impact of the fishery.” NMFS believes that this information is already addressed in NMFS’ National Standards 7 and 8 guidelines.

In § 600.1610(a)(2)(ii), NMFS created a distinct subparagraph regarding feasibility. NMFS added “The implementation of a standardized reporting” to the beginning of the sentence requiring that the “methodology must be feasible from cost, technical, and operational perspectives” for purposes of clarity. In response to public comment, NMFS deleted the requirement that a methodology “be designed to be implemented with available funding.” In place of this text, NMFS added a sentence to the end of § 600.1610(a)(2)(ii) that explains in recognition that costs and funding may vary from year to year, a Council must also address how implementation of the standardized reporting methodology may be adjusted while continuing to

meet the purpose described under § 600.1600.

In § 600.1610(a)(2)(iii), NMFS created a distinct subparagraph regarding data uncertainty. This subparagraph expands on the requirement in proposed § 600.1610(a)(2)(i) at 81 FR 9413, February 25, 2016, that a Council consider the quality of the data associated with the methodology when establishing or reviewing an SBRM. In place of this requirement, § 600.1610(a)(2)(iii) clarifies that a Council must address the uncertainty of the data resulting from the standardized reporting methodology. The standardized reporting methodology must be designed so that the uncertainty associated with the resulting bycatch data can be described, quantitatively or qualitatively. The Council should seek to minimize uncertainty in the resulting data, recognizing that different degrees of data uncertainty may be appropriate for different fisheries. NMFS made these changes in response to public comment and for purposes of clarity.

In § 600.1610(a)(2)(iv), NMFS created a distinct subparagraph regarding data use. To clarify the link between an SBRM and the assessment of bycatch, this first sentence of this subparagraph states: “A Council must address how data resulting from the standardized reporting methodology are used to assess the amount and type of bycatch occurring in the fishery.” NMFS also moved the proposed consultation provision (in § 600.1610(b) at 81 FR 9413, February 25, 2016) to this subparagraph, in response to public comment and to clarify the consultation process. Therefore, the second sentence of § 600.1610(a)(2)(iv) states: “A Council must consult with its scientific and statistical committee and/or the regional National Marine Fisheries Service science center on reporting methodology design considerations such as data elements, sampling designs, sample sizes, and reporting frequency.” NMFS made the consultation mandatory in the final rule. NMFS also removed reference to “advisory panels,” which was included in the consultation provision of the proposed rule, because the consultation is scientific in nature and is outside the scope of the advisory panel’s role.

NMFS moved the text stating that “a Council may also consider...the scientific methods and techniques available to collect and report bycatch data that could improve the quality of bycatch estimates” from proposed § 600.1610(a)(2)(ii) (at 81 FR 9413, February 25, 2016) to § 600.1610(a)(2)(iv), because NMFS believes this provision relates to data

use. In this sentence, NMFS changed “may” to “must” in the final rule, and added “record” between “collect” and “report” to mirror NMFS’ definition of a standardized reporting methodology.

Also in § 600.1610(a)(2)(iv), NMFS added a sentence at the end of the paragraph clarifying that different standardized reporting methodology designs may be appropriate for different fisheries.

To comport with the organizational changes in the final rule, NMFS changed § 600.1610(d) to paragraph (b). To clarify that a Council must undertake a review of their FMPs for consistency with the rule, NMFS added that a Council, in coordination with NMFS, must conduct a review of its FMPs for consistency with this rule. To clarify that a Council does not have to amend an FMP within 5 years of the effective date of the rule if the FMP is in compliance with the rule, NMFS also added that a Council does not need to amend an FMP if NMFS, in consultation with the Council, determines that the FMP is consistent with this rule. Although the Council initiates a review of SBRMs, that review should be done in coordination with NMFS; therefore NMFS added “in coordination with NMFS” to the second and last sentences of § 600.1610(b).

Minor, non-substantive grammatical changes were also made in the final regulatory text to improve clarity.

IV. National Environmental Policy Act

NMFS has made a determination to apply a Categorical Exclusion to this action under the National Environmental Policy Act. This action qualifies for a Categorical Exclusion because it is a regulation “of an administrative, financial, legal, technical or procedural nature, or the environmental effects of which are too broad, speculative or conjectural to lend themselves to meaningful analysis and will be subject later to the NEPA process, either collectively or case-by-case. . . .” See NOAA’s Administrative Orders 216–6 and 216–6A. If and when, as a result of reviewing an FMP for consistency with the MSA and this rule, a Council amends a specific FMP and/or fishery research plans, the Council and/or NMFS would prepare a NEPA analysis, as appropriate.

V. Classification

Pursuant to section 301(b) of the MSA, the NMFS Assistant Administrator has determined that this final rule is consistent with the Magnuson-Stevens Act and other applicable law.

This rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Council for Regulation of the Department of Commerce certified to the Chief Council for Advocacy of the Small Business Administration during the proposed rule stage that this rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule (see page 9417 at 81 FR 9413, February 25, 2016). In summary, this action interprets and provides guidance on section 303(a)(11) of the Magnuson-Stevens Fishery Conservation and Management Act (MSA), which requires that all Fishery Management Plans (FMPs) “establish a standardized reporting methodology to assess the amount and type of bycatch occurring in a fishery” (16 U.S.C. 1853(a)(11)). Because the action does not directly regulate any small entities, it will not directly alter the behavior of any entities operating in federally managed fisheries, and thus no direct economic effects on small entities (as described within the proposed action) are expected to result from this action. Therefore, no small entities will be directly affected by this action, and a reduction in profits for a substantial number of small entities is not expected. See 81 FR 9413, February 25, 2016. No public comments were received regarding this certification.

NMFS notes that on January 26, 2016, the Small Business Administration (SBA) issued a final rule revising the small business size standards for several industries, effective February 26, 2016 (81 FR 4469). The rule increased the size standard for Seafood Product Preparation and Packaging (NAICS code 311710) from 500 to 750 employees. Furthermore, on December 29, 2015, NMFS issued a final rule establishing a small business size standard of \$11 million in annual gross receipts for all businesses primarily engaged in the commercial fishing industry (NAICS 11411) for Regulatory Flexibility Act (RFA) compliance purposes only. See 80 FR 81194, December 29, 2015. The \$11 million standard became effective on July 1, 2016, and is to be used in place of the U.S. Small Business Administration’s (SBA) current standards of \$20.5 million, \$5.5 million, and \$7.5 million for the finfish (NAICS 114111), shellfish (NAICS 114112), and other marine fishing (NAICS 114119) sectors of the U.S. commercial fishing industry in all NMFS rules subject to the RFA after July 1, 2016. See 80 FR 81194, December 29, 2015. Pursuant to the RFA, and prior to July 1, 2016, the

certification was developed for this regulatory action using SBA’s size standards prior to February 26, 2016. NMFS has reviewed the analyses prepared for this regulatory action in light of the new size standards discussed above and has determined that the new size standards do not affect analyses prepared for this regulatory action. Further, because the action does not directly regulate any entities, any new size standard will not directly alter the behavior of any entities operating in federally managed fisheries, and thus no direct economic effects on commercial harvesting businesses, marinas, seafood dealers/wholesalers, or seafood processors are expected to result from this action. Thus, no small entities will be directly affected by this action and a reduction in profits for a substantial number of small entities is not expected, and NMFS has determined that the certification established during the proposed rule stage is still appropriate for this final action.

List of Subjects in 50 CFR Part 600

Administrative practice and procedure, Bycatch, Fisheries, Standardized Reporting Methodology.

Dated: January 6, 2017.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, NMFS amends 50 CFR part 600 as follows:

PART 600—MAGNUSON-STEVENS ACT PROVISIONS

■ 1. The authority citation for 50 CFR part 600 continues to read as follows:

Authority: 5 U.S.C. 561 and 16 U.S.C. 1801 *et seq.*

■ 2. Add subpart R to read as follows:

Subpart R—Standardized Bycatch Reporting Methodology

Sec.

600.1600 Purpose and scope.

600.1605 Definitions and word usage.

600.1610 Establishing and reviewing standardized bycatch reporting methodologies in fishery management plans.

§ 600.1600 Purpose and scope.

Section 303(a)(11) of the Magnuson-Stevens Act requires that any fishery management plan (FMP) with respect to any fishery shall establish a standardized reporting methodology to assess the amount and type of bycatch occurring in the fishery. 16 U.S.C. 1853(a)(11). The purpose of a

standardized reporting methodology is to collect, record, and report bycatch data in a fishery that, in conjunction with other relevant sources of information, are used to assess the amount and type of bycatch occurring in the fishery and inform the development of conservation and management measures that, to the extent practicable, minimize bycatch and bycatch mortality. This subpart sets forth requirements for and guidance on establishing and reviewing a standardized reporting methodology.

§ 600.1605 Definitions and word usage.

(a) *Definitions.* In addition to the definitions in the Magnuson-Stevens Act and § 600.10, *standardized reporting methodology* means an established, consistent procedure or procedures used to collect, record, and report bycatch data in a fishery, which may vary from one fishery to another. Bycatch assessment is not part of the standardized reporting methodology, but must be considered as described in § 600.1610(a)(2)(iv).

(b) *Word usage.* The terms “bycatch” and “fishery” are used in the same manner as in 16 U.S.C. 1802. The terms “must”, “should”, “may”, “will”, “could”, and “can” are used in the same manner as in § 600.305(c). The term “Council” is used in the same manner as in § 600.305(d)(10), and includes the regional fishery management Councils and the Secretary of Commerce, as appropriate (16 U.S.C. 1854(c) and (g)).

§ 600.1610 Establishing and reviewing standardized bycatch reporting methodologies in fishery management plans.

(a) *Establishing a standardized reporting methodology—(1) Fishery management plan contents.* An FMP must identify the required procedure or procedures that constitute the standardized reporting methodology for the fishery. The required procedures may include, but are not limited to, one or more of the following: Observer programs, electronic monitoring and reporting technologies, and self-reported mechanisms (e.g., recreational sampling, industry-reported catch and discard data). The FMP, or a fishery research plan authorized under 16 U.S.C. 1862,

must explain how the standardized reporting methodology meets the purpose described in § 600.1600, based on an analysis of the requirements under § 600.1610(a)(2). The FMP, or fishery research plan authorized under 16 U.S.C. 1862, may reference analyses and information in other FMPs, FMP amendments, Stock Assessment and Fishery Evaluation (SAFE) reports, or other documents. Councils should work together and collaborate on standardized reporting methodologies for fisheries that operate across multiple jurisdictions, as appropriate. In addition to proposing regulations necessary to implement the standardized reporting methodology, a Council should also provide in its FMP, or a fishery research plan authorized under 16 U.S.C. 1862, guidance to NMFS on how to adjust implementation of a standardized reporting methodology consistent with the FMP. See National Standard 6 guidelines, § 600.335.

(2) *Requirements for standardized reporting methodology.* The FMP must establish a standardized reporting methodology as provided under § 600.1610(a)(1) that meets the specific purpose described in § 600.1600. Due to the inherent diversity of fisheries, different standardized reporting methodologies may be appropriate for different fisheries. However, when establishing or reviewing a standardized reporting methodology, a Council must address the following:

(i) *Information about the characteristics of bycatch in the fishery.* A Council must address information about the characteristics of bycatch in the fishery, when available, including, but not limited to: The amount and type of bycatch occurring in the fishery, which may vary based on different fishing activities and operations; the importance of bycatch in estimating the fishing mortality of fish stocks; and the effect of bycatch on ecosystems.

(ii) *Feasibility.* The implementation of a standardized reporting methodology must be feasible from cost, technical, and operational perspectives. However, feasibility concerns do not exempt an FMP from the requirement to establish a standardized reporting methodology. Recognizing that costs and funding may

vary from year to year, a Council must also address how implementation of the standardized reporting methodology may be adjusted while continuing to meet the purpose described under § 600.1600.

(iii) *Data uncertainty.* A Council must address the uncertainty of the data resulting from the standardized reporting methodology. The standardized reporting methodology must be designed so that the uncertainty associated with the resulting bycatch data can be described, quantitatively or qualitatively. The Council should seek to minimize uncertainty in the resulting data, recognizing that different degrees of data uncertainty may be appropriate for different fisheries.

(iv) *Data use.* A Council must address how data resulting from the standardized reporting methodology are used to assess the amount and type of bycatch occurring in the fishery. A Council must consult with its scientific and statistical committee and/or the regional National Marine Fisheries Service science center on reporting methodology design considerations such as data elements, sampling designs, sample sizes, and reporting frequency. The Council must also consider the scientific methods and techniques available to collect, record, and report bycatch data that could improve the quality of bycatch estimates. Different standardized reporting methodology designs may be appropriate for different fisheries.

(b) *Review of FMPs.* All FMPs must be consistent with this subpart by February 21, 2022. Therefore, a Council, in coordination with NMFS, must conduct a review of its FMPs for consistency with this subpart. A Council does not need to amend an FMP if NMFS determines that it is consistent with this subpart. Thereafter, Councils, in coordination with NMFS, should conduct a review of standardized reporting methodologies at least once every 5 years in order to verify continued compliance with the MSA and this subpart.

[FR Doc. 2017–00405 Filed 1–18–17; 8:45 am]

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Proposed Rules

Federal Register

Vol. 82, No. 12

Thursday, January 19, 2017

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

Office of Personnel Management

5 CFR Parts 317, 430, and 534

Office of Management and Budget

5 CFR Part 1330

RIN 3206–AL20

Performance Appraisal System Certification

AGENCY: Office of Personnel Management and Office of Management and Budget.

ACTION: Proposed rule with request for comments.

SUMMARY: The U.S. Office of Personnel Management (OPM) and the U.S. Office of Management and Budget (OMB) jointly propose to implement certain requirements contained in the Senior Professional Performance Act of 2008, incorporate OPM policies and to reorganize information for ease of reading. OPM additionally proposes to make conforming changes and technical corrections, and to update and simplify the processes used based on over a decade of experience with the certification process and recommendations from an interagency workgroup.

DATES: OPM must receive comments on or before February 21, 2017.

ADDRESSES: You may submit comments, identified by “RIN 3206–AL20,” using any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. All submissions received through the Portal must include the agency name and docket number or Regulation Identifier Number (RIN) for this rulemaking.

Email: sespolicy@opm.gov. Include “RIN 3206–AL20” in the subject line of the message.

Fax: (202) 606–4264.

Mail, Hand Deliver/Courier comments: Address comments to Mr. Stephen T. Shih, Deputy Associate

Director for Senior Executive Services and Performance Management, Suite 7412, 1900 E Street NW., Washington, DC 20415–9700.

FOR FURTHER INFORMATION CONTACT: Myriam Mayobre by telephone at (202) 606–8046, by FAX at (202) 606–4264, or by email at myriam.mayobre@opm.gov.

SUPPLEMENTARY INFORMATION: This proposal updates current regulations to account for changes in statute, policies, and processes that have occurred since the current regulation became effective in 2004. This proposal also streamlines the existing process to decrease burden on agencies while ensuring OPM and OMB have information needed for certification.

On October 8, 2008, the President signed into law the Senior Professional Performance Act of 2008 (the Act), Public Law 110–372. The Act made significant changes in the law governing certification of senior employee performance appraisal systems. This rulemaking would revise subpart D of parts 430 and 1330 of title 5, Code of Federal Regulations to reflect the changes resulting from the Act. Other changes to the regulations not related to the Act have been included in this revision to update and simplify the processes used based on over a decade of experience with the certification process and recommendations from an interagency workgroup. OPM convened the workgroup in December 2014 as a result of a President’s Management Agenda recommendation made in 2011 by a separate workgroup, to follow up on recommendations made by a Chief Human Capital Officers workgroup held in February 2014, and as part of the current Presidential Management Agenda initiatives to improve the Senior Executive Service (SES). The workgroup was comprised of agency subject matter experts who were tasked to review the certification process and provide recommendations regarding the certification criteria and streamlining the process.

While OPM and OMB jointly propose to amend parts 430 and 1330 of title 5, Code of Federal Regulations, OPM additionally proposes to make the following changes to parts 317, 430 Subpart C, and 534 of title 5, Code of Federal Regulations, for which OPM alone is responsible. OPM proposes changes in 5 CFR 317.501(b)(2) and 317.503(g)(3) to fix erroneous internal

cross-references to certain regulations affecting those sections. OPM also proposes certain changes to final regulations on 5 CFR 430 subpart C—Managing Senior Executive Performance published September 25, 2015, 80 FR 57693 to update citations to the proposed regulation. Revisions to 5 CFR 430.309(e)(2) would further clarify higher level review.

OPM is proposing conforming changes to pay regulations at 5 CFR 534 subparts D and E. For the most part, these changes update citations from the current regulations with citations to the same or similar material in the proposed regulations or change the existing references in current regulation to “suspension” of an appraisal system certification with the term “termination” of certification. In 5 CFR 534 subpart D, OPM also proposes to revise 5 CFR 534.404(e)(1) to clarify that certification of an appraisal system does not provide an immediate opportunity to adjust the pay of current senior executives. Rather, pay adjustments for current senior executives must be based on an annual summary rating and, therefore, occur only after the completion of a rating cycle under the newly certified appraisal system. This should occur on the normal appraisal cycle and include a period of performance under the certified system that is at least equal to the agency’s minimum appraisal period. OPM also proposes to add new paragraph 534.404(c)(6) to address a technical issue associated with the 12-month rule and enable authorized agency officials to grant a pay adjustment up to 2 days before the expiration date of the 12-month restriction on pay adjustments that applies to a senior executive. This will allow agencies to make a pay adjustment consistent with an otherwise applicable annual performance and pay adjustment cycle. OPM finds this appropriate to support agencies in maintaining a cycle that provides for granting pay adjustments based upon performance on the first day of the same bi-weekly pay period each year (e.g., at the time of the statutory annual adjustment to General Schedule rates, which may occur 1 or 2 days short of a full 12-month period). OPM does not propose to require annual approval and documentation of the basis for this exception prior to its use. In 5 CFR 534 subpart E, OPM proposes to revise 5

CFR 534.505(a)(5) to add the review of proposed performance awards for senior professionals as a responsibility of the centralized review panel. This creates consistency with the duties of the performance review boards (PRB) for senior executives. OPM also proposes to revise 5 CFR 534.507(a)(2) to include a 14-day time period from the date specified in paragraph (a)(1) of that section in which an authorized agency official must provide notice to a senior professional concerning the reasons for a zero adjustment in pay, as required by paragraph (h) of that section. Specifying a 14-day time period will ensure that senior professionals receive such notices in a timely manner.

Key Changes to 5 CFR Parts 430 and 1330

The proposed regulations implement the provision in the Act that authorizes agencies to apply higher maximum rates of basic pay for employees in senior-level (SL) and scientific or professional (ST) positions (*i.e.*, senior professionals) paid under 5 U.S.C. 5376. An agency without an applicable certified appraisal system must use a maximum rate of basic pay for senior professionals that does not exceed the rate for level III of the Executive Schedule (EX–III). An agency with an applicable certified appraisal system may use a maximum rate of basic pay for senior professionals covered by the certified system that does not exceed the rate for level II of the Executive Schedule (EX–II).

The proposed regulation implements a section of the Act providing that certification may be granted beginning at any point in the year for a period not to exceed 24 months. Under rare and exceptional circumstances, the Director of OPM may extend certification for up to 6 additional months. Full certification will be granted for a period of 24 months. Provisional certification will be granted for a period of 12 months.

Since certification no longer expires at the end of a calendar year, there is no need for OPM to extend provisional certification into the following calendar year. That extension enabled agencies to maintain certification long enough to make pay adjustments using the higher maximum rate of the newly adjusted pay range and continued their access to the higher pay rate of EX–II.

OPM proposes to remove sections of the regulation that governed the renewal of an already fully certified system and described a process for automatic renewal based on an OPM/OMB review of the required agency annual report. OPM determined that this information alone is insufficient to assess whether

an agency's system continues to meet the certification criteria. An agency that intends to maintain its certification must submit a request for certification in accordance with proposed sections 430.407 and 1330.407.

OPM proposes to change the requirement of current sections 430.404(a)(6) and 1330.404(a)(6) that only the agency head or the official designated under paragraph (a)(5) of those sections may provide oversight of the agency's appraisal system and its results. The proposed regulations also add Communication of Results (*i.e.*, overall rating distributions, average adjustment in the rate of basic pay for each rating level, and average performance award for each rating level, as applicable) as a certification criterion. This change is consistent with OPM's current guidance that each agency must describe the communication of ratings and payouts to senior employees and other involved officials in its certification request. Additionally, the proposed regulations combine the criteria for *Alignment* and *Results* into a single criterion, Aligned Results.

OPM proposes to remove the references that distinguish requests for full certification from requests for provisional certification. As the certification process has evolved, OPM has found that submission of the same information is needed for all agency requests for certification. Based on review of an agency request, OPM, with OMB concurrence, may then grant full or provisional certification as appropriate. Reasons for which an agency would receive provisional rather than full certification are specified in the proposed regulations. OPM also proposes to remove the requirement for agencies to submit, as part of their certification requests, the process they use for ensuring ratings are not distributed arbitrarily or on a rotational basis. OPM believes this falls within the responsibilities of the oversight official to ensure the appraisal system is administered appropriately. OPM continues to require, as part of the oversight criterion, that an agency identify the official responsible for certifying that the senior employee appraisal process makes meaningful distinctions based on relative performance. OPM recognizes the ability to make meaningful distinctions in performance starts with the development of performance standards and requirements that clearly describe the different expectations at various performance levels. Agencies should consult their strategic plans and objectives when developing performance requirements to ensure

alignment with mission outcomes and organizational results. This first critical step falls to the rating official, in consultation with the senior employee, followed by the accurate application of these standards/requirements when assessing performance. The proper development of performance standards/requirements and the accurate assessment of performance compared to these standards/requirements should lead to meaningful distinctions in ratings. OPM has found that the role of the oversight official provides the appropriate level for ensuring ratings make meaningful distinctions on the basis of actual differences in levels of performance. Furthermore, OPM proposes to remove the requirement for an agency to submit, as part of its certification request, the process for reviewing performance standards, requirements, expectations, or ratings of employees supervised by senior employees, because OPM believes this too is a review that should be included in the responsibilities of the Oversight Official.

The proposed regulations introduce a new procedural framework that provides for shared responsibilities in assessing certification criteria. Instead of OPM assessing all criteria, OPM will assess Aligned Results, Performance Distinctions, and Pay Differentiation. OPM will seek OMB concurrence on its findings. Agencies will verify Organizational Assessment and Guidelines, Oversight, and Communication. The criteria verified by the agency will, however, be subject to periodic spot checks by OPM to ensure continued compliance. Spot checks will not be announced in advance and when they occur, agencies will submit to OPM the documentation they used as the basis of their verification of the applicable criteria. In addition, the proposed regulations allow for an agency to demonstrate compliance with the Aligned Results criterion through a peer review process. This peer review process will provide the option for an agency with full certification to either have its performance plans reviewed by another agency with a fully certified appraisal system or submit the performance plans to OPM. Agencies that maintain full certification may continuously use this peer review method to demonstrate compliance with the Aligned Results criterion subject to spot checks by OPM. To maintain the integrity of the peer review process, agencies will not be allowed to conduct reciprocal reviews.

OPM proposes to remove Consultation, Balance, and Accountability criteria from the

Certification Criteria and move them to a new section, Additional Appraisal Program Requirements and add the Training requirement to this same section. Based on over a decade of experience and careful deliberation by a cross-agency working group of subject matter experts, we have determined these important aspects of a successful and effective performance management system no longer need to be reviewed by OPM for the purpose of supporting a certification determination. Since they are vital to the success of a performance management system, are included in the design and application of the Basic SES appraisal system, and agencies already have incorporated them into their performance cultures, each agency will now be responsible for ensuring they continue to be properly applied within their organizations.

OPM proposes to modify the definition of Relative Performance to clarify that a senior employee's performance is compared to the performance expectations established for his or her position, including their contribution to agency performance as appropriate. The definition of Relative Performance also specifies that it does not permit peer ranking or peer comparison for rating purposes. OPM also proposes to remove Outstanding Performance from the definitions to avoid confusion with the commonly used Level 5 rating label—Outstanding. As used in the certification regulations, Outstanding Performance originally was intended to allow for separately identifying the highest performers even within the highest performance level, usually Level 5, which often uses the label Outstanding. Some additional terms have been defined, as noted in the table of changes. OPM also proposes to revise the title of this subpart from Performance Appraisal Certification for Pay Purposes to Performance Appraisal System Certification for accuracy.

Agencies will also be required to submit, as part of the certification request, the applicable agency SES or SL/ST pay setting and adjustment policy required under 5 CFR part 534 and the policy and procedures for granting performance awards under § 534.405 for SES or §§ 451.101(e) and 451.104(a)(3) for SL/ST. In order to

assess whether an agency is meeting the pay differentiation criterion for certification, OPM often finds it necessary to examine the pay policy to understand the context within which the reported pay adjustments have been authorized and performance awards have been granted. OPM also proposes that agencies make pay adjustments and performance awards for senior employees in a timely manner. These pay adjustments and awards for SES must have an effective date no later than 5 months after the end of the applicable appraisal period. For senior professionals, agencies must make pay adjustments, in compliance with requirements in § 534.505(b), at the same time as the adjustment to the General Schedule. This is the only time during the year annual increases in basic pay for senior professionals are permissible. Performance awards must be paid as soon as practicable after the end of the appraisal period. These timeliness requirements support the principles of performance-based compensation by ensuring the pay and awards are as close as practicable to the ratings upon which they are based.

OPM proposes to remove paragraphs addressing the limits on basic pay and aggregate total compensation because they are contained in 5 CFR part 534, subparts D and E and § 530.203(b) respectively.

Summary of Major Changes

These proposed regulations make the following major changes:

1. Proposed revisions make conforming changes as a result of Public Law 110–372, Senior Professional Performance Act of 2008.
 - Adds that an agency with an applicable certified appraisal system may apply the higher maximum rate of basic pay for senior professionals covered by the certified system.
 - Implements the provision of the Act where certification may be granted beginning at any point in the year for a period not to exceed 24 months as opposed to a calendar-year basis.
2. Proposed revisions address recommendations stemming from over a decade of experience with certification as well as from an interagency work group tasked to design an improved

certification process to support the President's Management Agenda recommendation to improve the SES.

- Provides for shared responsibilities in assessing certification criteria in which OPM assesses Aligned Results, Performance Distinctions, and Pay Differentiation and agencies will verify all other criteria.

- Adds new option for Peer Review—this would allow fully certified agencies to engage in a review of other fully certified agencies' performance plans to determine whether they meet the criterion for "Aligned Results," while prohibiting concurrent reciprocal reviews.

- Requires timely pay adjustments and performance awards for senior employees; for SES, not later than 5 months after the end of the appraisal period.

Request for Comments

In addition to the general request for comments on the proposed regulation, we would appreciate feedback focused specifically on the following questions:

- How could agencies best assess and highlight their organizational performance—strengthening alignment to individual SES performance requirements—to distinguish between SES performance levels and/or to objectively set high performance expectations for individual SES?
- Are there additional ways, or alternatives, OMB and OPM should consider to make the SES and SL/ST performance appraisal system certification process less resource-intensive, while still achieving the goal of tying performance to agency outcomes, and making meaningful distinctions amongst individuals' performance levels?

Complete Table of Changes

The following table lists all the proposed changes to the current regulations. The "current rule" column lists the regulations in the current subpart D. The "proposed rule" column indicates where matters addressed in the current regulation are addressed in the proposed regulation and where new material is being added. The third column explains each change.

| Current rule | Proposed rule | Explanation of change |
|----------------------------|--------------------------|--|
| Part 430, subpart D | | |
| 430.401(a) | 430.401(a) and (b) | Divides paragraph into multiple sections to increase clarity. |
| 430.401(b) | Removed | Removes paragraphs addressing the limits on basic pay and aggregate compensation because they are contained in 5 CFR part 534, subparts D and E and § 530.203(b) respectively. |

| Current rule | Proposed rule | Explanation of change |
|-------------------------------------|-----------------------------|---|
| 430.402 | 430.402 | Adds definitions for <i>Agency</i> , <i>Agency Head</i> , <i>Annual Summary Rating</i> , <i>Appraisal</i> , <i>Certification Criteria</i> , <i>Peer Review</i> , <i>Rating of Record</i> , <i>Senior Professional Review Panel (SPRP)</i> , updates <i>GPRA</i> to <i>GPRAMA</i> , clarifies the definitions of <i>Performance Expectations</i> , <i>Relative Performance</i> , and <i>Senior Executive</i> . Removes the definition for <i>Outstanding Performance</i> . |
| 430.403(a) | 430.403(a) | Edits made to increase clarity. |
| 430.403(b) | 430.403(b) | Adds provision that certifications are not renewable. |
| 430.403(c) | 430.403(c) | Moves requirement that agencies seeking certification must submit systems that have been approved by OPM. |
| 430.403(c) | Removed | Removes option for agencies to submit a new appraisal system(s) for certification that has not yet been approved by OPM. |
| 430.403(d) | 430.403(e) | Moves requirement that agencies submit for certification, separate systems for their senior professionals and SES members. Adds new requirement for a centralized review panel for agencies with 10 or more senior professionals. Also moves the option to include features in the senior professional appraisal system that are similar to the SES system. |
| 430.403(e) | 430.403(c) and (d) | Splits paragraph into two sections. |
| 430.404(a) | 430.404 | Edits made to increase clarity. |
| 430.404(a)(1) | 430.404(a)(1) | Moves certification criterion and changes name from <i>Alignment</i> to <i>Aligned Results</i> . |
| 430.404(a)(2) | 430.406(a) | Moves to Additional Appraisal System Requirements and clarifies. |
| 430.404(a)(3) | 430.404(a)(2) | Moves certification criterion and changes name from <i>Results</i> to <i>Aligned Results</i> . |
| 430.404(a)(4) | 430.404(a)(3) | New provision allowing for peer review of aligned results. |
| 430.404(a)(5) | 430.406(b) | Moves to Additional Appraisal System Requirements and clarifies. |
| 430.404(a)(6) | 430.405(a) | Moves certification criterion and simplifies. |
| 430.404(a)(7) | 430.405(b) | Moves certification criterion and clarifies. |
| 430.404(a)(8) | 430.406(c) | Moves to Additional Appraisal System Requirements, changes name from <i>Accountability</i> to <i>Accountability for the Performance Management of Subordinates</i> , and clarifies. |
| 430.404(a)(9) | 430.404(b)(2) | Moves the certification criterion, changes the name from <i>Performance Differentiation</i> to <i>Performance Distinctions</i> , and simplifies. |
| 430.404(a)(9) | 430.404(c)(1) and (2) | Moves certification criterion and clarifies. |
| 430.404(a)(9) | 430.404(c)(3) | Adds specific timeframe for making pay adjustments and awards in a timely manner. |
| 430.404(a)(9) | 430.404(c)(4) | Moves certification criterion and clarifies transparency in the process for making pay and awards decisions. |
| 430.404(b) | Removed | Addressed by defining agency head to mean an Inspector General when applying these provisions to Offices of the Inspector General. |
| 430.405(a) | 430.405(c) | Adds Communication of Results as a certification criterion. |
| 430.405(b) | 430.406(d) | Adds Training to Additional Appraisal System Requirements. |
| 430.405(b)(1) | 430.405 | Adds new section titled <i>Certification Criteria Verified by the Agency</i> . |
| 430.405(b)(1)(i) | 430.407 | Moves and clarifies. |
| 430.405(b)(1)(ii) | 430.407(a) | Moves and removes the requirement to identify whether the request is for full or provisional certification. Removes requests covering an agencywide system or a system that applies to one or more agency organizations or components. Specifies who must submit certification requests. |
| 430.405(b)(1)(iii) | 430.407(a)(1) | Moves and remains unchanged. |
| 430.405(b)(1)(iii)(A) and (B) | 430.407(a)(2) | Adds new paragraph explicitly requiring separate certification requests for Offices of Inspectors General. |
| 430.405(b)(1)(iii)(C) | 430.407(a)(3)(i) | Moves and remains unchanged. |
| 430.405(b)(2) | Removed | Removes applicable administrative instructions and implementing guidance from written requests for certification. |
| 430.405(b)(3) | 430.407(a)(3)(ii) | Moves and edits made to increase clarity. |
| 430.405(b)(3)(i) and (ii) | 430.404(b)(1) | Moves and clarifies. |
| 430.405(b)(3)(i) and (ii) | 430.404(b)(3) | Adds provision requiring agencies to appropriately assign the highest ratings to the best performers. |
| 430.405(b)(3)(i) and (ii) | 430.404(b)(4) | Moves and replaces <i>Outstanding Performance</i> with the highest level of performance. |
| 430.405(b)(3)(i) and (ii) | Removed | Removes requirement to submit a clearly defined process for reviewing initial ratings as well as the requirement to submit a review of supervised employees' performance standards, requirements, and ratings. |
| 430.405(b)(3)(i) and (ii) | 430.407 | Moves and simplifies. |
| 430.405(b)(3)(i) and (ii) | Removed | Removes distinction between requirements associated with full and provisional certification requests. |
| 430.405(b)(3)(i) and (ii) | 430.407(a)(4) | New requirement to include a sample of performance plans. |
| 430.405(b)(3)(i) and (ii) | 430.407(a)(5) | New requirement to include documentation of organizational performance results and relationship with ratings distribution. |

| Current rule | Proposed rule | Explanation of change |
|---------------------|---------------------------------|---|
| 430.405(b)(4) | 430.407(a)(6) and (7) | Moves and references the annual reporting requirement. Moves references to full certification and the two appraisal periods, by requiring data reported in the annual data call. |
| | 430.407(a)(7) | New requirement to submit documentation of the pay policy and procedures as well as policies established for awards programs. |
| 430.405(b)(5) | 430.407(a)(8) | Moves and remains unchanged. |
| | 430.407(b) | Requires agencies participating in peer review to submit such documentation as OPM requires. |
| 430.405(c) | 430.408(a) | Moves and simplifies. |
| 430.405(c)(1) | 430.408(a)(1) | Moves, redefines the certification period from 2 calendar years to 24 months, and clarifies the requirements for full certification. |
| 430.405(c)(2) | 430.408(a)(2) | Moves, deletes the option for OPM to extend provisional certification into the following calendar year, redefines the certification period from 1 calendar year to 12 months, and specifies reasons an agency would receive provisional rather than full certification. |
| 430.405(c)(3) | 430.410(a) | Moves and changes the word suspend to terminate. |
| | 430.408(b)(1) | Implements statutory authority of OPM Director to provide certification extensions. |
| | 430.408(b)(2) | New provision providing requirements for requesting a certification extension. |
| 430.405(d) | Removed | Removes paragraphs addressing the limits on basic pay and aggregate compensation because they are contained in 5 CFR part 534, subparts D and E and § 530.203(b), respectively. |
| 430.405(e)(2) | | |
| 430.405(f)(2) | | |
| 430.405(e)(1) | 430.408(a)(1)(i)–(iii) | Moves and restructures for clarity. Adds as a requirement for full certification, demonstration of appropriate system application based on data reports for the two most recent completed performance cycles. |
| 430.405(e)(3) | Removed | Removes automatic renewal of full certification. |
| 430.405(f)(1) | 430.408(a)(2)(i) and (ii) | Moves and restructures for clarity. |
| | 430.408(a)(2)(iii) | Adds as a reason for receiving provisional rather than full certification, the demonstration of appropriate system application based on data reports for only the most recent completed performance cycle. |
| 430.405(f)(3) | Removed | Removes requirement to resubmit application requesting provisional certification. |
| 430.405(g) | 430.409 | Moves and edits for increased clarity. Also removes the requirement to report aggregate total compensation. |
| 430.405(h)(1) | 430.410(a) | Combines redundant provisions previously at 430.405(c)(3) and 430.405(h)(1). |
| 430.405(h)(2) | 430.410(b) | Moves and changes the word suspension to termination. |
| 430.405(h)(3) | 430.410(c)–(e) | Moves and restructures for increased clarity. Changes the word suspension to termination. |
| 430.405(h)(4) | 430.410(f) | Moves, changes the word suspension to termination, and clarifies that a restored certification will terminate on the same date as the original certification. |
| 430.405(h)(5) | 430.410(g) | Moves and changes the word suspension to termination. |

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities, because they will apply only to Federal agencies and employees.

E.O. 12866, Regulatory Review

This rule has been reviewed by the U.S. Office of Management and Budget in accordance with E.O. 12866.

List of Subjects

5 CFR Parts 317 and 1330

Government employees.

List of Subjects in 5 CFR Parts 430

Decorations, Government employees.

List of Subjects in 5 CFR Part 534

Government employees, Hospitals, Students, and Wages.

U.S. Office of Management and Budget.

Shaun Donovan,

Director.

U.S. Office of Personnel Management.

Beth F. Cobert,

Acting Director.

Accordingly, OPM and OMB are proposing jointly to amend parts 430 and 1330 of title 5 of the Code of Federal Regulations, and OPM proposes to amend parts 317, 430, and 534 of title 5, Code of Federal Regulations as follows:

5 CFR Chapter I—Office of Personnel Management

PART 317—EMPLOYMENT IN THE SENIOR EXECUTIVE SERVICE

■ 1. The authority citation for part 317 continues to read as follows:

Authority: 5 U.S.C. 3392, 3393, 3395, 3397, 3592, 3593, 3595, 3596, 8414, and 8421.

Subpart E—Career Appointments

■ 2. In § 317.501, revise paragraph (b)(2) to read as follows:

§ 317.501 Recruitment and selection for initial SES career appointment be achieved from the brightest and most diverse pool possible.

* * * * *

(b) * * *

(2) Before an agency may fill an SES vacancy by an initial career appointment, it must post a vacancy announcement in USAJOBS for at least 14 calendar days, including the date of publication. Each agency's SES vacancy announcement must comply with criteria in § 330.104 of subpart A of this chapter, except for criteria pertaining to

veterans' preference, the Career Transition Assistance Program, and the Interagency Career Transition Assistance Program.

* * * * *

■ 3. In § 317.503, revise paragraph (g)(3) to read as follows:

§ 317.503 Probationary period.

* * * * *

(g) * * *

(3) The break in SES service was the result of military duty or compensable injury, and the time credited under paragraph (d)(3) of this section was not sufficient to complete the probationary period.

PART 430—MANAGING SENIOR EXECUTIVE PERFORMANCE

■ 4. The authority citation for Part 430 continues to read as follows:

Authority: 5 U.S.C. chapter 43 and 5307(d).

■ 5. In § 430.309, revise the last sentence of the introductory text in paragraph (e)(2), paragraph (e)(2)(ii), and the first sentence in paragraph (e)(2)(iii) to read as follows:

§ 430.309. Rating Performance

* * * * *

(e) * * *

(2) * * * The agency must provide each senior executive an opportunity for review of the initial summary rating by an employee, or (with the consent of the senior executive) a commissioned officer in the uniformed services on active duty in the agency, in a higher level in the agency than the official who prepared the initial rating.

* * * * *

(ii) When an agency cannot provide review by a higher-level official for a senior executive who receives an initial summary rating from the agency head because no such official exists in the agency, the agency must offer an alternative review as it determines appropriate; however, neither HLR nor alternative review may be provided by a member of the PRB that will make a recommendation under § 430.311(b)(2) concerning the senior executive or by an official who participated in determining the initial summary rating.

(iii) If a senior executive declines review by agency-designated higher-level officials, the agency may offer an alternative review but is not obligated to do so unless the only official in a higher level than the initial rater is the head of the agency. * * *

* * * * *

PART 430—PERFORMANCE MANAGEMENT

■ 6. The authority citation for part 430 continues to read as follows:

Authority: 5 U.S.C. chapter 43 and 5307(d).

■ 7. Revise subpart D to read as follows.

Subpart D—Performance Appraisal System Certification

Sec.

430.401 Purpose.

430.402 Definitions.

430.403 System certification.

430.404 Certification criteria verified by OPM/OMB.

430.405 Certification criteria verified by the agency.

430.406 Additional appraisal system requirements.

430.407 Agency certification requests.

430.408 OPM certification actions.

430.409 Annual reporting requirement.

430.410 Termination of certification.

Subpart D—Performance Appraisal System Certification

§ 403.401 Purpose.

(a) This subpart implements 5 U.S.C. 5307(d), which provides for certification of performance appraisal systems that as designed and applied make meaningful distinctions based on relative performance with respect to—

(1) Members of the Senior Executive Service (SES) paid under 5 U.S.C. 5382 and 5383; and

(2) Employees in senior-level (SL) and scientific or professional (ST) positions paid under 5 U.S.C. 5376.

(b) The regulations in this subpart strengthen the application of performance-based-pay principles to senior employees. Specifically, the statutory provisions that these regulations implement authorize an agency to apply a higher maximum rate of basic pay in setting and adjusting rates of basic pay for senior employees (consistent with 5 CFR part 534, subparts D and E) and apply a higher annual aggregate limitation on pay (consistent with 5 CFR part 530, subpart B) to its senior employees, when OPM, with OMB concurrence, has certified that the design and application of the agency's appraisal systems for these employees make meaningful distinctions based on relative performance. This subpart establishes the certification criteria and procedures that OPM will apply in considering agency requests for such certification.

403.402 Definitions.

In this subpart—

Agency means an agency as that term is defined in 5 U.S.C. 105 and an Office of Inspector General, which is considered a separate agency for

purposes of applying all provisions relating to the Senior Executive Service under the Inspector General Act of 1978 (5 U.S.C. App 6(d)).

Agency head means the head of an agency and includes the Inspector General when applying the provisions of this subpart to Offices of the Inspector General.

Annual summary rating means the overall rating level that an appointing authority assigns at the end of the appraisal period as defined in § 430.303.

Appraisal system means the policies, practices, and procedures an agency establishes under 5 U.S.C. chapter 43 and 5 CFR part 430, subparts B and C, or other applicable legal authority, for planning, monitoring, developing, evaluating, and rewarding employee performance. This includes appraisal systems and appraisal programs as defined in § 430.203 and performance management systems as defined in § 430.303.

Certification criteria means the factors used to determine whether an agency appraisal system as designed and applied makes meaningful distinctions based on relative performance.

GPRAMA means the Government Performance and Results Modernization Act of 2010.

OMB means the Office of Management and Budget.

OPM means the Office of Personnel Management.

Peer review means the review under § 430.404(a) of performance plans by one agency for another agency, both having fully certified performance appraisal systems, to determine whether they meet the certification criterion for Aligned Results.

Performance expectations means—

(1) the critical elements, performance requirements, and performance standards that constitute the senior executive performance plans, as defined in § 430.303, established for senior executives;

(2) the performance elements and standards that constitute the performance plans, as defined in § 430.203, established for senior professionals; or

(3) other appropriate means authorized under performance appraisal systems not covered by 5 U.S.C. chapter 43 for communicating what a senior employee is expected to do and the measures that demonstrate success, including contribution to agency performance where appropriate.

Program performance measures means results-oriented measures of performance, whether at the agency, component, or function level, which

include, for example, measures under GPRAMA.

PRB means Performance Review Board, as described in § 430.311.

Rating of record means the performance rating prepared at the end of an appraisal period for performance of agency-assigned duties over the entire period as defined in § 430.203.

Relative performance means the performance of a senior employee compared to the performance expectations established for his or her position (including contribution to agency performance) and those expectations must be set at a level that is sufficiently high to be commensurate with the authorities and responsibilities of a senior employee in the Federal Government. This does not permit peer ranking or peer comparison for rating purposes.

Senior employee means a senior executive or a senior professional.

Senior executive means a member of the Senior Executive Service (SES) paid under 5 U.S.C. 5382 and 5383.

Senior professional means an employee in a senior-level (SL) or scientific or professional position (ST) paid under 5 U.S.C. 5376.

SPRP means *Senior Professional Review Panel* as described in § 534.505(a)(5).

§ 430.403 System certification.

(a) OPM, with OMB concurrence, will certify an agency appraisal system under § 430.408 when a review of that system's design (*i.e.*, system documentation), implementation (*i.e.*, performance plans), and application (*i.e.*, pay, performance awards, and ratings upon which they are based) reveals that the agency meets the certification criteria established in §§ 430.404 and 430.405 and has followed the procedural requirements set forth in § 430.407, and results in a finding that the system as designed and applied makes meaningful distinctions based on relative performance and otherwise conforms to statutory and regulatory requirements relating to performance appraisal, pay, and awards.

(b) Each certification granted shall cover a specific period of time and is not renewable.

(c) Agencies subject to 5 U.S.C. chapter 43 and 5 CFR part 430 seeking certification of their appraisal systems must submit systems that have been approved by OPM under § 430.210 or § 430.314, as applicable.

(d) Agencies not subject to the appraisal provisions of 5 U.S.C. chapter 43 and 5 CFR part 430 seeking certification of their appraisal system(s) under this subpart must submit

appropriate documentation to demonstrate that each system complies with the appropriate legal authority that governs the establishment, implementation, and application of that system.

(e) For senior professionals, an agency must establish an appraisal system(s), as defined in § 430.402, that meets the requirements of 5 CFR part 430, subpart B, and is separate from the system(s) established to cover its SES members under 5 CFR part 430, subpart C. At its discretion, an agency may include system features in its senior professional appraisal system(s) that are the same as, or similar to, the features of its SES appraisal system(s), as appropriate. For the purpose of certification under this subpart, such senior professional appraisal system(s) with 10 or more senior professionals covered by the system(s), must include a requirement for centralized review of senior professionals' ratings of record and proposed pay and performance awards actions.

§ 430.404 Certification criteria verified by OPM/OMB.

To be certified, an agency's applicable appraisal system(s) for senior executives or senior professionals must meet the following certification criteria, as verified by OPM, with OMB concurrence:

(a) *Aligned results.* (1) Performance expectations for individual senior employees must derive from, and clearly align with, the agency's mission and organizational goals, such as those communicated through GPRAMA strategic goals, program and policy objectives, and/or annual performance plans and budget priorities.

(2) Performance plans must contain performance expectations, including at least one critical element focusing on business results, that—

(i) Apply to their respective areas of responsibility and control;

(ii) Reflect expected agency and/or organizational outcomes and outputs, performance targets or metrics, policy/program objectives, and/or milestones;

(iii) Identify specific programmatic crosscutting, external, and partnership-oriented goals or objectives, as applicable; and

(iv) Are stated in terms of observable, measurable, and/or demonstrable performance (*e.g.*, quality, quantity, timeliness, or cost effectiveness, as applicable).

(3) OPM may establish additional procedures to allow agencies to conduct peer reviews of the performance plans to determine whether the plans meet this criterion. When conducting peer

review, agencies may not conduct concurrent reciprocal reviews.

(b) *Performance distinctions.* (1) Appraisal systems must include summary levels of performance as described in 5 CFR 430.305(a)(6) for senior executives, and for senior professionals at least one summary level of performance above fully successful.

(2) Agency application of performance appraisal systems must—

(i) Result in meaningful distinctions based on relative performance; and

(ii) Take into account the assessment of the agency's performance against relevant program performance measures, as described in § 430.405(a), employee performance expectations, and such other relevant factors as may be appropriate.

(3) Authorized agency officials, as designated through agency delegated authority, must appraise senior employee performance accurately and realistically so that senior employees who have demonstrated the highest performance and/or exceptional contribution to the agency's performance receive the highest annual summary ratings or ratings of record, as applicable.

(4) Agencies with equivalent appraisal systems not otherwise subject to this part must provide for clearly distinguishing and identifying the rating that reflects the highest level of performance.

(5) Agencies may not equate the requirement to make distinctions based on relative performance to permitting a forced distribution of annual summary ratings or ratings of record, which is prohibited under §§ 430.208(c) and 430.305(a)(5). However, methods used to make distinctions among employees or groups of employees such as comparing, categorizing, and ranking employees or groups on the basis of their performance may be used for purposes other than assigning a summary level including, but not limited to, award determinations.

(c) *Pay differentiation.* (1) Agencies must ensure senior employees who have demonstrated the highest performance receive the highest annual summary ratings or ratings of record, as applicable, and the largest corresponding performance awards, pay adjustments, and rates of pay, in accordance with applicable limitations;

(2) Agencies must ensure differentiation is evident separately in the pay adjustments, performance awards, and rates of pay;

(3) Agencies must ensure they make pay adjustments and performance awards for senior employees in a timely manner.

(i) For senior executives, the pay adjustments authorized under 5 CFR 534.404(b)(3) and the performance awards authorized under 5 U.S.C. 5384 must have effective dates not later than 5 months after the end of the applicable appraisal period;

(ii) For senior professionals, agencies must make pay adjustments in accordance with the requirements in § 534.505(b) and pay performance awards as soon as practicable after the end of the appraisal period; and

(4) Agencies must develop processes for making pay decisions and granting awards affecting senior employees that comply with Governmentwide law, regulation, and guidance. To make these processes transparent agencies must provide access to the appraisal and pay policies that govern the decisions and communicate the results as required in § 430.405(c).

§ 430.405 Certification criteria verified by the agency.

To be certified, an agency's applicable appraisal system(s) for senior executives or senior professionals must meet the following certification criteria, as verified by the agency in accordance with instructions provided by OPM:

(a) *Organizational assessment and guidelines.* Agencies must comply with all applicable OMB requirements for assessing organizational performance and may use those assessments to inform the individual ratings of its senior employees. The results of these assessments are shared with individuals involved in the rating process through the issuance of guidelines based at least in part upon those assessments. The guidelines must—

(1) Address agency performance overall and with respect to each of its particular missions, components, programs, policy areas, and support functions—such as reports of the agency's GPRAMA goals, annual performance plans and targets, program performance measures, and other appropriate indicators;

(2) Be communicated by the agency head, or an individual specifically designated by the agency head for such purpose, to affected senior employees, their rating and reviewing officials, and PRB and SPRP members;

(3) Be provided at the conclusion of the appraisal period but before individual senior employee performance ratings are recommended, so that they inform individual performance appraisals; and

(4) Not take the form of quantitative limitations on the number of ratings at any given rating level.

(b) *Oversight.* The agency head or the individual specifically designated under paragraph (a)(2) of this section must certify for a particular senior employee appraisal system that—

(1) The senior employee rating process makes meaningful distinctions based on relative performance;

(2) The results of the senior employee appraisal process take into account the agency's assessment of its performance against program performance measures, as well as other relevant considerations, as appropriate;

(3) Performance awards, pay adjustments, and levels of pay based on the results of the rating process accurately reflect and recognize distinctions in individual performance and/or contribution to the agency's performance; and

(4) Final decisions include PRB or SPRP recommendations regarding senior employee ratings and must—

(i) Be consistent with 5 CFR part 430, subparts B and C; and

(ii) Appropriately reflect the employee's performance expectations, relevant program performance measures, and such other relevant factors as the PRB or SPRP may find appropriate.

(c) *Communication of results.*

Agencies must communicate annually to senior employees, rating and reviewing officials, and PRB or SPRP members the results of the application of the appraisal process (*i.e.*, overall ratings distributions, average adjustment in the rate of basic pay for each rating level, and average performance award for each rating level, as applicable) while assuring confidentiality of protected information.

§ 430.406 Additional appraisal system requirements.

To be certified, an agency's appraisal system must meet the requirements of 5 CFR part 430, subparts B or C, as applicable, or other applicable legal authority. Agencies are responsible for ensuring their senior employee appraisal systems provide for—

(a) *Consultation.* Performance expectations for senior employees must be developed with the input and involvement of the senior employees who are covered thereby;

(b) *Balance.* Performance expectations established in the individual senior employee appraisal plan must include two parts:

(1) Expected results; and

(2) Those technical, leadership and/or managerial competencies or behaviors that contribute to, and are necessary to distinguish, levels of performance. In addition, for senior employees in

supervisory positions, their performance expectations also must address appropriate measures or indicators of stakeholder and/or employee perspective when applicable, such that stakeholder/employee feedback is sought and used to inform decisions.

(c) *Accountability for the performance management of subordinates.* The performance expectations for individual senior employees in supervisory positions must clearly communicate their responsibility for ensuring—

(1) The performance expectations for individual subordinate employees clearly link to organizational mission, GPRAMA strategic goals, or other program or policy objectives; and

(2) The appraisal of their subordinate employees is based on established performance expectations that differentiate among the various levels of performance. An appraisal must be a realistic assessment of the employees' actual performance, including their contribution to organizational goals as measured in GPRAMA and other organizational plans.

(d) *Training.* Agencies must provide senior employees, rating and reviewing officials (including those in other services/appointments such as political appointments, Foreign Service, military, etc.), and PRB or SPRP members initial training, periodic refresher training, and annual reminders on the operation of the applicable agency performance management and pay and awards policies.

§ 430.407 Agency certification requests.

To receive system certification, an agency must provide documentation demonstrating that its appraisal system(s), in design, implementation, and application, meet the certification criteria in §§ 430.404 and 430.405 as well as the procedural requirements set forth in this section.

(a) In order for an agency's appraisal system to be certified, the agency head or designee must submit documentation in accordance with OPM instructions, including—

(1) A written request, which may include signed electronic formats, for certification of its appraisal system(s) to the Director of OPM, or an OPM official assigned to accept certification requests;

(2) Separate certification requests for systems applying to senior executives, senior professionals, and Offices of the Inspector General;

(3) A full description of the appraisal system(s) to be certified, including—

(i) Organizational and employee coverage information; and

(ii) Rating levels as described in § 430.404(b)(1) and (4) that establish

clear distinctions between levels of performance so senior employees receive ratings based on assessments of their actual performance relative to their established performance expectations in any given appraisal period;

(4) A sample of senior employee performance plans as specified by OPM, except as provided in paragraph (b) of this section;

(5) Documentation of organizational performance results and an explanation of how these results support the rating distribution in accordance with OPM instructions;

(6) Data required by the annual reporting requirement in § 430.409;

(7) Documentation of the pay policy and procedures for setting and adjusting pay and granting performance awards that includes—

(i) For the agency's senior executives covered by 5 CFR part 534, subpart D, the plan for setting and adjusting the rate of basic pay described in § 534.404(g);

(ii) For the agency's senior professionals covered by 5 CFR part 534, subpart E, the written procedures for setting and adjusting the rate of basic pay described in § 534.505; and

(iii) Policies established for award programs authorized under § 534.405 or responsibilities identified in § 451.106, as appropriate; and

(8) Any additional information that OPM and OMB may require to make a determination regarding certification.

(b) Agencies that participate in a peer review under § 430.404(a) must submit such documentation as OPM requires.

§ 430.408 OPM certification actions.

OPM will certify performance appraisal systems, with OMB concurrence, only for those agencies that comply with all related laws and regulations.

(a) *Granting certification.* At the request of an agency head or designee, the Director of OPM, at his or her discretion and in accordance with the requirements of this subpart and with OMB concurrence, may—

(1) Grant full certification, which covers a period of 24 months, of an agency's senior employee appraisal system(s) when the agency has—

(i) Demonstrated in the initial submission of its documentation, and without making any revisions directed by OPM, that it has designed and fully operationalized the certification criteria defined in §§ 430.404 and 430.405;

(ii) Met the documentation requirements in § 430.407; and

(iii) Demonstrated appropriate system application through the data reports required in § 430.409 based on the 2

most recently completed performance cycles (2 years of data).

(2) Grant provisional certification, which covers a period of 12 months, of an agency's senior employee appraisal system(s) when the agency has—

(i) Designed a senior employee appraisal system(s) that meets the certification criteria in §§ 430.404 and 430.405; and

(ii) Revised one or more senior employee performance plans in accordance with instructions from OPM in order to meet the certification requirements in § 430.404(a); or

(iii) Demonstrated appropriate system application through the data reports required in § 430.409 based on only the most recently completed performance cycle (1 year of data).

(3) Grant provisional certification to an agency more than once.

(b) *Extending certification.* (1) Consistent with the requirements of this subpart, the Director of OPM, at his or her discretion or upon the request of an agency head or designee, may grant a single extension of up to six additional months for an agency's appraisal system certification. The discretionary use of the Director's extension authority will be reserved for rare, exceptional circumstances.

(2) When requesting an extension, the agency head or designee must submit a written request, which may include signed electronic formats, to OPM outlining why the agency needs the extension and how the extension will support effective performance management. OPM will consider requests for extensions on a case-by-case basis.

§ 430.409 Annual reporting requirement.

Agencies must provide OPM with the annual summary ratings or ratings of record, as applicable, and rates of basic pay, pay adjustments, and performance and cash awards for their senior employees in accordance with instructions for OPM's annual data call and at any other time as needed to support a certification request.

§ 430.410 Termination of certification.

(a) Any time OPM determines that an agency's certified appraisal system is no longer in compliance with certification criteria, OPM, with OMB concurrence, may terminate such certification.

(b) An agency's system certification is terminated automatically when OPM withdraws performance appraisal system approval or mandates corrective action because of misapplication of the system as authorized under § 430.210(c) or § 430.314(c).

(c) OPM will notify the agency head at least 30 calendar days in advance of

the termination and the reason(s) for the termination, as well as any expected corrective action.

(d) Upon such termination, and until its system certification is reinstated, the agency must—

(1) Set a senior employee's rate of basic pay under 5 CFR part 534, subparts D or E as applicable, at a rate that does not exceed the rate for level III of the Executive Schedule.

(2) Limit aggregate compensation received in a calendar year by a senior employee to the rate for level I of the Executive Schedule.

(e) Performance awards, pay adjustments, and levels of pay in effect prior to such termination will remain in effect unless OPM finds that any such decision and subsequent action was in violation of law, rule, or regulation.

(f) OPM, with OMB concurrence, may reinstate certification to an agency whose certification has been terminated only after the agency demonstrates it has taken appropriate corrective action. A restored certification will terminate on the same date as the original certification. An agency with a terminated certification may choose to submit a new certification request once it has corrected the issue(s) that led to the termination.

(g) OPM may reinstate the certification of an appraisal system that has been terminated automatically under paragraph (b) of this section upon the agency's compliance with the applicable OPM-mandated corrective action(s).

PART 534—PAY UNDER OTHER SYSTEMS

■ 8. Revise the authority citation for part 534 to read as follows:

Authority: 5 U.S.C. 1104, 3161(d), 5307, 5351, 5352, 5353, 5376, 5382, 5383, 5384, 5385, 5541, 5550a, sec. 1125 of the National Defense Authorization Act for FY 2004, Pub. L. 108–136, 117 Stat. 1638 (5 U.S.C. 5304, 5382, 5383, 7302; 18 U.S.C. 207); and Pub. L. 110–372, 122 Stat. 4043 (5 U.S.C. 5304, 5307, 5376).

Subpart D—Pay and Performance Awards Under the Senior Executive Service.

■ 9. In § 534.403, revise the first sentence of paragraph (b) to read as follows:

§ 534.403 SES rate range.

* * * * *

(b) *Termination of certification of performance appraisal system.* A senior executive whose rate of basic pay is higher than the rate for level III of the Executive Schedule may not suffer a

reduction in pay because his or her agency's applicable performance appraisal system certification is terminated under 5 CFR 430.410. * * *

■ 10. In § 534.404—

- a. Revise paragraphs (b)(4)(ii) and (b)(4)(iii);
- b. Revise paragraphs (c)(1) and (c)(4) and add new paragraph (c)(6);
- c. Revise paragraph (e)(1);
- d. Revise paragraph (g)(3);
- e. Revise paragraph (i)(1).

The revisions and additions to read as follows:

§ 534.404 Setting and adjusting pay for senior executives.

* * * * *

(b) * * *

(4) * * *

(ii) A pay increase under paragraph (b)(4)(i) of this section may not be provided to a senior executive whose rate of basic pay is at or below the rate for level III of the Executive Schedule if such an increase would cause the senior executive's rate of basic pay to exceed the rate for level III of the Executive Schedule unless the senior executive has received an annual summary rating of outstanding for the most recently completed appraisal period and the agency head or designee who performs the functions described in 5 CFR 430.405(a)(2) and (b) (including the Inspector General, where applicable) has approved the increase in pay.

(iii) A pay increase under paragraph (b)(4)(i) of this section may not be provided to a senior executive whose rate of basic pay is above the rate for level III of the Executive Schedule unless the senior executive has received an annual summary rating of outstanding for the most recently completed appraisal period and the agency head or designee who performs the functions described in 5 CFR 430.405(a)(2) and (b) (including the Inspector General, where applicable) has approved the increase in pay. However, in the case of a senior executive whose rate of basic pay is above the rate for level III of the Executive Schedule and who has been rated below outstanding, but above fully successful, for the most recently completed appraisal period, the agency head or designee who performs the functions described in 5 CFR 430.405(a)(2) and (b) (including the Inspector General, where applicable) may approve such a pay increase in limited circumstances, such as for an exceptionally meritorious accomplishment.

* * * * *

(c) *12-month rule.* (1) An authorized agency official may adjust (*i.e.*, increase

or reduce) the rate of basic pay of a senior executive not more than once during any 12-month period. However, an agency may make a determination to provide an additional pay increase under certain conditions as prescribed in paragraphs (c)(3), (c)(4), and (c)(6) of this section without regard to whether the senior executive has received a pay adjustment during the previous 12-month period.

* * * * *

(4) An authorized agency official may approve increases in a senior executive's rate of basic pay more than once during a 12-month period if the agency head or designee who performs the functions described in 5 CFR 430.405(a)(2) and (b) (including the Inspector General, where applicable) determines that—

* * * * *

(6) When necessary to maintain an annual executive appraisal and pay adjustment cycle that permits pay adjustments on the first day of the 27th full bi-weekly pay period following the effective date of pay adjustments for the previous cycle, an authorized agency official may provide a pay adjustment to a senior executive not more than 2 days before an applicable 12-month period expires. The pay adjustment begins a new 12-month period for the purpose of paragraph (c)(1).

* * * * *

(e) *Adjustments in pay after certification of applicable performance appraisal system.* (1) In the case of an agency that obtains certification of a performance appraisal system for senior executives under 5 CFR part 430, subpart D, an authorized agency official may subsequently increase a covered senior executive's rate of basic pay based upon a performance appraisal under the certified system up to the rate for level II of the Executive Schedule, consistent with the limitations in § 534.403(a)(3), under the conditions prescribed in paragraph (b) of this section, if the senior executive is otherwise eligible for such an increase (*i.e.*, he or she did not receive a pay adjustment under § 534.404(c) during the previous 12-month period). An adjustment in pay made under this paragraph is considered a pay adjustment for the purpose of applying § 534.404(c).

* * * * *

(g) * * *

(3) The designation of the authorized agency official who has authority to set and adjust SES rates of pay for individual senior executives, subject to the requirement that the agency head or designee who performs the functions

described in 5 CFR 430.405(a)(2) and (b) (including the Inspector General, where applicable) must approve any determination to set a senior executive's rate of basic pay higher than the rate for level III of the Executive Schedule and must approve any determination to increase a senior executive's rate of basic pay more than once in any 12-month period; and

* * * * *

(i) *Setting pay following a break in SES service—*(1) *General.* Upon reappointment to the SES, an authorized agency official may set the rate of basic pay of a former senior executive at any rate within the SES rate range, subject to the limitations in § 534.403(a), if there has been a break in SES service of more than 30 days. If there has been a break in SES service of 30 days or less, the senior executive's rate of basic pay may be set at any rate within the SES rate range (without regard to whether the employee received a pay adjustment during the previous 12-month period), but not higher than the senior executive's former SES rate of basic pay. Where there has been a break in service of 30 days or less, the agency head or designee who performs the functions described in 5 CFR 430.405(a)(2) and (b) (including the Inspector General, where applicable) may approve a higher rate than the senior executive's former rate of basic pay, if warranted. Setting a rate of basic pay upon reappointment to the SES is considered a pay adjustment under § 534.404(c).

* * * * *

§ 534.503 [Amended].

■ 11. Amend § 534.503 as follows:

■ a. Remove the reference “§ 430.405(h)” from the definition “Certified” and add in its place “§ 430.410”, and remove from that definition the term “suspension” and add in its place “termination”;

■ b. Remove the reference “§ 430.405(h)” from the definition “Not certified” and add in its place “§ 430.410”, and remove from that definition the term “suspended” and add in its place “terminated”; and

■ c. Remove the reference “§ 430.404(a)(1) through (9)” and add in its place “§§ 430.404 and 430.405”.

■ 12. Amend § 534.505 as follows:

■ a. Remove the reference “§ 430.404(a)(6)(i), (ii) and (iii)” and add in its place “§ 430.405(b)(1), (2) and (3)”; and

■ b. Remove the reference “§ 430.403(d)” and add in its place “§ 430.403(e)”.

■ c. Revise paragraph (a)(5) to read as follows:

§ 534.505 Written procedures.

(a) * * *

(5) The administrative and management controls that will be applied to assure compliance with applicable statutes, OPM regulations, the agency's written procedures established under this section, the applicable maximum rate of basic pay in § 534.504(a), and, where applicable, the certification requirements set forth in part 430, subpart D of this chapter. In an agency that employs ten or more senior professionals, these controls must include centralized review of ratings proposed under § 430.208 of this chapter, pay actions proposed under § 534.507, and performance awards under § 451.104(a)(3) by a panel of individuals designated by the agency head to provide advice from an agency-wide perspective for authorized agency officials to consider before approving pay adjustments and performance awards on whether—

(i) Ratings of record and performance ratings proposed for senior professionals accurately reflect their individual performance, contributions to agency performance, or both, and take into account, as appropriate, assessment of the agency's performance against program performance measures and other relevant considerations; and

(ii) Proposed pay adjustments and performance awards for senior professionals conform to the requirements of §§ 534.507 and 451.104(a)(3) respectively and appropriately correspond to proposed ratings of record and performance ratings.

* * * *

§ 534.506 [Amended].

■ 13. Amend § 534.506 to remove the reference “§ 430.404(a)(6)(i), (ii) and (iii)” and add in its place “§ 430.405(b)(1), (2) and (3)”.

■ 14. In § 534.507, revise paragraph (a)(2) to read as follows:

§ 534.507 Annual increases in basic pay.

(a) * * *

(2) A determination by an authorized agency official to make a zero adjustment in pay after reviewing a senior professional's current rating of record or performance rating meets the requirement of paragraph (a)(1) of this section only if the notice required by paragraph (h) of this section is provided to the senior professional no later than 14 days after the date specified in paragraph (a)(1) of this section.

* * * *

■ 15. In § 534.509, revise paragraph (b) to read as follows:

§ 534.509 Preservation of an established rate of basic pay.

* * * *

(b) An SL or ST employee whose rate of basic pay is higher than the rate for level III of the Executive Schedule may not suffer a reduction in pay because his or her agency's applicable performance appraisal system certification expires or is terminated under § 430.410 of this chapter. See § 530.203(g) and (h) of this chapter for treatment of the aggregate pay limit when certification status changes during the calendar year.

* * * *

§ 534.510 [Amended].

■ 16. Amend § 534.510 to remove the references “§ 430.404(a)(6)(i), (ii) and (iii)” and add in their place “§ 430.405(b)(1), (2) and (3)” wherever they occur.

5 CFR Chapter III—Office of Management and Budget**Subchapter C—Joint Regulations With the Office of Personnel Management****PART 1330—HUMAN RESOURCES MANAGEMENT**

■ 17. The authority citation for part 1330 continues to read as follows:

Authority: 5 U.S.C. chapter 43 and 5307(d).

■ 18. Revise Subpart D of part 1330 to read as follows:

Subparts A—C [Reserved]**Subpart D—Performance Appraisal System Certification**

Sec.

1330.401 Purpose.

1330.402 Definitions.

1330.403 System certification.

1330.404 Certification criteria verified by OPM/OMB.

1330.405 Certification criteria verified by the agency.

1330.406 Additional appraisal system requirements.

1330.407 Agency certification requests.

1330.408 OPM certification actions.

1330.409 Annual reporting requirement.

1330.410 Termination of certification.

Authority: 5 U.S.C. 5307(d).

Subpart D—Performance Appraisal System Certification**§ 1330.401 Purpose.**

(a) This subpart implements 5 U.S.C. 5307(d), which provides for certification of performance appraisal systems that as designed and applied make meaningful distinctions based on relative performance with respect to—

(1) Members of the Senior Executive Service (SES) paid under 5 U.S.C. 5382 and 5383; and

(2) Employees in senior-level (SL) and scientific or professional (ST) positions paid under 5 U.S.C. 5376.

(b) The regulations in this subpart strengthen the application of performance-based-pay principles to senior employees. Specifically, the statutory provisions that these regulations implement authorize an agency to apply a higher maximum rate of basic pay in setting and adjusting rates of basic pay for senior employees (consistent with 5 CFR part 534, subparts D and E) and apply a higher annual aggregate limitation on pay (consistent with 5 CFR part 530, subpart B) to its senior employees, when OPM, with OMB concurrence, has certified that the design and application of the agency's appraisal systems for these employees make meaningful distinctions based on relative performance. This subpart establishes the certification criteria and procedures that OPM will apply in considering agency requests for such certification.

§ 1330.402 Definitions.

In this subpart—

Agency means an agency as that term is defined in 5 U.S.C. 105 and an Office of Inspector General, which is considered a separate agency for purposes of applying all provisions relating to the Senior Executive Service under the Inspector General Act of 1978 (5 U.S.C. App 6(d)).

Agency head means the head of an agency and includes the Inspector General when applying the provisions of this subpart to Offices of the Inspector General.

Annual summary rating means the overall rating level that an appointing authority assigns at the end of the appraisal period as defined in § 430.303.

Appraisal system means the policies, practices, and procedures an agency establishes under 5 U.S.C. chapter 43 and 5 CFR part 430, subparts B and C, or other applicable legal authority, for planning, monitoring, developing, evaluating, and rewarding employee performance. This includes appraisal systems and appraisal programs as defined in § 430.203 and performance management systems as defined in § 430.303.

Certification criteria means the factors used to determine whether an agency appraisal system as designed and applied makes meaningful distinctions based on relative performance.

GPRAMA means the Government Performance and Results Modernization Act of 2010.

OMB means the Office of Management and Budget.

OPM means the Office of Personnel Management.

Peer review means the review under § 1330.404(a) of performance plans by one agency for another agency, both having fully certified performance appraisal systems, to determine whether they meet the certification criterion for Aligned Results.

Performance expectations means—

(1) the critical elements, performance requirements, and performance standards that constitute the senior executive performance plans, as defined in § 430.303, established for senior executives;

(2) the performance elements and standards that constitute the performance plans, as defined in § 430.203, established for senior professionals; or

(3) other appropriate means authorized under performance appraisal systems not covered by 5 U.S.C. chapter 43 for communicating what a senior employee is expected to do and the measures that demonstrate success, including contribution to agency performance where appropriate.

Program performance measures means results-oriented measures of performance, whether at the agency, component, or function level, which include, for example, measures under GPRAMA.

PRB means Performance Review Board, as described in § 430.311.

Rating of record means the performance rating prepared at the end of an appraisal period for performance of agency-assigned duties over the entire period as defined in § 430.203.

Relative performance means the performance of a senior employee compared to the performance expectations established for his or her position (including contribution to agency performance) and those expectations must be set at a level that is sufficiently high to be commensurate with the authorities and responsibilities of a senior employee in the Federal Government. This does not permit peer ranking or peer comparison for rating purposes.

Senior employee means a senior executive or a senior professional.

Senior executive means a member of the Senior Executive Service (SES) paid under 5 U.S.C. 5382 and 5383.

Senior professional means an employee in a senior-level (SL) or scientific or professional position (ST) paid under 5 U.S.C. 5376.

SPRP means *Senior Professional Review Panel* as described in § 534.505(a)(5).

§ 1330.403 System certification.

(a) OPM, with OMB concurrence, will certify an agency appraisal system under § 1330.408 when a review of that system's design (*i.e.*, system documentation), implementation (*i.e.*, performance plans), and application (*i.e.*, pay, performance awards, and ratings upon which they are based) reveals that the agency meets the certification criteria established in §§ 1330.404 and 1330.405 and has followed the procedural requirements set forth in § 1330.407, and results in a finding that the system as designed and applied makes meaningful distinctions based on relative performance and otherwise conforms to statutory and regulatory requirements relating to performance appraisal, pay, and awards.

(b) Each certification granted shall cover a specific period of time and is not renewable.

(c) Agencies subject to 5 U.S.C. chapter 43 and 5 CFR part 430 seeking certification of their appraisal systems must submit systems that have been approved by OPM under § 430.210 or § 430.314, as applicable.

(d) Agencies not subject to the appraisal provisions of 5 U.S.C. chapter 43 and 5 CFR part 430 seeking certification of their appraisal system(s) under this subpart must submit appropriate documentation to demonstrate that each system complies with the appropriate legal authority that governs the establishment, implementation, and application of that system.

(e) For senior professionals, an agency must establish an appraisal system(s), as defined in § 1330.402, that meets the requirements of 5 CFR part 430, subpart B, and is separate from the system(s) established to cover its SES members under 5 CFR part 430, subpart C. At its discretion, an agency may include system features in its senior professional appraisal system(s) that are the same as, or similar to, the features of its SES appraisal system(s), as appropriate. For the purpose of certification under this subpart, such senior professional appraisal system(s) with 10 or more senior professionals covered by the system(s), must include a requirement for centralized review of senior professionals' ratings of record and proposed pay and performance awards actions.

§ 1330.404 Certification criteria verified by OPM/OMB.

To be certified, an agency's applicable appraisal system(s) for senior executives or senior professionals must meet the following certification criteria, as

verified by OPM, with OMB concurrence:

(a) *Aligned results.* (1) Performance expectations for individual senior employees must derive from, and clearly align with, the agency's mission and organizational goals, such as those communicated through GPRAMA strategic goals, program and policy objectives, and/or annual performance plans and budget priorities.

(2) Performance plans must contain performance expectations, including at least one critical element focusing on business results, that—

(i) Apply to their respective areas of responsibility and control;

(ii) Reflect expected agency and/or organizational outcomes and outputs, performance targets or metrics, policy/program objectives, and/or milestones;

(iii) Identify specific programmatic crosscutting, external, and partnership-oriented goals or objectives, as applicable; and

(iv) Are stated in terms of observable, measurable, and/or demonstrable performance (*e.g.*, quality, quantity, timeliness, or cost effectiveness, as applicable).

(3) OPM may establish additional procedures to allow agencies to conduct peer reviews of the performance plans to determine whether the plans meet this criterion. When conducting peer review, agencies may not conduct concurrent reciprocal reviews.

(b) *Performance distinctions.* (1) Appraisal systems must include summary levels of performance as described in 5 CFR 430.305(a)(6) for senior executives, and for senior professionals at least one summary level of performance above fully successful.

(2) Agency application of performance appraisal systems must—

(i) Result in meaningful distinctions based on relative performance; and

(ii) Take into account the assessment of the agency's performance against relevant program performance measures, as described in § 1330.405(a), employee performance expectations, and such other relevant factors as may be appropriate.

(3) Authorized agency officials, as designated through agency delegated authority, must appraise senior employee performance accurately and realistically so that senior employees who have demonstrated the highest performance and/or exceptional contribution to the agency's performance receive the highest annual summary ratings or ratings of record, as applicable.

(4) Agencies with equivalent appraisal systems not otherwise subject to this part must provide for clearly

distinguishing and identifying the rating that reflects the highest level of performance.

(5) Agencies may not equate the requirement to make distinctions based on relative performance to permitting a forced distribution of annual summary ratings or ratings of record, which is prohibited under §§ 430.208(c) and 430.305(a)(5). However, methods used to make distinctions among employees or groups of employees such as comparing, categorizing, and ranking employees or groups on the basis of their performance may be used for purposes other than assigning a summary level including, but not limited to, award determinations.

(c) *Pay differentiation.* (1) Agencies must ensure senior employees who have demonstrated the highest performance receive the highest annual summary ratings or ratings of record, as applicable, and the largest corresponding performance awards, pay adjustments, and rates of pay, in accordance with applicable limitations;

(2) Agencies must ensure differentiation is evident separately in the pay adjustments, performance awards, and rates of pay;

(3) Agencies must ensure they make pay adjustments and performance awards for senior employees in a timely manner.

(i) For senior executives, the pay adjustments authorized under 5 CFR 534.404(b)(3) and the performance awards authorized under 5 U.S.C. 5384 must have effective dates not later than 5 months after the end of the applicable appraisal period;

(ii) For senior professionals, agencies must make pay adjustments in accordance with the requirements in § 534.505(b) and pay performance awards as soon as practicable after the end of the appraisal period; and

(4) Agencies must develop processes for making pay decisions and granting awards affecting senior employees that comply with Governmentwide law, regulation, and guidance. To make these processes transparent agencies must provide access to the appraisal and pay policies that govern the decisions and communicate the results as required in § 1330.405(c).

§ 1330.405 Certification criteria verified by the agency.

To be certified, an agency's applicable appraisal system(s) for senior executives or senior professionals must meet the following certification criteria, as verified by the agency in accordance with instructions provided by OPM:

(a) *Organizational assessment and guidelines.* Agencies must comply with

all applicable OMB requirements for assessing organizational performance and may use those assessments to inform the individual ratings of its senior employees. The results of these assessments are shared with individuals involved in the rating process through the issuance of guidelines based at least in part upon those assessments. The guidelines must—

(1) Address agency performance overall and with respect to each of its particular missions, components, programs, policy areas, and support functions—such as reports of the agency's GPRAMA goals, annual performance plans and targets, program performance measures, and other appropriate indicators;

(2) Be communicated by the agency head, or an individual specifically designated by the agency head for such purpose, to affected senior employees, their rating and reviewing officials, and PRB and SPRP members;

(3) Be provided at the conclusion of the appraisal period but before individual senior employee performance ratings are recommended, so that they inform individual performance appraisals; and

(4) Not take the form of quantitative limitations on the number of ratings at any given rating level.

(b) *Oversight.* The agency head or the individual specifically designated under paragraph (a)(2) of this section must certify for a particular senior employee appraisal system that—

(1) The senior employee rating process makes meaningful distinctions based on relative performance;

(2) The results of the senior employee appraisal process take into account the agency's assessment of its performance against program performance measures, as well as other relevant considerations, as appropriate;

(3) Performance awards, pay adjustments, and levels of pay based on the results of the rating process accurately reflect and recognize distinctions in individual performance and/or contribution to the agency's performance; and

(4) Final decisions include PRB or SPRP recommendations regarding senior employee ratings and must—

(i) Be consistent with 5 CFR part 430, subparts B and C; and

(ii) Appropriately reflect the employee's performance expectations, relevant program performance measures, and such other relevant factors as the PRB or SPRP may find appropriate.

(c) *Communication of results.*

Agencies must communicate annually to senior employees, rating and

reviewing officials, and PRB or SPRP members the results of the application of the appraisal process (*i.e.*, overall ratings distributions, average adjustment in the rate of basic pay for each rating level, and average performance award for each rating level, as applicable) while assuring confidentiality of protected information.

§ 1330.406 Additional appraisal system requirements.

To be certified, an agency's appraisal system must meet the requirements of 5 CFR part 430, subparts B or C, as applicable, or other applicable legal authority. Agencies are responsible for ensuring their senior employee appraisal systems provide for—

(a) *Consultation.* Performance expectations for senior employees must be developed with the input and involvement of the senior employees who are covered thereby;

(b) *Balance.* Performance expectations established in the individual senior employee appraisal plan must include two parts:

(1) Expected results; and

(2) Those technical, leadership and/or managerial competencies or behaviors that contribute to, and are necessary to distinguish, levels of performance. In addition, for senior employees in supervisory positions, their performance expectations also must address appropriate measures or indicators of stakeholder and/or employee perspective when applicable, such that stakeholder/employee feedback is sought and used to inform decisions.

(c) *Accountability for the performance management of subordinates.* The performance expectations for individual senior employees in supervisory positions must clearly communicate their responsibility for ensuring—

(1) The performance expectations for individual subordinate employees clearly link to organizational mission, GPRAMA strategic goals, or other program or policy objectives; and

(2) The appraisal of their subordinate employees is based on established performance expectations that differentiate among the various levels of performance. An appraisal must be a realistic assessment of the employees' actual performance, including their contribution to organizational goals as measured in GPRAMA and other organizational plans.

(d) *Training.* Agencies must provide senior employees, rating and reviewing officials (including those in other services/appointments such as political appointments, Foreign Service, military, etc.), and PRB or SPRP members initial training, periodic refresher training, and

annual reminders on the operation of the applicable agency performance management and pay and awards policies.

§ 1330.407 Agency certification requests.

To receive system certification, an agency must provide documentation demonstrating that its appraisal system(s), in design, implementation, and application, meet the certification criteria in §§ 1330.404 and 1330.405 as well as the procedural requirements set forth in this section.

(a) In order for an agency's appraisal system to be certified, the agency head or designee must submit documentation in accordance with OPM instructions, including—

(1) A written request, which may include signed electronic formats, for certification of its appraisal system(s) to the Director of OPM, or an OPM official assigned to accept certification requests;

(2) Separate certification requests for systems applying to senior executives, senior professionals, and Offices of the Inspector General;

(3) A full description of the appraisal system(s) to be certified, including—

(i) Organizational and employee coverage information; and

(ii) Rating levels as described in § 1330.404(b)(1) and (4) that establish clear distinctions between levels of performance so senior employees receive ratings based on assessments of their actual performance relative to their established performance expectations in any given appraisal period;

(4) A sample of senior employee performance plans as specified by OPM, except as provided in paragraph (b) of this section;

(5) Documentation of organizational performance results and an explanation of how these results support the rating distribution in accordance with OPM instructions;

(6) Data required by the annual reporting requirement in § 1330.409;

(7) Documentation of the pay policy and procedures for setting and adjusting pay and granting performance awards that includes—

(i) For the agency's senior executives covered by 5 CFR part 534, subpart D, the plan for setting and adjusting the rate of basic pay described in § 534.404(g);

(ii) For the agency's senior professionals covered by 5 CFR part 534, subpart E, the written procedures for setting and adjusting the rate of basic pay described in § 534.505; and

(iii) Policies established for award programs authorized under § 534.405 or responsibilities identified in § 451.106, as appropriate; and

(8) Any additional information that OPM and OMB may require to make a determination regarding certification.

(b) Agencies that participate in a peer review under § 1330.404(a) must submit such documentation as OPM requires.

§ 1330.408 OPM certification actions.

OPM will certify performance appraisal systems, with OMB concurrence, only for those agencies that comply with all related laws and regulations.

(a) *Granting certification.* At the request of an agency head or designee, the Director of OPM, at his or her discretion and in accordance with the requirements of this subpart and with OMB concurrence, may—

(1) Grant full certification, which covers a period of 24 months, of an agency's senior employee appraisal system(s) when the agency has—

(i) Demonstrated in the initial submission of its documentation, and without making any revisions directed by OPM, that it has designed and fully operationalized the certification criteria defined in §§ 1330.404 and 1330.405;

(ii) Met the documentation requirements in § 1330.407; and

(iii) Demonstrated appropriate system application through the data reports required in § 1330.409 based on the 2 most recently completed performance cycles (2 years of data).

(2) Grant provisional certification, which covers a period of 12 months, of an agency's senior employee appraisal system(s) when the agency has—

(i) Designed a senior employee appraisal system(s) that meets the certification criteria in §§ 1330.404 and 1330.405; and

(ii) Revised one or more senior employee performance plans in accordance with instructions from OPM in order to meet the certification requirements in § 1330.404(a); or

(iii) Demonstrated appropriate system application through the data reports required in § 1330.409 based on only the most recently completed performance cycle (1 year of data).

(3) Grant provisional certification to an agency more than once.

(b) *Extending certification.* (1) Consistent with the requirements of this subpart, the Director of OPM, at his or her discretion or upon the request of an agency head or designee, may grant a single extension of up to six additional months for an agency's appraisal system certification. The discretionary use of the Director's extension authority will be reserved for rare, exceptional circumstances.

(2) When requesting an extension, the agency head or designee must submit a

written request, which may include signed electronic formats, to OPM outlining why the agency needs the extension and how the extension will support effective performance management. OPM will consider requests for extensions on a case-by-case basis.

§ 1330.409 Annual reporting requirement.

Agencies must provide OPM with the annual summary ratings or ratings of record, as applicable, and rates of basic pay, pay adjustments, and performance and cash awards for their senior employees in accordance with instructions for OPM's annual data call and at any other time as needed to support a certification request.

§ 1330.410 Termination of certification.

(a) Any time OPM determines that an agency's certified appraisal system is no longer in compliance with certification criteria, OPM, with OMB concurrence, may terminate such certification.

(b) An agency's system certification is terminated automatically when OPM withdraws performance appraisal system approval or mandates corrective action because of misapplication of the system as authorized under § 430.210(c) or § 430.314(c).

(c) OPM will notify the agency head at least 30 calendar days in advance of the termination and the reason(s) for the termination, as well as any expected corrective action.

(d) Upon such termination, and until its system certification is reinstated, the agency must—

(1) Set a senior employee's rate of basic pay under 5 CFR part 534, subparts D or E as applicable, at a rate that does not exceed the rate for level III of the Executive Schedule.

(2) Limit aggregate compensation received in a calendar year by a senior employee to the rate for level I of the Executive Schedule.

(e) Performance awards, pay adjustments, and levels of pay in effect prior to such termination will remain in effect unless OPM finds that any such decision and subsequent action was in violation of law, rule, or regulation.

(f) OPM, with OMB concurrence, may reinstate certification to an agency whose certification has been terminated only after the agency demonstrates it has taken appropriate corrective action. A restored certification will terminate on the same date as the original certification. An agency with a terminated certification may choose to submit a new certification request once it has corrected the issue(s) that led to the termination.

(g) OPM may reinstate the certification of an appraisal system that has been terminated automatically under paragraph (b) of this section upon the agency's compliance with the applicable OPM-mandated corrective action(s).

[FR Doc. 2017-01326 Filed 1-18-17; 8:45 am]

BILLING CODE 6325-39-P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 946

[Doc. No. AMS-SC-16-0110; SC17-946-1 CR]

Irish Potatoes Grown in Washington; Continuance Referendum

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Referendum order.

SUMMARY: This document directs that a referendum be conducted among eligible Washington potato producers to determine whether they favor continuance of the marketing order regulating the handling of Irish potatoes grown in Washington.

DATES: The referendum will be conducted from June 9 through June 23, 2017. Only current producers that were engaged in the production of fresh potatoes in Washington during the period of July 1, 2015, through June 30, 2016, are eligible to vote in this referendum.

ADDRESSES: Copies of the marketing order may be obtained from the Northwest Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1220 SW 3rd Avenue, Suite 305, Portland, OR 97204; Telephone: (503) 326-2724; from the Office of the Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250-0237; or on the Internet: <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Teresa Hutchinson or Gary D. Olson, Northwest Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (503) 326-2724, Fax: (503) 326-7440, or Email: Teresa.Hutchinson@ams.usda.gov or GaryD.Olson@ams.usda.gov.

SUPPLEMENTARY INFORMATION: Pursuant to Marketing Order No. 946 (7 CFR part

946), hereinafter referred to as the "order," and the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), hereinafter referred to as the "Act," it is hereby directed that a referendum be conducted to ascertain whether continuance of the order is favored by producers. The referendum shall be conducted from June 9 through June 23, 2017, among eligible Washington potato producers. Only current producers that were also engaged in the production of fresh potatoes in Washington during the period of July 1, 2015, through June 30, 2016, may participate in the continuance referendum.

USDA has determined that continuance referenda are an effective means for determining whether producers favor the continuation of marketing order programs. USDA would consider termination of the order if less than two-thirds of the producers voting in the referendum and producers of less than two-thirds of the volume of Washington potatoes represented in the referendum favor continuance of their program. In evaluating the merits of continuance versus termination, USDA will not exclusively consider the results of the continuance referendum. USDA will also consider all other relevant information regarding operation of the order and relative benefits and disadvantages to producers, handlers, and consumers to determine whether continuing the order would tend to effectuate the declared policy of the Act.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the ballot materials used in the referendum herein ordered have been submitted to and approved by the Office of Management and Budget (OMB) and have been assigned OMB No. 0581-0178, Vegetable and Specialty Crops. It has been estimated that it will take an average of 20 minutes for each of the approximately 270 Washington potato producers to cast a ballot. Participation is voluntary. Ballots postmarked after June 23, 2017, will not be included in the vote tabulation.

Teresa Hutchinson and Gary D. Olson of the Northwest Marketing Field Office, Specialty Crops Program, AMS, USDA, are hereby designated as the referendum agents of the Secretary of Agriculture to conduct this referendum. The procedure applicable to the referendum shall be the "Procedure for the Conduct of Referenda in Connection With Marketing Orders for Fruits, Vegetables, and Nuts Pursuant to the Agricultural Marketing Agreement Act of 1937, as Amended" (7 CFR part 900.400 *et seq.*).

Ballots will be mailed to all producers of record and may also be obtained from the referendum agents or from their appointees.

List of Subjects in 7 CFR Part 946

Marketing agreements, Potatoes, Reporting and recordkeeping requirements.

Authority: 7 U.S.C. 601-674.

Dated: January 12, 2017.

Elanor Starmer,
Administrator, Agricultural Marketing Service.

[FR Doc. 2017-01022 Filed 1-18-17; 8:45 am]

BILLING CODE 3410-02-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2016-8944; Airspace Docket No. 16-AGL-21]

RIN 2120-AA66

Proposed Modification and Establishment of Air Traffic Service (ATS) Routes; Northcentral United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify one jet route and five VHF Omnidirectional Range (VOR) Federal airways, and establish three Area Navigation (RNAV) T-routes in the northcentral United States. The FAA is proposing this action due to the planned decommissioning of the Brainerd, MN (BRD), VHF Omnidirectional Range/Tactical Air Navigation (VORTAC) navigation aid (NAVAID), which provides navigation guidance for portions of the ATS routes proposed to be amended by this action. The T-routes proposed to be established by this action would mitigate potential issues to the National Airspace System (NAS) route structure that may be caused by the proposed ATS route amendments. Overall, this action would enhance the safety and efficient management of aircraft within the NAS.

DATES: Comments must be received on or before March 6, 2017.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington, DC 20590; telephone:

1(800) 647-5527, or (202) 366-9826. You must identify FAA Docket No. FAA-2016-9319 and Airspace Docket No. 16-AGL-21 at the beginning of your comments. You may also submit comments through the Internet at <http://www.regulations.gov>. You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1 (800) 647-5527), is on the ground floor of the building at the above address.

FAA Order 7400.11A, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267-8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11A at NARA, call (202) 741-6030, or go to http://www.archives.gov/federal_register/code_offederal-regulations/ibr_locations.html.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Airspace Policy Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267-8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies the NAS route structure as necessary to

preserve the safe and efficient flow of air traffic within the NAS.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA-2016-9319 and Airspace Docket No. 16-AGL-21) and be submitted in triplicate to the Docket Management Facility (see "ADDRESSES" section for address and phone number). You may also submit comments through the internet at <http://www.regulations.gov>.

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA-2016-9319 and Airspace Docket No. 16-AGL-21." The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at <http://www.regulations.gov>. Recently published rulemaking documents can also be accessed through the FAA's Web page at http://www.faa.gov/air_traffic/publications/airspace_amendments/.

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see "ADDRESSES" section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during

normal business hours at the office of the Operations Support Group, Central Service Center, Federal Aviation Administration, 10101 Hillwood Blvd., Fort Worth, TX, 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016, and effective September 15, 2016. FAA Order 7400.11A is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11A lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

The FAA originally considered decommissioning activities for the Brainerd, MN (BRD), VOR would take place in 2019 as one of the candidate VORs identified for discontinuance by the VOR Minimum Operating Network (VOR MON) program and listed in the Final policy statement notice, "Provision of Navigation Services for the Next Generation Air Transportation System (NextGen) Transition to Performance-Based Navigation (PBN) (Plan for Establishing a VOR Minimum Operational Network)," published in the **Federal Register** of July 26, 2016 (81 FR 48694), Docket No. FAA-2011-1082. However, the lease for the property that the VOR is sited on is expiring in September 2017, and the FAA does not expect the lease to be renewed. As a result, the ATS routes that use the Brainerd, MN, VORTAC must be amended prior to the lease expiring. The affected ATS routes are Jet route J-25 and VOR Federal airways V-55, V-82, V-161, V-218, and V-413.

With the planned decommissioning of the Brainerd, MN, VORTAC, the remaining ground-based NAVAID coverage in the area is insufficient to enable the continuity of the affected airways. As such, proposed modifications to Jet route J-25 and VOR Federal airways V-55, V-82, V-161, V-218, and V-413 will result in gaps in the route structures. To overcome these gaps, the FAA is proposing to establish three new RNAV T-routes: T-330, T-354, and T-383.

The Proposal

The FAA is proposing an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to amend Jet route J-25 and VOR Federal airways V-55, V-82, V-161, V-218, and V-413. Additionally, the FAA is also proposing

to establish RNAV T-Routes T-330, T-354, and T-383. The planned decommissioning of the Brainerd VORTAC has made these actions necessary.

The proposed Jet route and VOR Federal airways changes are outlined below.

J-25: J-25 currently extends between the intersection of the United States/Mexico border and the Brownsville, TX (BRO), VORTAC 221° radial and the Winnipeg, MB, Canada (YWG), VORTAC. The FAA proposes to remove the route segment between the Gopher, MN (GEP), VORTAC and the Winnipeg, MB, Canada (YWG), VORTAC. The unaffected portion of the existing route would remain as charted.

V-55: V-55 currently extends between the Dayton, OH (DQN), VOR and the Bismarck, ND (BIS) VOR. The FAA proposes to remove the airway segment between the Siren, WI (RZN), VOR and the Park Rapids, MN (PKD), VOR. The unaffected portions of the existing airway would remain as charted in the two remaining segments.

V-82: V-82 currently extends between the Baudette, MN (BDE), VOR and the Dells, WI (DLL), VORTAC. The FAA proposes to remove the airway segment between the intersection of the Baudette, MN (BDE), VOR 194° and Brainerd, MN (BRD), VORTAC 331° radials (the BLUOX fix) and the Gopher, MN (GEP), VORTAC. Additionally, the BLUOX fix would be redefined in its existing location using radials from the Baudette, MN (BDE), VOR and the Park Rapids, MN (PKD) VOR. The unaffected portions of the existing airway would remain as charted in the two remaining segments.

V-161: V-161 currently extends between the Three Rivers, TX (ECA), VOR and the Winnipeg, MB, Canada (YWG), VORTAC. The FAA proposes to remove the airway segment between the Gopher, MN (GEP), VORTAC and the Grand Rapids, MN (GPZ), VOR. Additionally, the airway segment between the Grand Rapids, MN (GPZ), VOR and the International Falls, MN (INL), VORTAC would be re-designated as part of V-218. The unaffected portions of the existing airway would remain as charted in the two remaining segments.

V-218: V-218 currently extends between the Grand Rapids, MN (GPZ), VOR and the Lansing, MI (LAN), VORTAC. The FAA proposes to add the V-161 airway segment between the Grand Rapids, MN (GPZ), VOR and the International Falls, MN (INL), VORTAC to V-218. The existing V-218 airway will remain as charted with the addition of the airway segment from the

International Falls, MN (INL), VORTAC to the Grand Rapids, MN (GPZ), VOR included so the airway segments remain listed in a west to east order.

V-413: V-413 currently extends between the Ironwood, MI (IWD), VORTAC and Brainerd, MN (BRD), VORTAC. The FAA proposes to remove the airway segment between the Gopher, MN (GEP), VORTAC and the Brainerd, MN (BRD), VORTAC. The unaffected portion of the existing airway will remain as charted. Additionally, the airway description for the amended airway would be reversed to reflect from the Gopher, MN (GEP), VORTAC to the Ironwood, MI (IWD), VORTAC to list the airway segments in a south to north order consistent with odd numbered ATS route criteria.

The proposed RNAV T-routes to be established are outlined below.

T-330: T-330 would be established from the Grand Forks, MN (GFK), VOR to the Gopher, MN (GEP), VORTAC. This new RNAV T-route would extend over two existing fixes (WATAM, MN, and DAYLE, MN) and three new waypoints (BYZIN, ND; TAMMR, MN; and MAFLN, MN) being established. This T-route would mitigate the loss of portions of V-55 and V-413 airway segments as proposed and would provide RNAV T-route capability and connectivity with a more direct routing between the Grand Forks, ND, and Minneapolis, MN, terminal areas.

T-354: T-354 would be established from the Park Rapids, MN (PKD), VOR to the Siren, WI (RZN), VOR. This new RNAV T-route would extend over a new waypoint (named BRNRD) that is being established over the existing location of the Brainerd, MN (BRD), VORTAC. This T-route would mitigate the loss of the V-55 airway segment proposed to be removed.

T-383: T-383 would be established from the Gopher, MN (GEP), VORTAC to the BLUOX, MN, fix that would be redefined in its existing location using radials from the Baudette, MN (BDE), VOR and the Park Rapids, MN (PKD), VOR. This new RNAV T-route would also extend over the new waypoint (BRNRD) that is being established over the existing location of the Brainerd, MN (BRD), VORTAC. This T-route would mitigate the loss of the V-82 and V-413 airway segments proposed to be removed.

All radials in the route descriptions below that do not reflect True (T)/Magnetic (M) degree radial information are unchanged and stated in True degrees.

Jet routes are published in paragraph 2004, VOR Federal airways are published in paragraph 6010(a), and

United States Area Navigation Routes (low altitude T-routes) are published in paragraph 6011, of FAA Order 7400.11A dated August 3, 2016, and effective September 15, 2016, which is incorporated by reference in 14 CFR 71.1. The Jet routes, VOR Federal airways, and RNAV T-routes listed in this document would be subsequently published in the Order.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, “Environmental Impacts: Policies and Procedures” prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11A, Airspace Designations and Reporting Points, dated August 3, 2016 and

effective September 15, 2016, is amended as follows:

Paragraph 2004 Jet Routes.

* * * * *

J-25 [Amended]

From INT United States/Mexico border and Brownsville, TX, 221° radial; Brownsville; INT Brownsville 358° and Corpus Christi, TX, 178° radials; Corpus Christi; INT Corpus Christi 311° and San Antonio, TX, 174° radials; San Antonio; Centex, TX; Waco, TX; Ranger, TX; Tulsa, OK; Kansas City, MO; Des Moines, IA; Mason City, IA; to Gopher, MN.

* * * * *

Paragraph 6010 Domestic VOR Federal Airways.

* * * * *

V-55 [Amended]

From Dayton, OH; Fort Wayne, IN; Goshen, IN; Gipper, MI; Keeler, MI;

Pullman, MI; Muskegon, MI; INT Muskegon 327° and Green Bay, WI, 116° radials; Green Bay; Stevens Point, WI; INT Stevens Point 281° and Eau Claire, WI, 107° radials; Eau Claire; to Siren, WI. From Park Rapids, MN; Grand Forks, ND; INT Grand Forks 239° and Bismarck, ND, 067° radials; to Bismarck.

* * * * *

V-82 [Amended]

From Baudette, MN; to INT Baudette 194° and Park Rapids, MN, 003°T/359°M radials. From Gopher, MN; Farmington, MN; Rochester, MN; Nodine, MN; to Dells, WI.

* * * * *

V-161 [Amended]

From Three Rivers, TX; Center Point, TX; Llano, TX; INT Llano 026° and Millsap, TX, 193° radials; Millsap; Bowie, TX; Ardmore, OK; Okmulgee, OK; Tulsa, OK; Oswego, KS; Butler, MO;

Napoleon, MO; Lamoni, IA; Des Moines, IA; Mason City, IA; Rochester, MN; Farmington, MN; to Gopher, MN. From International Falls, MN; to Winnipeg, MB, Canada, excluding the airspace within Canada.

* * * * *

V-218 [Amended]

From International Falls, MN; Grand Rapids, MN; Gopher, MN; Waukon, IA; to Rockford, IL. From Keeler, MI; to Lansing, MI.

* * * * *

V-413 [Amended]

From Gopher, MN; INT Gopher 109° and Eau Claire, WI, 269° radials; Eau Claire; to Ironwood, MI.

* * * * *

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T-330 Grand Forks, ND (GFK) to Gopher, MN (GEP) [New]

| | | |
|-----------------------|---------|--|
| Grand Forks, ND (GFK) | VOR/DME | (Lat. 47°57'17.39" N., long. 097°11'07.33" W.) |
| BYZIN, ND | WP | (Lat. 47°29'03.97"N., long. 096°13'28.09"W.) |
| TAMMR, MN | WP | (Lat. 46°53'33.48"N., long. 095°42'56.42"W.) |
| WATAM, MN | FIX | (Lat. 46°25'52.91"N., long. 095°09'06.92"W.) |
| MAFLN, MN | WP | (Lat. 46°02'22.73"N., long. 094°37'21.86"W.) |
| DAYLE, MN | FIX | (Lat. 45°37'24.75"N., long. 093°55'34.20"W.) |
| Gopher, MN (GEP) | VORTAC | (Lat. 45°08'44.47"N., long. 093°22'23.45"W.) |

* * * * *

T-354 Park Rapids, MN (PKD) to Siren, WI (RZN) [New]

| | | |
|-----------------------|---------|--|
| Park Rapids, MN (PKD) | VOR/DME | (Lat. 46°53'53.34"N., long. 095°04'15.21"W.) |
| BRNRD, MN | WP | (Lat. 46°20'53.81"N., long. 094°01'33.54"W.) |
| Siren, WI (RZN) | VOR/DME | (Lat. 45°49'13.60"N., long. 092°22'28.26"W.) |

* * * * *

T-383 Gopher, MN (GEP) to BLUOX, MN [New]

| | | |
|------------------|--------|--|
| Gopher, MN (GEP) | VORTAC | (Lat. 45°08'44.47"N., long. 093°22'23.45"W.) |
| BRNRD, MN | WP | (Lat. 46°20'53.81"N., long. 094°01'33.54"W.) |
| BLUOX, MN | FIX | (Lat. 47°34'33.13" N., long. 095°01'29.11" W.) |

* * * * *

Issued in Washington, DC, on January 10, 2017.

Leslie M. Swann,

Acting Manager, Airspace Policy Group.

[FR Doc. 2017-01034 Filed 1-18-17; 8:45 am]

BILLING CODE 4910-13-P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 1 and 23

RIN 3038-AE36

Recordkeeping

AGENCY: Commodity Futures Trading Commission.

ACTION: Proposed rule.

SUMMARY: The Commodity Futures Trading Commission (the "Commission") is proposing to amend the recordkeeping obligations set forth in certain provisions of the Commission's regulations. The proposed amendments would permit recordkeepers to leverage advances in information technology as a means to reduce costs associated with the retention and production of paper and electronic records and to decrease the risks of cybersecurity threats, while maintaining necessary safeguards to ensure the integrity, availability, and accessibility of records required to be kept pursuant to the Commodity Exchange Act (the "CEA") or Commission regulations. In addition to providing recordkeepers with greater flexibility regarding the retention and

production of regulatory records, the proposed amendments would remove the requirements for electronic records to be kept in their native file format and for recordkeepers to enter into an arrangement with a third-party technical consultant with respect to electronically stored information.

DATES: Comments must be received on or before March 20, 2017.

ADDRESSES: You may submit comments, identified by RIN 3038-AE36, by any of the following methods:

- *CFTC Web site:* <https://comments.cftc.gov>. Follow the instructions for submitting comments through the Comments Online process on the Web site.

- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading

Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.

- *Hand Delivery/Courier*: Same as Mail, above.
- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the instructions for submitting comments. Please submit your comments using only one method.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to www.cftc.gov. You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act ("FOIA"), a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.¹

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from www.cftc.gov that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the rulemaking will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the FOIA.

FOR FURTHER INFORMATION CONTACT:

Eileen T. Flaherty, Director, (202) 418-5326, eflaherty@cftc.gov; Frank Fisanich, Chief Counsel, (202) 418-5949, ffisanich@cftc.gov; Andrew Chapin, Associate Chief Counsel, (202) 418-5465, achapin@cftc.gov; Katherine Driscoll, Associate Chief Counsel, (202) 418-5544, kdriscoll@cftc.gov; C. Barry McCarty, Special Counsel, (202) 418-6627, cmccarty@cftc.gov; or Jacob Chachkin, Special Counsel, (202) 418-5496, jchachkin@cftc.gov, Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, 1155 21st Street NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Background

A. Regulation 1.31 Recordkeeping Requirements

Commission regulation 1.31 sets forth recordkeeping requirements for all books and records required to be kept by the CEA and Commission regulations,

and implements the Commission's inspection and examination authority over such records.² Examination of books and records is one of the Commission's principal means of determining compliance with the CEA and Commission regulations.³

Paragraph (a) of § 1.31 describes the general requirement that books and records must be kept for five years and be readily accessible during the first two years. Different retention periods apply to certain oral communications and records of any swap or related cash or forward transaction. Paragraph (a) also provides that paper records shall be kept in their original form and electronic records in the format in which they were originally created (referred to as "native file format"), and defines the inspection and production rights of representatives of the Commission and the Department of Justice. In particular, § 1.31(a)(2) requires that production shall be made in a form specified by any representative of the Commission upon the representative's request.

Paragraph (b) of § 1.31 allows books and records to be stored on electronic storage or micrographic media, such as microfiche, provided that the recordkeeper complies with various technical requirements designed to ensure the integrity, availability, and accessibility of the electronically stored information. For example, this paragraph provides that any digital storage or medium or system must preserve the records exclusively in a non-rewritable, non-erasable format, known more commonly as the "write once, read-many," or "WORM" requirement. In addition, paragraph (b) requires a recordkeeper utilizing electronic storage media to develop and maintain an audit system to provide accountability over both the initial entry and the entry of each change to any original or duplicate record. Further, any person who uses only electronic storage media to preserve some or all of its required records shall enter into an arrangement with a third-party technical consultant ("Technical Consultant") capable of furnishing to the Commission or its representative any information stored electronically promptly upon request.

Paragraph (c) of § 1.31 requires recordkeepers to provide notice and a representation to the Commission prior to the initial use of an electronic storage

system that the electronic storage system satisfies the requirements set forth in § 1.31(b). Lastly, paragraph (d) of § 1.31 requires certain paper records, such as trading cards and documents with written trading information, to be maintained in hard-copy for the applicable retention period.

The Commission recognizes that the most recent substantive amendments to § 1.31 were made in 2012⁴ and, prior to that, in 1999.⁵ The 2012 Amendment clarified the retention period for records of oral communications leading to the execution of any swap or related cash or forward transaction for swap dealers and major swap participants, and to require that electronic records be retained in their native file format. The 1999 Amendment implemented all of the technical provisions regarding the use of electronic storage media in § 1.31(b) and (c), including the requirement to retain a Technical Consultant.

B. Petitions for Rulemaking

The Commission has received petitions for rulemaking from various industry groups requesting that the Commission amend § 1.31.⁶ Generally, the Petitioners state that certain requirements set forth in § 1.31 that were reasonable and prudent when adopted have become outdated and irrelevant. Absent any change, the Petitioners stated that recordkeepers must choose between accepted electronic distributed storage systems, which are essential for disaster recovery and privacy protection, and compliance with the letter of the law.

Specifically, the Petitioners have requested the following changes to § 1.31:

1. Amend § 1.31(a) to no longer require electronic records to be kept in their native file format;
2. Amend § 1.31(b) to eliminate the WORM requirement for electronic records; and

⁴ Adaptation of Regulations to Incorporate Swaps, 77 FR 66288 (Nov. 2, 2012) (the "2012 Amendment").

⁵ Recordkeeping, 64 FR 28735 (May 27, 1999) (the "1999 Amendment").

⁶ Petition for Rulemaking to Amend 1.31, 4.7(b) and (c), 4.23 and 4.33, Managed Funds Association, Investment Adviser Association, and Alternative Investment Management Association, dated July 21, 2014, and Petition for Rulemaking to Amend CFTC Regulations 4.12(c)(3), 4.23 and 4.33 Investment Company Institute, dated March 11, 2014 (collectively, the "Petitioners"). Regulations 4.23 and 4.33 set forth the recordkeeping requirements for commodity pool operators ("CPOs") and commodity trading advisors ("CTAs"), respectively. These regulations require CPOs and CTAs to keep certain books and records in accordance with § 1.31.

¹ 17 CFR 145.9. Commission regulations referred to herein are found at 17 CFR chapter I.

² Proposed Rule Requiring that Records Subject to Inspection, and Copies Thereof, Be Provided to the Commission, 43 FR 50699 (Oct. 31, 1978).

³ General Regulations; Inspection of Books and Records, 46 FR 21-01 (Jan. 2, 1981).

3. Amend § 1.31(b) to eliminate the requirement to enter into an agreement with a Technical Consultant.

With respect to native file format, the Petitioners note that programs used to store records electronically routinely become outdated and obsolete, and/or are no longer supported by information technology manufacturers. As a result, as represented by the Petitioners, recordkeepers must bear the burden of retaining these electronic records while updating to other, advanced systems for newly created records. Accordingly, the Petitioners request that the Commission amend § 1.31 in a manner that does not specify the format of any particular electronic record, so long as there is demonstrable and auditable integrity and fidelity in the preservation of the underlying data and contents.

With respect to the WORM requirement, the Petitioners assert that it is based on a concept that was state of the art nearly twenty years ago. Records are no longer stored electronically on optical disks or CD-ROMs. Currently, state of the art information technology relies on storage subject to restricted access and includes storage logs that reflect every single change to a file, in addition to archived copies. Absent any change, the Petitioners state that recordkeepers will be required to maintain dual systems that preserve the WORM requirement but also permit them to more properly secure and manage electronic records. Accordingly, the Petitioners request that the Commission amend § 1.31 to remove the WORM requirement.

With respect to the Technical Consultant, the Petitioners state that the need to retain and train a third-party to serve as a surrogate for access and production to electronic records is no longer necessary given the in-house technical expertise regarding information technology throughout the industry. In addition to the increased costs associated with retaining a Technical Consultant, the Petitioners also note that providing additional third parties with access to sensitive, confidential, and proprietary information greatly increases the risk of cybersecurity intrusions. Accordingly, the Petitioners request that the Commission amend § 1.31 to remove the requirement to retain a Technical Consultant.

In support of their request, Petitioners note that the Securities and Exchange Commission (“SEC”) adopted a recordkeeping rule for investment companies and investment advisers consistent with the changes they

propose.⁷ Rule 204–2(g) under the Investment Advisers Act of 1940 sets forth general principles that investment advisers must follow when arranging, accessing and reproducing their records. Similar provisions apply to the operators of investment companies pursuant to Rule 31a–2. In particular, Rule 204–2(g) does not tether advisers to any particular format, *i.e.*, native file format, nor does it require the use of Technical Consultants. The Petitioners note that in the 1999 Amendment the Commission expressly stated its intent to track existing recordkeeping provisions similar to those adopted by the SEC,⁸ and that, more recently in 2013, the Commission acknowledged that there are certain advantages to crafting regulations that “allow the Commission to fulfill its regulatory mandate while, at the same time, avoiding unnecessary regulatory burdens on dually-regulated [entities] with respect to . . . Commission recordkeeping requirements.”⁹ Accordingly, the Petitioners request that the Commission amend § 1.31 in a manner consistent with SEC Rule 204–2(g).

II. The Proposal

The Commission noted in the 1999 Amendment the importance of conducting an ongoing review of the standards articulated in the recordkeeping regulation to ensure that the requirements reflect to the extent possible the reality of established technological innovation.¹⁰ At the same time, the Commission recognized the value of consultation with the derivatives industry and its participants to determine how to best use available information technology that also is responsive to the Commission’s legitimate need to have access to complete and accurate records when necessary.¹¹

As the Petitioners highlighted, the Commission recognizes that recordkeeping has evolved significantly in the time since the last major revision to § 1.31 in 1999 from a paper-based system to electronically stored

information systems that leverage computers, databases, and even cloud computing. Back then, most records were created and maintained on paper, but recordkeepers began to explore better ways to store information electronically. Now the paradigm has shifted, and most information is produced and stored electronically on complex systems tailored to the needs of a given recordkeeper. These advances in information technology may have rendered certain technical elements of § 1.31 obsolete or outdated.

Accordingly, the Commission proposes to amend § 1.31 to reorganize and update the existing recordkeeping regulation, eliminating certain outdated provisions while still maintaining the ability of the Commission to examine and inspect required records. The Proposal is intended to be technology neutral so as technology develops the regulation should withstand such changes. The updates include new definitions, deletion of outdated terms, and revision of certain provisions to reflect advances in information technology. The Commission notes that many of the existing provisions and principles in § 1.31 have been retained, albeit in a revised format. The proposed regulation is divided into five subsections: (a) Definitions; (b) regulatory records policies and procedures; (c) duration of retention; (d) form and manner of retention; and (e) inspection and production of regulatory records.

A. Regulation 1.31(a): Definitions

The Commission proposes to reorganize § 1.31 by revising paragraph (a) to define certain terms to be referenced elsewhere within the revised regulation. Specifically, the Commission proposes to define the terms “electronic regulatory records”, “records entity”, and “regulatory records”. The Commission believes that defining these terms will provide greater clarity regarding the recordkeeping obligations applicable to all persons subject to § 1.31, particularly for those obligations related to electronic records.

For the ease of understanding and applying the proposed amendments to § 1.31, the Commission proposes to define “records entity” to mean “any person required by the Act or Commission regulations to keep regulatory records.” The Commission notes that numerous Commission regulations set forth particular requirements for CEA Section 1a(40) “registered entities”—such as derivatives clearing organizations, designated contract markets, swap execution facilities, and swap data

⁷ See Electronic Recordkeeping by Investment Companies and Investment Advisers, 66 FR 29224 (May 30, 2001). Given that intermediaries may engage in both securities and derivatives transactions, operators of investment companies may be required to register with the Commission as CPOs, and investment advisers similarly may be required to register as CTAs.

⁸ 64 FR at 28735.

⁹ See Harmonization of Compliance Obligations for Registered Investment Companies Required to Register as Commodity Pool Operators, 78 FR 52308 at 52309 (Aug. 22, 2013).

¹⁰ 64 FR at 28736.

¹¹ *Id.*

repositories—and for registrants—such as futures commission merchants, introducing brokers, CPOs, CTAs, floor brokers, floor traders, retail foreign exchange dealers, swap dealers, and major swap participants—to keep certain books and records in accordance with § 1.31. The Commission notes, however, that certain persons that are neither a registered entity nor a registrant may be required to keep certain books and records in accordance with § 1.31, as well.¹²

The Commission also proposes to replace existing references to “books and records” within § 1.31 with the term “regulatory records” and to differentiate between electronic and paper regulatory records. The Commission proposes to define “regulatory records” to mean “all books and records required to be kept by the Act or Commission regulations.” As a subset, the Commission proposes to define within § 1.31(a) “electronic regulatory records” to mean “all regulatory records other than paper regulatory records exclusively created and maintained by a records entity on paper.” The Commission has separately proposed Regulation Automated Trading and certain requirements regarding source code and manner of production of source code.¹³ This proposal does not address source code or the production of source code.

The Commission recognizes that certain regulatory records are not created electronically and that certain records entities may elect not to convert any paper regulatory records into an electronic format. By differentiating between paper and electronic regulatory records, the Commission can better preserve existing recordkeeping obligations applicable solely to records entities that do not create anything other than paper regulatory records.¹⁴

The Commission also believes that the term “books and records” in the traditional sense may no longer adequately convey that § 1.31 recordkeeping obligations extend to all associated electronic data. However, contrary to prior revisions to § 1.31

where the Commission specifically delineated the types of allowable media for electronic records storage,¹⁵ the Commission believes it is now appropriate to focus the recordkeeping obligations on the scope of required records, rather than a specific storage medium. Accordingly, the Commission proposes to further define the term “regulatory records” by adding the following descriptive language to include: Any record of any correction or other amendment to such books and records, provided that, with respect to such books and records stored electronically, regulatory records shall also include: (i) All data produced and stored electronically that describes, directly or indirectly, the characteristics of such books and records, including, without limitation, data that describes how, when, and, if relevant, by whom such electronically stored information was collected, created, accessed, modified, or formatted; and (ii) any data necessary to access, search, or display any such books and records.

The proposed language would more clearly state the existing requirement to maintain all prior versions of any regulatory record, no matter how modified. This is not a new recordkeeping obligation. Since 1993 the Commission has required electronic records to be created and maintained in a non-erasable, non-rewritable format for the retention period.¹⁶ Because the existing regulation requires electronic records be preserved exclusively in a non-rewritable, non-erasable format, it follows that each version of an electronic record must be created and maintained in a non-erasable, non-rewritable format. Therefore, the Commission is confirming that both the initial record and all subsequent versions are records within the definition and must be created, maintained, accessible, and produced consistent with the regulation.¹⁷

The proposed language also would clarify that electronically stored regulatory records are not limited to the data within a particular database or application, for example, but includes

the electronic information that identifies the manner in which any regulatory record is altered. The Commission understands that this information is more commonly known as “metadata,” and, at its core, is data about data. Regardless of the label, the Commission understands that metadata generally refers to any hidden text, formatting codes, formulae, history, tracking, and other information associated with an electronic file or data. Metadata is integral to the Commission’s ability to carry out both the inspection and investigation functions it is charged with under the CEA. To fully understand the data within a database, for example, requires knowledge of data relationships, what the information represents, and how it was generated. Once properly assembled and formatted in the form of a report, data within a database is readily understandable.

The Commission does not find it necessary at this time to define specific, technical terms related to information technology and electronically stored information, such as metadata or databases, as these technical terms may change over time. The Commission believes these are terms generally understood by practitioners notwithstanding a lack of a universal agreement on exact definitions.

The Commission notes that the requirement to provide data about data is not new. As set forth in current § 1.31(a)(2), production of any books and records shall be made “in a form specified by any representative of the Commission.” For the purpose of facilitating production requests pursuant § 1.31(a)(2), the Commission’s Division of Enforcement has developed and continually updates a document entitled “CFTC Data Delivery Standards.”¹⁸ Such standards describe the technical requirements for electronic document production to the Commission and specifically provides for the production of metadata associated with electronic records.

Finally, the Commission further proposes not to retain within the definition section certain definitions in the existing regulation, such as “native

¹² For example, Part 18 of the Commission’s regulations requires every trader who owns, holds or controls a reportable futures or option to “keep books and records showing all details concerning all positions and transactions in the commodity swap. . . .” 17 CFR 18.05. Traders are not limited to any Commission registrant or registered entity.

¹³ See Supplemental notice of proposed rulemaking, Regulation Automated Trading, 81 FR 85334 (Nov. 25, 2016).

¹⁴ Records entities who are currently in compliance with current § 1.31 will continue to be in compliance with proposed § 1.31, provided that they have written policies and procedures that meet the requirements of the Proposal.

¹⁵ See 36 FR 22286 (Nov. 24, 1971) (permitted the use of microfilm as a medium for maintaining certain records); 58 FR 27458 (May 10, 1993) (permitted the use of optical disk and CD-ROM); 64 FR 28735 (May 27, 1999) (permitted the use of other micrographic and electronic storage media).

¹⁶ See § 1.31(b)(1)(iii)(A).

¹⁷ Each version of a record must be retained for the applicable retention period which is based off the most recent version. For example, the initial record is created on Day 1 and the amended record is created on Year 4, Day 359. The amended record resets the retention period clock to Day 1 for both the initial record and amended record to ensure a comprehensive audit trail.

¹⁸ The Commission publishes the CFTC Data Delivery Standards on its Web site at: <http://www.cftc.gov/idc/groups/public/@lrenforcementactions/documents/file/enfdatadeliverystandards052716.pdf>. The Commission notes that other federal agencies, such as the SEC (<https://www.sec.gov/divisions/enforce/datadeliverystandards.pdf>), the Department of Justice (<https://www.justice.gov/atr/case-document/file/494686/download>) and the Department of Treasury Office of Foreign Asset Control (https://www.treasury.gov/resource-center/sanctions/OFAC-Enforcement/Documents/ofac_data_delivery.pdf) have similar data delivery standards.

file format”, “micrographic media” and “electronic storage media.” The Commission believes that the proposed revisions to § 1.31, described in greater detail below, obviate the need to retain these defined terms.

Request for comment: The Commission requests comment from all interested parties and the general public regarding the proposed definitions in § 1.31(a). The Commission encourages all comments including background information, actual market examples, best practice principles, and estimates of any asserted costs and expenses. Regarding the proposed definitions, the Commission specifically requests comment on the following questions:

- Should any of the proposed definitions be revised? If yes, please provide alternative suggestions.
- Should any of the proposed definitions be deleted?
- Should any previous definitions proposed for deletion, *e.g.*, “micrographic media,” be included in the revised regulation?
- Should other definitions be added, such as “metadata”, or “database”, or “paper regulatory records”?

B. Regulation 1.31(b): Regulatory Records Policies and Procedures

The Commission proposes to revise and re-state in new § 1.31(b) ongoing compliance obligations regarding written regulatory records policies and procedures currently set forth in § 1.31(b)(3). Specifically, the Commission proposes in revised § 1.31(b) to require all records entities to establish, maintain, and implement written policies and procedures reasonably designed to ensure that the records entity complies with its obligations under § 1.31, including without limitation, appropriate training of officers and personnel of the records entity regarding their responsibility for ensuring compliance with the obligations of the records entity under this section, and regular monitoring for such compliance.¹⁹

The Commission believes that the proposed obligations regarding written policies and procedures are generally consistent with the existing regulation and accepted industry practices. Currently, § 1.31(b)(3) requires anyone using electronic storage media to develop and maintain written operational procedures and controls (an “audit system”) designed to provide

accountability over both the initial entry of required records to the electronic storage media and the entry of each change made to any original or duplicate record maintained on the electronic storage media. Moreover, the written operational procedures and controls must be made available for examination at all times by any representative of the Commission.

With respect to training, the Commission does not find it necessary to prescribe specific requirements regarding the frequency and format of any training. Consistent with its approach towards mandatory ethics training for registrants, the Commission views the training on written policies and procedures as an ongoing responsibility rather than an episodic one.²⁰ The obligation to remain current on the legal requirements regarding compliance with § 1.31 is one that a records entity ignores at its peril. The Commission takes a similar view towards the proposed obligation for each records entity to monitor compliance with the entity’s policies and procedures on a “regular” basis.

Request for comment: The Commission requests comment from all interested parties and the general public regarding the proposed obligations regarding regulatory records policies and procedures in proposed § 1.31(b). The Commission encourages all comments including background information, actual market examples, best practice principles, and estimates of any asserted costs and expenses. Regarding the written policies and procedures requirements, the Commission specifically requests comment on the following questions:

- Should the training requirement be scaled down, phased-in, or eliminated depending on the number of employees, or depending on the nature of the entity’s business?

C. Regulation 1.31(c): Duration of Retention

The Commission proposes to re-state and clarify in revised § 1.31(c) the existing retention period requirements for categories of regulatory records currently set forth in § 1.31(a). Specifically, proposed § 1.31(c)(1) would state that a records entity shall keep regulatory records of any swap or related cash or forward transaction (as defined in § 23.200(i)), other than regulatory records of oral

communications, from the date the regulatory record was created until the termination, maturity, expiration, transfer, assignment, or novation date of the transaction and for a period of not less than five years after such date. The Commission proposes to incorporate by reference the definition of the term “related cash or forward transaction” in § 23.200(i).

Similarly, proposed § 1.31(c)(2) would state that a records entity that is required to retain oral communications shall keep regulatory records of such oral communications for a period of not less than one year from the date of such communication. This is consistent with the existing standard. The Commission proposes, however, to eliminate references to §§ 1.35(a) and 23.202(a)(1) and (b)(1) with respect to “oral communications” as future changes to those regulations, or the promulgation of new types of oral communications requirements, would require the Commission to contemporaneously amend § 1.31. Based on the foregoing proposed amendments, the Commission believes that the existing provision in § 23.203(b)(2) regarding the retention period of swaps-related information for swap dealers and major swap participants is redundant and therefore should be repealed. For all other regulatory records not addressed in proposed § 1.31(c)(1) and (2), proposed § 1.31(c)(3) would require a records entity to keep such records for a period of not less than five years from the date on which such record was created. However, proposed § 1.31(c)(4) would retain the existing retention period for regulatory records exclusively created and maintained on paper, *i.e.*, records must be readily accessible for no less than two years. This standard is consistent with the SEC’s standard applicable to investment advisers and operators of investment companies.²¹ Consistent with this change, the Commission proposes to remove the duplicative language from § 23.203(b)(1).

Request for comment: The Commission requests comment from all interested parties and the general public regarding the proposed retention periods in § 1.31(c). The Commission encourages all comments including background information, actual market

¹⁹ SEC Rule 204–2(a)(17) requires each investment adviser to maintain as part of its recordkeeping obligations, among other things, a copy of the adviser’s policies and procedures, and any records documenting the adviser’s annual review of those policies and procedures.

²⁰ 66 FR 53510 (Oct. 23, 2001) (“Rules Relating to Intermediaries of Commodity Interest Transactions”). With respect to mandatory ethics training, the Commission replaced prescriptive requirements set forth in § 3.34 with a Statement of Acceptable Practices.

²¹ SEC Rule 204–2(e) states that all books and records shall be maintained and preserved in an easily accessible place for a period of not less than five years from the end of the fiscal year during which the last entry was made on such record, the first two years in an appropriate office of the investment adviser. SEC Rule 31a–2 similarly requires the operator of an investment company to retain records for a minimum of six years the first two years in an easily accessible place.

examples, best practice principles, and estimates of any asserted costs and expenses. Regarding the proposed retention periods, the Commission specifically requests comment on the following questions:

- Are the proposed recordkeeping retention periods appropriate? If not, what modifications to the retention periods should be made?
- Given the advances in information technology, such as cloud storage, should the Commission extend the standard five year retention period?
- Is there a longer or shorter period of retention that would be appropriate for some records, and if so please specify which records and such time-frames?

D. Regulation 1.31(d): Form and Manner of Retention

The Commission proposes to revise § 1.31(d) to describe recordkeeping requirements regarding the form and manner in which regulatory records are retained by records entities. These proposed revisions are designed to ensure the integrity and availability of all regulatory records. The Commission is cognizant that other provisions of the Act and Commission regulations distinguish between different classes of records entities. In particular, the Commission recognizes that records entities that are not registered or required to be registered with the Commission in any capacity, nor are one of the enumerated “registered entities” defined in Section 1a(40) of the CEA or so required to be registered or designated,²² currently are not required to comply with the full panoply of recordkeeping requirements.²³ It is the Commission’s goal to preserve this distinction, especially in those cases

where a records entity exclusively maintains paper regulatory records.

The Commission proposes to re-state and revise in new § 1.31(d) certain requirements for regulatory records currently set forth in § 1.31(b)(1) through (3). In doing so, the Commission proposes to adopt a general standard in § 1.31(d)(1) to require each records entity to retain all regulatory records in a form and manner necessary to ensure the records’ and recordkeeping systems’ authenticity and reliability. This general requirement would not distinguish between paper and non-paper regulatory records.

With respect to electronic regulatory records, the Commission proposes to set forth in new § 1.31(d)(2)(i) through (iii) additional controls for records entities retaining electronic regulatory records. In particular, each records entity would be required to:

- (A) Have systems that maintain security, signature, chain of custody elements, and data as necessary to ensure the authenticity of the information contained in regulatory records and to monitor compliance with the Act and Commission regulations;
- (B) Have systems that ensure the records entity is able to produce regulatory records in accordance with this section, and ensure the availability of regulatory records in the event of an emergency or other disruption of the records entity’s record retention systems; and
- (C) Create and maintain an up-to-date inventory that identifies and describes each system that maintains information necessary for accessing or producing regulatory records.

The Commission believes that these requirements are not new and are consistent with certain SEC requirements.²⁴ Currently, § 1.31(b)(1)(ii)(B) mandates that electronic storage media verifies automatically the quality and accuracy of the storage media recording process. Existing rules require any records entity that utilizes electronic storage media to organize and maintain an accurate index of all information such that the location of any record may be immediately ascertained. Among other requirements, existing § 1.31(b)(3) requires any records

entity that utilizes electronic storage media to keep current a copy of the physical and logical format of the electronic storage media, the file format of all different information types maintained, documentation and information necessary to access records and indexes maintained on the electronic media.

Finally, based on the foregoing proposed amendments, the Commission believes that the existing provision in § 1.35(a)(5)(i) regarding the form and manner in which records of commodity interest and cash forward transactions should be maintained is redundant and therefore should be repealed.

Request for comment: The Commission requests comment from all interested parties and the general public regarding the proposed standards for form and manner of retention of regulatory records in § 1.31(d). The Commission encourages all comments including background information, actual market examples, best practice principles, and estimates of any asserted costs and expenses. With respect to the authenticity and reliability of regulatory records and recordkeeping systems, the Commission specifically requests comment on the following questions:

- Should the Commission routinely publish guidelines regarding the technical standards for electronic regulatory records?

With respect to potential impacts of the Proposal, the Commission specifically requests comment on the following questions:

- Would the Proposal require market participants to change their existing recordkeeping procedures under the Proposal? What, if any, transition or ongoing costs would result from such changes? Please provide details and estimates regarding any asserted costs.
- For entities who maintain digitized copies of paper records, what costs or other impacts would result under the Proposal?

E. Regulation 1.31(e): Inspection and Production of Regulatory Records

1. Inspection

The Commission proposes to re-state in revised § 1.31(e)(1) the right of inspection of the Commission and the United States Department of Justice (“DOJ”) in existing § 1.31(a)(1). Specifically, the Commission proposes § 1.31(e)(1) to state that all regulatory records shall be open to inspection by any representative of the Commission or the DOJ. The Commission previously determined that production of records is part of the Commission’s inspection

²² Section 1a(40) of the Act defines a “registered entity” to mean: (a) A board of trade designated as a contract market under section 5; (b) a derivatives clearing organization registered under section 5b; (c) a board of trade designated as a contract market under section 5f; (d) a swap execution facility registered under section 5h; (e) a swap data repository registered under section 21; and (f) with respect to a contract that the Commission determines is a significant price discovery contract, any electronic trading facility on which the contract is executed or traded.

²³ For example, part 20 of the Commission’s regulations sets forth requirements regarding large trader reporting for physical commodity swaps. Regulation 20.1 defines a “reporting entity” to mean a clearing member of a clearing organization or a swap dealer in one or more paired swaps or swaptions. Pursuant to § 20.6, only clearing organizations and reporting entities must keep all books and records in accordance with § 1.31. Any other person who exceeds the reportable level in any contract “shall keep books and records . . . in the record retention format that such person has developed in the normal course of its business operations.” All books and records kept pursuant to § 20.6, however, shall be furnished upon request to any Commission representative.

²⁴ With respect to electronic storage media, SEC Rule 204–2(g)(3) requires investment advisers to establish written procedures that: (1) Maintain and preserve the records, so as to reasonably safeguard them from loss, alteration, or destruction; (2) limit access to the records to properly authorized personnel and the SEC; and (3) reasonably ensure that any reproduction of a non-electronic original record on electronic storage media is complete, true, and legible when retrieved. SEC Rule 31a–2(f) sets forth similar requirements for the operators of investment companies.

powers.²⁵ Accordingly, the Commission has determined to limit reference to the DOJ in § 1.31 to a single reference in this paragraph. Any requirement for a records entity to produce regulatory records extends to DOJ as is currently the requirement.

Request for comment: The Commission requests comment from all interested parties and the general public regarding the proposed regulations set forth in § 1.31(e)(1). The Commission encourages all comments including background information, actual market examples, best practice principles, and estimates of any asserted costs and expenses.

2. Production

The Commission proposes to revise and re-state in new § 1.31(e)(2) the existing production requirement currently set forth in § 1.31(a)(2) and (b). Currently, a records entity is required to produce regulatory records in a form specified by any representative of the Commission, including the DOJ, upon the representative's request. If the requested book or record is stored either on micrographic media or electronic storage media, production shall be immediate.²⁶ Otherwise, all copies or originals shall be provided promptly.²⁷ The Commission proposes to amend this requirement in new § 1.31(e)(i) and (ii) to differentiate between the production of paper and electronic regulatory records, particularly with respect to the form and medium of requested electronic regulatory records.

With respect to the production of regulatory records exclusively created and maintained on paper, proposed § 1.31(e)(2) would require a records entity to produce such regulatory records promptly upon request. With respect to regulatory records other than paper regulatory records, proposed § 1.31(e)(3) would set forth the process by which a records entity must respond to a request from a Commission representative. In particular, § 1.31(e)(3)(i) would require a Commission representative to specify a reasonable form and medium in which a records entity must produce such regulatory records. Proposed

§ 1.31(e)(3)(ii) would require a records entity, at its own expense, to produce such regulatory records in the form and medium requested promptly, upon request, unless otherwise directed by the Commission representative.

The Commission recognizes that production, depending on the records, may require the records entity to engage multiple employees, officers, or directors in order to satisfy the production request, depending upon its size and scope. Historically, Commission staff has exercised broad discretion regarding production schedules and "typically exhibits flexibility. . . ." ²⁸ However, timely production is a Commission priority and the proposed "prompt" standard should not be interpreted as sanctioning any unnecessary delay. It is the Commission's understanding that most registrants maintain records electronically and therefore would be required under existing § 1.31 to produce said records immediately, subject to the discretion of Commission staff. The prompt production standard is therefore consistent with the existing standard. The Commission notes that the standard "promptly upon request" is also consistent with SEC Rule 17a-4 applicable to broker-dealers thereby maintaining a harmonized standard for entities that may be dually registered with the SEC and the CFTC.²⁹

In adopting this revised regulation, the Commission is cognizant of the need to balance the opportunities for recordkeepers to reduce costs and improve efficiencies regarding recordkeeping systems with the Commission's need for prompt access to complete and accurate records in a format that the Commission can process, *i.e.*, a useable format.³⁰ For the purposes of production, the Commission continues to believe that it is not sufficient to simply reduce electronic records to a paper format, *i.e.*, printing out data from a database and saving into a portable document file, or PDF. This type of production detracts from the Commission's ability to properly evaluate the integrity of the electronic records by accessing the associated metadata, for example. Based upon these principles, the Commission proposes to revise § 1.31 to permit a records entity that cannot promptly produce electronic regulatory records in

the form and medium requested by the Commission the opportunity to produce records in an alternative manner sufficient for the Commission to adequately inspect the records. The ultimate goal is not necessarily to obtain records in their "native file format," but rather in the most useable form and medium.

Finally, the Commission further proposes to adopt new § 1.31(e)(4) to preserve the existing right of a records entity to provide a representative of the Commission with an original regulatory record for reproduction by the representative in lieu of a copy currently set forth in § 1.31(a)(2). As with the existing provision, the Commission proposes to require the Commission representative to issue a receipt for the original regulatory record to the records entity upon request.

Request for comment: The Commission requests comment from all interested parties and the general public regarding the proposed inspection and production of regulatory records in § 1.31(e). The Commission encourages all comments including background information, actual market examples, best practice principles, and estimates of any asserted costs and expenses. Regarding the production of regulatory records, the Commission specifically requests comment on the following questions:

- Should the Commission impose a different standard with respect to the production of paper regulatory records or other regulatory records?
- Are there records entities that retain only paper regulatory records?

F. Other Matters

1. § 1.31(b)(4)—Technical Consultant

Consistent with the foregoing amendments and in response to the Petitioners' request, the Commission proposes to amend § 1.31(b)(4)(i) to remove the requirement for a records entity to enter into an arrangement with a Technical Consultant and provide the Technical Consultant with access to and the ability to download information from the records entity's electronic storage media to any acceptable medium. Further, the Commission proposes to remove the requirement set forth in § 1.31(b)(4)(ii) which requires the Technical Consultant to file with the Commission an acceptable undertaking regarding its ability and willingness to provide the Commission and DOJ with access to the information contained on the record entity's electronic storage media. The Commission concurs with the position taken by Petitioners that the information technology expertise within

²⁵ See 46 FR 21 (Jan. 3, 1981); *see also*, CFTC Letter 77-4 (Apr. 14, 1977).

²⁶ See § 1.31(b)(2)(i) and (ii). In addition, persons using electronic storage media must be ready at all times to provide, and immediately provide at the expense of the person required to keep such records, copies of such records on such compatible data processing media as defined in Commission regulation 15.00(d) which any representative of the Commission or the Department of Justice may request. Records must use a format and coding structure specified in the request. *See* § 1.31(b)(3)(i).

²⁷ *See* § 1.31(a)(2).

²⁸ FIA comment regarding proposed amendments to § 1.31. 64 FR 28735 at 28739 (May 27, 1999).

²⁹ SEC Rule 17a-1 similarly requires national securities exchanges and registered clearing agencies to "promptly furnish" records to any representative of the SEC upon request.

³⁰ *See* 77 FR at 66298 (referring to the 1999 Amendment).

the derivatives industry obviates the need for the Commission to require those records entities electing to store information electronically to engage a third party to ensure compliance with all applicable electronic recordkeeping obligations. However, to the extent that a records entity chose to use a third party or Technical Consultant, the records entity would remain responsible for compliance with the CEA and Commission regulations thereunder.

2. § 1.31(c)—Representation to the Commission

Consistent with the foregoing amendments and in response to the Petitioners' request, the Commission proposes to amend § 1.31 by removing existing § 1.31(c). This provision requires any person utilizing electronic storage media to provide a written representation to the Commission prior to the use of the system certifying that the system satisfies the requirements in existing paragraph (b)(1)(ii) and, where applicable, if the system will be using storage media other than optical disk or CD-ROM. Further, the written representation must include an affirmation from an individual consistent with § 1.10(d)(4), *i.e.*, the information provided is true and correct to the best knowledge and belief of the affirming individual. The Commission believes that the requirement set forth in proposed § 1.31(c)(2) regarding written policies and procedures for regulatory records obviates the need for any records entity to provide notice to the Commission regarding its compliance with § 1.31. Moreover, the Commission recognizes that references to optical disks and CD-ROM are outdated.

3. § 1.31(d)—Other Paper Regulatory Records

Consistent with the foregoing amendments, the Commission proposes to amend § 1.31 by removing current § 1.31(d). This provision states that certain paper records, such as trading cards and paper copies of electronically filed certified forms, must be retained in hard-copy for the required time period. The Commission believes that revised § 1.31 provides records entities with sufficient flexibility on how to retain regulatory records while maintaining the Commission's ability to access reliable regulatory information. Having eliminated the requirement for a records entity to retain regulatory records in a specific form and manner, the Commission believes that § 1.31(d) no longer serves any regulatory purpose.

Request for comment: The Commission requests comment from all interested parties and the general public

regarding the proposed deletion of existing provisions in § 1.31(b)(4), (c) and (d); and § 1.35(a)(5)(i). The Commission encourages all comments including background information, actual market examples, best practice principles, and estimates of any asserted costs and expenses.

4. Potential Technical Amendments

In conjunction with the Proposal, the Commission is reviewing its regulations for potential technical amendments related to § 1.31, including those part 4 regulations cited by Petitioners. This review may or may not result in a new proposed rulemaking.

Request for comment: The Commission requests comment from all interested parties and the general public regarding potential technical amendments to Commission regulations related to § 1.31. The Commission specifically requests comment whether the proposed changes to § 1.31 will resolve all outstanding issues regarding compliance with part 4 of the Commission's regulations identified by Petitioners. The Commission encourages all comments including background information, actual market examples, best practice principles, and estimates of any asserted costs and expenses.

III. Related Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA")³¹ requires Federal agencies, in promulgating regulations, to consider whether the rules they propose will have a significant economic impact on a substantial number of small entities and, if so, to provide a regulatory flexibility analysis regarding the economic impact on those entities.

As discussed above, because the Proposal relates to most recordkeeping obligations under the CEA and the Commission's regulations, it may affect the full spectrum of Commission registrants, all persons required to register but not registered with the Commission, and certain persons that are neither registered nor required to register with the Commission. The Commission has previously determined that certain registrants are not small entities for purposes of the RFA and, therefore, the requirements of the RFA do not apply to those entities.³² For

other registrants, however, the Commission has found it appropriate to consider whether such registrants should be deemed small entities for purposes of the RFA on a case-by-case basis, in the context of the particular Commission regulation at issue.³³ As certain persons affected by the Proposal, including Commission registrants, may be small entities for purposes of the RFA, the Commission considered whether this rulemaking would have a significant economic impact on any such persons.

As discussed above, the Proposal generally updates and simplifies existing Commission regulation 1.31 with new provisions that safeguard the same statutory-based principles previously identified by the Commission. It accomplishes this by deleting outdated terms and revising provisions to reflect advances in information technology, allowing records entities to benefit from evolving technological developments while maintaining necessary safeguards to ensure the reliability of the recordkeeping process.

The Commission believes that the proposed rules would impose only limited additional costs on small entities related to the requirement that they establish written recordkeeping policies and procedures. However, this new requirement is replacing existing requirements applicable to such persons in many cases, including the existing similar requirements discussed above to (i) Maintain an audit system and (ii) under certain circumstances, retain a Technical Consultant. Further, as part of the Proposal, the Commission is proposing to remove existing requirements that are expected to lower costs for all records entities, including small entities, by removing requirements that certain records be kept in paper form.

In light of the limited scope of the proposed changes and the added flexibility and expected cost-savings provided to small entities thereby, the Commission does not expect small entities that are records entities to incur

³¹ 5 U.S.C. 601 *et seq.*
³² See, e.g., Policy Statement and Establishment of Definitions of "Small Entities" for Purposes of the Regulatory Flexibility Act, 47 FR 18618 (Apr. 30, 1982) (futures commission merchants and commodity pool operators); Leverage Transactions, 54 FR 41068 (Oct. 5, 1989) (leverage transaction merchants); Regulation of Off-Exchange Retail Foreign Exchange Transactions and Intermediaries, 75 FR 55410, 55416 (Sept. 10, 2010) (retail foreign exchange dealers); and Registration of Swap Dealers and Major Swap Participants, 77 FR 2613, 2620 (Jan. 19, 2012) (swap dealers and major swap participants).

³³ See 47 FR at 18620 (commodity trading advisors and floor brokers); Registration of Floor Traders; Mandatory Ethics Training for Registrants; Suspension of Registrants Charged With Felonies, 58 FR 19575, 19588 (Apr. 15, 1993) (floor traders); and Introducing Brokers and Associated Persons of Introducing Brokers, Commodity Trading Advisors and Commodity Pool Operators; Registration and Other Regulatory Requirements, 48 FR 35248, 35276 (Aug. 3, 1983) (introducing brokers).

new costs, on a net basis, as a result of the Proposal. Consequently, the Commission finds that no significant economic impact on small entities will result from the Proposal.

Accordingly, the Chairman, on behalf of the Commission, hereby certifies pursuant to 5 U.S.C. 605(b) that the Proposal will not have a significant economic impact on a substantial number of small entities.

B. Paperwork Reduction Act

1. Background

The Paperwork Reduction Act of 1995 ("PRA")³⁴ imposes certain requirements on Federal agencies (including the Commission) in connection with their conducting or sponsoring any collection of information as defined by the PRA. The Proposal would result in a collection of information within the meaning of the PRA, as discussed below. The Commission therefore is submitting the Proposal to the Office of Management and Budget ("OMB") for review.

The Proposal contains a collection of information for which the Commission has previously received a control number from OMB. The title for this collection of information is "Adaptation of Regulations to Incorporate Swaps-Records of Transactions, OMB control number 3038-0090".³⁵ Collection 3038-0090 is currently in force with its control number having been provided by OMB.

The responses to the Proposal's collection of information are mandatory. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number issued by OMB.

As discussed above, in respect of collections of information, the Proposal would replace the existing audit system requirements with a requirement that records entities establish written recordkeeping policies and procedures. Such changes would result in revisions to collection 3038-0090. Therefore, the Commission proposes to revise collection 3038-0090 as described below.

2. Modification of Collection 3038-0090—Recordkeeping Policies and Procedures

The Commission estimates that the Proposal will require approximately 15,000 persons to develop and maintain

recordkeeping policies and procedures. This estimate includes approximately 8,792 registrants, 15 designated contract markets, 23 swap execution facilities, 4 swap data repositories, 15 designated clearing organizations, and 3,200 unregistered members of designated contract markets or swap execution facilities, with the balance reflecting the Commission's estimate of those persons that are required to register with the Commission, but have not so registered, and other persons neither registered nor required to register with the Commission.³⁶

Based on the above, the estimated additional hour burden for recordkeeping policies and procedures of 150,000 hours is calculated as follows:

Number of affected persons: 15,000.
Frequency of collection: Annually.

Estimated annual responses per registrant: 1.

Estimated aggregate number of annual responses: 15,000.

Estimated annual hour burden per registrant: 10.³⁷

Estimated aggregate annual hour burden: 150,000 (15,000 registrants × 10 hours per registrant).³⁸

3. Information Collection Comments

The Commission invites the public and other Federal agencies to comment on any aspect of the proposed information collection requirements discussed above. Pursuant to 44 U.S.C. 3506(c)(2)(B), the Commission solicits comments in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) evaluate the accuracy of the Commission's estimate of the burden of the proposed collection of information; (3) determine whether there are ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

Comments may be submitted directly to the Office of Information and Regulatory Affairs, by fax at (202) 395-6566, or by email at OIRASubmissions@omb.eop.gov. Please provide the Commission with a copy of submitted comments so that all comments can be summarized and addressed in the final rule preamble. Refer to the **ADDRESSES** section of this notice of proposed rulemaking for comment submission instructions to the Commission. A copy of the supporting statements for the collection of information discussed above may be obtained by visiting www.RegInfo.gov. OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

C. Cost-Benefit Considerations

Section 15(a) of the CEA³⁹ requires the Commission to consider the costs and benefits of its actions before issuing a regulation under the CEA. Section 15(a) further specifies that the costs and benefits shall be evaluated in light of the following five broad areas of market and public concern: (i) Protection of market participants and the public; (ii) efficiency, competitiveness and financial integrity of futures markets; (iii) price discovery; (iv) sound risk management practices; and (v) other public interest considerations. The Commission considers the costs and benefits resulting from its discretionary determinations with respect to the Section 15(a) considerations.

1. Costs

As discussed above in relation to the RFA, the Proposal generally updates and simplifies existing Commission regulation 1.31 by deleting outdated terms and revising provisions to reflect advances in information technology while safeguarding the statutory-based principles previously identified by the Commission. The Commission preliminarily believes that the Proposal would impose certain costs on records entities. These costs are those necessary to establish and maintain required written recordkeeping policies and procedures. The Commission believes that these costs will be quite limited. At

³⁶ With respect to registrants and registered entities, these numbers are based on the number of such persons so registered with the Commission as of November 2, 2016. With respect to the number of unregistered members of designated contract markets or swap execution facilities, see Agency Information Collection Activities: Proposed Collection Revision, Comment Request: Final Rule for Records of Commodity Interest and Related Cash or Forward Transactions, 80 FR 80327 (Dec. 24, 2015).

³⁷ This burden hour estimate reflects the Commission's assumption that many records entities already have policies and procedures that, in whole or in part, satisfy the proposed recordkeeping policies and procedures requirement.

³⁸ The Commission will also submit to OMB revisions to Collection 3038-0090 to reflect the Proposal's replacement of the audit system requirements in current Commission regulation 1.31.

³⁹ 7 U.S.C. 19(a).

³⁴ 44 U.S.C. 3501 *et seq.*

³⁵ See OMB Control No. 3038-0090, <http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=3038-0090#> (last visited Sep. 20, 2016).

the same time, the Commission preliminarily believes that the Proposal would also reduce current recordkeeping costs under Commission regulation 1.31, because the Proposal would increase flexibility provided to records entities and also eliminate certain requirements as described above (e.g., removing the requirements to have an audit system, to maintain electronic records in limited specified formats, and to retain a Technical Consultant).

2. Benefits

The Commission is committed to reviewing its regulations to ensure they keep pace with technological developments and industry trends, and reduce regulatory burden. The Commission believes that the Proposal will allow records entities to benefit from evolving technology while maintaining necessary safeguards to ensure the reliability of the recordkeeping process. By deleting outdated terms and revising provisions to reflect advances in information technology, the Proposal will allow records entities to utilize a wider range of currently available technology than previously allowed and remove requirements that the Commission believes are now obsolete, allowing records entities to reduce their costs. In addition, the Commission believes that the flexibility provided by the Proposal will, without further Commission rulemaking, allow records entities to adopt new technologies as such technologies evolve, allowing such persons to reduce their future costs.

Moreover, the Commission expects that the added flexibility provided by the Proposal will encourage records entities to utilize electronic storage rather than maintain paper regulatory records. The Commission expects that this conversion will benefit the Commission, the DOJ, and the commodity interest industry, generally, by making the universe of regulatory records more accessible and searchable.

In addition, as a result of the Proposal codifying industry practices to require recordkeeping policies and procedures and, in doing so, providing records entities with an opportunity to examine their own recordkeeping practices, the Commission expects that records entities may improve the quality of such practices and, thus, the accuracy and integrity of their regulatory records.

3. Section 15(a) Factors

Section 15(a) of the CEA requires the Commission to consider the costs and benefits of its actions before promulgating a regulation under the CEA or issuing certain orders. CEA

Section 15(a) further specifies that the costs and benefits shall be evaluated in light of five broad areas of market and public concern: (i) Protection of market participants and the public; (ii) efficiency, competitiveness, and financial integrity of futures markets; (iii) price discovery; (iv) sound risk management practices; and (v) other public interest considerations.

i. Protection of Market Participants and the Public

The Proposal will continue to protect the public by maintaining necessary safeguards to ensure the reliability of the recordkeeping process while allowing records entities to benefit from evolving technology.

ii. Efficiency, Competitiveness, and Financial Integrity of Markets

As discussed above, the Proposal may increase resource allocation efficiency by improving the way in which records are maintained. Otherwise, the Commission anticipates minimal change to the efficiency, competitiveness, and financial integrity of the markets.

iii. Price Discovery

The Commission believes that the Proposal may increase confidence and participation in the markets for the reasons discussed above. Nevertheless, the Commission does not anticipate a significant increase in liquidity or a significant improvement in price discovery as a result of this rulemaking.

iv. Sound Risk Management Practices

By improving recordkeeping policies and procedures, the Proposal may encourage records entities to analyze their recordkeeping practices and create or update policies and procedures related thereto.

v. Other Public Interest Considerations

The Commission has not identified any additional public interest considerations.

4. Request for Comments

The Commission invites public comment on its cost-benefit considerations, including the Section 15(a) factors described above. Commenters are also invited to submit any data or other information that they may have quantifying or qualifying the costs and benefits of the Proposal with their comment letters.

The Commission specifically seeks comment on the following:

- For those market participants with written operational procedures and controls that comply with current Commission regulation 1.31, what

transition costs, if any, will the Proposal's requirement for written policies and procedures entail?

- Are there any costs or benefits associated with the Proposal that the Commission has not considered in the Proposal? Please provide details and estimates regarding any asserted costs or benefits.

List of Subjects

17 CFR Part 1

Commodity futures, Reporting and recordkeeping requirements.

17 CFR Part 23

Authority delegations (Government agencies), Commodity futures, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Commodity Futures Trading Commission proposes to amend 17 CFR chapter I as follows:

PART 1—GENERAL REGULATIONS UNDER THE COMMODITY EXCHANGE ACT

- 1. The authority citation for part 1 continues to read as follows:

Authority: 7 U.S.C. 1a, 2, 5, 6, 6a, 6b, 6c, 6d, 6e, 6f, 6g, 6h, 6i, 6k, 6l, 6m, 6n, 6o, 6p, 6r, 6s, 7, 7a–1, 7a–2, 7b, 7b–3, 8, 9, 10a, 12, 12a, 12c, 13a, 13a–1, 16, 16a, 19, 21, 23, and 24 (2012).

- 2. Revise § 1.31 to read as follows:

§ 1.31 Regulatory records; retention and production.

(a) *Definitions.* For purposes of this section:

Electronic regulatory records means all regulatory records other than regulatory records exclusively created and maintained by a records entity on paper.

Records entity means any person required by the Act or Commission regulations in this chapter to keep regulatory records.

Regulatory records means all books and records required to be kept by the Act or Commission regulations in this chapter, including any record of any correction or other amendment to such books and records, provided that, with respect to such books and records stored electronically, regulatory records shall also include:

- (i) All data produced and stored electronically that describes, directly or indirectly, the characteristics of such books and records, including, without limitation, data that describes how, when, and, if relevant, by whom such electronically stored information was collected, created, accessed, modified, or formatted; and

(ii) Any data necessary to access, search, or display any such books and records.

(b) *Regulatory records policies and procedures.* Each records entity shall establish, maintain, and implement written policies and procedures reasonably designed to ensure that the records entity complies with its obligations under this section. Such policies and procedures shall provide for, without limitation, appropriate training of officers and personnel of the records entity regarding their responsibility for ensuring compliance with the obligations of the records entity under this section, and regular monitoring for such compliance.

(c) *Duration of retention.* Unless specified elsewhere in the Act or Commission regulations in this chapter:

(1) A records entity shall keep regulatory records of any swap or related cash or forward transaction (as defined in § 23.200(i) of this chapter), other than regulatory records of oral communications, from the date the regulatory record was created until the termination, maturity, expiration, transfer, assignment, or novation date of the transaction and for a period of not less than five years after such date.

(2) A records entity that is required to retain oral communications, shall keep regulatory records of oral communications for a period of not less than one year from the date of such communication.

(3) A records entity shall keep each regulatory record other than the records described in paragraph (c)(1) or (2) of this section for a period of not less than five years from the date on which the record was created.

(4) A records entity shall keep regulatory records exclusively created and maintained on paper readily accessible for no less than two years. A records entity shall keep electronic regulatory records readily accessible for the duration of the required record keeping period.

(d) *Form and manner of retention.* Unless specified elsewhere in the Act or Commission regulations in this chapter, all regulatory records must be created and retained by a records entity in accordance with the following requirements:

(1) *Generally.* Each records entity shall retain regulatory records in a form and manner that ensures the authenticity and reliability of such regulatory records in accordance with the Act and Commission regulations in this chapter.

(2) *Electronic regulatory records.* Each records entity maintaining electronic regulatory records shall establish

appropriate systems and controls that ensure the authenticity and reliability of electronic regulatory records, including, without limitation:

(i) Systems that maintain the security, signature, chain of custody elements, and data as necessary to ensure the authenticity of the information contained in electronic regulatory records and to monitor compliance with the Act and Commission regulations in this chapter;

(ii) Systems that ensure the records entity is able to produce electronic regulatory records in accordance with this section, and ensure the availability of such regulatory records in the event of an emergency or other disruption of the records entity's electronic record retention systems; and

(iii) The creation and maintenance of an up-to-date inventory that identifies and describes each system that maintains information necessary for accessing or producing electronic regulatory records.

(e) *Inspection and production of regulatory records.* Unless specified elsewhere in the Act or Commission regulations in this chapter, a records entity, at its own expense, must produce or make accessible for inspection all regulatory records in accordance with the following requirements:

(1) *Inspection.* All regulatory records shall be open to inspection by any representative of the Commission or the United States Department of Justice.

(2) *Production of paper regulatory records.* A records entity must produce regulatory records exclusively created and maintained on paper promptly upon request of a Commission representative.

(3) *Production of electronic regulatory records.* (i) A request from a Commission representative for electronic regulatory records will specify a reasonable form and medium in which a records entity must produce such regulatory records.

(ii) A records entity must produce such regulatory records in the form and medium requested promptly, upon request, unless otherwise directed by the Commission representative.

(4) *Production of original regulatory records.* A records entity may provide an original regulatory record for reproduction, which a Commission representative may temporarily remove from such entity's premises for this purpose. Upon request of the records entity, the Commission representative shall issue a receipt for any original regulatory record received. At the request of a Commission representative, a records entity shall, upon the return thereof, issue a receipt for the original

regulatory record returned by such representative.

■ 3. In § 1.35, revise paragraph (a)(5) to read as follows:

§ 1.35 Records of commodity interest and related cash or forward transactions.

(a) * * *

(5) *Form and manner.* All records required to be kept pursuant to paragraphs (a)(1), (2), (3), and (4) of this section, other than pre-trade communications, shall be kept in a form and manner that allows for the identification of a particular transaction.

* * * * *

PART 23—SWAP DEALERS AND MAJOR SWAP PARTICIPANTS

■ 4. The authority citation for part 23 continues to read as follows:

Authority: 7 U.S.C. 1a, 2, 6, 6a, 6b, 6b–1, 6c, 6p, 6r, 6s, 6t, 9, 9a, 12, 12a, 13b, 13c, 16a, 18, 19, 21.

Section 23.160 also issued under 7 U.S.C. 2(i); Sec. 721(b), Pub. L. 111–203, 124 Stat. 1641 (2010).

■ 5. In § 23.203, amend paragraph (b) as follows:

■ a. Revise paragraph (b)(1); and

■ b. Remove and reserve paragraph (b)(2).

The revisions to read as follows:

§ 23.203 Records; retention and inspection.

* * * * *

(b) * * * (1) The records required to be maintained by this chapter shall be maintained in accordance with the provisions of § 1.31 of this chapter, except as provided in paragraph (b)(3) of this section. All such records shall be open to inspection by any representative of the Commission, the United States Department of Justice, or any applicable prudential regulator. Records relating to swaps defined in section 1a(47)(A)(v) shall be open to inspection by any representative of the Commission, the United States Department of Justice, the Securities and Exchange Commission, or any applicable prudential regulator.

* * * * *

Issued in Washington, DC, on January 12, 2017, by the Commission.

Christopher J. Kirkpatrick,
Secretary of the Commission.

NOTE: The following appendices will not appear in the Code of Federal Regulations.

Appendices to Recordkeeping— Commission Voting Summary and Chairman's Statement

Appendix 1—Commission Voting Summary

On this matter, Chairman Massad and Commissioners Bowen and Giancarlo voted in the affirmative. No Commissioner voted in the negative.

Appendix 2—Statement of Chairman Timothy G. Massad

I have said many times that it is important for the CFTC to ensure its rules are up-to-date in light of technological changes, as outdated rules can create unnecessary burdens. That is why I'm pleased we are unanimously issuing this proposed rulemaking, which is in keeping with that goal.

Today's proposal will modernize recordkeeping and storage obligations set forth in CFTC rules, and make them technology neutral. By doing so, it will reduce costs for businesses and improve the quality of record preservation and production. Among other things, the proposal will provide greater flexibility when it comes to how records must be retained and produced. In this age where terabytes of storage easily fit in one's pocket, our rules should not refer to microfiche or require paper records.

Today's proposal is also an example of how the Commission is focusing on issues related to technological change generally in our markets. In this regard, there is much talk today about innovations that may come from financial technology. While it is the role of the private sector to develop innovations, I believe it is our role to ensure that the Commission's rules do not stand in the way of their potential. Today's proposal is a way to do just that.

I thank the CFTC staff for their work on this proposal and my fellow Commissioners for their support.

[FR Doc. 2017-01148 Filed 1-18-17; 8:45 am]

BILLING CODE 6351-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA-2016-N-1149]

Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products; Availability of Memorandum; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Reopening of comment period related to public hearing; availability of memorandum.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notification of public hearing, published in the **Federal Register** of September 1, 2016 (81 FR 60299) concerning our comprehensive review of our regulations and policies governing manufacturer communications regarding unapproved uses of approved or cleared medical products. FDA is also announcing that it has added a document to the docket for the public hearing entitled "Memorandum: Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products" (Memorandum). The Memorandum provides additional background on the issues FDA is considering as part of its comprehensive review, including a discussion of First Amendment considerations. In addition, elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of two draft guidance for industry that address manufacturer communications, one entitled "Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers," and the other entitled "Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers." FDA is reopening the comment period to provide the public an opportunity to review the Memorandum as it relates to the specific questions and issues identified in the notification of public hearing as well as review the two draft guidances and provide additional or new comments.

DATES: Submit either electronic or written comments by April 19, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-1149 for "Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products; Public Hearing; Requests for Comments." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kristin Davis, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4252, Silver Spring, MD 20993, 301-796-0418.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 1, 2016 (81 FR 60299), FDA published a notification of public hearing on firm communications regarding unapproved uses of approved or cleared medical products. FDA is currently engaged in a comprehensive review of its regulations and policies governing firms' communications about unapproved uses of approved or cleared medical products, and the comments on the notification of public hearing will inform FDA's policy development in this area.

Interested persons were originally given until January 9, 2017, to comment on the topics discussed in the notification of public hearing.

At the public hearing on November 9 and 10, 2016, a number of speakers presented legal views regarding the application of First Amendment principles to firm communications regarding unapproved uses of approved or cleared medical products. Some expressed the view that FDA had not sufficiently discussed the First Amendment in the notification of public hearing. In response to these comments, FDA is now placing the Memorandum in the docket for the public hearing to provide additional background on the issues it is considering as part of its review of its rules and policies relating to firm communications regarding unapproved uses of approved or cleared medical products, including a discussion of First Amendment considerations. In the notification of public hearing, FDA requested comments on a number of specific issues and questions identified throughout the document. The Memorandum is intended to help advance the discussion of these topics, and FDA is seeking input on the information in the Memorandum as it relates to these issues and questions in the notification of public hearing.

Furthermore, elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance for industry entitled "Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers," which provides answers to common questions regarding the communication of health care economic information about approved prescription drugs by medical product firms to payors, formulary committees, or other similar entities. The draft guidance also provides answers to common questions related to firms' communications about investigational drugs and devices (investigational products) to payors before FDA approval or clearance of such products.

Additionally, in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance for industry entitled "Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers." The guidance provides information for medical product firms about how FDA evaluates their medical product communications, including their promotional materials, that present information that is not contained in the FDA-required labeling for the product but that may be consistent with the FDA-required labeling for the product.

FDA is harmonizing the comment periods for the notification of public hearing and the two draft guidances, as all three documents relate to the overarching topic of firm communications regarding medical products, and interested persons may wish to review all the documents before submitting comments to any of the relevant dockets. FDA is requesting comments on both draft guidances by April 19, 2017.

To allow interested parties an opportunity to review the Memorandum and the two draft guidances, FDA is reopening the comment period for the notification of public hearing for an additional 90 days, until April 19, 2017. The Agency believes reopening the comment period for an additional 90 days for the notification of public hearing will allow adequate time for interested persons to submit comments without significantly delaying Agency decision making and policy development on these important issues.

Dated: January 6, 2017.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-01013 Filed 1-18-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG-127203-15]

RIN 1545-BN81

Transfers of Certain Property by U.S. Persons to Partnerships With Related Foreign Partners

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulation.

SUMMARY: In the Rules and Regulations section of this issue of the **Federal Register**, temporary regulations are being issued under sections 197, 704, 721(c), and 6038B of the Internal Revenue Code (Code) that address transfers of appreciated property by U.S. persons to partnerships with foreign partners related to the transferor. The temporary regulations affect U.S. partners in domestic or foreign partnerships. The text of the temporary regulations also serves as the text of these proposed regulations.

DATES: Written or electronic comments and requests for a public hearing must be received by April 19, 2017.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG-127203-15), Internal Revenue Service, Room 5203, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG-127203-15), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224, or sent electronically via the Federal eRulemaking Portal at <http://www.regulations.gov> (IRS REG-127203-15).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Ryan A. Bowen, (202) 317-6937; concerning submissions of comments or requests for a public hearing, Regina Johnson, (202) 317-6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The temporary regulations in the Rules and Regulations section of this issue of the **Federal Register** contain regulations under sections 197, 704, 721(c), and 6038B of the Code. The temporary regulations contain rules described in Notice 2015-54, 2015-34 I.R.B. 210, and override nonrecognition of gain under section 721(a) for transfers of property to a partnership with related foreign partners and with substantial related-party ownership unless certain requirements are satisfied. The text of the temporary regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations explains the temporary regulations and the corresponding proposed regulations.

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. It is hereby certified that the collection of information contained in this regulation will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required. This conclusion is based on the fact that the proposed regulations include a \$1,000,000 de minimis exception for certain transfers, and tangible property with built-in gain that does not exceed \$20,000 is excluded from the application of the

regulations. In addition, the regulations only apply when a U.S. transferor contributes property to a partnership with a related foreign partner, and persons related to the U.S. transferor own 80 percent or more of the interests in the partnership. Accordingly, the Treasury Department and the IRS expect that these regulations primarily will affect large domestic corporations. Pursuant to section 7805(f), this notice of proposed rulemaking has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under the **ADDRESSES** heading. The Treasury Department and the IRS request comments on all aspects of the proposed rules. All comments will be available at www.regulations.gov or upon request. A public hearing will be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these proposed regulations is Ryan A. Bowen, Office of Associate Chief Counsel (International). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding entries to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Section 1.721(c)-1 also issued under 26 U.S.C. 721(c).

Section 1.721(c)-2 also issued under 26 U.S.C. 721(c).

Section 1.721(c)-3 also issued under 26 U.S.C. 721(c).

Section 1.721(c)-4 also issued under 26 U.S.C. 721(c).

Section 1.721(c)-5 also issued under 26 U.S.C. 721(c).

Section 1.721(c)-6 also issued under 26 U.S.C. 721(c).

Section 1.721(c)-7 also issued under 26 U.S.C. 721(c).

* * * * *

■ **Par. 2.** Section 1.197-2 is amended by adding paragraphs (h)(12)(vii)(C) and (l)(5) to read as follows:

§ 1.197-2 Amortization of goodwill and certain other intangibles.

* * * * *

(h) * * *

(12) * * *

(vii) * * *

(C) [The text of proposed § 1.197-2(h)(12)(vii)(C) is the same as the text of § 1.197-2T(h)(12)(vii)(C) published elsewhere in this issue of the **Federal Register**.]

* * * * *

(l) * * *

(5) [The text of proposed § 1.197-2(l)(5) is the same as the text of § 1.197-2T(l)(5) published elsewhere in this issue of the **Federal Register**.]

* * * * *

■ **Par. 3.** Section 1.704-1 is amended by adding paragraph (b)(2)(iv)(f)(6) following the undesignated paragraph at the end of paragraph (b)(2)(iv)(f)(5) and adding paragraph (f) to read as follows:

§ 1.704-1 Partner's distributive share.

* * * * *

(b) * * *

(2) * * *

(iv) * * *

(f) * * *

(6) [The text of proposed § 1.704-1(b)(2)(iv)(f)(6) is the same as the text of § 1.704-1T(b)(2)(iv)(f)(6) published elsewhere in this issue of the **Federal Register**.]

* * * * *

(f) [The text of proposed § 1.704-1(f) is the same as the text of § 1.704-1T(f) published elsewhere in this issue of the **Federal Register**.]

* * * * *

■ **Par. 4.** Section 1.704-3 is amended by adding paragraphs (a)(13), (d)(5)(iii), and (g) to read as follows:

§ 1.704-3 Contributed property.

(a) * * *

(13) [The text of proposed § 1.704-3(a)(13) is the same as the text of § 1.704-3T(a)(13) published elsewhere in this issue of the **Federal Register**.]

* * * * *

(d) * * *

(5) * * *

(iii) [The text of proposed § 1.704-3(d)(5)(iii) is the same as the text of § 1.704-3T(d)(5)(iii) published

elsewhere in this issue of the **Federal Register**].

* * * * *

(g) [The text of proposed § 1.704–3(g) is the same as the text of § 1.704–3T(g) published elsewhere in this issue of the **Federal Register**].

■ **Par. 5.** Section 1.721(c)–1 is added to read as follows:

§ 1.721(c)–1 Overview, definitions, and rules of general application.

[The text of proposed § 1.721(c)–1 is the same as the text of § 1.721(c)–1T published elsewhere in this issue of the **Federal Register**].

■ **Par. 6.** Section 1.721(c)–2 is added to read as follows:

§ 1.721(c)–2 Recognition of gain on certain contributions of property to partnerships with related foreign partners.

[The text of proposed § 1.721(c)–2 is the same as the text of § 1.721(c)–2T published elsewhere in this issue of the **Federal Register**].

■ **Par. 7.** Section 1.721(c)–3 is added to read as follows:

§ 1.721(c)–3 Gain deferral method.

[The text of proposed § 1.721(c)–3 is the same as the text of § 1.721(c)–3T published elsewhere in this issue of the **Federal Register**].

■ **Par. 8.** Section 1.721(c)–4 is added to read as follows:

§ 1.721(c)–4 Acceleration events.

[The text of proposed § 1.721(c)–4 is the same as the text of § 1.721(c)–4T published elsewhere in this issue of the **Federal Register**].

■ **Par. 9.** Section 1.721(c)–5 is added to read as follows:

§ 1.721(c)–5 Acceleration event exceptions.

[The text of proposed § 1.721(c)–5 is the same as the text of § 1.721(c)–5T published elsewhere in this issue of the **Federal Register**].

■ **Par. 10.** Section 1.721(c)–6 is added to read as follows:

§ 1.721(c)–6 Procedural and reporting requirements.

[The text of proposed § 1.721(c)–6 is the same as the text of § 1.721(c)–6T published elsewhere in this issue of the **Federal Register**].

■ **Par. 11.** Section 1.721(c)–7 is added to read as follows:

§ 1.721(c)–7 Examples.

[The text of proposed § 1.721(c)–7 is the same as the text of § 1.721(c)–7T published elsewhere in this issue of the **Federal Register**].

■ **Par. 12.** Section 1.6038B–2 is amended by:

- 1. Revising paragraph (a)(3).
- 2. Adding paragraphs (a)(1)(iii), (c)(8), and (c)(9).
- 3. Revising paragraph (h)(3).
- 4. Adding paragraphs (j)(4) and (j)(5).

§ 1.6038B–2 Reporting of certain transfers to foreign partnerships.

(a) * * *

(1) * * *

(iii) [The text of proposed § 1.6038B–2(a)(1)(iii) is the same as the text of § 1.6038B–2T(a)(1)(iii) published elsewhere in this issue of the **Federal Register**].

* * * * *

(3) [The text of proposed § 1.6038B–2(a)(3) is the same as the text of § 1.6038B–2T(a)(3) published elsewhere in this issue of the **Federal Register**].

* * * * *

(c) * * *

(8) [The text of proposed § 1.6038B–2(c)(8) is the same as the text of § 1.6038B–2T(c)(8) published elsewhere in this issue of the **Federal Register**].

(9) [The text of proposed § 1.6038B–2(c)(9) is the same as the text of § 1.6038B–2T(c)(9) published elsewhere in this issue of the **Federal Register**].

* * * * *

(h) * * *

(3) [The text of proposed § 1.6038B–2(h)(3) is the same as the text of § 1.6038B–2T(h)(3) published elsewhere in this issue of the **Federal Register**].

* * * * *

(j) * * *

(4) [The text of proposed § 1.6038B–2(j)(4) is the same as the text of § 1.6038B–2T(j)(4) published elsewhere in this issue of the **Federal Register**].

(5) [The text of proposed § 1.6038B–2(j)(5) is the same as the text of § 1.6038B–2T(j)(5) published elsewhere in this issue of the **Federal Register**].

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2017–01048 Filed 1–18–17; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[REG–137604–07]

RIN 1545–BI35

Definition of Dependent

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Withdrawal of notice of proposed rulemaking and notice of proposed rulemaking.

SUMMARY: This document withdraws proposed regulations relating to the definition of an authorized placement agency for purposes of a dependency exemption for a child placed for adoption that were issued prior to the changes made to the law by the Working Families Tax Relief Act of 2004 (WFTRA). This document contains proposed regulations that reflect changes made by WFTRA and by the Fostering Connections to Success and Increasing Adoptions Act of 2008 (FCSIAA) relating to the dependency exemption. This document also contains proposed regulations that, to reflect current law, amend the regulations relating to the surviving spouse and head of household filing statuses, the tax tables for individuals, the child and dependent care credit, the earned income credit, the standard deduction, joint tax returns, and taxpayer identification numbers for children placed for adoption. These proposed regulations change the IRS's position regarding the category of taxpayers permitted to claim the childless earned income credit. In determining a taxpayer's eligibility to claim a dependency exemption, these proposed regulations change the IRS's position regarding the adjusted gross income of a taxpayer filing a joint return for purposes of the tiebreaker rules and the source of support of certain payments that originated as governmental payments. These regulations provide guidance to individuals who may claim certain child-related tax benefits.

DATES: Written or electronic comments and requests for a public hearing must be received by April 19, 2017.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–137604–07), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–137604–07), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC 20224, or sent electronically via the Federal eRulemaking Portal at www.regulations.gov (IRS REG–137604–07).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Victoria J. Driscoll, (202) 317–4718; concerning the submission of comments and requests for a public hearing, Regina Johnson, (202) 317–6901 (not toll-free calls).

SUPPLEMENTARY INFORMATION:

Background

This document withdraws a notice of proposed rulemaking (REG-107279-00) amending § 1.152-2(c)(2) of the Income Tax Regulations that was published in the **Federal Register** (65 FR 71277) on November 30, 2000 (2000 proposed regulations) relating to the definition of an authorized placement agency for purposes of a dependency exemption for a child placed for adoption under prior law. Prior law required that a child be placed with the taxpayer for adoption by an authorized placement agency. Section 152 of the Internal Revenue Code was amended by section 201 of WFTRA (Pub. L. 108-311, 118 Stat. 1166, 1169) to provide that a qualifying child eligible to be the dependent of a taxpayer may include a child lawfully placed with the taxpayer for adoption. Accordingly, the proposed regulations in § 1.152-2(c)(2) under prior law are withdrawn.

This document also contains proposed amendments to 26 CFR part 1 under sections 2, 3, 21, 32, 63, 151, 152, 6013, and to Part 301 under section 6109 to reflect the changes made by WFTRA and FCSIAA (Pub. L. 110-351, 122 Stat. 3949) relating to the dependency exemption, as well as changes to these sections by other acts. WFTRA amended section 152, in part, to provide a uniform definition of a qualifying child; FCSIAA added to the definition of a qualifying child the requirements that the child must be younger than the taxpayer and that the child must not file a joint return (other than as a claim for refund). FCSIAA also amended the rules that apply if two or more taxpayers are eligible to claim an individual as a qualifying child.

1. Dependency Rules

Under section 151, a taxpayer may deduct an exemption amount for a dependent as defined in section 152. Prior to WFTRA, section 151 contained many of the rules related to the definition of a dependent. WFTRA moved those rules to section 152. As amended, section 152(a) defines a *dependent* as a qualifying child or a qualifying relative. Taxpayers should note that a taxpayer's treatment of the dependency exemption under section 151 for a particular qualifying child or qualifying relative might have tax consequences under other Code provisions, such as the education tax credits under section 25A, the premium tax credit under section 36B, and the penalty for failure to maintain minimum essential coverage under section 5000A.

a. Individual Not a Dependent

Section 152(b) provides that an individual who is a qualifying child or a qualifying relative of a taxpayer is not a taxpayer's dependent in certain circumstances. Section 152(b)(2) provides that, to be a dependent of a taxpayer, an individual must not have filed a joint return with his or her spouse. However, the WFTRA conference report provides that the "restriction does not apply if the return was filed solely to obtain a refund and no tax liability would exist for either spouse if they filed separate returns." See H.R. Rep. No. 108-696, at 55 n.38 (2004) (Conf. Rep.).

b. Qualifying Child

WFTRA established under section 152(c) a uniform definition of a qualifying child. The legislative history identifies five child-related benefits to which the uniform definition applies: The filing status of head of household under section 2(b), the child and dependent care credit under section 21, the child tax credit under section 24, the earned income credit under section 32, and the dependency exemption under section 151. See H.R. Rep. No. 108-696, at 55-65.

Section 152(c) defines a qualifying child as an individual who bears a certain relationship to the taxpayer (qualifying child relationship test), has the same principal place of abode as the taxpayer for more than one-half of the taxable year (residency test), is younger than the taxpayer and is under the age of 19 (or age 24 if a full-time student or any age if permanently and totally disabled) (age test), does not provide more than one-half of his or her own support (qualifying child support test), and does not file a joint return with a spouse except to claim a refund of estimated or withheld taxes (joint return test).

c. Temporary Absence

A child is considered to reside in the same principal place of abode as a taxpayer during a temporary absence. Under the existing section 152 regulations, a nonpermanent failure to occupy a common abode by reason of illness, education, business, vacation, military service, or a custody agreement may be a temporary absence due to special circumstances. The existing regulations under section 2 defining surviving spouse and head of household include a similar rule relating to the effect of a temporary absence on the requirement to maintain a household, but add the requirement that it is reasonable to assume that the absent

person will return to the household. Under case law, a factor to consider in determining whether an absence is temporary is whether the individual intends to establish a new principal place of abode. In *Rowe v. Commissioner*, 128 T.C. 13 (2007), the court concluded that it was reasonable to assume that a taxpayer would return to her home after pretrial confinement and that the taxpayer's absence was temporary. See also *Hein v. Commissioner*, 28 T.C. 826 (1957) (*acq.*, 1958-2 CB 6), and Rev. Rul. 66-28 (1966-1 CB 31).

d. Two or More Taxpayers Eligible To Claim Individual as Qualifying Child

Section 152(c)(4) provides tiebreaker rules that apply if an individual meets the definition of a qualifying child for two or more taxpayers (eligible taxpayers). In general, the eligible taxpayer who is a parent (eligible parent) of the individual may claim the individual as a qualifying child or, if there is no eligible parent, then the individual may be claimed by the eligible taxpayer with the highest adjusted gross income.

If more than one of the eligible taxpayers is a parent of the individual, more than one eligible parent claims the individual as a qualifying child, and the eligible parents claiming the individual do not file a joint return with each other, the individual is treated as the qualifying child of the eligible parent claiming the individual with whom the individual resided for the longest period of time during the taxable year. If the individual resided with each eligible parent claiming the individual for the same amount of time during the taxable year, the individual is treated as the qualifying child of the eligible parent claiming the individual with the highest adjusted gross income.

If at least one, but not all, of two or more eligible taxpayers is a parent of the individual, but no eligible parent claims the individual as a qualifying child, another eligible taxpayer may claim the individual, but only if the eligible taxpayer's adjusted gross income is higher than the adjusted gross income of each eligible parent. Since 2009, IRS Publication 501, *Exemptions, Standard Deduction, and Filing Information*, has stated that "[i]f a child's parents file a joint return with each other, this rule may be applied by dividing the parents' combined AGI equally between the parents."

Notice 2006-86 (2006-2 CB 680) provides interim guidance on these rules prior to the amendments by FCSIAA. The notice provides that, except to the extent that a noncustodial

parent may claim the child as a qualifying child under the special rule for divorced or separated parents in section 152(e), discussed in the next paragraph, if more than one taxpayer claims a child as a qualifying child, the child is treated as the qualifying child of only one taxpayer (as determined under the tiebreaker rules of section 152(c)(4)) for purposes of the five provisions subject to the uniform definition of a qualifying child (the filing status of head of household under section 2(b), the child and dependent care credit under section 21, the child tax credit under section 24, the earned income credit under section 32, and the dependency exemption under section 151, as well as for purposes of the exclusion for dependent care assistance under section 129 (which may apply to the care of a dependent qualifying child under age 13)). Thus, in general, the tiebreaker rules for determining which taxpayer may claim a child as a qualifying child apply to these provisions as a group, rather than on a section-by-section basis.

Notice 2006–86 contains an exception to the rule that only one taxpayer may claim a child as a qualifying child for all purposes. Section 152(e) has a special rule for divorced or separated parents that determines who, as between the custodial and noncustodial parent, may claim a child as a qualifying child or qualifying relative if certain tests (different from the general tests under sections 152(c) and (d)) regarding residency and support are met and the custodial parent releases a claim to exemption for the child. The notice provides that, if this special rule applies, a noncustodial parent may claim a child as a qualifying child for purposes of the dependency exemption and the child tax credit (the only two of the provisions addressed in the notice to which section 152(e) applies in determining who is a qualifying child), and another taxpayer may claim the child for one or more of the other benefits to which section 152(e) does not apply.

Although FCSIAA affects other aspects of section 152(c)(4) and Notice 2006–86, there is nothing in FCSIAA that would compel a change in the rule described in Notice 2006–86 that an individual is treated as the qualifying child of only one taxpayer for the listed child-related tax benefits, except if the special rule in section 152(e) applies.

e. Qualifying Relative

Under section 152(d), a qualifying relative is an individual who bears a certain relationship to the taxpayer, including an individual who has the

same principal place of abode as the taxpayer and is a member of the taxpayer's household for the taxable year (qualifying relative relationship test), has gross income less than the exemption amount for the taxable year (gross income test), receives more than one-half of his or her support from the taxpayer (qualifying relative support test), and is not a qualifying child of any taxpayer (not a qualifying child test).

Notice 2008–5 (2008–1 CB 256) addresses whether a taxpayer meets the test under section 152(d)(1)(D) to claim an individual as a qualifying relative. That provision requires that the individual not be a qualifying child of either the taxpayer or any other taxpayer during a taxable year beginning in the calendar year in which the taxpayer's taxable year begins. The notice provides that, for purposes of section 152(d)(1)(D), an individual is not a qualifying child of “any other taxpayer” if the individual's parent (or other person for whom the individual is defined as a qualifying child) is not required by section 6012 to file an income tax return and (1) does not file an income tax return, or (2) files an income tax return solely to obtain a refund of withheld income taxes.

f. Support Tests

Under section 152(c)(1)(D), to be a taxpayer's qualifying child, an individual must not have provided over one-half of the individual's own support for the calendar year. Under section 152(d)(1)(C), to be a taxpayer's qualifying relative, a taxpayer must have provided over one-half of an individual's support for the calendar year.

Regarding governmental payments to a person with a qualifying need, the WFTRA conference report, H.R. Rep. No. 108–696, at 57, states that “[g]overnmental payments and subsidies (e.g., Temporary Assistance [for] Needy Families, food stamps, and housing) generally are treated as support provided by a third party.” The IRS has successfully asserted in litigation that governmental payments provided to a parent to aid a family with dependent children and used by the parent for support of her children was support of the children provided by the government, and not support provided by the parent. See *Lutter v. Commissioner*, 61 T.C. 685 (1974), *affd. per curiam*, 514 F.2d 1095 (7th Cir. 1975).

2. Surviving Spouse and Head of Household, and Conforming Changes

Prior to amendment by section 803(b) of the Tax Reform Act of 1969 (Pub. L.

91–172, 83 Stat. 487), section 2(a) provided that the return of a surviving spouse is treated as a joint return for purposes of the tax rates, the tax tables for individuals, and the standard deduction. Following the 1969 amendments, section 2(a) defines the term *surviving spouse* for purposes of section 1. The return of a taxpayer filing as a surviving spouse is no longer treated as a joint return under sections 2, 3, or 63. Section 3 provides tax tables for certain individuals in lieu of the tax imposed by section 1. Section 63(c) provides the same basic standard deduction for a taxpayer filing as a surviving spouse as a taxpayer filing a joint return. Accordingly, a taxpayer filing as a surviving spouse is no longer treated as filing a joint return for any tax purpose, but rather, a taxpayer filing as a surviving spouse simply uses the same tax rates under section 1, the same amounts in the tax tables under section 3, and the same standard deduction under section 63 as a taxpayer filing a joint return.

Generally, under section 2(b), to qualify as a head of household, a taxpayer must maintain a household that is the principal place of abode of a qualifying child or other dependent for more than one-half of the taxable year. If the dependent is a parent of the taxpayer and the parent does not share a principal place of abode with the taxpayer, the household maintained by the taxpayer must be the parent's principal place of abode for the entire taxable year.

Prior to WFTRA, section 21 required that a taxpayer maintain a household to claim the credit for dependent care expenses, and regulations on maintaining a household were published under that section. WFTRA removed that requirement from the dependent care credit.

3. Earned Income Credit

Section 32 provides a tax credit to eligible taxpayers who work and have earned income below a certain dollar amount. Before the amendment of section 32 by the Omnibus Reconciliation Act of 1993 (Pub. L. 103–66, 107 Stat. 312), the earned income credit (EIC) was allowable only to a taxpayer with one or more qualifying children. If an individual met the definition of a qualifying child for more than one taxpayer, a tiebreaker rule in section 32 determined which taxpayer was allowed to claim the individual as a qualifying child for the EIC. For taxable years beginning after 1993, section 32(c)(1)(A)(ii) allows a taxpayer without a qualifying child to claim the EIC (childless EIC) if certain

requirements are met. Although there is no regulatory guidance on this issue, since 1995, the IRS has taken the position in IRS Publication 596, *Earned Income Credit*, that if an individual meets the definition of a qualifying child for more than one taxpayer and the individual is not treated as the qualifying child of a taxpayer under the tiebreaker rules, then that taxpayer is precluded from claiming the childless EIC. WFTRA moved the tiebreaker rules from section 32 to section 152(c)(4).

Before repeal in 2010, section 3507 allowed advance payment of the EIC. Section 3507 was repealed by the FAA Air Transportation Modernization and Safety Improvement Act (Pub. L. 111–226, 124 Stat. 2389).

4. Additional Standard Deduction for the Aged and Blind

Before the amendments to sections 63 and 151 made by the Tax Reform Act of 1986 (Pub. L. 99–514, 100 Stat. 2085), a taxpayer was entitled to an additional personal exemption under section 151 for the taxpayer or the taxpayer's spouse (or both), if either was age 65 or older or was blind at the close of the taxable year. As amended, section 63 provides an additional standard deduction for age or blindness instead of an additional personal exemption under section 151.

Explanation of Provisions

The proposed regulations reflect statutory amendments to sections 2, 3, 21, 32, 63, 151, 152, 6013, and 6109. In addition, the regulations address certain significant issues arising under these sections and modify certain IRS positions, as explained below.

1. Dependency Exemption

Consistent with the amendments made to sections 151 and 152 by WFTRA, the proposed regulations move rules related to the definition of a dependent from the regulations under section 151 to the regulations under section 152.

a. Relationship Test

i. General Rules

Section 152(c)(2) provides that a qualifying child must be a child or a descendant of a child of the taxpayer, or a brother, sister, stepbrother, or stepsister of the taxpayer, or a descendant of any of these relatives. Section 152(d)(2) provides that a qualifying relative must bear a certain relationship to the taxpayer, which includes a child or a descendant of a child, a brother, sister, stepbrother, stepsister, parent or ancestor of a parent, or an aunt or uncle of the taxpayer. An individual (other than the taxpayer's

spouse) who is not related to the taxpayer in one of the named relationships nevertheless may satisfy the relationship test for a qualifying relative if the individual has the same principal place of abode as the taxpayer and is a member of the taxpayer's household for the taxpayer's taxable year.

The proposed regulations adopt the rule in Notice 2008–5 regarding whether an individual is a qualifying child of a taxpayer for purposes of determining whether that individual may be a qualifying relative. That is, the proposed regulations provide that an individual is not a qualifying child of a person if that person is not required to file an income tax return under section 6012, and either does not file an income tax return or files an income tax return solely to claim a refund of estimated or withheld taxes.

ii. Adopted Child—Adoption by Individual Other Than the Taxpayer

Prior to 2005, for purposes of the relationship test, a person's legally adopted child was treated as that person's child by blood. Specifically, section 152(b)(2) provided that "a legally adopted child of an individual (and a child who is a member of an individual's household, if placed with such individual by an authorized placement agency for legal adoption by such individual), . . . shall be treated as a child of such individual by blood." Therefore, a taxpayer other than the adopting "individual" could be eligible to claim an exemption for an adopted child. For example, the parent of the adopting parent could claim a dependency exemption for the legally adopted child of the taxpayer's son or daughter (just as biological grandparents may claim an exemption for a grandchild) if all other requirements were met.

WFTRA amended section 152 to change the reference from a child placed by an authorized placement agency for adoption to a child who is "lawfully placed" for legal adoption. In making that change, however, WFTRA also changed the reference to the adopting person from "an individual" to "the taxpayer," so that section 152(f)(1)(B) currently provides that a legally adopted individual of the taxpayer is treated as a child by blood of the taxpayer. The use of the word "taxpayer" rather than "individual" arguably limits the recognition of a relationship through adoption only to those situations in which the taxpayer claiming a dependency exemption for the child is the person who adopts the child. This interpretation of the amended statutory

language would diverge from the results of a legal adoption under property, inheritance, and other nontax law, and from the prior tax treatment of adoptions—a significant change in the applicable law. However, there is nothing in the legislative history indicating that Congress intended to limit the treatment of an adopted child as a child by blood in this manner or that otherwise suggests this change in language was intended to effect a change in existing law.

To fill this apparent gap in the statute, the proposed regulations provide that any child legally adopted by a "person," or any child who is placed with a "person" for legal adoption by that "person," is treated as a child by blood of that person for purposes of the relationship tests under sections 152(c)(2) and 152(d)(2). Similarly, the proposed regulations provide that an eligible foster child is a child who is placed with a "person" rather than with a taxpayer.

iii. Adopted Child and Foster Child—Child Placement

Although WFTRA removed the reference to an authorized placement agency from the provisions relating to an adopted child in section 152(f)(1)(B), the reference to an authorized placement agency continues to appear in section 152(f)(1)(C), relating to an eligible foster child. Prior to amendment by WFTRA, section 152 treated a child who was a member of an individual's household pending adoption as a child by blood of the individual for purposes of the relationship test only if the child was a foster child living with the individual or if the child was placed with the individual by an authorized placement agency for adoption by the individual. Similarly, § 301.6109–3(a) currently provides that a taxpayer may obtain an adoption taxpayer identification number (ATIN) only for a child who was placed for adoption by an authorized placement agency.

As amended by WFTRA, section 152 treats a child placed for adoption as a child by blood of the taxpayer if the child "is lawfully placed with the taxpayer for legal adoption by the taxpayer." A child may be lawfully placed for legal adoption by an authorized placement agency, the child's parents, or other persons authorized by State law to place children for legal adoption. These proposed regulations reflect the changes made by WFTRA and amend the regulations under section 6109 to provide that the IRS will assign an ATIN to a child who has been lawfully placed with a person for legal adoption.

Under section 152(f)(1)(A)(ii) and § 1.152-1(b)(1)(iii) of these proposed regulations, the term *child* also includes an eligible foster child of the taxpayer as defined in 152(f)(1)(C), that is, a child who is placed with the taxpayer by an authorized placement agency or by the judgment, decree, or other order of a court of competent jurisdiction.

iv. Definition of Authorized Placement Agency

The 2000 proposed regulations under § 1.152-2(c)(2) defined an authorized placement agency for purposes of the prior law regarding a child placed for legal adoption. These proposed regulations define an authorized placement agency for purposes of the definition of an eligible foster child and withdraw the 2000 proposed regulations, which defined that term without reference to an Indian Tribal Government (ITG).

These proposed regulations provide that an *authorized placement agency* may be a State, the District of Columbia, a possession of the United States, a foreign country, an agency or organization authorized by, or a political subdivision of, any of these entities to place children in foster care or for adoption. Under the Indian Child Welfare Act of 1978 (25 U.S.C. chapter 21), ITGs and states perform similar functions for foster care and adoption programs. Thus, the proposed regulations provide that an authorized placement agency also may be an ITG (as defined in section 7701(a)(40)), or an agency or organization authorized by, or a political subdivision of, an ITG that places children in foster care or for adoption.

b. Residency Test—Principal Place of Abode

For purposes of determining whether an individual has the same principal place of abode as the taxpayer in applying the residency test for a qualifying child and the relationship test for a qualifying relative who does not have one of the listed relationships to the taxpayer, the proposed regulations provide that the term *principal place of abode* means a person's main home or dwelling where the person resides. A person's principal place of abode need not be the same physical location throughout the taxable year and may be temporary lodging such as a homeless shelter or relief housing resulting from displacement caused by a natural disaster.

The proposed regulations further provide that a taxpayer and an individual have the same principal place of abode despite a temporary

absence by either person. A person is temporarily absent if, based on the facts and circumstances, the person would have resided with the taxpayer but for the temporary absence and it is reasonable to assume the person will return to reside at the place of abode. Thus, the proposed regulations adopt the "reasonable to assume" language from the existing regulations under section 2. The proposed regulations indicate that a nonpermanent failure to occupy the abode by reason of illness, education, business, vacation, military service, institutionalized care for a child who is permanently and totally disabled (as defined in section 22(e)(3)), or incarceration may be treated as a temporary absence due to special circumstances. This definition of temporary absence applies to the residency test for a qualifying child, to the relationship test for a qualifying relative who does not have a listed relationship to the taxpayer, and to the requirements to maintain a household for surviving spouse and head of household.

For purposes of the residency test for a qualifying child, the proposed regulations provide that an individual is treated as having the same principal place of abode as the taxpayer for more than one-half of the taxable year if the individual resides with the taxpayer for at least 183 nights during the taxpayer's taxable year or for at least 184 nights during the taxpayer's taxable year that includes a leap day (residing for more than one-half of the taxable year). The proposed regulations further provide that an individual resides with the taxpayer for a night if the individual sleeps (1) at the taxpayer's residence, or (2) in the company of the taxpayer when the individual does not sleep at the taxpayer's residence (for example, when the parent and the child are on vacation). The regulations provide additional rules for counting nights if a night extends over two taxable years and for taxpayers who work at night.

The proposed regulations provide special rules for determining whether an individual satisfies a residency test if the individual is born or dies during the taxable year, is adopted or placed for adoption, is an eligible foster child, or is a missing child.

c. Age Test

The age test for a qualifying child requires that an individual be younger than the taxpayer claiming the individual as a qualifying child, and the individual must not have attained the age of 19 (or age 24 if the individual is a student). The age requirement is

treated as satisfied if the individual is permanently and totally disabled.

For purposes of this age test, the proposed regulations substantially adopt the existing definition of a student. Accordingly, the proposed regulations provide that the term *student* means an individual who, during some part of each of 5 calendar months during the calendar year in which the taxable year of the taxpayer begins, is a full-time student at an educational organization described in section 170(b)(1)(A)(ii) or is pursuing a full-time course of institutional on-farm training under the supervision of an accredited agent of an educational institution or of a State or political subdivision of a State. An *educational organization*, as defined in section 170(b)(1)(A)(ii), is a school normally maintaining a regular faculty and curriculum and having a regularly enrolled body of students in attendance at the place where its educational activities are regularly carried on.

d. Support Tests

In determining whether an individual provided more than one-half of the individual's own support (qualifying child support test), or whether a taxpayer provided more than one-half of an individual's support (qualifying relative support test), the proposed regulations compare the amount of support provided by the individual or the taxpayer to the total amount of the individual's support from all sources. In general, the amount of an individual's support from all sources includes support the individual provides and income that is excludable from gross income. The proposed regulations further provide that the amount of an item of support is the amount of expenses paid or incurred to furnish the item of support. If support is furnished in the form of property or a benefit (such as lodging), the amount of that support is the fair market value of the item furnished (Rev. Rul. 58-302 (1958-1 CB 62)).

The proposed regulations provide that the term *support* includes food, shelter, clothing, medical and dental care, education, and similar items for the benefit of the supported individual. Support does not include Federal, State, and local income taxes, or Social Security and Medicare taxes, of an individual paid from the individual's own income (Rev. Rul. 58-67 (1958-1 CB 62)), funeral expenses (Rev. Rul. 65-307 (1965-2 CB 40)), life insurance premiums, or scholarships received by a taxpayer's child who is a student as defined in section 152(f)(2).

The proposed regulations provide that medical insurance premiums are treated as support. These premiums include Part A Basic Medicare premiums, if any, under Title XVIII of the Social Security Act (42 U.S.C. 1395c to 1395i-5), Part B Supplemental Medicare premiums under Title XVIII of the Social Security Act (42 U.S.C. 1395j to 1395w-6), Part C Medicare + Choice Program premiums under Title XVIII of the Social Security Act (42 U.S.C. 1395w-21 to 1395w-29), and Part D Voluntary Prescription Drug Benefit Medicare premiums under Title XVIII of the Social Security Act (42 U.S.C. 1395w-101 to 1395w-154). However, medical insurance proceeds, including benefits received under Medicare Part A, Part B, Part C, and Part D, are not treated as support and are disregarded in determining the amount of the individual's support. Thus, only the premiums paid and the unreimbursed portion of the expenses for the individual's medical care are support. See Rev. Rul. 64-223 (1964-2 CB 50); and Rev. Rul. 70-341 (1970-2 CB 31), revoked in part by Rev. Rul. 79-173 (1979-1 CB 86) to the extent that it held that Part A Medicare benefits are included as a recipient's contribution to support. In addition, services provided to individuals under the medical and dental care provisions of the Armed Forces Act (10 U.S.C. chapter 55) are not treated as support and are disregarded in determining the amount of the individual's support. Finally, payments from a third party (including a third party's insurance company) for the medical care of an injured individual in satisfaction of a legal claim for the personal injury of the individual are not items of support and are disregarded in determining the amount of the individual's support. See Rev. Rul. 64-223.

The proposed regulations provide that, in general, governmental payments and subsidies are treated as support provided by a third party. Consistent with previously issued rulings and case law, these payments and subsidies include, for example, Temporary Assistance for Needy Families (TANF) (42 U.S.C. 601-619), low-income housing assistance (42 U.S.C. 1437f), benefits under the Supplemental Nutrition Assistance Program (7 U.S.C. chapter 51), Supplemental Security Income payments (42 U.S.C. 1381-1383f), foster care maintenance payments, and adoption assistance payments. See H.R. Rep. No. 108-696, at 57 (2004) (Conf. Rep.); *Gulvin v. Commissioner*, 644 F.2d 2 (5th Cir. 1981); and Rev. Rul. 74-153 (1974-1 CB 20).

However, unlike the subsidies described in the previous paragraph that generally are based solely on need, old age benefits under section 202(b) of Title II of the Social Security Act (SSA) (42 U.S.C. 402) are based on an individual's earnings and contributions into the Social Security system and thus are treated as support provided by the recipient to the extent the recipient uses the payments for support. See Rev. Rul. 58-419 (1958-2 CB 57), as modified by Rev. Rul. 64-222 (1964-2 CB 47). Similarly, Social Security survivor and disability insurance benefit payments made under section 202(d) of the SSA to the child of a deceased or disabled parent are treated as support provided by the child to the extent those payments are used for the child's support. See Rev. Rul. 57-344 (1957-2 CB 112) and Rev. Rul. 74-543 (1974-2 CB 39).

The proposed regulations provide a special rule for governmental payments used by the recipient or other intended beneficiary to support another individual. The proposed regulations draw a distinction between: (1) Governmental payments (such as Social Security old age benefits, or survivor and disability insurance benefits for a child) made to a recipient that are intended to benefit a particular named individual (whether the recipient, or another intended beneficiary for whom the recipient merely acts as the payee on behalf of that other intended beneficiary); and (2) governmental payments made to a recipient that are intended to support the recipient and other individuals (such as TANF). Although the governmental payments of the former variety are intended to benefit a particular named individual, because money is fungible, the intended beneficiary might use the governmental payments to support another individual. In this situation, the proposed regulations provide that, if the intended beneficiary (whether the recipient or another individual) uses the governmental payments to support another individual, that amount would constitute support of that other individual provided by the intended beneficiary. Similarly, the proposed regulations provide that the use of governmental payments of the latter variety by the recipient to support another individual would constitute support of that other individual provided by the recipient, whereas any part of such a payment used for the support of the recipient would constitute support of the recipient by a third party. For example, if a mother receives TANF and uses the TANF

payments to support her children, the proposed regulations treat the mother as having provided that support. Thus, the IRS will no longer assert the position that it took in *Lutter*, which concerned payments received by a mother under a program that was the predecessor of TANF. The Treasury Department and the IRS are proposing this rule for the administrative convenience of both the IRS and taxpayers to avoid the need to trace the use of such governmental payments, as opposed to the use of other funds of the recipient, for the support of another individual.

The Treasury Department and IRS request comments on whether various payments made pursuant to the Patient Protection And Affordable Care Act (Public Law 111-148, 124 Stat. 119) in the form of a cost-sharing reduction, an advanced payment of the premium tax credit, or as a reimbursement of health insurance premiums in the form of a premium tax credit, when used for the benefit of another individual, are support provided by the recipient of those benefits or support provided by a third party.

e. Citizenship

Under section 152(b)(3)(A), an individual who is not a citizen or national of the United States is not a dependent unless the individual is a resident of the United States, Canada, or Mexico. Nevertheless, consistent with the exception for certain adopted children in section 152(b)(3)(B), the proposed regulations provide that an adopted child of a taxpayer who is a U.S. citizen or national may qualify as a dependent if, for the taxpayer's taxable year, the child has the same principal place of abode as the taxpayer and is a member of the taxpayer's household, and otherwise qualifies as the taxpayer's dependent.

f. Tiebreaker Rules

The proposed regulations change the interpretation in Publication 501 regarding a taxpayer's adjusted gross income on a joint return and provide that, in applying the tiebreaker rules that treat an individual as the qualifying child of the eligible taxpayer with the higher or highest adjusted gross income, the adjusted gross income of a taxpayer who files a joint tax return is the total adjusted gross income shown on the return. The prior interpretation is changed to be consistent with other Code sections that require the filing of a joint return to claim a benefit and therefore calculate income based on the entire amount shown on the joint return. For example, the earned income credit under section 32 calculates the

earned income amount based on the entire amount shown on the joint return. This joint return rule also is relevant for determining whether section 152(c)(4)(C) applies. Under that provision, if an eligible parent does not claim an individual as a qualifying child, another eligible taxpayer may claim the individual as a qualifying child only if that taxpayer's adjusted gross income is higher than the adjusted gross income of any eligible parent.

The proposed regulations also expand the tiebreaker rule in section 152(c)(4)(C) to address the situation in which an eligible parent does not claim an individual as a qualifying child and two or more taxpayers, none of whom is a parent, are eligible to claim the individual as a qualifying child and each has adjusted gross income higher than any eligible parent. In this situation, the proposed regulations provide that the individual is treated as the qualifying child of the eligible taxpayer with the highest adjusted gross income.

g. Child of Parents Who Are Divorced, Separated, or Living Apart

Section 152(e) provides, in general, that a child is treated as the qualifying child or qualifying relative of a noncustodial parent for a calendar year if, among other things, the custodial parent provides to the noncustodial parent a written declaration that the custodial parent will not claim the child as a dependent for any taxable year beginning in that calendar year. Under section 152(e)(2)(B), the noncustodial parent must attach the written declaration to his or her return.

The proposed regulations provide that the noncustodial parent must attach a copy of the written declaration to an original or amended return. A taxpayer may submit a copy of the written declaration to the IRS during an examination of that parent's return. However, to provide certainty for both taxpayers and the IRS, the proposed regulations provide that a copy of a written declaration attached to an amended return or provided during an examination will not meet the requirements of section 152(e) and § 1.152-5(e) if the custodial parent signed the written declaration after the custodial parent filed a return claiming a dependency exemption for the child for the year at issue, and the custodial parent has not filed an amended return to remove that claim to a dependency exemption. The proposed regulations provide similar rules for a parent revoking a written declaration.

h. Filing a Return Solely To Obtain a Refund of Taxes

Individuals who file an income tax return solely to obtain a refund of estimated or withheld taxes are subject to special rules under various provisions of section 152. Section 152(c)(1)(E) provides that, for an individual to be a qualifying child of a taxpayer, the individual cannot have filed a joint return "other than only for a claim of refund." Section 152(b)(2) provides that, for an individual to be a dependent of a taxpayer, the individual cannot have filed a joint return with the individual's spouse. However, the WFTRA conference report states that "[t]his restriction does not apply if the return was filed solely to obtain a refund and no tax liability would exist for either spouse if they filed separate returns." Section 152(d)(1)(D) provides that, to be a qualifying relative, an individual may not be the qualifying child of the taxpayer or of any other taxpayer. Notice 2008-5 concludes that an individual is not the qualifying child of "any other taxpayer," within the meaning of section 152(d)(1)(D), if the person who could have claimed the individual as a qualifying child does not have a filing obligation and either does not file a return or files a return solely to obtain a refund of withheld taxes.

The proposed regulations provide a similar exception to the rule in section 152(b)(1) that a taxpayer cannot have a dependent if the taxpayer himself or herself is a dependent of another taxpayer. Specifically, the proposed regulations provide that an individual is not a dependent of a person if that person is not required to file an income tax return under section 6012 and either does not file an income tax return or files an income tax return solely to claim a refund of estimated or withheld taxes.

2. Surviving Spouse, Head of Household, and Conforming Changes

The proposed regulations amend the regulations under section 2 regarding the definition of surviving spouse and the definition of head of household to conform to the amendments made by WFTRA. To reflect the amendments made by the Tax Reform Act of 1969, the proposed regulations remove from the regulations under sections 2, 3, and 6013 references to the return of a surviving spouse being treated as a joint return. The proposed regulations also revise and move from the regulations under section 21 to the regulations under section 2 the definition of maintaining a household, in part, to conform to the amendments to section

21 made by WFTRA, which removed the requirement that a taxpayer maintain a household to claim the credit under section 21.

a. Surviving Spouse

From the time of the 1969 amendment until the enactment of WFTRA, section 2(a)(1)(B) provided that a taxpayer who is a surviving spouse described in section 2(a)(1)(A) may file as a surviving spouse (and thus may use the tax rates of joint filers) only if the taxpayer "maintains as his home a household which constitutes for the taxable year the principal place of abode (as a member of such household) of a dependent (i) who (within the meaning of section 152) is a son, stepson, daughter, or stepdaughter of the taxpayer, and (ii) with respect to whom the taxpayer is entitled to a deduction for the taxable year under section 151." Thus, the member of the taxpayer's household had to be a son or daughter or stepson or stepdaughter for whom the taxpayer was entitled to a dependency deduction.

WFTRA amended section 2(a), as well as certain other sections such as section 42 relating to the low-income housing credit and section 125 relating to cafeteria plans, to provide that the reference to section 152 applies "without regard to subsections (b)(1), (b)(2), and (d)(1)(B)." These three subsections, respectively: (1) Deny a dependency exemption to a dependent, (2) deny a dependency exemption for a person filing a joint return with his or her spouse, and (3) require the gross income of a qualifying relative to be less than the amount of the dependency exemption. Thus, the language inserted by the WFTRA technical amendment to section 2(a) was intended to broaden the class of individuals whose members could qualify a taxpayer as a surviving spouse for purposes of section 2. See also Staff of Joint Comm. on Taxation, 108th Cong., *General Explanation of Tax Legislation Enacted in the 108th Congress* 130 (Comm. Print 2005) ("technical and conforming amendments . . . provide that an individual may qualify as a dependent for certain purposes . . . without regard to whether the individual has gross income . . . or is married and files a joint return.")

However, in amending section 2(a) for this purpose, WFTRA inserted the direction to exclude the three referenced provisions after the reference to section 152 in section 2(a)(1)(B)(i). Thus, this section currently provides, "(i) who (within the meaning of section 152, determined without regard to subsections (b)(1), (b)(2), and (d)(1)(B)

thereof) is a son, stepson, daughter, or stepdaughter of the taxpayer.” Because section 2(a)(1)(B)(ii) continues to require that the taxpayer be entitled to a deduction under section 151 for the dependent (a requirement that could not be met if any of these three sections applied), read literally, section 2(a)(1)(B)(ii) would override the intent of the statutory change in section 2(a)(1)(B)(i), thus preventing the WFTRA amendment from effecting any change in the statute. Therefore, to give effect to the statutory amendment, the proposed regulations construe the language added by WFTRA instead to modify the section 152 requirements that apply in determining whether the taxpayer is entitled to the dependency exemption under section 151 for purposes of section 2(a)(1)(B)(ii). Accordingly, the proposed regulations provide that an individual is a dependent for purposes of section 2(a) if the taxpayer may claim a deduction under section 151 for the individual without applying sections 152(b)(1), (b)(2), and (d)(1)(B).

b. Head of Household

The proposed regulations under section 2(b) update and simplify the existing regulations defining head of household. Consistent with the statutory amendments to the definition of a dependent, the proposed regulations provide rules on qualifying as a head of household by maintaining a household that is the principal place of abode of a qualifying child or a dependent. The proposed regulations on head of household apply the rules in the proposed regulations under section 152 for determining principal place of abode, including whether an absence is temporary.

c. Maintaining a Household

The proposed regulations provide that a taxpayer maintains a household only if the taxpayer pays more than one-half of the cost related to operating the household for the relevant period. Expenses related to operating the household include property taxes, mortgage interest, rent, utility charges, upkeep and repairs, property insurance, and food consumed on the premises. A taxpayer may treat a home’s fair market rental value as a cost of maintaining a household (instead of the sum of payments for mortgage interest, property taxes, and insurance). The proposed regulations provide rules that, in certain circumstances, prorate on a monthly basis the annual cost of maintaining a household when a qualifying child or dependent resides in the household for less than the entire taxable year. The

proposed regulations also, in certain circumstances, recognize the creation of a new household during a year and treat shared living quarters as separate households.

3. Tax Tables for Individuals

The proposed regulations remove from the regulations under section 3 references to the return of a surviving spouse being treated as a joint return to conform to the amendments made by the Tax Reform Act of 1969. The proposed regulations also update the regulations under section 3 to reflect current law.

4. Earned Income Credit

The proposed regulations conform the regulations under section 32 to amendments made to section 32 by WFTRA. Consistent with the 2010 repeal of section 3507 by the FAA Air Transportation Modernization and Safety Improvement Act, the proposed regulations delete the paragraphs of the regulations under section 32 discussing advance payment of the earned income credit.

In addition, the proposed regulations reflect a change in the IRS’s position on the interaction of sections 152(c)(4) and 32. Specifically, the proposed regulations provide that, if an individual meets the definition of a qualifying child under section 152(c)(1) for more than one taxpayer and the individual is not treated as the qualifying child of one such taxpayer under the tiebreaker rules of section 152(c)(4), then the individual also is not treated as a qualifying child of that taxpayer for purposes of section 32(c)(1)(A). Thus, that taxpayer may be an eligible individual under section 32(c)(1)(A)(ii) and may claim the childless EIC if he or she meets the other requirements of that section. The Treasury Department and the IRS have concluded that this change in position is consistent with the language and purpose of section 32 and will be less confusing to taxpayers and easier for the IRS to administer.

The problems with the current rule may be illustrated by the following example. Two sisters (B and C) live together and each of them is a low-income taxpayer. Neither has a child and each may claim the childless EIC under section 32(c)(1)(A)(ii). Later, B has a child, and B’s child meets the definition of a qualifying child under section 152(c)(1) for both B and C. The child is treated as the qualifying child of B under the tiebreaker rules of section 152(c)(4), and B may claim the EIC as an eligible individual with a qualifying child under section 32(c)(1)(A)(i). Under

the current rule, C would not be allowed to claim the childless EIC under section 32(c)(1)(A)(ii). The Treasury Department and the IRS have determined that allowing C to continue to claim the childless EIC after the child is born is equitable and consistent with the purpose of section 32 to assist working, low-income taxpayers. Accordingly, the proposed regulations provide that, if an individual is not treated as a qualifying child of a taxpayer after applying the tiebreaker rules of section 152(c)(4), then the individual will not prevent that taxpayer from qualifying for the childless EIC.

5. Additional Standard Deduction for the Aged and Blind

The proposed regulations remove the provisions on additional exemptions for age and blindness from the regulations under section 151 and add regulations under section 63 on the additional standard deduction for the aged and the blind to reflect the changes made by the Tax Reform Act of 1986. The proposed regulations amend the regulations under section 63 to remove a cross reference to now-repealed statutory provisions relating to a charitable deduction for taxpayers who do not itemize. To limit impediments to electronic filing, the proposed regulations also delete the requirement that a taxpayer claiming a tax benefit for blindness must attach a certificate or statement to the taxpayer’s tax return. Instead, a taxpayer must maintain the certificate or statement in the taxpayer’s records.

Applicability Date

These regulations are proposed to apply to taxable years beginning after the date the regulations are published as final regulations in the **Federal Register**. Pending the issuance of the final regulations, taxpayers may choose to apply these proposed regulations in any open taxable years.

Effect on Other Documents

When finalized, the proposed regulations will obsolete Rev. Rul. 57–344, Rev. Rul. 58–67, Rev. Rul. 58–302, Rev. Rul. 64–223, Rev. Rul. 65–307, Rev. Rul. 70–341, Rev. Rul. 74–153, Rev. Rul. 74–543, Rev. Rul. 79–173, Rev. Rul. 84–89, Notice 2006–86, and Notice 2008–5.

Special Analyses

Certain IRS regulations, including these, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. The regulations affect individuals and do not impose a

collection of information on small entities, therefore the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Statement of Availability of IRS Documents

IRS revenue procedures, revenue rulings, notices and other guidance cited in this preamble are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS Web site at <http://www.irs.gov>.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS, as prescribed in this preamble under the "Addresses" heading. The IRS and Treasury Department request comments on all aspects of the proposed rules. All comments will be available at www.regulations.gov or upon request. A public hearing will be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the hearing will be published in the **Federal Register**.

Drafting Information

The principal authors of these proposed regulations are Christina M. Glendening and Victoria J. Driscoll of the Office of Associate Chief Counsel (Income Tax and Accounting). However, other personnel from the Treasury Department and the IRS participated in the development of the regulations.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Withdrawal of Notice of Proposed Rulemaking

Accordingly, under authority of 26 U.S.C. 7805, the notice of proposed rulemaking (REG-107279-00) that was published in the **Federal Register** on

November 30, 2000 (65 FR 71277), is withdrawn.

Proposed Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 301 are proposed to be amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.2–1 is revised to read as follows:

§ 1.2–1 Returns of surviving spouse and head of household.

(a) *In general.* Tax is determined under section 1(a) for a return of a surviving spouse, as defined in section 2(a) and § 1.2–2(a). Tax is determined under section 1(b) for a return of a head of household, as defined in section 2(b) and § 1.2–2(b).

(b) *Death of a spouse.* If married taxpayers have different taxable years solely because of the death of either spouse, the taxable year of the deceased spouse is deemed to end on the last day of the surviving spouse's taxable year for purposes of determining their eligibility to file a joint return for that year. For rules relating to filing a joint return in the year a spouse dies, see section 6013 and the related regulations.

(c) *Tax tables.* For rules on the use of the tax tables that apply to individuals, see section 3 and the related regulations.

(d) *Change in rates.* For the treatment of taxable years during which a change in the tax rates occurs, see section 15.

(e) *Applicability date.* This section applies to taxable years beginning after the date these regulations are published as final regulations in the **Federal Register**.

■ **Par. 3.** Section 1.2–2 is revised to read as follows:

§ 1.2–2 Definitions and special rules.

(a) *Surviving spouse*—(1) *In general.* If a taxpayer is eligible to file a joint return under section 6013 (without applying section 6013(a)(3)) for the taxable year in which the taxpayer's spouse dies, the taxpayer qualifies as a surviving spouse for each of the two taxable years immediately following the year of the spouse's death if the taxpayer—

(i) Has not remarried before the close of the taxable year; and

(ii) Maintains as the taxpayer's home a household that is for the taxable year the principal place of abode of a son or daughter (including by adoption), stepson, or stepdaughter who is a member of the taxpayer's household and

who is a dependent of the taxpayer within the meaning of paragraph (a)(2) of this section.

(2) *Dependent.* An individual is a dependent of a taxpayer for purposes of this paragraph (a) if the taxpayer may claim a deduction under section 151 for the individual, without applying sections 152(b)(1), (b)(2), and (d)(1)(B).

(b) *Head of household*—(1) *In general.* A taxpayer qualifies as a head of household if the taxpayer is not married at the end of the taxable year, is not a surviving spouse, as defined in paragraph (a) of this section, and either—

(i) Maintains as the taxpayer's home a household that is for more than one-half of the taxable year the principal place of abode of a qualifying child or dependent of the taxpayer, within the meaning of paragraph (b)(2) of this section, who is a member of the taxpayer's household during that period; or

(ii) Maintains a household, whether or not the taxpayer's home, that is for the taxable year the principal place of abode of a parent of the taxpayer, within the meaning of paragraph (b)(3) of this section.

(2) *Qualifying child or dependent*—(i) *Qualifying child.* An individual is a qualifying child for purposes of this paragraph (b) if the individual is a qualifying child of the taxpayer as defined in section 152(c) and the related regulations, determined without applying section 152(e). However, if the individual is married at the end of the taxpayer's taxable year, the individual is not a qualifying child for purposes of this section if the individual is not the taxpayer's dependent because of the limitations of section 152(b)(2) (relating to an individual filing a joint return with his or her spouse) or 152(b)(3) (relating to individuals who are citizens or nationals of other countries).

(ii) *Dependent.* An individual is a dependent for purposes of this paragraph (b) if the individual is the taxpayer's dependent, within the meaning of section 152 without applying sections 152(d)(2)(H) (relating to an individual qualifying as a member of the household) and 152(d)(3) (relating to the special rule for multiple support agreements) for whom the taxpayer may claim a deduction under section 151.

(3) *Parent.* An individual is a parent of the taxpayer for purposes of this paragraph (b) if the individual is the taxpayer's father or mother, including a father or mother who legally adopted the taxpayer, and is the taxpayer's dependent within the meaning of section 152 without applying section 152(d)(3), relating to the special rule for

multiple support agreements, for whom the taxpayer may claim a deduction under section 151.

(4) *Limitation.* An individual may qualify only one taxpayer as a head of household for taxable years beginning in the same calendar year.

(5) *Marital status.* For purposes of this paragraph (b), the marital status of a taxpayer is determined at the end of the taxpayer's taxable year. A taxpayer is considered not married if the taxpayer is legally separated from the taxpayer's spouse under a decree of divorce or separate maintenance, if at any time during the taxable year the taxpayer's spouse is a nonresident alien, or if the provisions of section 7703(b) are satisfied. A taxpayer is considered married if the taxpayer's spouse, other than a spouse who is a nonresident alien, dies during the taxable year.

(6) *Nonresident alien.* A taxpayer does not qualify as a head of household if the taxpayer is a nonresident alien, as defined in section 7701(b)(1)(B), at any time during the taxable year.

(c) *Member of the household.* An individual is a member of a taxpayer's household if the individual and the taxpayer reside in the same living quarters and the taxpayer maintains the household, in part, for the benefit of the individual. An individual is a member of a taxpayer's household despite a temporary absence due to special circumstances. An individual is not treated as a member of the taxpayer's household if, at any time during the taxable year of the taxpayer, the relationship between the individual and the taxpayer violates local law. See § 1.152-4(c)(2) for rules relating to temporary absences.

(d) *Maintaining a household*—(1) *In general.* A taxpayer maintains a household only if during the taxable year the taxpayer pays more than one-half of the cost of operating the household for the mutual benefit of the residents. These expenses include property taxes, mortgage interest, rent, utility charges, upkeep and repairs, property insurance, and food consumed on the premises. A taxpayer may treat a home's fair market rental value as a cost of maintaining a household, instead of the sum of payments for property taxes, mortgage interest, and property insurance. Expenses of maintaining a household do not include—

(i) The cost of clothing, education, medical treatment, vacations, life insurance, and transportation;

(ii) The value of services performed in the household by the taxpayer or any other person qualifying the taxpayer as a head of household or as a surviving spouse; or

(iii) An expense paid or reimbursed by any other person.

(2) *Proration of costs.* In determining whether a taxpayer pays more than one-half of the cost of maintaining a household that is the principal place of abode of a qualifying child or dependent for less than a taxable year, the cost for the entire taxable year is prorated on the basis of the number of calendar months the qualifying child or dependent resides in the household. A period of less than a calendar month is treated as a full calendar month. Thus, for example, if the cost of maintaining a household for a taxable year is \$30,000, and a taxpayer shares a principal place of abode with a qualifying child or dependent from May 20 to December 31, the taxpayer must furnish more than \$10,000 ($8/12$ of $\$30,000 \times 50$ percent) in maintaining the household from May 1 to December 31 to satisfy the requirements of this paragraph (d).

(3) *New household.* If a new household is established during the taxpayer's taxable year (for example, if spouses separate and one moves out of the family home with the child), the cost of maintaining the new household for the year is the cost of maintaining that household beginning with the date the new household is established. If one spouse and the child remain in the family home and the other parent moves out of the home, the cost of maintaining the household for the year is the cost of maintaining the household beginning with the date the other spouse moves out.

(4) *Birth, death, adoption, or placement.* If an individual is a member of a household for less than a taxable year as a result of the individual's birth, death, adoption, or placement with a taxpayer for adoption or in foster care during that year, the requirement that the individual be a member of the household for more than one-half of the taxable year is satisfied if the individual is a member of the household for more than one-half of the period after the individual's birth, adoption, or placement for adoption or in foster care or before the individual's death.

(5) *Shared residence*—(i) *In general.* If two or more taxpayers not filing a joint return reside in the same living quarters, each taxpayer may be treated as maintaining a separate household if each provides more than one-half of the cost of maintaining the separate household. For this purpose, two households in the same living quarters are not considered separate households if any individual in one household is the spouse of any individual in the other household, or if any individual in one household may claim, or would

have priority under the tiebreaker rules in section 152(c)(4) to claim, any individual in the other household as a dependent.

(ii) *Examples.* The following examples illustrate the rules in this paragraph (d)(5). In each example, assume that if a taxpayer may be treated as residing in a separate household, that taxpayer provides more than one-half of the cost of maintaining that household.

Example 1. Two sisters and their respective children reside in the same living quarters. Neither sister may claim the other sister as a dependent. Each sister pays more than one-half of the expenses for herself and her children, and each sister claims each of her own children as a dependent. Because neither sister may claim the other sister as a dependent, and because neither sister would have priority to claim any of the other sister's children as a qualifying child under the tiebreaker rules of section 152(c)(4), each sister is treated as maintaining a separate household.

Example 2. A and B, an unmarried couple, have two children together (C1 and C2) and all four individuals live in the same living quarters for the entire tax year. Both A and B contribute to paying the expenses of the couple and the two children. A has higher adjusted gross income than B. Each parent files a tax return. Under the tiebreaker rules in section 152(c)(4), the parent with the higher adjusted gross income (in this case, A) would have priority to claim each child as a qualifying child if both claimed the child. As a result, B may not be treated as maintaining a separate household with either child or both children. Therefore, if B may be claimed as A's dependent, then all four individuals are members of the same household. However, if B may not be claimed as A's dependent, B may be treated as maintaining a separate household consisting solely of B, even if B claims one of the children as a dependent on B's return.

Example 3. The facts are the same as in *Example 2* of this paragraph (d)(5)(ii) except that A and B do not have any children together; C1 is the child of A and C2 is the child of B. Neither A nor B may claim the other as a dependent, and each parent pays more than one-half of the expenses for himself or herself and his or her child. Because neither A nor B may claim the other adult or the other adult's child as a dependent, each adult is treated as maintaining a separate household.

Example 4. Grandparent, Parent, and Child live together and Child meets the definition of a qualifying child for both Parent and Grandparent. Both Parent and Grandparent pay their respective expenses, and both contribute to paying Child's expenses. Neither Parent nor Grandparent may claim the other as a dependent. Under the tiebreaker rules of section 152(c)(4), Parent would have priority over Grandparent to claim Child as a qualifying child. Therefore, Grandparent may not be treated as maintaining a household for Grandparent and Child separate from the household of Parent. However, Parent may be treated as maintaining a household for Parent and

Child separate from the household of Grandparent.

(e) *Special rules for maintaining a household*—(1) *Principal place of abode*. For purposes of this section, the term *principal place of abode* has the same meaning as in section 152 and § 1.152-4(c).

(2) *Part-year residence*. If, during the taxable year, an individual who may qualify a taxpayer as head of household is born or dies, is adopted or lawfully placed for adoption with the taxpayer, is an eligible foster child, or is a missing child, whether the taxpayer maintained a household that is the principal place of abode of the individual for the required period is determined under § 1.152-4(d) and (e).

(3) *Change of location*. A taxpayer may maintain a household even though the physical location of the household changes.

(f) *Certain married individuals living apart*. An individual who is considered not married under section 7703(b) also is considered not married for all purposes of part I of subchapter A of chapter 1 of the Code.

(g) *Applicability date*. This section applies to taxable years beginning after the date these regulations are published as final regulations in the **Federal Register**.

■ **Par. 4.** Section 1.3-1 is revised to read as follows:

§ 1.3-1 Tax tables for individuals.

(a) *In general*. Except as otherwise provided in paragraph (b) of this section, in lieu of the tax imposed by section 1, an individual who does not itemize deductions for the taxable year and whose taxable income for the taxable year does not exceed the ceiling amount as defined in paragraph (c) of this section, must determine his or her tax liability under the prescribed tax tables in tax forms and publications of the Internal Revenue Service. The individual must use the appropriate tax rate category under the tax tables. The tax imposed under section 3 and this section shall be treated as tax imposed by section 1.

(b) *Exceptions*. Section 3 and this section do not apply to (1) an individual making a return for a period of fewer than 12 months as a result of a change in annual accounting period, or (2) an estate or trust.

(c) *Ceiling amount defined*. The ceiling amount means the highest amount of taxable income for which a tax amount is determined in the tax tables for the tax rate category in which the taxpayer falls.

(d) *Special rule for surviving spouse*. A taxpayer filing as a surviving spouse

uses the same tax rate category as a taxpayer filing a joint return.

(e) *Applicability date*. This section applies to taxable years beginning after the date these regulations are published as final regulations in the **Federal Register**.

■ **Par. 5.** Section 1.21-1 is amended by revising paragraph (a)(1), removing paragraph (h), redesignating paragraphs (j), (k), and (l) as paragraphs (h), (j), and (k), and revising newly redesignated paragraph (k) to read as follows:

§ 1.21-1 Expenses for household and dependent care services necessary for gainful employment.

(a) *In general*. (1) Section 21 allows a credit to a taxpayer against the tax imposed by chapter 1 for employment-related expenses for household services and care (as defined in paragraph (d) of this section) of a qualifying individual (as defined in paragraph (b) of this section). The purpose of the expenses must be to enable the taxpayer to be gainfully employed (as defined in paragraph (c) of this section). For taxable years beginning after December 31, 2004, a qualifying individual must have the same principal place of abode (as defined by paragraph (g) of this section) as the taxpayer for more than one-half of the taxable year.

* * * * *

(k) *Applicability date*—(1) *In general*. Except as provide in paragraph (k)(2) of this section, this section and §§ 1.21-2 through 1.21-4 apply to taxable years ending after August 14, 2007.

(2) *Exception*. Paragraph (a)(1) of this section applies to taxable years beginning after the date these regulations are published as final regulations in the **Federal Register**.

■ **Par. 6.** Section 1.32-2 is amended by revising the section heading, adding paragraph (c)(3), and revising paragraph (e) to read as follows:

§ 1.32-2 Earned income credit.

* * * * *

(c) * * *

(3) *Qualifying child*—(i) *In general*. For purposes of this section, a qualifying child of the taxpayer is a qualifying child as defined in section 152(c), determined without applying sections 152(c)(1)(D) and 152(e).

(ii) *Application of tie-breaker rules*. For purposes of determining whether a taxpayer is an eligible individual under section 32(c)(1)(A), if an individual meets the definition of a qualifying child under paragraph (c)(3)(i) of this section for more than one taxpayer and the individual is treated as the qualifying child of a taxpayer under the tiebreaker rules of section 152(c)(4) and

the related regulations, then that taxpayer may be an eligible individual under section 32(c)(1)(A)(i) and may claim the earned income credit for a taxpayer with a qualifying child if all other requirements of section 32 are satisfied. If an individual meets the definition of a qualifying child under paragraph (c)(3)(i) of this section for more than one taxpayer and the individual is not treated as the qualifying child of a taxpayer under the tiebreaker rules of section 152(c)(4) and the related regulations, then the individual also is not treated as a qualifying child of that taxpayer in the taxable year for purposes of section 32(c)(1)(A). Thus, that taxpayer may be an eligible individual under section 32(c)(1)(A)(ii) and may claim the earned income credit for a taxpayer without a qualifying child if all other requirements are satisfied.

(iii) *Examples*. The following examples illustrate the rules of this paragraph (c). In each example, the taxpayer uses the calendar year as the taxpayer's taxable year and, except to the extent indicated, each taxpayer meets the requirements to claim the benefit(s) described in the example.

Example 1. Child, Parent, and Grandparent share the same principal place of abode for the taxable year. Child meets the definition of a qualifying child under paragraph (c)(3)(i) of this section for both Parent and Grandparent (and for no other person) for the taxable year. Parent claims the earned income credit with Child as Parent's qualifying child. Under the tiebreaker rules of section 152(c)(4)(A) and the related regulations, Child is treated as the qualifying child of Parent and is not treated as the qualifying child of Grandparent. Under section 32(c)(1) and paragraph (c)(3)(ii) of this section, Parent is an eligible individual under section 32(c)(1)(A)(i) who may claim the earned income credit for a taxpayer with a qualifying child, and Grandparent is an eligible individual under section 32(c)(1)(A)(ii) who may claim the earned income credit for a taxpayer without a qualifying child.

Example 2. The facts are the same as in *Example 1* of this paragraph (c)(3)(iii), except that Grandparent, rather than Parent, claims Child as a qualifying child, and Grandparent's adjusted gross income is higher than Parent's adjusted gross income. Under the tiebreaker rules of section 152(c)(4)(C) and the related regulations, Child is treated as the qualifying child of Grandparent and is not treated as the qualifying child of Parent. Under section 32(c)(1) and paragraph (c)(3)(ii) of this section, Grandparent is an eligible individual under section 32(c)(1)(A)(i) who may claim the earned income credit for a taxpayer with a qualifying child, and Parent is an eligible individual under section 32(c)(1)(A)(ii) who

may claim the earned income credit for a taxpayer without a qualifying child.

* * * * *

(e) *Applicability date*—(1) *In general*. Except as provided in paragraph (e)(2) of this section, this section applies to taxable years beginning after March 5, 2003.

(2) *Exception*. Paragraph (c)(3) of this section applies to taxable years beginning after the date these regulations are published as final regulations in the **Federal Register**.

§ 1.63–1 [Amended]

■ **Par. 7.** Section 1.63–1 is amended by:

■ 1. Removing the language “the zero bracket amount and” from the section heading.

■ 2. Removing the language “section 63(g)” and replacing it with the language “section 63(e)” in paragraph (a).

■ **Par. 8.** Section 1.63–2 is revised to read as follows:

§ 1.63–2 Standard deduction.

The standard deduction means the sum of the basic standard deduction and the additional standard deduction.

■ **Par. 9.** Section 1.63–3 is added to read as follows:

§ 1.63–3 Additional standard deduction for the aged and blind.

(a) *In general*. A taxpayer who, at the end of the taxable year, has attained age 65 or is blind is entitled to an additional standard deduction amount. The additional standard deduction amount is the sum of the amounts to which the taxpayer is entitled under paragraphs (b) and (c) of this section. If an individual meets the requirements for both the additional amount for the aged and the additional amount for the blind, the taxpayer is entitled to both additional amounts.

(b) *Additional amount for the aged*—(1) *Aged taxpayer or spouse*. A taxpayer is entitled to an additional amount under section 63(f)(1) if the taxpayer has attained age 65 before the end of the taxable year. If spouses file a joint return, each spouse who has attained age 65 before the end of the taxable year for which the spouses file the joint return is entitled to an additional amount. A married taxpayer who files a separate return is entitled to an additional amount for the taxpayer's spouse if the spouse has attained age 65 before the end of the taxable year and, for the calendar year in which the taxable year of the taxpayer begins, the spouse has no gross income and is not the dependent of another taxpayer. The taxpayer is not entitled to an additional amount if the spouse dies before

attaining age 65, even though the spouse would have attained age 65 before the end of the taxpayer's taxable year.

(2) *Age determined*. For purposes of section 63(f) and this paragraph (b), a taxpayer's age is determined as of the last day of the taxpayer's taxable year. A person attains the age of 65 on the first moment of the day preceding his or her sixty-fifth birthday.

(c) *Additional amount for the blind*—(1) *Blind taxpayer or spouse*. A taxpayer is entitled to an additional amount under section 63(f)(2) if the taxpayer is blind at the end of the taxable year. If spouses file a joint return, each spouse who is blind at the end of the taxable year for which the spouses file the joint return is entitled to an additional amount. A married taxpayer who files a separate return is entitled to an additional amount for the taxpayer's spouse if the spouse is blind and, for the calendar year in which the taxable year of the taxpayer begins, the spouse has no gross income and is not the dependent of another taxpayer. If the spouse dies during the taxable year, the date of death is the time for determining the spouse's blindness.

(2) *Blindness determined*. A taxpayer who claims an additional amount allowed by section 63(f)(2) for the blind must maintain in the taxpayer's records a statement from a physician skilled in the diseases of the eye or a registered optometrist stating that the physician or optometrist has examined the person for whom the additional amount is claimed and, in the opinion of the physician or optometrist, the person's central visual acuity did not exceed 20/200 in the better eye with correcting lenses, or the person's visual acuity was accompanied by a limitation in the field of vision such that the widest diameter of the visual field subtends an angle no greater than 20 degrees. The statement must provide that the physician or optometrist examined the person in the taxpayer's taxable year for which the amount is claimed, or that the physician or optometrist examined the person in an earlier year and that the visual impairment is irreversible.

(d) *Applicability date*. This section and §§ 1.63–1(a) and 1.63–2 apply to taxable years beginning after the date these regulations are published as final regulations in the **Federal Register**.

■ **Par. 10.** Section 1.151–1 is amended by revising paragraphs (a)(1), (c), and (d) to read as follows:

§ 1.151–1 Deductions for personal exemptions.

(a) * * * (1) In computing taxable income, an individual is allowed a deduction for the exemptions for an

individual taxpayer and spouse (the personal exemptions) and the exemption for a dependent of the taxpayer.

* * * * *

(c) *Additional exemption for dependent*. Section 151(c) allows a taxpayer an exemption for each individual who is a dependent (as defined in section 152) of the taxpayer for the taxable year. See §§ 1.152–1 through 1.152–5 for rules relating to dependents.

(d) *Applicability date*. Paragraphs (a)(1) and (c) of this section apply to taxable years beginning after the date these regulations are published as final regulations in the **Federal Register**.

§§ 1.151–2, 1.151–3, and 1.151–4 [Removed]

■ **Par. 11.** Sections 1.151–2, 1.151–3, and 1.151–4 are removed.

■ **Par. 12.** Section 1.152–0 is added under the undesignated center heading Deductions for Personal Exemptions to read as follows:

§ 1.152–0 Table of contents.

This section lists the captions contained in § 1.152–1 through § 1.152–5.

§ 1.152–1 General rules for dependents.

- (a) In general.
 - (1) Dependent defined.
 - (2) Exceptions.
 - (i) Dependents ineligible.
 - (ii) Married dependents.
 - (iii) Citizens or nationals of other countries.
 - (b) Definitions.
 - (1) Child.
 - (i) In general.
 - (ii) Adopted child.
 - (iii) Eligible foster child.
 - (iv) Authorized placement agency.
 - (2) Student.
 - (3) Brother and sister.
 - (4) Parent.
- (c) Applicability date.

§ 1.152–2 Qualifying child.

- (a) In general.
- (b) Qualifying child relationship test.
- (c) Residency test.
- (d) Age test.
 - (1) In general.
 - (2) Disabled individual.
 - (e) Qualifying child support test.
 - (f) Joint return test.
 - (g) Child who is eligible to be claimed as a qualifying child by more than one taxpayer.
 - (1) In general.
 - (i) More than one eligible parent.
 - (ii) Eligible parent not claiming.
 - (iii) One eligible parent and other eligible taxpayer(s).
 - (iv) No eligible parent.
 - (2) Determination of adjusted gross income of a person who files a joint return.
 - (3) Coordination with other provisions.
 - (4) Examples.

§ 1.152–3 Qualifying relative.

- (a) In general.

- (b) Qualifying relative relationship test.
- (c) Gross income test.
 - (1) In general.
 - (2) Income of disabled or handicapped individuals.
 - (d) Qualifying relative support test.
 - (1) In general.
 - (2) Certain income of taxpayer's spouse.
 - (3) Support from stepparent.
 - (4) Multiple support agreements.
 - (e) Not a qualifying child test.
 - (1) In general.
 - (2) Examples.
- § 1.152-4 Rules for a qualifying child and a qualifying relative.
 - (a) Support.
 - (1) In general.
 - (2) Payments made during the year for unpaid or future support.
 - (3) Governmental payments.
 - (i) Governmental payments as support.
 - (A) In general.
 - (B) Examples.
 - (ii) Governmental payments based on a taxpayer's contributions.
 - (A) In general.
 - (B) Examples.
 - (iii) Payments used for support of another individual.
 - (4) Medical insurance.
 - (5) Medical care payments from personal injury claim.
 - (6) Scholarships.
 - (b) Relationship test.
 - (1) Joint return.
 - (2) Divorce or death of spouse.
 - (c) Principal place of abode.
 - (1) In general.
 - (2) Temporary absence.
 - (3) Residing with taxpayer for more than one-half of the taxable year.
 - (i) In general.
 - (ii) Nights of residence.
 - (A) Nights counted.
 - (B) Night straddling two taxable years.
 - (C) Exception for a parent who works at night.
 - (D) Absences.
 - (4) Examples.
 - (d) Residence for a portion of a taxable year because of special circumstances.
 - (1) Individual who is born or dies during the year.
 - (2) Adopted child or foster child.
 - (e) Missing child.
 - (1) Qualifying child.
 - (2) Qualifying relative.
 - (3) Age limitation.
 - (4) Application.
 - § 1.152-5 Special rule for a child of divorced or separated parents or parents who live apart.
 - (a) In general.
 - (b) Release of claim by custodial parent.
 - (1) In general.
 - (2) Support, custody, and parental status.
 - (i) In general.
 - (ii) Multiple support agreement.
 - (3) Release of claim to child.
 - (c) Custody.
 - (d) Custodial parent.
 - (1) In general.
 - (2) Night straddling taxable years.
 - (3) Absences.
 - (4) Special rule for equal number of nights.
 - (5) Exception for a parent who works at night.

- (e) Written declaration.
 - (1) Form of declaration.
 - (i) In general.
 - (ii) Form designated by IRS.
 - (2) Attachment to return.
 - (i) In general.
 - (ii) Examples.
 - (3) Revocation of written declaration.
 - (i) In general.
 - (ii) Form of revocation.
 - (iii) Attachment to return.
 - (4) Ineffective declaration or revocation.
 - (5) Written declaration executed in a taxable year beginning on or before July 2, 2008.
 - (f) Coordination with other sections.
 - (g) Examples.
 - (h) Applicability date.
 - (1) In general.
 - (2) Exception.

■ **Par. 13.** Section 1.152-1 is revised to read as follows:

§ 1.152-1 General rules for dependents.

(a) *In general*—(1) *Dependent defined*. Except as provided in section 152(b) and paragraph (a)(2) of this section, the term *dependent* means a qualifying child as described in § 1.152-2 or a qualifying relative as described in § 1.152-3. In general, an individual may be treated as the dependent of only one taxpayer for taxable years beginning in the same calendar year.

(2) *Exceptions*—(i) *Dependents ineligible*. If an individual is a dependent of a taxpayer for a taxable year of the taxpayer, the individual is treated as having no dependents for purposes of section 152 and the related regulations in the individual's taxable year beginning in the calendar year in which that taxable year of the taxpayer begins. For purposes of this paragraph (a)(2)(i), an individual is not a dependent of a person if that person is not required to file an income tax return under section 6012 and either does not file an income tax return or files an income tax return solely to claim a refund of estimated or withheld taxes.

(ii) *Married dependents*. An individual is not treated as a dependent of a taxpayer for a taxable year of the taxpayer if the individual files a joint return, other than solely to claim a refund of estimated or withheld taxes, with the individual's spouse under section 6013 for the taxable year beginning in the calendar year in which that taxable year of the taxpayer begins.

(iii) *Citizens or nationals of other countries*. An individual who is not a citizen or national of the United States is not treated as a dependent of a taxpayer unless the individual is a resident, as defined in section 7701(b), of the United States or of a country contiguous to the United States (Canada or Mexico). This limitation, however,

does not apply to an adopted child, as defined in section 152(f)(1)(B) and paragraph (b)(1)(ii) of this section, if the taxpayer is a citizen or national of the United States and the child has the same principal place of abode as the taxpayer and is a member of the taxpayer's household, within the meaning of §§ 1.152-4(c) and 1.2-2(c), respectively, for the taxpayer's taxable year. See § 1.152-4(d)(2) for rules relating to residence for a portion of a taxable year. A taxpayer and the child have the same principal place of abode for the taxpayer's taxable year if the taxpayer and child have the same principal place of abode for the entire portion of the taxable year following the placement of the child with the taxpayer.

(b) *Definitions*. The following definitions apply for purposes of section 152 and the related regulations.

(1) *Child*—(i) *In general*. The term *child* means a son, daughter, stepson, or stepdaughter, or an eligible foster child, within the meaning of paragraph (b)(1)(iii) of this section, of the taxpayer.

(ii) *Adopted child*. In determining whether an individual bears any of the relationships described in paragraph (b)(1)(i) of this section, § 1.152-2(b), or § 1.152-3(b), a legally adopted child of a person, or a child who is lawfully placed with a person for legal adoption by that person, is treated as a child by blood of that person. A child lawfully placed with a person for legal adoption by that person includes a child placed for legal adoption by a parent, an authorized placement agency, or any other person(s) authorized by law to place a child for legal adoption.

(iii) *Eligible foster child*. The term *eligible foster child* means a child who is placed with a person by an authorized placement agency or by judgment, decree, or other order of any court of competent jurisdiction.

(iv) *Authorized placement agency*. The term *authorized placement agency* means a State, the District of Columbia, a possession of the United States, a foreign country, an Indian Tribal Government (ITG) (as defined in section 7701(a)(40)), or an agency or organization that is authorized by a State, the District of Columbia, a possession of the United States, a foreign country, an ITG, or a political subdivision of any of the foregoing, to place children for legal adoption or in foster care.

(2) *Student*. The term *student* means an individual who, for some part of each of five calendar months, whether or not consecutive, during the calendar year in which the taxable year of the taxpayer begins, either is a full-time student at an

educational organization, as defined in section 170(b)(1)(A)(ii), or is pursuing a full-time course of institutional on-farm training under the supervision of an accredited agent of an educational organization or of a State or political subdivision of a State. A full-time student is one who is enrolled for the number of hours or courses that the educational organization considers full-time attendance.

(3) *Brother and sister.* The terms *brother* and *sister* include a brother or sister by half blood.

(4) *Parent.* The term *parent* refers to a biological or adoptive parent of an individual. It does not include a stepparent who has not adopted the individual.

(c) *Applicability date.* This section, and §§ 1.152–2, 1.152–3, and 1.152–4 apply to taxable years beginning after the date these regulations are published as final regulations in the **Federal Register**.

■ **Par. 14.** Section 1.152–2 is revised to read as follows:

§ 1.152–2 Qualifying child.

(a) *In general.* The term *qualifying child* of a taxpayer for a taxable year means an individual who satisfies the tests described in paragraphs (b), (c), (d), (e), and (f) of this section. If an individual satisfies the definition of a qualifying child for more than one taxpayer, then the tiebreaker rules in paragraph (g) of this section apply. See, however, section 152(e) and § 1.152–5 for a special rule for a child of divorced or separated parents or parents who live apart.

(b) *Qualifying child relationship test.* The individual must bear one of the following relationships to the taxpayer—

(1) A child of the taxpayer or descendant of such a child; or
(2) A brother, sister, stepbrother, or stepsister of the taxpayer, or a descendant of any of these relatives.

(c) *Residency test.* The individual must have the same principal place of abode as the taxpayer for more than one-half of the taxable year. Generally, an individual has the same principal place of abode as the taxpayer for more than one-half of the taxable year if the individual resides with the taxpayer for more than one-half of the taxable year. See § 1.152–4(c) for rules relating to principal place of abode and temporary absence and for determining whether an individual resides with the taxpayer for more than one-half of the taxable year.

(d) *Age test—(1) In general.* The individual must be younger than the taxpayer claiming the individual as a qualifying child and must not have

attained the age of 19, or age 24 if the individual is a student within the meaning of § 1.152–1(b)(2), as of the end of the calendar year in which the taxpayer's taxable year begins. For purposes of this section, an individual attains an age on the anniversary of the individual's birth.

(2) *Disabled individual.* This age requirement is treated as satisfied if the individual is permanently and totally disabled, as defined in section 22(e)(3), at any time during the calendar year.

(e) *Qualifying child support test.* The individual must not provide more than one-half of the individual's own support for the calendar year in which the taxpayer's taxable year begins. See § 1.152–4(a) for rules relating to the definition and sources of an individual's support.

(f) *Joint return test.* The individual must not file a joint return, other than solely to claim a refund of estimated or withheld taxes, under section 6013 with the individual's spouse for the taxable year beginning in the calendar year in which the taxpayer's taxable year begins.

(g) *Child who is eligible to be claimed as a qualifying child by more than one taxpayer—(1) In general.* Under section 152(c)(4), if an individual satisfies the definition of a qualifying child for two or more taxpayers (eligible taxpayers) for a taxable year beginning in the same calendar year, the following rules apply.

(i) *More than one eligible parent.* If more than one eligible taxpayer is a parent of the individual (eligible parent), any one of the eligible parents may claim the individual as a qualifying child. However, if more than one eligible parent claims the individual as a qualifying child, and those eligible parents do not file a joint return with each other, the individual is treated as the qualifying child of the eligible parent claiming the individual with whom the individual resides for the longest period of time during the taxable year as determined under § 1.152–4(c)(3). If the individual resides for the same amount of time during the taxable year with each eligible parent claiming the child, the individual is treated as the qualifying child of the eligible parent with the highest adjusted gross income who claims the individual.

(ii) *Eligible parent not claiming.* If at least one eligible taxpayer is a parent of the individual, but no eligible parent claims the individual as a qualifying child, the individual may be treated as the qualifying child of another eligible taxpayer only if that taxpayer's adjusted gross income exceeds both the adjusted gross income of each eligible parent of the individual and the adjusted gross

income of each other eligible taxpayer, if any.

(iii) *One eligible parent and other eligible taxpayer(s).* Except as provided in paragraph (g)(1)(i) or (ii) of this section, if there are two or more eligible taxpayers, only one of whom is the parent of the individual, the individual is treated as the qualifying child of the eligible parent.

(iv) *No eligible parent.* If no eligible taxpayer is a parent of the individual, the individual is treated as the qualifying child of the eligible taxpayer with the highest adjusted gross income for the taxable year.

(2) *Determination of adjusted gross income of a person who files a joint return.* For purposes of section 152 and the related regulations, the adjusted gross income of each person who files a joint return is the total adjusted gross income shown on the joint return.

(3) *Coordination with other provisions.* Except to the extent that section 152(e) and § 1.152–5 apply, if more than one taxpayer may claim a child as a qualifying child, the child is treated as the qualifying child of only one taxpayer for purposes of head of household filing status under section 2(b), the child and dependent care credit under section 21, the child tax credit under section 24, the earned income credit under section 32, the exclusion from income for dependent care assistance under section 129, and the dependency exemption under section 151. Thus, the taxpayer claiming the individual as a qualifying child under any one of these sections is the only taxpayer who may claim any credit or exemption under these other sections for that same individual for a taxable year beginning in the same calendar year as the taxpayer's taxable year. If section 152(e) applies, however, the noncustodial parent may claim the child as a qualifying child for purposes of the dependency exemption and the child tax credit, and another person may claim the child for purposes of one or more of these other provisions. See § 1.152–5 for rules under section 152(e).

(4) *Examples.* The following examples illustrate the rules in this paragraph (g). In the examples, each taxpayer uses the calendar year as the taxpayer's taxable year, the child is a qualifying child (as described in section 152(c) and this section) of each taxpayer, and, except to the extent indicated, each taxpayer meets the requirements to claim the benefit(s) described in the example.

Example 1. (i) A and B, parents of Child, are married to each other. A, B, and Child share the same principal place of abode for the first 8 months of the year. Thus, both parents satisfy the qualifying child residency

test of paragraph (c) of this section. For the last 4 months of the year, the parents live apart from each other, and B and Child share the same principal place of abode. Section 152(e), relating to divorced or separated parents, does not apply. The parents file as married filing separately for the taxable year, and both parents claim Child as a qualifying child.

(ii) Under paragraph (g)(1)(i) of this section, Child is treated as a qualifying child of B for all purposes, because Child resided with B for the longer period of time during the taxable year. Because section 152(e) does not apply, Child may not be treated as a qualifying child of A for any purpose.

Example 2. (i) The facts are the same as in *Example 1* of this paragraph (g)(4), except that B does not claim Child as a qualifying child.

(ii) Because A and B are not both claiming the same child as a qualifying child, under paragraph (g)(1)(i) of this section, Child is treated as a qualifying child of A.

Example 3. (i) Child, Child's parent (D), and Grandparent share the same principal place of abode. D is not married and is not a qualifying child or dependent of Grandparent, and Grandparent is not D's dependent. Section 152(e), relating to divorced or separated parents, does not apply. Under paragraph (a) of this section, Child meets the definition of a qualifying child of both D and Grandparent. D claims Child as a qualifying child for purposes of the child and dependent care credit under section 21, the earned income credit under section 32, and the dependency exemption under section 151. Grandparent claims Child as a qualifying child for purposes of head of household filing status under section 2(b).

(ii) Under paragraph (g)(1)(iii) of this section, Child is treated as the qualifying child of D for all purposes, because D is eligible to claim and claims Child as D's qualifying child. Because D is eligible to claim and claims Child as D's qualifying child, under paragraph (g)(3) of this section, Child may not be treated as a qualifying child of Grandparent for any purpose. Grandparent erroneously claimed Child as Grandparent's qualifying child for purposes of head of household filing status under section 2(b). If D had not claimed Child as D's qualifying child for any purpose, under paragraph (g)(1)(ii) of this section, Grandparent could have claimed Child as Grandparent's qualifying child if Grandparent's adjusted gross income (AGI) exceeded D's AGI. In that situation, under paragraph (g)(3) of this section, Grandparent could have claimed Child as Grandparent's qualifying child for purposes of any of the child-related tax benefits, provided that Grandparent had met the requirements of those sections.

Example 4. (i) The facts are the same as in *Example 3* of this paragraph (g)(4), except that Child's parents, D and E, are married to each other and share the same principal place of abode with Child and Grandparent for the entire taxable year. Under paragraph (a) of this section, Child meets the definition of a qualifying child of both parents and Grandparent. D and E file a joint return for the taxable year and do not claim Child as a qualifying child for any purpose.

(ii) Because D or E may claim Child as a qualifying child but neither claims Child as a qualifying child for any purpose, under paragraph (g)(1)(ii) of this section, Grandparent may claim Child as a qualifying child if Grandparent's AGI exceeds the total AGI reported on the joint return of D and E.

Example 5. (i) The facts are the same as in *Example 4* of this paragraph (g)(4), except that D and E are divorced from each other, E moved into a separate residence during that year and is the noncustodial parent, and section 152(e), relating to divorced or separated parents, applies. E attaches to E's return a Form 8332 on which D agrees to release D's claim to a dependency exemption for Child and E claims Child as a qualifying child for purposes of the dependency exemption and the child tax credit.

(ii) Under paragraph (g)(3) of this section, Child is treated as a qualifying child of E for purposes of the dependency exemption and the child tax credit. Child may be treated as a qualifying child of D for purposes of the earned income credit. If D claims Child as a qualifying child for purposes of the earned income credit, under paragraph (g)(1)(iii) of this section, Child may not be treated as a qualifying child of Grandparent for any purpose.

Example 6. (i) F and G, parents of two children, are married to each other. F, G, and both children share the same principal place of abode for the entire taxable year. F and G file as married filing separately for the taxable year. F claims the older child as a qualifying child for purposes of the child tax credit, dependency exemption, and the child and dependent care credit. G claims the younger child as a qualifying child for purposes of the same three tax benefits.

(ii) The older child is treated as a qualifying child of F and the younger child is treated as a qualifying child of G. The tiebreaker rule of paragraph (g)(1)(i) of this section does not apply because F and G are not claiming the same child as a qualifying child.

■ **Par. 15.** Section 1.152-3 is revised to read as follows:

§ 1.152-3 Qualifying relative.

(a) *In general.* The term *qualifying relative* of a taxpayer for a taxable year means an individual who satisfies the tests described in paragraphs (b), (c), (d), and (e) of this section. See, however, section 152(e) and § 1.152-5 for a special rule for a child of divorced or separated parents or parents who live apart.

(b) *Qualifying relative relationship test.* The individual must bear one of the following relationships to the taxpayer:

- (1) A child or descendant of a child;
- (2) A brother, sister, stepbrother, or stepsister;
- (3) A father or mother, or an ancestor of either;
- (4) A stepfather or stepmother;
- (5) A niece or nephew;
- (6) An aunt or uncle;

(7) A son-in-law, daughter-in-law, father-in-law, mother-in-law, brother-in-law, or sister-in-law; or

(8) An individual (other than one who at any time during the taxable year was the taxpayer's spouse, determined without regard to section 7703) who for the taxable year of the taxpayer has the same principal place of abode as the taxpayer and is a member of the taxpayer's household. See § 1.2-2(c) for the definition of a member of the household, and § 1.152-4(c) for rules relating to the meaning of principal place of abode and the meaning of temporary absence.

(c) *Gross income test*—(1) *In general.* The individual's gross income for the calendar year in which the taxable year begins must be less than the exemption amount as defined in section 151(d).

(2) *Income of disabled or handicapped individuals.* For purposes of paragraph (c)(1) of this section, the gross income of an individual who is permanently and totally disabled, as defined in section 22(e)(3), at any time during the taxable year does not include income for services performed by the individual at a sheltered workshop, as defined in section 152(d)(4)(B), if—

(i) The principal reason for the individual's presence at the workshop is the availability of medical care there; and

(ii) The individual's income arises solely from activities at the workshop that are incident to the medical care.

(d) *Qualifying relative support test*—(1) *In general.* The individual must receive over one-half of the individual's support from the taxpayer for the calendar year in which the taxpayer's taxable year begins. See § 1.152-4(a) for rules relating to support.

(2) *Certain income of taxpayer's spouse.* A payment to a spouse that is includible in the payee spouse's gross income under section 71 (relating to alimony and separate maintenance payments) or section 682 (relating to income of an estate or trust in the case of divorce) is not treated as a payment by the payor spouse for the support of any dependent.

(3) *Support from stepparent.* Any support provided to or for the benefit of an individual by a stepparent of the individual is treated as support provided by the individual's parent who is married to the stepparent.

(4) *Multiple support agreements.* If more than one-half of an individual's support is provided by two or more persons together, a taxpayer is treated as having contributed over one-half of the support of that individual for the calendar year if—

(i) No one person contributes more than one-half of the individual's support;

(ii) Each member of the group that collectively contributes more than one-half of the support of the individual would have been entitled to claim the individual as a dependent for a taxable year beginning in that calendar year but for the fact that the group member alone did not contribute more than one-half of the individual's support;

(iii) The taxpayer claiming the individual as a qualifying relative contributes more than 10 percent of the individual's support; and

(iv) Each other group member who contributes more than 10 percent of the support of the individual furnishes to the taxpayer claiming the individual as a dependent a written declaration that the other person will not claim the individual as a dependent for any taxable year beginning in that calendar year.

(e) *Not a qualifying child test*—(1) *In general.* The individual must not be a qualifying child of the taxpayer or of any other taxpayer for any taxable year beginning in the calendar year in which the taxpayer's taxable year begins. An individual is not a qualifying child of a person, however, if that person is not required to file an income tax return under section 6012, and either does not file an income tax return or files an income tax return solely to claim a refund of estimated or withheld taxes.

(2) *Examples.* The following examples illustrate the rules in this paragraph (e). In each example, each taxpayer uses the calendar year as the taxpayer's taxable year, and except to the extent otherwise indicated, each taxpayer meets the requirements to claim the benefits described in the example.

Example 1. For the taxable year, B provides more than one-half of the support of an unrelated friend, C, and C's 3-year-old child, D, who are members of B's household. No taxpayer other than C is eligible to claim D as a qualifying child. C has no gross income, is not required by section 6012 to file a Federal income tax return, and does not file a Federal income tax return for the taxable year. Under paragraph (e)(1) of this section, because C does not have a filing requirement and does not file an income tax return, D is not treated as a qualifying child of C, and B may claim both C and D as B's qualifying relatives.

Example 2. The facts are the same as in *Example 1* of this paragraph (e)(2) except that C has earned income of \$1,500 during the taxable year, had income tax withheld from C's wages, and is not required by section 6012 to file an income tax return. C files an income tax return solely to obtain a refund of withheld taxes and does not claim the earned income credit under section 32. Under paragraph (e)(1) of this section,

because C does not have a filing requirement and files only to obtain a refund of withheld taxes, D is not treated as a qualifying child of C, and B may claim both C and D as B's qualifying relatives.

Example 3. The facts are the same as in *Example 2* of this paragraph (e)(2) except that C's earned income is more than the amount of the dependency exemption for that year. C files an income tax return for the taxable year to obtain a refund of withheld taxes and claims the earned income credit. Because C filed an income tax return to obtain the earned income credit and not solely to obtain a refund of withheld taxes, D is a qualifying child of a taxpayer (C), and B may not claim D as a qualifying relative. B also may not claim C as a qualifying relative because C fails the gross income test under paragraph (c) of this section.

■ **Par. 16.** Redesignate § 1.152–4 as § 1.152–5, and add a new § 1.152–4 to read as follows:

§ 1.152–4 Rules for a qualifying child and a qualifying relative.

(a) *Support*—(1) *In general.* The term *support* includes food, shelter, clothing, medical and dental care, education, and similar items. Support does not include an individual's Federal, State, and local income taxes paid from the individual's own income or assets, Social Security and Medicare taxes under section 3101 paid from the individual's own income, life insurance premiums, or funeral expenses. In determining whether an individual provided more than one-half of the individual's own support for purposes of § 1.152–2(e), or whether a taxpayer provided more than one-half of an individual's support for purposes of § 1.152–3(d), the amount of support provided by the individual, or the taxpayer, is compared to the total amount of the individual's support from all sources. For these purposes, except as otherwise provided in this paragraph (a), the amount of an individual's total support is the amount of support from all sources, and includes support the individual provides and amounts that are excludable from gross income. Generally, the amount of an item of support is the amount of expense paid or incurred to furnish the item of support. If the item of support furnished is property or a benefit, such as lodging, however, the amount of the item of support is the fair market value of the item.

(2) *Payments made during the year for unpaid or future support.* For purposes of determining the amount of support provided in a calendar year, an amount paid in a calendar year after the calendar year in which the liability is incurred is treated as paid in the year of payment. An amount paid in a calendar year before due, whether or not made in the form of a lump sum payment in

settlement of a person's liability for support, is treated as support paid during the calendar year of payment rather than the calendar year when payment is due. A payment of a liability from amounts set aside in trust in a prior year is treated as made in the year in which the liability is paid.

(3) *Governmental payments*—(i) *Governmental payments as support*—(A) *In general.* Except as provided in paragraph (a)(3)(iii) of this section, governmental payments and subsidies for an item of support are support provided by a third party, the government.

(B) *Examples.* Payments of Temporary Assistance for Needy Families (42 U.S.C. 601–619), low-income housing assistance (42 U.S.C. 1437f), Supplemental Nutrition Assistance Program benefits (7 U.S.C. chapter 51), Supplemental Security Income payments (42 U.S.C. 1381–1383f), foster care maintenance payments, and adoption assistance payments are governmental payments and subsidies for an item of support as described in paragraph (a)(3)(i)(A) of this section.

(ii) *Governmental payments based on a taxpayer's contributions*—(A) *In general.* Except as provided in paragraph (a)(3)(iii) of this section, governmental payments based on a taxpayer's earnings and contributions into the Social Security system are support provided by the individual for whose benefit the payments are made to the extent those payments are used for that individual's support.

(B) *Examples.* Social Security old age benefits under section 202(b) of Title II of the Social Security Act (SSA) (42 U.S.C. 402) are governmental payments based on a taxpayer's earnings and contributions into the Social Security system as described in paragraph (a)(3)(ii)(A) of this section. Similarly, Social Security survivor and disability insurance benefits paid under section 202(d) of the SSA to, or for the benefit of, the child of a deceased or disabled parent are treated as support provided by the child to the extent those payments are used for the child's support.

(iii) *Payments used for support of another individual.* Governmental payments and subsidies described in paragraph (a)(3)(i) of this section and governmental payments described in paragraph (a)(3)(ii) of this section that are used by the recipient or other intended beneficiary to support another person are support of that person provided by the recipient or other intended beneficiary, rather than support provided by a third party, the government.

(4) *Medical insurance.* Medical insurance premiums, including Part A Basic Medicare premiums, if any, under Title XVIII of the Social Security Act (42 U.S.C. 1395c to 1395i-5), Part B Supplemental Medicare premiums under Title XVIII of the Social Security Act (42 U.S.C. 1395j to 1395w-6), Part C Medicare + Choice Program premiums under Title XVIII of the Social Security Act (42 U.S.C. 1395w-21 to 1395w-29), and Part D Voluntary Prescription Drug Benefit Medicare premiums under Title XVIII of the Social Security Act (42 U.S.C. 1395w-101 to 1395w-154), are treated as support. Medical insurance proceeds, including benefits received under Medicare Part A, Part B, Part C, and Part D, are not treated as items of support and are disregarded in determining the amount of the individual's support. Services provided to an individual under the medical and dental care provisions of the Armed Forces Act (10 U.S.C. chapter 55) are not treated as support and are disregarded in determining the amount of the individual's support.

(5) *Medical care payments from personal injury claim.* Payments for the medical care of an injured individual from a third party, including a third party's insurance company, in satisfaction of a legal claim for the personal injury of the individual are not treated as items of support and are disregarded in determining the amount of the individual's support.

(6) *Scholarships.* Amounts a student who is the child of the taxpayer receives as a scholarship for study at an educational organization described in section 170(b)(1)(A)(ii) are not treated as an item of support and are disregarded in determining the amount of the student's support.

(b) *Relationship test*—(1) *Joint return.* A taxpayer may satisfy the relationship test described in § 1.152-2(b) (relating to a qualifying child) or in § 1.152-3(b) (relating to a qualifying relative) if a described relationship exists between an individual and the taxpayer claiming that individual as a qualifying child or qualifying relative, even though the taxpayer files a joint return with his or her spouse who does not have a described relationship with the individual.

(2) *Divorce or death of spouse.* If the relationship between the taxpayer and an individual claimed by that taxpayer as a dependent results from a marriage, the taxpayer's qualifying relationship with the individual continues after the termination of the marriage by divorce or death.

(c) *Principal place of abode*—(1) *In general.* The term *principal place of*

abode of a person means the primary or main home or dwelling where the person resides. A person's principal place of abode need not be the same physical location throughout the taxable year and may be temporary lodging such as a homeless shelter or relief housing resulting from displacement caused by a natural disaster.

(2) *Temporary absence.* The taxpayer and an individual have the same principal place of abode despite a temporary absence by either person because of special circumstances. An absence is temporary if the person would have resided at the place of abode but for the absence and, under the facts and circumstances, it is reasonable to assume that the person will return to reside at the place of abode. An individual who does not reside with the taxpayer because of a temporary absence is treated as residing with the taxpayer. For example, a nonpermanent failure to occupy the abode by reason of illness, education, business, vacation, military service, institutionalized care for a child who is totally and permanently disabled (as defined in section 22(e)(3)), or incarceration may be treated as a temporary absence because of special circumstances. If an infant must remain in a hospital for a period of time after birth and would have resided with the taxpayer during that period but for the hospitalization, the infant is treated as having the same principal place of abode as the taxpayer during the period of hospitalization.

(3) *Residing with taxpayer for more than one-half of the taxable year*—(i) *In general.* An individual has the same principal place of abode as the taxpayer for more than one-half of the taxable year if the individual resides with the taxpayer for at least 183 nights during the taxpayer's taxable year, or 184 nights if the taxable year includes a leap day.

(ii) *Nights of residence*—(A) *Nights counted.* For purposes of determining whether an individual resides with the taxpayer for more than one-half of the taxable year, an individual resides with a taxpayer for a night if the individual sleeps—

(1) At the taxpayer's principal place of abode, whether or not the taxpayer is present; or

(2) In the company of the taxpayer when the individual does not sleep at the taxpayer's principal place of abode (for example, when the taxpayer and the individual are on vacation).

(B) *Night straddling two taxable years.* If an individual resides with a taxpayer for a night that extends over two taxable years, that night is allocated to the taxable year in which the night begins.

(C) *Exception for a parent who works at night.* If, in a calendar year, because of a taxpayer's nighttime work schedule, an individual resides for at least 183 days, or 184 days if the taxable year includes a leap day, but not nights with the taxpayer, the individual is treated as residing with the taxpayer for more than one-half of the taxable year.

(D) *Absences.* An individual who does not reside with a taxpayer for a night because of a temporary absence as described in paragraph (c)(2) of this section is treated as residing with the taxpayer for that night if the individual would have resided with the taxpayer for that night but for the absence.

(4) *Examples.* The following examples illustrate the rules of this paragraph (c). In each example, each taxpayer uses the calendar taxable year, and section 152(e) does not apply.

Example 1. B and C are the divorced parents of Child. In 2015, Child sleeps at B's principal place of abode for 210 nights and at C's principal place of abode for 155 nights. Under paragraph (c)(3) of this section, Child resides with B for at least 183 nights during 2015 and has the same principal place of abode as B for more than one-half of 2015.

Example 2. D and E are the divorced parents of Child, and Grandparent is E's parent. In 2015, Child resides with D for 140 nights, with E for 135 nights, and with Grandparent for the last 90 nights of the year. None of these periods is a temporary absence. Under paragraph (c)(3) of this section, Child does not have the same principal place of abode as D, E, or Grandparent for more than one-half of 2015.

Example 3. The facts are the same as in *Example 2* of this paragraph (c)(4), except that, for the 90-day period that Child lives with Grandparent, E is temporarily absent on military service. Child would have lived with E if E had not been absent during that period. Under paragraphs (c)(2) and (c)(3)(ii)(D) of this section, Child is treated as residing with E for 225 nights in 2015 and, therefore, Child has the same principal place of abode as E for more than one-half of 2015.

Example 4. The facts are the same as in *Example 2* of this paragraph (c)(4), except that, for the last 90 days of the year Child, who is 18, moves into Child's own apartment and begins full-time employment. Because Child's absence is not temporary, under paragraph (c)(2) of this section, Child is not treated as residing with D or E for the 90 nights. Under paragraph (c) of this section, Child does not have the same principal place of abode as D or E for more than one-half of 2015.

Example 5. F and G are the divorced parents of Child. In 2015, Child sleeps at F's principal place of abode for 170 nights and at G's principal place of abode for 170 nights. Child spends 25 nights of the year away from F and G at a summer camp. Child would have spent those nights with F if Child had not gone to summer camp. Under paragraphs (c)(2) and (c)(3)(ii)(D) of this section, Child is treated as residing with F for 195 nights and,

therefore, Child has the same principal place of abode as F for more than one-half of 2015.

Example 6. H and J are the divorced parents of Child. In 2015, Child sleeps at H's principal place of abode for 180 nights and at J's principal place of abode for 180 nights. For 5 nights during that year, Child sleeps at Grandparent's abode or at the house of a friend. Child would have spent all 5 nights at H's house if Child had not slept at Grandparent's or a friend's house. Under paragraphs (c)(2) and (c)(3)(ii)(D) of this section, Child is treated as residing with H for 185 nights and, therefore, Child has the same principal place of abode as H for more than one-half of 2015.

(d) *Residence for a portion of a taxable year because of special circumstances*—(1) *Individual who is born or dies during the year.* If an individual is born or dies during a taxpayer's taxable year, the residency test for a qualifying child is treated as met if the taxpayer and the individual have the same principal place of abode for more than one-half of the portion of the taxable year during which the individual is alive. If an individual is born or dies during a taxpayer's taxable year, the relationship test for a qualifying relative who is a member of the taxpayer's household is treated as met if the taxpayer and the individual have the same principal place of abode for the entire portion of the taxable year during which the individual is alive.

(2) *Adopted child or foster child.* If, during a taxpayer's taxable year, the taxpayer adopts a child, a child is lawfully placed with a taxpayer for legal adoption by that taxpayer, or an eligible foster child is placed with a taxpayer, the residency test for a qualifying child and the residency requirement under § 1.152–1(a)(2)(iii) for a child who is not a citizen or national of the United States are treated as met if the taxpayer and the child have the same principal place of abode for more than one-half of the portion of the taxable year as required for a qualifying child, or for the entire taxable year as required for a noncitizen, following the placement of the child with the taxpayer.

(e) *Missing child*—(1) *Qualifying child.* A child of the taxpayer who is presumed by law enforcement authorities to have been kidnapped by someone who is not a member of the family of either the child or the taxpayer, and who had for the taxable year in which the kidnapping occurred the same principal place of abode as the taxpayer for more than one-half of the portion of the taxable year before the date of the kidnapping, is treated as meeting the residency test for a qualifying child, as described in § 1.152–2(c), of the taxpayer for all taxable years ending during the period

that the child is missing. Also, the child is treated as meeting the residency test in the year of the child's return if the child has the same principal place of abode as the taxpayer for more than one-half of the portion of the taxable year following the date of the child's return.

(2) *Qualifying relative.* A child of the taxpayer who is presumed by law enforcement authorities to have been kidnapped by someone who is not a member of the family of either the child or the taxpayer, and who was a qualifying relative of the taxpayer for the portion of the taxable year before the date of the kidnapping, is treated as a qualifying relative, as described in section 152(d) and § 1.152–3, of the taxpayer for all taxable years ending during the period that the child is missing. Also, the child is treated as a qualifying relative of the taxpayer in the year of the child's return if the child is a qualifying relative of the taxpayer for the portion of the taxable year following the date of the child's return.

(3) *Age limitation.* The special rules provided in this paragraph (e) cease to apply as of the first taxable year of the taxpayer beginning after the calendar year in which there is a determination that the child is dead or, if earlier, in which the child would have attained age 18.

(4) *Application.* This paragraph (e) applies solely for purposes of determining surviving spouse or head of household filing status under section 2, the child tax credit under section 24, the earned income credit under section 32, and the dependency exemption under section 151.

■ **Par. 17** In newly redesignated § 1.152–5, paragraphs (e)(2), (e)(3)(iii), and (h) are revised to read as follows:

§ 1.152–5 Special rule for a child of divorced or separated parents or parents who live apart.

* * * * *

(e) * * *

(2) *Attachment to return*—(i) *In general.* A noncustodial parent must attach a copy of the written declaration to the parent's original or amended return for each taxable year for which the noncustodial parent claims an exemption for the child. A noncustodial parent may submit a copy of the written declaration to the IRS during an examination to substantiate a claim to a dependency exemption for a child. A copy of a written declaration attached to an amended return, or provided during an examination, will not meet the requirement of this paragraph (e) if the custodial parent signed the written declaration after the custodial parent filed a return claiming a dependency

exemption for the child for the year at issue, and the custodial parent has not filed an amended return to remove that claim to a dependency exemption for the child.

(ii) *Examples.* The following examples illustrate the rules of this paragraph (e).

Example 1. Custodial parent (CP) files her 2015 return on March 1, 2016, and claims a dependency exemption for Child. At noncustodial parent's (NCP) request, CP signs a Form 8332 for the 2015 tax year on April 15, 2016. On April 15, NCP files his return claiming a dependency exemption for Child and attaches the signed Form 8332 to his return. Under section 152(e) and paragraph (b) of this section, NCP is allowed a dependency exemption for Child for 2015, and CP is not allowed a dependency exemption for Child for that year.

Example 2. The facts are the same as in **Example 1** of this paragraph (e)(2)(ii), except NCP files on April 15, 2016, a request for an extension to file his tax return because he does not have a signed Form 8332. CP signs the Form 8332 for the 2015 tax year in August of 2016, and NCP files his return a week later. NCP claims a dependency exemption for Child and attaches the signed Form 8332 to his return. Under section 152(e) and paragraph (b) of this section, NCP is allowed a dependency exemption for Child for 2015, and CP is not allowed a dependency exemption for Child for that year.

Example 3. CP files his 2015 return on March 1, 2016, and claims a dependency exemption for Child. NCP files her return on April 15, 2016, and does not claim a dependency exemption for Child, even though her divorce decree allocates the dependency exemption for Child to her. CP signs a Form 8332 for the 2015 tax year in August of 2016, and NCP files an amended return a week later and attaches the signed Form 8332 to her amended return claiming a dependency exemption for Child. Under paragraph (e)(2) of this section, NCP is not allowed a dependency exemption for Child for 2015 if CP has not amended his return to remove a claim to the dependency exemption for Child for that year.

(3) * * *

(iii) *Attachment to return.* The parent revoking the written declaration must attach a copy of the revocation to the parent's original or amended return for each taxable year for which the parent claims a child as a dependent as a result of the revocation. The parent revoking the written declaration must keep a copy of the revocation and evidence of delivery of the notice to the other parent, or of the reasonable efforts to provide actual notice. A parent may submit a copy of a revocation to the IRS during an examination to substantiate a claim to a dependency exemption for the child.

* * * * *

(h) *Applicability date*—(1) *In general.* Except as provided in paragraph (h)(2)

of this section, this section applies to taxable years beginning after July 2, 2008.

(2) *Exception.* Paragraphs (e)(2) and (e)(3)(iii) of this section apply to taxable years beginning after the date these regulations are published as final regulations in the **Federal Register**.

§ 1.6013-1 [Amended]

■ **Par. 18.** Section 1.6013-1 is amended by removing paragraph (e).

PART 301—PROCEDURE AND ADMINISTRATION

■ **Par. 19.** The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 20.** Section 301.6109-3 is amended by:

■ 1. Revising the first sentence and adding a sentence to the end of the paragraph in paragraph (a)(1).

■ 2. Revising paragraphs (b), (c)(1)(ii), the fourth and fifth sentences of (c)(2) introductory text, and paragraph (d).

The revisions and addition read as follows:

§ 301.6109-3 IRS adoption taxpayer identification numbers.

(a) *In general*—(1) *Definition.* An IRS adoption taxpayer identification number (ATIN) is a temporary taxpayer identifying number assigned by the Internal Revenue Service (IRS) to a child (other than an alien individual as defined in § 301.6109-1(d)(3)(i)) who has been placed lawfully with a prospective adoptive parent for legal adoption by that person. * * * A child lawfully placed with a prospective adoptive parent for legal adoption includes a child placed for legal adoption by the child's parent or parents by blood, an authorized placement agency, or any other person authorized by State law to place a child for legal adoption.

* * * * *

(b) *Definitions*—(1) Authorized placement agency has the same meaning as in § 1.152-1(b)(1)(iv).

(2) *Child* means a child who has not been adopted but has been placed lawfully with a prospective adoptive parent for legal adoption by that person.

(3) *Prospective adoptive parent* means a person in whose household a child has been placed lawfully for legal adoption by that person.

(c) * * *

(1) * * *

(ii) The child has been placed lawfully with the prospective adoptive parent for legal adoption by that person;

* * * * *

(2) * * * In addition, the application must include documentary evidence the IRS prescribes to establish that a child has been placed lawfully with the prospective adoptive parent for legal adoption by that person. Examples of acceptable documentary evidence establishing lawful placement for a legal adoption may include—

* * * * *

(d) *Applicability date*—(1) *In general.* Except as otherwise provided in paragraph (d)(2) of this section, the provisions of this section apply to income tax returns due (without regard to extension) on or after April 15, 1998.

(2) *Exception.* Paragraphs (a)(1), (b), (c)(1)(ii), and (c)(2) of this section apply to income tax returns due (without regard to extension) on or after the date these regulations are published as final regulations in the **Federal Register**.

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2017-01056 Filed 1-18-17; 8:45 am]

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DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR Part 42

[Docket No. OAG 154; AG Order No. 3818-2017]

RIN 1105-AB50

Amendment of Regulations Implementing Section 504 of the Rehabilitation Act of 1973—Nondiscrimination Based on Disability in Federally Assisted Programs or Activities

AGENCY: Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Justice is issuing this notice of proposed rulemaking to revise its regulation implementing section 504 of the Rehabilitation Act of 1973, as applicable to programs and activities receiving financial assistance from the Department, in order to incorporate amendments to the statute, including the changes in the meaning and interpretation of the applicable definition of disability required by the ADA Amendments Act of 2008; incorporate requirements stemming from judicial decisions; update accessibility standards applicable to new construction and alteration of buildings and facilities; update certain provisions to promote consistency with

comparable provisions implementing title II of the Americans with Disabilities Act; and make other non-substantive clarifying edits, including updating outdated terminology and references that currently exist in 28 CFR part 42, such as changing the word “handicapped” and similar variations of that word to language referencing “individuals with disabilities,” modifying the order of the regulatory provisions to group like provisions together, and adding some headings to make the regulation more user-friendly.

DATES: All comments must be submitted on or before March 20, 2017.

ADDRESSES: You may submit comments, identified by RIN 1105-AB50, by any one of the following methods:

• *Federal eRulemaking portal:* <http://www.regulations.gov>. Follow the Web site's instructions for submitting comments.

• *Regular U.S. mail:* Disability Rights Section, Civil Rights Division, U.S. Department of Justice, P.O. Box 2885, Fairfax, VA 22031-0885.

• *Overnight, courier, or hand delivery:* Disability Rights Section, Civil Rights Division, U.S. Department of Justice, 1425 New York Avenue NW., Suite 4055, Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT:

Rebecca Bond, Chief, Disability Rights Section, Civil Rights Division, U.S. Department of Justice, at (202) 307-0663 (voice or TTY) (not a toll-free number); or Michael Alston, Director, Office for Civil Rights, Office of Justice Programs, U.S. Department of Justice, at (202) 307-0690 (not a toll-free number). Information may also be obtained from the Department's toll-free ADA Information Line at (800) 514-0301 (voice), or (800) 514-0383 (TTY).

You may obtain copies of this notice of proposed rulemaking (NPRM) in an alternative format by calling the ADA Information Line at (800) 514-0301 (voice), or (800) 514-0383 (TTY). This NPRM is also available on the ADA Home Page at <http://www.ada.gov>.

SUPPLEMENTARY INFORMATION:

Electronic Submission of Comments and Posting of Public Comments

You may submit electronic comments to <http://www.regulations.gov>. When submitting comments electronically, you must include “RIN 1105-AB50” in the subject field, and you must include your full name and address. Electronic files should avoid the use of special characters or any form of encryption and should be free of any defects or viruses.

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public record and made available for public inspection online at <http://www.regulations.gov>. Submission postings will include any personal identifying information (such as your name, address, etc.) included in the text of your comment. If you include personal identifying information (such as your name, address, etc.) in the text of your comment but do not want it to be posted online, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also include all the personal identifying information you want redacted along with this phrase. Similarly, if you submit confidential business information as part of your comment but do not want it to be posted online, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted on <http://www.regulations.gov>.

I. Executive Summary

Purpose

The Department of Justice (Department) is issuing this rule in order to revise and update its regulation implementing section 504 of the Rehabilitation Act of 1973 (section 504) as applicable to programs and activities receiving financial assistance from the Department. Section 504 prohibits discrimination on the basis of disability in federally conducted and assisted programs or activities. The Department implements the requirements of section 504 for federally assisted programs through its regulation at 28 CFR part 42, subpart G (federally assisted regulation).

Major Provisions

The major provisions of this proposed rule can be summarized as follows.

First, the NPRM proposes to revise the regulatory text to incorporate a range of statutory amendments to the Rehabilitation Act, including the following: (1) Changes in the meaning and interpretation of the definition of “disability” required by the ADA Amendments Act of 2008, which also amended section 504’s definition of “disability;” (2) the addition of definitions of “drugs” and “illegal use of drugs” and the exclusion from coverage of an individual who is currently engaging in the illegal use of

drugs, all of which are definitions used in the ADA; (3) the adoption of “person first” language, such as changing the term “handicapped person” to “individual with a disability”; and (4) the application of the ADA title I standards to determinations of employment discrimination under section 504.

Second, the proposed regulation incorporates into the regulatory text existing requirements, which stem from longstanding Supreme Court decisions interpreting section 504, by adding provisions setting forth the “direct threat” defense and the obligation to provide reasonable accommodations.

Third, the proposed rule updates the section 504 accessibility standards applicable to new construction and alteration of buildings and facilities from the Uniform Federal Accessibility Standards to the 2010 ADA Standards for Accessible Design.

Fourth, the proposed rule revises the language of certain provisions, including the general nondiscrimination prohibitions and the requirement to provide auxiliary aids and services, in order to promote consistency with comparable provisions implementing title II of the ADA. The rule also eliminates the exception for provision of auxiliary aids and services for recipients that have fewer than fifteen employees.

Fifth, the proposed rule revises the regulation’s compliance procedures: (1) To provide alternative remedies for the Department in cases where a recipient of Federal assistance fails to provide compliance information, such as compliance reports or information sought by beneficiaries; (2) to provide for the protection of confidential information without barring the responsible Department official or designee from accessing information necessary for evaluating or seeking to enforce compliance with the federally assisted regulation; and (3) to direct the filing of complaints alleging violations of section 504 by recipients of financial assistance from the Department with the Office of Justice Programs.

Summary of Benefits and Costs

This rulemaking is not considered economically significant under Executive Order 12866. Additionally, the Department is certifying that the rule will not have a significant economic impact on a substantial number of small entities in accordance with the Regulatory Flexibility Act, as amended.

II. Background

A. Section 504 Legislative and Regulatory History

The Department of Justice (Department) implements the requirements of section 504 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. 794 (section 504), which prohibits discrimination on the basis of disability in federally conducted and assisted programs or activities, through its regulations at 28 CFR part 39, applicable to programs and activities conducted by the Department (federally conducted regulation), and 28 CFR part 42, subpart G, applicable to recipients to whom the Department extends Federal financial assistance (federally assisted regulation).

On June 3, 1980, the Department published its section 504 federally assisted regulation. See 28 CFR part 42, subpart G, 45 FR 37620. Since then, Congress has amended certain provisions of the Rehabilitation Act of 1973, Public Law 93–112 (Sept. 26, 1973) (Rehabilitation Act), necessitating revisions to the Department’s section 504 federally assisted regulation.¹ The Americans with Disabilities Act of 1990, Public Law 101–336 (July 26, 1990) (ADA), revised the Rehabilitation Act to include definitions of the terms “drugs” and “illegal use of drugs,” explaining that these terms were to be interpreted consistent with the principles of the Controlled Substances Act, 21 U.S.C. 801 *et seq.* See 29 U.S.C. 705(10). The ADA also amended the Rehabilitation Act to expressly exclude from coverage an individual who is currently engaging in the illegal use of drugs. See 29 U.S.C. 705(10), (20)(C). The Rehabilitation Act Amendments of 1992, Public Law 102–569 (Oct. 29, 1992) (the 1992 Amendments), adopted the use of “person first” language by changing the term “handicapped person” to “individual with a disability” and provided that the standards applied under title I of the ADA shall apply to determinations of employment discrimination under section 504. More recently, the ADA Amendments Act of 2008 (ADA Amendments Act), Public Law 110–325 (Sept. 25, 2008), revised the meaning and interpretation of the definition of “disability” under section 504 to align them with the ADA. In addition, there have been significant

¹ See, e.g., Public Law 99–506 (Oct. 21, 1986); Public Law 100–259 (Mar. 22, 1988); Public Law 100–630 (Nov. 7, 1988); Public Law 101–336 (July 26, 1990); Public Law 102–569 (Oct. 29, 1992); Public Law 103–382 (Oct. 20, 1994); Public Law 105–220 (Aug. 7, 1998); Public Law 107–110 (Jan. 8, 2002); Public Law 110–325 (Sept. 25, 2008); Public Law 113–128 (July 22, 2014).

Supreme Court decisions interpreting section 504 requirements relating to the principles of “direct threat” and reasonable accommodation. *See, e.g., Sch. Bd. of Nassau Cty. v. Arline*, 480 U.S. 273 (1987); *Alexander v. Choate*, 469 U.S. 287 (1985); *Se. Cmty. Coll. v. Davis*, 442 U.S. 397 (1979). Although *Arline*, *Choate*, and *Davis* have been applied by lower courts since their issuance, the Department’s existing section 504 federally assisted regulation does not clearly enunciate the Court’s holdings. The Department has not amended its section 504 federally assisted regulation since its original publication other than through the adoption in 2003 of certain amendments to implement the provisions of the Civil Rights Restoration Act of 1987. *See* 68 FR 51334 (Aug. 26, 2003); Public Law 100–259 (Mar. 22, 1988). The revisions to this regulation are part of the Department’s retrospective plan under Executive Order 13563, completed in 2011.

B. Relationship Between Section 504 and the ADA

Title II of the ADA prohibits discrimination on the basis of disability by public entities (*i.e.*, State and local governments and their agencies) and is modeled on section 504. 42 U.S.C. 12132 (“[N]o qualified individual with a disability shall, by reason of such disability, be excluded from participation in or be denied the benefits of services, programs, or activities of a public entity, or be subjected to discrimination by any such entity.”). A significant amount of financial assistance from the Department goes to entities that are also covered by title II of the ADA. In addition, the Department provides financial assistance to some entities covered by title III of the ADA.² Title II and section 504 are generally understood to impose similar requirements, given the similar language employed in the ADA and the Rehabilitation Act and the congressional directive that the ADA be construed to grant at least as much protection as provided by the regulations implementing the Rehabilitation Act. *See, e.g.*, 42 U.S.C. 12201(a).³ Many of

the changes that the Department is proposing are intended to conform the language of specific provisions in the section 504 regulation to corresponding provisions in the title II regulation, many of which were updated in 2010. The Department believes it is in the interest of the recipients who have to apply the requirements of both section 504 and title II that, where appropriate, the comparable requirements in the corresponding regulations for both statutes are expressed in comparable language.

II. Section-by-Section Analysis

This section provides a detailed description of the Department’s proposed changes to the section 504 federally assisted regulation and the reasoning behind the proposals. If the Department is not proposing a change to a regulation section, the unchanged section is not discussed. The Department is proposing to modify the order and names of some of the regulatory provisions to group like provisions together and make the regulation more user-friendly. This section-by-section analysis follows the revised order of the regulatory text.

General

Section 42.502—Application, Broad Coverage, and Relationship to Other Laws

The Department proposes to revise existing § 42.502 to add clarifying language to the discussion of the application of this subpart, to add a new paragraph (b), which addresses the broad scope of coverage required by the ADA Amendments Act and the section 504 federally assisted regulation, and to move and revise the discussion of the relationship to other laws from existing § 42.505(h) to a new paragraph (c) in this section.

Section 42.502(a)—Application

The Department proposes to add a sentence clarifying that this subpart does not apply to programs or activities

conducted by the Department. The Department’s section 504 federally assisted regulation is found at 28 CFR part 39.

Section 42.502(b)—Broad Scope of Coverage

The ADA Amendments Act was signed into law on September 25, 2008, and became effective on January 1, 2009. Congress enacted the ADA Amendments Act in order to ensure that the definition of disability is broadly construed and applied without extensive analysis, and to supersede Supreme Court decisions that had too narrowly interpreted the ADA’s definition of disability.⁴ The ADA Amendments Act not only amended the meaning and interpretation of the definition of disability applicable to the ADA, it also amended the Rehabilitation Act of 1973 to require similar changes to the meaning and interpretation of section 504’s definition of disability at 29 U.S.C. 705(20)(B).

The ADA Amendments Act does not alter the basic elements of the definition of disability in the ADA and section 504, but it significantly clarifies how the term “disability” is to be interpreted and adds important rules of construction to inform that interpretation. Specifically, Congress directed that the definition of disability shall be construed broadly and that the determination of whether an individual has a disability should not demand extensive analysis. ADA Amendments Act, sec. 2(b)(5), 4(a).

Congress also authorized the Equal Employment Opportunity Commission (EEOC) and the Department to issue regulations implementing the ADA Amendments Act changes, including rules of construction. *See id.*, sec. 6(a)(2); 42 U.S.C. 12205a. The Department’s ADA Amendments Act regulation, along with the EEOC’s title I ADA Amendments Act regulation, include introductory sections describing the requirement to construe the definition of disability broadly and sets forth rules of construction consistent with that goal. *See* 28 CFR 35.101(b) and 29 CFR 1630.1(c)(4).⁵ The Department’s

² Title III prohibits discrimination on the basis of disability by: (1) Public accommodations (*i.e.*, private entities that own, operate, lease, or lease to places of public accommodation); (2) newly constructed and altered commercial facilities; and (3) private entities that offer certain examinations and courses related to educational and occupational certification. Recipients of Federal assistance that are also title III entities must comply with both the section 504 and the title III regulations.

³ The 1992 Amendments revised the Rehabilitation Act’s findings, purpose, and policy

provisions to incorporate language acknowledging the discriminatory barriers faced by persons with disabilities, and recognizing that persons with disabilities have the right to “enjoy full inclusion and integration in the economic, political, social, cultural and educational mainstream of American society.” 29 U.S.C. 701(a)(3) as amended. The legislative history to the 1992 Amendments states “[t]he statement of purpose and policy is a reaffirmation of the precepts of the Americans with Disabilities Act, which has been referred to as the 20th century emancipation proclamation for individuals with disabilities. It is the Committee’s intent that these principles guide the policies, practices, and procedures developed under all titles of the [Rehabilitation] Act.” S. Rep. 102–357 at 14 (Aug. 3, 1992); H.R. Rep. 102–822 at 81 (Aug. 10, 1992).

⁴ Congress specifically found that the holdings of the Supreme Court in *Toyota Motor Manufacturing, Kentucky, Inc. v. Williams*, 534 U.S. 184 (2002), and *Sutton v. United Air Lines, Inc.*, 527 U.S. 471 (1999), narrowed the broad scope of protection intended to be afforded by the ADA. ADA Amendments Act, sec. 2. Congress also stated that one of the purposes of the ADA Amendments Act is “to convey that it is the intent of Congress that the primary object of attention in cases brought under the ADA should be whether entities covered under the ADA have complied with their obligations * * *.” *Id.*, sec. 2(b)(5).

⁵ The Department’s ADA Amendments Act regulation followed the EEOC approach in

proposed “scope of coverage” provision at § 42.502(b) is modeled on the ADA’s broad construction provision and provides that, consistent with the ADA Amendments Act’s purpose of reinstating a broad scope of protection under both the ADA and section 504, the definition of “disability” in the pertinent subpart “shall be construed broadly in favor of expansive coverage to the maximum extent permitted by the terms of section 504.” The new provision further provides that the primary object of attention in cases brought under that subpart “should be whether entities covered under section 504 have complied with their obligations and whether discrimination has occurred, not whether the individual meets the definition of ‘disability.’” The question of whether an individual meets the definition of “disability” under this subpart should not demand extensive analysis.

Section 42.502(c)—Relationship to Other Law

The Department is proposing to move its provision addressing the relationship of section 504 to State and local laws that provide lesser protections for persons with disabilities from its location in the current regulation at § 42.505(h) to § 42.502(c)(1) in the revised regulation. The Department is proposing a minor edit to this provision by adding “obviated by or otherwise” before “affected” so that the provision would read: “The obligation to comply with this subpart is not obviated by or otherwise affected by the existence of any State or local law or other requirement that, on the basis of disability, imposes prohibitions or limits upon the eligibility of qualified individuals with disabilities to receive services or to practice any occupation or profession.”

In addition, the Department is proposing to add a new provision at § 42.502(c)(2) that addresses the relationship between section 504 and other Federal, State, and local laws that provide greater protections to persons with disabilities. In the ADA, Congress expressly provided that nothing in the ADA invalidated or limited the remedies, rights, and procedures of any Federal law, or State or local law that provides greater or equal protection for the rights of individuals with disabilities. *See* 42 U.S.C. 12201(b). The Department incorporated this principle into its ADA title II and title III

regulations at 28 CFR 35.103(b) and 28 CFR 36.103(c), respectively. The Department believes that these principles are equally applicable to section 504. Proposed § 42.502(c)(2) incorporates these principles and provides that “[t]his subpart does not invalidate or limit the remedies, rights, and procedures of any other Federal law, or State or local law (including State common law), that provide greater or equal protection for the rights of individuals with disabilities or individuals associated with them.”

Section 42.503—Definitions

The Department proposes revising certain definitions to make them consistent with the language used to define corresponding terms in the Department’s ADA regulations; deleting terminology that is no longer necessary or has become obsolete; revising or adding certain terms to incorporate statutory changes to the Rehabilitation Act; adding other definitions for clarity; and making minor technical edits to existing definitions. Also, for ease of reference, the Department proposes moving the “definitions” section, currently codified at § 42.540, to the beginning of the subpart at § 42.503.

First, in order to ensure consistency of terminology between section 504 and the ADA, the Department is proposing to add definitions of the following terms from the Department’s ADA title II regulation at 28 CFR 35.104: “2004 ADAAG,” “2010 Standards,” “Auxiliary aids and services,” “Current illegal use of drugs,” “Historic preservation programs,” “Qualified interpreter,” “Qualified reader,” and “Video remote interpreting (VRI) service.”

The Department also proposes to delete several terms from the regulation, including “Alcohol abuse,” “Benefit,” and “Handicap,” as well as obsolete references to Departmental components that no longer exist within the Department. First, with respect to “alcohol abuse,” the Department believes the term is no longer necessary given that the definition was only applicable to the regulation’s employment provisions, and those provisions are being revised to reference the requirements in title I of the ADA, in accordance with section 503(b) of the 1992 Amendments (codified at 29 U.S.C. 791(f)). Second, the Department also proposes to delete the definition of “benefit” as unnecessary given that the meaning of “benefit” is commonly understood. Third, the Department proposes to delete the definition of “handicap,” as it is neither necessary nor appropriate following the “people first” language changes from the 1992

Amendments, which use the term “disability.” And fourth, the Department proposes to delete the definitions of “LEAA,” “NIJ,” “BJS,” “OJARS,” and “OJJDP.” Some of these offices no longer exist, and to account for future changes in organization, the regulation, where appropriate, will refer generally to “grant-making components of the Department.”

Finally, the Department proposes the following revisions and additions to the “definitions” section to incorporate statutory changes to the Rehabilitation Act and to provide greater clarity and consistency of terminology.

“Applicant”

The Department proposes to add the definition of “applicant” to the proposed regulation using language consistent with the definition in the Department’s regulation implementing title VI of the Civil Rights Act, at 28 CFR 42.102(h).

“Component”

The Department proposes to add a definition of “component” to the proposed regulation. Given the various names for the Department’s subagencies (*e.g.*, bureaus, agencies, boards, etc.), the Department believes that the term “component” would provide a simpler and less confusing reference.

“Department”

The Department proposes to revise the definition of “department” to clarify that the term includes all of the Department’s components.

“Direct Threat”

The Department proposes to add, with respect to non-employment services, programs, and activities, a definition of “direct threat” that is based upon the definition provided in the Department’s title II regulation at 28 CFR 35.104. The Department also proposes to include, for the employment context, an additional paragraph that adopts the definition of “direct threat” in the EEOC’s regulation at 29 CFR 1630.2(r).

“Disability”

As previously discussed, the ADA Amendments Act not only amended the meaning and interpretation of the definition of “disability” applicable to the ADA, it also amended the Rehabilitation Act of 1973 to require similar changes to the meaning and interpretation of the definition of “disability” at 29 U.S.C. 705(20)(B), applicable to section 504. The Department has decided that rather than spelling out the meaning and interpretation of the definition of

incorporating a broad construction provision and rules of construction to embody the requirements of the ADA Amendments Act. *See* 81 FR 53203 (Aug. 11, 2016).

disability in this regulation, it will incorporate by reference the Department's title II definition of disability found at 28 CFR part 35, which has recently undergone revisions to reflect the requirements of the ADA Amendments Act. Due to the changes that the ADA Amendments Act made to the meaning and interpretation of the definition of disability, participants in recipients' programs and activities who, before, may not have been determined to have a disability under section 504, may now be found to have a disability.

The Rehabilitation Act and the ADA define "disability" as including: (1) A physical or mental impairment that substantially limits a major life activity; (2) a record of such an impairment; or (3) being regarded as having such an impairment. 29 U.S.C. 705(9)(B); 42 U.S.C. 12102(1). The ADA Amendments Act does not alter these three basic elements of the definition of disability, but it does significantly clarify how the term "disability" is to be interpreted and adds important rules of construction to inform that interpretation. Congress directed that the definition of disability shall be construed broadly and that the determination of whether an individual has a disability should not demand extensive analysis. 42 U.S.C. 12102. The Department proposes to update its section 504 federally assisted regulation to reflect these changes.

"Drug"

The ADA amended the Rehabilitation Act to include a definition of "drug." See ADA sec. 512(b) (codified at 29 U.S.C. 705(10)). The Department proposes to add that definition to its regulation.

"Facility"

The Department proposes to revise the existing definition of "facility" to conform more closely to the definition of "facility" in the Department's title II regulation by including within the definition's scope sites, complexes, rolling stock or other conveyances.

"Historic Properties"

The Department proposes to include a definition of "historic properties" that is substantially similar to that provided in the Department's title II regulation, 28 CFR 35.104.

"Illegal Use of Drugs"

The Department proposes to replace the existing definition of "drug abuse" with a definition that is substantially similar to the definition of "illegal use of drugs" that was added to the Rehabilitation Act by the ADA in 1990.

See ADA § 512(b) (codified at 29 U.S.C. 705(10)).

"Individual With a Disability"

The Department proposes to replace the definition of "handicapped person" with "individual with a disability," consistent with the 1992 Amendments, which provide "people first" language (e.g., "individuals with disabilities") and which define "individual with a disability" as "any person who has a disability as defined in [section 3 of the ADA]." See 29 U.S.C. 705(20)(B). Consistent with the definition in the Department's ADA title II regulation, the proposed definition also clarifies that the term "individual with a disability" does not include an individual who is currently engaging in the illegal use of drugs, when a recipient acts on the basis of such use. The proposed definition eliminates references to individuals who would not be considered to have a disability for purposes of employment, as such references are no longer necessary because the regulation now references the EEOC regulation at 29 CFR part 1630 with respect to discrimination on the basis of disability in employment.

"Primary Recipient"

The Department proposes to add a definition of "primary recipient" to the regulation. The Department proposes to adopt a definition that is substantially similar to the definition of "primary recipient" provided in the Department's regulation implementing title VI of the Civil Rights Act, at 28 CFR 42.102(g). The revised regulation defines "primary recipient" as "any recipient that is authorized or required to extend Federal financial assistance to another recipient."

"Qualified Individual With a Disability"

The Department proposes to replace the definition of "qualified handicapped person" with "qualified individual with a disability." With respect to employment, the proposed definition incorporates the definition of "qualified" as provided in the EEOC regulation at 29 CFR 1630.2(m), which implements the employment standards of title I of the ADA, in accordance with section 503(b) of the 1992 Amendments (codified at 29 U.S.C. 791(f)). With respect to programs or activities, the proposed definition is substantially similar to the definition of "qualified individual with a disability" from the Department's ADA title II regulation, 28 CFR 35.104.

"Subrecipient"

The Department proposes to add a definition of "subrecipient" to the proposed regulation. Entities receiving Federal financial assistance through a primary recipient also must comply with the Department's section 504 federally assisted regulation.

General Nondiscrimination Requirements

Section 42.510—General Prohibitions Against Discrimination

Section 42.510(b)–(f)—Prohibited Discriminatory Actions

The Department proposes to update and clarify the discriminatory actions prohibited under § 42.503 of the Department's current regulation. With the exception of the revisions addressed below, the Department proposes retaining the same prohibited discriminatory actions as in the current regulation but, where applicable, adopting the language that is provided in the Department's ADA title II regulation for consistency, and reorganizing and re-titling some of the provisions, as appropriate. For instance, the provision relating to the prohibition on retaliation and intimidation at § 42.503(b)(1)(vii) in the current regulation has been moved to a new section at proposed § 42.510(k). The Department also proposes to add several regulatory provisions that are consistent with provisions in the Department's ADA title II regulation and that further illustrate the types of actions that are prohibited discrimination under section 504. The Department notes that current § 42.503(g) (renumbered as § 42.510(l)) states that "[t]he enumeration of specific forms of prohibited discrimination in this subpart is not exhaustive but only illustrative."

The Department's current regulation at § 42.503(b)(iv) prohibits a recipient from denying "a qualified [person with a disability] an equal opportunity to participate in the program or activity by providing services to the program." This prohibition does not clearly explain how a qualified individual with a disability would be denied an equal opportunity to participate in a program or activity "by providing services" to the program. The Department is proposing to revise this paragraph for clarity but is not changing the meaning. The revised paragraph (renumbered as § 42.510(b)(1)(v)) states that a recipient may not "[d]eny a qualified individual with a disability an equal opportunity to provide services to the program or activity." Under this provision, for example, a recipient that uses

volunteers to provide services may not refuse to allow individuals with disabilities to work as volunteers.

The Department proposes to delete the provision in the Department's current regulation at § 42.503(b)(5), which provides that "[a] recipient is prohibited from discriminating on the basis of handicap in aid, benefits, or services operating without Federal financial assistance where such action would discriminate against the handicapped beneficiaries or participants in any program or activity of the recipient receiving Federal financial assistance." This provision no longer appears to be necessary given the expanded definition of "program or activity" provided under the Civil Rights Restoration Act, 42 U.S.C. 2000d-4a, which, in the case of assistance to a State or local government, includes all the operations of the department or agency to which funding is extended.

The Department proposes to move the requirements in existing § 42.503(e) and (f), which currently address the recipient's obligation to ensure effective communication to applicants, employees and beneficiaries, to new § 42.511, which specifically addresses the recipient's communication requirements in greater detail, consistent with the Department's title II regulation at 28 CFR 35.160, 35.161, and 35.164. The Department has also conformed the language of these provisions to the language of the title II regulation. It notes that the definition of "auxiliary aids" that is in § 42.503(f) of the existing regulation is replaced by the revised definition of "auxiliary aids and services" provided in the renumbered definitional section at proposed § 42.503.

Section 42.510(g)—Reasonable Accommodations

The Department proposes to add a new provision at § 42.510(g)(1) that affirmatively states the longstanding section 504 obligation to provide reasonable accommodations by making changes to policies, practices, and procedures unless those changes can be shown to pose a fundamental alteration to the program or activity or an undue financial and administrative burden.⁶

The obligation to modify policies, practices, or procedures was first enunciated by the Supreme Court in *Southeastern Community College v. Davis*, 442 U.S. 397 (1979), which held that while section 504 prohibits the exclusion of an otherwise qualified individual with a disability from participation in a federally funded program solely by reason of the individual's disability, that person is not protected by section 504 if, in order to meet reasonable eligibility standards, the person needs program or policy modifications that would fundamentally alter the nature of the provider's program. Because the *Davis* Court analyzed the case in terms of the proper interpretation of the statutory term "otherwise qualified," agency section 504 regulations promulgated immediately after *Davis* addressed the obligation to provide reasonable accommodations outside of the employment arena by defining "qualified handicapped person," as one who meets the essential eligibility requirements of the program and who can achieve the purpose of the program or activity without modifications in the program or activity that the agency can demonstrate would result in a fundamental alteration in its nature. *See, e.g.*, 28 CFR 39.103 (the Department's section 504 federally conducted regulation).

Subsequently, in *Alexander v. Choate*, 469 U.S. 287 (1985), which addressed a section 504 challenge to a State policy reducing the annual number of days of inpatient hospital care covered by the State's Medicaid program, the Court implicitly acknowledged that the obligation to provide reasonable accommodations could be considered as an affirmative obligation, noting, "the question of who is 'otherwise qualified' and what actions constitute 'discrimination' under the section would seem to be two sides of a single coin; the ultimate question is the extent to which a grantee is required to make reasonable modifications [accommodations] in its programs for the needs of the handicapped." *Id.* at 299 n.19.

Alexander also introduced the concept of undue financial and administrative burden as a limitation on the reasonable accommodation obligation. In responding to the petitioners' contention that *any* durational limitation on inpatient coverage in a State Medicaid plan is a

violation of section 504, the court stated: "It should be obvious that the administrative costs of implementing such a regime would be well beyond the accommodations that are required under *Davis*." *Id.* at 308.

Over the past decades, in keeping with these Supreme Court decisions, Federal courts and Federal agencies have regularly acknowledged Federal agencies' affirmative obligation to ensure that recipients provide qualified individuals with disabilities reasonable accommodations in programs and activities unless the recipient can demonstrate that making these accommodations would fundamentally alter the program or activity or result in an undue financial and administrative burden. However, traditionally, agencies' section 504 regulations have lacked a specific provision implementing this requirement outside of the employment arena.⁷

The Department notes that title I of the ADA also uses the term "reasonable accommodation" to apply to the job application process, work environment, or manner or circumstances under which the position held or desired is customarily performed, and the ability to enjoy equal benefits and privileges of employment. However, the specific ADA title I regulatory requirements related to this term should not be applied to non-employment related requests for reasonable accommodations under section 504, and the Department proposes to clarify at proposed § 42.510(g)(3) that with respect to employment, the definitions and standards that apply to "reasonable accommodation" and "undue hardship" in the EEOC's regulation implementing title I of the ADA apply to this subpart.

In addition, when Congress enacted the ADA Amendments Act, it expressly provided that a covered entity need not provide a reasonable modification [or accommodation] to policies, practices, or procedures to an individual who meets the definition of disability under the "regarded as" prong. ADA Amendments Act, sec. 6(a)(1). While Congress did not specifically apply this provision of the ADA Amendments Act to section 504, the Department believes that it is equally appropriate to apply this limitation to reasonable accommodations under section 504 and proposes to adopt this limitation at § 42.510(g)(2) of this regulation.

⁶ Courts generally have interpreted the obligation to provide reasonable accommodations under section 504 consistently with the obligation to provide reasonable modifications under title II. *See, e.g., Forest City Daily Hous., Inc. v. Town of N. Hempstead*, 175 F.3d 144, 151 (2d Cir. 1999) (analyzing reasonable accommodations in the same way under the FHA, ADA, and Section 504); *Super v. J. D'Amelia & Associates, LLC*, No. 3:09CV831 SRU, 2010 WL 3926887, at *3 (D. Conn. Sept. 30, 2010) ("The relevant portions of the FHA, ADA,

and Section 504 offer the same guarantee that a covered entity . . . must provide reasonable accommodations in order to make the entity's benefits and programs accessible to people with disabilities.").

⁷ The principle of "reasonable accommodation" is addressed in agency section 504 regulations with respect to employment. *See, e.g.*, the Department's current section 504 federally assisted regulation at 28 CFR 42.511 and U.S. Department of Health and Human Services' section 504 federally assisted regulation at 45 CFR 84.12.

Lastly, the Department notes that the necessary reasonable accommodations will vary based on the need of the individual and the impact of the accommodation on the recipient. Where the recipient receives funding from multiple Federal agencies, each Federal agency's particular requirements will also impact the types of reasonable accommodations that a recipient must provide.

Section 42.510(h)—Prohibition on Surcharges

It has been a longstanding principle under both section 504 and the ADA that recipients or covered entities may not charge affected individuals or groups for the cost of measures required to provide an individual or group with nondiscriminatory treatment. This principle is already set forth in the Department's title II regulation at 28 CFR 35.130(f), and the Department is proposing to add it to § 42.510(h) of the Department's section 504 federally assisted regulation as well.

Section 42.510(i)—Prohibition on Associational Discrimination

The Department's ADA regulations provide protection for individuals associated with individuals with disabilities.⁸ While the Rehabilitation Act does not expressly refer to individuals associated with individuals with disabilities, it does permit “any person aggrieved by any act or failure to act by any recipient of Federal assistance or Federal provider of such assistance” to bring suit under the Rehabilitation Act. 29 U.S.C. 794a(a)(2) (emphasis added). Courts have recognized this provision as providing the basis for associational standing

under the Rehabilitation Act and noted that despite the differences in authorizing language under the Rehabilitation Act and the ADA, “[i]t is widely accepted that under both the [Rehabilitation Act] and the ADA, non-disabled individuals have standing to bring claims when they are injured because of their association with a disabled person.” *McCullum v. Orlando Reg'l Healthcare Sys., Inc.*, 768 F.3d 1135, 1142 (11th Cir. 2014) (citing cases). Accordingly, the Department is proposing to add § 42.510(i), which specifically prohibits a recipient from excluding or otherwise denying aid, benefits, or services of its programs or activities to an individual because of that individual's relationship or association with an individual with a known disability.

Section 42.510(j)—Eligibility Criteria

The Department proposes to add a new provision at § 42.510(j) that prohibits a recipient from imposing or applying eligibility criteria that screen out or tend to screen out an individual with a disability or any class of individuals with disabilities from fully and equally enjoying any aid, benefit, or service, unless such criteria can be shown to be necessary for the provision of the aid, benefit, or service being offered. This principle is already set forth in the Department's title II regulation at 28 CFR 35.130(b)(8). The prohibition of the imposition of “criteria that ‘tend to’ screen out an individual with a disability” actually had its origins in the Department of Health and Human Services' section 504 regulation at 45 CFR 84.13 (1991), which was cited by the Department in its 1991 title II rulemaking. *See* 28 CFR part 35, app. B, 56 FR 35694, 35705 (July 26, 1991). Accordingly, the Department believes that it is appropriate to add this provision to the general prohibitions against discrimination section.

Section 42.511—Communications

The Department is proposing to reorganize and revise its articulation of recipients' longstanding obligation to ensure that communications are effectively conveyed to individuals with disabilities and to provide appropriate auxiliary aids and services, using language that generally conforms with the effective communication provisions in the Department's title II regulation at 28 CFR 35.160, 35.161, and 35.164. Specifically, the Department is proposing to move the provisions addressing communication in the section 504 regulation from the general nondiscrimination obligations in current § 42.503(e) and (f), place these

revised provisions in a new § 42.511, and generally conform the language to the title II provisions. As mentioned earlier, the Department has revised the definitions section of the regulation at proposed § 42.503 to include definitions of the terms “auxiliary aids and services,” “qualified interpreter,” “qualified reader,” and “video remote interpreting (VRI) service.” Finally, the Department is proposing to remove the limitation on the obligation to provide auxiliary aids for recipients with fewer than 15 employees, currently found in § 42.503(f).

Section 42.511(a)—General Obligation

Proposed § 42.511(a) sets forth the general obligation (formerly set forth in § 42.503(e)) that a recipient take “appropriate steps to ensure that communications with applicants, participants, beneficiaries, members of the public, and companions with disabilities are as effective as communications with others.” This general obligation parallels the general communications requirement in the ADA title II regulation, at 28 CFR 35.160(a)(1). The Department recognizes that since the Department's section 504 federally assisted regulation was first issued in 1980, electronic and information technology has changed the way that recipients communicate with interested persons. Individuals with disabilities—like other members of the public—should be able to equally engage with a recipient's services, programs, and activities using electronic and information technology. Opportunities for such engagement require that electronic and information technology be accessible to ensure that communication with individuals with disabilities is as effective as communication with others.

Section 42.511(b)—Auxiliary Aids and Services

Proposed § 42.511(b)(1), which tracks language in existing § 42.503(f), provides that “[a] recipient shall furnish appropriate auxiliary aids and services where necessary to afford qualified individuals with disabilities, including applicants, participants, beneficiaries, companions, and members of the public, an equal opportunity to participate in, and enjoy the benefits of, a service, program, or activity of a recipient.” Proposed § 42.511(b)(2) provides that “[t]he type of auxiliary aid or service necessary to ensure effective communication will vary in accordance with the method of communication used by the individual; the nature, length, and complexity of the communication involved; and the

⁸ Titles I and III of the ADA explicitly forbid discrimination because of the known disability of an individual with whom the individual is known to have a “relationship or association.” 42 U.S.C. 12112(b)(4), 12182(b)(1)(E). Although title II does not have corresponding language, the legislative history of the ADA demonstrates Congress's intent to include association within the scope of discrimination prohibited by title II. The House Committee on Education and Labor indicated that title II's prohibitions should be “identical to those set out in the applicable provisions of titles I and III.” H.R. Rep. No. 101–485(II), at 84 (1990), *reprinted in* 1990 U.S.C.C.A.N. 303, 367. The House Report went on to indicate that: “Unlike the other titles in this Act, title II does not list all of the forms of discrimination that the title is intended to prohibit. * * * [T]he Attorney General [is directed] to issue regulations setting forth the forms of discrimination prohibited. The Committee intends that the regulations under title II incorporate interpretations of the term discrimination set forth in titles I and III of the ADA to the extent that they do not conflict with the Section 504 regulations.” H.R. Rep. No. 101–485(III), at 52 (1990), *reprinted in* 1990 U.S.C.C.A.N. 445, 475. Thus, the Department's regulations under both titles II and III prohibit associational discrimination. *See* 28 CFR 35.130(g) and 28 CFR 36.205.

context in which the communication is taking place. In determining what types of auxiliary aids and services are necessary, a recipient entity shall give primary consideration to the requests of individuals with disabilities. In order to be effective, auxiliary aids and services must be provided in accessible formats, in a timely manner, and in such a way as to protect the privacy and independence of the individual with a disability.”

An example of an auxiliary aid, which would apply in the corrections setting, would be the provision of videophones or other video-based telecommunication services to ensure that incarcerated individuals with disabilities can communicate as effectively as others who use public telephones made available by the facility.

Section 42.511(c)—Limitations on Use of Accompanying Adults or Children as Interpreters

Proposed § 42.511(c) includes the express limitations on the use of accompanying adults or children as interpreters that are specified in the ADA title II rule at 28 CFR 35.160. Under section 504, responsibility for providing effective communication, including the use of interpreters, falls directly on recipients, and they may not require an individual to bring someone to serve as an interpreter. Consistent with the ADA provisions, proposed § 42.511(c) provides that a recipient may rely on an adult or minor child companion to interpret only in very limited emergency circumstances when no qualified interpreters are available. Specifically, proposed § 42.511(c)(2)–(3) only apply to emergencies involving an “imminent threat to the safety or welfare of an individual or the public.” The imminent threat exception is not intended to apply to the typical and foreseeable emergency situations that are part of the normal operations of institutions, such as visits to the emergency room or responses by law enforcement to situations involving a threat to the safety or welfare of an individual or the public. As such, a recipient may rely on an accompanying individual to interpret or facilitate communication under the proposed § 42.511(c)(2)–(3) imminent threat exception only in truly exigent circumstances, *i.e.*, where any delay in providing immediate services to the individual could have life-altering or life-ending consequences.

In nonemergency circumstances, a recipient may rely on an adult companion (but not a minor child) to interpret only when, (1) the individual requests this, (2) the accompanying

adult agrees, and (3) reliance on the accompanying adult is appropriate under the circumstances. Under no circumstances may a recipient rely on an accompanying adult to interpret when there is reason to doubt the individual’s impartiality or effectiveness.

Section 42.511(d)—Video Remote Interpreting (VRI) Services

When the Department updated its title II effective communication provisions to include performance requirements for VRI, at 28 CFR 35.160(d), the intent was to ensure that if VRI is used, it would be used in a manner that makes it as effective as when sign language interpreters are provided on site. The Department certainly has recognized that VRI can be an effective method of providing interpreting services in certain circumstances, but not in others. *See* 75 FR 56164, 56196 (Sept. 15, 2010). For example, VRI should be effective in many situations involving routine medical care, as well as in the emergency room where urgent care is important, but no in-person interpreter is available; however, VRI may not be effective in situations involving surgery or other medical procedures where the patient is limited in his or her ability to see the video screen. Similarly, VRI may not be effective in situations where there are multiple people in a room and the information exchanged is highly complex and fast-paced. The Department recognizes that in these and other situations, such as where communication is needed for persons who are deaf-blind, it may be necessary to summon an in-person interpreter to assist certain individuals.

Since the Department added this language to its title II regulation, it has become aware that some entities subject to title II, particularly in the medical environment, have not properly evaluated whether VRI is effective in particular situations, nor have they understood that these standards require that the VRI image is actually positioned so that it can be seen by the individual with a hearing disability. For example, in some circumstances, a patient who is lying prone while receiving medical treatment may have difficulty seeing the image on the screen and thus may be unable to communicate effectively using the remote sign language interpreter. Similarly, a pregnant woman who is deaf and who needs to regularly change positions while receiving medical assistance during labor and delivery may not always be able to see the image on the screen. Accordingly, the Department is adding language in its proposed VRI provision to expressly

clarify that the VRI image must be positioned so that the individual with a hearing disability can easily see the interpreter on the screen.

Proposed § 42.511(d) states that a recipient that provides qualified interpreters via VRI services shall ensure that it provides “[a] sharply delineated image that is large enough to display the interpreter’s face, arms, hands, and fingers, and the participating individual’s face, arms, hands, and fingers, and can be seen by the participating individual regardless of the individual’s body position.”

Section 42.511(e)—Telecommunications

Proposed § 42.511(e) incorporates the ADA title II regulatory requirement, at 28 CFR 35.161, that where a public entity communicates by telephone with applicants and beneficiaries, text telephones (TTY) or equally effective telecommunications systems must be used to communicate with individuals with disabilities. Unlike the corresponding ADA requirement at 28 CFR 35.161(a), however, § 42.511(e)(1) eliminates a specific reference to TTYS. The Department has become aware that individuals with hearing and speech disabilities are increasingly using other forms of telecommunication systems, including cellular phones, videophones, video relays, and internet-based communication systems, in lieu of TTYS. Thus, § 42.511(e)(1) provides that “[w]here a recipient communicates by telephone with applicants, participants, beneficiaries, members of the public, and companions with disabilities, the recipient shall communicate with individuals who are deaf or hard of hearing or have speech disabilities using telecommunication systems that provide equally effective communication.”

Additionally, the Department is aware that individuals with disabilities are concerned that, in some cases, emergency response services lack the ability to communicate with individuals who use methods of communication other than TTYS, such as text messaging or videophones, to communicate effectively. In July 2010, the Department issued an Advance Notice of Proposed Rulemaking on the Accessibility of Next Generation 9–1–1 Services, in which the Department made clear its intention to modify title II’s telephone emergency services provision, at 28 CFR 35.162, to address these and other changes, and included a specific reference to video relay service as an example of a type of relay service. 75 FR 43446 (July 26, 2010). Although that regulation has not yet been released, the Department maintains that, under title II’s general requirement at 28 CFR 35.161(a),

emergency response public safety answering points always have been covered by the general obligation to ensure effective communication. Similarly, under section 504, recipients' provision of emergency response services, like other aid, benefits, or services provided by recipients in their programs or activities, is covered by the overarching obligation to provide effective communication.

Proposed § 42.511(e)(2) addresses the use of automated-attendant systems and specifies that "[w]hen a recipient uses an automated-attendant system, including, but not limited to, voice mail and messaging, or an interactive voice response system, for receiving and directing incoming telephone calls, that system must provide effective real-time communication with individuals using auxiliary aids and services, including, but not limited to TTYs and all forms of FCC-approved telecommunications relay systems, including Internet-based relay systems." In proposed § 42.511(e)(3), the Department proposes a requirement that recipients must respond to all types of relay services, including video relay services, in the same manner that they respond to other telephone calls. This provision tracks title II, at 28 CFR 35.161(c), but includes an updated reference to the U.S. Code citation establishing the types of FCC-approved relay services, which include telephone relay, video relay, and IP relay.

Section 42.511(f)—Limitations

Finally, the Department is proposing to remove a limitation that currently appears in § 42.503(f). This provision directs that the obligation to provide auxiliary aids is mandatory for recipients with 15 or more employees, but indicates that Departmental officials may require recipients employing fewer than 15 persons to comply with this requirement "when [compliance] would not significantly impair the ability of the recipient to provide its benefits or services." The Department is proposing to remove this limitation for several reasons. First, this limitation is of minimal consequence because the vast majority of recipients of Federal financial assistance from the Department are already required by either title II or title III of the ADA to provide auxiliary aids or services in order to ensure effective communication. Second, all recipients, regardless of size, are not required, in providing effective communication, to take any action that the recipient can demonstrate would result in a fundamental alteration to the program or activity or pose undue financial and

administrative burdens. Third, the Department already has the discretion whether to impose these obligations on recipients with fewer than 15 employees. Finally, given that Congress specifically intended that the principles of the ADA guide the policies, practices, and procedures developed under the Rehabilitation Act,⁹ the Department believes the removal of this limitation better serves the purpose shared by both the ADA and Rehabilitation Act to enable individuals with disabilities to "enjoy full inclusion and integration into the economic, political, social, cultural, and educational mainstream of American society." 29 U.S.C. 701(a)(3). The Department is interested in public comment about its proposal to eliminate the fifteen employee threshold for provision of auxiliary aids and services.

Section 42.512—Employment

The Department maintains the prohibition of discrimination in employment against any qualified individual with a disability and proposes to revise § 42.512 to conform to the 1992 Amendments, which amended title V of the Rehabilitation Act to apply the same employment standards set forth in title I of the ADA to employment discrimination claims under section 504. Accordingly, the proposed rule deletes the existing requirements related to discriminatory employment practices and references the standards applied under title I of the ADA, 42 U.S.C. 12111 *et seq.*, the EEOC's title I regulation at 29 CFR part 1630, and, to the extent such sections relate to employment, the provisions of sections 501 through 504 and 511 of the ADA, as amended. Note that the Department's regulation at 28 CFR part 37 continues to govern the procedures to be followed by the Federal agencies responsible for processing and resolving complaints or charges of employment discrimination filed against recipients when jurisdiction exists under both section 504 and title I of the ADA.

Section 42.513—Direct Threat

The Department proposes to add a new provision at § 42.513 addressing direct threat to others as a limitation on the requirement to comply with this subpart, in accordance with the ADA. The applicability of the "direct threat" concept to section 504 of the Rehabilitation Act was first set forth in the Supreme Court decision *School Board of Nassau County, Florida v. Arline*, 480 U.S. 273 (1987). In *Arline*, the Supreme Court directed that under

section 504 of the Rehabilitation Act, the determination of whether a person with a contagious disease is otherwise qualified must be made on an individualized basis, taking into account the: nature of the risk to others (how the disease is transmitted); duration of the risk to others (how long the carrier is infectious); severity of the risk to others (what the potential harm is to third parties); and probability the disease will be transmitted and will cause varying degrees of harm to others. The Court made it clear that the individualized inquiry required appropriate findings of fact about these factors, based on reasonable medical judgments given the current state of medical knowledge. While *Arline* arose out of allegations that an individual was not "otherwise qualified" under section 504 because she had a "contagious disease" that arguably posed a danger to the health and safety of others, the individualized inquiry and the specific analysis required by *Arline* apply to any exclusion on the basis of an allegation that a person with a disability poses a "direct threat" to the health or safety of others, including outside the communicable disease context. *See, e.g., EEOC v. Amego, Inc.*, 110 F.3d 135, n.6 (1st Cir. 1997) ("While the language of the 'direct threat' provision is not limited to instances where the threat comes from communicable diseases, the provision originated in the communicable disease context." (citing H.R. Rep. No. 101-485 (II), at 76, 1990 U.S.C.C.A.N. at 358-59)).

Congress turned to *Arline* as the foundation for incorporating the "direct threat" concept into the ADA. *See* H.R. Rep. No. 101-485 (III), at 45; 42 U.S.C. 12111(3). The House Report stated: "While the *Arline* case involved a contagious disease, * * * the reasoning in that case is applicable to other circumstances. A person with a disability must not be excluded, or found to be unqualified, based on stereotypes or fear." *Id.* Congress conceived of the "direct threat" concept arising in the context of a challenge to an individual's qualifications, or standing alone as a basis for exclusion. The Department's 1991 section-by-section analysis for the title II regulation indicated that the incorporation of the *Arline* "direct threat" concept and analysis was essential, "if the law is to achieve its goal of protecting disabled individuals from discrimination based on prejudice, stereotypes, or unfounded fear, while giving appropriate weight to legitimate concerns, such as the need to avoid exposing others to significant health and safety risks." 28 CFR part 35,

⁹ *See* S. Rep. 102-357 at 14 (Aug. 3, 1992); H.R. Rep. 102-822 at 82 (Aug. 10, 1992).

app. B. The ADA regulatory language for titles II and III addresses determinations of “direct threat[s]” at 28 CFR 35.104, 36.104 (definitions) and at 28 CFR 35.139, 36.208 in a substantially similar manner. The title II and III regulations define “direct threat” as “a significant risk to the health or safety of others that cannot be eliminated by a modification of policies, practices, or procedures, or by the provision of auxiliary aids or services * * *.” 28 CFR 35.104, 36.104. Consistent with *Arline*, the regulations set forth evaluative criteria directing that determinations as to whether an individual’s disability constitutes a direct threat to others must be based on individualized findings of fact that take into account the nature, duration, and severity of the risk to others, the likelihood that injury might occur, and whether reasonable accommodations could mitigate the risk to others. Accordingly, the Department is proposing to revise its section 504 regulation to include language addressing a “direct threat” that will be consistent with the standards articulated in *Arline* and the language in the Department’s ADA title II and III regulations.

Additionally, the Department proposes to include a new paragraph at proposed § 42.513(c) that addresses “direct threat” in the employment discrimination context. As provided in the definitions section, the applicable definition of “direct threat” in the employment discrimination context includes significant risk of substantial harm to self. The Department is therefore proposing to include a paragraph that provides that an employer does not have to employ an individual who would pose a “direct threat” as that term is defined in the EEOC’s regulation implementing title I of the ADA at 29 CFR 1630.2(r) and 1630.15(b).

Section 42.514—Illegal Use of Drugs

The ADA amended the Rehabilitation Act to exclude individuals engaging in illegal drug use from coverage of section 504. *See* ADA, sec. 512 (codified at 29 U.S.C. 705(10)). The Department proposes to include a new provision at § 42.514 that reflects this requirement and uses the same language that is set forth in the comparable provision in the regulation implementing title II of the ADA at 28 CFR 35.131.

Section 42.515—Claims of No Disability

In § 42.515, the Department proposes to add a new provision stating that “[n]othing in this subpart shall provide the basis for a claim that an individual without a disability was subject to

discrimination because of a lack of disability, including a claim that an individual with a disability was granted a reasonable accommodation that was denied to an individual without a disability.” This provision is consistent with a recent amendment to title V of the ADA by section 6 of the ADA Amendments Act. *See* ADA Amendments Act, sec. 6 (codified at 42 U.S.C. 12201(g)). While Congress did not expressly apply this provision to section 504 at that time, the Department believes that in order to maintain appropriate consistency between title II of the ADA and section 504, this principle should be equally applicable to the Department’s regulatory provisions for federally assisted programs and activities.

Program Accessibility

Section 42.521—Existing Facilities

Section 42.521 addresses the obligations of recipients to operate each program or activity subject to this subpart so that when viewed in its entirety, the program or activity is readily accessible to and usable by individuals with disabilities. This obligation, which applies to existing facilities, is generally known as “program accessibility.” The comparable obligation is found in the ADA title II regulation at 28 CFR 35.150. The Department is proposing to make non-substantive changes to certain provisions in § 42.521 in order to conform them to the corresponding language in the title II regulation, including adding a specific provision at § 42.521(b)(3) to address how a historic preservation program shall achieve program accessibility where structural changes would threaten or destroy the historically significant features of a historic property. Aligning the section 504 provision addressing historic preservation programs with the title II provision will ensure that recipients subject to both the ADA and section 504 may follow the same rules with respect to historic preservation.

In conforming the language of § 42.521 to the corresponding title II provision, the Department is also proposing to add an affirmative statement to the regulation at § 42.521(a)(2) making it clear that the longstanding limitations of undue financial and administrative burden and fundamental alteration apply to the obligation to provide program accessibility. *See Alexander v. Choate*, 469 U.S. 287 (1985); *Se. Cmty. Coll. v. Davis*, 442 U.S. 397 (1979).

The Department is also proposing several other revisions to § 42.521. In

§ 42.521(b)(1), the Department is proposing to update the references to the accessibility standards that apply to structural changes to buildings and facilities made for the purposes of providing program accessibility so that the section references the 2010 ADA Standards for Accessible Design (2010 Standards), which the Department is proposing to adopt in § 42.522 below.

The Department’s proposed adoption of the 2010 Standards as the standard under section 504 for new construction and alterations raises the question of whether recipients will have to update elements in buildings or facilities currently compliant with the Uniform Federal Accessibility Standards (UFAS) that are not otherwise being altered, in order to comply with the 2010 Standards. In order to provide certainty to recipients and individuals with disabilities alike, the Department is proposing to add a safe harbor provision at § 42.521(b)(2), which specifies that “elements that have not been altered in existing facilities on or after [INSERT EFFECTIVE DATE OF THE RULE], and that comply with the corresponding technical and scoping specifications for those elements in the Uniform Federal Accessibility Standards (UFAS), * * * are not required to be modified to be brought into compliance with the requirements set forth in the 2010 Standards.” This provision is similar to the safe harbor provision in the Department’s ADA title II regulation at 28 CFR 35.150(b)(2)(i).

Section 42.521(c)—Small Providers

The Department’s current regulation at § 42.521(c) provides that “[i]f a recipient with fewer than fifteen employees finds, after consultation with [an individual with a disability] seeking its services, that there is no method of complying with § 42.521(a) other than making a significant alteration in its existing facilities, the recipient may, as an alternative, refer the [individual with a disability] to other available providers of those services that are accessible.” When the Civil Rights Restoration Act (CRRA) took effect in 1988, it amended section 504 to provide that small providers are not required “to make significant structural alterations to their existing facilities for the purpose of assuring program accessibility, if alternative means of providing the services are available. The terms used in this subsection shall be construed with reference to the regulations existing on the date of the enactment of this subsection.” *See* Public Law 100–259, sec. 4 (Mar. 22, 1988), codified at 29 U.S.C. 794(c). The legislative history of the CRRA referenced, and explicitly

affirmed, provisions similar to the proposed § 42.521(c) that existed in certain Federal agency section 504 regulations on March 22, 1988, including those from the U.S. Department of Agriculture (USDA) and the U.S. Department of Veterans Affairs (VA). *See* S. Rep. No. 100–64(I) at 23–24 (June 5, 1987). The USDA’s section 504 regulation provided (and continue to provide) that a recipient who is a small provider may, as an alternative, refer an individual with a disability “to other providers of those services that are accessible at no additional cost” to the individual with a disability. 7 CFR 15b.18(c). The VA’s section 504 regulation provided (and continue to provide) that “[w]here referrals [by small providers] are necessary, transportation costs shall not exceed costs to and from recipients’ programs or activities.” 38 CFR 18.422(c). The legislative history also set forth expectations about small providers’ obligations to individuals with disabilities when making their facilities accessible would involve a significant structural alteration. The legislative history cited to the Department of Health and Human Services’ (HHS) regulation, noting that under the regulation, small providers may exercise the exception only after determining “that the other provider’s program is, in fact, accessible and that the other provider is willing to provide the services.” S. Rep. No. 100–64 (I), at 23–24 (citing to HHS rule at 45 CFR 84.22(c)); *see* 42 FR 22676, 22689 (May 4, 1977). The legislative history further observed that under the regulation, prior to making any referral, the small providers must ensure that there are “no resulting additional obligations to the [individual with a disability].” S. Rep. No. 100–64 (I), at 23; *see* 42 FR 22676, 22689 (May 4, 1977). Referencing the HHS, VA, and USDA regulations, the legislative history affirmed that the new statutory “subsection makes it clear that the special rules now contained in the above described regulations are now specifically statutorily authorized.” S. Rep. No. 100–64 (I), at 24.

The Department is proposing to revise its small provider provision to reflect Congress’s intent when it revised section 504. Accordingly, the Department proposes to revise § 42.521(c) to provide that a recipient with fewer than 15 employees who finds, after consultation with an individual with a disability seeking its services, that there is no method of complying with § 42.521(a) other than making a significant alteration to its existing facilities, may, as an alternative,

refer the individual with a disability to alternative providers of available accessible services. The proposed revision further provides that for these purposes, in order to ensure that the services are available, the small provider “must first determine that the alternative provider’s services are accessible, the alternative provider is willing to provide the services, the services are available at no additional cost to the individual with a disability, and transportation costs to and from the alternative provider do not exceed costs to and from the small provider.” As with all providers subject to section 504, if the cost of making structural changes as a means of providing program accessibility in existing facilities is an undue financial and administrative burden, then the small provider is not obligated to make those changes. The Department notes that in the vast majority of cases, small providers are also subject either to the program accessibility requirements of title II of the ADA or the barrier removal obligation of title III of the ADA.

Section 42.521(d)—Written Plan Required for Certain Recipients To Achieve Program Accessibility

The Department is proposing to revise § 42.521(d) to clarify that this provision only refers to those circumstances where a written plan was originally required for recipients subject to the rule when it first took effect. The Department is proposing to replace all references in this section that set compliance dates for specific requirements in relation to the “effective date of this subpart” with references to the actual dates when compliance was required. These changes will maintain continuity of regulatory requirements by clarifying that the original effective date of the subpart (and other deadlines based on this original effective date), and not the date these proposed amendments take effect, is the operative date for compliance with this section of the regulation.

Section 42.521(e)—Notice of Location of Accessible Facilities

Under § 42.521(e) of the Department’s current regulation, the recipient is required to adopt and implement procedures to ensure that interested persons, including persons with various types of disabilities, can obtain information as to the existence and location of accessible services, activities, and facilities. The Department proposes to make a non-substantive revision to the provision on notice of location of accessible facilities

(renumbered as § 42.521(e)(1)) to reflect updated terminology describing certain disabilities.

Proposed § 42.521(e)(2) clarifies the obligation to provide notice by adding language consistent with the existing title II obligation at 28 CFR 35.163(b) requiring signs at a primary entrance to each of the recipient’s inaccessible facilities, if any, directing users to an accessible facility or a location where they can obtain information about accessible facilities.

Section 42.522—Program Accessibility in Jails, Detention and Correctional Facilities, and Community Correctional Facilities

The Department is proposing to add a new section entitled “Program accessibility in jails, detention and correctional facilities, and community correctional facilities.” This section, which is modeled after the Department’s title II regulation at 28 CFR 35.152, provides additional guidance about the specific application of section 504’s general requirements to these facilities operated by or on behalf of recipients of Federal financial assistance from the Department. While all of the jails, detention and correctional facilities, and community correctional facilities funded by the Department are also public entities subject to the title II requirements, because the Department provides assistance to so many of the agencies that operate these facilities, it believes it will be helpful to recipients to understand that the same requirements apply under both statutes. The Department has added some language that clarifies that the requirements in this section are in addition to the general requirements of this subpart and intends that this section be interpreted consistent with 28 CFR 35.152.

Section 42.523—New Construction and Alterations

Section 42.523(a) and (b)—Design and Construction; Alteration

Section 42.522(a) of the Department’s current regulation requires that, if construction of a recipient’s facility commenced after the effective date of the regulation, the facility must be designed and constructed so that it is readily accessible to and usable by individuals with disabilities. In proposed § 42.523(a), the Department proposes to replace the reference to the “effective date of this subpart” with “July 3, 1980,” which was the date the Department’s original section 504 regulation took effect. This will maintain continuity of regulatory

requirements by clarifying that the original effective date of the subpart, and not the date these proposed amendments take effect, is the operative date for compliance with this section of the regulation.

Section 42.522(a) of the Department's existing regulation also requires that facility alterations commenced after the effective date of the regulation that affect or may affect the facility's usability must be carried out so that, to the maximum extent feasible, the altered portion of the facility is readily accessible to and usable by individuals with disabilities. The Department proposes to separate this requirement into its own paragraph at proposed § 42.523(b) and to update its phrasing for clarity. For the same purposes as the new construction paragraph above, the Department proposes to replace the reference to the "effective date of this subpart" with "July 3, 1980."

Section 42.523(c)(1)—Adoption of Updated Accessibility Standards

The Department proposes to revise § 42.523 to adopt the 2010 Standards for new construction and alterations in lieu of the Uniform Federal Accessibility Standards (UFAS).¹⁰ Section 42.522 of the Department's current regulation provides that any new construction or structural alterations made by recipients must be made in compliance with UFAS, 49 FR 31528, app. A (Aug. 7, 1984). UFAS was adopted in 1991 as the applicable accessibility standard for section 504 as part of a joint rulemaking with several other agencies, moderated by the Department pursuant to its coordinating authority for section 504 under Executive Order 12250. The Department and participating agencies adopted UFAS to diminish the possibility that some recipients of Federal financial assistance would face conflicting enforcement standards either between section 504 and the Architectural Barriers Act of 1968 (which applies to all buildings and facilities built, altered, or leased with Federal dollars), or among the section 504 regulations of different Federal agencies. 55 FR 52136, 52136–37 (1990). The Department adopted the 2010

Standards for all new construction and alterations commenced on or after March 15, 2012, for entities subject to titles II or III of the ADA. 75 FR 56164, 56182 (Sept. 15, 2010). Until that time, both UFAS and the 1991 ADA Standards for Accessible Design were options for compliance with title II.

The Department's proposed § 42.523(c)(1) would require that recipients comply with the 2010 Standards beginning one year from the publication date of the final rule. In addition, the Department recognizes that many but not all of its recipients are also subject to the ADA and are already required to comply with the 2010 Standards. In order to minimize the timeframe during which recipients subject to section 504 and the ADA must comply with two separate accessibility standards, the Department proposes that beginning with the publication of the final rule in the **Federal Register** and until the 2010 Standards take effect under section 504, recipients will have the choice of complying with either UFAS or the 2010 Standards.¹¹ Regardless of which accessibility standard recipients choose to use during this time period, recipients must consistently rely on one accessibility standard and may not designate one accessibility standard for one part of a facility and the other for the remainder.

While in some circumstances the ADA imposes different obligations on public entities as compared to private entities, section 504 does not differentiate between public and private recipients of Federal financial assistance. Accordingly, neither the Department's section 504 regulation nor UFAS imposes different scoping and technical accessibility requirements on recipients based upon their status as public or private entities.

Although in nearly all circumstances the requirements in the 2010 Standards for buildings and facilities subject to either title II or title III of the ADA are the same, there are several instances where the requirements differ. Most significantly, Exception 1 of section 206.2.3 of the 2010 Standards exempts

certain multistory buildings owned by private entities from the requirement to provide an elevator to facilitate an accessible route throughout the building. This exemption does not apply to buildings owned by public entities.¹² Section 217.4.3 of the 2010 Standards also specifies TTY requirements for public buildings that are different than those required for private buildings. In order to maintain the required consistency in the accessibility requirements applicable to all its recipients, regardless of whether they are public or private entities, the Department proposes to require all buildings and facilities subject to its section 504 federally assisted regulation to comply with the 2010 Standards' scoping and technical requirements for a "public building or facility," which are the requirements for buildings subject to title II of the ADA.

UFAS and the 2010 Standards also have differing requirements for employee work areas.¹³ Sections 4.1.2(17) and 4.1.4(4–13) of UFAS require that most employee work areas be accessible where those areas would result in the employment of individuals with disabilities, and that 5% of all work stations in an employee work area be accessible. Sections 203.9 and 207.1 of the 2010 Standards require only that work areas be designed for approach, entry, and exit by individuals with disabilities. Subject to certain exceptions, section 206.2.8 of the 2010 Standards requires common use circulation paths in employee work areas to be accessible to allow individuals with disabilities to move within the space. As the Department previously noted in its "Analysis and Commentary on the 2010 Standards for Accessible Design," the 2010 Standards' approach to work areas provides access for individuals with disabilities to approach, enter, and exit work areas such that reasonable accommodations to those work areas can then be made as required by the ADA and section 42.511 of the Department's current regulation. 28 CFR part 36, app. B, https://www.ada.gov/regs2010/titleIII_2010/reg3_2010_appendix_b.htm. The

¹⁰ In the preamble to the revised final title II regulation that adopted the 2010 Standards as new ADA accessibility standards, the Department stated that Federal agencies that extend Federal financial assistance should revise their section 504 regulations to adopt the 2010 Standards as updated standards for new construction and alterations that supersede UFAS. 75 FR 56164, 56213 (Sept. 15, 2010). The Department also stated its intent to work with Federal agencies to revise their section 504 regulations in the near future to adopt the 2010 Standards as the appropriate accessibility standard for their recipients.

¹¹ This choice is in keeping with the Department's March 2011 memorandum advising Federal agencies that until such time as they update their agency's regulation implementing the federally assisted provisions of section 504, they may notify covered entities that they may use the 2010 Standards as an acceptable alternative to UFAS. Memorandum from Thomas E. Perez on Permitting Entities Covered by the Federally Assisted Provisions of Section 504 of the Rehabilitation Act to Use the 2010 ADA Standards for Accessible Design as an Alternative Accessibility Standard for New Construction and Alterations (Mar. 29, 2011), www.ada.gov/504_memo_standards.htm (last visited Mar. 10, 2016).

¹² The Department also notes that the current accessibility standard, UFAS, has no elevator exemption for private entities. Therefore, requiring private entities that are subject to both title III of the ADA and section 504 to comply with the requirements for public buildings and facilities in the 2010 Standards imposes no new burdens on those entities.

¹³ In addition, section 4.1.2(13) of UFAS requires visual alarms where warning systems are provided. Section 215.3 of the 2010 Standards require that audible alarms in employee work areas have wiring such that visual alarms can be integrated into the alarm system.

Department expects that maintaining consistent application of the 2010 Standards will streamline compliance for many recipients, particularly those that are subject to titles II or III of the ADA.

In addition, the Department's current section 504 federally assisted regulation at § 42.522(b) allows departures from the requirements of UFAS if the other methods used provide "substantially equivalent or greater access to and usability of the building." This concept of departure from the accessibility standards is retained in this regulation (renumbered as § 42.523(c)(1)(v)), but the phrasing is adjusted for consistency with the title II regulation.

Lastly, the Department notes that a recipient that receives funding from multiple Federal agencies must ensure that it is compliant with the accessibility standards of each agency from which it receives Federal funding.

Section 42.523(c)(2) and (3)—Triggering Events for Compliance With the Applicable Accessibility Standards

As discussed above, the Department is proposing that all recipients must comply with the 2010 Standards in lieu of UFAS one year from the publication date of the final rule in the **Federal Register**. In recognition of the fact that buildings and facilities may be in the planning, design, or construction phases for a number of years, the Department is proposing to specify "triggering events" that would determine which buildings and facilities must comply as of the compliance date. The Department is proposing, however, to use different "triggering events" for application of the 2010 Standards to new construction and alterations for "public entities" that receive financial assistance from the Department as compared to "private entities" that receive such assistance. These two different categories of "triggering events" are based upon the "triggering events" specified in the Department's title II and title III rules at 28 CFR 35.151(c) and 28 CFR 36.406(a), respectively. The Department expects that maintaining consistency with the ADA requirements in this regard will simplify application of the 2010 Standards for recipients already subject to either title II or title III.

Thus, the Department is proposing that recipients that are private entities may choose either UFAS or the 2010 Standards when one of the following events has occurred on or after the date of publication of the final rule in the **Federal Register** but before the compliance date for the 2010 Standards: (1) The last application for a building permit or permit extension is certified to

be complete by a State, county, or local government; (2) in those jurisdictions where the government does not certify completion of applications, the last application for a building permit or permit extension is received by the State, county, or local government; or (3) if no permit is required, the commencement of physical construction or alterations.

Similarly, the Department is proposing that recipients that are private entities must comply with the 2010 Standards as of one year from publication of this rule in the **Federal Register** when one of the following events has occurred on or after one year from the date of publication of the final rule in the **Federal Register**: (1) The last application for a building permit or permit extension is certified to be complete by a State, county, or local government; (2) in those jurisdictions where the government does not certify completion of applications, the last application for a building permit or permit extension is received by the State, county, or local government; or (3) if no permit is required, the commencement of physical construction or alterations.

For public entities receiving Federal financial assistance from the Department, the Department is proposing to use the commencement of physical construction or alterations on or after the publication date of the final rule but before the required compliance date of the 2010 Standards as the "triggering event" for the choice of standards permitted by § 42.523(c)(1). Similarly, the Department is proposing to use the commencement of physical construction or alterations on or after one year from publication of the final rule in the **Federal Register** as the "triggering event" for the requirement to comply with the 2010 Standards. This is consistent with the approach the Department took for compliance with the 2010 Standards under title II of the ADA.

The Department is proposing at § 42.523(c)(3) to add a provision similar to the language in the ADA regulations at 28 CFR 35.151(c)(4) in title II and 28 CFR 36.406(a)(4) in title III that states that "ceremonial groundbreaking or razing of structures prior to site preparation will not be considered to commence or start physical construction or alterations."

42.523(c)(4)—Compliance With the Architectural Barriers Act of 1968

Facilities designed, built, altered, or leased with Federal funds are subject to the requirements of the Architectural Barriers Act of 1968, as amended, 42

U.S.C. 4151–57 (ABA). Facilities that receive Federal financial assistance from the Department are required to comply with the ABA accessibility standards adopted by the General Services Administration (GSA), which is the Federal agency responsible for adopting ABA standards for all buildings subject to the ABA except for residential structures; buildings, structures, and facilities of the Department of Defense (DOD); and buildings, structures and facilities of the U.S. Postal Service (USPS).¹⁴ The U.S. Access Board is the enforcing authority with respect to complaints under the ABA.

Many, but not all, buildings and facilities used by recipients for their programs or activities are also covered by the ABA. Until recently, UFAS served as the applicable accessibility standard under both section 504 federally assisted regulations and the ABA, and, therefore, facilities that complied with UFAS were also in compliance with the ABA. While there is significant overlap between the current ABA standards and the 2010 Standards, there are a number of differences. Recipients subject to both statutes need to be aware of the requirements of both accessibility standards and need to comply with both. Thus, the Department is proposing at § 42.523(c)(4) to add a provision reminding recipients that "[n]othing in this section relieves recipients whose facilities are covered by the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151–4157), from their responsibility of complying with the requirements of that Act and any implementing regulations."

Procedures

Section 42.530—Administrative Procedures for Recipients

Certain provisions of § 42.505 of the existing regulation (renumbered as § 42.530) impose administrative requirements related to the designation of a responsible employee for compliance with this subpart (§ 42.505(d) of the current regulation), adoption of grievance procedures (§ 42.505(e) of the current regulation), and provision of notice of nondiscrimination (§ 42.505(f) of the

¹⁴ The U.S. Access Board is charged with promulgating accessibility guidelines that form the basis of the ABA standards adopted by GSA, Department of Housing and Urban Development (HUD), DOD, and USPS. See 42 U.S.C. 4151 *et seq.* On July 23, 2004, the Access Board published its final revised ABA Accessibility Guidelines (2004 ABAAS). See 69 FR 44084. In 2005, GSA adopted the 2004 ABAAS as the enforceable standard for Federal facilities under its jurisdiction. See 41 CFR 102–76.65.

current regulation). The existing regulatory provisions apply these specific requirements automatically to all recipients: Employing 50 or more persons; and receiving Federal financial assistance from the Department of \$25,000 or more (in the case of the designated employee and grievance procedures) or more than \$25,000 (in the case of the provision of notice). However, the existing regulatory provisions also give the Department discretion whether to apply these requirements to “any recipient with fewer than fifty employees and receiving less than \$25,000” in financial assistance from the Department. *See* § 42.505(g).

The Department is seeking public comment on whether it should revise paragraphs 42.505(d), (e) and (f) of the existing regulation (renumbered as 42.530(c), (d) and (e)), to delete any references to size of grant award, so that the number of employees (50 or more) is the only criteria triggering the application of the administrative requirements in these three paragraphs. State and local governments already are subject to comparable requirements under title II of the ADA. *See* 28 CFR 35.104, 35.105. The Department is interested in public comment on how many recipients with 50 or more employees receive grants from the Department of less than \$25,000 and thus, would be affected if the Department were to revise the rule in this manner. The Department is also interested in public comment on whether it should change or eliminate the number of employees or the grant amount that triggers these requirements, what the new threshold number of employees or grant amount should be to trigger the obligation to meet these requirements, the number of affected recipients if the Department makes this change, and the costs related to making this change.

Section 42.530(b)—Self-Evaluation

The Department is maintaining the provision requiring recipients to conduct a self-evaluation as a historical requirement but is revising it to refer to the requirements in the past tense. The Department’s current regulation at § 42.505(c) requires in part that a recipient, “within one year of the effective date of this subpart, evaluate and modify its policies and practices that do not meet the requirements of this subpart.” The Department is proposing to make a non-substantive revision to § 42.530(b) of this paragraph by replacing the phrase “within one year of the effective date of this subpart,” with the actual date that was

a year from when the subpart originally took effect, which is “July 3, 1981.” While this provision does not require recipients to conduct a self-evaluation beyond the original deadline of July 3, 1981, the Department is retaining this provision because the self-evaluation requirement under section 504 is cross-referenced in the Department’s ADA title II regulation at 28 CFR 35.105(d).

Section 42.530(d)—Adoption of Grievance Procedures

Section 42.505(e) of the current regulation requires recipients to adopt grievance procedures. The Department proposes to make a non-substantive change to this provision (renumbered as § 42.530(d)) to clarify that the procedures adopted by the recipient must incorporate appropriate due process standards. The Department also proposes to revise this paragraph to clarify that any individual may file a complaint with the Department without having first used the recipient’s grievance procedures.

Section 42.530(e)—Notice

Section 42.505(f) of the current regulation requires a recipient that employs 50 or more persons and that receives Federal financial assistance from the Department of more than \$25,000 to take appropriate initial and continuing steps to notify participants, beneficiaries, applicants, employees, and unions or professional organizations holding collective bargaining or professional agreements with the recipient that it does not discriminate on the basis of disability in violation of section 504 and this subpart. This provision also delineates the methods of initial and continuing notification to include “the posting of notices, publication in newspapers and magazines, placement of notices in recipients’ publication, and distribution of memoranda or other written communications.”

The proposed regulation maintains the requirement that the notice shall state that the recipient does not discriminate in its programs or activities with respect to access, treatment, or employment and shall include the identification of the person responsible for coordinating compliance with this subpart and where to file section 504 complaints with the Department and, where applicable, with the recipient. The Department encourages recipients to consider including in their notice information relating to the availability of auxiliary aids and services, procedures for obtaining such aids and services, contact information for the

responsible employee, and the availability of grievance procedures.

The Department recognizes that the methods by which a recipient communicates with interested persons have changed significantly since this regulation was promulgated and that this regulation, as currently written, does not reflect the current and future state of information dissemination. With the growth of the Internet and the World Wide Web, the Department has determined that the regulation should also reference postings on a recipient’s Web site as a permissible method of communication and is proposing to include “publications on the recipient’s internet Web site” as a method of initial and continuing notification in the regulation (renumbered as § 42.530(e)(1)). Many of the publications that previously were available in print such as pamphlets, brochures, maps, course catalogs, policies, and procedures are now posted on recipients’ Web sites and can be printed or downloaded by an interested person viewing the Web site.

The Department has deleted the reference in this section to the initial notification deadline because the requirement to provide notice is a continuing obligation and the initial notification deadline has long passed.

Section 42.530(f)

The Department is proposing to remove the reference to paragraph (c)(2) in the current § 42.505(g) (renumbered as § 42.530(f)), which addresses self-evaluation as a potential requirement for recipients with fewer than 50 employees. The self-evaluation provision at paragraph (c)(2) (renumbered as paragraph (b)(2) in this section) is a historical requirement and does not apply to current or future recipients.

Section 42.531—Assurances Required

Section 42.531(a)—Assurances Required

The Department is proposing to revise its provisions on assurances from government agencies at current § 42.504(b) and assurances from institutions at current § 42.504(c) to align these provisions with the definition of “program or activity” that was adopted by the Department in 2003 as a result of the Civil Rights Restoration Act and *Cureton v. NCAA*, 198 F.3d 107 (3d Cir. 1999). *See* 68 FR 51334, 51364 (Aug. 26, 2003). Before the CRRA, the definition of “program” was limited to “the operations of the agency or organizational unit of government receiving or substantially benefiting from the Federal assistance awarded,

e.g., a police department or department of corrections.” 45 FR 37620, 37626 (June 3, 1980). Therefore, it was necessary, for instance, to clarify that the assurance applied to the entire agency or agency of the same governmental unit if the policies of the other agency would affect the “program” (as defined at that time) for which Federal financial assistance was requested. However, it is no longer necessary to include that clarification, given that the definition of “program or activity” that was adopted in 2003 encompasses “all of the operations of the entity of a State or local governmental agency or department that distributes the federal assistance to another State or local governmental agency or department and all of the operations of the State or local governmental entity to which the financial assistance is extended.” See 68 FR 51334, 51336, 51364 (Aug. 26, 2003).

Additionally, the definition of “program or activity” adopted in 2003 also includes educational institutions, corporations and other private organization, and plants. The Department is proposing to revise current § 42.504(c) to ensure that the applicability of the nondiscrimination requirements is also addressed with respect to these entities consistent with the definition of “program or activity.”

Section 42.531(b)—Duration of Obligation

The Department’s current section 504 federally assisted regulation at § 42.504(d) provides that “[w]here the Federal financial assistance is to provide or is in the form of real or personal property, the assurance will obligate the recipient and any transferee for the period during which the property is being used for the purpose for which the Federal financial assistance is extended or for another purpose involving the provisions of similar benefits, or for as long as the recipient retains ownership or possession of the property, whichever is longer. In all other cases the assurance will obligate the recipient for the period during which Federal financial assistance is extended.” The Department proposes several clarifications to the duration of obligation requirement. First, the Department proposes to have the assurance apply to improvements provided by Federal financial aid and assistance, in addition to real or personal property. Second, the Department proposes to reference the provision of federally assisted services, in addition to benefits, as a determinant of the duration of assurance obligations.

Finally, the Department proposes to replace the reference “[i]n all other cases” with “[w]hen the Federal financial assistance is not in the form of real or personal property or improvements” to clarify the particular circumstances under which the assurance continues to apply to the recipient during the period for which Federal financial assistance is extended.

Section 42.532—Compliance and Enforcement Procedures

The Department is maintaining the compliance and enforcement procedures provision from § 42.530 of its current regulation and has renumbered it as § 42.532. In an effort to account for future changes in organization and to eliminate obsolete references to some components that no longer exist within the Department, the Department proposes to replace the references to “LEAA, NIJ, BJS, OJARS, and OJDDP” with the phrase “a grant-making component of the Department.” In addition, the Department is proposing to revise § 42.530(c) which currently provides that “[i]n the case of programs or activities funded by LEAA, NIJ, BJS, OJARS, and OJDDP, the refusal to provide requested information under paragraph (a) of this section and [28 CFR] 42.106 *will be enforced* pursuant to the provisions of section 803(a) of title I of the Omnibus Crime Control and Safe Streets Act” as amended (emphasis added). The Department believes that, in addition to the termination of funds as a remedy under section 803(a) and its successor statute, 42 U.S.C. 3783, the Department should also have the discretion to consider, where appropriate, a more measured response to a recipient’s refusal to provide requested information and therefore, should be able to avail itself of “the remedies, procedures and rights set forth in title VI of the Civil Rights Act of 1964 * * * available to any person aggrieved by any act or failure to act by any recipient of Federal assistance,” consistent with the Rehabilitation Act. See 29 U.S.C. 794a(a)(2). Accordingly, the Department proposes to revise § 42.530(c) of the existing regulation (renumbered as § 42.532(a)(2)) to read “[i]n the case of programs or activities funded by a grant-making component of the Department, the refusal to provide access to sources of information pursuant to 28 CFR 42.106(c) *may be enforced* using the procedures cited in paragraph (a)(i) of this section or using the provisions of section 803(a) of title I of the Omnibus Crime Control and Safe Streets Act” as amended (emphasis added). The Department proposes to delete paragraphs (d) and (e) of existing

§ 42.530. Paragraph (d) established a 180-day limitation period from July 3, 1980, to file complaints of acts of discrimination that occurred prior to July 3, 1980. This provision is no longer necessary. Similarly, the Department proposes deleting paragraph (e) because it establishes a procedure for which the statute of limitations has long passed and is thus no longer necessary.

The Department also proposes to move its existing provision addressing remedial action from existing § 42.505(a) to proposed § 42.532(c) because the requirement for remedial action arises after a finding of discrimination has been made in accordance with the procedures set forth in this section. The Department believes that the placement of the remedial action provision in the compliance procedures section is a more logical placement than its current location in the administrative requirements section. The Department also proposes making non-substantive edits to the existing language.

Lastly, the Department proposes to add a new paragraph at proposed § 42.532(d) that directs complaints alleging violations of section 504 by recipients of financial assistance from the Department to be filed with the Office of Justice Programs. The Office of Justice Programs is the entity within the Department that enforces section 504.

III. Regulatory Analysis

A. Executive Order 13563 and 12866—Regulatory Planning and Review

This NPRM has been drafted in accordance with Executive Order 13563 of January 18, 2011, 76 FR 3821, Improving Regulation and Regulatory Review, and Executive Order 12866 of September 30, 1993, 58 FR 51735, Regulatory Planning and Review. Executive Order 13563 directs agencies, to the extent permitted by law, to propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs; tailor the regulation to impose the least burden on society, consistent with obtaining the regulatory objectives; and, in choosing among alternative regulatory approaches, select those approaches that maximize net benefits. Executive Order 13563 recognizes that some benefits and costs are difficult to quantify and provides that, where appropriate and permitted by law, agencies may consider and discuss qualitatively values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.

The Department has determined that this proposed rule is a “significant regulatory action” as defined by Executive Order 12866, sec. 3(f). The Department has determined, however, that this proposed rule is not an economically significant regulatory action, as it will not have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. This NPRM has been reviewed by the Office of Management and Budget (OMB) pursuant to Executive Orders 12866 and 13563.

This rule provides necessary revisions to the Department’s current section 504 federally assisted regulation to: (1) Incorporate amendments to the statute including the changes in the meaning and interpretation of the applicable definition of disability required by the ADA Amendments Act; (2) incorporate requirements stemming from judicial decisions; (3) update accessibility standards applicable to new construction and alteration of buildings and facilities; (4) update certain provisions to promote consistency with comparable provisions implementing title II of the ADA; and (5) make other non-substantive clarifying edits. The proposed regulation is intended to promote consistency of judicial interpretations and predictability of executive enforcement of section 504 of the Rehabilitation Act, as it pertains to federally assisted programs.

This rule does not significantly change any existing substantive obligations of recipients subject to the Department’s federally assisted regulation because, with the exception of the updated accessibility standard, the Department is incorporating into its section 504 regulation definitions and requirements arising out of statutory amendments to the Rehabilitation Act and longstanding Supreme Court decisions. Moreover, the Department’s adoption of the 2010 Standards as the updated accessibility standard under section 504 will have the effect of simplifying the obligations of its recipients. It should not result in any substantial costs since the vast majority of its recipients are already required to comply with the 2010 Standards because they are either State or local governments covered by title II of the ADA or public accommodations subject to title III of the ADA. The harmonization of the section 504 accessibility requirements with the ADA’s requirements will result in

recipients being subject to only one accessibility standard (the 2010 Standards) instead of two and could have the effect of reducing costs since recipients will no longer have to be familiar with and apply up to two sets of requirements. Lastly, the conformance of section 504’s regulatory provisions with the existing comparable regulatory provisions implementing title II of the ADA will not result in any substantial costs because the requirements under section 504 will remain substantially the same. Title II of the ADA is modeled on section 504 of the Rehabilitation Act of 1973, and Congress intended, through its 1992 Amendments to the Rehabilitation Act, that the principles underlying the ADA also apply to all sections of the Rehabilitation Act, including section 504. As a result, courts have generally treated claims under title II and section 504 the same.

Title III of the ADA applies to the activities of all public accommodations (including nonprofit organizations) funded by the Department with the exception of those recipients that fall within the ADA’s exemption for “religious organizations or entities controlled by religious organizations.” See 42 U.S.C. 12187. Based on the following data from the Department’s grant-making components, the Department estimates that:

- Of the approximately 6395 recipients¹⁵ directly funded by the Office of Justice Programs (OJP), approximately 34 have self-identified as faith-based organizations and may well qualify for the ADA exemption.
- Of the approximately 1478 recipients¹⁶ funded by the Community Oriented Policing Services (COPS) Office, 0 have self-identified faith-based organizations.
- Of the approximately 1739 discretionary grantees and 2934 discretionary subgrantees¹⁷ funded by the Office on Violence Against Women

¹⁵ This number is based upon OJP’s data on active awards as of June 7, 2016. While it is possible that multiple awards may be provided to a single recipient, the Department is assuming a one to one correspondence between award and recipient for purposes of this analysis. The Department has no data on the number of subrecipients funded by OJP, or the number of those subrecipients that may qualify for the ADA religious exemption.

¹⁶ This number is based upon COPS’ data on active awards as of June 6, 2016. While it is possible that multiple awards may be provided to a single recipient, the Department is assuming a one to one correspondence between award and recipient for purposes of this analysis.

¹⁷ This data reflects information that OVW collects from its discretionary grantees in their July–December 2014 semi-annual progress reports and from its subgrantees in their annual 2014 progress reports.

(OVW), approximately 84 have self-identified as faith-based organizations and may well qualify for the ADA exemption.

This data suggests a total of approximately 118 grantees and subgrantees collectively that are self-identified as faith-based organizations. However, because the Department has no data on the number of subrecipients funded by OJP or whether any of them are in fact religious entities, this number may be higher. OJP has previously estimated that there are approximately 100 total faith-based grantees and subgrantees funded by OVW and 50 total faith-based grantees and subgrantees funded by OJP, for a total estimate of 150 grantees and subgrantees from OJP and OVW collectively that are faith-based organizations.¹⁸ Therefore, we estimate between 118 and 150 total faith-based grantees and subgrantees.

The recipients falling under the ADA’s religious exemption could be affected by any incremental changes in the accessibility requirements that result from the change in the applicable standard from UFAS to the 2010 Standards if they engage in new construction or alterations of the facilities serving the program or activity funded by the Department. As discussed in the preamble, however, because of the safe harbor set forth in proposed § 42.521(b)(2), these recipients will not have any obligation to modify any elements in their existing facilities that are compliant with UFAS unless they alter those elements after the compliance date for the Standards takes effect.

A subset of these recipients falling under the ADA religious exemption—those with fewer than 15 employees that were previously exempt from the automatic obligation to provide auxiliary aids and services—may be affected by the proposed elimination of the 15 employee threshold for that obligation. Some of these entities may have fewer than 15 employees.

Given the small subset of recipients who could potentially be affected and the infinite variations of the type of new construction or alteration that could occur along with the type of auxiliary aid or service that could be provided, it would not be feasible to quantify the impact of these changes on an individual basis. However, the Department believes that generally costs for individual recipients would not likely be significant.

¹⁸ This number comes from the Department’s proposed rule to amend 28 CFR part 38, titled “Partnerships with Faith-Based and Other Neighborhood Organizations; Proposed Rule,” 80 FR 47316, 47322 (Aug. 6, 2015).

The Department is interested in public comment on whether its assumptions are correct as to the following: (1) The number of recipients that fall within the ADA exemption for religious organizations or organizations controlled by religious organizations; (2) how many subrecipients funded by OJP may fall within the ADA religious exemption; (3) how many of these recipients also have fewer than 15 employees and whether this particular provision should have a compliance date later than the general effective date of the rule; and (4) the costs to individual recipients not being significant. The Department believes that the costs of this rule will be significantly less than \$100 million in any given year. The Department is interested in public comment on its assumptions that the costs of this rule will be significantly less than \$100 million in any given year.

B. Regulatory Flexibility Act

The Attorney General, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 605(b), has reviewed this regulation, and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. With the exception of the updated accessibility standard, the substantive changes to the section 504 regulation reflect the Department's incorporation of definitions and requirements arising out of statutory amendments to the Rehabilitation Act and longstanding Supreme Court decisions. Moreover, the Department's adoption of the 2010 Standards as the updated accessibility standard under section 504 will have the effect of simplifying the obligations of its recipients and should not result in any additional costs since the vast majority of its recipients are already required to comply with the 2010 Standards because they are either State or local governments covered by title II of the ADA or public accommodations subject to title III of the ADA. The harmonization of the section 504 accessibility requirements with the ADA requirements will result in recipients being subject to only one accessibility standard (the 2010 Standards) instead of two. Additionally, the conformance of section 504's regulatory provisions with existing comparable provisions implementing title II of the ADA will not result in any additional costs for the vast majority of recipients funded by the Department. Lastly, the rule does not include reporting requirements and imposes no new recordkeeping requirements. Even if the Department assumed that all of the recipients that

may be subject to the ADA's religious exemption qualify as "small organizations" and would be affected by the incremental changes in the accessibility standards and the elimination of the 15-employee threshold for the requirement to provide auxiliary aids and services, the Department believes that the number of small entities affected by this rule, compared to the thousands of recipients funded by the Department's grant-making components does not constitute a "significant number of small entities" affected by this rule. The Department is interested in public comment on its assumptions about the impact of the revisions to its section 504 regulation on small entities that receive Federal financial assistance from the Department.

C. Executive Order 13132: Federalism

Executive Order 13132 directs that, to the extent practicable and permitted by law, an agency shall not promulgate any regulation that has federalism implications, that imposes substantial direct compliance costs on State and local governments, that is not required by statute, or that preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. Because each change proposed by this rule does not have federalism implications as defined in the Executive Order, does not impose direct compliance costs on State and local governments, is required by statute, or does not preempt State law within the meaning of the Executive Order, the Department has concluded that compliance with the requirements of section 6 is not necessary.

D. Plain Language Instructions

The Department makes every effort to promote clarity and transparency in its rulemaking. In any regulation, there is a tension between drafting language that is simple and straightforward and drafting language that gives full effect to issues of legal interpretation. The Department is proposing a number of changes to this regulation to enhance its clarity and satisfy the plain language requirements, including revising the organizational scheme and adding headings to make it more user-friendly. The Department operates a toll-free ADA Information Line (800) 514-0301 (voice) and (800) 514-0383 (TTY) that the public is welcome to call to obtain assistance in understanding anything in this proposed rule. If any commenter has suggestions for how the regulation could be written more clearly, please provide comments using the contact

information provided in the introductory section of this proposed rule entitled, **FOR FURTHER INFORMATION CONTACT**.

E. Paperwork Reduction Act

This proposed rule does not contain any new or revised "collection[s] of information" as defined by the Paperwork Reduction Act of 1995. 44 U.S.C. 3501 *et seq.*

F. Unfunded Mandates Reform Act

Section 4(2) of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1503(2), excludes from coverage under that Act any proposed or final Federal regulation that "establishes or enforces any statutory rights that prohibit discrimination on the basis of race, color, religion, sex, national origin, age, handicap, or disability." Accordingly, this rulemaking is not subject to the provisions of the Unfunded Mandates Reform Act.

List of Subjects for 28 CFR Part 42

Administrative practice and procedure, Buildings and facilities, Civil rights, Communications, Grant programs, Individuals with disabilities, Reporting and recordkeeping requirements.

By the authority vested in me as Attorney General by law, including 5 U.S.C. 301, 28 U.S.C. 509, 510, 29 U.S.C. 794, Executive Order 12250, part 42 of title 28 of the Code of Federal Regulations is proposed to be amended as follows:

PART 42—NONDISCRIMINATION; EQUAL EMPLOYMENT OPPORTUNITY; POLICIES AND PROCEDURES

■ 1. Revise Subpart G to read as follows:

Subpart G—Nondiscrimination Based on Disability in Federally Assisted Programs or Activities—Implementation of Section 504 of the Rehabilitation Act of 1973

Sec.

General

- § 42.501 Purpose.
- § 42.502 Application, broad coverage, and relationship to other laws.
- § 42.503 Definitions.
- §§ 42.504–42.509 [Reserved]

General Nondiscrimination Requirements

- § 42.510 General prohibitions against discrimination.
- § 42.511 Communications. SECTNO≤
- § 42.512 Employment.
- § 42.513 Direct threat.
- § 42.514 Illegal use of drugs.
- § 42.515 Claims of no disability.
- § 42.516–42.519 [Reserved]

Program Accessibility

- § 42.520 Discrimination prohibited.
- § 42.521 Existing facilities.
- § 42.522 Program accessibility in jails, detention and correctional facilities, and community correctional facilities.
- § 42.523 New construction and alterations.
- §§ 42.524–42.529 [Reserved]

Procedures

- § 42.530 Administrative procedures for recipients.
- § 42.531 Assurances required.
- § 42.532 Compliance and enforcement procedures.
- § 42.533–42.539 [Reserved]
- Appendix—Appendix A to Subpart G of Part 42—Federal Financial Assistance Administered by the Department of Justice to Which This Subpart Applies.
- Appendix—Appendix B to Subpart G of Part 42 [Reserved].
- Appendix—Appendix C to Subpart G of Part 42—Department Regulations Under Title VI of the Civil Rights Act of 1964 (28 CFR 42.106–42.110) Which Apply to This Subpart
- Appendix—Appendix C to Subpart G of Part 42—OJARS' Regulations Under the Omnibus Crime Control and Safe Streets Act, as Amended, Which Apply to This Subpart (28 CFR 42.205 and 42.206)

Authority: 5 U.S.C. 301; 28 U.S.C. 509, 510; 29 U.S.C. 794; E.O. 12250.

General**§ 42.501 Purpose.**

The purpose of this subpart is to implement section 504 of the Rehabilitation Act of 1973, as amended, which prohibits discrimination on the basis of disability in any program or activity receiving Federal financial assistance.

§ 42.502 Application, broad coverage, and relationship to other laws.

(a) *Application.* This subpart applies to each recipient of Federal financial assistance from the Department of Justice and to each program or activity receiving such assistance. The requirements of this subpart do not apply to the ultimate beneficiaries of Federal financial assistance in the program or activity receiving Federal financial assistance. This subpart does not apply to programs or activities conducted by the Department of Justice.

(b) *Broad scope of coverage.* Consistent with the ADA Amendments Act's purpose of reinstating a broad scope of protection under both the Americans with Disabilities Act and section 504, the definition of "disability" in this subpart shall be construed broadly in favor of expansive coverage to the maximum extent permitted by the terms of section 504. The primary object of attention in cases brought under this subpart should be

whether entities covered under section 504 have complied with their obligations and whether discrimination has occurred, not whether the individual meets the definition of "disability." The question of whether an individual meets the definition of "disability" should not demand extensive analysis.

(c) *Relationship to other laws.*

(1) The obligation to comply with this subpart is not obviated by or otherwise affected by the existence of any State or local law or other requirement that, on the basis of disability, imposes prohibitions or limits upon the eligibility of qualified individuals with disabilities to receive aid, benefits, or services or to practice any occupation or profession.

(2) This subpart does not invalidate or limit the remedies, rights, and procedures of any other Federal law, or State or local law (including State common law), that provide greater or equal protection for the rights of individuals with disabilities or individuals associated with them.

§ 42.503 Definitions.

As used in this subpart the term—
2004 ADAAG means the requirements set forth in appendices B and D to 36 CFR part 1191 (2009).

2010 Standards means the 2010 ADA Standards for Accessible Design, which consist of the 2004 ADAAG and the requirements contained in 28 CFR 35.151.

The Act means the Rehabilitation Act of 1973, Public Law 93–112, as amended, 29 U.S.C. 701 *et seq.*

Applicant means one who submits an application, request, or plan required to be approved by the designated Department official or by a primary recipient, as a condition to eligibility for Federal financial assistance.

Auxiliary aids and services include—

(1) Qualified interpreters on-site or through video remote interpreting (VRI) services; note takers; real-time computer-aided transcription services; written materials; exchange of written notes; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including real-time captioning; voice, text, and video-based telecommunications products and systems, including text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible electronic and information technology; or other effective methods of making aurally

delivered information available to individuals who are deaf or hard of hearing.

(2) Qualified readers; taped texts; audio recordings; Brailled materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs (SAP); large print materials; accessible electronic and information technology; or other effective methods of making visually delivered materials available to individuals who are blind or have low vision;

(3) Acquisition or modification of equipment or devices; and

(4) Other similar services and actions.

Component means any specific division, operating bureau, or other organizational unit of the Department of Justice.

Current illegal use of drugs means illegal use of drugs that occurred recently enough to justify a reasonable belief that a person's drug use is current or that continuing use is a real and ongoing problem.

Department means the Department of Justice, including each of its specific divisions, operating bureaus, and other organizational units.

Direct threat means

(1) With respect to any aid, benefit, or service provided under a program or activity subject to this subpart, a significant risk to the health or safety of others that cannot be eliminated by a modification of policies, practices, or procedures, or by the provision of auxiliary aids or services.

(2) With respect to employment, the term as defined by the Equal Employment Opportunity Commission's regulation implementing title I of the Americans with Disabilities Act of 1990, at 29 CFR 1630.2(r).

Disability has the same meaning as given in 28 CFR part 35.

Drug means a controlled substance as defined in schedules I through V of section 202 of the Controlled Substances Act, 21 U.S.C. 812.

Facility means all or any portion of buildings, structures, sites, complexes, equipment, roads, walks, passageways, parking lots, rolling stock, or other conveyances, including the site where the building, property, structure, or equipment is located, or other real or personal property or interest in such property.

Federal financial assistance means any grant, cooperative agreement, loan, contract (other than a direct Federal procurement contract or a contract of insurance or guaranty), subgrant, contract under a grant, or any other arrangement by which the Department

provides or otherwise makes available assistance in the form of—

- (1) Funds;
- (2) Services of Federal personnel;
- (3) Real and personal property or any interest in or use of such property, including—

- (i) Transfers or leases of such property for less than fair market value or for reduced consideration; and

- (ii) Proceeds from a subsequent transfer or lease of such property if the Federal share of its fair market value is not returned to the Federal Government; and

- (4) Any other thing of value by way of grant, loan, contract or cooperative agreement.

Historic preservation programs means programs conducted by recipients of Federal financial assistance that have preservation of historic properties as a primary purpose.

Historic Properties means those buildings or facilities that are eligible for listing in the National Register of Historic Places, or such properties designated as historic under a statute of the appropriate State or local government body.

Illegal use of drugs means the use of one or more drugs, the possession or distribution of which is unlawful under the Controlled Substances Act, 21 U.S.C. 812. The term *illegal use of drugs* does not include the use of a drug taken under supervision by a licensed health care professional, or other uses authorized by the Controlled Substances Act or other provisions of Federal law.

Individual with a disability means any person who has a disability. The term *individual with a disability* does not include an individual who is currently engaging in the illegal use of drugs, when the recipient acts on the basis of such use.

Primary recipient means any recipient that is authorized or required to extend Federal financial assistance to another recipient.

Program or activity means all of the operations of any entity described in paragraphs (1) through (4) of this section, any part of which is extended Federal financial assistance—

- (1)(i) A department, agency, special purpose district, or other instrumentality of a State or of a local government; or

- (ii) The entity of such State or local government that distributes such assistance and each such department or agency (and each other State or local government entity) to which the assistance is extended, in the case of assistance to a State or local government;

- (2)(i) A college, university, or other postsecondary institution, or a public system of higher education; or

- (ii) A local educational agency, as defined in 20 U.S.C. 7801, system of vocational education, or other school system;

- (3)(i) An entire corporation, partnership, or other private organization, or an entire sole proprietorship if—

- (A) Assistance is extended to such corporation, partnership, private organization, or sole proprietorship as a whole; or

- (B) The corporation, partnership, private organization, or sole proprietorship is principally engaged in the business of providing education, health care, housing, social services, or parks and recreation; or

- (ii) The entire plant or other comparable, geographically separate facility to which Federal financial assistance is extended, in the case of any other corporation, partnership, private organization, or sole proprietorship; or

- (4) Any other entity which is established by two or more of the entities described in paragraph (s)(1), (2), or (3) of this section.

Qualified individual with a disability means—

- (1) With respect to any aid, benefit, or service provided under a program or activity subject to this subpart, an individual with a disability who, with or without reasonable accommodations in rules, policies, or procedures, the removal of architectural, communication, or transportation barriers, or the provision of auxiliary aids or services, meets the essential eligibility requirements for receipt of services or the participation in programs or activities provided by a recipient; and

- (2) With respect to employment, the definition of “qualified” in the Equal Employment Opportunity Commission’s regulation implementing title I of the Americans with Disabilities Act of 1990, at 29 CFR 1630.2(m), applies to this subpart.

Qualified interpreter means an interpreter who, via a video remote interpreting (VRI) service or an on-site appearance, is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary. *Qualified interpreters* include, for example, sign language interpreters, oral transliterators, and cued-language transliterators.

Qualified reader means a person who is able to read effectively, accurately, and impartially using any necessary specialized vocabulary.

Recipient means any State or unit of local government, any instrumentality of a State or unit of local government, any public or private agency, institution, organization, or other public or private entity, or any person to which Federal financial assistance is extended directly or through another recipient, including any successor, assignee, or transferee of a *recipient*, but excluding the ultimate beneficiary of the assistance.

Section 504 means section 504 of the Rehabilitation Act of 1973, Public Law 93–112, 87 Stat. 394, 29 U.S.C. 794, as amended.

Subrecipient means an entity to which a primary recipient extends Federal financial assistance.

Ultimate beneficiary is one among a class of persons who are entitled to benefit from, or otherwise participate in, a program or activity receiving Federal financial assistance and to whom the protections of this subpart extend. The *ultimate beneficiary* class may be the general public or some narrower group of persons.

Video remote interpreting (VRI) service means an interpreting service that uses video conference technology over dedicated lines or wireless technology offering high-speed, wide-bandwidth video connection that delivers high-quality video images as provided in § 42.511.

General Nondiscrimination Requirements

§ 42.510 General prohibitions against discrimination.

(a) *General.* No qualified individual with a disability shall, solely on the basis of disability, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity subject to this subpart.

(b) *Discriminatory actions prohibited.*
(1) A recipient may not, in providing any program or activity subject to this subpart directly, or through contractual, licensing, or other arrangements, on the basis of disability—

- (i) Deny a qualified individual with a disability the opportunity accorded others to participate in, or benefit from, the aid, benefit, or service;

- (ii) Afford a qualified individual with a disability an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded others;

- (iii) Provide a qualified individual with a disability with an aid, benefit, or service that is not as effective in affording equal opportunity to obtain the same result, to gain the same benefit,

or to reach the same level of achievement as that provided to others;

(iv) Provide different or separate aid, benefits, or services to individuals with disabilities or to any class of individuals with disabilities than are provided to others unless such action is necessary to provide qualified individuals with disabilities or any class of individuals with disabilities with aid, benefits, or services that are as effective as that provided to others;

(v) Deny a qualified individual with a disability an equal opportunity to provide services to the program or activity;

(vi) Deny a qualified individual with a disability an opportunity to participate as a member of a planning or advisory board;

(vii) Aid or perpetuate discrimination against a qualified individual with a disability by providing assistance to an agency, organization, or person that discriminates on the basis of disability in providing any aid, benefit, or service to beneficiaries of the recipient's program or activity;

(viii) Permit the participation in the program or activity of agencies, organizations, or persons which discriminate against individuals with disabilities who participate in or benefit from the recipient's program; or

(ix) Otherwise limit a qualified individual with a disability in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving the aid, benefit, or service.

(2) A recipient may not deny a qualified individual with a disability the opportunity to participate in any aid, benefits, or services that are not separate or different, despite the existence of permissibly separate or different aid, benefits, or services.

(3) A recipient may not, directly or through contractual, licensing, or other arrangements, utilize criteria or methods of administration—

(i) That have the effect of subjecting qualified individuals with disabilities to discrimination on the basis of disability;

(ii) That have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the recipient's program or activity with respect to individuals with disabilities; or

(iii) That perpetuate the discrimination of another recipient if both recipients are subject to common administrative control or are departments or agencies, special purpose districts, or other instrumentalities of the same State or local government unit.

(4) A recipient may not, in determining the site, or a location of a facility, make selections—

(i) That have the effect of excluding individuals with disabilities from, denying them the benefits of, or otherwise subjecting them to discrimination on the basis of disability; or

(ii) That have the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the program or activity with respect to individuals with disabilities.

(5) An entity not otherwise receiving Federal financial assistance but using a facility provided with the aid of Federal financial assistance after the effective date of this subpart is prohibited from discriminating on the basis of disability.

(6) A recipient, in the selection of procurement contractors, may not use criteria that subject qualified individuals with disabilities to discrimination on the basis of disability.

(7) A recipient may not administer a licensing or certification program in a manner that subjects qualified individuals with disabilities to discrimination on the basis of disability, nor may a recipient establish requirements for any of the programs or activities of entities that are licensed or certified that subject qualified individuals with disabilities to discrimination on the basis of disability. The programs or activities of entities that are licensed or certified by a recipient are not, themselves, covered by this subpart unless those entities are also recipients of Federal financial assistance from the Department.

(c) This subpart does not prohibit the exclusion of individuals without disabilities or specified classes of individuals with disabilities from aid, benefits, or services limited by Federal statute or executive order to individuals with disabilities or a different class of individuals with disabilities.

(d) Nothing in this subpart prohibits a recipient from providing aid, benefits, or services to individuals with disabilities or to a particular class of individuals with disabilities beyond those required by this part.

(e) *Integrated setting.* A recipient shall administer programs and activities in the most integrated setting appropriate to the needs of qualified individuals with disabilities.

(f) Nothing in this subpart shall be construed to require an individual with a disability to accept an accommodation, aid, service, opportunity, or benefit provided under section 504 or this subpart which such individual chooses not to accept.

(g) *Reasonable accommodations.* (1) A recipient shall make reasonable accommodations in policies, practices, or procedures when such accommodations are necessary to avoid discrimination on the basis of disability, unless the recipient can demonstrate that making the accommodations would fundamentally alter the nature of the program or activity or result in undue financial and administrative burdens.

(2) A recipient is not required to provide a reasonable accommodation to an individual who meets the definition of disability solely under the "regarded as" prong of the definition of disability as defined in 28 CFR 35.104.

(3) With respect to employment, the definitions and standards applied to "reasonable accommodation" and "undue hardship" in the Equal Employment Opportunity Commission's regulation implementing title I of the Americans with Disabilities Act, at 29 CFR 1630.2(o) and (p), and 1630.9, apply to this subpart.

(h) *Prohibition on surcharges.* A recipient may not place a surcharge on a particular individual with a disability or any class of individuals with disabilities to cover the costs of measures, such as the provision of auxiliary aids, reasonable accommodations, or program accessibility, that are required to provide that individual or class with the nondiscriminatory treatment required by the Act or this subpart.

(i) *Prohibition on associational discrimination.* A recipient shall not exclude or otherwise deny aid, benefits, or services of its program or activity to an individual because of that individual's relationship or association with an individual with a known disability.

(j) *Prohibition on discriminatory eligibility criteria.* A recipient shall not impose or apply eligibility criteria that screen out or tend to screen out an individual with a disability or any class of individuals with disabilities from fully and equally enjoying any aid, benefit, or service unless such criteria can be shown to be necessary for the provision of the aid, benefit, or service being offered.

(k) *Prohibition on intimidation and retaliation.* A recipient shall not intimidate or retaliate against any individual, with or without a disability, for the purpose of interfering with any right secured by section 504 or this subpart.

(l) The enumeration of specific forms of prohibited discrimination in this subpart is not exhaustive but only illustrative.

§ 42.511 Communications.

(a) *General.* (1) A recipient shall take appropriate steps to ensure that communications with applicants, participants, beneficiaries, members of the public, and companions with disabilities are as effective as communications with others.

(2) For purposes of this section, “companion” means a family member, friend, or associate of an individual seeking access to a program, or activity of a recipient, who, along with such individual, is an appropriate person with whom the recipient should communicate.

(b) *Auxiliary aids and services.* (1) A recipient shall furnish appropriate auxiliary aids and services where necessary to afford qualified individuals with disabilities, including applicants, participants, beneficiaries, companions, and members of the public, an equal opportunity to participate in, and enjoy the benefits of, a service, program, or activity, of a recipient.

(2) The type of auxiliary aid or service necessary to ensure effective communication will vary in accordance with the method of communication used by the individual; the nature, length, and complexity of the communication involved; and the context in which the communication is taking place. In determining what types of auxiliary aids and services are necessary, a recipient entity shall give primary consideration to the requests of individuals with disabilities. In order to be effective, auxiliary aids and services must be provided in accessible formats, in a timely manner, and in such a way as to protect the privacy and independence of the individual with a disability.

(c) *Limitations on use of accompanying adults or children as interpreters.*

(1) A recipient shall not require an individual with a disability to bring another individual to interpret for him or her.

(2) A recipient shall not rely on an adult accompanying an individual with a disability to interpret or facilitate communication except—

(i) In an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no interpreter available; or

(ii) When the individual with a disability specifically requests that the accompanying adult interpret or facilitate communication, the accompanying adult agrees to provide such assistance, and reliance on that adult for such assistance is appropriate under the circumstances.

(3) A recipient shall not rely on a minor child to interpret or facilitate communication, except in an emergency involving an imminent threat to the safety or welfare of an individual or the public when there is no interpreter available.

(d) *Video remote interpreting (VRI) services.* A recipient that provides qualified interpreters via VRI services shall ensure that it provides—

(1) Real-time, full-motion video and audio over a dedicated high-speed, wide-bandwidth video connection or wireless connection that delivers high-quality video images that do not produce lags, choppy, blurry, or grainy images, or irregular pauses in communication;

(2) A sharply delineated image that is large enough to display the interpreter’s face, arms, hands, and fingers, and the participating individual’s face, arms, hands, and fingers, and can be seen by the participating individual regardless of the individual’s body position;

(3) A clear, audible transmission of voices; and

(4) Adequate training to users of the technology and other involved individuals so that they may quickly and efficiently set up and operate the VRI.

(e) *Telecommunications.* (1) Where a recipient communicates by telephone with applicants, participants, beneficiaries, members of the public, and companions with disabilities, the recipient shall communicate with individuals who are deaf or hard of hearing or have speech disabilities using telecommunication systems that provide equally effective communication.

(2) When a recipient uses an automated-attendant system, including, but not limited to, voice mail and messaging, or an interactive voice response system, for receiving and directing incoming telephone calls, that system must provide effective real-time communication with individuals using auxiliary aids and services, including, but not limited to TTYs and all forms of FCC-approved telecommunications relay systems, including Internet-based relay systems.

(3) A recipient shall respond to telephone calls from a relay service, established under 47 U.S.C. 225, including telephone relay, video relay, and Internet protocol (IP) relay in the same manner that it responds to other telephone calls.

(f) *Limitations.* This section does not require the recipient to take any action that it can demonstrate would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens. In

those circumstances where the recipient believes that the proposed action would fundamentally alter the program or activity or would result in undue financial and administrative burdens, the recipient has the burden of proving that compliance with § 42.511 would result in such alteration or burdens. The decision that compliance would result in such alteration or burdens must be made by the head of the recipient or the head’s designee after considering all resources available for use in the funding and operation of the program or activity, and it must be accompanied by a written statement of the reasons for reaching that conclusion. If an action otherwise required by this section would result in such an alteration or such burdens, the recipient shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that, to the maximum extent possible, persons with a disability receive the aid, benefits, and services of the program or activity.

§ 42.512 Employment.

(a) *Discrimination prohibited.* (1) *General.* No qualified individual with a disability shall, on the basis of disability, be subjected to discrimination in employment under any program or activity to which this subpart applies.

(2) *Employment discrimination standards.* The standards used to determine whether paragraph (a)(1) of this section has been violated shall be the standards applied under title I of the Americans with Disabilities Act of 1990 (ADA), 42 U.S.C. 12111 *et seq.*, and, as such sections relate to employment, the provisions of sections 501 through 504 and 511 of the ADA of 1990, as amended (codified at 42 U.S.C. 12201–12204, 12210), as implemented in the Equal Employment Opportunity Commission’s regulation at 29 CFR part 1630. The procedures to be used to determine whether paragraph (a) of this section has been violated shall be the procedures set forth in § 42.532 of this subpart.

42.513 Direct threat.

(a) This subpart does not require a recipient to permit an individual to participate in or benefit from the program or activity of that recipient when that individual poses a direct threat to the health or safety of others.

(b) In determining whether an individual poses a direct threat to the health or safety of others, a recipient must make an individualized assessment, based on reasonable judgment that relies on current medical

knowledge or on the best available objective evidence, to ascertain—the nature, duration, and severity of the risk; the probability that the potential injury will actually occur; and whether reasonable accommodations in policies, practices, or procedures or the provision of auxiliary aids or services will mitigate the risk.

(c) An employer does not have to employ an individual who would pose a direct threat as that term is defined in the Equal Employment Opportunity Commission's regulation implementing title I of the Americans with Disabilities Act of 1990, at 29 CFR 1630.2(r) and 1630.15(b).

§ 42.514 Illegal use of drugs.

(a) *General.* Except as provided in paragraph (c) of this section, “Health and drug rehabilitation services,” this subpart does not prohibit discrimination against an individual based on that individual's current use of illegal drugs.

(b) *Non-discrimination requirement.* A recipient shall not discriminate on the basis of illegal use of drugs against an individual who is not engaging in current illegal use of drugs and who—

(1) Has successfully completed a supervised drug rehabilitation program or has otherwise been rehabilitated successfully;

(2) Is participating in a supervised rehabilitation program; or

(3) Is erroneously regarded as engaging in such use.

(c) *Health and drug rehabilitation services.* (1) A recipient shall not deny health services, or services provided in connection with drug rehabilitation, to an individual on the basis of that individual's current illegal use of drugs, if the individual is otherwise entitled to such services.

(2) A drug rehabilitation or treatment program may deny participation to individuals who engage in illegal use of drugs while they are in the program.

(d) *Drug testing.* (1) This subpart does not prohibit a recipient from adopting or administering reasonable policies or procedures, including but not limited to drug testing, designed to ensure that an individual who formerly engaged in the illegal use of drugs is not now engaging in current illegal use of drugs.

(2) Nothing in paragraph (d)(1) of this section shall be construed to encourage, prohibit, restrict, or authorize the conducting of testing for the illegal use of drugs.

§ 42.515 Claims of no disability.

Nothing in this subpart shall provide the basis for a claim that an individual without a disability was subject to discrimination because of a lack of

disability, including a claim that an individual with a disability was granted a reasonable accommodation that was denied to an individual without a disability.

Program Accessibility

§ 42.520 Discrimination prohibited.

A recipient shall ensure that no qualified individual with a disability is denied the benefits of, excluded from participation in, or otherwise subjected to discrimination under any program or activity receiving Federal financial assistance because the recipient's facilities are inaccessible to or unusable by individuals with a disability.

§ 42.521 Existing facilities.

(a) *Accessibility.* A recipient shall operate its program or activity so that when each part of the program or activity is viewed in its entirety, it is readily accessible to and usable by individuals with disabilities. This section does not—

(1) Necessarily require a recipient to make each of its existing facilities or every part of an existing facility accessible to and usable by individuals with disabilities;

(2) Require a recipient to take any action that it can demonstrate would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens. In those circumstances where the recipient believes that the proposed action would fundamentally alter the program or activity or would result in undue financial and administrative burdens, the recipient has the burden of proving that compliance with § 42.521(a) of this subpart would result in such alteration or burdens. The decision that compliance would result in such alteration or burdens must be made by the head of the recipient or the head's designee after considering all resources available for use in the funding and operation of the program or activity, and must be accompanied by a written statement of the reasons for reaching that conclusion. If an action required to comply with this section would result in such an alteration or such burdens, a recipient shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure to the maximum extent possible, that individuals with disabilities receive the benefits or services of the program or activity; or

(3) Require a recipient to take any action that would threaten or destroy the historically significant features of a historic property.

(b) *Methods.* (1) *General.* A recipient may comply with the requirements of this section through such means as, reassignment of services to accessible buildings, assignment of aides to beneficiaries, home visits, delivery of services at alternate accessible sites, alteration of existing facilities and construction of new facilities in conformance with § 42.522, redesign or acquisition of equipment, use of accessible rolling stock or other conveyances, or any other methods that result in making its service, program, or activity readily accessible to and usable by individuals with disabilities. A recipient is not required to make structural changes in existing facilities where other methods are effective in achieving compliance with this section. In choosing among available methods for meeting the requirements of this section, a recipient shall give priority to those methods that serve qualified individuals with disabilities in the most integrated setting appropriate.

(2) *Safe harbor.* For the purposes of complying with this section, elements that have not been altered in existing facilities on or after [INSERT EFFECTIVE DATE OF THE RULE], and that comply with the corresponding technical and scoping specifications for those elements in the Uniform Federal Accessibility Standards (UFAS), 49 FR 31528, app. A (Aug. 7, 1984), are not required to be modified to be brought into compliance with the requirements set forth in the 2010 Standards.

(3) *Historic preservation programs.* In meeting the requirements of this section in historic preservation programs, a recipient shall give priority to methods that provide physical access to individuals with disabilities. In cases where a physical alteration to a historic property is not required because of paragraph (a)(2) or (3) of this section, alternative methods of achieving program accessibility include—

(i) Using audio-visual materials and devices to depict those portions of an historic property that cannot otherwise be made accessible;

(ii) Assigning persons to guide individuals with disabilities into or through portions of historic properties that cannot otherwise be made accessible; or

(iii) Adopting other innovative methods.

(c) *Small providers.* If a recipient with fewer than fifteen employees finds, after consultation with an individual with a disability seeking its services, that there is no method of complying with § 42.521(a) other than making a significant alteration to its existing facilities, the recipient may, as an

alternative, refer the individual with a disability to alternative providers of available accessible services. For the purposes of this paragraph, in order to ensure that the services are available, the small provider must first determine that the alternative provider's services are accessible, the alternative provider is willing to provide the services, the services are available at no additional cost to the individual with a disability, and transportation costs to and from the alternative provider do not exceed costs to and from the small provider.

(d) *Written plan required for certain recipients to achieve program accessibility.* Recipients subject to this subpart as of October 1, 1980, and required to make structural changes in order to provide program accessibility, were required to develop, by January 3, 1981, a written plan setting forth the steps to be taken to complete the changes, together with a schedule for making the changes. The plan should have been developed with the assistance of interested persons, including individuals with disabilities or organizations representing individuals with disabilities and was to be made available for public inspection. The plan should have, at a minimum—

(1) Identified physical obstacles in the recipient's facilities that limit the accessibility of its program or activity to individuals with disabilities;

(2) Described in detail the methods that would be used to make the facilities accessible;

(3) Specified the schedule for taking the steps necessary to achieve full accessibility under § 42.521(a) and, if the time period of the transition plan was longer than one year, identified the steps that would be taken during each year of the transition period; and

(4) Indicated the person responsible for implementation of the plan.

(e) *Notice of location of accessible facilities.* (1) *General.* A recipient shall adopt and implement procedures to ensure that interested individuals with disabilities, including individuals with an intellectual disability, learning disability, vision or hearing disability, or other disability, can obtain information as to the existence and location of services, activities, and facilities that are accessible to and usable by individuals with disabilities.

(2) *Signs at primary entrances.* A recipient shall provide signs at a primary entrance to each of its inaccessible facilities directing users to an accessible facility or a location at which they can obtain information about accessible facilities. The international symbol for accessibility

shall be used at each accessible entrance of a facility.

§ 42.522 Program accessibility in jails, detention and correctional facilities, and community correctional facilities.

(a) *Applicability.* This section specifically applies to a recipient that is responsible for the operation or management of adult and juvenile justice jails, detention and correctional facilities, and community correctional facilities, either directly or through contractual, licensing, or other arrangements with public or private entities, in whole or in part, including private correctional facilities.

(b)(1) In addition to the other requirements of this subpart, a recipient shall ensure that qualified inmates or detainees with disabilities shall not, because a facility is inaccessible to or unusable by individuals with disabilities, be excluded from participation in, or be denied the benefits of, the services, programs, or activities of a recipient, or be subjected to discrimination by any recipient.

(2) A recipient shall ensure that inmates or detainees with disabilities are housed in the most integrated setting appropriate to the needs of the individuals. Unless it is appropriate to make an exception, a recipient—

(i) Shall not place inmates or detainees with disabilities in inappropriate security classifications because of their disabilities;

(ii) Shall not place inmates or detainees with disabilities in designated medical areas unless they are actually receiving medical care or treatment;

(iii) Shall not place inmates or detainees with disabilities in facilities that do not offer the same aid, benefits, and services as the facilities where they would otherwise be housed; and

(iv) Shall not deprive inmates or detainees with disabilities of visitation with family members by placing them in distant facilities where they would not otherwise be housed.

(3) A recipient shall implement reasonable policies, including physical modifications to additional cells in accordance with the 2010 Standards, so as to ensure that each inmate with a disability is housed in a cell with the accessible elements necessary to afford the inmate access to safe, appropriate housing.

§ 42.523 New construction and alterations.

(a) *Design and construction.* Each new facility constructed by, on behalf of, or for the use of a recipient shall be designed and constructed in such a manner that the facility is readily accessible to and usable by individuals

with disabilities, if the construction was commenced after July 3, 1980.

(b) *Alteration.* Each facility or part of a facility, which is altered by, on behalf of, or for the use of, a recipient after July 3, 1980, in a manner that affects or could affect the usability of the facility or part of the facility shall to the maximum extent feasible be altered in such manner that the altered portion of the facility is readily accessible to and usable by individuals with a disability.

(c) *Accessibility standards, compliance dates, and triggering events.*

(1) Applicable accessibility standards—

(i) New construction and alterations of buildings or facilities undertaken on or after March 7, 1988, but before [INSERT DATE OF PUBLICATION OF THE FINAL RULE IN THE **Federal Register**] shall comply with the Uniform Federal Accessibility Standards (UFAS).

(ii) New construction and alterations of buildings or facilities undertaken after [INSERT DATE OF PUBLICATION OF THE FINAL RULE IN THE **Federal Register**] but before [INSERT DATE ONE YEAR FROM PUBLICATION DATE OF THE FINAL RULE IN THE **Federal Register**] must comply with either UFAS or the 2010 Standards.

(iii) New construction and alterations of buildings or facilities undertaken on or after [INSERT DATE ONE YEAR FROM PUBLICATION DATE OF THE FINAL RULE IN THE **Federal Register**] must comply with the 2010 Standards.

(iv) New construction and alterations of buildings or facilities undertaken in compliance with the 2010 Standards shall comply with the scoping and technical requirements for a “public building or facility” regardless of whether the recipient is a public entity as defined in 28 CFR 35.104 or a private entity.

(v) Departures from particular requirements of either standard by the use of other methods shall be permitted when it is clearly evident that equivalent access to the facility or part of the facility is thereby provided.

(vi) For purposes of compliance with UFAS, section 4.1.6(1)(g) of UFAS shall be interpreted to exempt from the requirements of UFAS only mechanical rooms and other spaces that, because of their intended use, will not require accessibility to the public or beneficiaries or result in the employment or residence therein of persons with physical disabilities.

(2) *Triggering events for compliance with accessibility standards.* (i) *Private entities.* (A) Private entities may choose one of the Standards specified in paragraph (c)(1)(ii) of this section if: The last application for a building permit or

permit extension for such construction or alterations is certified to be complete by a State, county, or local government; or, in those jurisdictions where the government does not certify completion of applications, the last application for a building permit or permit extension is received by the State, county, or local government; or, where no permit is required, physical construction or alterations have commenced, on or after [INSERT PUBLICATION DATE OF THE FINAL RULE IN THE **Federal Register**] and before [INSERT DATE ONE YEAR FROM PUBLICATION DATE OF THE FINAL RULE IN THE **Federal Register**].

(B) Private entities must comply with paragraph (c)(1)(iii) of this section if: the last application for a building permit or

permit extension for such construction or alterations is certified to be complete by a State, county, or local government; or, in those jurisdictions where the government does not certify completion of applications, the last application for a building permit or permit extension is received by the State, county, or local government; or, in jurisdictions where no permit is required, physical construction or alteration has commenced, on or after [INSERT DATE ONE YEAR FROM PUBLICATION DATE OF THE FINAL RULE IN THE **Federal Register**].

(ii) *Public entities.* (A) Public entities may choose one of the Standards specified in paragraph (c)(1)(ii) of this section if new physical construction or

alterations commence after [INSERT DATE OF PUBLICATION OF THE FINAL RULE IN THE **Federal Register**] but before [INSERT DATE ONE YEAR FROM PUBLICATION DATE OF THE FINAL RULE IN THE **Federal Register**].

(B) Public entities must comply with paragraph (c)(1)(iii) of this section if new physical construction or alterations commence on or after [INSERT DATE ONE YEAR FROM PUBLICATION DATE OF THE FINAL RULE IN THE **Federal Register**].

(3) For the purposes of this section, ceremonial groundbreaking or razing of structures prior to site preparation will not be considered to commence or start physical construction or alterations.

TABLE OF APPLICABLE STANDARDS FOR COMPLYING WITH 28 CFR 42.522

| Compliance dates for new construction and alterations | Applicable standards for complying with 28 CFR 42.522 |
|---|---|
| After March 7, 1988 and before [INSERT DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER]. | UFAS. |
| After [INSERT DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER] and before [INSERT DATE ONE YEAR FROM PUBLICATION DATE OF THE FINAL RULE IN THE FEDERAL REGISTER]. | UFAS or the scoping and technical requirements for a “public building or facility” in the 2010 Standards. |
| On or after [INSERT DATE ONE YEAR FROM PUBLICATION DATE OF THE FINAL RULE IN THE FEDERAL REGISTER]. | The scoping and technical requirements in the 2010 Standards for a “public building or facility”. |

(4) *Compliance with the Architectural Barriers Act of 1968.* Nothing in this section relieves recipients whose facilities are covered by the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151–57), from the responsibility of complying with the requirements of that Act and any implementing regulations.

Procedures

§ 42.530 Administrative procedures for recipients.

(a) *Voluntary action.* A recipient may take steps, in addition to any action that is required by this subpart, to increase the participation of qualified individuals with disabilities in the recipient’s program or activity.

(b) *Self-evaluation.* (1) A recipient was required, by July 3, 1981, to evaluate and modify its policies and practices that did not meet the requirements of this subpart. During this process, the recipient was required to seek the advice and assistance of interested persons, including individuals with disabilities or organizations representing individuals with disabilities. During this period and thereafter, the recipient was required to take any necessary remedial steps to eliminate the effects of discrimination

that resulted from adherence to these policies and practices.

(2) A recipient employing 50 or more persons and receiving Federal financial assistance from the Department of \$25,000 or more was required, for at least three years following completion of the evaluation required under paragraph (c)(1) of this section, to maintain on file, make available for public inspection, and provide to the Department on request—

(i) A list of the interested persons consulted;

(ii) A description of areas examined and problems identified; and

(iii) A description of modifications made and remedial steps taken.

(c) *Designation of responsible employee.* A recipient employing 50 or more persons and receiving Federal financial assistance from the Department of \$25,000 or more shall designate at least one person to coordinate compliance with this subpart.

(d) *Adoption of grievance procedures.* A recipient employing 50 or more persons and receiving Federal financial assistance from the Department of \$25,000 or more and receiving Federal financial assistance from the Department of \$25,000 or more shall adopt grievance procedures that incorporate appropriate due process

standards (e.g., adequate notice, fair hearing) and provide for the prompt and equitable resolution of complaints alleging any action prohibited by this subpart except that such procedures need not be established with respect to complaints from applicants for employment. Any individual may file a complaint with the Department in accordance with the procedures at § 42.532 without having first used a recipient’s grievance procedures.

(e) *Notice.* (1) A recipient employing 50 or more persons and receiving Federal financial assistance from the Department of \$25,000 or more shall, on a continuing basis, notify participants, beneficiaries, applicants, employees and unions or professional organizations holding collective bargaining or professional agreements with the recipient that it does not discriminate on the basis of disability in violation of section 504 and this subpart. The notification shall state, where appropriate, that the recipient does not discriminate in its programs or activities with respect to access, treatment, or employment. The notification shall also include identification of the person responsible for coordinating compliance with this subpart and where to file section 504 complaints with the Department and, where applicable, with

the recipient. Methods of initial and continuing notification may include the posting of notices, publication in newspapers and magazines, publication on the recipient's internet Web site, placement of notices in the recipient's publications, and distribution of memoranda or other written communications.

(2) Recruitment materials or publications containing general information that a recipient makes available to participants, beneficiaries, applicants, or employees shall include a policy statement of nondiscrimination on the basis of disability.

(f) The Department may require any recipient with fewer than 50 employees and receiving Federal financial assistance from the Department of \$25,000 or more to comply with paragraphs (c) through (e) of this section.

§ 42.531 Assurances required.

(a) *Assurances.* (1) *General.* Every application for Federal financial assistance covered by this subpart shall contain an assurance that the program or activity will be conducted in compliance with the requirements of section 504 and this subpart. Each component within the Department that provides Federal financial assistance shall specify the form of the foregoing assurance and shall require applicants for Department financial assistance to obtain like assurances from subrecipients, contractors and subcontractors, transferees, successors in interest, and others connected with the program or activity. Each component shall specify the extent to which an applicant will be required to confirm that the assurances provided by secondary recipients are being honored. Each assurance shall include provisions giving notice that the United States has a right to seek judicial enforcement of section 504, this subpart, and the assurance.

(2) *Assurances from government departments or agencies.* Assurances from departments or agencies of State and local governments described in paragraph (1) of the definition of "program or activity" at § 42.503 shall extend to any other department or agency of the same governmental unit if the policies of the other department or agency will affect the aid, benefits, or services for which Federal financial assistance is requested.

(3) *Assurances from other entities.* The assurances required with respect to any entity described in paragraph (3)(ii) of the definition of "program or activity" at section 42.503 shall be applicable to the entire plant or other

comparable, geographically separate facility. The assurances required with respect any other entity described in paragraph (2) or (3) of the definition of "program or activity" at § 42.503 shall be applicable to the entire entity.

(b) *Duration of obligation.* Where the Federal financial assistance is to provide or is in the form of real or personal property or improvements, the assurance will obligate the recipient and any transferee for the period during which the property is being used for the purpose for which the Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits, or for as long as the recipient retains ownership or possession of the property, whichever is longer. When the Federal financial assistance is not in the form of real or personal property or improvements, the assurance will obligate the recipient for the period during which Federal financial assistance is extended.

(c) *Covenants.* With respect to any transfer of real property, the transfer document shall contain a covenant running with the land assuring nondiscrimination on the condition described in paragraph (b) of this section. Where the property is obtained from the Federal Government, the covenant may also include a condition coupled with a right to be reserved by the Department to revert title to the property in the event of a breach of the covenant.

(d) *Remedies.* The failure to secure either an assurance or a sufficient assurance from a recipient shall not impair the right of the Department to enforce the requirements of section 504 and this subpart.

§ 42.532 Compliance and enforcement procedures.

(a)(1) The procedural provisions applicable to title VI of the Civil Rights Act of 1964, 28 CFR 42.106–42.110, apply to this subpart, except that the provision contained in § 42.108(c)(3) and § 42.110(e) that requires the Attorney General's approval before the imposition of any sanction against a recipient, does not apply to programs or activities funded by a grant-making component of the Department. The applicable provisions contain requirements for compliance information (§ 42.106), conduct of investigations (§ 42.107), procedure for effecting compliance (§ 42.108), hearings (§ 42.109), and decisions and notices (§ 42.110). *See* appendix C.

(2) In the case of programs or activities funded by a grant-making component of the Department, the requirement to provide access to sources

of information pursuant to 28 CFR 42.106(c) may be enforced using the procedures cited in paragraph (a)(1) of this section or using the provisions of section 803(a) of title I of the Omnibus Crime Control and Safe Streets Act, as amended by the Justice System Improvement Act of 1979, Public Law 96–157, 93 Stat. 1167.

(b) In the case of programs or activities funded by a grant-making component of the Department, the timetables and standards for investigation of complaints and for the conduct of compliance reviews contained in § 42.205(c)(1) through (c)(3) and § 42.206(c) and (d) are applicable to this subpart except that any finding of noncompliance shall be enforced as provided in paragraph (a) of this section. *See* appendix D.

(c) *Remedial action.* (1) If the Department finds that a recipient has discriminated against an individual on the basis of disability in violation of section 504 or this subpart, the recipient shall take such remedial action the Department considers necessary to overcome the effects of the discrimination.

(2) The Department may, where necessary to overcome the effects of discrimination in violation of section 504, or this subpart, require a recipient to take remedial action—

(i) With respect to individuals with disabilities who are no longer participants in the recipient's program or activity but who were participants in the program when such discrimination occurred; and

(ii) With respect to individuals with disabilities who would have been participants in the program had the discrimination not occurred.

(d) Complaints of violations of section 504 by recipients of Federal financial assistance from the Department should be filed with the Office for Civil Rights at the Office of Justice Programs.

Appendix A to Subpart G of Part 42—Federal Financial Assistance Administered by the Department of Justice to Which This Subpart Applies

Note: Failure to list a type of Federal assistance in appendix A shall not mean, if section 504 is otherwise applicable, that a program or activity is not covered.

Editorial Note: For the text of appendix A to subpart G, see appendix A to subpart C of this part.

**Appendix B to Subpart G of Part 42—
[Reserved]****Appendix C to Subpart G of Part 42—
Department Regulations Under Title VI
of the Civil Rights Act of 1964 (28 CFR
42.106–42.110) Which Apply to This
Subpart**

Editorial Note: For the text of appendix C, see §§ 42.106 through 42.110 of this part.

**Appendix D to Subpart G of Part 42—
OJARS' Regulations Under the
Omnibus Crime Control and Safe
Streets Act, as Amended, Which Apply
to This Subpart (28 CFR 42.205 and
42.206)**

Editorial Note: For the text of appendix D, see §§ 42.205 and 42.206 of this part.

Dated: January 11, 2017.

Loretta E. Lynch,
Attorney General.

[FR Doc. 2017–01057 Filed 1–18–17; 8:45 am]

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**ENVIRONMENTAL PROTECTION
AGENCY****40 CFR Part 52**

**[EPA–R10–OAR–2016–0784; FRL–9958–41–
Region 10]**

**Air Plan Approval; Washington:
General Regulations for Air Pollution
Sources, Southwest Clean Air Agency
Jurisdiction**

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Washington State Implementation Plan (SIP) that were submitted by the Washington Department of Ecology (Ecology) in coordination with Southwest Clean Air Agency (SWCAA) on December 20, 2016. In the fall of 2014 and spring of 2015, the EPA approved numerous revisions to Ecology's general air quality regulations. However, our approval of the updated Ecology regulations applied only to geographic areas where Ecology, and not a local air agency, has jurisdiction, and statewide to source categories over which Ecology has sole jurisdiction. Under the Washington Clean Air Act, local clean air agencies may adopt equally stringent or more stringent requirements in lieu of Ecology's general air quality regulations, if they so choose. Therefore, the EPA stated that we would evaluate the general air quality regulations as they

apply to local jurisdictions in separate, future actions. If finalized, this proposed action would approve the submitted SWCAA general air quality regulations to replace or supplement the corresponding Ecology regulations for sources in SWCAA's jurisdiction, including implementation of the minor new source review and nonattainment new source review permitting programs. This action would also approve a limited subset of Ecology regulations, for which there are no corresponding SWCAA corollaries, to apply in SWCAA's jurisdiction.

DATES: Written comments must be received on or before February 21, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–OAR–2016–0784 at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from [Regulations.gov](http://www.regulations.gov). The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: Jeff Hunt at (206) 553–0256, or hunt.jeff@epa.gov.

SUPPLEMENTARY INFORMATION: Throughout this document whenever “we,” “us,” or “our” is used, it is intended to refer to the EPA.

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I. Background for Proposed Action

On January 27, 2014, Ecology submitted revisions to update the general air quality regulations contained in Chapter 173–400 of the Washington Administrative Code (WAC), which the EPA approved in three phases on October 3, 2014 (79 FR 59653), November 7, 2014 (79 FR 66291), and April 29, 2015 (80 FR 23721). Because the Washington Clean Air Act allows local clean air agencies to adopt equally stringent or more stringent standards than the State regulations contained in Chapter 173–400 WAC, the EPA’s approval of Ecology’s January 2014 submittal applied only to geographic areas and source categories under Ecology’s direct jurisdiction. We stated that we would address the applicability of Chapter 173–400 WAC in local clean air agency jurisdictions on a case-by-case basis in separate, future actions.

II. Washington SIP Revisions

On December 20, 2016, the Director of Ecology, as the Governor’s designee for SIP revisions, submitted a request to update the general air quality regulations as they apply to the jurisdiction of SWCAA. SWCAA’s jurisdiction consists of Clark, Cowlitz, Lewis, Skamania and Wahkiakum counties, excluding facilities subject to Energy Facility Site Evaluation Council (EFSEC) jurisdiction, Indian reservations and any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, and facilities subject to the applicability sections of 173–405–012, 173–410–012, and 173–415–012, as discussed in Section III.C. *Scope of Proposed Action*. Appendices A and B

of the SIP revision, included in the docket for this action, show the SWCAA 400 *General Regulations for Air Pollution Sources* submitted for approval to apply in lieu of Chapter 173–400 WAC for sources within SWCAA’s jurisdiction. The regulations contained in SWCAA 400 generally mirror the Ecology corollaries contained in WAC 173–400, with minor adaptations to address local priorities and local air pollution concerns. A summary of the provisions is provided below.

A. SWCAA 400–010 Policy and Purpose

Aside from the name change “Southwest Air Pollution Control Authority” to “Southwest Clean Air Agency” this section remains unmodified since the EPA’s last approval (62 FR 8624, February 26, 1997). The EPA reviewed SWCAA 400–010 and is proposing to approve this provision to apply in lieu of WAC 173–400–010 within SWCAA’s jurisdiction.

B. SWCAA 400–020 Applicability

The EPA’s October 3, 2014 approval of the Ecology regulations included a revised version of WAC 173–400–020 which clarified that local clean air agencies have the option to implement equally stringent or more stringent corollaries to apply in lieu of Chapter 173–400 WAC, or parts of Chapter 173–400 WAC, for sources within its jurisdiction. SWCAA added 400–020(2) to reflect this revision of WAC 173–400–020. Specifically, SWCAA 400–020(2) states, “The Agency implements and enforces the Washington Administrative Code as adopted by Ecology in Title 173 under Chapter 70.94 RCW, except where the Agency has adopted corresponding provisions. Agency adopted provisions apply in lieu of the corresponding WAC provisions.” SWCAA 400–020(2) also clarifies that SWCAA has chosen not to adopt WAC 173–400–930, which provides an optional, alternative means of satisfying new source review permitting requirements for emergency engines in jurisdictions that choose to adopt this provision. As discussed later in this preamble, SWCAA 400–072 *Small Unit Notification for Selected Source Categories* does contain alternative means of satisfying new source review requirements for some emergency service internal combustion engines. However, SWCAA 400–072 covers only a subset of the equipment addressed by WAC 173–400–930, and is not intended by SWCAA to be a corollary to apply in lieu of WAC 173–400–930. All other applicability provisions of SWCAA 400–020 remain

unchanged since the EPA’s last approval on February 26, 1997. The EPA reviewed SWCAA 400–020 and is proposing to approve this provision to apply in lieu of WAC 173–400–020 within SWCAA’s jurisdiction.

C. SWCAA 400–030 Definitions

The majority of definitions contained in SWCAA 400–030 are adapted or copied verbatim from the definitions contained in WAC 173–400–030, as approved by the EPA in October 3, 2014. A notable exception is SWCAA 400–030(4) “Air contaminant” or “air pollutant.” In SWCAA 400–030(4), the agency clarifies that for the purposes of regulation under the Washington SIP, air contaminant means only, “(a) Those air contaminants for which the EPA has established National Ambient Air Quality Standards (NAAQS) and precursors to such NAAQS pollutants as determined by EPA for the applicable geographic area; and (b) Any additional air contaminants that are required to be regulated under Part C of Title I of the Federal Clean Air Act (CAA), but only for the purpose of meeting the requirements of Part C or to the extent those additional air contaminants are regulated in order to avoid such requirements.” This clarification is consistent with the EPA’s interpretation of section 110 of the CAA, and the EPA’s response to comments in our approval of the Chapter 173–400 WAC general provisions (79 FR 59653, October 3, 2014, at page 59654). Similarly, SWCAA is not submitting and the EPA is not proposing to approve SWCAA 400–030(21) “Climate Change” and SWCAA 400–030(129) “Toxic Air Pollutant” because they are not related to the criteria pollutants regulated under title I of the CAA, not essential for meeting and maintaining the NAAQS, or not related to the requirements for SIPs under section 110 of the CAA. The remainder of the SWCAA definitions, not otherwise adapted from the WAC, generally copy or cite to Federal definitions or internal SWCAA definitions previously approved in other sections. With the exception of SWCAA 400–030(21) and (129), we are proposing to approve SWCAA 400–030 to apply in lieu of WAC 173–400–030 within SWCAA’s jurisdiction.

D. SWCAA 400–036 Portable Sources From Other Washington Jurisdictions

The EPA’s October 3, 2014 approval included Ecology’s regulations in WAC 173–400–036. WAC 173–400–036 allows portable sources to relocate and operate in any other clean air agency jurisdiction within the State, without obtaining a site-specific or permitting

agency-specific order of approval, if the permitting authority in the destination jurisdiction has adopted this provision. Under WAC 173-400-036, before a source can move it must: Already have an approved notice of construction order identifying the emission units as a portable source; submit a relocation notice and a copy of the applicable portable source order of approval to the permitting agency with jurisdiction over the intended operation location a minimum of fifteen calendar days before the portable source begins operation at the new location; submit the emissions inventory required under WAC 173-400-105 to each permitting agency in whose jurisdiction the portable source operated during the preceding year; and limit operations to one year or less. A source moving into a nonattainment area that emits a pollutant or precursor for which the area is classified as nonattainment must obtain a site-specific order of approval and may not rely on this provision. Major stationary sources must comply with all otherwise applicable Prevention of Significant Deterioration (PSD) requirements. SWCAA 400-036 generally follows the language of WAC 173-400-036 with minor revisions to reflect the SWCAA-specific permitting and emissions inventory regulations. The EPA also notes that portable sources that move within SWCAA's jurisdiction are regulated under the new source review requirements of SWCAA 400-110(6), which is a minor difference from the process used under the WAC. We believe these minor differences do not affect approvability. The EPA reviewed SWCAA 400-036 and we are proposing to approve this provision to apply in lieu of WAC 173-400-036 within SWCAA's jurisdiction.

E. SWCAA 400-040 General Standards for Maximum Emissions

SWCAA 400-040 generally follows the language of WAC 173-400-040, with minor changes to reflect SWCAA's regulatory structure or to improve clarity. SWCAA submitted revisions to the introductory paragraph of 400-040 and sections (1)(b), (1)(e), (3), (5), (6), (7), and (8) for approval into the SIP. Other regulatory provisions contained in SWCAA 400-040 were not submitted and SWCAA is not requesting revision of these provisions in the SIP at this time.

The revised regulations in sections (1)(b), (1)(e), (3), (5), (6), (7), and (8) set out general requirements for reasonably available control technology (RACT), visible emissions, fugitive emissions, sulfur dioxide concentrations, and dust control. These general requirements

apply to all sources and emission units, unless applicable emission unit-specific standards are contained in another section of the regulations. Because the submitted SWCAA 400-040 regulatory text is consistent with our October 2014 approval of the corresponding WAC 173-400-040 provisions, we are proposing to approve the introductory paragraph of SWCAA 400-040 and sections (1)(b), (1)(e), (3), (5), (6), (7), and (8) to apply in lieu of WAC 173-400-040 within SWCAA's jurisdiction.

F. SWCAA 400-050 Emission Standards for Combustion and Incineration Units

SWCAA 400-050 is similar in format and content to WAC 173-400-050 *Emission Standards for Combustion and Incineration Units*, with changes to reflect SWCAA's regulatory structure or local pollution concerns, or to improve clarity. SWCAA 400-050(1) provides particulate matter emission standards that are nearly identical to WAC 173-400-050(1), which the EPA approved in our October 3, 2014 action. SWCAA 400-050(2) adds a fuel oil sulfur content limit that is not present in WAC 173-400-050. The December 20, 2016 submittal explains that this sulfur content limit became effective January 1, 2013, and is consistent with Best Available Control Technology (BACT) limits that have routinely been incorporated into SWCAA air discharge permits for combustion sources in recent years. SWCAA 400-050(4) provides criteria for modifying the default oxygen correction factor when appropriate, such as where the source is also subject to a New Source Performance Standard (NSPS) and that standard has a different oxygen correction factor. This mirrors the corresponding EPA-approved provision in WAC 173-400-050(3). The EPA is therefore proposing approval of SWCAA 400-050(1), (2), and (4) to apply in lieu of the corresponding provisions of WAC 173-400-050 within SWCAA's jurisdiction.

Consistent with the EPA's October 2014 final action on WAC 173-400-050, SWCAA is not submitting and the EPA is not proposing to approve, certain provisions in SWCAA 400-050 which do not regulate criteria pollutants covered under title I of the CAA, are not essential for meeting and maintaining the NAAQS, and are not required for SIPs under section 110 of the CAA. Specifically, SWCAA requested that the EPA remove SWCAA 400-050(3) from the SIP. This subsection, which regulates total carbonyls from incineration units, corresponds to WAC 173-400-050(2). In the EPA's October

2014 final action we removed WAC 173-400-050(2) from the SIP, stating that total carbonyls are not a criteria air pollutant or an EPA designated precursor to criteria pollutants, and are not appropriate for inclusion in a SIP. Similarly, SWCAA is not submitting, and the EPA is not proposing to approve, SWCAA 400-050(5) and (6), which are emission guidelines for commercial, industrial, and small municipal waste combustion units regulated under section 111 of the CAA which are not related to section 110 of the CAA and not appropriate for approval into the SIP.

G. SWCAA 400-052 Stack Sampling of Major Combustion Sources

Ecology first submitted SWCAA 400-052 for incorporation into the SIP in 1994. The intent was to establish a regime of emission testing for large combustion sources that predated the establishment of SWCAA and had not undergone new source review. In the December 20, 2016 submittal, SWCAA explains that all major sources that would otherwise be subject to this provision already have periodic testing requirements established via new source review and/or compliance assurance monitoring imposed under the Air Operating Permit (AOP) program. For this reason, SWCAA requested that the EPA remove SWCAA 400-052 from the SIP. The EPA reviewed SWCAA's demonstration that removal of this provision would not interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable requirement of section 110 of the CAA and is proposing to remove SWCAA 400-052 from the SIP. The demonstration can be found in the docket for this action.

H. SWCAA 400-060 Emission Standards for General Process Units

SWCAA 400-060 follows the SIP-approved requirements of WAC 173-400-060, which stipulate that no person shall cause or allow the emission of particulate material from any general process operation in excess of 0.23 grams per dry cubic meter at standard conditions of exhaust gas. SWCAA 400-060 and WAC 173-400-060 use slightly different methods to determine compliance. WAC 173-400-060 cites test methods found in 40 CFR parts 51, 60, 61 and 63 or contained in Ecology's "Source Test Manual—Procedures for Compliance Testing." SWCAA 400-060 cites test methods from 40 CFR parts 51, 60, 61 and 63 and any other appropriate test procedures approved in advance by both SWCAA and the EPA. The EPA has

reviewed this minor difference in rule language regarding test methods and is proposing to approve SWCAA 400–060 to apply in lieu of WAC 173–400–060 in SWCAA’s jurisdiction.

I. SWCAA 400–070 General Requirements for Certain Source Categories

SWCAA submitted revisions to SWCAA 400–070 sections (1), (2)(b), (3)(a), (4), (8)(a), (8)(b), (13), (15)(a), (15)(b), and (15)(d) for approval into the SIP. Other regulatory provisions contained in SWCAA 400–070 were not submitted and SWCAA is not requesting revision of these provisions in the SIP at this time.

SWCAA 400–070, which sets separate standards applicable to certain source categories, generally follows the language of the SIP-approved provisions of WAC 173–400–070, with some differences. For example, WAC 173–400–070(1) sets requirements for the use of wigwam burners designed to dispose of wood waste; whereas SWCAA 400–070(1) banned the use of wigwam or equivalent type burners effective January 1, 1994. SWCAA 400–070(2)(b) and (3)(a) regulate hog fuel boilers and orchard heaters, respectively, with regulatory text identical to WAC 173–400–070(2)(b) and (3)(a). SWCAA 400–070 contains no provisions that correspond to WAC 173–400–070(4) and (6), which regulate grain elevators and certain wood waste burners, respectively. This has the effect of making SWCAA 400–070 more stringent, subjecting these source categories to all general standards rather than providing source category exemptions from the general standards. SWCAA 400–070(4), which regulates catalytic cracking units, corresponds to WAC 173–400–070(5). In the December 20, 2016 submittal, SWCAA notes that its jurisdiction has no existing catalytic cracking units. Therefore SWCAA 400–070(4) focuses exclusively on the new source review and BACT requirements similar to WAC 173–400–070(5)(b). SWCAA 400–070(8), (13), and (15), which regulate abrasive blasting, natural gas fired water heaters, and outdoor wood-fired boilers, have no corresponding provisions in WAC 173–400–070. Unlike WAC 173–400–070, which provides exemptions from the general requirements of WAC 173–400–040, 173–400–050, and 173–400–060, the source category-specific requirements of SWCAA 400–070 are in addition to any general requirements that apply. This has the effect of making SWCAA 400–070 more stringent than WAC 173–400–070 for these source categories. Lastly, the version of

SWCAA 400–070(6) currently incorporated into the SIP requires “that all gasoline dispensing facilities shall meet all the provisions of SWAPCA 400–110(8) and SWAPCA 491 *Emission Standards and Controls for Sources Emitting Gasoline Vapors*.” Because SWCAA 400–070(6) merely points to other SIP-approved requirements for informational purposes, SWCAA requested that the EPA remove SWCAA 400–070(6) from the SIP.

The EPA is proposing to approve SWCAA 400–070 sections (1), (2)(b), (3)(a), (4), (8)(a), (8)(b), (13), (15)(a), (15)(b), and (15)(d) to apply in lieu of WAC 173–400–070 within SWCAA’s jurisdiction. The EPA is also proposing to grant SWCAA’s request to remove SWCAA 400–070(6) from the SIP because removal of this provision would not interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable requirement of section 110 of the CAA. We are also proposing to remove SWCAA 400–070(8)(c) [formerly 400–070(7)(d)] from the SIP because this provision related to toxic air pollutants, regulated outside the scope of the SIP, was inadvertently included in our February 26, 1997 approval of SWCAA 400–070 (62 FR 8624).

J. SWCAA 400–072 Small Unit Notification for Selected Source Categories

SWCAA 400–072 has no corresponding provision in the WAC; however in many ways it is similar to the EPA-approved WAC 173–400–560 *General Orders of Approval*. In our proposed approval of WAC 173–400–560 we explained that this provision provides an alternative path to meeting minor new source review permit obligations for certain new sources where the permitting authority had considerable experience in issuing approvals, where the BACT emission controls have not been changing or anticipated to change in the near future, and the use of BACT emission controls will protect the NAAQS (79 FR 39351, July 10, 2014, at page 39354). To date, Ecology has issued general orders of approval under WAC 173–400–560 for dairy anaerobic digesters, concrete batch plants, gas-powered emergency electric generators, rock crushers, small water heaters and steam generating boilers, auto body shops, and asphalt plants. SWCAA 400–072 covers some of the same source categories, but takes a different approach. Rather than relying on issuance of general orders of approval, SWCAA 400–072 sets monitoring, emission limit, recordkeeping, testing, and reporting

requirements for certain small scale source categories via regulation. Included in the December 20, 2016 submittal, is a demonstration of how SWCAA 400–072 provides equivalent or better protection than facility-specific minor new source review permits. SWCAA asserts that certain source categories, such as coffee roasters, would likely be exempt under the new source review permitting thresholds of the WAC, making SWCAA 400–072 more stringent in some cases. The EPA reviewed the regulatory requirements of SWCAA 400–072 covering coffee roasters, small gas fired boilers and heaters, emergency service internal combustion engines, petroleum dry cleaners, and rock crushers. We are proposing to determine that SWCAA 400–072 meets the criteria for approval under section 110 of the CAA. We note that SWCAA did not submit, and the EPA is not proposing to approve the specific provisions of SWCAA 400–072(5)(a)(ii)(B), (5)(d)(ii)(B), (5)(d)(iii)(A), (5)(d)(iii)(B) and all reporting requirements related to toxic air pollutants, because they are not related to the criteria pollutants regulated under title I of the CAA, not essential for meeting and maintaining the NAAQS, not related to the requirements for SIPs under section 110 of the CAA, or contain unbounded director discretion provisions not appropriate for the SIP. With the exceptions noted above, we are proposing to approve SWCAA 400–072.

K. SWCAA 400–074 Gasoline Transport Tanker Registration

SWCAA 400–074, which regulates gasoline transport tankers, has no corresponding provision in Chapter 173–400 WAC. Aside from minor revisions to address the agency name change and readability, SWCAA 400–074 remains unchanged since the EPA’s last approval on February 26, 1997. As part of the December 20, 2016 submittal, SWCAA requested that the EPA remove SWCAA 400–074(2) from the SIP because this agency registration fee provision is not a required element for SIPs under section 110 of the CAA. The EPA is proposing to approve the updated text of SWCAA 400–074, except for SWCAA 400–074(2), which the EPA proposes to remove from the SIP.

L. SWCAA 400–081 Startup and Shutdown

SWCAA 400–081 generally follows the language of the EPA-approved WAC 173–400–081 *Startup and Shutdown*, with minor revisions for readability and clarity. These provisions require that the

respective agencies consider any physical and operational constraints on the ability of a stationary source or source category to comply with the applicable technology based standard during startup or shutdown. Under SWCAA 400–081(1) and the corresponding provision of WAC 173–400–081(4), no provision of SWCAA 400–081 shall be construed to authorize emissions in excess of SIP-approved emission standards unless previously approved by the EPA as a SIP amendment. We reviewed SWCAA 400–081 and are proposing to approve this provision to apply in lieu of WAC 173–400–081 within SWCAA’s jurisdiction.

M. SWCAA 400–091 Voluntary Limits on Emissions

SWCAA 400–091 generally follows the language of WAC 173–400–091, which the EPA approved in our October 3, 2014 final action. These provisions authorize the respective agencies to issue regulatory orders setting voluntary limits on the potential to emit of a source, allowing the source to avoid applicability of certain major source programs such as PSD. SWCAA 400–091 contains the same substantive requirements of WAC 173–400–091 with minor revisions to reflect the SWCAA regulatory structure and to improve clarity. We reviewed SWCAA 400–091 and are proposing to approve this provision to apply in lieu of WAC 173–400–091 in SWCAA’s jurisdiction. We also note that the current SIP includes a reference to SWCAA 400–090 which was renumbered to SWCAA 400–091 on September 21, 1995. We are proposing to correct this typographical error which was inadvertently not addressed as part of our prior February 26, 1997 action.

N. SWCAA 400–100 Registration Requirements and SWCAA 400–101 Emission Units Exempt From Registration Requirements

In the January 27, 2014 submittal of the general air quality regulations, Ecology explained that WAC 173–400–100 *Registration Program* was no longer a means of determining the applicability of Washington’s new source review permitting requirements and did not impose air pollution control requirements on sources or implement Federal standards. As described in the proposal for our October 3, 2014 final action, we removed WAC 173–400–100 from the SIP for sources under Ecology’s direct jurisdiction (79 FR 39351, July 10, 2014, at page 79 FR 39354). Similarly, the December 20, 2016 submittal explains that SWCAA revised its registration program under SWCAA

400–100 and 400–101 to disconnect it from new source review permitting program applicability. Removing it from the SIP would therefore be consistent with our removal of WAC 173–400–100 from the SIP. We have reviewed SWCAA 400–100 and 400–101 and are proposing to grant SWCAA’s request to remove these provisions from the SIP because removal would not interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable requirement of CAA section 110.

O. SWCAA 400–10 Records, Monitoring and Reporting

SWCAA 400–105 generally follows WAC 173–400–105, which the EPA approved in October 3, 2014 final action. It contains the emissions inventory, monitoring, reporting, and recordkeeping requirements for sources under SWCAA’s jurisdiction. SWCAA 400–105 differs slightly from the WAC in applicability, deadlines for reporting, list of reportable pollutants, and monitoring requirements, but not in a substantive way. For example, SWCAA 400–105 applies to all registered sources and sources subject to operating permits under title V of the CAA; whereas WAC 173–400–105 applies to all sources receiving notification from the Director of Ecology. In practical terms, the scope is the same. Similarly, SWCAA’s submittal deadline for emissions inventory information is March 15th, as opposed to the 105th day of the calendar year under the WAC. SWCAA 400–105(1) contains additional reportable pollutants than the WAC, including toxic air pollutants. As previously discussed, SWCAA is not submitting and the EPA is not approving provisions related to toxic air pollutants that are inappropriate for SIP approval under section 110 of the CAA.

With respect to the difference in monitoring requirements, SWCAA 400–105(4)(e) requires compliance with the specifications and reporting requirements of 40 CFR part 60, Appendices B and F, in addition to the specifications and reporting requirements of 40 CFR 51, Appendix P, Sections 3–5 required under WAC 173–400–105(5)(e). SWCAA 400–105(4)(f) explicitly contemplates the use of continuous process parameter monitoring and/or frequent stack testing as potential surrogates to continuous emission monitoring; whereas WAC 173–400–105(5)(f) states that alternative monitoring and reporting procedures “will generally take the form of stack tests” but allows agency discretion in determining other alternatives. In practical terms, the requirements are the

same. We reviewed SWCAA 400–105 and are proposing to approve this provision to apply in lieu of WAC 173–400–105 within SWCAA’s jurisdiction, except for the reporting requirements related to toxic air pollutants which are inappropriate for SIP approval under section 110 of the CAA.

P. SWCAA 400–106 Emission Testing and Monitoring at Air Contaminant Sources

SWCAA 400–106(1)(a), (b), and (c) take the EPA-approved emission testing requirements of WAC 173–400–105(4) and incorporate them in another section with additional requirements not cited in the WAC and not submitted for the EPA’s approval. SWCAA 400–106(1)(a), (b), and (c), although different in structure, are nearly identical to WAC 173–400–105(4). The key difference is that SWCAA 400–106(1)(b) allows the use of selected Oregon Department of Environmental Quality test methods, due to the geographic proximity to Oregon; whereas the WAC does not. We reviewed SWCAA 400–106(1)(a), (b), and (c) and are proposing to approve these provisions to apply in lieu of WAC 173–400–105(4) within SWCAA’s jurisdiction.

Q. SWCAA 400–109 Air Discharge Permit Applications

SWCAA 400–109 contains the applicability and permit application procedures for new source review (NSR) that corresponds to the EPA-approved provisions of WAC 173–400–110. The most significant difference is that SWCAA 400–109 contains generally lower, more stringent NSR-applicability exemption thresholds than the corresponding WAC provisions for many of the criteria pollutants. For example, SWCAA 400–109(3)(d) sets exemption emission thresholds for nitrogen oxides, sulfur dioxide, and volatile organic compounds at one ton per year (tpy) compared to two tpy under the SIP-approved provisions of WAC 173–400–110(5). Any stationary source that is not otherwise exempt under SWCAA 400–109(3)(e), discussed below, must undergo preconstruction permitting review if uncontrolled potential emissions are above these threshold levels. Like the WAC, if the stationary source emissions are significant enough to be considered “major” for a given pollutant, SWCAA 400–109 directs the reader to the relevant portions of WAC 173–400–700 through 750 for the PSD program administered by Ecology, and SWCAA 400–800 through 860 for major source nonattainment NSR administered by SWCAA. All other stationary sources, or

certain pollutants at a stationary source, which fall between the minor NSR exemption emission thresholds and the thresholds for “major” stationary sources are subject to the minor NSR permitting program administered by SWCAA.

SWCAA 400–109(3)(e) also contains equipment and activity exemptions comparable to the EPA-approved provisions of WAC 173–400–110(4), with some differences in source categories to reflect local pollution concerns. The majority of equipment and activity exemptions contained in SWCAA 400–109(3)(e) remain the same since the EPA’s last approval in 1997. As part of the December 20, 2016 submittal, SWCAA provided a demonstration to show that the new exemptions added since the EPA’s last approval are unlikely to cause or contribute to an exceedance of the NAAQS. These new exemptions cover certain wastewater treatment plants, water heaters, and emergency internal combustion engines. SWCAA’s demonstration describes how these source categories are covered by other local or Federal standards, such as the Federal engine standards contained in 40 CFR 63, subpart ZZZZ, or have been found by SWCAA to have emissions below the thresholds contained in SWCAA 400–109(3)(d).

The EPA reviewed SWCAA 400–109 and is proposing to determine that it meets the criteria for approvability under CAA section 110. The EPA also notes that SWCAA did not submit, and the EPA does not propose to approve, the toxic air pollutant provisions contained in SWCAA 400–109(3)(d) and (3)(e)(ii) because they are outside the scope of this proposed action under section 110 of the CAA. Lastly, under section 110(a)(2)(L) of the CAA, the State, or local agencies acting in lieu of the State, must demonstrate the ability to collect adequate fees for permitting major sources. SWCAA is therefore submitting SWCAA 400–109(4) to demonstrate adequate fee authority to implement the major source nonattainment NSR program under SWCAA 400–800 through 860. While the EPA reviews these submissions to confirm adequate authority, the EPA generally does not include local or State agency fees as part of the Washington SIP incorporated by reference in 40 CFR 52.2470(c). The EPA is also proposing to correct an error from our previous approval in 1997 when the fee provisions of SWCAA 400–109(4) were inadvertently incorporated by reference. With the exceptions noted above, we are proposing to approve SWCAA 400–109

to apply in lieu of WAC 173–400–110 within SWCAA’s jurisdiction.

R. SWCAA 400–110 Application Review Process for Stationary Sources (New Source Review); SWCAA 400–111 Requirements for New Sources in a Maintenance Plan Area; SWCAA 400–112 Requirements for New Sources in Nonattainment Areas; and SWCAA 400–113 Requirements for New Sources in Attainment or Nonclassifiable Areas

As part of the December 20, 2016 submittal, SWCAA explains that an effort was made to align the SWCAA NSR program to be as consistent as possible with the EPA-approved Ecology regulations contained in the WAC. Differences are generally insubstantial, with slightly different numbering systems, procedures, and edits for readability. One key difference is that the SWCAA NSR program contains more stringent NSR provisions for “designated maintenance plan areas” to ensure continued compliance with the NAAQS under SWCAA 400–111. In these areas, if a violation of an ozone ambient air quality standard or a second violation of the carbon monoxide ambient air quality standard has occurred, SWCAA may require the application of lowest achievable emission rate (LAER) for the maintenance pollutant(s) and any pollutant for which the proposed new source or modification is major.

Other less substantive differences between the SWCAA NSR program and the Ecology program under the WAC are discussed below. SWCAA 400–110 *Application Review Process for Stationary Sources (New Source Review)* requires compliance with the State Environmental Policy Act as part of the completeness and final determination criteria. This requirement is not explicitly stated in the corresponding provisions of WAC 173–400–111 but nonetheless still applies, making the two program equivalent in effect. The SWCAA regulations also differ slightly from the WAC with respect to portable sources. SWCAA 400–110(6) applies to the relocation of portable sources permitted by SWCAA; whereas SWCAA 400–036 applies to relocation of portable sources permitted by other jurisdictions. The WAC does not make this distinction and regulates all portable sources under WAC 173–400–036. This minor distinction does not result in a substantive difference between the two respective NSR programs. WAC 173–400–111 also does not address reopening of approval orders for cause, so there is no corresponding section to SWCAA 400–

110(10). Lastly, for the convenience of the reader, SWCAA 400–112 *Requirements for New Sources in Nonattainment Areas* and SWCAA 400–113 *Requirements for New Sources in Attainment or Nonclassifiable Areas* contain pointers to the toxic air pollutant and visibility regulations that are not explicitly contained in the corresponding WAC provisions. As previously noted, SWCAA did not submit and the EPA is not proposing to approve the provisions related to toxic air pollutants in SWCAA 400–110(1)(d), 400–111(7), 400–112(6), and 400–113(5), because the regulation of toxic air pollutants is outside the scope of this action under section 110 of the CAA. With the exceptions noted above, we are proposing to approve SWCAA 400–110 through 113, including SWCAA’s additional requirements for designated maintenance areas, to apply in lieu of WAC 173–400–111 through 113 within SWCAA’s jurisdiction.

S. SWCAA 400–114 Requirements for Replacement or Substantial Alteration of Emission Control Technology at an Existing Stationary Source

SWCAA 400–114 is derived from the statutory provisions of the Washington Clean Air Act, in particular Revised Code of Washington (RCW) 70.94.153. Under SWCAA 400–114, any replacement or substantial alteration of emission control technology installed on an existing stationary source or emission unit, excluding routine maintenance, repair or parts replacement, shall require submission of an air discharge permit application for determining NSR applicability under SWCAA 400–110. If the stationary source or emission unit is subject to NSR, all requirements under SWCAA 400–111, 400–112, and/or 400–113 shall apply. If the replacement or substantial alteration is not subject to NSR, then reasonably available control technology (RACT) or other requirements shall apply as dictated by RCW 70.94. Aside from minor wording changes for clarity, SWCAA 400–114 remains substantially unchanged since the EPA’s last approval of this provision in 1997. We reviewed SWCAA 400–114 and are proposing to determine that it meets the criteria for approvability under CAA section 110. The corresponding Ecology provision of WAC 173–400–114 is currently not in the SIP. However, the EPA is also proposing to approve SWCAA 400–114 to apply in lieu of WAC 173–400–114 should this WAC provision be approved into the SIP at some future time.

T. SWCAA 400–116 Maintenance of Equipment

SWCAA 400–116 has no corresponding provision under the WAC. This regulation requires that all process and pollution control equipment be maintained and operated in good working order. SWCAA 400–116(3) gives the agency authority to require that an Operations and Maintenance (O&M) plan be developed and implemented for each emission unit or piece of control or capture equipment in order to assure continuous compliance with approval conditions. SWCAA 400–116 remains substantially unchanged since the EPA's last approval in 1997, aside from minor wording changes for readability. We reviewed the updated version of SWCAA 400–116 and we propose to approve the changes.

U. SWCAA 400–130 Use of Emission Reduction Credits; SWCAA 400–131 Deposit of Emission Reduction Credits Into Bank; and SWCAA 400–136 Maintenance of Emission Reduction Credits in Bank

SWCAA 400–130, 400–131, and 400–136 correspond to the Ecology provisions of WAC 173–400–131 and WAC 173–400–136, which the EPA approved on November 7, 2014 (79 FR 59653). These provisions implement a program to issue emission reduction credits (ERCs) useable for offsets required by the major nonattainment NSR permitting program and the attainment area offset provisions for sources under SWCAA 400–113(3) and its corollary, WAC 173–400–113(4). ERCs under this program may also be used as creditable emission reductions for netting purposes in the major nonattainment NSR and PSD permitting programs provided they meet the requirements set forth in the definitions of “major modification” in those programs. SWCAA's ERC program contains all of the functional requirements of the WAC, but does not contain provisions for discounting issued ERCs as provided in WAC 173–400–136(6). An approvable ERC program need not include provisions which spell out how banked ERC's would be discounted, but it cannot include provisions which would prevent the air authority from reducing or cancelling ERC's when necessary to attain and maintain the NAAQS. SWCAA's rules do not include any provisions which would prevent it from doing such as part of the development of an attainment or maintenance plan. SWCAA's ERC program also contains provisions for the establishment and maintenance of an ERC bank to

document and track outstanding ERCs, which does not exist in the WAC.

We reviewed SWCAA's ERC program and are proposing to determine that it meets the criteria for approvability under section 110 of the CAA. We are also proposing to approve SWCAA 400–130, 400–131, and 400–136 to apply in lieu of WAC 173–400–131 and 173–400–136 within SWCAA's jurisdiction.

V. SWCAA 400–151 Retrofit Requirements for Visibility Protection and SWCAA 400–161 Compliance Schedules

Aside from minor wording changes for clarity, SWCAA 400–151 and 400–161 remain substantially unchanged since the EPA's last approval of these provisions on February 26, 1997. Both provisions include the substantive requirements of the corresponding Ecology regulations contained in WAC 173–400–151 and 173–400–161. The most significant change is the modification of SWCAA 400–151 and 400–030 to more clearly define the term “existing stationary facility” to be consistent with the definition contained in 40 CFR 51.301, under the EPA's visibility protection program requirements. We reviewed SWCAA 400–151 and 400–161 and are proposing to approve these provision to apply in lieu of WAC 173–400–151 and 173–400–161 within SWCAA's jurisdiction.

W. SWCAA 400–171 Public Involvement

SWCAA 400–171 closely follows WAC 173–400–171 *Public Notice and Opportunity for Public Comment*, which the EPA approved on April 29, 2015 (80 FR 23721). The most significant change to SWCAA 400–171 since the EPA's last approval in 1997 regards the EPA's interpretation of “prominent advertisement.” Specifically, 40 CFR 51.161(b) establishes that the opportunity for public comment with respect to NSR permitting shall include, among other requirements, a notice by “prominent advertisement” in the affected area. Historically this information was shared using a public notice in a newspaper. However in an April 17, 2012 guidance for minor NSR programs, included in the docket for this action, the EPA acknowledged the public's increased use of web based sources of information and clarified that the “prominent advertisement” requirement at 40 CFR 51.161(b)(3) is media neutral.¹ As a result, SWCAA

modified the language of SWCAA 400–171 to mirror the EPA and Ecology's use of the term “prominent advertisement.” All other changes to SWCAA 400–171 were insignificant changes, such as updating reference dates or minor revisions to improve clarity for the reader. Lastly, SWCAA did not submit and the EPA is not proposing to approve SWCAA 400–171(2)(a)(xii) regarding public participation procedures for toxic air pollutants, because it is outside the scope of our approval under section 110 of the CAA. With the exception noted above, we are proposing to approve SWCAA 400–171 to apply in lieu of WAC 173–400–171 within SWCAA's jurisdiction.

X. SWCAA 400–190 Requirements for Nonattainment Areas; SWCAA 400–200 Vertical Dispersion Requirement, Creditable Stack Height and Dispersion Techniques; SWCAA 400–205 Adjustment for Atmospheric Conditions; and SWCAA 400–210 Emission Requirements of Prior Jurisdictions

Aside from minor updates to the citations, these long-standing provisions remain substantially unchanged since the EPA's last approval in 1997. They also closely match the corresponding EPA-approved Ecology provisions of WAC 173–400–190, 173–400–200, 173–400–205, and 173–400–210. Minor revisions include the updating of SWCAA 400–190 to reflect the major source specific nonattainment NSR requirements contained in SWCAA 800 through 860. SWCAA also revised SWCAA 400–200 to include vertical dispersion requirements that are not present in the corresponding WAC requirements. SWCAA is not submitting, and the EPA is not proposing to approve, these additional requirements contained in SWCAA 400–200(1). The remaining changes reflect the name change from “Southwest Air Pollution Control Authority” to “Southwest Clean Air Agency” that occurred after the EPA's 1997 approval. With the exception of SWCAA 400–200(1) noted above, we are proposing to approve SWCAA 400–190, 400–200, 400–205, and 400–210 to apply in lieu of the corresponding Ecology provisions in WAC 173–400–190, 173–400–200, 173–400–205, and 173–400–210.

¹ Janet McCabe, Principal Deputy Assistant Administrator, “Minor New Source Review Program Public Notice Requirements under 40 CFR 51.161(b)(3).” Memorandum to EPA Air Division Directors, Regions 1–10, April 17, 2012.

Y. SWCAA 400–220 Requirements for Board Members; SWCAA 400–230 Regulatory Actions and Civil Penalties; SWCAA 400–240 Criminal Penalties; SWCAA 400–250 Appeals; SWCAA 400–260 Conflict of Interest; SWCAA 400–270 Confidentiality of Records and Information; and SWCAA 400–280 Powers of Agency

The EPA reviews and approves state and local clean air agency submissions to ensure they provide adequate enforcement authority and other general authority to implement and enforce the SIP. However, regulations describing such agency enforcement and other general authority are generally not incorporated by reference so as to avoid potential conflict with the EPA's independent authorities. The EPA reviewed and is proposing to approve SWCAA 400–220, 400–230, 400–240, 400–250, 400–260, 400–270, and 400–280 as providing SWCAA adequate enforcement and other general authority for purposes of implementing and enforcing its SIP. However, we are not proposing to incorporate these provisions by reference into the SIP codified in 40 CFR 52.2470(c). Instead, the EPA is proposing to include these provisions in 40 CFR 52.2470(e), *EPA Approved Nonregulatory Provisions and Quasi-Regulatory Measures*, as approved but not incorporated by reference regulatory provisions. The EPA is also proposing to approve SWCAA 400–220, 400–230, 400–240, 400–250, and 400–260 to apply in lieu of the corresponding Ecology provisions of WAC 173–400–220, 173–400–230, 173–400–240, 173–400–250, and 173–400–260. SWCAA 400–270 and 400–280 have no corresponding provisions in the WAC.

Z. SWCAA 400–800 Major Stationary Source and Major Modification in a Nonattainment Area; SWCAA 400–810 Major Stationary Source and Major Modification Definitions; SWCAA 400–820 Determining If a New Stationary Source or Modification to a Stationary Source Is Subject to These Requirements; SWCAA 400–830 Permitting Requirements; SWCAA 400–840 Emission Offset Requirements; SWCAA 400–850 Actual Emissions—Plantwide Applicability Limitation (PAL); SWCAA 400–860 Public Involvement Procedures

Aside from minor edits to the citations to reflect the SWCAA regulatory structure, the SWCAA major nonattainment NSR program contained

in SWCAA 400–800 through 860 is nearly identical to the Ecology major nonattainment NSR program in WAC 173–400–800 through 860, which the EPA approved on November 7, 2014 (79 FR 59653). We note that Ecology's major nonattainment NSR program for PM_{2.5} under WAC 173–400–800 through 860 was reviewed pursuant to the EPA's 2008 PM_{2.5} New Source Review Rule (73 FR 28321, May 16, 2008). The EPA's 2008 rule was remanded to the EPA by the U.S. Court of Appeals for the District of Columbia Circuit and replaced by a revised implementation rule published August 24, 2016, which imposes additional requirements for PM_{2.5} nonattainment areas (81 FR 58010). Because SWCAA does not have nonattainment areas within its jurisdiction for any criteria pollutant, including PM_{2.5}, the EPA did not review SWCAA 400–800 through 860 for consistency with the newly revised PM_{2.5} implementation rule; nor does SWCAA have an obligation to submit rule revisions to address the 2016 PM_{2.5} implementation rule at this time. However, we note that the federal major nonattainment NSR requirements remain unchanged for all other criteria pollutants since our review and approval of WAC 173–400–800 through 860. We are therefore proposing approval of SWCAA 400–800 through 860 as meeting the current major nonattainment NSR requirements for all criteria pollutants except PM_{2.5} and proposing to approve these provisions to apply in lieu of the corresponding Ecology provisions of WAC 173–400–800 through 860.

AA. WAC 173–400–117 Special Protection Requirements for Federal Class I Areas; WAC 173–400–118 Designation of Class I, II, and III Areas; and WAC 173–400–560 General Order of Approval

As discussed above, WAC 173–400–020(1) states that, “The provisions of this chapter shall apply statewide, except for specific subsections where a local authority has adopted and implemented corresponding local rules that apply only to sources subject to local jurisdiction as provided under RCW 70.94.141 and 70.94.331.” SWCAA 400 does not contain any rules that correspond to the EPA-approved provisions of WAC 173–400–117, 173–400–118, or 173–400–560. In this action, the EPA therefore proposes to approve these WAC provisions within SWCAA's jurisdiction, which the EPA has previously approved into the

Washington SIP for areas under Ecology's jurisdiction.

BB. Appendix A—SWCAA Method 9, Visual Opacity Determination Method and Appendix B—Description of Vancouver Ozone and Carbon Monoxide Maintenance Area Boundary

SWCAA Appendix A corresponds to the EPA Test Method 9—*Visual Determination of the Opacity of Emissions from Stationary Sources* contained in 40 CFR part 60, Appendix A. SWCAA explains that, “The difference between the SWCAA Method 9 and EPA Method 9 is in the data reduction section. The SWCAA method establishes a three-minute period in any one-hour period where opacity cannot exceed an opacity limit. For the SWCAA method, 13 readings in a 1-hour period or less, above the established opacity limit, no matter how much, constitutes a violation. The EPA method is an arithmetic average of any 24 consecutive readings at 15-second intervals. These values are averaged and this average value cannot exceed the established opacity limit.” The different data reduction methods are needed to accommodate the differences in the forms of the opacity standards in 40 CFR part 60 and in SWCAA's rules. The EPA reviewed SWCAA Appendix A and we are proposing to determine that it meets the requirements for approval under section 110 of the CAA.

SWCAA Appendix B—*Description of Vancouver Ozone and Carbon Monoxide Maintenance Area Boundary* was previously submitted as part of the Vancouver Carbon Monoxide Maintenance Plan (61 FR 54560, October 21, 1996) and the Vancouver Portion of the AQMA Ozone Maintenance Plan (62 FR 27204, May 19, 1997). While it remains unchanged, the EPA is proposing to revise 40 CFR 52.2470(c)—*Table 8—Additional Regulations Approved for the Southwest Clean Air Agency (SWCAA) Jurisdiction* to more clearly include Appendix B.

III. The EPA's Proposed Action

A. Regulations To Approve and Incorporate by Reference Into the SIP

The EPA proposes to approve and incorporate by reference into the Washington SIP at 40 CFR 52.2470(c)—*Table 8—Additional Regulations Approved for the Southwest Clean Air Agency (SWCAA) Jurisdiction*, the SWCAA and Ecology regulations listed in Tables 1 and 2 below for sources within SWCAA's jurisdiction.

TABLE 1—SOUTHWEST CLEAN AIR AGENCY (SWCAA) REGULATIONS FOR PROPOSED APPROVAL AND INCORPORATION BY REFERENCE

| State/local citation | Title/subject | State/local effective date | Explanation |
|--|---|----------------------------|--|
| SWCAA 400—General Regulations for Air Pollution Sources | | | |
| 400–010 | Policy and Purpose | 03/18/01 | Except: 400–030(21) and (129). |
| 400–020 | Applicability | 10/09/16 | |
| 400–030 | Definitions | 10/09/16 | |
| 400–036 | Portable Sources From Other Washington Jurisdictions. | 10/09/16 | |
| 400–040 | General Standards for Maximum Emissions | 10/09/16 | Except: 400–040(1)(a), (c) and (d); 400–040(2); and 400–040(4). |
| 400–050 | Emission Standards for Combustion and Incineration Units. | 10/09/16 | Except: 400–050(3); 400–050(5); and 400–050(6). |
| 400–060 | Emission Standards for General Process Units | 10/09/16 | Except: 400–070(2)(a); 400–070(3)(b); 400–070(5); 400–070(6); 400–070(7); 400–070(8)(c); 400–070(9); 400–070(10); 400–070(11); 400–070(12); 400–070(14); and 400–070(15)(c). |
| 400–070 | General Requirements for Certain Source Categories. | 10/09/16 | |
| 400–072 | Small Unit Notification for Selected Source Categories. | 10/09/16 | |
| 400–074 | Gasoline Transport Tanker Registration | 11/15/09 | |
| 400–081 | Startup and Shutdown | 10/09/16 | Except: 400–074(2). |
| 400–091 | Voluntary Limits on Emissions | 10/09/16 | Except: Reporting requirements related to toxic air pollutants. |
| 400–105 | Records, Monitoring and Reporting | 10/09/16 | |
| 400–106 | Emission Testing and Monitoring at Air Contaminant Sources. | 10/09/16 | Except: 400–106(1)(d) through (g); and 400–106(2). |
| 400–109 | Air Discharge Permit Applications | 10/09/16 | Except: The toxic air pollutant emissions thresholds contained in 400–109(3)(d); 400–109(3)(e)(ii); and 400–109(4). |
| 400–110 | Application Review Process for Stationary Sources (New Source Review). | 10/09/16 | Except: 400–110(1)(d). |
| 400–111 | Requirements for New Sources in a Maintenance Plan Area. | 10/09/16 | Except: 400–111(7). |
| 400–112 | Requirements for New Sources in Nonattainment Areas. | 10/09/16 | Except: 400–112(6). |
| 400–113 | Requirements for New Sources in Attainment or Nonclassifiable Areas. | 10/09/16 | Except: 400–113(5). |
| 400–114 | Requirements for Replacement or Substantial Alteration of Emission Control Technology at an Existing Stationary Source. | 11/09/03 | |
| 400–116 | Maintenance of Equipment | 11/09/03 | |
| 400–130 | Use of Emission Reduction Credits | 10/09/16 | |
| 400–131 | Deposit of Emission Reduction Credits Into Bank | 10/09/16 | |
| 400–136 | Maintenance of Emission Reduction Credits in Bank | 10/09/16 | |
| 400–151 | Retrofit Requirements for Visibility Protection | 11/09/03 | |
| 400–161 | Compliance Schedules | 03/18/01 | |
| 400–171 | Public Involvement | 10/09/16 | Except: 400–171(2)(a)(xii). |
| 400–190 | Requirements for Nonattainment Areas | 10/09/16 | |
| 400–200 | Vertical Dispersion Requirement, Creditable Stack Height and Dispersion Techniques. | 10/09/16 | Except: 400–200(1). |
| 400–205 | Adjustment for Atmospheric Conditions | 03/18/01 | |
| 400–210 | Emission Requirements of Prior Jurisdictions | 03/18/01 | |
| 400–800 | Major Stationary Source and Major Modification in a Nonattainment Area. | 10/09/16 | |
| 400–810 | Major Stationary Source and Major Modification Definitions. | 10/09/16 | |
| 400–820 | Determining If a New Stationary Source or Modification to a Stationary Source is Subject to These Requirements. | 10/09/16 | |
| 400–830 | Permitting Requirements | 10/09/16 | |
| 400–840 | Emission Offset Requirements | 10/09/16 | |
| 400–850 | Actual Emissions—Plantwide Applicability Limitation (PAL). | 10/09/16 | |
| 400–860 | Public Involvement Procedures | 10/09/16 | |
| Appendix A | SWCAA Method 9 Visual Opacity Determination Method. | 10/09/16 | |
| Appendix B | Description of Vancouver Ozone and Carbon Monoxide Maintenance Area Boundary. | 10/09/16 | |

TABLE 2—WASHINGTON STATE DEPARTMENT OF ECOLOGY REGULATIONS FOR PROPOSED APPROVAL AND INCORPORATION BY REFERENCE

| State/local citation | Title/subject | State/local effective date | Explanation |
|---|--|----------------------------|---|
| Chapter 173–400 WAC, General Regulations for Air Pollution Sources | | | |
| 173–400–117 | Special Protection Requirements for Federal Class I Areas. | 12/29/12 | For permits issued under the applicability provisions of WAC 173–400–800. |
| 173–400–118 | Designation of Class I, II, and III Areas | 12/29/12 | Except: The part of 173–400–560(1)(f) that says, “173–460 WAC”. |
| 173–400–560 | General Order of Approval | 12/29/12 | |

B. Regulations To Approve But Not Incorporate by Reference

In addition to the regulations proposed for approval and incorporation by reference above, the EPA reviews and approves state and local clean air agency submissions to ensure they provide adequate enforcement authority and other general authority to implement and enforce the SIP. However, regulations describing such agency enforcement and other general authority are generally not incorporated by reference so as to avoid potential conflict with the EPA's independent authorities. As discussed above, the EPA has reviewed and is proposing to approve SWCAA 400–220 *Requirements for Board Members*, SWCAA 400–230 *Regulatory Actions and Civil Penalties*, SWCAA 400–240 *Criminal Penalties*, SWCAA 400–250 *Appeals*, SWCAA 400–260 *Conflict of Interest*, SWCAA 400–270 *Confidentiality of Records and Information*, and SWCAA 400–280 *Powers of Agency* as having adequate enforcement and other general authority for purposes of implementing and enforcing its SIP, but is not incorporating these sections by reference into the SIP codified in 40 CFR 52.2470(c). Instead, the EPA is proposing to include these sections in 40 CFR 52.2470(e), *EPA Approved Nonregulatory Provisions and Quasi-Regulatory Measures*, as approved but not incorporated by reference regulatory provisions.

C. Regulations to Remove From the SIP

The Ecology regulations contained in Washington's SIP at 40 CFR 52.2470(c)—Table 8—*Additional Regulations Approved for the Southwest Clean Air Agency (SWCAA) Jurisdiction* were last approved by the EPA on June 2, 1995 (60 FR 28726). As previously discussed, under the Washington Clean Air Act local clean air agencies have the option of adopting and implementing equally stringent or more stringent corresponding provisions to apply in lieu of Chapter 173–400 WAC, or parts

of Chapter 173–400 WAC. With the exception of updated versions of WAC 173–400–117, 173–400–118, and 173–400–560, SWCAA requested that the submitted SWCAA regulations replace the existing WAC provisions currently in the SIP for its jurisdiction. Also, as previously discussed, the EPA is proposing to remove from the SIP SWCAA 400–050(3) [formerly 400–050(2)], 400–052, 400–070(6), 400–070(8)(c) [formerly 400–070(7)(c) and (d)], 400–074(2), 400–100, 400–101, and 400–109(4) because removal of these provisions would not interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable requirement of section 110 of the CAA. We also note that the SIP includes a reference to SWCAA 400–090 which was renumbered to SWCAA 400–091 on September 21, 1995. We are proposing to remove the reference to SWCAA 400–090 in the SIP which was inadvertently not addressed as part of our February 26, 1997 approval of SWCAA 400–091 (62 FR 8624).

D. Scope of Proposed Action

This proposed revision to the SIP applies specifically to the SWCAA jurisdiction incorporated into the SIP at 40 CFR 52.2470(c)—Table 8. As discussed in our October 3, 2014 action (79 FR 59653, at page 59654), local air agency jurisdiction in Washington is generally defined on a geographic basis; however there are exceptions. By statute, SWCAA does not have authority for sources under the jurisdiction of the Energy Facility Site Evaluation Council (EFSEC). See Revised Code of Washington Chapter 80.50. Under the applicability provisions of WAC 173–405–012, 173–410–012, and 173–415–012, SWCAA also does not have jurisdiction for kraft pulp mills, sulfite pulping mills, and primary aluminum plants. For these sources, Ecology retains statewide, direct jurisdiction. Ecology also retains statewide, direct jurisdiction for the PSD permitting program. Therefore, the EPA is not

approving into 40 CFR 52.2470(c)—Table 8 those provisions of Chapter 173–400 WAC related to the PSD program. Specifically, these provisions are WAC 173–400–116 and WAC 173–400–700 through 750, which the EPA has already approved as applying statewide.

As described in our April 29, 2015 action, jurisdiction to implement the visibility permitting program contained in WAC 173–400–117 varies depending on the situation. Ecology retains authority to implement WAC 173–400–117 as it relates to PSD permits. See 80 FR 23721. However, for facilities subject to major nonattainment NSR under the applicability provisions of SWCAA 400–800, we are proposing that SWCAA would be responsible for implementing those parts of WAC 173–400–117 as they relate to major nonattainment NSR permits. See 80 FR 23726. If finalized, the EPA is also proposing to modify the visibility protection Federal Implementation Plan contained in 40 CFR 52.2498 to reflect the approval of WAC 173–400–117 as it applies to implementation of the major nonattainment NSR program in SWCAA's jurisdiction.

Lastly, this SIP revision is not approved to apply in Indian reservations in the State, or any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction.

IV. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the regulations shown in the tables in section III.A. *Regulations to Approve and Incorporate by Reference into the SIP* and the rules proposed for removal from the SIP in section III.C. *Regulations to Remove from the SIP*. The EPA has made, and will continue to make, these materials generally available through www.regulations.gov and/or at the EPA

Region 10 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely approves the state's law as meeting Federal requirements and does not impose additional requirements beyond those imposed by the state's law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
 - Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
 - Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
 - Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
 - Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
 - Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
 - Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
 - Is not subject to the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because this action does not involve technical standards; and
 - Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).
- In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not

impose substantial direct costs on tribal governments or preempt tribal law. This SIP revision is not approved to apply in Indian reservations in the State, or any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: January 4, 2017.

Dennis J. McLerran,

Regional Administrator, Region 10.

[FR Doc. 2017-01090 Filed 1-18-17; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

42 CFR Part 100

National Vaccine Injury Compensation Program: Statement of Reasons for Not Conducting a Rulemaking Proceeding

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Denial of petition for rulemaking.

SUMMARY: In accordance with section 2114(c)(2)(B) of the Public Health Service Act, 42 U.S.C. 300aa-14(c)(2)(B), notice is hereby given concerning the reasons for not conducting a rulemaking proceeding to add neurological disorders or conditions as injuries associated with seasonal influenza vaccines to the Vaccine Injury Table.

DATES: Written comments are not being solicited.

FOR FURTHER INFORMATION CONTACT:

Narayan Nair, MD, Director, Division of Injury Compensation Programs (DICP), Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 8N146B, Rockville, Maryland 20857, or by telephone 301-443-6593.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986, (Vaccine Act), Title III of Public Law 99-660, established the National

Vaccine Injury Compensation Program (VICP) for persons found to be injured by vaccines.¹ Under this federal program, petitions for compensation are filed with the United States Court of Federal Claims (Court). The Court, acting through special masters, makes findings as to eligibility for, and amount of, compensation. To gain entitlement to compensation under VICP for a covered vaccine, a petitioner must establish a vaccine-related injury or death in one of the following ways (unless another cause is found): (1) By proving that the first symptom of an injury or condition, as defined by the Qualifications and Aids to Interpretation, occurred within the time period listed on the Vaccine Injury Table (Table), and, therefore, is presumed to be caused by a vaccine; (2) by proving vaccine causation, if the injury or condition is not on the Table or did not occur within the time period specified on the Table; or (3) by proving that the vaccine significantly aggravated a pre-existing condition.

The statute authorizing VICP provides for the inclusion of additional vaccines in VICP when they are recommended by the Centers for Disease Control and Prevention for routine administration to children.² Consistent with section 13632(a)(3) of Public Law 103-66, the regulations governing VICP provide that such vaccines will be included in the Table as of the effective date of an excise tax to provide funds for the payment of compensation with respect to such vaccines.³ The statute authorizing VICP also authorizes the Secretary to create and modify a list of injuries, disabilities, illnesses, conditions, and deaths (and their associated time frames) associated with each category of vaccines included on the Table.⁴ Finally, the Vaccine Act provides that:

[a]ny person (including the Advisory Commission on Childhood Vaccines) [the Commission] may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—

(A) Receipt of any recommendation of the Commission, or

(B) 180 days after the date of the referral to the Commission, whichever occurs first, the Secretary shall conduct a rule-making proceeding on the matters proposed in the petition or publish

¹ 42 U.S.C. 300aa-10 *et seq.*

² Section 2114(e)(2) of the PHS Act, 42 U.S.C. 300aa-14(e)(2).

³ 42 CFR 100.3(c)(8).

⁴ Sections 2114(c) and 2114(e)(2) of the PHS Act, 42 U.S.C. 300aa-14(c) and 300aa-14(e)(2).

in the **Federal Register** a statement or reasons for not conducting such proceeding.⁵

On January 28, 2016, a private citizen submitted a petition to the Department of Health and Human Services (HHS) requesting that: (1) Any adverse neurological disorder or condition be added to the Table for the seasonal influenza vaccines; and (2) if any adverse neurological disorder or condition was too broad in scope, then at least anaphylaxis, Shoulder Injury Related to Vaccine Administration (SIRVA), vasovagal syncope, multiple sclerosis (MS), Guillain-Barré Syndrome (GBS), transverse myelitis (TM), and myelitis be added to the Table for the seasonal influenza vaccine. The petitioner asserted that based on Vaccine Adverse Event Reporting System (VAERS) data and Department of Justice (DOJ) quarterly reports on vaccine settlements, which were presented at Commission meetings, there is sufficient evidence to add these conditions as injuries associated with the seasonal influenza vaccine to the Table. The petitioner did not provide any medical or scientific literature to accompany the request.

Pursuant to the Vaccine Act, the petition was referred to the Commission on June 3, 2016. The Commission voted unanimously to recommend that the Secretary not proceed with rulemaking to amend the Table to include “any adverse neurological disorder or condition,” MS, TM, or myelitis as injuries associated with seasonal influenza vaccines as requested in the petition.

The petitioner requested the addition of any adverse neurological disorder or condition to the Table for the seasonal influenza vaccine. The petitioner alleged that the DOJ quarterly reports on vaccine settlement cases and VAERS data support the inclusion of all of these conditions to the Table. However, neither of these sources of data is sufficient to modify the Table. The DOJ quarterly report is the report that DOJ provides and discusses at the quarterly Commission meetings and is made available to the public at <http://www.hrsa.gov/advisorycommittees/childhoodvaccines/meetings.html>. The report includes a list of adjudicated settlements for the applicable quarter by vaccine and alleged injury, and time frame from petition filing to settlement filing. In negotiated settlements between the parties, HHS has not concluded, based upon review of the evidence, that the alleged vaccine(s) caused the alleged injury. These settlements are not an

admission by the United States or the Secretary of Health and Human Services that the vaccine caused the petitioner’s alleged injury, and, in settled cases, the Court does not determine that the vaccine caused the injury. Therefore, a settlement cannot be characterized as a decision by HHS or by the Court that the vaccine caused an injury. Thus, information from negotiated settlements cannot be used to establish that vaccines cause certain injuries.

The purposes of VAERS data are to: Detect new, unusual, or rare vaccine adverse events; identify potential patient risk factors for particular types of adverse events; identify vaccine lots with increased numbers or types of reported adverse events; and assess the safety of newly licensed vaccines. The VAERS data are considered a useful tool in vaccine safety, but VAERS reports by themselves generally cannot demonstrate that vaccines cause injuries.

In 2008, the Secretary contracted with the Institute of Medicine (IOM) to review the epidemiologic, clinical, and biological evidence regarding adverse health events associated with specific vaccines covered by VICP. The results of this review were published in the 2012 IOM Report, “*Adverse Effects of Vaccines: Evidence and Causality*.” This report reviewed 8 of the 12 vaccines covered by the VICP and provided 158 causality conclusions. The 2012 IOM Report reviewed the medical and scientific literature regarding a causal relationship between seasonal influenza vaccines and the following conditions: Encephalopathy, encephalitis, seizures, acute disseminated encephalomyelitis, TM, optic neuritis, neuromyelitis optica, MS, MS relapse, GBS, chronic inflammatory demyelinating polyneuropathy, Bell’s palsy, brachial neuritis, and small fiber neuropathy. The IOM concluded that the evidence is inadequate to accept or reject a causal relationship between influenza vaccines and the above conditions. Therefore, “any adverse neurological disorder or condition,” as suggested by the petitioner will not be added as injuries caused by the seasonal influenza vaccine to the Table since the medical and scientific literature is not sufficient to support this change.

The petitioner also requested that certain conditions be added to the Table if “any adverse neurological disorder or condition” could not be added to the Table. These conditions include: Anaphylaxis, SIRVA, vasovagal syncope, MS, GBS, TM, and myelitis. The petitioner stated that VAERS and settlement data from quarterly reports support the inclusion of these

conditions for seasonal influenza vaccines to the Table. However, as explained above, the VAERS data and the DOJ quarterly report do not demonstrate that vaccines cause injuries and do not establish causality. As stated previously, the 2012 IOM Report reviewed the medical and scientific literature regarding causal relationships between seasonal influenza vaccines and MS, TM, and myelitis. The IOM concluded that the evidence is inadequate to accept or reject a causal relationship between influenza vaccines and these conditions.

More recent studies support the lack of an association between the seasonal influenza vaccine and neurologic conditions, such as MS. The Williamson, et al. study found no substantiation to reports suggesting a link between MS and vaccines and that most of the studies that purported an increased risk of MS or relapse of MS after vaccination were small case series, which are methodologically less robust than other epidemiologic studies.⁶ In addition, Langer-Gould, et al. conducted a nested case control study that found no long-term association between vaccines and MS or other central nervous system acquired demyelinating syndromes.⁷ Therefore, MS, TM, and myelitis will not be added to the Table as injuries associated with the seasonal influenza vaccine since the medical and scientific literature is not sufficient to support those changes.

HHS proposed certain changes to the Vaccine Injury Table in a Notice of Proposed Rulemaking (NPRM) published in the **Federal Register** on July 29, 2015 (80 Fed. Reg. 45132 (July 29, 2015)). Among other proposed changes, anaphylaxis, SIRVA, GBS, and vasovagal syncope were proposed to be added as injuries for seasonal influenza vaccines. HHS is adding these injuries with the final rule, titled “National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table,” concurrently publishing in the **Federal Register**.

In conclusion, there is no reliable evidence to support the addition of “any adverse neurological disorder or condition,” MS, TM, or myelitis to the Table as injuries associated with the seasonal influenza vaccine. Therefore, the Table will not be amended at this time to include those injuries on the Table.

⁶ Williamson et al. Vaccines in Multiple Sclerosis, *Curr Neurol Neurosci Rep* 2016 16:36.

⁷ Langer-Gould et al., Vaccines and the risk of MS and other CNS Demyelinating Diseases, *JAMA Neurol.* 2014;71(12): 1506–13.

⁵ Section 2114(c)(2) of the PHS Act, 42 U.S.C. 300aa–14(c)(2).

Dated: January 9, 2017.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2017-00700 Filed 1-18-17; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HOMELAND SECURITY

48 CFR Parts 3001, 3002, 3024, and 3052

[Docket No. DHS-2017-0008]

RIN 1601-AA79

Homeland Security Acquisition Regulation (HSAR); Privacy Training (HSAR Case 2015-003)

AGENCY: Office of the Chief Procurement Officer, Department of Homeland Security (DHS).

ACTION: Proposed rule.

SUMMARY: DHS is proposing to amend the Homeland Security Acquisition Regulation (HSAR) to add a new subpart, update an existing clause, and add a new contract clause to require contractors to complete training that addresses the protection of privacy, in accordance with the Privacy Act of 1974, and the handling and safeguarding of Personally Identifiable Information and Sensitive Personally Identifiable Information.

DATES: Interested parties should submit written comments to one of the addresses shown below on or before March 20, 2017, to be considered in the formation of the final rule.

ADDRESSES: Submit comments identified by HSAR Case 2015-003, Privacy Training, using any of the following methods:

- *Regulations.gov:* <http://www.regulations.gov>.

Submit comments via the Federal eRulemaking portal by entering "HSAR Case 2015-003" under the heading "Enter Keyword or ID" and selecting "Search." Select the link "Submit a Comment" that corresponds with "HSAR Case 2015-003." Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "HSAR Case 2015-003" on your attached document.

- *Fax:* (202) 447-0520
- *Mail:* Department of Homeland Security, Office of the Chief Procurement Officer, Acquisition Policy and Legislation, ATTN: Ms. Candace Lightfoot, 245 Murray Drive, Bldg. 410 (RDS), Washington, DC 20528.

Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal information provided. To confirm receipt of your comment(s), please check <http://www.regulations.gov>, approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Candace Lightfoot, Procurement Analyst, DHS, Office of the Chief Procurement Officer, Acquisition Policy and Legislation at (202) 447-0882 or email HSAR@hq.dhs.gov. When using email, include HSAR Case 2015-003 in the "Subject" line.

SUPPLEMENTARY INFORMATION:

I. Background

DHS contracts currently require contractor and subcontractor employees to complete privacy training before accessing a Government system of records; handling Personally Identifiable Information (PII) or Sensitive PII (SPII); or designing, developing, maintaining, or operating a Government system of records. This training is completed upon award of the procurement and at least annually thereafter.

DHS is proposing to (1) include Privacy training requirements in the HSAR and (2) make the training more easily accessible by hosting it on a public Web site. This approach ensures all applicable DHS contractors and subcontractors are subject to the same requirements while removing the need for Government intervention to provide access to the Privacy training.

This proposed rule standardizes the Privacy training requirement across all DHS contracts by amending the HSAR to:

(1) Add the terms "personally identifiable information" and "sensitive personally identifiable information" at HSAR 3002.1, Definitions. The definition of "personally identifiable information" is taken from OMB Circular A-130 Managing Information as a Strategic Resource,¹ published July 27, 2016. The definition of "sensitive personally identifiable information" is derived from the DHS lexicon, Privacy Incident Handling Guidance, and the Handbook for Safeguarding Sensitive Personally Identifiable Information. These definitions are necessary because these terms appear in proposed HSAR

3024.70, Privacy Training and HSAR 3052.224-7X, Privacy Training.

(2) Add a new subpart at HSAR 3024.70, Privacy Training addressing the requirements for privacy training. HSAR 3024.7001, Scope identifies the applicability of the subpart to contracts and subcontracts. HSAR 3024.7002, Definitions defines the term "handling." The definition of "handling" was developed based upon a review of definitions for the term developed by other Federal agencies. HSAR 3024.7003, Policy identifies when contractors and subcontracts are required to complete the DHS privacy training. This subsection also requires the submission of training completion certificates for all contractor and subcontractor employees as a record of compliance. HSAR 3024.7004, Contract Clause, identifies when Contracting Officers must insert HSAR 3052.224-7X Privacy Training in solicitations and contracts. DHS welcomes respondents to offer their views on the following questions in particular:

A. What burden, if any, is associated with the requirement to complete DHS-developed privacy training?

B. What value, if any, is associated with providing industry the flexibility to develop its own privacy training given a unique set of Government requirements?

(3) Amend sub paragraph (b) of the HSAR 3052.212-70, Contract Terms and Conditions Applicable to DHS Acquisition of Commercial Items to add HSAR 3052.224-7X, Privacy Training. This change is necessary because HSAR 3052.224-7X is applicable to the acquisition of commercial items; and

(4) Add a new subsection at HSAR 3052.224-7X, Privacy Training to provide the text of the proposed clause. The proposed clause requires contractor and subcontractor employees to complete privacy training before accessing a Government system of records; handling Personally Identifiable Information (PII) or Sensitive PII (SPII); or designing, developing, maintaining, or operating a Government system of records. The training shall be completed within thirty (30) days of contract award and on an annual basis thereafter. The contractor shall maintain copies of training certificates for all contractor and subcontractor employees as a record of compliance and provide copies of the training certificates to the contracting officer. Subsequent training certificates to satisfy the annual privacy training requirement shall be submitted via email notification not later than October 31st of each year. The contractor shall attach training certificates to the email

¹ OMB Circular A-130 *Managing Information as a Strategic Resource* is accessible at <https://www.whitehouse.gov/sites/default/files/omb/assets/OMB/circulars/a130/a130revised.pdf>.

notification and the email notification shall state that the required training has been completed for all contractor and subcontractor employees.

These proposed revisions to the HSAR are necessary to ensure contractors and subcontractors properly handle PII and SPII. This includes PII and SPII contained in a system of records consistent with subsection (e) Agency requirements, and subsection (m) Government contractors, of the Privacy Act of 1974, Section 552a of title 5, United States Code (5 U.S.C. 552a).

Other applicable authorities that address the responsibility for Federal agencies to ensure appropriate handling and safeguarding of PII include the following Office of Management and Budget (OMB) memoranda and policies: OMB Memorandum M-07-16, "Safeguarding Against and Responding to the Breach of Personally Identifiable Information" issued May 22, 2007; OMB Memorandum M-10-23, "Guidance for Agency Use of Third-Party Web sites and Applications" issued June 25, 2010 (this memorandum contains the most current definition of PII, and clarifies the definition provided in M-07-16); OMB Circular No. A-130 "Managing Information as a Strategic Resource," which identifies significant requirements for safeguarding and handling PII and reporting any theft, loss, or compromise of such information. DHS has also developed internal guidance that addresses the handling and protection of PII, including the DHS Privacy Incident Handling Guidance and the DHS Handbook for Safeguarding Sensitive Personally Identifiable Information. The DHS Privacy Incident Handling Guidance informs DHS and its components, employees, senior officials, and contractors of their obligation to protect PII, and establishes policies and procedures defining how they must respond to the potential loss or compromise of PII. The DHS Handbook for Safeguarding Sensitive Personally Identifiable Information sets minimum standards for how DHS personnel and contractors should handle SPII in paper and electronic form during their work activities.

This proposed rule is part of a broader initiative within DHS to (1) ensure contractors understand their responsibilities with regard to safeguarding controlled unclassified information (CUI); (2) contractor and subcontractor employees complete information technology (IT) security awareness training before access is provided to DHS information systems and information resources or contractor-

owned and/or operated information systems and information resources where CUI is collected, processed, stored or transmitted on behalf of the agency; (3) contractor and subcontractor employees sign the DHS RoB before access is provided to DHS information systems, information resources, or contractor-owned and/or operated information systems and information resources where CUI is collected, processed, stored or transmitted on behalf of the agency; and (4) contractor and subcontractor employees complete privacy training before accessing a Government system of records; handling personally identifiable information (PII) and/or sensitive PII information; or designing, developing, maintaining, or operating a system of records on behalf of the Government.

II. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804. DHS has included a discussion of the estimated costs and benefits of this rule in the Paperwork Reduction Act supporting statement, which can be found in the docket for this rulemaking.

III. Regulatory Flexibility Act

DHS expects this proposed rule may have an impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because the proposed rule requires contractor and subcontractor employees to be properly trained on the requirements, applicable laws, and appropriate safeguards designed to ensure the security and confidentiality of PII before access a Government system of records; handle PII or SPII; or design, develop, maintain, or operate a system of records on behalf of the Government. Although the Privacy Act of 1974 has been in place for over 40 years, the rapidly changing information security landscape requires the Federal government to strengthen its contracts to ensure that contractor and

subcontractor employees comply with the Act and are aware of their responsibilities for safeguarding PII and SPII. Therefore, an Initial Regulatory Flexibility Analysis (IRFA) has been prepared consistent with 5 U.S.C. 603, and is summarized as follows:

1. Description of the Reasons Why Action by the Agency Is Being Taken

DHS is proposing to amend the HSAR to require all contractor and subcontractor employees that will have access to a Government system of records; handle PII or SPII; or design, develop, maintain, or operate a system of records on behalf of the Government, complete training that addresses the requirements for the protection of privacy and the handling and safeguarding of PII and SPII. The purpose of this proposed rule is to require contractors to identify its employees who require access, ensure that those employees complete privacy training before being granted access and annually thereafter, provide the Government evidence of the completed training, and maintain evidence of completed training in accordance with the records retention requirements of the contract.

2. Succinct Statement of the Objectives of, and Legal Basis for, the Rule

The objective of this rule is to require contractor and subcontractor employees to complete Privacy training before accessing a Government system of records; handling PII and/or SPII; or designing, developing, maintaining, or operating a Government system of records. This proposed rule requires contractors to identify who will be responsible for completing privacy training, and to emphasize and create awareness of the critical importance of privacy training in an effort to reduce the occurrences of privacy incidents.

The training imposed by this proposed rule is required by the provisions of the Privacy Act (5 U.S.C. 552a), Title III of the E-Government Act of 2002 and the Federal Information Security Modernization Act (FISMA) of 2014. This proposed rule requires contractors to identify its employees and subcontractor employees who require access to PII and SPII, ensure that those employees complete privacy training before being granted access to such information and annually thereafter, provide the Government evidence of the completed training, and maintain evidence of completed training.

3. Description of and, Where Feasible, Estimate of the Number of Small Entities To Which the Rule Will Apply

This proposed rule will apply to contractor and subcontractor employees who require access to a Government system of records; handle PII or Sensitive PII; or design, develop, maintain, or operate a system of records on behalf of the Government. The estimated number of small entities to which the rule will apply is 6,628 respondents of which 4,162 are projected to be small businesses.

This estimate is based on a review and analysis of internal DHS contract data and Fiscal Year (FY) 2014 data reported to the Federal Procurement Data System (FPDS). It is anticipated that this rule will be primarily applicable to procurement actions with a Product and Service Code (PSC) of "D" Automatic Data Processing and Telecommunication and "R" Professional, Administrative and Management Support. PSCs will be adjusted as additional data becomes available through HSAR clause implementation to validate future burden projections.

4. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Rule, Including an Estimate of the Classes of Small Entities Which Will Be Subject to the Requirement and the Type of Professional Skills Necessary

The projected reporting and recordkeeping associated with this proposed rule is kept to the minimum necessary to meet the overall objectives. DHS minimized the burden associated with this proposed rule by developing the training and making it publicly accessible at <http://www.dhs.gov/dhs-security-and-training-requirements-contractors>. DHS has also minimized burden by providing automatically generated certificates at the conclusion of the training. Training shall be completed within thirty (30) days of contract award and on an annual basis thereafter. Initial training certificates for each contractor and subcontractor employee shall be provided to the Government not later than thirty (30) days after contract award. Subsequent training certificates to satisfy the annual privacy training requirement shall be submitted via email notification not later than October 31st of each year. The contractor shall attach training certificates to the email notification and the email notification shall state that the required training has been completed for all contractor and subcontractor

employees and include copies of the training certificates.

5. Identification, to the Extent Practicable, of All Relevant Federal Rules Which May Duplicate, Overlap, or Conflict With the Rule

There are no rules that duplicate, overlap or conflict with this rule.

6. Description of Any Significant Alternatives to the Rule Which Accomplish the Stated Objectives of Applicable Statutes and Which Minimize Any Significant Economic Impact of the Rule on Small Entities

There are no practical alternatives that will accomplish the objectives of the proposed rule.

DHS will be submitting a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the IRFA may be obtained from the point of contact specified herein. DHS invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DHS will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (HSAR Case 2015-003), in correspondence.

IV. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) applies because this proposed rule contains information collection requirements. Accordingly, DHS will be submitting a request for approval of a new information collection requirement concerning this rule to the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

A. Public reporting burden for this collection of information is estimated to be approximately 30 minutes (.50 hours) per response to comply with the requirements, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The total annual projected number of responses per respondent is estimated at four (4). The estimated annual total burden hours are as follows:

Title: Homeland Security Acquisition Regulation: Privacy Training.

Type of Request: New Collection.

Number of Respondents: 6,628.

Responses per Respondent: 4.

Annual Responses: 26,512.

Average Burden per Response: Approximately 0.50.

Annual Burden Hours: 13,256.

Needs and Uses: DHS needs the information required by 3052.224-7X, Privacy Training to properly track contractor compliance with the training requirements identified in the clause.

Affected Public: Businesses or other for-profit institutions.

Respondent's Obligation: Required to obtain or retain benefits.

Frequency: Upon award of procurement and annually thereafter.

B. Request for Comments Regarding Paperwork Burden.

You may submit comments identified by DHS docket number [DHS-2017-0008], including suggestions for reducing this burden, not later than March 20, 2017 using any one of the following methods:

(1) Via the internet at Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

(2) Via email to the Department of Homeland Security, Office of the Chief Procurement Officer, at HSAR@hq.dhs.gov.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the HSAR, and will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Requesters may obtain a copy of the supporting statement from the Department of Homeland Security, Office of the Chief Procurement Officer, Acquisition Policy and Legislation, via email to HSAR@hq.dhs.gov. Please cite OMB Control No. 1600-0022 Privacy Training and Information Security Training, in the "Subject" line.

List of Subjects in 48 CFR Parts 3001, 3002, 3024 and 3052

Government procurement.

Therefore, DHS proposes to amend 48 CFR parts 3001, 3002, 3024 and 3052 to read as follows:

■ 1. The authority citation for 48 CFR parts 3001, 3002, 3024, and 3052 is revised to read as follows:

Authority: 5 U.S.C. 301-302, 41 U.S.C. 1707, 41 U.S.C. 1702, 41 U.S.C. 1303(a)(2), 48 CFR part 1, subpart 1.3, and DHS Delegation Number 0702.

PART 3001—FEDERAL ACQUISITION REGULATIONS SYSTEM

Subpart 3001.1—Purpose, Authority, Issuance

■ 2. Amend section 3001.106 by revising paragraph (a) to add a new OMB Control Number as follows:

3001.106 OMB Approval under the Paperwork Reduction Act.

(a) * * *

OMB Control No. 1600–0022 (Privacy Training)

* * * * *

PART 3002—DEFINITIONS OF WORDS AND TERMS

■ 3. Amend section 3002.101 by adding, in alphabetical order, the definitions: for “Personally Identifiable Information (PII),” and “Sensitive Personally Identifiable Information (SPII)” to read as follows:

* * * * *

“Personally Identifiable Information (PII)” means information that can be used to distinguish or trace an individual’s identity, either alone or when combined with other information that is linked or linkable to a specific individual.

* * * * *

“Sensitive Personally Identifiable Information (SPII)” is a subset of PII, which if lost, compromised or disclosed without authorization, could result in substantial harm, embarrassment, inconvenience, or unfairness to an individual. Some forms of PII are sensitive as stand-alone elements.

(1) Examples of stand-alone SPII include: Social Security numbers (SSN), driver’s license or state identification number, Alien Registration Numbers (A-number), financial account number, and biometric identifiers such as fingerprint, voiceprint, or iris scan.

(2) Additional examples of SPII include any groupings of information that contain an individual’s name or other unique identifier plus one or more of the following elements:

- (i) Truncated SSN (such as last 4 digits)
- (ii) Date of birth (month, day, and year)
- (iii) Citizenship or immigration status
- (iv) Ethnic or religious affiliation
- (v) Sexual orientation
- (vi) Criminal history
- (vii) Medical information
- (viii) System authentication

information such as mother’s maiden name, account passwords or personal identification numbers (PIN)

(3) Other PII may be SPII depending on its context, such as a list of

employees and their performance ratings or an unlisted home address or phone number. In contrast, a business card or public telephone directory of agency employees contains PII but is not SPII.

PART 3024—PROTECTION OF PRIVACY AND FREEDOM OF INFORMATION

■ 4. Amend part 3024 by adding subpart 3024.70:

Subpart 3024.70—Privacy Training

- 3024.7001 Scope.
- 3024.7002 Definitions.
- 3024.7003 Policy.
- 3024.7004 Contract Clause.

3024.7001 Scope.

This section applies to contracts and subcontracts where contractor and subcontractor employees require access to a Government system of records; handle Personally Identifiable Information (PII) or Sensitive PII (SPII); or design, develop, maintain, or operate a Government system of records.

3024.7002 Definitions.

As used in this subpart—

“Handling” means any use of Personally Identifiable Information (PII) or Sensitive PII (SPII), including but not limited to marking, safeguarding, transporting, disseminating, re-using, storing, capturing, and disposing of the information.

3024.7003 Policy.

(a) Contractors are responsible for ensuring that contractor and subcontractor employees complete DHS privacy training initially upon award of the procurement, and at least annually thereafter, before contractor and subcontractor employees—

(1) Access to a Government system of records;

(2) Handle PII or SPII; or

(3) Design, develop, maintain, or operate a system of records on behalf of the Government.

(b) The contractor shall ensure employees identified in paragraph (a) of this section complete the required training, maintain evidence that the training has been completed and provide copies of the training completion certificates to the Contracting Officer and/or Contracting Officer’s Representative for inclusion in the contract file.

(c) Each contractor and subcontractor employee who requires access to a Government system of records; handles PII or SPII; or designs, develops, maintains, or operates a Government system of records, shall be granted

access or allowed to retain such access only if the individual has completed Department of Homeland Security privacy training requirements.

3024.7004 Contract Clause.

Contracting officers shall insert the clause at (HSAR) 48 CFR 3052.224–7X, Privacy Training, in solicitations and contracts when contractor and subcontractor employees may have access to a Government system of records; handle PII or SPII; or design, develop, maintain, or operate a system of records on behalf of the Government.

PART 3052—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 5. Amend paragraph (b) of section 3052.212–70 to add 3052.224–7X Privacy Training as follows:

3052.212–70 Contract terms and conditions applicable to DHS acquisition of commercial items.

Contract Terms and Conditions Applicable to DHS Acquisition of Commercial Items (DATE)

* * * * *

(b) * * *

____ 3052.224–7X Privacy Training

■ 6. Amend part 3052 by adding section 3052.224–7X Privacy Training, to read as follows:

3052.224–7X Privacy training.

As prescribed in (HSAR) 48 CFR 3024.7004 contract clause, insert the following clause:

Privacy Training (DATE)

(a) The Contractor shall ensure that all Contractor and subcontractor employees complete the Department of Homeland Security (DHS) training titled, Privacy at DHS: Protecting Personally Identifiable Information accessible at <http://www.dhs.gov/dhs-security-and-training-requirements-contractors>, before such employees—

(1) Access a Government system of records;

(2) Handle personally identifiable information or sensitive personally identifiable information; or

(3) Design, develop, maintain, or operate a system of records on behalf of the Government.

(b) Training shall be completed within thirty (30) days of contract award and be completed on an annual basis thereafter not later than October 31st of each year. Any new Contractor or subcontractor employees assigned to the contract shall complete the training before accessing the information identified in paragraph (a) of this clause. The Contractor shall maintain copies of the training certificates for all Contractor and subcontractor employees as a record of compliance. Initial training certificates for each Contractor and subcontractor employee

shall be provided to the Contracting Officer and/or Contracting Officer's Representative (COR) via email notification not later than thirty (30) days after contract award or assignment to the contract. Subsequent training certificates to satisfy the annual training requirement shall be submitted to the Contracting Officer and/or COR via email notification not later than October 31st of each year. The Contractor shall attach training certificates to the email notification and the email notification shall list all Contractor and subcontractor employees required to complete the training and state the required Privacy training has been completed for all Contractor and subcontractor employees.

(c) The Contractor shall insert the substance of this clause in all subcontracts and require subcontractors to include this clause in all lower-tier subcontracts.

(End of clause)

Soraya Correa,

Chief Procurement Officer, Department of Homeland Security.

[FR Doc. 2017-00752 Filed 1-18-17; 8:45 am]

BILLING CODE 9110-9B-P

DEPARTMENT OF HOMELAND SECURITY

48 CFR Parts 3001, 3002, 3004, and 3052

[Docket No. DHS-2017-0006]

RIN 1601-AA76

Homeland Security Acquisition Regulation (HSAR); Safeguarding of Controlled Unclassified Information (HSAR Case 2015-001)

AGENCY: Office of the Chief Procurement Officer, Department of Homeland Security (DHS).

ACTION: Proposed rule.

SUMMARY: DHS is proposing to amend the Homeland Security Acquisition Regulation (HSAR) to modify a subpart, remove an existing clause and reserve the clause number, update an existing clause, and add a new contract clause to address requirements for the safeguarding of Controlled Unclassified Information (CUI).

DATES: Comments on the proposed rule should be submitted in writing to one of the addresses shown below on or before March 20, 2017, to be considered in the formation of the final rule.

ADDRESSES: Submit comments identified by HSAR Case 2015-001, Safeguarding of Controlled Unclassified Information, using any of the following methods:

- *Regulations.gov:* <http://www.regulations.gov>.

Submit comments via the Federal eRulemaking portal by entering "HSAR

Case 2015-001" under the heading "Enter Keyword or ID" and selecting "Search." Select the link "Submit a Comment" that corresponds with "HSAR Case 2015-001." Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "HSAR Case 2015-001" on your attached document.

- *Fax:* (202) 447-0520
- *Mail:* Department of Homeland Security, Office of the Chief Procurement Officer, Acquisition Policy and Legislation, ATTN: Ms. Shaundra Duggans, 245 Murray Drive, Bldg. 410 (RDS), Washington, DC 20528.

Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Shaundra Duggans, Procurement Analyst, DHS, Office of the Chief Procurement Officer, Acquisition Policy and Legislation at (202) 447-0056 or email HSAR@hq.dhs.gov. When using email, include HSAR Case 2015-001 in the "Subject" line.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this proposed rule is to implement adequate security and privacy measures to safeguard Controlled Unclassified Information (CUI) and facilitate improved incident reporting to DHS. This proposed rule does not apply to classified information. These measures are necessary because of the urgent need to protect CUI and respond appropriately when DHS contractors experience incidents with DHS information. Recent high-profile breaches of Federal information further demonstrate the need to ensure that information security protections are clearly, effectively, and consistently addressed in contracts. This proposed rule strengthens and expands existing HSAR language to ensure adequate security for CUI that is accessed by contractors; collected or maintained by contractors on behalf of an agency; and/or for Federal information systems that collect, process, store or transmit such information. The proposed rule identifies CUI handling requirements as well as incident reporting requirements, including timelines and required data elements. The proposed rule also includes inspection provisions and

post-incident activities and requires certification of sanitization of Government and Government-Activity related files and information. Additionally, the proposed rule requires that contractors have in place procedures and the capability to notify and provide credit monitoring services to any individual whose Personally Identifiable Information (PII) or Sensitive PII (SPII) was under the control of the contractor or resided in the information system at the time of the incident.

This rule addresses the safeguarding requirements specified in the Federal Information Security Modernization Act (FISMA) of 2014 (44 U.S.C. 3551, *et seq.*), Office of Management and Budget (OMB) Circular A-130, *Managing Information as a Strategic Resource*,¹ relevant National Institutes of Standards and Technology (NIST) guidance, Executive Order 13556, *Controlled Unclassified Information*² and its implementing regulation at 32 CFR part 2002,³ and the following OMB Memoranda: M-07-16, *Safeguarding Against and Responding to the Breach of Personally Identifiable Information*; M-14-03, *Enhancing the Security of Federal Information and Information Systems*; and Reporting Instructions for the Federal Information Security Management Act and Agency Privacy Management as identified in various OMB Memoranda.⁴ Ongoing efforts by OMB and DHS with regard to implementation of FISMA, such as the issuance of Binding Operational Directives, and DHS implementation of the CUI program, may require future HSAR revisions in this area. DHS intends to harmonize the HSAR to be consistent with the requirements of these ongoing efforts.

II. Discussion and Analysis

This proposed rule is part of a broader initiative within DHS to (1) ensure contractors understand their responsibilities with regard to safeguarding controlled unclassified information (CUI); (2) contractor and subcontractor employees complete

¹ OMB Circular A-130 *Managing Information as a Strategic Resource* is accessible at <https://www.whitehouse.gov/sites/default/files/omb/assets/OMB/circulars/a130/a130revised.pdf>.

² Executive Order 13556 *Controlled Unclassified Information* is accessible at <https://www.gpo.gov/fdsys/pkg/FR-2010-11-09/pdf/2010-28360.pdf>.

³ 32 CFR part 2002 is accessible at <https://www.gpo.gov/fdsys/pkg/FR-2016-09-14/pdf/2016-21665.pdf>.

⁴ These memoranda include M-03-19, M-04-25, M-05-15, M-06-20, M-07-19, M-08-212, M-09-29, M-10-15, M-11-33, M-12-20, M-14-04, M-15-01, M-16-03, and M-16-04. These memoranda can be accessed at: https://www.whitehouse.gov/omb/memoranda_default.

information technology (IT) security awareness training before access is provided to DHS information systems and information resources or contractor-owned and/or operated information systems and information resources where CUI is collected, processed, stored or transmitted on behalf of the agency; (3) contractor and subcontractor employees sign the DHS RoB before access is provided to DHS information systems, information resources, or contractor-owned and/or operated information systems and information resources where CUI is collected, processed, stored or transmitted on behalf of the agency; and (4) contractor and subcontractor employees complete privacy training before accessing a Government system of records; handling personally identifiable information (PII) and/or sensitive PII information; or designing, developing, maintaining, or operating a system of records on behalf of the Government.

DHS is proposing to amend and expand an existing HSAR subpart. This proposed rule would (1) add new definitions; (2) clarify the applicability of the subpart; (3) remove an existing clause and reserve the clause number; (4) revise an existing clause; and (5) add a new clause to implement expanded safeguarding requirements and identify new policies for incident reporting, incident response, notification and credit monitoring. Each of these proposed changes are described in detail below.

(1) DHS is proposing to revise subpart 3002.101, Definitions, to define “adequate security,” “controlled unclassified information,” “Federal information,” “Federal information system,” “handling,” “information resources,” “information security,” and “information system,” and remove the definition of sensitive information. The definition of the terms “adequate security,” “Federal information,” and “Federal information system” is taken from OMB Circular A-130, *Managing Information as a Strategic Resource*. The definition of controlled unclassified information is taken from its implementing regulation at 32 CFR part 2002. The definition of “handling” was developed based upon a review of definitions for the term developed by other Federal agencies. The definition for the term “information security” is taken from FISMA 2014 (44 U.S.C. 3552(b)(3)) and the definitions for the terms “information resources” and “information system” are taken from 44 U.S.C. 3502(6) and 44 U.S.C. 3502(8) respectively. The definition of “sensitive information” is removed because it is being replaced with

“controlled unclassified information” consistent with Executive Order 13556 and its implementing regulation at 32 CFR part 2002. This rule also adds five (5) new categories/subcategories of CUI titled Homeland Security Agreement Information, Homeland Security Enforcement Information, Operations Security Information, Personnel Security Information, and Sensitive Personally Identifiable Information for consistency with NARA’s CUI regulation (32 CFR part 2002). The definitions of these terms are needed because these terms appear in the new proposed clause at 3052.204-7X, *Safeguarding of Controlled Unclassified Information*.

(2) DHS is proposing to revise subpart 3004.470, Security requirements for access to unclassified facilities, Information Technology resources, and sensitive information, to change the title of the subpart and to clarify the applicability of the subpart to the acquisition lifecycle. The title of the subpart would be changed to “Security requirements for access to unclassified facilities, information resources, and controlled unclassified information” and a new subsection for definitions would be added under the subpart. Accordingly, the subsections would be renumbered as follows: 3004.470-1 Scope, 3004.470-2 Definitions, 3004.470-3 Policy, and 3004.470-4 Contract Clauses. Originally, the title of this subpart contained the term “information technology resources;” however, this term is inconsistent with 44 U.S.C. 3502(6) which defines the term “information resources.” Subsection 3004.470-1, Scope, would be amended for consistency in terminology and to make clear the applicability of the subpart to the acquisition lifecycle. Subsection 3004.470-2, Definitions, would be added to define the term “incident.” The definition for “incident” is taken from FISMA 2014 (44 U.S.C. 3552(b)(2)). This term could not be defined at 3002.1, Definitions, because the meaning of the term “incident” in this subpart differs from the meaning it is given in other parts of the HSAR. Additionally, this definition is needed because this term appears in the clause at 3052.204-7X, *Safeguarding of Controlled Unclassified Information*. Subsection 3004.470-3, Policy, would be revised to (a) remove explicit references to Departmental policies and procedures to safeguard CUI that are subject to change and provide a public facing link for which these policies and procedures can be accessed and (b) make clear the requirements for

completion of security forms and background investigations for contractor employees that require recurring access to Government facilities or CUI. Subsection 3004.470-4, Contract Clauses, would be revised to remove reference to 3052.204-70, Security Requirements for Unclassified Information Technology Resources and identify the applicability of the clause at 3052.204-7X, *Safeguarding of Controlled Unclassified Information*, to solicitations, contracts, and subcontracts.

(3) Clause 3052.204-70, Security Requirements for Unclassified Information Technology Resources, would be removed and the clause number reserved. This change is necessary because the addition of the clause at 3052.204-7X *Safeguarding of Controlled Unclassified Information* eliminates the need for this clause.

(4) A new clause at 3052.204-7X, *Safeguarding of Controlled Unclassified Information*, would be added to ensure adequate protection of CUI. The new clause adds definitions and identifies CUI handling requirements, Authority to Operate requirements, incident reporting and response requirements, PII and SPII notification requirements, credit monitoring requirements, sanitization of Government and Government-Activity related files and information requirements, other reporting requirements, and subcontract requirements. Each of these requirements is described below.

(a) Definitions

This section would add definitions, which also appear in part at 3002.1 Definitions and 3004.470-2 Definitions, as follows: “adequate security,” “Controlled Unclassified Information,” “Federal information,” “Federal information system,” “handling,” “Homeland Security Agreement Information,” “Homeland Security Enforcement Information,” “incident,” “information resources,” “information security,” “information system,” “Operations Security Information,” “Personnel Security Information,” and “Sensitive Personally Identifiable Information.” The definitions of these terms are needed because these terms appear in 3052.204-7X, *Safeguarding of Controlled Unclassified Information*.

(b) Handling of Controlled Unclassified Information

This section sets forth specific requirements for contractors and subcontractors when handling CUI in order to better protect against the threat of persistent cyber-attacks and prevent the compromise of CUI, including PII.

These requirements include being in compliance with the DHS policies and procedures in effect at the time of contract award. These policies and procedures are located on a public Web site titled DHS Security and Training Requirements for Contractors which can be accessed via <http://www.dhs.gov/dhs-security-and-training-requirements-contractors>. This Web site identifies Departmental policies and procedures that contractors must comply with related to personnel security, information security, IT security, and privacy. The Web site also identifies and provides contractors with access to IT security awareness and privacy training. The policies and training requirements contained on this Web site are existing requirements that DHS routinely includes in the terms and conditions of its contracts, some of which are pre-existing through HSAR 3052.204–70 *Security Requirements for Unclassified Information Technology Resources* and 3052.204–71 *Contractor Employee Access*. Part of the intent of this proposed rulemaking is to increase transparency by consolidating these existing requirements in a single location that is easily accessible by the public. Changes to these policies and procedures will be reflected on the Web site and changes that impact contract performance will be communicated to the contractor by the Government.

Handling requirements also include not using or redistributing any CUI collected, processed, stored, or transmitted by the contractor, except as specified in the contract and not maintaining SPII in the contractor's invoicing, billing, and other recordkeeping systems maintained to support financial or other administrative functions. DHS believes that maintaining SPII in the contractor's invoicing, billing, and other recordkeeping systems creates unnecessary risk of compromise and is not otherwise needed to achieve contract administration functions. DHS welcomes comments regarding whether other categories of CUI should be similarly excluded from a contractor's invoicing, billing, and other recordkeeping systems. Through these and other requirements set forth in the proposed clause and discussed in detail in the following sections, the Department believes that contractors and subcontractors will provide adequate security from the unauthorized access and disclosure of CUI.

(c) Authority To Operate

FISMA defines a comprehensive framework for ensuring the protection of Government information, operations

and assets against natural or man-made threats. This section sets forth information security requirements contractors operating a Federal information system must meet prior to collecting, processing, storing, or transmitting CUI in that information system as required by FISMA and set forth in NIST Special Publication 800–53, *Recommended Security and Privacy Controls for Federal Information Systems and Organizations*. The requirements include completing the security authorization process, including the preparation of security authorization package and obtaining an independent assessment; renewal of the security authorization; security review; and Federal reporting and continuous monitoring.⁵

Security authorization involves comprehensive testing and evaluation of security features (also known as controls) of an information system. It addresses software and hardware security safeguards; considers procedural, physical, and personnel security measures; and establishes the extent to which a particular design (or architecture), configuration, and implementation meets a specified set of security requirements throughout the life cycle of the information system. It also considers procedural, physical, and personnel security measures employed to enforce information security policy. The security authorization package includes a Security Plan, Contingency Plan, Contingency Plan Test Results, Configuration Management Plan, Security Assessment Plan, and Security Assessment Report. These documents are used to record the results of the security authorization process and provide evidence that the process was followed correctly. A Federal information system, which includes a contractor information system operating on behalf of an agency, must be granted an Authority to Operate (ATO) before it is granted permission to collect, process, store, or transmit CUI. The ATO is the official management decision given by a senior organizational official to authorize operation of an information

⁵ DHS is aware that NIST Special Publication 800–171, *Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations*, was released in June 2015 to provide federal agencies with recommended requirements for protecting the confidentiality of Controlled Unclassified Information on non-Federal information systems; however, the information system security requirements in this proposed rulemaking are focused on Federal information systems, which include contractor information systems operating on behalf of an agency. Consistent with 32 CFR part 2002, these information systems are not subject to the requirements of NIST Special Publication 800–171.

system based on the implementation of an agreed-upon set of security controls.

The independent assessment is used to validate the security and privacy controls in place for the information system prior to submission of the security authorization package to the Government for review and acceptance. Once an ATO is accepted and signed by the Government, it is valid for three (3) years and must be renewed at that time unless otherwise specified in the ATO letter. The Government uses random security reviews as an additional level of verification to ensure security controls are in place, enforced and operating effectively. The contractor shall afford access to DHS, the Office of the Inspector General, other Government organizations, and contractors working in support of the Government access to the Contractor's facilities, installations, operations, documentation, databases, networks, systems, and personnel used in the performance of this contract to conduct security reviews. In addition, contractors operating information systems on behalf of the Government shall comply with Federal reporting and information system continuous monitoring requirements. Reporting requirements are determined by OMB on an annual basis and are defined in the Fiscal Year 2015 DHS Information Security Performance Plan.⁶ The plan is updated annually to reflect any new or revised reporting requirements from OMB.

(d) Incident Reporting

This section sets forth incident reporting requirements for contractors and subcontractors when reporting known or suspected incidents, including known or suspected incidents that involve PII and/or SPII. The incident reporting requirements described in this section allow the Department to gather the information necessary to formulate an effective incident response plan for incident mitigation and resolution. These requirements include: Reporting all known or suspected incidents to the Component Security Operations Center and notifying the contracting officer and contracting officer's representative of the incident; reporting known or suspected incidents that involve PII or SPII within one hour of discovery and all other incidents within eight hours of discovery; encrypting CUI using FIPS 140–2 Security Requirements for

⁶ The Fiscal Year 2015 DHS Information Security Performance Plan can be found at: <http://www.dhs.gov/dhs-security-and-training-requirements-contractors>.

Cryptographic Modules and refraining from including CUI in the subject or body of any email; providing additional data elements when reporting incidents involving PII or SPII; and making clear that an incident shall not, by itself, be interpreted as evidence that the contractor failed to provide adequate information security safeguards for CUI.

The timing for reporting incidents involving PII or SPII is consistent with OMB Memorandum M-07-16, *Safeguarding Against and Responding to the Breach of Personally Identifiable Information*. The timing for reporting incidents unrelated to PII or SPII was derived from existing Departmental policy for reporting incidents related to other categories of CUI such as CVI, Protected Critical Infrastructure Information (PCII), and Sensitive Security Information (SSI). Controlled unclassified information is required to be excluded from the subject or body of an email and encrypted to prevent further compromise of the information when reporting incidents. The additional data elements required when reporting incidents involving PII or SPII are needed to assist in the Department's understanding of the incident and aid in an effective response. DHS also wants to encourage industry to timely report incidents to the Department by making it clear that such reporting does not automatically mean the contractor has failed to provide adequate security or otherwise meet the requirements of the contract.

(e) Incident Response

This section identifies incident response requirements and activities. Incident response activities such as inspections, investigations, forensic reviews, etc. are used to quickly assess, remediate and protect CUI and are conducted whenever an incident is reported to DHS. The goal of these activities is to determine what data was or could have been accessed by an intruder, build a timeline of intruder activity, determine methods and techniques used by the intruder, find the initial attack vector, identify any features/aspects in the information security protections, and provide remediation recommendations to restore the protection of the data. Incident response activities may also include contract compliance analyses.

(f) PII and SPII Notification Requirements

This section sets forth the notification procedures and capability requirements for Contractors when notifying any individual whose PII and/or SPII was under the control of the Contractor or

resided in the information system at the time of the incident. The method and content of any notification by the Contractor shall be coordinated with, and subject to prior written approval by the Contracting Officer utilizing the DHS Privacy Incident Handling Guidance. When appropriate, notification of those affected and/or the public allows those individuals affected by the incident the opportunity to take steps to help protect themselves. Such notification is also consistent with the "openness principle" of the Privacy Act which calls for agencies to inform individuals about how their information is being accessed and used, and may help individuals mitigate the potential harms resulting from an incident.

The Department realizes that there are existing state notification laws that industry must also follow. Therefore, DHS welcomes comments regarding the impact, if any, that existing state notification laws will have on industry's ability to comply with this notification requirement.

(g) Credit Monitoring

This section sets forth the requirement that the contractor, when appropriate, is required to provide credit monitoring services, including call center services, if directed by the Contracting Officer, to any individual whose PII or SPII was under the control of the contractor, or resided in the information system, at the time of the incident for a period beginning the date of the incident and extending not less than 18 months from the date the individual is notified. Credit monitoring is a commercial service that can assist individuals in early detection of instances of identity theft. Credit monitoring services notify individuals of changes that appear in their credit report, such as creation of new accounts, changes to their existing accounts or personal information, or new inquiries for credit. Such notification affords individuals the opportunity to take steps to minimize any harm associated with unauthorized or fraudulent activity. The section is only applicable when an incident involves PII or SPII.

The Department deliberately made the provision of notification and credit monitoring services independent from an assessment of fault or lack of compliance with the contract terms and conditions. In accordance with OMB Memorandum M-07-16, *Safeguarding Against and Responding to the Breach of Personally Identifiable Information*, agencies have the responsibility to notify individuals whose PII or SPII may have been compromised without

unreasonable delay. This notification has often been delayed while detailed forensic analysis and contract compliance inspections are occurring. Under this new provision, notification and credit monitoring, when appropriate, will occur more rapidly as it is not dependent upon any determination of contractor fault or noncompliance. DHS is also aware that sophisticated cyber-attacks can occur despite compliance with contract requirements. In these instances, even though there is no contractor noncompliance, there may still be a need to notify individuals and provide credit monitoring services. Additionally, DHS wants to emphasize that the provisions for notification and credit monitoring services are only applicable when (1) contractor and/or subcontractor employees may have access to PII/SPII or (2) information systems are used to collect, process, store, or transmit PII/SPII on behalf of the agency. DHS is considering broadening the credit monitoring requirement to include identity protection, identity restoration, and related services. DHS welcomes comments regarding the impact, if any, of this change.

(h) Certificate of Sanitization of Government and Government-Activity Related Files and Information

Upon the conclusion of the contract by expiration, termination, cancellation, or as otherwise identified in the contract, the Contractor must return all CUI to DHS or destroy it physically or logically as identified in the contract. This destruction must conform to the guidelines for media sanitization contained in NIST SP-800-88, *Guidelines for Media Sanitization*. Further, the contractor must certify and confirm sanitization of media using the template provided in Appendix G of the publication.

(i) Other Reporting Requirements

The purpose of this section is to make clear that the requirements of this clause do not rescind the Contractor's responsibility for compliance with other applicable U.S. Government statutory or regulatory requirements that may apply to its contract(s).

(j) Subcontracts

This section requires that contractors insert the clause at 3052.204-7X *Safeguarding of Controlled Unclassified Information* in all subcontracts and require subcontractors to include this clause in all lower-tier subcontracts. The requirements of this clause are applicable to all contractors and

subcontractors that (1) will have access to CUI; (2) collect or maintain CUI on behalf of the agency; or (3) operate Federal information systems, including contractor information systems operated on behalf of the agency, to collect, process, store, or transmit CUI.

(5) Clause 3052.212–70, *Contract Terms and Conditions Applicable to DHS Acquisition of Commercial Items*, would be revised to remove 3052.204–70, *Security Requirements for Unclassified Information Technology Resources*; identify Alternate II as an option under subparagraph (b) of 3052.204–71 *Contractor Employee Access*; and add 3052.204–7X *Safeguarding of Controlled Unclassified Information* under subparagraph (b) of the clause. The addition of 3052.204–7X *Safeguarding of Controlled Unclassified Information* eliminates the need for 3052.204–70 *Security Requirements for Unclassified Information Technology Resources*. Because of this 3052.204–70 would be removed and the clause number reserved. Alternate II to 3052.204–71 was inadvertently omitted as an option under the listing of clauses and alternates available for selection under 3052.212–70. This addition corrects that omission. Subparagraph (b) of 3052.212–70 would also be amended to add 3052.204–7X *Safeguarding of Controlled Unclassified Information* because the requirements of these clauses are applicable to the acquisition of commercial items.

(6) Other considerations. DHS is considering making changes to subpart 3004.470–3, *Contract Clauses*, and the clause at 3052.204–71, *Contractor Employee Access*. These changes would harmonize the text of the clause with the requirements of the final version of 3052.204–7X *Safeguarding of Controlled Unclassified Information* by removing outdated and/or unnecessary definitions (i.e., sensitive information and information technology resources); renumbering the paragraphs of the clause as a result of the removal of the definitions for the terms “sensitive information” and “information technology resources”; and making clear in the prescription for the clause the need for information security regardless of the setting, including educational institutions and contractor facilities. DHS believes that the protection of CUI is paramount regardless of where the information resides. DHS is also seeking comment on making the clause at 3052.204–7X, *Safeguarding of Controlled Unclassified Information*, applicable to all services contracts. DHS believes this broader applicability would ensure that contractors are aware of the Government’s requirements

related to CUI. In addition, the Government believes that the requirements of the clause are written in such a way that they would be self-deleting when they are not applicable to a solicitation or contract. DHS welcomes comments regarding the impact, if any, on including 3052.204–7X, *Safeguarding of Controlled Unclassified Information*, in all services contracts. DHS also welcomes comments and feedback on industry’s understanding of the concept of self-deleting and if the use of alternates to 3052.204–7X, *Safeguarding of Controlled Unclassified Information*, is needed to ensure proper understanding and application of the clause.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under Section 6(b) of E.O. 12866, *Regulatory Planning and Review*, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

This proposed rule addresses the safeguarding requirements specified in the FISMA, OMB Circular A–130, *Managing Information as a Strategic Resource*, relevant NIST guidance, Executive Order 13556, *Controlled Unclassified Information* and its implementing regulation at 32 CFR part 2002, and multiple OMB Memoranda. DHS considered both the costs and benefits associated with the requirements of proposed clause *Safeguarding of Controlled Unclassified Information*, specifically those requirements believed to be of most import to industry such as the requirement to: Obtain an independent assessment, perform continuous monitoring, report all known and suspected incidents, provide notification and credit monitoring services in the event an incident impacts PII, document sanitization of Government and Government-activity-related files and information, as well as ensure overall compliance with the requirements of the proposed clause.

To determine the estimated costs of these requirements DHS requested cost

information from multiple vendors whose contracts with DHS include requirements similar to this proposed rule; obtained cost input from the Federal Risk and Authorization Management Program (FedRAMP), for which DHS is a participant; reviewed the Congressional Budget Office (CBO) Cost Estimate for the Personal Data Protection and Breach Accountability Act of 2011; reviewed pricing from the General Service Administration’s (GSA) recently awarded Identity Protection Services (IPS) blanket purchase agreements (BPAs); and reviewed internal price data from DHS’s Managed Compliance Services and notification and credit monitoring services contracts. These activities identified that: (1) The cost of an independent assessment can range from \$30,000 to \$150,000 with an average cost of \$112,872; (2) the equipment costs to perform continuous monitoring can range from \$76,340 to \$350,000 with an average cost of \$213,170 while the labor costs to perform continuous monitoring can range from \$47,000 to \$65,000 for an average cost of \$55,674; (3) the cost of reporting an incident to DHS ranges between \$500 and \$1,500 per incident; (4) the cost of notifying individuals that there has been an incident with their PII ranges from \$1.03 to \$4.60 per person; (5) the cost of credit monitoring services range between \$60 and \$260 per person; (6) a specific cost for the certificate of sanitization of Government and Government-Activity-Related files and information cannot be determined as the methods of sanitization vary widely depending on the categorization of the system and the media on which the data is stored; and (7) costs associated with Full-time Equivalent (FTE) oversight of the requirements of proposed clause *Safeguarding of Controlled Unclassified Information* ranges from \$65,000 to \$324,000. Detailed information on how DHS arrived at these costs and ranges is provided below.

There are a multitude of benefits associated with the requirements of proposed clause *Safeguarding of Controlled Unclassified Information*. These benefits impact both DHS and contractors with which it conducts business. Benefits related to specific provisions of the proposed clause are addressed below; however, it is important to note the overarching benefit of transparency. While several of the requirements of the proposed clause have been routinely included in DHS contracts (e.g., Authority to Operate, notification, and credit monitoring), this proposed rulemaking standardizes the applicability of these requirements and

makes clear to contractors considering doing business with DHS the standards and requirements to which they will be held as it relates to the (1) handling of the Department's CUI, (2) security requirements when such information will be collected or maintained on behalf of the agency or collected, processed, stored, or transmitted in a Federal information system, including contractor information systems operating on behalf of the agency, and (3) potential notification and credit monitoring requirements in the event of an incident that impacts personally identifiable information (PII) and/or sensitive PII (SPII). The current lack of standardization and transparency has been point of contention for industry and a common concern raised when DHS has requested feedback from industry.

Overview of Costs

Independent Assessment

DHS is proposing that vendors obtain an independent assessment to validate the security and privacy controls in place for an information system prior to submission of the security authorization package to the Government for review and acceptance. In general, when assessing compliance with a standard or set of requirements, there are three alternatives: (1) First party attestation or self-certification, (2) second party attestation (*i.e.*, internal independent), or (3) third party attestation. While the first two options may be considered the least economically burdensome, third party attestation is an accepted best practice in commercial industry as objectivity increases with independence. DHS is proposing to require that vendors obtain an independent assessment from a third party to ensure a truly objective measure of an entity's compliance with the requisite security and privacy controls. Recent high-profile breaches of Federal information further demonstrate the need for Departments, agencies, and industry to ensure that information security protections are clearly, effectively, and consistently addressed and appropriately implemented in contracts. Additionally, the benefits of using a third party to perform an independent assessment also extend to the contractor as the contractor can use the results of the independent assessment to demonstrate its cybersecurity excellence for customers other than DHS.

The cost of an independent assessment varies widely depending upon the complexity of the information system, the categorization of the

information system (low, moderate, or high impact), and the sophistication of the contractor. Additionally, DHS does not have a mechanism to track the costs of independent assessments performed under its contracts. Because of the multiple factors that influence the cost of an independent assessment and lack of a tracking mechanism for associated costs, DHS is unable to identify with specificity the costs of implementing this requirement. As such, we sought to identify a range of costs based on the actual data we were able to access. DHS performed the following activities to obtain this data:

- Requested cost information from multiple vendors whose contracts with DHS require an independent assessment as part of the security authorization process;
- Obtained cost input from FedRAMP, for which DHS is a participant, as the program requires cloud service providers to obtain an independent assessment from a Third Party Assessment Organization; and
- Reviewed internal data from DHS's Managed Compliance Services contract. DHS uses this contract to perform internal independent assessments.

The cost information received from DHS vendors ranged from \$30,000 to \$123,615. The vendors whose costs were on the higher end of this range included costs for the independent party as well as internal labor costs associated with performing the independent assessment whereas the vendor on the low end of the spectrum did not. FedRAMP data indicates the estimated costs on an independent assessment to be approximately \$150,000 while costs under DHS's internal contract for this service ranges between \$35,000 and \$45,000. When considering the data from DHS's internal contract for independent assessment services, it is important to note that these figures do not capture the labor costs of the Government employees involved in the process as the Government does not typically track the costs incurred for services performed by its own workforce. Because of this, it is both anticipated and expected that contractor costs for independent assessments will exceed the costs the Government incurs as contractor costs typically include not only the cost of the independent third party but also internal labor costs to facilitate the independent assessment and resolve any resultant findings.

Based on the above data points, the cost of an independent assessment can range from \$30,000 to \$150,000 or an average cost of \$112,872. Because it seems likely that most vendors will

have to account for necessary staff time, the average cost was developed by averaging only those cost estimates that included both internal and external labor costs. Neither the range nor the average cost identified is absolute as there are multiple factors that influence the cost of this service. Internal historical data indicates it takes approximately 162 labor hours to complete an independent assessment. This adds to the variance as the costs are dependent upon the labor categories and rates used to perform the assessment. Also, it is important to note that the assessment is required to be performed by an independent party. As such, the actual cost of the assessment is largely dependent upon agreements that the contractor is responsible for negotiating. Contractors with preexisting relationships with entities that perform independent assessments may be able to obtain more competitive pricing. Contractors new to this requirement may not. DHS welcomes comments from industry regarding the estimated costs associated with compliance with the requirement to obtain an independent assessment.

Continuous Monitoring

Proposed clause *Safeguarding of Controlled Unclassified Information* requires that contractors operating Federal information systems, which includes contractor information systems operating on behalf of the Government, or maintaining or collecting information on behalf of the Government, comply with information system continuous monitoring requirements. Continuous monitoring is not a new requirement for DHS contractors. Existing HSAR clause 3052.204-70, *Security Requirements for Unclassified Information Technology Resources*, requires contractors to comply with DHS Sensitive System Policy Publication 4300A. This publication and its implementing guidance addresses continuous monitoring requirements. DHS is seeking to be more clear and transparent with contractor requirements by expressly identifying this requirement in proposed clause *Safeguarding of Controlled Unclassified Information*.

The costs associated with continuous monitoring are not fixed and can vary widely. For example, a contractor that has previously gone through DHS's security authorization process is more likely to have in place the hardware, software, and personnel to perform continuous monitoring. In this instance, the costs associated with performing this requirement would be lower than a contractor who does not have preexisting hardware, software, and

personnel in place to satisfy these requirements.

Because of the multiple factors that influence the cost of continuous monitoring, DHS is unable to identify with specificity the costs of implementing this requirement. As such, we sought to identify a range of costs based on the actual data we were able to access. DHS performed the following activities to obtain this data:

- Requested cost information from multiple vendors whose contracts with DHS include similar continuous monitoring requirements; and
- Reviewed internal historical data.

The cost information received from DHS vendors ranged from \$65,000 to \$397,000. Vendors on the lower end of this range already had the hardware and software in place to perform continuous monitoring as the costs proposed only include labor. Alternatively, the vendors on the higher end of this range documented costs associated with hardware, software, and labor. For example, the cost breakdown from the vendor that reported costs of \$397,000 included a one-time equipment fee of \$350,000 and annual labor costs of \$47,000. Alternatively, the vendor that submitted costs of \$65,000 only proposed labor costs and is using preexisting hardware and software to perform continuous monitoring.

A review of internal historical data indicates the cost of continuous monitoring ranges from \$6,000 to \$18,000. It is important to note that the internal historical data assumes the vendor has the appropriate tools to perform continuous monitoring (e.g., the ability to scan their assets) and does not include costs for the labor required to support continuous monitoring activities. It is both anticipated and expected that in many instances contractor costs for continuous monitoring will exceed the costs the Government incurs for the same service as contractor costs include the costs of hardware/software to perform continuous monitoring as well as labor costs to support continuous monitoring activities.

Using the above data points, the equipment costs to perform continuous monitoring can range from \$76,340 to \$350,000 with an average cost of \$213,170. The average cost was developed by averaging the equipment costs received. Alternatively, labor costs to perform continuous monitoring can range from \$47,000 to \$65,000 for an average cost of \$55,674. The average cost was developed by averaging the labor costs received. Please note these ranges and average costs are not absolute as the costs associated with

continuous monitoring vary based on the tools (i.e., hardware or software) and methods (e.g., internal staff, contractor support, new hires) the contractor uses to implement the continuous monitoring requirements. The Government anticipates costs will decline over time as contractors become more sophisticated and build the necessary infrastructure to support this activity. DHS welcomes comments from industry regarding the estimated costs associated with compliance with the requirement to perform continuous monitoring.

Incident Reporting

This proposed rule requires contractors to report known or suspected incidents that involve PII or sensitive PII (SPII) within one hour of discovery and all other incidents (i.e., those incidents impacting any other category of CUI) within eight hours of discovery. DHS specifically included language in the regulatory text stating that an incident shall not, by itself, be interpreted as evidence that the contractor has failed to provide adequate information security safeguards for CUI, or has otherwise failed to meet the requirements of the contract. This language was added because DHS understands that sophisticated cyber-attacks can occur despite compliance with contract requirements.

The cost to prepare and report an incident to DHS varies based on the type(s) of information impacted by the incident and the complexity of the incident. Proposed clause *Safeguarding of Controlled Unclassified Information* requires incidents to be reported to the Component Security Operations Center (SOC), or the DHS Enterprise SOC if the Component SOC is unavailable, in accordance with 4300A Sensitive Systems Handbook Attachment F Incident Response. However, if PII is impacted by the incident, the contractor must provide additional information in its incident report. Also, for incidents that impact multiple systems or multiple components of a system, it may take the contractor more resources (e.g., time) to obtain some of the data points that are required to be provided when reporting an incident.

To determine the cost of preparing and reporting an incident, DHS performed the following activities:

- Requested cost information from multiple vendors whose contracts with DHS include similar incident reporting requirements; and
- Reviewed internal historical data.

It was difficult to use the information submitted by the vendors queried to

establish an estimated cost. The information provided either included both incident reporting and incident response (i.e., investigation and remediation activities) or annual training and testing requirements. Because of this we had to rely on internal historical data to establish an estimate solely responsive to the incident reporting requirements identified in the proposed clause. This data indicates the estimated cost of reporting an incident to DHS ranges between \$500 and \$1,500 per incident. DHS estimates that 822 vendors are subject to the requirements of this proposed rule and that each vendor may report up to one known or suspected incident per year for a total estimated cost range of \$411,000 to \$1,233,000. DHS welcomes comments from industry regarding the estimated costs associated with incident reporting.

Notification and Credit Monitoring

In the event of an incident that impacts PII/SPII, it may be necessary to perform certain incident response activities such as notification and credit monitoring. Contractors should not assume that all incident response activities will take place when a known or suspected incident is reported to DHS as the determination on the appropriate incident response activities is based upon investigation of the known or suspected incident. DHS uses a deliberative process to investigate and determine if an incident has occurred. This process begins with the contractor's submission of an Incident report to the Component or DHS SOC. The SOC staff use the incident report information to investigate and determine if an actual incident occurred. More often than not, an incident has not occurred and further incident response activities are not needed. If the SOC determines that incident has occurred, additional investigation and analyses happen to determine the nature and scope of the incident and US-CERT is engaged as necessary. If the incident involves PII/SPII, the Government will determine if notification and the provision of credit monitoring services is appropriate. DHS believes notification and credit monitoring, when appropriate, will occur more rapidly as the provision of these services is no longer dependent upon any determination of contractor fault or noncompliance.

To determine the cost of notifying individuals, DHS performed the following activities:

- Requested cost information from multiple vendors whose contracts with

DHS include similar notification requirements;

- Reviewed pricing from DHS's department-wide contract for credit monitoring services;
- Reviewed the CBO Cost Estimate for the Personal Data Protection and Breach Accountability Act of 2011;
- Reviewed pricing from the GSA's recently awarded IPS BPAs; and
- Reviewed GSA's Professional Services Schedule, Financial and Business Solutions, Category 520 19 Data Breach Analysis.

The cost information we received from DHS vendors indicates that vendors price these requirements using different methods. One vendor bundled the cost of notification in its continuous monitoring costs while another bundled these costs as with those associated with incident reporting. In these instances we are unable to determine which portion of the costs are associated with the notification requirements. The cost submitted by the one vendor that separately priced this requirement was \$4.06 per person. The pricing for notification in the Department's internal contract for credit monitoring services is significantly lower than the costs proposed by DHS's vendors, *i.e.*, \$1.57 per person.

While the CBO report referenced above did not provide a cost estimate for notification, the following information was provided: "According to industry sources, the sensitive, personally identifiable information of millions of individuals is illegally accessed or otherwise breached every year. However, according to those sources, 46 states already have laws requiring notification in the event of a security breach. In addition, it is the standard practice of most businesses to notify individuals if a security breach occurs. Therefore, CBO estimates that the notification requirements would not impose significant additional costs on businesses."

GSA's IPS BPAs contain bundled fixed unit pricing for services that not only exceed the requirements of proposed clause *Safeguarding of Controlled Unclassified Information* (*i.e.*, dedicated, branded Web site; identity restoration services; and identity theft insurance services) but also includes notification. As such, DHS is unable to determine which portion of the fixed unit price is applicable to notification services. A review of GSA's Professional Services Schedule indicates only two vendors with specific pricing for notification services. This includes the vendor for which DHS has a Department-wide contract for credit monitoring and notification services.

Pricing for the other vendor is \$0.54 per letter plus postage, *i.e.*, \$1.03. Based on this data, the cost of notifying individuals that there has been an incident with their PII ranges from \$1.03 to \$4.60 per person. DHS welcomes comments from industry regarding the estimated costs associated with compliance with the requirement to provide notification services.

Proposed clause *Safeguarding of Controlled Unclassified Information* requires contractors to provide credit monitoring services, including call center services, if directed by the Contracting Officer, to any individual whose PII/SPII was under the control of the contractor, or resided in the information system, at the time of the incident for a period beginning the date of the incident and extending not less than 18 months from the date the individual is notified.

The costs associated with this requirement vary depending on the method the contractor uses to provide services. For example, some contractors choose to satisfy this requirement through cyber insurance while others choose to subcontract these services with credit monitoring service providers. To estimate a cost for credit monitoring services, DHS performed the following activities:

- Requested cost information from multiple vendors whose contracts with DHS include similar credit monitoring requirements;
- Reviewed pricing from DHS's department-wide contract for credit monitoring services;
- Reviewed the CBO Cost Estimate for the Personal Data Protection and Breach Accountability Act of 2011; and
- Reviewed pricing from the General Service Administration's (GSA) recently awarded Identity Protection Services (IPS) blanket purchase agreements (BPAs).

The cost information we received from DHS vendors indicates that vendors satisfy these requirements using different methods. One vendor used cyber insurance while others satisfied this requirements through subcontracts with credit monitoring service providers. In instances where subcontracts are used, the pricing ranged from \$61.71 to \$260 per person. We assume that this variance in cost stems from the vendor's ability to negotiate favorable pricing with its subcontractors. It is also important to note that credit monitoring service providers frequently offer volume discounts that can lower the costs of services. However, all vendors under contracts with DHS may not be able to capitalize on these discounts as the

amount of PII provided to a contractor is based upon the services being provided and can vary greatly from contract to contract.

The pricing in the Department's internal contract for credit monitoring services is significantly lower than the costs proposed by DHS's vendors, *i.e.*, \$1.89 per person. It is important to note that DHS was able to obtain such favorable pricing because the cost of credit monitoring services are paid for everyone that receives notification of the incident without regard to their actual acceptance/request for credit monitoring. According to the CBO report referenced above, "[t]he cost of bulk purchases of the credit-monitoring or reporting services is about \$60 per person according to credit industry professionals."

As it relates to GSA's IPS BPAs, the published price lists do not mirror the credit monitoring provisions of DHS's proposed clause *Safeguarding of Controlled Unclassified Information*. For example, the IPS BPAs contain bundled fixed unit pricing for services that exceed the requirements of the proposed clause (*i.e.*, dedicated, branded Web site; identity restoration services; and identity theft insurance services). Additionally, the pricing includes volume discounts based on the number of individuals receiving services. The prices ranged from \$12.21 (per person per year if 10,000–24,999) to \$38 (per person per year if more than 10,000).

Based on the aforementioned information, DHS believes the most likely costs for these services range between \$60 and \$260 per person. DHS welcomes comments from industry regarding the estimated costs associated with compliance with the requirement to provide credit monitoring. DHS also requests feedback from industry on how many individuals typically sign up for credit monitoring after being notified that an incident has occurred that impacts their PII/SPII?

Certificate of Sanitization

Proposed clause *Safeguarding of Controlled Unclassified Information* requires contractors to return all CUI to DHS and certify and confirm the sanitization of all Government and Government-Activity related files and information. Destruction must conform to the guidelines for media sanitization contained in NIST SP-800-88, Guidelines for Media Sanitization. The contractor is also required to use the template provided in NIST Special Publication 800-88, Guidelines for Media Sanitization, Appendix G when

submitting the Certificate of Sanitization.

NIST SP 800–88 identifies the proper and applicable techniques and controls for sanitization and disposal decisions, considering the security categorization of the associated system's confidentiality. Applicable sanitization methods depend on the media in which the data is stored. Following sanitization, NIST SP 800–88 requires a certificate of media disposition to be completed for each piece of electronic media that has been sanitized. The proposed clause *Safeguarding of Controlled Unclassified Information* requires contractors to certify that applicable media have been sanitized using the template provided in Appendix G of NIST SP 800–88. In short, this template states that a system or hardware has been sanitized of all information. The costs associated with media sanitization do not arise from completion of the template. The costs arise from the sanitization activities themselves. A specific cost cannot be provided as the methods of sanitization vary widely depending on the categorization of the system and the media on which the data is stored. DHS requests comments from industry regarding the estimated costs associated with compliance with the requirement to sanitize Government and Government-Activity-Related files and information.

Oversight and Compliance

As discussed above, the costs associated with oversight and compliance with the requirements contained in proposed clause *Safeguarding of Controlled Unclassified Information* are not easily quantifiable. Implementation costs stem directly from a vendor's pre-existing information security posture. Several vendors, particularly those operating in the IT space, have been complying with these requirements for years. In these instances, the vendors have the existing infrastructure (*i.e.*, hardware, software, and personnel) to implement these requirements and implementation costs are lower. The same is also true for many vendors that provide professional services to the Government and use IT to provide those services. Alternatively, vendors with less experience and capability in this area will incur costs associated with procuring the hardware and software necessary to implement these requirements, as well as the labor costs associated with any new personnel needed to implement and oversee these requirements. Costs will vary depending on the hardware and software selected and the skill set each contractor requires

in its employee(s) responsible for ensuring compliance with these requirements. It is anticipated that these costs will be passed on to the Department, and that over time these vendors will become more sophisticated in this area and costs will decline. It is also important to note that the information security measures proposed in this rulemaking are quite similar to those industry already employs internal to their business operations. However, based on the feedback we received from vendors, the costs associated with FTE oversight of these requirements ranges from \$65,000 to \$324,000. This range is not absolute as it is entirely dependent upon the vendor's approach to oversight, *i.e.*, a single individual, multiple personnel, and the seniority of the position, all of which directly impact costs. Also, it is important to note that requirements of this type are generally not priced as a separate line item and are typically captured in overhead estimates. As such, DHS does not have clear insight into the costs associated with this requirement. DHS welcomes comments from industry regarding the estimated costs associated with ensuring proper oversight and compliance with the requirements of proposed clause *Safeguarding of Controlled Unclassified Information*.

Overview of Benefits

Clear Notification of System Requirements

Feedback from industry has consistently indicated the need for transparency and clear and concise requirements as it relates to information security. The requirements of proposed clause *Safeguarding of Controlled Unclassified Information* is, in part, intended to satisfy this request. Previously information security requirements were either imbedded in a requirements document (*i.e.*, Statement of Work, Statement of Objectives, or Performance Work Statement) or identified through existing HSAR clause 3052.204–70, *Security Requirements for Unclassified Information Technology Requirements*. This approach (1) created inconsistencies in the identification of information security requirements for applicable contracts, (2) required the identification and communication of security controls for which compliance was necessary after contract award had been made, and (3) resulted in delays in contract performance.

Proposed clause *Safeguarding of Controlled Unclassified Information* substantially mitigates the concerns with DHS's previous approach. Through the Government provided Requirements

Traceability to Matrix (RTM) contractors will know at the solicitation level the security requirements for which they must comply. The RTM identifies the security controls that must be implemented on an information system that collects, processes, stores, or transmits CUI and is necessary for the contractor to prepare its security authorization package. Clear identification of these requirements at the solicitation level affords contractors the ability to (1) assess their qualifications and ability to fully meet the Government's requirements, (2) make informed business decisions when deciding to compete on Government requirements, and (3) engage subcontractors, if needed, early in the process to enable them the ability to be fully responsive to the Government's requirements. Similarly, the Government benefits from clear identification of its requirements. Presumably, proposals/quotations will be submitted by contractors fully qualified and able to meet the requirements of the effort. During the evaluation phase of a procurement, the Government will be able to assess a contractor's information security posture and ability to comply with the requirements of the RTM. Such an evaluation should reduce post-award delays in contractor performance and mitigate the need to reissue solicitations as a result of a contractor's inability to comply with mandatory security requirements.

Improved Notification to the Public Regarding Data Breaches

Proposed clause *Safeguarding of Controlled Unclassified Information* requires contractors to have in place procedures and the capability to notify any individual whose PII) and/or SPII was under the control of the contractor or resided in the information system at the time of an incident no later than 5 business days after being directed to notify individuals, unless otherwise approved by the contracting officer. Such a requirement is consistent with OMB Memorandum M–07–16, *Safeguarding Against and Responding to the Breach of Personally Identifiable Information*, which states that agencies have the responsibility to notify individuals whose PII or SPII may have been compromised without unreasonable delay. In the past, this notification has often been delayed while detailed forensic analysis and contract compliance inspections are occurring. Under this new provision, notification and credit monitoring, when appropriate, will occur more rapidly as it is not dependent upon any

determination of contractor fault or noncompliance.

The content and method of any notification sent by a contractor must be coordinated with and approved by the contracting officer. At a minimum, this notification must include: A brief description of the incident; a description of the types of PII or SPII involved; a statement as to whether the PII or SPII was encrypted or protected by other means; steps individuals may take to protect themselves; what the contractor and/or the Government are doing to investigate the incident, to mitigate the incident, and to protect against any future incidents; and information identifying who individuals may contact for additional information. Such notification is consistent with the "openness principle" of the Privacy Act which calls for agencies to inform individuals about how their information is being accessed and used, and may help individuals mitigate the potential harms resulting from an incident.

Provision of Credit Protection to Impacted Individuals

Proposed clause *Safeguarding of Controlled Unclassified Information* requires contractors to provide credit monitoring services, including call center services to any individual whose PII or SPII was under the control of the contractor, or resided in the information system, at the time of the incident for a period beginning on the date of the incident and extending not less than 18 months from the date the individual is notified when directed by the contracting officer. Credit monitoring services can be particularly beneficial to the affected public as they can assist individuals in the early detection of identity theft as well as notify individuals of changes that appear in their credit report, such as creation of new accounts, changes to their existing accounts or personal information, or new inquiries for credit. Such notification affords individuals the opportunity to take steps to minimize any harm associated with unauthorized or fraudulent activity.

Incident Reporting

Proposed clause *Safeguarding of Controlled Unclassified Information* requires contractors and subcontractors to report all known or suspected incidents to the Component SOC. If the Component SOC is not available, the report shall be made to the DHS Enterprise SOC. While such a requirement is not new for DHS, compliance with this requirement is critical. The mission of DHS is unique in that we, through the National

Protection and Programs Directorate's Office of Cybersecurity and Communications, are also responsible for the identification and sharing of cyber threat indicators. These cyber threat indicators and defensive measures are shared among federal and non-federal entities consistent with the need to protect information systems from cybersecurity threats, mitigate cybersecurity threats, and comply with any other applicable provisions of law authorized by the Cybersecurity Information Sharing Act of 2015. Because of this mission requirement, DHS is not only concerned with actors who are successful in breaching our defenses, we are also concerned with attempts to breach those defenses. Knowledge of these attempts enables us to perform any necessary investigations and determine/establish new procedures to strengthen our defenses and prevent them from becoming successful. This information is then in turn shared with the interagency and non-Federal entities to enable them to take the necessary measures to be able to defend against similar attacks.

Improved Incident Response Time

Previously contractors were not consistently provided with specific incident reporting timelines. As such, the timeliness of incident reporting was determined by the contractor. Standardizing incident reporting timelines through proposed clause *Safeguarding of Controlled Unclassified Information* ensures timely incident reporting. Timely reporting of incidents is critical to prevent the impact of the incident from expanding, ensure incident response and mitigation activities are undertaken quickly, and ensure individuals are timely notified of the possible or actual compromise of their personally identifiable information and offered credit monitoring services when applicable.

IV. Regulatory Flexibility Act

DHS expects this proposed rule may have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* Therefore, an Initial Regulatory Flexibility Analysis (IRFA) has been prepared consistent with 5 U.S.C. 603, and is summarized as follows:

1. Description of the Reasons Why Action by the Agency Is Being Considered

Cybersecurity has been identified as one of the most serious economic and national security challenges our nation faces. The frequency of cyber-attacks,

including attempts to gain unauthorized access to CUI collected or maintained by or on behalf of an agency and information systems that collect, process, store, or transmit such information, has prompted the Government to expand its cybersecurity efforts across the Federal landscape. Part of the DHS mission is to protect the nation's cybersecurity and to coordinate responses to cyber-attacks and security vulnerabilities. As part of that mission, DHS is proposing to amend the HSAR to expand its current security measures for safeguarding CUI to include additional requirements for the safeguarding of CUI that is accessed by contractors, collected or maintained by contractors on behalf of the agency, and Federal information systems, which includes contractor information systems operating on behalf of the Government, that collect, process, store or transmit CUI. These proposed revisions to the HSAR are necessary to ensure the integrity, confidentiality, and availability of CUI.

2. Succinct Statement of the Objectives of, and Legal Basis for, the Rule

The objective of this rule is to expand on existing Departmental IT security requirements. These existing IT security requirements are provided in the clause at HSAR 3052.204–70, Security Requirements for Unclassified Information Technology Resources, and applicable DHS policy and guidance. The existing clause is more narrowly focused on information systems connected to a DHS network or operated by a contractor for DHS. This rule proposes to remove the existing clause and provide a new expanded clause. Unlike the existing clause, this proposed rule extends the scope to require that CUI be safeguarded wherever such information resides, including government-owned and operated information systems, government-owned and contractor operated information systems, contractor-owned and/or operated information systems operating on behalf of the Government, and any situation where contractor and/or subcontractor employees may have access to CUI consistent with the requirements of FISMA. This proposed rule also establishes uniform incident reporting and response activities that contractors and subcontractors must comply with in the event of an incident. The proposed rule also requires contractors and subcontractors have in place procedures and the capability to notify and provide credit monitoring services to any individual whose Personally Identifiable Information (PII) or

Sensitive PII (SPII) was under the control of the contractor, or resided in the information system, at the time of the incident. Additionally, this proposed rule requires contractors and subcontractors to certify and confirm the sanitization of Government and Government-Activity related files and information. These collective measures will help DHS mitigate information security risks related to information as well as gather information for future improvements in information security policy.

The requirement to safeguard CUI is specified in the Federal Information Security Modernization Act of 2014 (44 U.S.C. 3551, *et seq.*), OMB Circular A–130, *Managing Information as a Strategic Resource*, relevant National Institutes of Standards and Technology (NIST) guidance, Executive Order 13556, *Controlled Unclassified Information* and its implementing regulation at 32 CFR part 2002, and various OMB Memoranda, to include: M–07–16, *Safeguarding Against and Responding to the Breach of Personally Identifiable Information*; M–14–03, *Enhancing the Security of Federal Information and Information Systems*; and Reporting Instructions for the Federal Information Security Management Act and Agency Privacy Management and Guidance on Federal Information Security and Privacy Management Requirements as identified in various OMB Memoranda.

3. Description of and, Where Feasible, Estimate of the Number of Small Entities To Which the Rule Will Apply

This rule will apply to DHS contractors that require access to CUI, collect or maintain CUI on behalf of the Government, or operate Federal information systems, which includes contractor information systems operating on behalf of the agency, that collect, process, store or transmit CUI.

For Fiscal Year (FY) 2014, DHS awarded nearly 13,000 new contract awards to large and small businesses, with over 35 percent of all contracts awarded to small businesses. The estimate of the number of small entities to which the proposed rule will apply was established by reviewing FPDS data for FY 2014, internal DHS contract data, experience with similar safeguarding requirements used in certain DHS contracts, and the most likely applicable Product and Service Codes (PSCs). The data review identified 2,525 unique vendors were awarded contracts under the most likely applicable PSCs in FY 2014, including small and large businesses. However, not all contractors awarded contracts under the most likely

applicable PSCs will be subject to proposed clause *Safeguarding of Controlled Unclassified Information*. A number of factors determine the applicability of the proposed clause and would require analysis on a case-by-case basis. Further, the proposed clause is separated by those entities that are granted access to CUI but information systems will not be operated on behalf of the agency to collect, process, store or transmit CUI, and those that are required to meet the Authority to Operate (ATO) requirements because information systems will be used to collect, process, store or transmit CUI on behalf of the agency. Based on the data reviewed, the estimated number of annual respondents subject to the *Safeguarding of Controlled Unclassified Information* clause is estimated at 822 respondents. The proposed revision to the HSAR includes a flow-down provision that applies to subcontractors. However, DHS does not believe this requirement will add to the estimated number of respondents when an ATO is required because it is anticipated that a single information system will be used to collect, process, store, or transmit CUI in most instances. A review of DHS historical data shows that at least 35 percent of new contracts are awarded to small businesses. Therefore, it is assumed that 35 percent of the projected annual number of respondents will also be small businesses, or approximately 288 respondents.

Although the proposed HSAR clause is new, DHS contractors are currently required to comply with Departmental IT security policy and guidance. It is assumed that the average DHS IT services contractor covered by this clause will have high operational security readiness posture. However, the requirements of the proposed clause have been expanded to include professional services contractors that have access to CUI, collect or maintain CUI on behalf of the Government, and/or operate Federal information systems, including contractor information systems operating on behalf of the agency, that collect, process, store or transmit CUI to perform the requirements of their contract(s). While these contractors may not have the same operational security readiness posture of the average DHS IT services contractor, the expansion and implementation of these safeguarding requirements is necessary to further reduce risks and potential vulnerabilities.

4. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Rule, Including an Estimate of the Classes of Small Entities Which Will be Subject to the Requirement and the Type of Professional Skills Necessary

Reporting and recordkeeping requirements include those requirements necessary to ensure adequate security controls are in place when contractor and/or subcontractor employees will have access to sensitive CUI, collect or maintain CUI on behalf of the Government, and/or operate Federal information systems, which includes contractor information systems operating on behalf of the agency, that are used to collect, process, store, or transmit CUI. The reporting and recordkeeping requirements vary depending on if an Authority to Operate (ATO) is required. If an ATO is not required, the reporting and recordkeeping requirements include: Incident Reporting, Notification (if the incident involves PII/SPII), Credit Monitoring (if the incident involves PII/SPII), and Certification of Sanitization. If an ATO is required, the reporting and recordkeeping requirements include: Incident Reporting, Notification (if the incident involves PII/SPII), Credit Monitoring (if the incident involves PII/SPII), Certification of Sanitization, Security Authorization Package, Independent Assessment, Renewal of ATO, and Federal Reporting and Continuous Monitoring.

Typical contract awards that may include the requirement for access to CUI include contracts awards with a PSC of “D” Automatic Data Processing and Telecommunication and “R” Professional, Administrative and Management Support. However, this is not an all-inclusive list. Additional PSCs will be added and projections will be adjusted as additional data becomes available through HSAR clause implementation. This continued process will assist in validating future projections. It is estimated that the average contractor will utilize a mid-level manager with IT expertise to ensure compliance with the requirements of this rule.

5. Identification, to the Extent Practicable, of All Relevant Federal Rules Which May Duplicate, Overlap, or Conflict With the Rule

There are no rules that duplicate, overlap or conflict with this rule.

6. Description of Any Significant Alternatives to the Rule Which Accomplish the Stated Objectives of Applicable Statutes and Which Minimize any Significant Economic Impact of the Rule on Small Entities

No significant alternatives were identified that would accomplish the stated objectives of the rule. The information security requirements associated with this rule are not geared towards a type of contractor; the requirements are based on the sensitivity of the information, the impact on the program, the Government and security in the event CUI is breached. That standard would not vary based on the size of the entity.

DHS will be submitting a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the IRFA may be obtained from the point of contact specified herein. DHS invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DHS will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610, *et seq.* (HSAR Case 2015–001), in correspondence.

V. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) applies. The proposed rule contains information collection requirements. Accordingly, DHS will be submitting a request for approval of a new information collection requirement concerning this rule to the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

The collection requirements for this rule are based on a new HSAR clause, 3052.204–7X *Safeguarding of Controlled Unclassified Information*.

A. The average public reporting burden for this collection of information is estimated to be approximately 50 hours per response to comply with the requirements, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. This average is based on an estimated 36 hours per response to comply with the requirements when an ATO *is not* required an estimated 120 hours to comply with the requirements when an ATO *is* required (*i.e.*, when a contractor is required to submit Security Authorization (SA) package). Security Authorization package consists of the

following: Security Plan, Security Assessment Report, Plan of Action and Milestones, Security Control Assessor Transmittal Letter (documents the Security Control Assessor's recommendation (*i.e.*, Authorization to Operate or Denial to Operate), and any supplemental information requested by the Government (*e.g.*, Contingency Plan, final Risk Assessment, Configuration Management Plan, Standard Operating Procedures, Concept of Operations). Additional requirements include an Independent Assessment, Security Review, Renewal of the ATO which is required every three years, and Federal Reporting and Continuous Monitoring Requirements.

The total annual projected number of responses per respondent is estimated at 1. Based on aforementioned information the annual total burden hours are estimated as follows:

Title: Homeland Security Acquisition Regulation: Safeguarding of Controlled Unclassified Information.

Type of Request: New Collection.

Total Number of Respondents: 822.

Responses per Respondent: 1.

Annual Responses: 822.

Average Burden per Response: Approximately 50.

Annual Burden Hours: Approximately 41,100.

Needs and Uses: DHS needs the information required by 3052.204–7X to implement the requirements for safeguarding against unauthorized contractor disclosure and inappropriate use of CUI that contractors and subcontractors may have access to during the course of contract performance.

Affected Public: Businesses or other for-profit institutions.

Respondent's Obligation: Required to obtain or retain benefits.

Frequency: On occasion.

B. Request for Comments Regarding Paperwork Burden.

You may submit comments identified by DHS docket number [DHS–2017–0006], including suggestions for reducing this burden, not later than [insert date 60 days after publication in the **Federal Register**] using any one of the following methods:

(1) Via the internet at Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

(2) Via email to the Department of Homeland Security, Office of the Chief Procurement Officer, at HSAR@hq.dhs.gov.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the HSAR,

and will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Requesters may obtain a copy of the supporting statement from the Department of Homeland Security, Office of the Chief Procurement Officer, Acquisition Policy and Legislation, via email to HSAR@hq.dhs.gov. Please cite OMB Control No. 1600–0023, Safeguarding of Controlled Unclassified Information, in all correspondence.

List of Subjects in 48 CFR Parts 3001, 3002, 3004 and 3052

Government procurement.

Therefore, DHS proposes to amend 48 CFR parts 3001, 3002, 3004 and 3052 as follows:

■ 1. The authority citation for 48 CFR parts 3001, 3002, 3004 and 3052 is revised to read as follows:

Authority: 5 U.S.C. 301–302, 41 U.S.C. 1707, 41 U.S.C. 1702, 41 U.S.C. 1303(a)(2), 48 CFR part 1, subpart 1.3, and DHS Delegation Number 0702.

PART 3001—FEDERAL ACQUISITION REGULATIONS SYSTEM

■ 2. In section 3001.106 amend paragraph (a) by adding a new OMB Control Number as follows:

3001.106 OMB Approval under the Paperwork Reduction Act.

(a) * * *

OMB Control No. 1600–0023 (Safeguarding of Controlled Unclassified Information)

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PART 3002—DEFINITIONS OF WORDS AND TERMS

3002.101 [Amended]

■ 3. Amend section 3002.101 by adding, in alphabetical order, the definitions of “Adequate Security,” “Controlled Unclassified Information (CUI),” “Federal Information,” “Federal Information System,” “Handling,” “Information Resources,” “Information Security,” and “Information System” to read as follows:

“Adequate Security” means security protections commensurate with the risk resulting from the unauthorized access, use, disclosure, disruption,

modification, or destruction of information. This includes ensuring that information hosted on behalf of an agency and information systems and applications used by the agency operate effectively and provide appropriate confidentiality, integrity, and availability protections through the application of cost-effective security controls.

* * * * *

“Controlled Unclassified Information (CUI)” is any information the Government creates or possesses, or an entity creates or possesses for or on behalf of the Government (other than classified information) that a law, regulation, or Government-wide policy requires or permits an agency to handle using safeguarding or dissemination controls. Within the context of DHS, this includes such information which, if lost, misused, disclosed, or, without authorization is accessed, or modified, could adversely affect the national or homeland security interest, the conduct of Federal programs, or the privacy of individuals. This definition includes the following CUI categories and subcategories of information:

(1) Chemical-terrorism Vulnerability Information (CVI) as defined in Title 6, Code of Federal Regulations, part 27 “Chemical Facility Anti-Terrorism Standards,” and as further described in supplementary guidance issued by an authorized official of the Department of Homeland Security (including the Revised Procedural Manual “Safeguarding Information Designated as Chemical-Terrorism Vulnerability Information” dated September 2008);

(2) Protected Critical Infrastructure Information (PCII) as set out in the Critical Infrastructure Information Act of 2002 (Title II, Subtitle B, of the Homeland Security Act, Public Law 107–296, 196 Stat. 2135), as amended, the implementing regulations thereto (Title 6, Code of Federal Regulations, part 29) as amended, the applicable PCII Procedures Manual, as amended, and any supplementary guidance officially communicated by an authorized official of the Department of Homeland Security (including the PCII Program Manager or his/her designee);

(3) Sensitive Security Information (SSI) as defined in Title 49, Code of Federal Regulations, part 1520, “Protection of Sensitive Security Information,” as amended, and any supplementary guidance officially communicated by an authorized official of the Department of Homeland Security (including the Assistant Secretary for the Transportation Security Administration or his/her designee) to

include DHS MD 11056.1, “Sensitive Security Information (SSI)” and, within the Transportation Security Administration, TSA MD 2010.1, “SSI Program”;

(4) Homeland Security Agreement Information means information DHS receives pursuant to an agreement with state, local, tribal, territorial, and private sector partners that is required to be protected by that agreement. DHS receives this information in furtherance of the missions of the Department, including, but not limited to, support of the Fusion Center Initiative and activities for cyber information sharing consistent with the Cybersecurity Information Security Act;

(5) Homeland Security Enforcement Information means unclassified information of a sensitive nature lawfully created, possessed, or transmitted by the Department of Homeland Security in furtherance of its immigration, customs, and other civil and criminal enforcement missions, the unauthorized disclosure of which could adversely impact the mission of the Department;

(6) International Agreement Information means information DHS receives pursuant to an information sharing agreement or arrangement, with a foreign government, an international organization of governments or any element thereof, an international or foreign public or judicial body, or an international or foreign private or non-governmental organization, that is required by that agreement or arrangement to be protected;

(7) Information Systems Vulnerability Information (ISVI) means:

(i) DHS information technology (IT) internal systems data revealing infrastructure used for servers, desktops, and networks; applications name, version and release; switching, router, and gateway information; interconnections and access methods; mission or business use/need. Examples of information are systems inventories and enterprise architecture models. Information pertaining to national security systems and eligible for classification under Executive Order 13526, will be classified as appropriate;

(ii) Information regarding developing or current technology, the release of which could hinder the objectives of DHS, compromise a technological advantage or countermeasure, cause a denial of service, or provide an adversary with sufficient information to clone, counterfeit, or circumvent a process or system;

(8) Operations Security Information means information that could constitute an indicator of U.S. Government

intentions, capabilities, operations, or activities or otherwise threaten operations security;

(9) Personnel Security Information means information that could result in physical risk to DHS personnel or other individuals that DHS is responsible for protecting;

(10) Physical Security Information means reviews or reports illustrating or disclosing facility infrastructure or security vulnerabilities related to the protection of Federal buildings, grounds, or property. For example, threat assessments, system security plans, contingency plans, risk management plans, business impact analysis studies, and certification and accreditation documentation;

(11) Privacy Information, which includes information referred to as Personally Identifiable Information. Personally Identifiable Information (PII) means information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual; and

(12) Sensitive Personally Identifiable Information (SPII) is a subset of PII, which if lost, compromised or disclosed without authorization, could result in substantial harm, embarrassment, inconvenience, or unfairness to an individual. Some forms of PII are sensitive as stand-alone elements.

(i) Examples of stand-alone PII include: Social Security numbers (SSN), driver's license or state identification number, Alien Registration Numbers (A-number), financial account number, and biometric identifiers such as fingerprint, voiceprint, or iris scan.

(ii) Additional examples of SPII include any groupings of information that contain an individual's name or other unique identifier plus one or more of the following elements:

- (A) Truncated SSN (such as last 4 digits)
- (B) Date of birth (month, day, and year)
- (C) Citizenship or immigration status
- (D) Ethnic or religious affiliation
- (E) Sexual orientation
- (F) Criminal history
- (G) Medical information
- (H) System authentication

information such as mother's maiden name, account passwords or personal identification numbers (PIN)

(iii) Other PII may be “sensitive” depending on its context, such as a list of employees and their performance ratings or an unlisted home address or phone number. In contrast, a business card or public telephone directory of agency employees contains PII but is not sensitive.

“Federal Information” means information created, collected, processed, maintained, disseminated, disclosed, or disposed of by or for the Federal Government, in any medium or form.

“Federal Information System” means an information system used or operated by an agency or by a contractor of an agency or by another organization on behalf of an agency.

“Handling” means any use of controlled unclassified information, including but not limited to marking, safeguarding, transporting, disseminating, re-using, and disposing of the information.

* * * * *

“Information Resources” means information and related resources, such as personnel, equipment, funds, and information technology.

“Information Security” means protecting information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction in order to provide—

(1) integrity, which means guarding against improper information modification or destruction, and includes ensuring information nonrepudiation and authenticity;

(2) confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and

(3) availability, which means ensuring timely and reliable access to and use of information.

“Information System” means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information.

* * * * *

PART 3004—ADMINISTRATIVE MATTERS

■ 4. Revise subpart 3004.4 to read as follows:

Subpart 3004.4—Safeguarding Classified and Controlled Unclassified Information within Industry

3004.470 Security requirements for access to unclassified facilities, information resources, and controlled unclassified information.

- 3004.470–1 Scope.
- 3004.470–2 Definitions.
- 3004.470–3 Policy.
- 3004.470–4 Contract Clauses.

3004.470–1 Scope.

This section implements DHS policies for assuring adequate security of

unclassified facilities, information resources, and controlled unclassified information (CUI) during the acquisition lifecycle.

3004.470–2 Definitions.

As used in this subpart—
“Incident” means an occurrence that—

- (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or
- (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies.

3004.470–3 Policy.

(a) DHS requires that CUI be safeguarded wherever such information resides. This includes government-owned and operated information systems, government-owned and contractor operated information systems, contractor-owned and/or operated information systems operating on behalf of the agency, and any situation where contractor and/or subcontractor employees may have access to CUI. There are several Department policies and procedures (accessible at <http://www.dhs.gov/dhs-security-and-training-requirements-contractors>) which also address the safeguarding of CUI. Compliance with these policies and procedures, as amended, is required.

(b) DHS requires contractor employees that require recurring access to Government facilities or access to CUI to complete such forms as may be necessary for security or other reasons, including the conduct of background investigations to determine fitness. Department policies and procedures that address contractor employee fitness are contained in Instruction Handbook Number 121–01–007, The Department of Homeland Security Personnel Suitability and Security Program. Compliance with these policies and procedures, as amended, is required.

3004.470–4 Contract Clauses.

(a) Contracting officers shall insert the basic clause at (HSAR) 48 CFR 3052.204–71, Contractor Employee Access, in solicitations and contracts when contractor and/or subcontractor employees require recurring access to Government facilities or access to CUI. Contracting officers shall insert the basic clause with its Alternate I for acquisitions requiring contractor access to Government information resources. For acquisitions in which contractor and/or subcontractor employees will not

have access to Government information resources, but the Department has determined contractor and/or subcontractor employee access to CUI or Government facilities must be limited to U.S. citizens and lawful permanent residents, the contracting officer shall insert the clause with its Alternate II. Neither the basic clause nor its alternates shall be used unless contractor and/or subcontractor employees will require recurring access to Government facilities or access to CUI. Neither the basic clause nor its alternates should ordinarily be used in contracts with educational institutions.

(b) Contracting officers shall insert the clause at (HSAR) 48 CFR 3052.204–7X, Safeguarding of Controlled Unclassified Information, in solicitations and contracts where:

(1) Contractor and/or subcontractor employees will have access to CUI;

(2) CUI will be collected or maintained on behalf of the agency; or

(3) Federal information systems, which include contractor information systems operated on behalf of the agency, are used to collect, process, store, or transmit CUI.

(c) If the clauses prescribed in subsections (a) and/or (b) are included in a prime contract, the prime contractor shall include the clauses in subsections (a) and/or (b), in its contract(s) with subcontractors. If a subcontract includes the clauses prescribed in subsections (a) and/or (b) and the subcontractor has contracts with lower-tier subcontractors, the lower-tier subcontracts shall include the clauses in subsections (a) and/or (b).

PART 3052—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

3052.204–70 [Removed and Reserved].

■ 5. Remove and reserve section 3052.204–70.

■ 6. Add section 3052.204–7X to read as follows:

3052.204–7X Safeguarding of Controlled Unclassified Information.

As prescribed in (HSAR) 48 CFR 3004.470–4(b), insert the following clause:

Safeguarding of Controlled Unclassified Information (DATE)

(a) *Definitions.* As used in this clause—
“Adequate Security” means security protections commensurate with the risk resulting from the unauthorized access, use, disclosure, disruption, modification, or destruction of information. This includes ensuring that information hosted on behalf of an agency and information systems and applications used by the agency operate effectively and provide appropriate

confidentiality, integrity, and availability protections through the application of cost-effective security controls.

“Controlled Unclassified Information (CUI)” is any information the Government creates or possesses, or an entity creates or possesses for or on behalf of the Government (other than classified information) that a law, regulation, or Government-wide policy requires or permits an agency to handle using safeguarding or dissemination controls. Within the context of DHS, this includes such information which, if lost, misused, disclosed, or, without authorization is accessed, or modified, could adversely affect the national or homeland security interest, the conduct of Federal programs, or the privacy of individuals. This definition includes the following CUI categories and subcategories of information:

(i) Chemical-terrorism Vulnerability Information (CVI) as defined in Title 6, Code of Federal Regulations, part 27 “Chemical Facility Anti-Terrorism Standards,” and as further described in supplementary guidance issued by an authorized official of the Department of Homeland Security (including the Revised Procedural Manual “Safeguarding Information Designated as Chemical-Terrorism Vulnerability Information” dated September 2008);

(ii) Protected Critical Infrastructure Information (PCII) as set out in the Critical Infrastructure Information Act of 2002 (Title II, Subtitle B, of the Homeland Security Act, Public Law 107–296, 196 Stat. 2135), as amended, the implementing regulations thereto (Title 6, Code of Federal Regulations, part 29) as amended, the applicable PCII Procedures Manual, as amended, and any supplementary guidance officially communicated by an authorized official of the Department of Homeland Security (including the PCII Program Manager or his/her designee);

(iii) Sensitive Security Information (SSI) as defined in Title 49, Code of Federal Regulations, part 1520, “Protection of Sensitive Security Information,” as amended, and any supplementary guidance officially communicated by an authorized official of the Department of Homeland Security (including the Assistant Secretary for the Transportation Security Administration or his/her designee) to include DHS MD 11056.1, “Sensitive Security Information (SSI)” and, within the Transportation Security Administration, TSA MD 2010.1, “SSI Program”;

(iv) Homeland Security Agreement Information means information DHS receives pursuant to an agreement with state, local, tribal, territorial, and private sector partners that is required to be protected by that agreement. DHS receives this information in furtherance of the missions of the Department, including, but not limited to, support of the Fusion Center Initiative and activities for cyber information sharing consistent with the Cybersecurity Information Security Act;

(v) Homeland Security Enforcement Information means unclassified information of a sensitive nature lawfully created, possessed, or transmitted by the Department of Homeland Security in furtherance of its

immigration, customs, and other civil and criminal enforcement missions, the unauthorized disclosure of which could adversely impact the mission of the Department;

(vi) International Agreement Information means information DHS receives pursuant to an information sharing agreement or arrangement with a foreign government, an international organization of governments or any element thereof, an international or foreign public or judicial body, or an international or foreign private or non-governmental organization, that is required by that agreement or arrangement to be protected;

(vii) Information Systems Vulnerability Information (ISVI) means:

(A) DHS information technology (IT) internal systems data revealing infrastructure used for servers, desktops, and networks; applications name, version and release; switching, router, and gateway information; interconnections and access methods; mission or business use/need. Examples of information are systems inventories and enterprise architecture models. Information pertaining to national security systems and eligible for classification under Executive Order 13526, will be classified as appropriate;

(B) Information regarding developing or current technology, the release of which could hinder the objectives of DHS, compromise a technological advantage or countermeasure, cause a denial of service, or provide an adversary with sufficient information to clone, counterfeit, or circumvent a process or system;

(viii) Operations Security Information means information that could constitute an indicator of U.S. Government intentions, capabilities, operations, or activities or otherwise threaten operations security;

(ix) Personnel Security Information means information that could result in physical risk to DHS personnel or other individuals that DHS is responsible for protecting;

(x) Physical Security Information means reviews or reports illustrating or disclosing facility infrastructure or security vulnerabilities related to the protection of Federal buildings, grounds, or property. For example, threat assessments, system security plans, contingency plans, risk management plans, business impact analysis studies, and certification and accreditation documentation;

(xi) Privacy Information, which includes information referred to as Personally Identifiable Information (PII). PII means information that can be used to distinguish or trace an individual's identity, either alone, or when combined with other information that is linked or linkable to a specific individual; and

(xii) Sensitive Personally Identifiable Information (SPII) is a subset of PII, which if lost, compromised, or disclosed without authorization, could result in substantial harm, embarrassment, inconvenience, or unfairness to an individual. Some forms of PII are sensitive as stand-alone elements.

(A) Examples of stand-alone SPII include: Social Security numbers (SSN), driver's license or state identification number, Alien

Registration Numbers (A-number), financial account number, and biometric identifiers such as fingerprint, voiceprint, or iris scan.

(B) Additional examples of SPII include any groupings of information that contain an individual's name or other unique identifier plus one or more of the following elements:

- (1) Truncated SSN (such as last 4 digits)
- (2) Date of birth (month, day, and year)
- (3) Citizenship or immigration status
- (4) Ethnic or religious affiliation
- (5) Sexual orientation
- (6) Criminal history
- (7) Medical information
- (8) System authentication information such as mother's maiden name, account passwords or personal identification numbers (PIN)

(C) Other PII may be SPII depending on its context, such as a list of employees and their performance ratings or an unlisted home address or phone number. In contrast, a business card or public telephone directory of agency employees contains PII but is not SPII.

“Federal information” means information created, collected, processed, maintained, disseminated, disclosed, or disposed of by or for the Federal Government, in any medium or form.

“Federal information system” means an information system used or operated by an agency or by a contractor of an agency or by another organization on behalf of an agency.

“Handling” means any use of controlled unclassified information, including but not limited to marking, safeguarding, transporting, disseminating, re-using, storing, capturing, and disposing of the information.

“Incident” means an occurrence that—

(i) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or

(ii) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies.

“Information Resources” means information and related resources, such as personnel, equipment, funds, and information technology.

“Information Security” means protecting information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction in order to provide—

(i) integrity, which means guarding against improper information modification or destruction, and includes ensuring information nonrepudiation and authenticity;

(ii) confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and

(iii) availability, which means ensuring timely and reliable access to and use of information.

“Information System” means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information.

(b) *Handling of Controlled Unclassified Information.*

(1) Contractors and subcontractors must provide adequate security to protect CUI

from unauthorized access and disclosure. Adequate security includes compliance with DHS policies and procedures in effect at the time of contract award. These policies and procedures are accessible at <http://www.dhs.gov/dhs-security-and-training-requirements-contractors>.

(2) The Contractor shall not use or redistribute any CUI handled, collected, processed, stored, or transmitted by the Contractor except as specified in the contract.

(3) The Contractor shall not maintain SPII in its invoicing, billing, and other recordkeeping systems maintained to support financial or other administrative functions. It is acceptable to maintain in these systems the names, titles and contact information for the Contracting Officer's Representative (COR) or other Government personnel associated with the administration of the contract, as needed.

(4) Any Government data provided, developed, obtained under the contract, or otherwise under the control of the contractor, shall not become part of the bankruptcy estate in the event a contractor and/or subcontractor enters into bankruptcy proceedings.

(c) *Authority to Operate*. This subsection is applicable only to Federal information systems, which includes contractor information systems operating on behalf of the agency. The Contractor shall not collect, process, store or transmit CUI within a Federal information system until an Authority to Operate (ATO) has been accepted and signed by the Component or Headquarters CIO, or designee. Once the ATO has been accepted and signed by the Government, the Contracting Officer shall incorporate the ATO into the contract as a compliance document. Unless otherwise specified in the ATO letter, the ATO is valid for three (3) years. An ATO is granted at the sole discretion of the Government and can be revoked at any time. Contractor receipt of an ATO does not create any contractual right of access or entitlement. The Government's acceptance of the ATO does not alleviate the Contractor's responsibility to ensure the information system controls are implemented and operating effectively.

(1) *Complete the Security Authorization process*. The Security Authorization (SA) process shall proceed according to *DHS Sensitive Systems Policy Directive 4300A* (Version 12.0, September 25, 2015), or any successor publication; *DHS 4300A Sensitive Systems Handbook* (Version 12.0, November 15, 2015), or any successor publication; and the *Security Authorization Process Guide* including templates. These policies and templates are accessible at <http://www.dhs.gov/dhs-security-and-training-requirements-contractors>.

(i) *Security Authorization Package*. SA package shall be developed using the Government provided Requirements Traceability Matrix and SA templates. SA package consists of the following: Security Plan, Contingency Plan, Contingency Plan Test Results, Configuration Management Plan, Security Assessment Plan, Security Assessment Report, and Authorization to Operate Letter. Additional documents that may be required include a Plan(s) of Action and Milestones and Interconnection Security

Agreement(s). The Contractor shall submit a signed copy of the SA package, validated by an independent third party, to the COR for acceptance by the Headquarters or Component CIO, or designee, at least thirty (30) days prior to the date of operation of the information system. The Government is the final authority on the compliance of the SA package and may limit the number of resubmissions of modified documents.

(ii) *Independent Assessment*. Contractors shall have an independent third party validate the security and privacy controls in place for the information system(s). The independent third party shall review and analyze the SA package, and report on technical, operational, and management level deficiencies as outlined in *NIST Special Publication 800-53 Security and Privacy Controls for Federal Information Systems and Organizations* accessible at <http://csrc.nist.gov/publications/PubsSPs.html>. The Contractor shall address all deficiencies before submitting the SA package to the COR for acceptance.

(2) *Renewal of ATO*. Unless otherwise specified in the ATO letter, the ATO shall be renewed every three (3) years. The Contractor is required to update its SA package as part of the ATO renewal process for review and verification of security controls. Review and verification of security controls is independent of the system production date and may include onsite visits that involve physical or logical inspection of the Contractor environment to ensure controls are in place. The updated SA package shall be submitted for acceptance by the Headquarters or Component CIO, or designee, at least 90 days before the ATO expiration date. The Contractor shall update its SA package by one of the following methods:

(i) Updating the SA package in the DHS Information Assurance Compliance System; or

(ii) Submitting the updated SA package directly to the COR.

(3) *Security Review*. The Government may elect to conduct random periodic reviews to ensure that the security requirements contained in this contract are being implemented and enforced. The Government, at its sole discretion, may obtain the assistance from other Federal agencies and/or third-party firms to aid in security review activities. The Contractor shall afford access to DHS, the Office of the Inspector General, other Government organizations, and contractors working in support of the Government access to the Contractor's facilities, installations, operations, documentation, databases, networks, systems, and personnel used in the performance of this contract. The Contractor shall, through the Contracting Officer and COR, contact the Headquarters or Component CIO, or designee, to coordinate and participate in review and inspection activity by Government organizations external to the DHS. Access shall be provided, to the extent necessary as determined by the Government (including providing all requested images), for the Government to carry out a program of inspection, investigation, and audit to safeguard against threats and hazards to the

integrity, availability and confidentiality of Government data or the function of computer systems used in performance of this contract and to preserve evidence of computer crime.

(4) *Federal Reporting and Continuous Monitoring Requirements*. Contractors operating information systems on behalf of the Government shall comply with Federal reporting and information system continuous monitoring requirements. Reporting requirements are determined by the Government and are defined in the Fiscal Year 2015 DHS Information Security Performance Plan, or successor publication, accessible at <http://www.dhs.gov/dhs-security-and-training-requirements-contractors>. The plan is updated on an annual basis. Annual, quarterly, and monthly data collection will be coordinated by the Government. The Contractor shall provide the Government with all information to fully satisfy Federal reporting requirements for information systems. The Contractor shall provide the COR with requested information within three (3) business days of receipt of the request. Unless otherwise specified in the contract, monthly continuous monitoring data shall be stored at the Contractor's location for a period not less than one year from the date the data is created. The Government may elect to perform information system continuous monitoring and IT security scanning of information systems from Government tools and infrastructure.

(d) *Incident Reporting Requirements*.

(1) All known or suspected incidents shall be reported to the Component Security Operations Center (SOC) in accordance with *4300A Sensitive Systems Handbook Attachment F Incident Response*. If the Component SOC is not available, the Contractor shall report to the DHS Enterprise SOC. Contact information for the DHS Enterprise SOC is accessible at <http://www.dhs.gov/dhs-security-and-training-requirements-contractors>. The Contractor shall also notify the Contracting Officer and COR using the contact information identified in the contract. If the report is made by phone, or the email address for the Contracting Officer or COR is not immediately available, the Contractor shall contact the Contracting Officer immediately after reporting to the Component or DHS Enterprise SOC. All known or suspected incidents involving PII or SPII shall be reported within one hour of discovery. All other incidents shall be reported within eight hours of discovery.

(2) The Contractor shall not include any CUI in the subject or body of any email. The Contractor shall transmit CUI using *FIPS 140-2 Security Requirements for Cryptographic Modules* compliant encryption methods, accessible at <http://csrc.nist.gov/groups/STM/cmvp/standards.html>, to protect CUI in attachments to email. Passwords shall not be communicated in the same email as the attachment.

(3) An incident shall not, by itself, be interpreted as evidence that the Contractor has failed to provide adequate information security safeguards for CUI, or has otherwise failed to meet the requirements of the contract.

(4) If an incident involves PII or SPII, in addition to the incident reporting guidelines in *4300A Sensitive Systems Handbook Attachment F Incident Response*, Contractors shall also provide as many of the following data elements that are available at the time the incident is reported, with any remaining data elements provided within 24 hours of submission of the initial incident report:

- (i) Data Universal Numbering System (DUNS);
- (ii) Contract numbers affected unless all contracts by the company are affected;
- (iii) Facility CAGE code if the location of the event is different than the prime contractor location;
- (iv) Point of contact (POC) if different than the POC recorded in the System for Award Management (address, position, telephone, email);
- (v) Contracting Officer POC (address, telephone, email);
- (vi) Contract clearance level;
- (vii) Name of subcontractor and CAGE code if this was an incident on a subcontractor network;
- (viii) Government programs, platforms or systems involved;
- (ix) Location(s) of incident;
- (x) Date and time the incident was discovered;
- (xi) Server names where CUI resided at the time of the incident, both at the Contractor and subcontractor level;
- (xii) Description of the Government PII or SPII contained within the system; and
- (xiii) Any additional information relevant to the incident.

(e) *Incident Response Requirements.*

(1) All determinations by the Department related to incidents, including response activities, notifications to affected individuals and/or Federal agencies, and related services (e.g., credit monitoring) will be made in writing by the Contracting Officer.

(2) The Contractor shall provide full access and cooperation for all activities determined by the Government to be required to ensure an effective incident response, including providing all requested images, log files, and event information to facilitate rapid resolution of incidents.

(3) Incident response activities determined to be required by the Government may include, but are not limited to, the following:

- (i) Inspections,
- (ii) Investigations,
- (iii) Forensic reviews,
- (iv) Data analyses and processing, and
- (v) Revocation of the Authority to Operate.

(4) The contractor shall preserve and protect images of known affected information systems identified in paragraph (b) of this section and all relevant monitoring/packet capture data for at least 90 days from submission of the incident report to allow DHS to request the media or decline interest.

(5) The Government, at its sole discretion, may obtain assistance from other Federal agencies and/or third-party firms to aid in incident response activities.

(f) *PII and SPII Notification Requirements.* This subsection is only applicable when an incident involves PII/SPII.

(1) The Contractor shall have in place procedures and the capability to notify any

individual whose PII and/or SPII was under the control of the Contractor or resided in the information system at the time of the incident not later than 5 business days after being directed to notify individuals, unless otherwise approved by the Contracting Officer. The method and content of any notification by the Contractor shall be coordinated with, and subject to prior written approval by the Contracting Officer utilizing the DHS Privacy Incident Handling Guidance accessible at <http://www.dhs.gov/dhs-security-and-training-requirements-contractors>. The Contractor shall not proceed with notification unless directed in writing by the Contracting Officer.

(2) Subject to Government analysis of the incident and the terms of its instructions to the Contractor regarding any resulting notification, the notification method may consist of letters to affected individuals sent by first class mail, electronic means, or general public notice, as approved by the Government. Notification may require the Contractor's use of address verification and/or address location services. At a minimum, the notification shall include:

- (i) A brief description of the incident;
- (ii) A description of the types of PII or SPII involved;
- (iii) A statement as to whether the PII or SPII was encrypted or protected by other means;
- (iv) Steps individuals may take to protect themselves;
- (v) What the Contractor and/or the Government are doing to investigate the incident, to mitigate the incident, and to protect against any future incidents; and
- (vi) Information identifying who individuals may contact for additional information.

(g) *Credit Monitoring Requirements.* This subsection is only applicable when an incident involves PII/SPII. In the event that an incident involves PII or SPII, the Contractor may be directed by the Contracting Officer to:

- (1) Provide notification to affected individuals as described in paragraph (f).
- (2) Provide credit monitoring services to individuals whose PII or SPII was under the control of the Contractor or resided in the information system at the time of the incident for a period beginning the date of the incident and extending not less than 18 months from the date the individual is notified. Credit monitoring services shall be provided from a company with which the Contractor has no affiliation. At a minimum, credit monitoring services shall include:

- (i) Triple credit bureau monitoring;
- (ii) Daily customer service;
- (iii) Alerts provided to the individual for changes and fraud; and
- (iv) Assistance to the individual with enrollment in the services and the use of fraud alerts.

(3) Establish a dedicated call center. Call center services shall include:

- (i) A dedicated telephone number to contact customer service within a fixed period;
- (ii) Information necessary for registrants/enrollees to access credit reports and credit scores;

(iii) Weekly reports on call center volume, issue escalation (i.e., those calls that cannot be handled by call center staff and must be resolved by call center management or DHS, as appropriate), and other key metrics;

(iv) Escalation of calls that cannot be handled by call center staff to call center management or DHS, as appropriate;

(v) Customized Frequently Asked Questions, approved in writing by the Contracting Officer in coordination with the Headquarters or Component Privacy Officer; and

(vi) Information for registrants to contact customer service representatives and fraud resolution representatives for credit monitoring assistance.

(h) *Certificate of Sanitization of Government and Government-Activity-Related Files and Information.* Upon the conclusion of the contract by expiration, termination, cancellation, or as otherwise indicated in the contract, the Contractor shall return all CUI to DHS and/or destroy it physically and/or logically as identified in the contract. Destruction shall conform to the guidelines for media sanitization contained in *NIST SP-800-88, Guidelines for Media Sanitization*. The Contractor shall certify and confirm the sanitization of all Government and Government-Activity related files and information. The Contractor shall submit the certification to the COR and Contracting Officer following the template provided in *NIST Special Publication 800-88, Guidelines for Media Sanitization, Appendix G*.

(i) *Other Reporting Requirements.* Incident reporting required by this clause in no way rescinds the Contractor's responsibility for other incident reporting pertaining to its unclassified information systems under other clauses that may apply to its contract(s), or as a result of other applicable U.S. Government statutory or regulatory requirements.

(j) *Subcontracts.* The Contractor shall insert this clause in all subcontracts and require subcontractors to include this clause in all lower-tier subcontracts.

(End of clause)

■ 7. Amend paragraph (b) of section 3052.212-70 to remove 3052.204-70 Security Requirements for Unclassified Information Technology Resources; add Alternate II of 3052.204-71, Contractor Employee Access; and add 3052.204-7X, Safeguarding of Controlled Unclassified Information, as follows:

3052.212-70 Contract terms and conditions applicable to DHS acquisition of commercial items.

Contract Terms and Conditions Applicable to DHS Acquisition of Commercial Items (Date)

* * * * *

(b) * * *
 ___ 3052.204-71 Contractor Employee Access.

___ Alternate I

___ Alternate II

* * * * *

3052.204–7X Safeguarding of Controlled Unclassified Information.

Soraya Correa,

Chief Procurement Officer, Department of Homeland Security.

[FR Doc. 2017–00758 Filed 1–18–17; 8:45 am]

BILLING CODE 9110–9B–P

DEPARTMENT OF HOMELAND SECURITY

48 CFR Parts 3001, 3002, 3039, and 3052

[Docket No. DHS–2017–0007]

RIN 1601–AA78

Homeland Security Acquisition Regulation (HSAR); Information Technology Security Awareness Training (HSAR Case 2015–002)

AGENCY: Office of the Chief Procurement Officer, Department of Homeland Security (DHS).

ACTION: Proposed rule.

SUMMARY: DHS is proposing to amend the Homeland Security Acquisition Regulation (HSAR) to add a new subpart, update an existing clause, and add a new contract clause to standardize information technology security awareness training and DHS Rules of Behavior requirements for contractor and subcontractor employees who access DHS information systems and information resources or contractor-owned and/or operated information systems and information resources capable of collecting, processing, storing or transmitting controlled unclassified information (CUI).

DATES: Interested parties should submit written comments to one of the addresses shown below on or before March 20, 2017, to be considered in the formation of the final rule.

ADDRESSES: Submit comments identified by HSAR Case 2015–002, Information Technology Security Awareness Training, using any of the following methods:

- *Regulations.gov:* <http://www.regulations.gov>.

Submit comments via the Federal eRulemaking portal by entering “HSAR Case 2015–002” under the heading “Enter Keyword or ID” and selecting “Search.” Select the link “Submit a Comment” that corresponds with “HSAR Case 2015–002.” Follow the instructions provided at the “Submit a Comment” screen. Please include your name, company name (if any), and “HSAR Case 2015–002” on your attached document.

- *Fax:* (202) 447–0520.

• *Mail:* Department of Homeland Security, Office of the Chief Procurement Officer, Acquisition Policy and Legislation, ATTN: Ms. Shaundra Duggans, 245 Murray Drive, Bldg. 410 (RDS), Washington, DC 20528.

Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Shaundra Duggans, Procurement Analyst, DHS, Office of the Chief Procurement Officer, Acquisition Policy and Legislation at (202) 447–0056 or email HSAR@hq.dhs.gov. When using email, include HSAR Case 2015–002 in the “Subject” line.

SUPPLEMENTARY INFORMATION:

I. Background

DHS contracts currently require contractor and subcontractor employees to complete information technology (IT) security awareness training before accessing DHS information systems and information resources. This training is initially completed upon award of the procurement and at least annually thereafter. DHS contracts also require such employees to sign the DHS Rules of Behavior (RoB) before access is provided to DHS information systems and information resources. The DHS RoB is a document that defines the responsibilities and obligations imposed on all individuals with access to DHS information systems and information resources. The DHS RoB holds users accountable for actions taken while accessing DHS information systems and using DHS information resources capable of collecting, processing, storing or transmitting controlled unclassified information (CUI).

DHS is proposing to (1) include IT security awareness training and RoB requirements in the HSAR and (2) make the training and RoB more easily accessible by hosting them on a public Web site. This approach ensures all applicable DHS contractors and subcontractors are subject to the same IT security awareness training and RoB requirements while removing the need for Government intervention to provide access to the IT security awareness training and RoB.

This rule proposes to standardize the IT security awareness training and DHS RoB requirements across DHS contracts by amending the HSAR to:

(1) Add the terms “controlled unclassified information,” “information resources” and “information system” to HSAR 3002.1, Definitions and remove the definition of the term “sensitive information” at HSAR 3002.1, Definitions. The definition of “controlled unclassified information” is taken from its implementing regulation at 32 CFR part 2002. The definitions of “information resources” and “information system” are derived from 44 U.S.C. 3502(6) and 44 U.S.C. 3502(8) respectively. The definition of “sensitive information” is removed because it is being replaced with “controlled unclassified information” consistent with Executive Order 13556 and its implementing regulation at 32 CFR part 2002. These definitions are necessary because these terms appear in proposed HSAR 3039.70 Information Technology Security Awareness Training and HSAR 3052.239–7X, Information Technology Security Awareness Training.

(2) Add a new subpart at 3039.70, Information Technology Security Awareness Training. HSAR 3039.7001, Scope, identifies the applicability of the subpart to contracts and subcontracts where contractor and subcontractor employees may have access to DHS information systems and information resources or contractor-owned and/or operated information systems and information resources capable of collecting, processing, storing or transmitting CUI. HSAR 3039.7002, Policy, subparagraph (a) requires contractors and subcontractors that may have access to DHS information systems and information resources or contractor-owned and/or operated information systems and information resources capable of collecting, processing, storing or transmitting CUI to complete IT security awareness training initially upon award of the procurement and annually thereafter. This subsection requires the contractor to maintain evidence that the training has been completed and provide copies of the training completion certificates to the contracting officer. Subparagraph (b) requires contractor and subcontractor employees to sign the DHS RoB before receiving access to DHS information systems and/or information resources and before contractor-owned and/or operated information systems can be used to collect, process, store, or transmit CUI. This subsection requires the contractor to maintain signed copies of the DHS RoB and provide signed copies to the contracting officer. HSAR 3039.7003, Contract Clause, identifies when contracting officers must insert

HSAR 3052.239–7X, Information Technology Security Awareness Training, in solicitations and contracts.

(3) Amend subparagraph (b) of the clause at HSAR 3052.212–70, Contract Terms and Conditions Applicable to DHS Acquisition of Commercial Items, to add HSAR 3052.239–7X Information Technology Security Awareness Training. This change is necessary because HSAR 3052.239–7X is applicable to the acquisition of commercial items.

(4) Add a new subsection at HSAR 3052.239–7X, Information Technology Security Awareness Training, to provide the text of the proposed clause. The proposed clause requires contractor and subcontractor employees to complete IT security awareness training before accessing DHS information systems/information resources and before contractor-owned and/or operated information systems are used to collect, process, store, or transmit CUI. Training shall be completed within thirty (30) days of contract award and on an annual basis thereafter. The contractor shall maintain copies of training certificates for all contractor and subcontractor employees as a record of compliance and provide copies of the training certificates to the contracting officer. Subsequent training certificates to satisfy the annual IT security awareness training requirement shall be submitted via email notification not later than October 31st of each year. The contractor shall attach training certificates to the email notification and the email notification shall state the required training has been completed for all contractor and subcontractor employees. The proposed clause also requires the contractor to ensure all employees and subcontractor employees sign the DHS RoB before accessing DHS information systems and information resources. The DHS RoB shall also be signed before a contractor-owned and/or operated information system or information resource can be used to collect, process, store or transmit CUI and before contractor and/or subcontractor employees can access the information system or information resource. The contractor shall maintain signed copies of the DHS RoB for all contractor and subcontractor employees as a record of compliance and provide signed copies of the RoB to the contracting officer not later than thirty (30) days after contract award.

These proposed revisions to the HSAR are necessary to ensure contractors and subcontractors understand their roles and responsibilities in ensuring the security of systems and the confidentiality,

integrity, and availability of CUI. They are consistent with the provisions of (1) the Federal Information Security Modernization Act of 2014 (FIMSA) (44 U.S.C. 3551, *et seq.*) and (2) Title 5, Code of Federal Regulations, Part 930, Subpart C, (5 CFR 930.301). 44 U.S.C. 3554(b)(4) requires agencies to provide security awareness training to inform personnel, including contractors and other users of information systems that support the operations and assets of the agency, of information security risks associated with their activities; and their responsibilities in complying with agency policies and procedures designed to reduce these risks. 5 CFR 930.301 requires all users of Federal information systems be exposed to security awareness materials at least annually. Users of Federal information systems include employees, contractors, students, guest researchers, visitors, and others who may need access to Federal information systems and applications.

This proposed rule is part of a broader initiative within DHS to (1) ensure contractors understand their responsibilities with regard to safeguarding controlled unclassified information (CUI); (2) contractor and subcontractor employees complete information technology (IT) security awareness training before access is provided to DHS information systems and information resources or contractor-owned and/or operated information systems and information resources where CUI is collected, processed, stored or transmitted on behalf of the agency; (3) contractor and subcontractor employees sign the DHS RoB before access is provided to DHS information systems, information resources, or contractor-owned and/or operated information systems and information resources where CUI is collected, processed, stored or transmitted on behalf of the agency; and (4) contractor and subcontractor employees complete privacy training before accessing a Government system of records; handling personally identifiable information (PII) and/or sensitive PII information; or designing, developing, maintaining, or operating a system of records on behalf of the Government.

II. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563

emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, is subject to review under Section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804. DHS has included a discussion of the estimated costs and benefits of this rule in the Paperwork Reduction Act supporting statement, which can be found in the docket for this rulemaking.

III. Regulatory Flexibility Act

DHS expects this proposed rule may have an impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because the proposed rule requires contractor and subcontractor employees who will need access to DHS information systems and information resources or contractor-owned and/or operated information systems and information resources capable of collecting, processing, storing or transmitting controlled unclassified information (CUI) to be properly trained on the requirements, applicable laws, and appropriate safeguards designed to ensure the security and confidentiality of the information systems and information resources. Therefore, an Initial Regulatory Flexibility Analysis (IRFA) has been prepared consistent with 5 U.S.C. 603, and is summarized as follows:

1. Description of the Reasons Why Action by the Agency Is Being Taken

DHS is proposing to amend the HSAR to require that all contractor and subcontractor employees who will need access to DHS information systems and information resources or contractor-owned and/or operated information systems and information resources capable of collecting, processing, storing or transmitting CUI complete IT security awareness training and sign the DHS RoB before access to such systems and resources is granted. The purpose of this action is to require contractors to identify its employees who require access, ensure that those employees complete IT security awareness training before being granted access and annually thereafter, provide the Government evidence of the completed training, and maintain evidence of completed training in accordance with the records retention requirements of the contract.

2. Succinct Statement of the Objectives of, and Legal Basis for, the Rule.

The objective of this proposed rule is to require contractor and subcontractor employees to complete IT security awareness training before access is granted to DHS information systems and information resources or contractor-owned and/or operated information systems and information resources capable of collecting, processing, storing or transmitting CUI.

The training imposed by this rule is required by the provisions of FISMA (44 U.S.C. 3551, *et seq.*) and Title 5, Code of Federal Regulations, Part 930, Subpart C, (5 CFR 930.301). 44 U.S.C. 3554(b)(4) requires agencies to provide security awareness training to inform personnel, including contractors and other users of information systems that support the operations and assets of the agency, of information security risks associated with their activities; and their responsibilities in complying with agency policies and procedures designed to reduce these risks. 5 CFR 930.301 requires all users of Federal information systems be exposed to security awareness materials at least annually.

3. Description of and, Where Feasible, Estimate of the Number of Small Entities To Which the Rule Will Apply

This proposed rule will apply to contractor and subcontractor employees who require access to DHS information systems and information resources or contractor-owned and/or operated information systems and information resources capable of collecting, processing, storing or transmitting CUI. The estimated number of small entities to which the rule will apply is 2,185 respondents of which 1,212 are projected to be small businesses.

This estimate is based on a review and analysis of internal DHS contract data and Fiscal Year (FY) 2014 data reported to the Federal Procurement Data System (FPDS). It is anticipated that this rule will be primarily applicable to procurement actions with a Product and Service Code (PSC) of "D" Automatic Data Processing and Telecommunication. PSCs will be adjusted as additional data becomes available through HSAR clause implementation to validate future burden projections.

4. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Rule, Including an Estimate of the Classes of Small Entities Which Will Be Subject to the Requirement and the Type of Professional Skills Necessary

The projected reporting and recordkeeping associated with this proposed rule is kept to the minimum necessary to meet the overall objectives. For instance, DHS has minimized the burden by making the IT security awareness training and DHS RoB publicly accessible at <http://www.dhs.gov/dhs-security-and-training-requirements-contractors>. IT security awareness training shall be completed within thirty (30) days of contract award and on an annual basis thereafter. Training certificates are automatically generated at the conclusion of the training. The DHS RoB shall be signed before contractor and subcontractor employees can access DHS information systems and information. The DHS RoB shall also be signed before a contractor-owned and/or operated information system or information resource can be used to collect, process, store or transmit CUI and before contractor and/or subcontractor employees can access the information system. Initial training certificates for each contractor and subcontractor employee, and signed copies of the RoB, shall be provided to the Government not later than thirty (30) days after contract award. Subsequent training certificates to satisfy the annual IT security awareness training requirement shall be submitted via email notification not later than October 31st of each year. The contractor shall attach training certificates to the email notification and the email notification shall state the required training has been completed for all contractor and subcontractor employees.

5. Identification, to the Extent Practicable, of All Relevant Federal Rules Which May Duplicate, Overlap, or Conflict With the Rule

There are no rules that duplicate, overlap or conflict with this rule.

6. Description of Any Significant Alternatives to the Rule Which Accomplish the Stated Objectives of Applicable Statutes and Which Minimize Any Significant Economic Impact of the Rule on Small Entities

There are no practical alternatives that will accomplish the objectives of the proposed rule. In an effort to reduce duplication and to address common IT security training requirements across

Government, DHS has partnered with the Defense Information Systems Agency (DISA) to provide its online IT security awareness training, CyberAwareness Challenge, for DHS contractor and subcontractor employees. Common IT security awareness training provides a streamlined, efficient, and cost-effective solution for DHS to provide IT security awareness training for contractor and subcontractor employees.

DHS will be submitting a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the IRFA may be obtained from the point of contact specified herein. DHS invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DHS will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610, (HSAR Case 2015-002), in correspondence.

IV. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) applies because this proposed rule contains information collection requirements. Accordingly, DHS will be submitting a request for approval of a new information collection requirement concerning this rule to the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

A. Public reporting burden for this collection of information is estimated to be approximately 30 minutes (.50 hours) per response to comply with the requirements, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The total annual projected number of responses per respondent is estimated to be four (4). The annual total burden hours are estimated as follows:

Title: Homeland Security Acquisition Regulation: Information Technology Security Awareness Training.

Type of Request: New Collection.

Number of Respondents: 2,185.

Responses per Respondent: 4.

Annual Responses: 8,740.

Average Burden per Response:

Approximately 0.50.

Annual Burden Hours: 4,370.

Needs and Uses: DHS needs the information required by 3052.239-7X, Information Technology Security Awareness Training, to properly track contractor compliance with the training

and DHS RoB requirements identified in the clause.

Affected Public: Businesses or other for-profit institutions.

Respondent's Obligation: Required to obtain or retain benefits.

Frequency: Upon award of procurement and annually thereafter.

B. Request for Comments Regarding Paperwork Burden.

You may submit comments identified by DHS docket number [DHS–2017–0007], including suggestions for reducing this burden, not later than March 20, 2017 using any one of the following methods:

(1) Via the internet at Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

(2) Via email to the Department of Homeland Security, Office of the Chief Procurement Officer, at HSAR@hq.dhs.gov.

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the HSAR, and will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Requesters may obtain a copy of the supporting statement from the Department of Homeland Security, Office of the Chief Procurement Officer, Acquisition Policy and Legislation, via email to HSAR@hq.dhs.gov. Please cite OMB Control No. 1600–0022, Privacy Training and Information Technology Security Awareness Training, in the “Subject” line.

List of Subjects in 48 CFR Parts 3001, 3002, 3039 and 3052

Government procurement.

Therefore, DHS proposes to amend 48 CFR parts 3001, 3002, 3039 and 3052 as follows:

■ 1. The authority citation for parts 3001 and 3002 is revised to read as follows:

Authority: 5 U.S.C. 301–302, 41 U.S.C. 1707, 41 U.S.C. 1702, 41 U.S.C. 1303(a)(2), 48 CFR part 1, subpart 1.3, and DHS Delegation Number 0702.

PART 3001—FEDERAL ACQUISITION REGULATIONS SYSTEM

■ 2. In section 3001.106 amend paragraph (a) by adding a new OMB Control Number as follows:

3001.106 OMB Approval under the Paperwork Reduction Act.

(a) * * *

OMB Control No. 1600–0022

(Information Technology Security Awareness Training)

* * * * *

PART 3002—DEFINITIONS OF WORDS AND TERMS

■ 3. Amend section 3002.101 by adding, in alphabetical order, the definitions for Controlled Unclassified Information (CUI), “Information Resources,” and “Information System” to read as follows:

* * * * *

“Controlled Unclassified Information (CUI)” is any information the Government creates or possesses, or an entity creates or possesses for or on behalf of the Government (other than classified information) that a law, regulation, or Government-wide policy requires or permits an agency to handle using safeguarding or dissemination controls. Within the context of DHS, this includes such information which, if lost, misused, disclosed, or, without authorization is accessed, or modified, could adversely affect the national or homeland security interest, the conduct of Federal programs, or the privacy of individuals. This definition includes the following CUI categories and subcategories of information:

(1) Chemical-terrorism Vulnerability Information (CVI) as defined in Title 6, Code of Federal Regulations, part 27 “Chemical Facility Anti-Terrorism Standards,” and as further described in supplementary guidance issued by an authorized official of the Department of Homeland Security (including the Revised Procedural Manual “Safeguarding Information Designated as Chemical-Terrorism Vulnerability Information” dated September 2008);

(2) Protected Critical Infrastructure Information (PCII) as set out in the Critical Infrastructure Information Act of 2002 (Title II, Subtitle B, of the Homeland Security Act, Public Law 107–296, 196 Stat. 2135), as amended, the implementing regulations thereto (Title 6, Code of Federal Regulations, part 29) as amended, the applicable PCII Procedures Manual, as amended, and any supplementary guidance officially communicated by an authorized official of the Department of Homeland Security

(including the PCII Program Manager or his/her designee);

(3) Sensitive Security Information (SSI) as defined in Title 49, Code of Federal Regulations, part 1520, “Protection of Sensitive Security Information,” as amended, and any supplementary guidance officially communicated by an authorized official of the Department of Homeland Security (including the Assistant Secretary for the Transportation Security Administration or his/her designee) to include DHS MD 11056.1, “Sensitive Security Information (SSI)” and, within the Transportation Security Administration, TSA MD 2010.1, “SSI Program”;

(4) Homeland Security Agreement Information means information DHS receives pursuant to an agreement with state, local, tribal, territorial, and private sector partners that is required to be protected by that agreement. DHS receives this information in furtherance of the missions of the Department, including, but not limited to, support of the Fusion Center Initiative and activities cyber information sharing consistent with the Cybersecurity Information Security Act;

(5) Homeland Security Enforcement Information means unclassified information of a sensitive nature lawfully created, possessed, or transmitted by the Department of Homeland Security in furtherance of its immigration, customs, and other civil and criminal enforcement missions, the unauthorized disclosure of which could adversely impact the mission of the Department;

(6) International Agreement Information means information DHS receives pursuant to an information sharing agreement or arrangement, with a foreign government, an international organization of governments or any element thereof, an international or foreign public or judicial body, or an international or foreign private or non-governmental organization, that is required by that agreement or arrangement to be protected;

(7) Information Systems Vulnerability Information (ISVI) means:

(i) DHS information technology (IT) internal systems data revealing infrastructure used for servers, desktops, and networks; applications name, version and release; switching, router, and gateway information; interconnections and access methods; mission or business use/need. Examples of information are systems inventories and enterprise architecture models. Information pertaining to national security systems and eligible for

classification under Executive Order 13526, will be classified as appropriate;

(ii) Information regarding developing or current technology, the release of which could hinder the objectives of DHS, compromise a technological advantage or countermeasure, cause a denial of service, or provide an adversary with sufficient information to clone, counterfeit, or circumvent a process or system;

(8) Operations Security Information means information that could constitute an indicator of U.S. Government intentions, capabilities, operations, or activities or otherwise threaten operations security;

(9) Personnel Security Information means information that could result in physical risk to DHS personnel or other individuals that DHS is responsible for protecting;

(10) Physical Security Information means reviews or reports illustrating or disclosing DHS facility infrastructure or security vulnerabilities related to the protection of Federal buildings, grounds, or property. For example, threat assessments, system security plans, contingency plans, risk management plans, business impact analysis studies, and certification and accreditation documentation;

(11) Privacy Information, which includes information referred to as Personally Identifiable Information (PII). PII means information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual; and

(12) Sensitive Personally Identifiable Information (SPII) is a subset of PII, which if lost, compromised or disclosed without authorization, could result in substantial harm, embarrassment, inconvenience, or unfairness to an individual. Some forms of PII are sensitive as stand-alone elements.

(i) Examples of stand-alone PII include: Social Security numbers (SSN), driver's license or state identification number, Alien Registration Numbers (A-number), financial account number, and biometric identifiers such as fingerprint, voiceprint, or iris scan.

(ii) Additional examples of SPII include any groupings of information that contain an individual's name or other unique identifier plus one or more of the following elements:

- (A) Truncated SSN (such as last 4 digits)
- (B) Date of birth (month, day, and year)
- (C) Citizenship or immigration status
- (D) Ethnic or religious affiliation
- (E) Sexual orientation
- (F) Criminal history
- (G) Medical information

(H) System authentication information such as mother's maiden name, account passwords or personal identification numbers (PIN)

(iii) Other PII may be SPII depending on its context, such as a list of employees and their performance ratings or an unlisted home address or phone number. In contrast, a business card or public telephone directory of agency employees contains PII but is not SPII.

* * * * *

"Information Resources" means information and related resources, such as personnel, equipment, funds, and information technology.

"Information System" means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information.

* * * * *

■ 4. Revise part 3039 to read as follows:

PART 3039—ACQUISITION OF INFORMATION TECHNOLOGY

Subpart 3039.70—Information Technology Security Awareness Training

- 3039.7001 Scope.
- 3039.7002 Policy.
- 3039.7003 Contract Clause.

Authority: 5 U.S.C. 301–302, 41 U.S.C. 1707, 41 U.S.C. 1702, 41 U.S.C. 1303(a)(2), 48 CFR part 1, subpart 1.3, and DHS Delegation Number 0702.

3039.7001 Scope.

This section applies to contracts and subcontracts where contractor and subcontractor employees may have access to DHS information systems and information resources or contractor-owned and/or operated information systems and information resources capable of collecting, processing, storing or transmitting controlled unclassified (CUI) information.

3039.7002 Policy.

(a) Contractors and subcontractors that may have access to DHS information systems and information resources or contractor-owned and/or operated information systems and information resources capable of collecting, processing, storing or transmitting CUI shall take IT security awareness training initially upon award of the procurement and annually thereafter. The contractor shall ensure such employees complete the required training, maintain evidence that the training has been completed and provide copies of the training

completion certificates to the Contracting Officer and/or Contracting Officer's Representative (COR) for inclusion in the contract file.

(b) The DHS Rules of Behavior (RoB) is a document that informs users of their responsibilities and obligations when accessing DHS information systems and/or information resources. The RoB also informs users that they will be held accountable for actions taken while accessing DHS information systems and/or using DHS information resources. Contractor and subcontractor employees shall sign the DHS RoB before receiving access to DHS information systems and/or information resources. In addition, contractor and subcontractor employees shall sign the DHS RoB before a contractor-owned and/or operated information system or information resource can be used to collect, process, store or transmit CUI. The contractor shall maintain signed copies of the DHS RoB for all contractor and subcontractor employees as a record of compliance, in accordance with the records retention requirements of the contract, and provide signed copies of the DHS RoB to the Contracting Officer and/or COR for inclusion in the contract file.

3039.7003 Contract Clause.

Contracting officers shall insert the clause at (HSAR) 48 CFR 3052.239–7X, Information Technology Security Awareness Training, in solicitations and contracts where contractor and subcontractor employees, during the course of performance, may gain access to DHS information systems and information resources or contractor-owned and/or operated information systems and information resources capable of collecting, processing, storing or transmitting CUI.

PART 3052—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 5. The authority citation for part 3052 is revised to read as follows:

Authority: 5 U.S.C. 301–302, 41 U.S.C. 1707, 41 U.S.C. 1702, 41 U.S.C. 1303(a)(2), 48 CFR part 1, subpart 1.3, and DHS Delegation Number 0702. Clause 3052.212–70 [Amended]

■ 6. Amend paragraph (b) of section 3052.212–70 to add 3052.239–7X Information Technology Security Awareness Training as follows:

3052.212–70 Contract terms and conditions applicable to DHS acquisition of commercial items.

Contract Terms And Conditions Applicable To Dhs Acquisition Of Commercial Items (Date)

* * * * *

(b) * * *

3052.239–7X Information Technology Security Awareness Training

■ 7. Amend part 3052 by adding section 3052.239–7X to read as follows:

3052.239–7X Information technology security awareness training.

As prescribed in (HSAR) 48 CFR 3039.7004 contract clause, insert the following clause:

Information Technology Security Awareness Training (Date)

(a) *Information Technology Security Awareness Training.* The Contractor shall ensure that all employees and subcontractor employees complete information technology (IT) security awareness training before access is provided to DHS information systems and information resources. The Contractor shall also ensure that employees and subcontractor employees complete IT security awareness training before a contractor-owned and/or operated information system or information resource can be used to collect, process, store or transmit controlled unclassified information (CUI). Training shall be completed within thirty (30) days of contract award and be completed on an annual basis thereafter not later than October 31st of each year. Any new Contractor employees and subcontractor employees assigned to the contract shall complete the training before accessing DHS information systems and information resources or contractor-owned and/or operated information systems and information resources capable of collecting, processing, storing or transmitting CUI under the contract. IT security awareness training is accessible at <http://www.dhs.gov/dhs-security-and-training-requirements-contractors>. The Contractor shall maintain copies of training certificates for all Contractor and subcontractor employees as a record of compliance. Initial training certificates for each Contractor and subcontractor employee shall be provided to the Contracting Officer and/or Contracting Officer's Representative (COR) not later than thirty (30) days after contract award or assignment to the contract. Subsequent training certificates to satisfy the annual IT security awareness training requirement shall be submitted to the Contracting Officer and/or COR via email notification not later than October 31st of each year. The Contractor shall attach training certificates to the email notification and the email notification shall list all Contractor and subcontractor employees required to take the training and state the required IT security awareness training has been completed for all Contractor and subcontractor employees.

(b) *Rules of Behavior.* The Contractor shall ensure that all employees and subcontractor

employees sign the DHS Rules of Behavior (RoB) before access is provided to DHS information systems and information resources. The Contractor shall also ensure that employees and subcontractor employees sign the DHS RoB before a contractor-owned and/or operated information system or information resource can be used to collect, process, store or transmit CUI and before access to the contractor-owned and/or operated information system or information resource is provided to the employee. The RoB shall be signed within thirty (30) days of contract award. Any new Contractor employees and subcontractor employees assigned to the contract shall also sign the DHS RoB before accessing DHS information systems and information resources or contractor-owned and/or operated information systems and information resources capable of collecting, processing, storing or transmitting CUI. The DHS RoB is accessible at <http://www.dhs.gov/dhs-security-and-training-requirements-contractors>. The Contractor shall maintain signed copies of the DHS RoB for all Contractor and subcontractor employees as a record of compliance. Signed copies of the RoB shall be provided to the Contracting Officer and/or COR not later than thirty (30) days after contract award or assignment to the contract. The DHS RoB will be reviewed annually and the COR will provide notification when a review is required.

(c) *Subcontracts.* The Contractor shall insert this clause in all subcontracts and require subcontractors to include this clause in all lower-tier subcontracts.

(End of clause)

Soraya Correa,

Chief Procurement Officer, Department of Homeland Security.

[FR Doc. 2017–00754 Filed 1–18–17; 8:45 am]

BILLING CODE 9110–9B–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 174

[Docket No. PHMSA–2016–0015 (HM–263)]

RIN 2137–AF21

Hazardous Materials: FAST Act Requirements for Real-Time Train Consist Information by Rail

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Advance notice of proposed rulemaking (ANPRM).

SUMMARY: PHMSA requests comment on certain provisions of the Fixing America's Surface Transportation (FAST) Act of 2015. The FAST Act directs the Secretary of Transportation to require Class I railroads that transport

hazardous materials to generate accurate, real-time, and electronic train consist information. Further, the FAST Act includes provisions for the railroads to provide fusion centers with electronic train consist information to share with State and local first responders, emergency response officials, and law enforcement personnel during an accident, incident, or emergency. In support of developing regulations to implement the FAST Act mandates, PHMSA specifically requests comments and information on baseline changes, affected entities, and costs and benefits related to fusion centers collecting train consist information from railroads and disseminating this information in the event of an emergency.

DATES: Comments must be received by April 19, 2017.

ADDRESSES: You may submit comments identified by Docket No. PHMSA–2016–0015 (HM–263) by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 1–202–493–2251.

- *Mail:* Docket Management System; U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, Routing Symbol M–30, 1200 New Jersey Avenue SE., Washington, DC 20590.

- *Hand Delivery:* To the Docket Management System; Room W12–140 on the ground floor of the West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: All submissions must include the agency name and docket number for this ANPRM at the beginning of the comment. To avoid duplication, please use only one of these four methods. All comments received will be posted without change to the Federal Docket Management System (FDMS), including any personal information.

Docket: For access to the dockets to read background documents or comments received, go to <http://www.regulations.gov> or DOT's Docket Operations Office (see **ADDRESSES**).

Privacy Act: Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the document (or signing the document, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** (See 65 FR 19477, April 11, 2000), or you may visit <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Dirk Der Kinderen, (202) 366-4460, Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590-0001.

SUPPLEMENTARY INFORMATION:

Abbreviations and Terms

ANPRM Advance Notice of Proposed Rulemaking
 CFR Code of Federal Regulations
 DHS Department of Homeland Security
 DOJ Department of Justice
 DOT Department of Transportation
 EOC Emergency Operations Center
 FAST Act Fixing America's Surface Transportation Act of 2015
 FDMS Federal Docket Management System
 FR Federal Register
 Fusion Center State and Major Urban Area Fusion Center
 HHFT High-Hazard Flammable Liquid Train
 HMR Hazardous Materials Regulations
 IT Information Technology
 MOU Memorandum of Understanding
 NPRM Notice of Proposed Rulemaking
 O&M Operations and Management
 PHMSA Pipeline and Hazardous Materials Safety Administration
 RIA Regulatory Impact Analysis
 RIN Regulation Identifier Number
 SAR Suspicious Activity Reporting
 SERC State Emergency Response Commission
 U.S.C. United States Code

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I. Background

A. FAST Act

On December 4, 2015, President Barack Obama signed legislation titled, "Fixing America's Surface Transportation Act of 2015," or the "FAST Act." (See Pub. L. 114-94.) The FAST Act includes the "Hazardous Materials Transportation Safety Improvement Act of 2015" (sections 7001 through 7311), which instructs the Secretary of Transportation ("Secretary") to make specific regulatory amendments to the Hazardous Materials Regulations (HMR; 49 CFR parts 171-180). The FAST Act requires Class I railroads to generate accurate, real-time, and electronic train consist information that can be provided "to State and local first responders,

emergency response officials, and law enforcement personnel that are involved in the response to or investigation of an accident, incident, or public health or safety emergency involving the rail transportation of hazardous materials" and request such electronic train consist information. Section 7302 of the FAST Act is structured as follows:

- Section 7302(a)(1), (2), (5), and (7) apply to the sharing of the accurate, real-time, and electronic train consist information covering all hazardous materials with fusion centers.
- Section 7302(a)(3) and (4) apply to sharing advance notification and information on high-hazard flammable trains (HHFTs) with State Emergency Response Commissions (SERCs) in accordance with Emergency Order DOT-OST-2014-0067.
- Section 7302(a)(6) establishes security and confidentiality protections to prevent the public release of security-sensitive electronic train consist information or the advance notification of HHFT movements to unauthorized persons.

PHMSA intends to publish a notice of proposed rulemaking (NPRM) that will propose regulations to address §§ 7302(a)(1), (2), (5), (6) and (7) of the FAST Act. PHMSA is addressing the SERC notification portion of the FAST Act (§§ 7302(a)(3), (4) and (6)) in a separate rulemaking titled "Hazardous Materials: Oil Spill Response Plans and Information Sharing for High-Hazard Flammable Trains" (RIN: 2137-AF08).¹ Sections 7302(a)(1), (2), (5), (6), and (7) of the FAST Act are discussed in greater detail as follows.

Section 7302(a)(1)(A) directs the Secretary to issue regulations requiring Class I railroads transporting hazardous materials to generate accurate, real-time, and electronic train consist information, including:

- The identity, quantity, and location of hazardous materials on a train;
- The point of origin and destination of the train;
- Any emergency response information or resources required by the Secretary; and
- An emergency response point of contact designated by the Class I railroad.

Subparagraph (a)(1)(B) further directs the Secretary to issue regulations requiring Class I railroads to enter into a memorandum of understanding (MOU) with each applicable fusion center to provide the fusion center with secure and confidential access to the

electronic train consist information for each train transporting hazardous materials in the jurisdiction of the fusion center.

Section 7302(a)(2) directs the Secretary to issue regulations requiring each applicable fusion center to provide the electronic train consist information to State and local first responders, emergency response officials, and law enforcement personnel who are involved in the response to or investigation of an accident, incident, or public health or safety emergency involving the rail transportation of hazardous materials and request such electronic train consist information.

Section 7302(a)(5) directs the Secretary to issue regulations prohibiting any Class I railroad, employee, or agent from withholding, or causing to be withheld, the train consist information from first responders, emergency response officials, and law enforcement personnel described in § 7302(a)(2) in the event of an incident, accident, or public health or safety emergency involving the rail transportation of hazardous materials.

Section 7302(a)(6) directs the Secretary to issue regulations establishing security and confidentiality protections, including protections from the public release of proprietary information or security-sensitive information, to prevent the release of real-time train consist information to unauthorized persons.

Section 7302(a)(7) instructs the Secretary to issue regulations allowing each Class I railroad to enter into an MOU with any Class II railroad or Class III railroad that operates trains over the Class I railroad's line to incorporate the Class II railroad or Class III railroad's (*i.e.*, regional and short line railroads) train consist information within the existing framework described in § 7302(a)(1).²

B. Fusion Centers

The FAST Act requires the Secretary to issue regulations requiring fusion centers to participate in the gathering and dissemination of electronic train consist information. Section 7302(b)(4) of the FAST Act indicates that the term "fusion center" means a collaborative effort of two or more Federal, State, local, or Tribal government agencies that combines resources, expertise, or information with the goal of maximizing the ability of such agencies to detect, prevent, investigate, apprehend, and

¹ On July 29, 2016, PHMSA published a Notice of Proposed Rulemaking, <https://www.regulations.gov/document?D=PHMSA-2014-0105-0240>.

² Classification of carriers (railroads) is based on annual operating revenues. A breakout of Class I, II and III railroads can be reviewed at 49 CFR part 1201—Railroad Companies under the General Instructions at 1-1(a).

respond to criminal or terrorist activity (6 U.S.C. 124(j)(1)). Since 2003, the U.S. Department of Homeland Security (DHS) and the U.S. Department of Justice (DOJ) have published guidance to support the development and implementation of fusion centers as centralized entities to improve the sharing of threat-related information related to criminal or terrorist activity. Located in states and major urban areas throughout the country, fusion centers are owned, operated, and staffed by State and local agencies with support from Federal partners. The federal support consists of deployed personnel, training, technical assistance, exercise support, security clearances, and connectivity to federal systems, technology, and grant funding to detect, prevent, investigate, apprehend, and respond to criminal or terrorist activity.³ Specifically, grants from Federal agencies, including DHS and DOJ, are leveraged by states to support fusion center operations in executing their respective missions.

Fusion centers (1) are owned and operated by State and local entities and designated by their respective governor;⁴ (2) serve as primary focal points within the state and local environment for the receipt, analysis, gathering, and sharing of criminal or terrorist threat-related information among Federal, State, local, Tribal,⁵ and territorial partners; and (3) contribute to the Information Sharing Environment through their role in receiving threat information from the Federal government; analyzing that information in the context of their local environment; disseminating that information to local agencies; and gathering tips, leads, and suspicious activity reporting (SAR) from local agencies and the public. Fusion centers receive information from a variety of sources, including SAR from stakeholders within their jurisdictions, as well as federal information and intelligence. They analyze the information, reports and threat to disseminate to their customers (e.g., law enforcement and homeland security officials), thereby assisting homeland security partners at all levels of government to identify and address immediate and emerging threats. The mission and scope of a fusion center's operation is guided by the State or local agency that oversees its operations.

Some fusion centers only process terrorism information, while others also address criminal-related information. This focus is directed by the respective State and/or local agency.

The intelligence and information collected, analyzed, and shared may be strategic, as well as tactical. Information gathering and dissemination occur on an ongoing basis. Fusion centers are in a unique position to empower front-line law enforcement, public safety, fire service,⁶ emergency response,⁷ public health,⁸ critical infrastructure protection,⁹ and private sector security personnel to gather lawfully and share threat-related information, in accordance with the fusion centers' missions and authorities. They provide interdisciplinary expertise and situational awareness to inform decision-making at all levels of government. Fusion centers conduct analyses and facilitate information sharing, assisting law enforcement and homeland security partners in preventing, protecting against, and responding to crime and terrorism.

A fusion center differs from an emergency operations center (EOC). Fusion centers and EOCs serve distinct, but complementary roles in supporting the country's homeland security efforts. Fusion centers empower homeland security partners through the lawful gathering, analysis, and sharing of threat-related information, while EOCs primarily provide information and support to incident management and response/recovery coordination activities.¹⁰

II. Request for Public Comment

With respect to the FAST Act mandate to develop regulations applicable to fusion centers, PHMSA is requesting comment and information specific to the impact on State and local government fusion center operations and first responders, emergency response officials, law enforcement personnel, railroads, and any other entity that is impacted by this mandate. The purpose of this ANPRM is to inform the Regulatory Impact Analysis (RIA) of this rulemaking.

The request for comment, including information and data are focused on the baseline changes, implementation, and

costs and benefits affecting entities—fusion centers, railroads, and first responders—that would be impacted by a rulemaking outlining regulations to prepare, gather, share, and acquire train consist information. While most of these questions are focused on fusion center operations, we welcome comments from all stakeholders on any of these questions.

A. Affected Entities Questions

1. How many fusion centers are located in your State, including those associated with major urban areas?

2. How many fusion centers in your State, including those associated with major urban areas, would be affected by the provisions of § 7302 of the FAST Act? How many would be required to collect and disseminate information? Would it be possible to designate one fusion center within your State to collect and disseminate train consist data?

3. How many Class II and III railroads would be affected by § 7302(a)(7) of the FAST Act? This section of the FAST Act allows Class I railroads to enter into an MOU with any Class II or Class III railroad that operates trains over the Class I railroad's line to incorporate the Class II or Class III railroads' train consist information within the existing framework described in § 7302(a)(1). How many Class I railroads would enter into an MOU?

B. Baseline Questions

4. Are fusion centers in your State 24/7 operations? If not, describe the coverage of operations on a daily/weekly basis?

5. Per the DHS Web site description of fusion center activities referenced in the subsection titles "Fusion Centers," how frequently do fusion centers in your State receive, analyze, gather, and share threat-related information? Do fusion centers in your State currently perform these activities for hazardous materials on trains? Does performance of the activities occur based on a shipment or is it more routine and constant (i.e., a 24/7 operation)?

6. Describe the current level of information technology (IT) and data collection and information management system capabilities of your State's fusion centers. Do they have the ability to receive and disseminate real-time train consist information?

7. How many employees work at your State's fusion centers? How many fusion center employees are employees of your State, employees of localities, and other types of employees?

8. How does your State fund fusion center operations? How are grants used?

³ See <https://www.dhs.gov/national-network-fusion-centers-fact-sheet>.

⁴ See <https://www.dhs.gov/fusion-center-locations-and-contact-information>.

⁵ See <http://www.it.ojp.gov/documents/TribalParticipationinFusionCenters.pdf>.

⁶ See <http://it.ojp.gov/docdownloader.aspx?ddid=1280>.

⁷ See <https://www.dhs.gov/fusion-centers-and-emergency-operations-centers>.

⁸ See <http://www.it.ojp.gov/docdownloader.aspx?ddid=1450>.

⁹ See <http://www.it.ojp.gov/docdownloader.aspx?ddid=1136>.

¹⁰ See <https://www.dhs.gov/fusion-centers-and-emergency-operations-centers>.

Please provide any data on the current cost and budget of your State's fusion center operations. What are the break-out costs by labor and IT?

9. How do first responders currently receive information, or train consist information, for hazardous materials in your State?

10. How do railroads transmit train consist information for hazardous materials incidents? Do railroads currently send information on hazardous materials train consists to fusion centers? If so, is this information sent electronically, such as by the AskRail app, or by some other means? ¹¹ Do railroads send this information to both state and large urban area fusion centers?

11. Do railroad employees use electronic devices to update train consist information? Are these devices proprietary rail-specific devices, or off-the-shelf tablets or smartphones with apps that enable train consists to be updated and that information relayed to Railinc or some other railroad database? ¹²

12. PHMSA is also aware of handheld readers.¹³ Are these readers capable of tracking changes to train consists and interfacing with rail databases such as Railinc to update train consist information in real-time by cellular or wifi connections? If such devices are not currently capable of performing this task, is development of this capability in process? How much do these devices cost, what is their read range, and what are the ongoing service costs for these devices?

13. Have all Class I railroads developed means by which changes to hazardous material train consists can be updated in real-time and relayed electronically to the railroads or other entities?

14. Are there electronic systems that operate on a 24/7 basis to relay changes to train consists in real-time at all hours and locations throughout the day?

C. Implementation Questions

The following questions relate to how stakeholders would implement § 7302 of the FAST Act.

15. Would your State identify a particular fusion center to collect and disseminate information for your entire State, including major urban areas? If not, what other implementation alternatives would your State consider?

16. What type of IT solutions would you consider or require for your State's

fusion center operations to receive, route, and disseminate real-time train consist information? Are there any IT or network solutions that would provide automated collection and routing to first responders on a 24/7 basis?

17. Would your State's fusion centers use the same employees to conduct criminal, terrorism, and hazardous material information collection and dissemination activities? Would employees require specialization in these areas?

18. How many and what types of additional employees would be required to implement the provisions of § 7302 of the FAST Act?

19. How many real-time train consist notifications would be received and disseminated by your State's fusion center operations? How long would it take to process, analyze, and disseminate notifications?

20. How would railroads transmit this information to fusion centers? If no system to relay this information to fusion centers exists, what resources and investments would be necessary to develop such a system (e.g., IT development, IT hardware to record changes to train consists in real-time, etc.)?

21. If further IT development or other implementation resources are required, what is a reasonable time frame for railroads to develop these resources? What barriers might prevent the timely development and deployment of these resources?

22. How would first responders receive real-time train consist information? Would first responders need any additional communication and technology equipment or enhancements?

D. Costs Questions

23. What is the additional cost to your State's fusion center operations to implement the provisions of § 7302 of the FAST Act? What are the initial startup planning and capital investment costs and how long would initial startup take in terms of months? What are the recurring operations and management (O&M) costs? What are the costs and frequencies of any upgrades beyond initial startup and O&M costs? What are the initial and recurring training costs? Please provide quantitative data if possible.

24. What is the cost to collect, maintain, and disseminate real-time train consist notification?

25. What are the costs associated with electronic devices to record and relay changes to train consists in real-time?

26. What are the costs to establish security and confidentiality protections,

including protections from the public release of proprietary information or security-sensitive information, to prevent the release of real-time train consist information to unauthorized persons?

27. What are the costs for Class I railroads to enter into an MOU with any Class II railroad or Class III railroad that operates trains over the Class I railroad's line to incorporate the Class II railroad's or Class III railroad's train consist information within the existing framework described in § 7302(a)(1)?

28. What are the costs for Class I railroads to enter into an MOU with each applicable fusion center to provide the fusion center with secure and confidential access to the electronic train consist information for each train transporting hazardous materials in the jurisdiction of the fusion center?

29. What are the costs to first responders to receive information disseminated from fusion centers?

30. How and where would State fusion centers recover costs to implement the provisions of § 7302 of the FAST Act? Would implementation require grant funding? If so, from where or whom?

E. Benefits Questions

31. As a result of implementing § 7302 of the FAST Act, would there be a reduction in the response time and incident-related costs and damages? Would there be a reduction in the duration of evacuations? Please provide quantitative data if possible.

32. What kind of avoided consequences and benefits to communities will be realized as a result of implementing the provisions of § 7302 of the FAST Act? Avoided consequences may include reduced risks of harm to the public and environment in terms of fatalities, injuries and hospitalizations, property loss, and damages associated with release of hazardous materials into the environment.

33. Would railroads experience any business benefits from having accurate electronic records of train consists in real-time (e.g., better ability to update customers on shipment location or delivery times/dates, more efficient utilization of railroad resources, etc.)? If so, please quantify to the extent possible.

III. Regulatory Analysis

A. Executive Order 12866, Executive Order 13563, and DOT Regulatory Policies and Procedures

This ANPRM has not been designated a "significant regulatory action" under

¹¹ For more information on the AskRail App, see <https://askrail.us/>.

¹² For more information on Railinc, see <https://www.railinc.com/rportal/web/guest/home>.

¹³ See <http://www.aettag.com/>.

section 3(f) of Executive Order 12866, “Regulatory Planning and Review.” 58 FR 51735 (Oct. 4, 1993). Accordingly, this ANPRM has not been reviewed by the Office of Management and Budget (OMB) and is not considered to be a significant regulatory action under the DOT Regulatory Policies and Procedures of February 26, 1979. See 44 FR 11034.

Executive Order 13563, “Improving Regulation and Regulatory Review,” 76 FR 3821 (Jan. 21, 2011), supplements and reaffirms the principles, structures, and definitions governing regulatory review that were established in Executive Order 12866. Together, Executive Orders 12866 and 13563 require agencies to regulate in the “most cost-effective manner,” to make a “reasoned determination that the benefits of the intended regulation justify its costs,” and to develop regulations that “impose the least burden on society.”

Additionally, Executive Orders 12866 and 13563 require agencies to provide a meaningful opportunity for public participation. Therefore, PHMSA solicits comment on the questions raised in this ANPRM.

B. Executive Order 13132

Executive Order 13132, “Federalism,” 64 FR 43255 (Aug. 10, 1999), requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” We invite State and local governments with an interest in this rulemaking to comment on any effect that revisions to the HMR relative to the FAST Act mandate may cause.

C. Executive Order 13175

Executive Order 13175, “Consultation and Coordination with Indian Tribal Governments,” 65 FR 67249 (Nov. 9, 2000), requires agencies to assure meaningful and timely input from Indian tribal government representatives in the development of rules that “significantly or uniquely affect” Indian communities and impose “substantial and direct compliance costs” on such communities. We invite Indian tribal governments to provide comment(s) on any potential impacts of a rulemaking to implement the FAST Act mandate.

D. Regulatory Flexibility Act, Executive Order 13272, and DOT Policies and Procedures

The Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, requires agencies to consider whether a rulemaking would have a “significant economic impact on a substantial number of small entities.” Small entities include small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations under 50,000.

As such, PHMSA solicits input from small entities on the questions presented in this ANPRM. If you believe the FAST Act mandate would have a significant economic impact on a substantial number of small entities, please submit a comment to PHMSA. In your comment, explain the extent of the impact, and whether there may be alternative approaches to consider that would minimize any significant impact on small business while still meeting the agency’s statutory safety objectives.

Any future proposed rule would be developed in accordance with Executive Order 13272, “Proper Consideration of Small Entities in Agency Rulemaking,” 67 FR 53461 (Aug. 16, 2002), as well as DOT’s procedures and policies, so as to promote compliance with the Regulatory Flexibility Act to ensure that potential impacts on small entities of a regulatory action are properly considered.

E. Paperwork Reduction Act

Section 1320.8(d), title 5, Code of Federal Regulations requires that PHMSA provide interested members of the public and affected agencies an opportunity to comment on information collection and recordkeeping requests. It is possible that new or revised information collection requirements could occur as a result of any future rulemaking action. We invite comment on the need for any collection of information and paperwork burdens that may apply as result of a future rulemaking.

F. National Environmental Policy Act

The National Environmental Policy Act of 1969, 42 U.S.C. 4321–4375, requires Federal agencies to consider the consequences of major Federal actions and prepare a detailed statement on actions significantly affecting the quality of the human environment. The Council on Environmental Quality (CEQ) regulations require Federal agencies to conduct an environmental review considering (1) the need for the proposed action, (2) alternatives to the

proposed action, (3) probable environmental impacts of the proposed action and alternatives, and (4) the agencies and persons consulted during the consideration process. See 40 CFR 1508.9(b). PHMSA welcomes any data or information related to environmental impacts that may result from this rulemaking.

G. Privacy Act

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the document (or signing the document, if submitted on behalf of an association, business, labor union, etc.). You may review DOT’s complete Privacy Act Statement in the **Federal Register** at 65 FR 19477 (April 11, 2000), or you may visit <http://www.dot.gov/privacy.html>.

H. Executive Order 13609 and International Trade Analysis

Under Executive Order 13609, “Promoting International Regulatory Cooperation,” 77 FR 26413 (May 4, 2012), agencies must consider whether the impacts associated with significant variations between domestic and international regulatory approaches are unnecessary, or may impair the ability of American business to export and compete internationally. In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are, or would be, adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.

Similarly, the Trade Agreements Act of 1979, Public Law 96–39, as amended by the Uruguay Round Agreements Act, Public Law 103–465, prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. For purposes of these requirements, Federal agencies may participate in the establishment of international standards, so long as the standards have a legitimate domestic objective, such as providing for safety, and do not operate to exclude imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

PHMSA participates in the establishment of international standards in order to protect the safety of the

American public, and we have assessed the effects of this ANPRM to ensure that it does not cause unnecessary obstacles to foreign trade. Accordingly, this rulemaking is consistent with Executive Order 13609 and PHMSA's obligations under the Trade Agreement Act, as amended.

I. Statutory/Legal Authority for This Rulemaking

Federal hazardous materials transportation law, 49 U.S.C. 5101 *et seq.*, authorizes the Secretary of Transportation to prescribe regulations for the safe transportation, including security, of hazardous materials in intrastate, interstate, and foreign commerce. The Secretary has delegated this authorization to the Administrator for PHMSA. See 49 CFR 1.97. PHMSA is issuing this ANPRM to gather necessary information in development of the regulatory impact analysis in support of this rulemaking.

J. Regulation Identifier Number (RIN)

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

Issued in Washington, DC, on January 13, 2017, under authority delegated in 49 CFR part 1.97.

William Schoonover,

Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2017-01240 Filed 1-18-17; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 217

[Docket No. 160809705-6705-01]

RIN 0648-BG25

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Space Vehicle and Missile Launch Operations at Pacific Spaceport Complex Alaska, Kodiak Island, Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS has received an application, pursuant to the Marine Mammal Protection Act (MMPA), from the Alaska Aerospace Corporation (AAC) for authorization to take small numbers of marine mammals incidental to launching space launch vehicles and other smaller missile systems at the Pacific Spaceport Complex Alaska (PSCA) for the period of March 15, 2017, through March 14, 2022. NMFS is proposing regulations to govern that take, and requests comments on the proposed regulations.

DATES: Comments and information must be received no later than February 21, 2017.

ADDRESSES: You may submit comments on this document by any of the following methods:

- **Electronic submission:** Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to www.regulations.gov, enter 2017-0002 in the "Search" box, click the "Comment Now!" icon, complete the required fields, and enter or attach your comments.

- **Mail:** Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East West Highway, Silver Spring, MD 20910.

Instructions: NMFS may not consider comments if they are sent by any other method, to any other address or individual, or received after the end of the comment period. Attachments to electronic comments will be accepted in Microsoft Word or Excel or Adobe PDF file formats only. To help NMFS process and review comments more efficiently, please use only one method to submit comments. All comments received are a part of the public record and will generally be posted on www.regulations.gov without change. All personal identifying information (e.g., name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter N/A in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Stephanie Egger, Office of Protected Resources, NMFS, (301) 427-8401.

SUPPLEMENTARY INFORMATION:

Availability

A copy of AAC's application and any supporting documents, as well as a list of the references cited in this document, may be obtained online at: www.nmfs.noaa.gov/pr/permits/incidental/research.htm. In case of problems accessing these documents, please call the contact listed above (see **FOR FURTHER INFORMATION CONTACT**).

Purpose and Need for Regulatory Action

This proposed rule, to be issued under the authority of the MMPA, would establish a framework for authorizing the take of marine mammals incidental to launching space vehicles, target missiles, and other smaller missile systems at the PSCA. We received an application from AAC requesting 5-year regulations and authorization to take one species of marine mammals. Take would occur by Level B harassment only, incidental to the space vehicle launches (also referred to as rocket launches). The regulations would be valid from March 15, 2017, to March 14, 2022. Please see *Background* below for definitions of harassment.

Legal Authority for the Proposed Action

Section 101(a)(5)(A) of the MMPA directs the Secretary of Commerce to allow, upon request, the incidental, but not intentional taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region for up to five years if, after notice and public comment, the agency makes certain findings and issues regulations that set forth permissible methods of taking pursuant to that activity, as well as monitoring and reporting requirements. Section 101(a)(5)(A) of the MMPA and the implementing regulations at 50 CFR part 216, subpart I provide the legal basis for issuing this proposed rule containing 5-year regulations, and for any subsequent Letters of Authorization (LOA). As directed by this legal authority, this proposed rule contains mitigation, monitoring, and reporting requirements.

Summary of Major Provisions Within the Proposed Rule

The following provides a summary of some of the major provisions within the proposed rulemaking for AAC's rocket launch activities. We have preliminarily determined that AAC's adherence to the proposed mitigation, monitoring, and reporting measures listed below would achieve the least adverse impact practicable on the affected marine mammals. They include:

- Required monitoring of Ugak Island to detect the presence and abundance of marine mammals before and after deployment of rocket launch operations.
- Required monitoring of Ugak Island to survey the presence and abundance of marine mammals once per year (outside of rocket launch operations).
- Required mitigation of using time-lapsed photography to determine the immediate response impacts to marine mammals during rocket launches, particularly during the pupping season (should rocket launches occur during that time).

Background

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined “negligible impact” in 50 CFR 216.103 as “an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.”

Except with respect to certain activities not pertinent here, the MMPA defines “harassment” as: Any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breaching, nursing, breeding, feeding, or sheltering (Level B harassment).

Summary of Request

On April 25, 2016, NMFS received a request for regulations from AAC for the taking of small numbers of marine mammals incidental to launching space launch vehicles long-range and other smaller missile systems at the PSCA. We received revised drafts on June 20, 2016, and September 19, 2016. On September 27, 2016, we published a notice of receipt of AAC’s application in the **Federal Register** (81 FR 66264), requesting comments and information for thirty days related to AAC’s request. On November 10, 2016, we received an adequate and complete application. We received comments from the Marine Mammal Commission (MMC) which we

considered in the development of this proposed rule.

AAC proposes taking of small numbers of marine mammals incidental to rocket launch operations specifically noise from space vehicles and missile launches that may result in the Level B harassment of harbor seals (*Phoca vitulina richardii*). NMFS has previously issued regulations and subsequent LOAs to AAC authorizing the taking of marine mammals incidental to launches at PSCA (76 FR 16311, March 23, 2011; and 71 FR 4297, January 26, 2006). The current regulations recently expired on March 22, 2016; hence, AAC has applied for new regulations. The proposed regulations, if issued, would be effective from March 15, 2017, through March 14, 2022.

Description of the Specified Activity

Overview

PSCA is located on the Narrow Cape Peninsula, on Kodiak Island in the Gulf of Alaska. Kodiak Island is approximately 99 miles (mi) long and 10 to 60 mi wide. PSCA is approximately 22 air mi from the City of Kodiak, which is the largest settlement on the Kodiak Island. The land area occupied by PSCA is owned by the State of Alaska and is administered by AAC under terms of an Interagency Land Management Assignment (ILMA) issued by AAC’s sister agency, the Alaska Department of Natural Resources. AAC conducts space vehicle and missile launches from the PSCA. Launch operations are authorized under license from the Federal Aviation Administration (FAA), Office of the Associate Administrator for Space Transportation, in accordance with the facility’s Environmental Assessment (EA) and stipulations in the EA’s Finding of No Significant Impact (FONSI) (FAA 1996) and subsequent licenses (FAA 1998, 2003, 2005, and 2013). The area considered to be affected by PSCA launch operations was defined in a September 1996 meeting involving AAC and its environmental consultant (University of Alaska Anchorage’s Environment and Natural Resources Institute), and government agencies represented by the FAA, NMFS, the U.S. Fish and Wildlife Service (FWS), and the Alaska Department of Environmental Conservation (ADEC). Attendees at that meeting reviewed information on the known effects of rocket operations on the environment, and defined the expected impact area to be within a 6-mi radius of the launch pad area, inclusive of Ugak Island. A more recent EA was completed in April 2016 that addresses the potential environmental

impacts of the proposed action where the FAA would modify the AAC launch site operator license for the PSCA. The EA evaluates the potential environmental impacts of modifying the launch site operator license to include medium-lift launch capability at PSCA with the addition of new infrastructure necessary to support these types of launches, including the construction of a launch pad and associated facilities.

There are several marine mammals present in the waters offshore, however, the only marine mammals anticipated to be affected by the specified activities are pinnipeds hauled out on Ugak Island.

Dates and Duration

The specified activity may occur at any time during the 5-year period of validity of the proposed regulations. Dates and duration of individual rocket launches are inherently uncertain. Launch timing is not determined by AAC, but is driven by customer needs that include variables ranging from: (1) Availability of down range assets necessary to support launch, (2) orbital parameters, and (3) exigencies requiring rapid response to requests for replacement of lost assets, or to augment existing ones to support vital defense, humanitarian, or commercial needs. Launches can, and do, occur year round. Typical launches will be spread out in time; however, some of these launches may occur in clusters to meet a customer’s need.

Launch planning is a dynamic process, and launch delays, which can last from hours to more than a year, can and do occur. Launch delays occur due to variables ranging from technical issues to adverse weather. These factors have controlling influence over the numbers of vehicles by class that are actually launched in any given year from PSCA. Launches take place year round when all variables affecting launch decisions are in correct alignment.

AAC estimates the total number of vehicles that might be launched from PSCA over the course of the 5-year period covered by the requested rulemaking is 45, with an average of nine launches per year. However, in previous years, AAC did not launch the authorized number, but fewer or none in some years. Few launches are on contract at this time, so a specific distribution cannot be given. The first anticipated launch is estimated to occur in May 2017. Generally, the frequency will be separated by months or years; however, there may be limited instances of a rapid succession of launches in the course of hours, or days. Launches can, and do, occur year-round. The duration

of the possible disturbance will be at levels that may cause disturbances for only a few seconds tapering off to inaudible in a few minutes.

Specified Geographical Region

The PSCA facility occupies 3,717 acres of state-owned lands on the eastern side of Kodiak Island. Ugak Island lies approximately three to four mi to the south/southeast of the launch pads on Kodiak Island (see Figure 2 in AAC's application). Ugak Island is about two mi long by about one mi wide. The land slopes steeply upward from a spit on the island's northern most point, which has previously been (although not in consistently in recent years) used as a Steller sea lion (*Eumetopias jubatus*) haulout (see Figures 3 in AAC's application), to the southwest, culminating in cliffs that are approximately 1,000 feet (ft) in elevation. These cliffs run the entire length of the island's long axis. Eastward, the narrow Outer Continental Shelf (OCS) ends about 20 mi offshore, where it plunges precipitously to the North Pacific abyss. Near shore water depths to the immediate south and west of the island range to several hundred feet. Harbor seal haulouts are present mainly on Ugak Island's eastern shores, but also in smaller numbers at the northern end of the island (see Figure 3 in AAC's application).

Detailed Description of Activities

Orbital and suborbital launch vehicles (i.e., rockets, missiles) are launched from PSCA as part of the aerospace industry. A rocket launch operation takes years to plan and execute, as well as a large preparation effort weeks before the launch. In preparation for the launch, launch vehicles are checked, integrated, and erected. At this time, PSCA has two launch pads, designated as Launch Pad 1 (LP1) and Launch Pad 2 (LP2). LP1 is capable of launching small lift class vehicles and is 3.5 mi from the nearest point on Ugak Island. Small lift vehicles are generically categorized as being capable of carrying payloads of up to 4,400 pounds (lb). LP1 has a flame trench that directs exhaust (and much of the sound) horizontally eastward during liftoff, while LP2 is a flat pad. LP1 is larger and better suited for the larger vehicles within AAC's capabilities. The vehicles that produce the most sound are likely to be launched from LP1.

PSCA launch azimuths range from 110 degrees to 220 degrees. The eastern most launch azimuth of 110 degrees is within a few degrees of most orbital launches, and crosses the extreme eastern edge of Ugak Island where

several pinniped haulouts are found. Modeling done of Castor 120 space launches indicates the vehicle is passing through 45,000 ft altitude by the time it reaches the island about 70 seconds post launch (FAA 1996).

A typical launch vehicle is deployed by igniting the vehicle through a controlled means to send it on a very specific flight path. The ignition starts a burn on the ground that usually lasts less than several seconds after which the vehicle accelerates upward rapidly. During launch, burning fuel from the launch vehicle creates noise and light in the surrounding area. The components of a launch that may result in take are a source of noise and light on Kodiak Island created by the first stage vehicle motor, as the operation of launch vehicle engines produce sound pressures that may be high enough to cause a disturbance. Combustion noise and jet noise are the two main sources of sound pressures and are projected in all directions. The sound produced subsides to inaudible within a few minutes.

Another component of the AAC's launches includes security overflights. In the days preceding the launch, these occur approximately three times per day based on the long-term average. Flights associated with the launch will not approach occupied pinniped haulouts on Ugak Island by closer than 0.25 mi (0.4 kilometer (km)), and will maintain a vertical distance of 1,000 ft (305 meter (m)) from the haulouts when within 0.5 mi (0.8 km), unless indications of human presence or activity warrant closer inspection of the area to assure that national security interests are protected in accordance with law. Over the operational history of these flights, aircraft have been operated within the 0.25 mi limit on two occasions; both involved direct overflight of the Steller sea lion northwestern haulout spit, which was unoccupied each time the incursions occurred.

Description of the Sound Sources

This section contains a brief technical background on sound, the characteristics of certain sound types and the proposed sound sources relevant to AAC's specified activity.

Pulsed sound sources (e.g., sonic booms, explosions, gunshots, impact pile driving) produce signals that are brief (typically considered to be less than one second), broadband, atonal transients (ANSI 1986; Harris 1998; NIOSH 1998; ISO 2003; ANSI 2005) and occur either as isolated events or repeated in some succession. Pulsed sounds are all characterized by a relatively rapid rise from ambient

pressure to a maximal pressure value followed by a rapid decay period that may include a period of diminishing, oscillating maximal and minimal pressures, and generally have an increased capacity to induce physical injury as compared with sounds that lack these features.

Non-pulsed sounds can be tonal, narrowband, or broadband, brief or prolonged, and may be either continuous or non-continuous (ANSI 1995; NIOSH 1998). Some of these non-pulsed sounds can be transient signals of short duration but without the essential properties of pulses (e.g., rapid rise time). Examples of non-pulsed sounds include those produced by rocket launches and landings, vessels, aircraft, machinery operations such as drilling or dredging, and vibratory pile driving. The duration of such sounds, as received at a distance, can be greatly extended in a highly reverberant environment.

Sound travels in waves, the basic components of which are frequency, wavelength, velocity, and amplitude. Frequency is the number of pressure waves that pass by a reference point per unit of time and is measured in hertz (Hz) or cycles per second. Wavelength is the distance between two peaks of a sound wave; lower frequency sounds have longer wavelengths than higher frequency sounds and attenuate (decrease) more rapidly in shallower water. Amplitude is the height of the sound pressure wave or the 'loudness' of a sound and is typically measured using the decibel (dB) scale. A dB is the ratio between a measured pressure (with sound) and a reference pressure (sound at a constant pressure, established by scientific standards). It is a logarithmic unit that accounts for large variations in amplitude; therefore, relatively small changes in dB ratings correspond to large changes in sound pressure. When referring to sound pressure levels (SPLs; the sound force per unit area), sound is referenced in the context of underwater sound pressure to 1 microPascal (μPa). One pascal is the pressure resulting from a force of one newton exerted over an area of one square meter. The source level (SL) represents the sound level at a distance of 1 m from the source (referenced to 1 μPa). The received level is the sound level at the listener's position. Note that all underwater sound levels in this document are referenced to a pressure of 1 μPa and all airborne sound levels in this document are referenced to a pressure of 20 μPa .

Root mean square (rms) is the quadratic mean sound pressure over the duration of an impulse, and is calculated by squaring all of the sound

amplitudes, averaging the squares, and then taking the square root of the average (Urick 1983). Rms accounts for both positive and negative values; squaring the pressures makes all values positive so that they may be accounted for in the summation of pressure levels (Hastings and Popper 2005). This measurement is often used in the context of discussing behavioral effects, in part because behavioral effects, which often result from auditory cues, may be better expressed through averaged units than by peak pressures.

Sound exposure level (SEL; represented as dB re 1 $\mu\text{Pa}^2\text{-s}$) represents the total energy contained within a pulse, and considers both intensity and duration of exposure. For a single pulse, the numerical value of the SEL measurement is usually 5–15 dB lower than the rms sound pressure in dB re 1 μPa , with the comparative difference between measurements of rms and SEL measurements often tending to decrease with increasing range (Greene 1997; McCauley *et al.*, 1998). Peak sound pressure is the maximum instantaneous sound pressure measurable in the water at a specified distance from the source, and is represented in the same units as the rms sound pressure. Another common metric is peak-to-peak sound pressure (p-p), which is the algebraic difference between the peak positive and peak negative sound pressures. Peak-to-peak pressure is typically approximately 6 dB higher than peak pressure (Southall *et al.*, 2007).

Proposed Sound Sources for AAC

We now describe specific airborne acoustic sources for AAC. Sounds levels are different for each type of vehicle and further discussed below. Orbital and suborbital vehicles may be launched from several locations on site; however, no launch pads are closer to the haulouts on Ugak Island than LP1, from which the largest and, therefore, loudest vehicles will be launched. A description of each class of space launch and smaller launch vehicles are provided in the application and summarized here.

Peacekeeper Derivatives—Castor 120, Athena, Minotaur IV and V, and Taurus I

The Castor 120 was the base vehicle analyzed in the EA conducted by the FAA (US FAA 1996) in support of the

decision to issue a launch license to AAC. The Castor 120 uses solid fuel and produces about 371,000 lbs of thrust. The motor mass is about 116,000 lbs and the motor is 347 inches (in) long and 93 in wide. Modeling shows the rocket is about eight mi above the earth's surface when it overflies Ugak Island, and that the sonic boom reaches earth between 21 to 35 mi down range, which is past the OCS and over the North Pacific abyss (US FAA 1996). Sound pressure from the Castor 120 at the spit on Ugak Island's northern most point was measured to be 101.4 dBA (dBA can be defined as dB with A-weighting designed to match the average frequency response of human hearing and enables comparison of the intensity of noise with different frequency characteristics) SEL. None of the vehicles expected to be flown from PSCA over the five-year period covered by this proposed rule is known to be louder than the Castor 120.

Minuteman Derivative—Minotaur I

The Minotaur I is a small lift solid propellant space launch vehicle, the first stage of which is a modified Minuteman II. The first stage motor has a diameter of 4.5 ft. This launch vehicle has not yet been flown from PSCA. Sound pressure monitoring of two Minotaur I launches was accomplished at Vandenberg Air Force Base, California (VAFB). The data were collected 1.4 mi away from the launch point and show sound pressure levels of 104.9 to 107.0 dBA (SEL) at that distance. Sound energy at sea level decreases with the square of the distance, and given that the spit on Ugak Island's northern most point is two mi further (*i.e.*, spit is 3.5 mi from the launch point), the anticipated sound pressure levels from a Minotaur I at the spit on Ugak Island's northern most point would be less than that of the Castor 120.

Trident Derivatives—C-4 Trident I

The C-4 is a solid fueled vehicle and its first stage has a diameter of 6.1 ft, which is about 1.5 ft less than the Castor 120. Because it is significantly smaller in diameter than the Castor 120 and uses a similar fuel, it is anticipated that sound pressure levels at the spit on Ugak Island's northern most point

would be less than those of the Castor 120.

Polaris Derivatives—A-3 STARS

The Strategic Target System (STARS) utilizes the first stage of the Polaris A-3, which is solid fueled and measures 4.5 ft in diameter. Several STARS systems have been flown from PSCA. Recorded sound pressure levels at Ugak Island have ranged from 90.2 to 91.4 dBA (SEL).

Smaller Vehicles and Tactical Rocket Systems

A number of smaller missile systems, such as tactical or target vehicles, have the possibility of being flown from PSCA. Representative smaller systems range from about a foot in diameter up to about four foot in diameter. Sound pressures from these smaller systems are not available, but will be substantially less than those from the space launch and ballistic vehicles described and pose little potential for disturbance to marine mammals.

Even smaller systems ranging down in size to several inches in diameter will conceivably be flown as well. Small sounding and research rockets (defined as less than 5,000 lbs in weight) will be excluded from this request, including its mitigations and reporting, as the rockets' small shape and energy are too small to transmit an appreciable sound pressure on Ugak Island, and are expected to be well below the threshold for an active response.

Summary of Launch Vehicles

Table 1 provides motor diameters and representative sound pressures for various launch vehicles, some of which have been launched previously from PSCA. The listed vehicles include various ballistic launch vehicles and the small lift Castor 120 space launch vehicle, as well as smaller target/interceptor systems and tactical rocket systems. All PSCA sound measurements reported in Table 1 were taken at a distance of 3.5 mi from the launch pad at the nearest point of Ugak Island. It is important to note that the Castor 120 (previously launched from PSCA) is the loudest launch vehicle motor expected to be launched from PSCA over the 5-year period covered by the proposed regulations.

TABLE 1—PAST AND ANTICIPATED LAUNCH VEHICLES

| Previously Launched & Recorded at PSCA (also Potentially Launched in Future) | | | | | | | |
|--|----------------|---------|---------------------------|----------------------------------|-----------|------------|-------------|
| Launch designator | Launch vehicle | Date | Distance to haulout | Motor diameter (ft) ¹ | SEL (dBA) | Lmax (dBA) | LPeak (dBA) |
| QRLV | | 11/5/98 | 3.5 mi ² | 4.3 | 88.4 | 78.2 | 97.0 |

TABLE 1—PAST AND ANTICIPATED LAUNCH VEHICLES—Continued

| Previously Launched & Recorded at PSCA (also Potentially Launched in Future) | | | | | | | |
|--|---------------------|---------|---------------------------|----------------------------------|------------------|------------|-------------|
| Launch designator | Launch vehicle | Date | Distance to haulout | Motor diameter (ft) ¹ | SEL (dBA) | Lmax (dBA) | LPeak (dBA) |
| QRLV | | 9/15/99 | 3.5 mi ² | 4.3 | 92.2 | 81.5 | 101.5 |
| QRLV | | 3/22/01 | 3.5 mi ² | 4.3 | 80.3 | 73.3 | 87.2 |
| Athena | Castor 120 | 9/29/01 | 3.5 mi ² | 7.75 | 101.4 | 90.8 | 115.9 |
| FT-04-1 | Polaris A-3 | 2/23/06 | 4.1 mi | 4.5 | 92.3 | 86.0 | 109.0 |
| FTG-02 | STARS. | | | | | | |
| FTG-02 | Polaris A-3 | 9/01/06 | 4.1 mi | 4.5 | 90.1 | 83.1 | 105.6 |
| FTG-02 | STARS. | | | | | | |
| FTG-03a | Polaris A-3 | 9/28/07 | 4.1 mi | 4.5 | 91.4 | 84.2 | 107.3 |
| FTG-03a | STARS. | | | | | | |
| FTX-03 | Polaris A-3 | 7/18/08 | 4.1 mi | 4.5 | 89.6 | 83.0 | 108.3 |
| FTX-03 | STARS. | | | | | | |
| | Minotaur I | | | 4.5 | ² 90+ | | |
| | C-4 Trident I | | | 6.1 | | | |
| | Castor I | | | 2.6 | | | |
| | SR19/SR773 | | | 4.3 | | | |
| | SR19/SR19 | | | 4.3 | | | |
| | Castor IVB | | | 3.3 | | | |
| Tactical Vehicles .. | | | | <1.5 | | | |

Notes:¹ Motor sound pressures from solid fueled motors, roughly, correlate to motor diameter.² Estimated.

Spent first stage rocket motors impact the ocean from 11 to more than 300 mi down range, depending on launch vehicle. Sonic booms reach the earth's surface beyond the OCS (US FAA 1996). Both falling first stage rocket motors and sonic booms are too far from land to take pinnipeds and are not expected to affect whales.

Description of Marine Mammals in the Area of the Specified Activity

Sections 4 and 5 of AAC's application and the monitoring reports contain

detailed information on the abundance, status, and distribution of the species on Ugak Island from surveys that they have conducted over the last decade. This information is summarized below and may be viewed in detail at <http://www.nmfs.noaa.gov/pr/permits/incidental/research.htm>. Additional information is available in the NMFS SARs for Alaska at <http://www.nmfs.noaa.gov/pr/sars/region.htm>.

Marine mammals under NMFS' jurisdiction that occur in the vicinity of

PSCA include the harbor seal, Steller sea lion, gray whale (*Eschrichtius robustus*), humpback whale (*Megaptera novaeangliae*) (Table 2). All are protected under the MMPA and the Steller sea lion and humpback whale are listed as threatened or endangered under the Endangered Species Act (ESA). Sea otters (*Enhydra lutris*) also occur in the area, but are managed by FWS; therefore, sea otters are not discussed further in this application.

TABLE 2—SUMMARY OF MMPA SPECIES

| Common name | Scientific name | Status | Occurrence | Seasonality | Daily counts |
|------------------------|---------------------------------|------------------|----------------|--|--------------|
| Harbor seal | <i>Phoca vitulina</i> | MMPA | Common | Year-round, Trends toward Summer | 32–1,500 |
| Steller sea lion | <i>Eumetopias jubatus</i> | Endangered | Rare | Trends toward Summer | 0–19 |
| Gray whale | <i>Eschrichtius robustus</i> .. | MMPA | Seasonal | Spring and fall | 0–32 |
| Humpback whale | <i>Megaptera novaeangliae</i> . | Endangered | Seasonal | Summer and fall | 0–4 |

Airborne noise is generally reflected at the sea surface outside of a 26 degrees cone extending downward from the ascending rocket (Richardson *et al.*, 1995); therefore, little sound energy passes into the sea across the air-water boundary. Submerged animals would have to be directly underneath the rocket to hear it, and given the hypersonic velocity of launch vehicles in the atmosphere, the duration of sounds reaching any cetacean would be discountable. In addition, all spent rocket motors will fall into the open ocean over deep water. Given the very

short time a cetacean is at the surface, direct impact from spent motors can be discounted as can any noise related impacts. Based on these reasons, NMFS does not anticipate take of cetaceans incidental to the specified activity; hence, they will not be discussed further.

Steller Sea Lions

After discussions with AAC and NOAA's Alaska Regional Office (AKR), it was determined there would be no take of Steller sea lions for the proposed activities. In the most recent National

Marine Mammal Laboratory (NMML) survey (NOAA's Alaska Fisheries Science Center) of a location within the action area (July 2015) and of Ugak Island, no sea lions were observed (Fritz *et al.*, 2015). Personal communication between AKR and L. Fritz (Research Fishery Biologist, NMML's Alaska Ecosystem Program) (September 28, 2016) indicate that sea lions have rarely been seen on Ugak Island in recent times. Under those surveys, sea lions were last seen at Ugak Island during the summer of 1994, when one sea lion was observed, and in December 1994, when

20 sea lions were documented (L. Fritz pers. comm. 2016). Sea lions were last seen in large numbers during the 1985–1986 surveys when more than 300 sea lions were observed. It was concluded that the habitat on Ugak Island is not highly suitable for sea lions (L. Fritz pers. comm. 2016).

In addition, AAC has been conducting regular aerial marine mammal surveys since 2006 as a requirement of their previous regulations and LOAs and has also documented Steller sea lion presence as rare. During their previous regulations (2011–2016), 17 aerial surveys were flown. During those surveys, Steller sea lions were only seen in one year with 19 observed in September 2011 at East Ugak Rock away from the Ugak spit haulout. This was the last sighting of Steller sea lions by AAC. Prior to 2011, sea lions were seen in small numbers on occasion during the 2006–2008 surveys. In 2006, 6 out of 14 surveys found sea lions, ranging from one to eight animals. In 2007, 1 out of 8 surveys revealed two sea lions. In 2008, 8 out of 8 surveys found one to five sea lions. AAC also noted that the Ugak spit haulout looks smaller than it has in the past (AAC 2016). The spit is under the influence of longshore currents and its geomorphology shifts over time (AAC 2016). This may now make it unsuitable as a haulout and it may have thus been abandoned by sea lions.

It was determined that take will not occur for Steller sea lions based on the

historic and recent survey data available. Sea lions are likely absent from the area (except a rare visitor) and the likelihood of an animal being present during the nine times a year a launch may be planned is highly unlikely. Therefore, Steller sea lions are not discussed further in these proposed regulations.

The only marine mammals anticipated to be affected by the specified activities and proposed as take for Level B harassment are harbor seals hauled out on Ugak Island and therefore they are the only marine mammal discussed further in these proposed regulations.

Harbor Seals

Harbor seals range from Baja California north along the west coasts of Washington, Oregon, California, British Columbia, and Southeast Alaska; west through the Gulf of Alaska, Prince William Sound, and the Aleutian Islands; and north in the Bering Sea to Cape Newenham and the Pribilof Islands. The current statewide abundance estimate for Alaskan harbor seals is 205,090 (Boveng *et al.* in press as cited in Muto *et al.*, 2015), based on aerial survey data collected during 1998–2011. In 2010, harbor seals in Alaska were partitioned into 12 separate stocks based largely on genetic structure (Allen and Angliss 2010). Harbor seals have declined dramatically in some parts of their range over the past few decades, while in other parts their

numbers have increased or remained stable over similar time periods.

Seals on Ugak Island are considered part of the South Kodiak stock (Table 3)—ranging from Middle Cape on the west coast of Kodiak Island southwest to Chirikof Island and east along the south coast of Kodiak Island to Spruce Island, including the Trinity Islands, Tugidak Island, Sitkinak Island, Sundstrom Island, Aiaktalik Island, Geese Islands, Two Headed Island, Sitkalidak Island, Ugak Island, and Long Island (Muto *et al.*, 2015). A significant portion of the harbor seal population within the South Kodiak stock is located at and around Tugidak Island off the southwest coast of Kodiak Island. Sharp declines in the number of seals present on Tugidak were observed between 1976 and 1998. The highest rate of decline was 21 percent per year between 1976 and 1979 (Pitcher 1990 as cited by Muto *et al.*, 2015). While the number of seals on Tugidak has stabilized and shown some evidence of increase since the decline, the population in 2000 remained reduced by 80 percent compared to the levels in the 1970s (Jemison *et al.*, 2006 as cited by Muto *et al.*, 2015). The current (2007–2011) estimate of the South Kodiak population trend is –461 seals per year, with a probability that the stock is decreasing of 0.72 (Muto *et al.*, 2015). Only the South Kodiak stock is considered in this application because other stocks occur outside the geographic area under consideration.

TABLE 3—HARBOR SEAL STATUS INFORMATION

| Species | Stock | ES/MMPA status; Strategic (Y/N) ¹ | Stock abundance (N _{min} , most recent abundance survey) ² | PBR ³ | Annual M/SI ⁴ | Relative occurrence/season of occurrence |
|-------------------|------------------------|--|--|------------------|--------------------------|---|
| Harbor seal | South Kodiak (Alaska). | —; N | 19,199 (17,479; 2011) | 314 | 128 | Harbor seals are year-round inhabitants of Ugak Island, Alaska. |

¹ Endangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (—) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR (see footnote 3) or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

² N_{min} is the minimum estimate of stock abundance. The most recent abundance survey that is reflected in the abundance estimate is presented; there may be more recent surveys that have not yet been incorporated into the estimate.

³ Potential biological removal, defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population size (OSP).

⁴ These values, found in NMFS' SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (e.g., commercial fisheries, subsistence hunting, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value. All values presented here are from the final 2015 Harbor Seal, Alaska SAR. (http://www.nmfs.noaa.gov/pr/sars/pdf/stocks/alaska/2015/ak2015_sehr.pdf).

Harbor seals are the most abundant marine mammal species found within the action area and present year-round. Based on AAC aerial survey counts from launch monitoring reports conducted since January 2006, approximately 97 percent of all harbor seals are found on

the eastern shore of Ugak Island, approximately 5 mi from LP1. The eastern shore is backed by high steep cliffs that reach up to 1,000 ft above sea level. These cliffs form a visual and acoustic barrier to rocket operations, and limit effects on the species.

Additionally, sound pressure recordings that showed surf and wind-generated sound pressures at sea level were generally in the greater than >70 dBA (SEL) range on the best weather and surf days (Cuccarese *et al.*, 1999; 2000); while sound pressures at sea level can

exceed 100 dBA (SEL) during inclement weather. Ugak's eastern shore is windward to prevailing winds and surf noise is routinely high. The remaining three percent of the harbor seals identified during surveys are found at the northern shore of Ugak Island. Harbor seals located on the northern

shore are not as protected from launch noise, and therefore may be harassed (Level B) incidentally to AAC's rocket launch activities. However, harbor seal abundance on the northern shore is limited due to the lack of suitable habitat (*i.e.*, few beaches). During 30 aerial surveys conducted by AAC during

six rocket launches from 2006–2008, no seals were observed on North Ugak Island on 19 occasions. During surveys when seals were present, the average abundance was 25 seals with a single day count of 125 individuals (Figure 1 below).

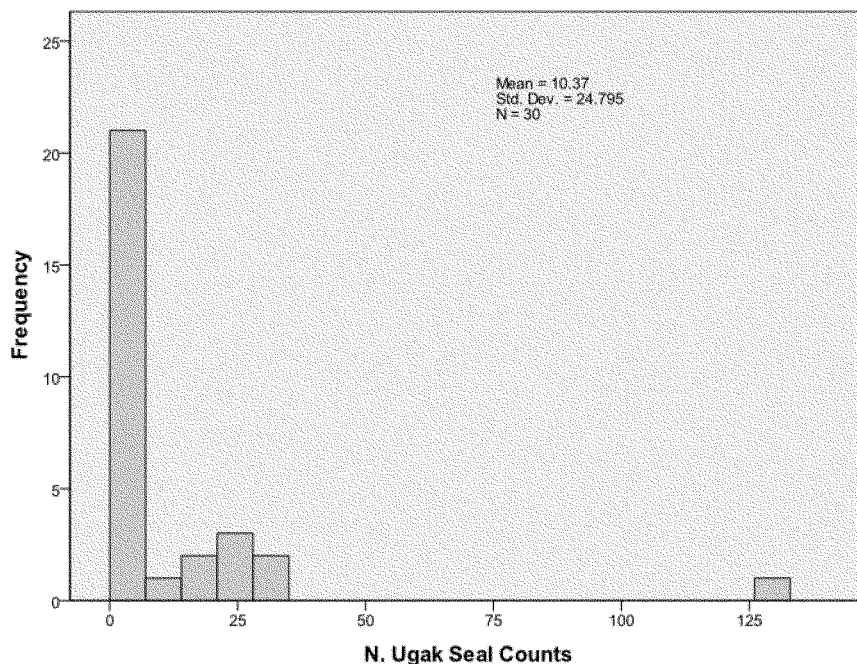


Figure 1. Harbor Seal Count Frequency at the Northwest Spit¹. ¹Frequency of harbor seal counts at the northwest spit during 30 aerial surveys conducted during pre- and post-launch aerial surveys, Kodiak Island, 2006–2008. Unpublished data collected by ABR, Inc. in association with R&M Consultants, Inc. Note: no seals were seen at the northwest spit during 19 of 30 surveys.

Because access to Ugak Island harbor seal haulouts is difficult, little is known of how seals use these habitats. Harbor seals generally breed and molt where they haulout, so it is assumed that both of these activities take place on Ugak Island. This assumption is supported by the fact that young seals have routinely been seen there during aerial surveys. These haulouts are the only haulouts used by harbor seals within the 6-mi radius area designated as being affected by launch operations.

Harbor seals haul out on rocks, reefs, beaches, and drifting glacial ice (Allen and Angliss 2014). They are non-migratory; their local movements are associated with tides, weather, season, food availability, and reproduction, as well as sex and age class (Allen and Angliss 2014; Boveng *et al.*, 2012;

Lowry *et al.*, 2001; Swain *et al.*, 1996). Pupping in Alaska generally takes place in May and June; while molting generally occurs from June to October.

Potential Effects of the Specified Activity on Marine Mammals

Marine mammals produce sounds in various contexts and use sound for various biological functions including, but not limited to (1) social interactions; (2) foraging; (3) orientation; and (4) predator detection. Interference with producing or receiving these sounds may result in adverse impacts. Audible distance, or received levels (RLs) will depend on the nature of the sound source, ambient noise conditions, and the sensitivity of the receptor to the sound (Richardson *et al.*, 1995). Type and significance of marine mammal reactions to noise are likely to be

dependent on a variety of factors including, but not limited to, the behavioral state (*e.g.*, resting, socializing, etc.) of the animal at the time it receives the stimulus, frequency of the sound, distance from the source, and the level of the sound relative to ambient conditions (Southall *et al.*, 2007). In general, marine mammal impacts from loud noise can be characterized as auditory and non-auditory. The generic thresholds described below (Table 4) are used to estimate when harassment may occur (*i.e.*, when an animal is exposed to levels equal to or exceeding the relevant criterion) in specific contexts. However, useful contextual information that may inform our assessment of effects is typically lacking and we consider these thresholds as step functions.

TABLE 4—CURRENT ACOUSTIC EXPOSURE CRITERIA FOR PINNIPEDS

| Criterion | Definition | Threshold |
|-------------------------------------|-----------------------------|---|
| Level B harassment (underwater) ... | Behavioral disruption | 120 dB (non-impulse, continuous source, <i>i.e.</i> , combustion effects of launch vehicles) (rms). |
| Level B harassment (airborne) | Behavioral disruption | 90 dB (harbor seals). |

While low-frequency cetaceans and pinnipeds have been observed to respond behaviorally to low- and mid-frequency sounds (*e.g.*, Frankel, 2005), there is little evidence of behavioral responses in these species to high-frequency sound exposure (*e.g.*, Jacobs and Terhune 2002; Kastelein *et al.*, 2006). If a marine mammal does perceive a signal from an AAC acoustic source, it is likely that the response would be, at most, behavioral in nature.

As discussed above, launch operations are a major source of acoustic stimuli on Kodiak Island and can reach pinniped haulouts on Ugak Island. The activities proposed for taking of marine mammals under these regulations have the potential to cause harassment through acoustic stimuli. The PSCA launch activities create two types of noise: continuous (but short-duration) noise, due mostly to combustion effects of launch vehicles; and impulsive noise, due to sonic boom effects. Generally, noise is generated from four sources during launches: (1) Combustion noise from launch vehicle chambers; (2) jet noise generated by the interaction of the exhaust jet and the atmosphere; (3) combustion noise from the post-burning of combustion products; and (4) sonic booms. Launch noise levels are highly dependent on the type of first-stage booster and the fuel used to propel the vehicle. Therefore, there is a great similarity in launch noise production within each class size of launch vehicles. For the proposed activity, sonic booms will reach the earth's surface beyond the OCS (US FAA 1996) and are not anticipated to impact marine mammals and are therefore not discussed further.

Noise from rocket launches may cause the pinnipeds to lift their heads, move towards the water, or enter the water. It is unlikely there would be significant visual disturbance as space vehicles would be too far away to cause significant stimuli. Modeling done of Castor 120 space launches indicates the vehicle is passing through 45,000 ft altitude by the time it reaches Ugak Island about 70 seconds following launch (US FAA 1996). Therefore, we have determined that the possibility of marine mammal harassment from visual stimuli associated with the proposed activities is so low as to be considered

discountable and it is therefore not considered further.

Disturbance of pinnipeds caused by AAC's rocket launches would be expected to last for only short periods of time, separated by significant amounts of time in which no disturbance occurs. Because such disturbance is sporadic, rather than chronic, and of low intensity, individual marine mammals are unlikely to incur any detrimental impacts to vital rates or ability to forage and, thus, loss of fitness. Correspondingly, even local populations, are extremely unlikely to accrue any significantly detrimental impacts, much less the overall stocks of animals. To comply with their previous regulations, AAC attempted to collect video footage of pinnipeds during launches; however, weather, technical, and accessibility issues prevented video from being obtained. Therefore, no immediate responses of pinnipeds to AAC launch noise have been documented. AAC will attempt another method of documenting pinniped response to launch noise by using time-lapsed photography methods. Time lapse photography has already been implemented by NOAA for other pinnipeds (Steller sea lions) in harsh conditions of the western Aleutians of the U.S. with great success.

The infrequent (approximately nine times per year) and brief (approximately one minute as heard from Ugak Island) nature of these sounds that would result from a rocket launch is not expected to alter the population dynamics of harbor seals which utilize Ugak Island as a haulout site. Current harbor seal numbers on Ugak Island total around 1,500 (R&M 2009), which is an increase of about 1,100 since the 1990s (ENRI 1995–1998); therefore, population dynamics of harbor seals have also not been negatively impacted from past launches originating from PSCA.

Harbor seal pups could be present at times during AAC's rocket launches, but harbor seal pups are extremely precocious, swimming and diving immediately after birth and throughout the lactation period, unlike most other phocids which normally enter the sea only after weaning (Lawson and Renouf 1985; Cottrell *et al.*, 2002; Burns *et al.*, 2005). In summary, they found that the most critical bonding time is within

minutes after birth. As such, it is unlikely that infrequent disturbance resulting from AAC's rocket launches would interrupt the brief mother-pup bonding period within which disturbance could result in separation. NMFS recognizes the critical bonding time needed between a harbor seal mother and her pup to ensure pup survival and maximize pup health. Harbor seals pups are weaned from their mother within approximately four weeks; however, the most critical bonding time is immediately (minutes) after birth. Lawson and Renouf (1987) conducted an in-depth study to investigate harbor seal mother/pup bonds in response to natural and anthropogenic disturbance. In summary, they found that a mutual bond is developed within five minutes of birth, and both the mother and pup play a role in maintaining contact with each other. The study showed a bilateral bond, both on land and in the water, and that mothers would often wait for or return to a pup if it did not follow her. Pups would follow or not move away from their mother as she approached. Most notably, mothers demonstrated overt attention to their pups while in the water and during times of disturbance on the nursery. Increased involvement by the mothers in keeping the pairs together during disturbances became obvious as they would wait for, or return to, their young if the pups fell behind.

Given that pups are precocious at birth, bonds between mothers and pups are known to form within minutes of birth, and other characteristics of mother/pup bonding described above, NMFS has preliminarily determined that Level A harassment or mortality is unlikely to occur and can therefore be discounted.

Finally, PSCA has conducted up to three security overflights per day in the days preceding a launch. Several studies of both harbor seals and Steller sea lions cited in Richardson *et al.* (2005), suggest that these animals respond significantly less to overflights of both planes and helicopters that occur above 305 m (0.2 mi). NMFS does not anticipate harassment from overflights to occur as they generally would remain at least 0.25 mi from a haulout; however, if pilot or crew notice overt responses from

pinnipeds (e.g., flushing) to aircraft, this would be noted and reported to NMFS in the flight report. Observations made of any animals displaced by a security overflight are reported to the environmental monitoring team for inclusion in their report of monitoring results.

The following information provides background on marine mammal responses to launch noise that has been gathered under previous LOAs and Incidental Harassment Authorizations for similar rocket launch activities, including at VAFB in California, and been used to inform our analysis for AAC's proposed rocket launch activities.

Marine Mammal Response to Launch Noise at VAFB

Seals may leave a haulout site and enter the water due to the noise created by launch vehicles during launch operations. The percentage of seals leaving a haulout increases with noise level up to approximately 100 dB ASEL (A-weighted SEL), after which almost all seals leave, although data have shown that some percentage of seals have remained on shore during launches. Time-lapse video photography during four launch events at VAFB revealed that the seals that reacted to the launch noise, but did not leave the haulout were all adults. Because adult seals reacted less strongly than younger seals, this suggests that adults had possibly experienced other launch disturbances and had habituated to them.

The louder the launch noise, the longer it took for seals to begin returning to the haulout site and for the numbers to return to pre-launch levels. Seals may begin to return to the haulout site within 2–55 min of the launch disturbance, and the haulout site usually returned to pre-launch levels within 45–120 min. In two past Athena IKONOS launches with ASELs of 107.3 and 107.8 dB at the closest haulout site, seals began to haulout again approximately 16–55 min post-launch (Thorson *et al.*, 1999a; 1999b). In contrast, noise levels from an Atlas launch and several Titan II launches had ASELs ranging from 86.7 to 95.7 dB at the closest haulout, and seals began to return to the haulout site within 2–8 min post-launch (Thorson and Francine 1997; Thorson *et al.*, 2000).

Auditory Brainstem Response Tests at VAFB

To justify that the potential for permanent threshold shift (PTS) is unlikely, Auditory Brainstem Response (ABR) testing on 21 seals during rocket launches at VAFB was conducted.

VAFB launches create sonic booms over pinniped haulouts, therefore, noise from these launches are much louder than what would be audible at haulouts on Ugak Island (sonic booms are not audible from Ugak Island). To determine if harbor seals experience changes in their hearing sensitivity as a result of launch noise at VAFB, ABR testing was conducted on harbor seals for four Titan IV launches, one Taurus launch, and two Delta IV launches by the USAF in accordance with issued scientific research permits. Following standard ABR testing protocol, the ABR was measured from one ear of each seal using sterile, sub-dermal, stainless steel electrodes. A conventional electrode array was used, and low-level white noise was presented to the non-tested ear to reduce any electrical potentials generated by the non-tested ear. A computer was used to produce the click and an 8 kilohertz (kHz) tone burst stimuli, through standard audiometric headphones. Over 1,000 ABR waveforms were collected and averaged per trial. Initially the stimuli were presented at SPLs loud enough to obtain a clean reliable waveform, and then decreased in 10 dB steps until the response was no longer reliably observed. Once response was no longer reliably observed, the stimuli were then increased in 10 dB steps to the original SPL. By obtaining two ABR waveforms at each SPL, it was possible to quantify the variability in the measurements.

Good replicable responses were measured from most of the seals, with waveforms following the expected pattern of an increase in latency and decrease in amplitude of the peaks, as the stimulus level was lowered. One seal had substantial decreased acuity to the 8 kHz tone-burst stimuli prior to the launch. The cause of this hearing loss was unknown, but was most likely congenital or from infection. Another seal had a great deal of variability in waveform latencies in response to identical stimuli. This animal moved repeatedly during testing, which may have reduced the sensitivity of the ABR testing on this animal for both the click and 8 kHz tone burst stimuli. Two of the seals were released after pre-launch testing but prior to the launch of the Titan IV B–34, as the launch was delayed for many days, and five days is the maximum duration permitted to hold the seals for testing.

Detailed analysis of the changes in waveform latency and waveform replication of the ABR measurements for the 14 seals showed no detectable changes in the seals' hearing sensitivity as a result of exposure to the launch noise. The delayed start (1.75 to 3.5 hrs

after the launches) for ABR testing allows for the possibility that the seals may have recovered from a temporary threshold shift (TTS) before testing began. However, it can be said with confidence that the post-launch tested animals did not have permanent hearing changes due to exposure to the launch noise from the Titan IV, Taurus, or Delta IV SLVs. These results are consistent with previous NMFS conclusions for such activities in its prior rulemakings (63 FR 39055, July 21, 1998; 69 FR 5720, February 6, 2004; 74 FR 6236, February 6, 2009). Given the distance from the pad area to Ugak Island and the measured sound levels from the Castor 120 (101.4 dB), for the loudest space vehicle used at the PSCA, pinniped auditory injury is not anticipated. Therefore, PTS is not a concern for pinnipeds exposed to launch noise from the PSCA as noise levels at this location are below those experienced during the VAFB launches, and sonic booms are not audible on Ugak Island.

Summary of Marine Mammal Impacts from Launches

NMFS does not anticipate a significant impact on any of the species or stocks of marine mammals from launches from PSCA. The effects of the activities are expected to be limited to short-term startle responses and localized behavioral changes. In general, if the received level of the noise stimulus exceeds both the background (ambient) noise level and the auditory threshold of the animals, and especially if the stimulus is novel to them, there may be a behavioral response. The probability and degree of response will also depend on the season, the group composition of the pinnipeds, and the type of activity in which they are engaged. Minor and brief responses, such as short-duration startle or alert reactions, are not likely to constitute disruption of behavioral patterns, such as migration, nursing, breeding, feeding, or sheltering and would not cause injury or mortality to marine mammals. On the other hand, startle and alert reactions accompanied by large-scale movements, such as stampedes into the water of hundreds of animals, may rise to the degree of Level A harassment because they could result in injury of individuals. In addition, such large-scale movements by dense aggregations of marine mammals or at pupping sites could potentially lead to takes by injury or death. However, there is no potential for large-scale movements leading to serious injury or mortality near for the harbor seals at the northern end of Ugak Island because, historically, the number of harbor seals hauled out near the site

is less than 30 individuals, and these animals do not stampede, but flush into the water. Based on similar observational data (at VAFB) and for the largest launch vehicle, the Castor 120 (approximately 101.4 dBA), NMFS anticipates that if seals are disturbed there may be a startle response and flush into the water. Harbor seals would likely return to haulout sites on Ugak Island within 2 to 55 minutes of the launch disturbance. No PTS is anticipated, and the likelihood of TTS is low. In addition, because aircraft will fly at altitudes greater than 305 m (1,000 ft) around pinniped haulouts and rookeries, animals are not anticipated to react to security overflights.

The potential effects to marine mammals described in this section of the document do not take into consideration the proposed monitoring and mitigation measures described later in this document (see the "Proposed Mitigation" and "Proposed Monitoring and Reporting" sections) which, as noted, should affect the least adverse impact practicable on affected marine mammal species and stocks.

Anticipated Effects on Marine Mammal Habitat

Solid fuel rocket boosters would fall into the ocean away from any known or potential haulouts. All sonic booms that reach the earth's surface would be expected to occur over open ocean beyond the OCS. Airborne launch sounds would mostly reflect or refract from the water surface and, except for sounds within a cone of approximately 26 degrees directly below the launch vehicle, would not penetrate into the water column. The sounds that would penetrate would not persist in the water for more than a few seconds. Overall, rocket launch activities from PSCA would not be expected to cause any impacts to habitats used by marine mammals, including pinniped haulouts, or to their food sources.

Proposed Mitigation

In order to issue an incidental take authorization (ITA) under section 101(a)(5)(A) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of affecting the least adverse impact practicable on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses.

To minimize impacts on pinnipeds at haulout sites, the AAC has proposed, as part of their specified activities, the

following mitigation measures: (1) Security overflights immediately associated with the launch would not approach occupied pinniped haulouts on Ugak Island by closer than 0.25 mi (0.4 km), and would maintain a vertical distance of 1,000 ft (305 m) from the haulouts when within 0.5 mi (0.8 km), unless indications of human presence or activity warrant closer inspection of the area to assure that national security interests are protected in accordance with law; (2) if launch monitoring or quarterly aerial surveys indicate that the distribution, size, or productivity of the potentially affected pinniped populations has been affected due to the specified activity, the launch procedures and the monitoring methods would be reviewed, in cooperation with NMFS, and, if necessary, appropriate changes may be made through modifications to a given LOA, prior to conducting the next launch of the same vehicle under that LOA; (3) AAC will purchase and install time-lapsed photography systems in order to survey each of the three pinniped haulout locations around Ugak Island to confirm the abundance of pinnipeds at the haulouts and allow for the more complete surveying efforts. The number of camera systems, equipment capabilities, placement of the systems to be used, and the daily photo frequency will be determined through a cooperative effort between AAC, NMFS, and field experts; (4) AAC will conduct a correlation study in coordination with NMFS. The purpose of the study is to evaluate the effectiveness of the time-lapsed photography systems (specifically, the accuracy of the photography systems compared with aerial count surveys). The results of this study will determine the need to continue aerial surveys. The study will be conducted through a minimum of five launches; and (5) All Castor 120 equivalent launches will be conducted at LP1 which is equipped with a concrete and water-filled flame trench. The purpose of the flame trench is to direct smoke away from the launch pad and to absorb light and noise at their respective peaks (*i.e.* lift-off) to reduce the noise created during each launch.

NMFS has carefully evaluated AAC's proposed mitigation measures and considered a range of other measures in the context of ensuring that NMFS prescribes the means of affecting the least adverse impact practicable on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another: (1) The manner

and the degree to which the successful implementation of the measure is expected to minimize adverse impacts to marine mammals; (2) the proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and (3) the practicability of the measure for applicant implementation, including consideration of personnel safety, and practicality of implementation. The proposed mitigation measures take scientific studies (Richardson *et al.*, 2005) of overflight effects on pinnipeds into consideration. Lastly, the adaptive nature of the proposed mitigation measures allow for adjustments to be made if launch monitoring or quarterly aerial surveys indicate that impacts to the distribution, size, or productivity of pinniped populations are occurring.

Based on our evaluation of the applicant's proposed measures, as well as other measures considered by NMFS or recommended by the public in the prior rulemaking, NMFS has preliminarily determined that the proposed mitigation measures provide the means of affecting the least adverse impacts practicable on marine mammals species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an ITA for an activity, Section 101(a)(5)(A) of the MMPA states that NMFS must set forth "requirements pertaining to the monitoring and reporting of such taking." The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for ITAs must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present. AAC proposes the following for monitoring and reporting: (1) Deploy time-lapsed photography systems designed to monitor pinniped abundance and detect pinniped responses to rocket launches conducted under these regulations. AAC will monitor the effectiveness of these systems, comparing the results to aerial surveys from at least five launches; (2) Ensure the time-lapsed photography systems will be in place and operating in locations that allow for visual monitoring of all three pinniped haulouts during launches; (3) Relocate the time-lapsed photography systems in cooperation with NMFS after five launches if the system is not accurately capturing all three pinniped haulouts and total pinniped abundance during

the launches; (4) Review and log pinniped presence, abundance, behavior, and re-occupation time from the data obtained from the time-lapsed photography systems and report results to NMFS within 90 days of the first five launches under this system; (5) Conduct one pre-launch aerial survey and one post-launch aerial survey for each launch similar to previous years. AAC will conduct a minimum of one aerial survey annually (in the event no launch occurs during a calendar year); and (6) Conduct quarterly aerial surveys, ideally during mid-day coinciding with low tide, to obtain data on pinniped presence, abundance, and behavior within the action area to determine long-term trends in pinniped haulout use. Results of these quarterly surveys will be reported once as part of the year-end summary report. Data collected would include number of seals per haulout, by age class when possible, and if any disturbance behavior is noted from aircraft presence.

Estimated Take by Incidental Harassment

The following text describes the potential range of takes possible of harbor seals on PSCA during launches. AAC estimates that up to 45 launches may occur from PSCA over the course of the 5-year period covered by the proposed rulemaking. Annually, AAC requests nine launches to be authorized. AAC estimates that no more than one launch would occur over a 4-week period, and it is likely the frequency of launches would be less than this estimate.

Harbor seals of all age classes hauled out on the northern shores of Ugak Island may become alert or flush into the water in response to rocket to launches from PSCA. The total number of harbor seals present on Ugak Island ranges up to a maximum of approximately 1,500 seals in the last ten years, and 1,150 seals in the last five years. However, approximately 97 percent of harbor seals are found at the eastern shore haulout where they are sheltered from launch effects by the 1,000 ft cliffs that stand between this haulout and PSCA. Only about three percent of harbor seals use the northern haulout across from PSCA because of the lack of suitable beaches. When present, the majority of counts at the northern haulout were of less than 25 individuals (Figure 1). An exceptional one-time high count of about 125 seals occurred within the last 10 years. The mean number of harbor seals present at the northern haulout is 10 seals with a standard deviation of 25 seals. Therefore, a representative harbor seal

population at the northern haulout of 35 seals (the mean plus one standard deviation) is used for the following take estimate.

Assuming that all 35 harbor seals at the northern haulout are expected to be present and taken by Level B Harassment during a launch, and that all 9 launches are of the Castor 120 (loudest space vehicle), a maximum of 315 harbor seals annually could be taken by Level B harassment with 1,575 harbor seals taken over the 5-year effective period of the regulations. Depending on the type of rocket being launched, the time of day, time of the year, weather conditions, tide and swell conditions, the number of seals that may be taken will range between 0 and 35 per launch. Launches may occur at any time of the year, so any age classes and gender may be taken.

SELs from the loudest launch may reach approximately 101.4 dBA at the traditional Steller sea lion haulout (approximately 3.5 mi from the launch site) which is similar distance to the northern beaches where harbor seal haulout (approximately 4 mi from the launch site). Based on this recorded level and the fact that audible launch noise would be very short in duration, harbor seals are not expected to incur PTS, and the chance of TTS is low to unlikely. No injury or mortality of harbor seals is anticipated, nor would any be authorized. Therefore, NMFS proposes to authorize harbor seal take, by Level B harassment only, incidental to launches from PSCA.

As discussed above, security overflights associated with a launch would not closely approach or circle any pinniped. Therefore, incidental take from this activity is not anticipated. Should the pilot or crew on the plane observe pinnipeds reacting to their presence, the plane would increase altitude and note the number of animals reacting to the plane. These data would be included in AAC's marine mammal reports.

Previous Monitoring

The primary monitoring method has involved conducting aerial surveys along set transect lines to observe and count harbor seals and Steller sea lions. Marine mammals other than harbor seals and Steller sea lions, although observed and recorded, were not specifically targeted by the launch-related aerial surveys. Marine mammal abundance and distribution were recorded during aerial surveys flown in a single-engine fixed-wing airplane with floats. The aerial survey route was designed for harbor seals and Steller sea lions and was flown using a Global

Positioning System (GPS) for navigation. All surveys were intended to be flown within two hours of the daytime low tide and during mid-day, when haulout attendance peaks for harbor seals.

The aerial survey schedule during the formal monitoring period consisted of daily surveys one day prior to the launch, immediately following the launch (on the launch day), and each day of the three days following the launch date, weather conditions permitting (NMFS 2008). Two additional surveys were often conducted prior to the formal monitoring period at AAC's discretion. The two additional surveys were conducted to balance the pre-launch sample size with the three post-launch surveys to allow calculation of the variance in pre-launch counts for subsequent statistical analysis. The aerial surveys were flown 1,000 ft above sea level at 80–90 nautical mph and the flight line was kept ≥ 0.25 mi from known haulouts. Digital photographs of groups of pinnipeds (generally greater than 10 pinnipeds) were taken with a Nikon D70 camera (equipped with a 70 to 300 millimeter zoom lens) or a Canon Powershot S5 camera with image stabilized zoom. Images were reviewed on a personal computer and counts of pinnipeds were summarized from sets of overlapping images. All counts greater than 15 pinnipeds were made from digital images taken from the aircraft, unless the images were blurred or underexposed, in which cases the visual estimates were used.

Foul weather, daylight considerations, launch timing, and timing of tidal flux have all contributed to the difficulty in collecting the data. Foul weather precludes aerial surveys primarily due to visibility, excessive turbulence, and other dangerous conditions. In addition, rockets can often be launched during periods of weather that are not conducive to operation of small aircraft.

Total counts on Ugak Island (both the northern and eastern haulouts combined) have increased steadily and remained stable since the 1990s from several hundred (ENRI 1995–1998) up to a peak of about 1,500 in the last 10 years (R&M 2008). The number of harbor seals tallied at Ugak Island during the July 2008 FTX–03 surveys reached a record for monitoring surveys at 1,534 seals (R&M 2008). Table 5 presents daily counts, by species, of the marine mammals that have been observed during launch-related environmental monitoring activities from 2006–2008. Seal numbers in Table 5 are highest during August and September because they were conducted during the annual molt, when maximal

numbers of harbor seals tend to haulout
(Calambokidis *et al.*, 1987).

TABLE 5—MARINE MAMMAL OBSERVATIONS (2006–2008) DURING LAUNCH-RELATED ENVIRONMENTAL MONITORING WITHIN SIX-MI RADIUS STUDY AREA AND ON HAULOUTS ON UGAK ISLAND

| Date | Steller sea lion ¹ | Harbor seal ² | Gray whale | Humpback whale | Pre-launch survey (number days pre-launch) | Post-Launch survey (number days post-launch) |
|-----------|-------------------------------|--------------------------|------------|----------------|--|--|
| 2/18/2006 | | 684 | | | Yes (5). | |
| 2/19/2006 | | 519 | 2 | | Yes (4). | |
| 2/20/2006 | | 201 | | | Yes (3). | |
| 2/21/2006 | | 405 | 8 | | Yes (2). | |
| 2/22/2006 | | 350 | | | Yes (1). | |
| 2/23/2006 | | 211 | 1 | | | Yes (Same Day). |
| 2/24/2006 | | 270 | 1 | | | Yes (1). |
| 2/25/2006 | | 58 | | | | Yes (2). |
| 8/28/2006 | 3 | 495 | | | Yes (3). | |
| 8/29/2006 | 4 | 652 | | | Yes (2). | |
| 8/31/2006 | 38 | 901 | | | Yes (1). | |
| 9/1/2006 | 2 | 961 | | | | Yes (Same Day). |
| 9/2/2006 | 1 | 954 | 2 | 1 | | Yes (1). |
| 9/3/2006 | 1 | 789 | | 1 | | Yes (2). |
| 5/23/2007 | | 136 | 2 | | Yes (2). | |
| 5/27/2007 | | 402 | 3 | | | Yes (2). |
| 5/28/2007 | | 224 | 1 | | | Yes (3). |
| 9/25/2007 | | 381 | 4 | | Yes (3). | |
| 9/26/2007 | 2 | 265 | | | Yes (2). | |
| 9/27/2007 | | 461 | 8 | | Yes (1). | |
| 9/30/2007 | | 686 | 6 | | | Yes (2). |
| 10/1/2007 | | 748 | | | | Yes (3). |
| 7/15/2008 | 4 | 700 | 9 | | Yes (3). | |
| 7/16/2008 | 5 | 611 | 32 | | Yes (2). | |
| 7/17/2008 | 1 | 853 | 9 | | Yes (1). | |
| 7/18/2008 | 4 | 840 | 12 | | | Yes (Same Day). |
| 7/19/2008 | 4 | 744 | 1 | | | Yes (1). |
| 7/20/2008 | 5 | 610 | 5 | | | Yes (2). |
| 7/21/2008 | 3 | 1534 | | | | Yes (3). |
| 12/7/2008 | 1 | 971 | 5 | | | Yes (2). |

Notes:

1. Steller sea lions pup mid-May to mid-July and breed late-May to late-July at rookeries. Molt is late July to early December (Hoover 1988). Haulouts are used for resting. Ugak Island is a haulout not a rookery. The Ugak Haulout has been used in the past between July and October.

2. Harbor seals pup from mid-May to late-June (Jemison and Kelly 2001) and molt from June to October. Both periods contain peaks in haulout attendance.

3. Five individuals observed by aerial survey, eight captured on unmanned video.

During the most effective period of the recent regulations (2011–2016), there were 17 quarterly surveys flown (Table 6). An average of 644 harbor seals was observed with a range of 32 to 1133 seals and standard deviation of 307 seals. From the first quarter of the calendar year through the fourth, the average number of seals was as follows: 441, 698, 608, and 810, respectively (AAC 2016).

TABLE 6—MARINE MAMMAL OBSERVATIONS (2011–2016) DURING LAUNCH-RELATED ENVIRONMENTAL MONITORING WITHIN SIX-MI RADIUS STUDY AREA AND ON HAULOUTS ON UGAK ISLAND

| Year | Quarter | Date | Time (local) | Number sea lions | Number harbor seals | Notes |
|------|---------------|-----------|--------------|------------------|---------------------|---|
| 2011 | 2nd (Apr–Jun) | N/A | | | | Source selection for flights. |
| 2011 | 3rd (Jul–Sep) | 21–Sep–11 | 1330–1430 | 19 | 462 | Only sea lion sighting. |
| 2011 | 4th (Oct–Dec) | 5–Dec–11 | | | | Postponed twice due to multiple storms. |
| 2012 | 1st (Jan–Mar) | Mar–12 | 0930–1030 | 0 | 32 | Results Typical. |
| 2012 | 2nd (Apr–Jun) | N/A | | | | Postponed due to storms. |
| 2012 | 3rd (Jul–Sep) | 8–Jul–12 | 1600–1626 | 0 | 747 | Results Typical. |
| 2012 | 4th (Oct–Dec) | 20–Oct–12 | 1200–1330 | 0 | 975 | Results Typical. |
| 2013 | 1st (Jan–Mar) | 16–Mar–13 | 1209–1334 | 0 | 823 | Results Typical. |
| 2013 | 2nd (Apr–Jun) | 16–Jun–13 | 1342–1408 | 0 | 332 | Results Typical. |
| 2013 | 3rd (Jul–Sep) | 1–Oct–13 | 1210–1316 | 0 | 955 | Results Typical. |
| 2013 | 4th (Oct–Dec) | 14–Nov–13 | N/A–N/A | 0 | 847 | Results Typical. |
| 2014 | 1st (Jan–Mar) | 21–Jan–14 | 1115–1230 | 0 | 144 | Results Typical. |
| 2014 | 2nd (Apr–Jun) | 5–Apr–14 | 1218–1338 | 0 | 1133 | Results Typical. |
| 2014 | 3rd (Jul–Sep) | 3–Jul–14 | 1110–1239 | 0 | 513 | Results Typical. |
| 2014 | 4th (Oct–Dec) | 30–Oct–14 | 1100–1207 | 0 | 810 | Results Typical. |

TABLE 6—MARINE MAMMAL OBSERVATIONS (2011–2016) DURING LAUNCH-RELATED ENVIRONMENTAL MONITORING WITHIN SIX-MI RADIUS STUDY AREA AND ON HAULOUTS ON UGAK ISLAND—Continued

| Year | Quarter | Date | Time (local) | Number sea lions | Number harbor seals | Notes |
|------------|---------------------|-----------------|--------------|------------------|---------------------|------------------|
| 2015 | 1st (Jan–Mar) | 26–Jan–15 | 1100–1200 | 0 | 312 | Results Typical. |
| 2015 | 2nd (Apr–Jun) | 23–Apr–15 | 1230–1330 | 0 | 631 | Results Typical. |
| 2015 | 3rd (Jul–Sep) | 24–Aug–15 | 1520–1610 | 0 | 726 | Results Typical. |
| 2015 | 4th (Oct–Dec) | 18–Oct–15 | 1100–1154 | 0 | 609 | Results Typical. |
| 2016 | 1st (Jan–Mar) | 21–Mar–16 | 1100–1200 | 0 | 898 | Results Typical. |

Previous rocket launches did not appear to depress the daily attendance of pinnipeds at haulouts on Ugak Island (Table 7).

TABLE 7—HARBOR SEAL COUNTS PRE- AND POST-LAUNCH [2006–2008]

| Launch name/date | Numbers pre launch | Numbers post launch |
|---------------------------------------|-------------------------------|-------------------------------|
| FT–04–1 (02/23/06) ¹ | ⁶ 350 | ⁶ 211 |
| FTG–02 (09/01/06) ² | ⁷ 901 | ⁷ 961 |
| FTG–03 (05/27/07) ³ | ⁷ ⁸ 136 | ⁷ ⁸ 402 |
| FTG–03a (09/28/07) ⁴ | ⁷ 461 | ⁹ 0 |
| FTX–03 (07/18/08) ⁵ | ⁷ 853 | ⁷ 840 |

1. R&M et al. 2006. Environmental Monitoring Report FT–04–1 Launch. Report for Alaska Aerospace Development Corporation. Anchorage, Alaska. 28pp + Appendices.

2. R&M et al. 2006. Environmental Report FTG–02 Launch. Report for Alaska Aerospace Development Corporation. Anchorage, Alaska. 32pp + Appendices.

3. R&M et al. 2007. Environmental Monitoring Report FTG–03 Launch. Report for Alaska Aerospace Development Corporation. Anchorage, Alaska. 24pp + Appendices.

4. R&M et al. 2007. Environmental Monitoring Report FTG–03a Launch. Report for the Alaska Aerospace Development Corporation. Anchorage, Alaska. 28pp + Appendices.

5. R&M et al. 2008. Environmental Monitoring Report FTX–03 Launch. Report for Alaska Aerospace Development Corporation. Anchorage, Alaska. 29pp + Appendices.

6. Visual count; launch coincided with execution of LOA that requires photographic documentation of seal numbers.

7. Counts from photographs.

8. Data are not representative of launch period. Sole pre-launch survey was done two days prior to launch (weather precluded surveys on launch day), and first post launch survey was done two days after launch due to adverse weather conditions.

9. Survey occurred at high tide when haulouts were flooded.

Analyses and Preliminary Determinations

Negligible Impact Analysis

NMFS has defined “negligible impact” in 50 CFR 216.103 as “. . . an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.” A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.*, population-level effects). An estimate of the number of Level B harassment takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be “taken” through behavioral harassment, we consider other factors, such as the likely nature of any responses (*e.g.*, intensity, duration), the context of any responses (*e.g.*, critical reproductive time or location, migration), as well as the number and nature of estimated Level A

harassment takes, the number of estimated mortalities, and effects on habitat. In making a negligible impact determination, NMFS considers (and should explicitly address whenever possible) the following:

(1) The number of anticipated injuries, serious injuries, or mortalities;

(2) The number, nature, and intensity, and duration of Level B harassment (all relatively limited);

(3) The context in which the takes occur (*i.e.*, impacts to areas of significance, impacts to local populations, and cumulative impacts when taking into account successive/ contemporaneous actions when added to baseline data);

(4) The status of stock or species of marine mammals (*i.e.*, depleted, not depleted, decreasing, increasing, stable, impact relative to the size of the population);

(5) Impacts on habitat affecting rates of recruitment/survival; and

(6) The effectiveness of monitoring and mitigation measures.

For reasons stated previously in this document, the specified activities are

not likely to cause long-term behavioral disturbance, abandonment of the haulout area, serious injury, or mortality because:

(1) The possibility of injury, serious injury, or mortality may reasonably be considered discountable;

(2) The effects of the activities are expected to be limited to short-term startle responses and localized behavioral changes;

(3) The considerable evidence, based on over 10 years of monitoring data, suggesting no long-term changes in the use by harbor seal haulouts in the project area as a result of launch operations. Launches will not occur more than a maximum of nine times per year over the next five years. In past years, AAC has conducted zero to two launches on an annual basis. NMFS has analyzed the specified activity to include disturbance events of up to nine launches per year as AAC anticipate the capability to carry out more efficient mission turn-around time over the duration of the proposed regulations;

(4) Based on aerial survey data, the harbor seal population on Ugak Island has increased and is stable. As discussed previously, the population of harbor seals on Ugak Island has increased steadily from several hundred in the 1990s (ENRI 1995–1998) to a peak of about 1,500 in 2008 (R&M 2007a, 2007b, 2008, 2009). Therefore, NMFS does not believe there would be any long-term impact on the health of the population. Given harbor seals are considered a species that is easily disturbed, their resilience to launch effects suggest impacts from launches are short-term and negligible;

(5) Solid fuel rocket boosters would fall into the ocean away from any known or potential haulouts. All sonic booms that reach the earth's surface would be expected to occur over open ocean beyond the OCS. Airborne launch sounds would mostly reflect or refract from the water surface and, except for sounds within a cone of approximately 26 degrees directly below the launch vehicle, would not penetrate into the water column. The sounds that would penetrate would not persist in the water for more than a few seconds. Overall, rocket launch activities from PSCA would not be expected to cause any impacts to habitats used by marine mammals, including pinniped haulouts, or to their food sources or would impact their survival, and;

(6) Mitigation measures to reduce noise from launches once in the air are virtually impossible; however, the noise generated on the launch pad during ignition moves through a deep trench (called a flame trench or flame bucket) that diverts the noise/exhaust toward the northwest (away from Ugak Island).

In addition, improved monitoring would better enable AAC and NMFS to determine if impacts from rocket launches are having short-term and long-term impacts on the present day pinniped populations on Ugak Island. The time-lapse photography system would be able to detect impacts (takes) from launch exposure, including the number of pinnipeds flushing at the haulout sites, while quarterly aerial surveys would aid in determining long-term trends of pinniped abundance. The proposed monitoring measures contained within this notice are specifically designed to, among other things, determine if Level B Harassment is occurring due to rocket launches from AAC.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the mitigation and monitoring measures,

NMFS preliminarily finds that space vehicle and missile launches at the PSCA will have a negligible impact on the affected marine mammal species or stock.

Small Numbers Analysis

The numbers of proposed authorized takes would be considered small relative to the relevant stocks or populations, eight percent for harbor seals. But, it is important to note that the number of expected takes does not necessarily represent of the number of individual animals expected to be taken. Our small numbers analysis accounts for this fact. Multiple exposures to Level B harassment can accrue to the same individuals over the course of an activity that occurs multiple times in the same area (such as AAC's proposed activity). This is especially likely in the case of species that have limited ranges and that have site fidelity to a location within the project area, as is the case with harbor seals.

As described above, harbor seals are non-migratory, rarely traveling more than 50 km from their haulout sites. Thus, while the estimated abundance of the South Kodiak stock of harbor seals is 19,199 (Muto *et al.*, 2015), a substantially smaller number of individual harbor seals is expected to occur within the project area. We expect that, because of harbor seals' site fidelity to locations at Ugak Island, and because of their limited ranges, the same individuals are likely to be taken repeatedly over the course of the proposed activities. Therefore, the number of exposures to Level B harassment over the course of proposed authorization (the total number of takes described in the Estimated Take by Incidental Harassment section) is expected to accrue to a much smaller number of individuals. The maximum number of harbor seals expected to be taken by Level B harassment over the 5-year regulations is 1,575. As we believe the same individuals are likely to be taken repeatedly over the course of the proposed activities, we use the estimate of 1,575 individual animals taken for the purposes of estimating the percentage of the stock abundance likely to be taken.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the mitigation and monitoring measures, we preliminarily find that small numbers of marine mammals will be taken relative to the populations of the affected species or stocks.

Impact on Availability of Affected Species for Taking for Subsistence Uses

Several communities on Kodiak Island use harbor seals (and Steller sea lions) for subsistence uses. The communities closest to Ugak Island are Old Harbor and Kodiak City; each is over 35 miles from Ugak Island. The Alaska Native Harbor Seal Commission quantified the Kodiak area subsistence take of harbor seals (and Steller sea lions) in a report issued in 2011. Within the last ten years, 2011, 2008, 2007, and 2006 were surveyed. On average, during the years surveyed in the last 10 years, Kodiak city took 35.3 harbor seals and Old Harbor took 35.2 harbor seals annually. Specific locations of take are not mentioned in this document.

Based on the distance from each community and the opportunities closer to each community, either a small fraction of the averages provided, or no take can be estimated from each community. It is possible that some fraction of the average number of harbor seals taken listed above were taken from Ugak Island specifically, but there is no documentation to support that conclusion.

There is no expectation that harbor seals will abandon sealing grounds, based on AAC's launches or the launches at other launch sites (*e.g.*, VAFB). In addition, no permanent barriers will be placed between the subsistence hunter and pinnipeds on Ugak Island. There are temporary closures of Ugak Island for a portion of a 24-hour day during each launch.

AAC will consult (as they have for previous regulations) with the Alaska Native Harbor Seal Commission as well as the Kodiak communities before the issuance of any final regulations to ensure project activities do not impact relevant subsistence uses of marine mammals implicated by this action.

Endangered Species Act

There is one marine mammal species under NMFS' jurisdiction that is listed as endangered under the ESA with confirmed or possible occurrence in the action area, the Steller sea lion. NMFS and AAC consulted internally with AKR under the ESA on its proposed issuance of AAC's 2017 MMPA regulations and subsequent LOAs. It was determined that no effect would occur from the proposed activities; therefore, ESA consultation, formal or informal is not required.

National Environmental Policy Act

In 1996, the FAA prepared an EA, and subsequently issued FONSI, for AAC's proposal to construct and operate a

launch site at Narrow Cape on Kodiak Island, Alaska. Since 1998, AAC has provided monitoring reports related to noise and marine mammal impacts associated with ongoing rocket launches from PSCA. After reviewing the new information contained in the monitoring reports, and considering the MMC's comments that impacts to harbor seals should be more comprehensively addressed, NMFS decided that a more current environmental analysis was necessary. In 2005, NMFS prepared an EA and associated FONSI on the Promulgation of Regulations Authorizing Take of Marine Mammals Incidental to Rocket Launches at Pacific Spaceport Complex Alaska, Kodiak Island, Alaska, and the Issuance of Subsequent Letters of Authorization. NMFS found that the promulgation of a 5-year rulemaking in 2006 and issuance of subsequent LOAs would not significantly impact the quality of the human environment and therefore issued a FONSI. Accordingly, preparation of an Environmental Impact Statement or Supplemental Environmental Impact Statement for this action was not necessary. A more recent EA and FONSI was completed in April 2016 that addresses the potential environmental impacts of the proposed action where the FAA would modify the AAC launch site operator license for the PSCA. The EA evaluates the potential environmental impacts of modifying the launch site operator license to include medium-lift launch capability at PSCA with the addition of new infrastructure necessary to support these types of launches, including the construction of a launch pad and associated facilities. NMFS has determined that the proposed action was fully analyzed in the previous NEPA documents, particularly the 2016 EA, and NMFS will adopt the 2016 EA as necessary for the final issuance of the regulations and subsequent LOA(s).

Classification

Pursuant to the procedures established to implement section 6 of Executive Order 12866, the Office of Management and Budget has determined that this proposed rule is not significant.

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), the Chief Counsel for Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. A description of this rule and its purpose are found in the preamble to this

proposed rule, and are not repeated here. The provisions of the rule will apply directly only to AAC. AAC is a public corporation of the State of Alaska involved in space vehicles and guided missiles, and it employs approximately 45 people. SBA's regulations implementing the RFA have no "small" size standards for public administration entities that administer and oversee government programs and activities that are not performed by private establishments. Accordingly, no small entity will be affected by this proposed rule.

The AAC may use a small number of contractors to provide services related to the proposed reporting requirements. However, none of the authorizations or requirements imposed by this action will result in any of AAC's contractors expending any resources in order to be in compliance with these proposed regulations. Thus, the rule would have no effect, directly or indirectly, on these small entities.

Because AAC is the only entity that would be directly affected by this proposed regulation and because the effects of this regulation would impose no costs on any of the contractors—whether they are large or small entities—there will be no significant economic impact on a substantial number of small entities. Accordingly, no regulatory flexibility analysis is necessary, and none has been prepared.

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act (PRA) unless that collection of information displays a currently valid OMB control number. This proposed rule contains a collection-of-information requirement subject to the provisions of the PRA. This collection has been approved previously by OMB under section 3504(b) of the PRA issued under OMB control number 0648-0151, which includes applications for LOAs and reports.

List of Subjects in 50 CFR Part 217

Exports, Fish, Imports, Indians, Labeling, Marine mammals, Penalties, Reporting and record-keeping requirements, Seafood, Transportation.

Dated: January 9, 2017.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For reasons set forth in the preamble, 50 CFR part 217 is proposed to be amended as follows:

PART 217—REGULATIONS GOVERNING THE TAKE OF MARINE MAMMALS INCIDENTAL TO SPECIFIED ACTIVITIES

■ 1. The authority citation for part 217 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*, unless otherwise noted.

■ 2. Add subpart H to part 217 to read as follows:

Subpart H—Taking of Marine Mammals Incidental to Space Vehicle and Missile Launches at Pacific Spaceport Complex Alaska (PSCA), Alaska by Alaska Aerospace Corporation (AAC).

Sec.

217.70 Specified activity and specified geographical region.

217.71 [Reserved]

217.72 Permissible methods of taking.

217.73 Prohibitions.

217.74 Mitigation.

217.75 Requirements for monitoring and reporting.

217.76 Letter of Authorization.

217.77 Renewal of a Letter of Authorization.

217.78 Modifications to a Letter of Authorization.

Subpart H—Taking of Marine Mammals Incidental to Space Vehicle and Missile Launches at Pacific Spaceport Complex Alaska (PSCA), Kodiak Island, Alaska by Alaska Aerospace Corporation (AAC).

§ 217.70 Specified activity and specified geographical region.

(a) Regulations in this subpart apply only to the AAC at the PSCA on Kodiak Island, Alaska, and those persons it authorizes to conduct activities on its behalf for the taking of marine mammals that occurs in the area outlined in paragraph (b) of this section and incidental to conducting up to nine space vehicle launches each year from PSCA, for a total of 45 launches over the 5-year period of these regulations.

(b) The incidental take of marine mammals under the activity identified in paragraph (a) of this section is limited to 315 harbor seals (*Phoca vitulina richardii*) of all ages annually (total of 1,575 seals over the 5-year period of these regulations).

§ 217.71 [Reserved]**§ 217.72 Permissible methods of taking.**

Under a Letter of Authorization (LOA) issued pursuant to § 216.106 of this chapter and § 217.70, the holder of the LOA (herein after AAC) and its contractors may incidentally, but not intentionally, take harbor seals by Level B harassment in the course of conducting space vehicle and missile launch activities within the area described in § 217.70(a), provided all terms, conditions, and requirements of these regulations and such Letter of Authorization are complied with.

§ 217.73 Prohibitions.

Notwithstanding takings contemplated in § 217.70(b) and authorized by an LOA issued under § 216.106 of this chapter and § 217.76, no person in connection with the activities described in § 217.70 may:

- (a) Take any marine mammal not specified in § 217.70(b);
- (b) Take any marine mammal specified in § 217.70(b) other than by incidental, unintentional Level B harassment;
- (c) Take a marine mammal specified in § 217.70(b) if NMFS determines such taking results in more than a negligible impact on the species or stocks of such marine mammal; or
- (d) Violate, or fail to comply with, the terms, conditions, and requirements of this subpart or an LOA issued under § 216.106 of this chapter and § 217.76.

§ 217.74 Mitigation.

(a) When conducting operations identified in § 217.70(a), the mitigation measures contained in the LOA issued under § 216.106 of this chapter and § 217.76 must be implemented. The activity identified in § 217.70(a) must be conducted in a manner that minimizes, to the greatest extent practicable, adverse impacts on marine mammals and their habitats. These mitigation measures include (but are not limited to):

- (1) Security overflights associated with a launch will not approach occupied pinniped haulouts on Ugak Island by closer than 0.25 miles (mi) (0.4 kilometer (km)), and will maintain a vertical distance of 1,000 feet (ft) (305 meter (m)) from the haulouts when within 0.5 mi (0.8 km), unless indications of human presence or activity warrant closer inspection of the area to assure that national security interests are protected in accordance with law;
- (2) If launch monitoring detects pinniped injury or death, or if long-term trend counts from quarterly aerial

surveys indicate that the distribution, size, or productivity of the potentially affected pinniped populations has been affected due to the specified activity, the launch procedures and the monitoring methods will be reviewed, in cooperation with NMFS, and, if necessary, appropriate changes may be made through modifications to a given LOA, prior to conducting the next launch of the same vehicle under that LOA;

(3) AAC will purchase and install time-lapsed photography systems in order to survey each of the three pinniped haulout locations around Ugak Island to confirm the abundance of pinnipeds at the haulouts and allow for the more complete surveying efforts. The number of camera systems, equipment capabilities, placement of the systems to be used, and the daily photo frequency will be determined through a cooperative effort between AAC, NMFS, and field experts;

(4) AAC will conduct a correlation study in coordination with NMFS. The purpose of the study is to evaluate the effectiveness of the time-lapsed photography systems (specifically, the accuracy of the photography systems compared with aerial count surveys). The results of this study will determine the need to continue aerial surveys. The study will be conducted through a minimum of five launches;

(5) All Castor 120 equivalent launches will be conducted at LP1 which is equipped with a concrete and water-filled flame trench. The purpose of the flame trench is to direct smoke away from the launch pad and to absorb light and noise at their, respective peaks (*i.e.* lift-off) to reduce the noise created during each launch; and

(6) Additional mitigation measures as contained in an LOA.

(b) [Reserved]

§ 217.75 Requirements for monitoring and reporting.

(a) Holders of LOAs issued pursuant to § 216.106 of this chapter and § 217.76 for activities described in § 217.70(a) are required to cooperate with NMFS, and any other Federal, State, or local agency with authority to monitor the impacts of the activity on marine mammals. Unless specified otherwise in the LOA, the holder of the LOA must notify the Administrator, Alaska Region, NMFS, by letter, email or telephone, at least two weeks prior to each launch. If the authorized activity identified in § 217.70(a) is thought to have resulted in the mortality or injury of any marine mammals or take of marine mammals not identified in § 217.70(b), then the holder of the LOA must notify the

Director, Office of Protected Resources, NMFS, or designee, by telephone (301-427-8401), within 48 hours of the injury or death.

(b) Holders of LOAs must designate qualified, on-site individuals approved in advance by NMFS, as specified in the LOA, to:

(1) Deploy for AAC, time-lapsed photography systems designed to monitor pinniped abundance and detect pinniped responses to rocket launches conducted under these regulations. AAC will monitor the effectiveness of these systems, comparing the results to aerial surveys from at least five launches;

(2) Ensure the time-lapsed photography systems will be in place and operating in locations that allow for visual monitoring of all three pinniped haulouts during launches.

(3) Relocate the time-lapsed photography systems in cooperation with NMFS after five launches if the system is not accurately capturing all three pinniped haulouts and total pinniped abundance during the launches;

(4) Review and log pinniped presence, abundance, behavior, and re-occupation time from the data obtained from the time-lapsed photography systems and report results to NMFS within 90 days of the first five launches under this system;

(5) Conduct one pre-launch aerial survey and one post-launch aerial survey for each launch. AAC will conduct a minimum of one aerial survey annually (in the event no launch occurs during a calendar year); and

(6) Conduct quarterly aerial surveys, ideally during mid-day coinciding with low tide, to obtain data on pinniped presence, abundance, and behavior within the action area to determine long-term trends in pinniped haulout use. Results of these quarterly surveys will be reported once as part of the annual report required under paragraph (e) of this section.

(c) Holders of LOAs must conduct additional monitoring as required under an LOA.

(d) Holders of an LOA must submit a report to the Alaska Region Administrator, NMFS, within 90 days after each launch. This report must contain the following information:

- (1) Date(s) and time(s) of the launch;
- (2) Location of the time-lapsed photography systems;
- (3) Design of the monitoring program for the time-lapsed photography systems and a description of how data is stored and analyzed; and
- (4) Results of the monitoring program for the time-lapsed photography

systems, including, but not necessarily limited to:

(i) Numbers of pinnipeds, by species and age class (if possible), present on the haulout prior to commencement of the launch;

(ii) Numbers of pinnipeds, by species and age class (if possible), that may have been harassed, including the number that entered the water as a result of launch noise;

(iii) The length of time pinnipeds remained off the haulout during post-launch monitoring;

(iv) Number of harbor seal pups that may have been injured or killed as a result of the launch; and

(v) Other behavioral modifications by pinnipeds that were likely the result of launch noise.

(e) An annual report must be submitted on March 1 of each year that will include results of the aerial quarterly trend counts of pinnipeds and comparison of the results using the time-lapsed photography systems on Ugak Island. Future aerial surveys may be reduced if the time-lapsed photography systems capture similar or better data than aerial surveys.

(f) A final report must be submitted at least 90 days prior to expiration of these regulations if new regulations are sought or 180 days after expiration of regulations. This report will:

(1) Summarize the activities undertaken and the results reported in all previous reports;

(2) Assess the impacts of launch activities on pinnipeds within the action area, including potential for pup injury and mortality;

(3) Assess the cumulative impacts on pinnipeds and other marine mammals from multiple rocket launches; and

(4) State the date(s), location(s), and findings of any research activities related to monitoring using time-lapsed photography systems on marine mammal populations.

§ 217.76 Letter of Authorization.

(a) To incidentally take marine mammals pursuant to these regulations, AAC must apply for and obtain an LOA.

(b) An LOA, unless suspended or revoked, may be effective for a period of time not to exceed the expiration date of these regulations.

(c) If an LOA expires prior to the expiration date of these regulations, AAC must apply for and obtain a renewal of the LOA.

(d) In the event of projected changes to the activity or to mitigation and monitoring measures required by an LOA, AAC must apply for and obtain a modification of the LOA as described in § 217.77.

(e) The LOA will set forth:

(1) The number of marine mammals, by species and age class, authorized to be taken;

(2) Permissible methods of incidental taking;

(3) Means of effecting the least practicable adverse impact (*i.e.*, mitigation) on the species of marine mammals authorized for taking, its habitat, and on the availability of the species for subsistence uses; and

(4) Requirements for monitoring and reporting.

(f) Issuance of an LOA shall be based on a determination that the level of taking will be consistent with the findings made for the total taking allowable under these regulations.

(g) Notice of issuance or denial of an LOA will be published in the **Federal Register** within 30 days of a determination.

§ 217.77 Renewal of a Letter of Authorization.

(a) An LOA issued under § 216.106 of this chapter and § 217.76 for the activity identified in § 217.70(a) will be renewed or modified upon request by the applicant, provided that:

(1) The proposed specified activity and mitigation, monitoring, and reporting measures, as well as the anticipated impacts, are the same as those described and analyzed for these regulations (excluding changes made pursuant to the adaptive management provision in § 217.77(c)(1)), and

(2) NMFS determines that the mitigation, monitoring, and reporting measures required by the previous LOA under these regulations were implemented.

(b) For an LOA modification or renewal requests by the applicant that include changes to the activity or the mitigation, monitoring, or reporting (excluding changes made pursuant to the adaptive management provision in § 217.77(c)(1)) that do not change the findings made for the regulations or result in no more than a minor change in the total estimated number of takes (or distribution by species or years), NMFS may publish a notice of proposed LOA in the **Federal Register**, including the associated analysis illustrating the change, and solicit public comment before issuing the LOA.

(c) An LOA issued under § 216.106 of this chapter and § 217.76 for the activity identified in § 217.70(a) may be modified by NMFS under the following circumstances:

(1) Adaptive Management—NMFS may modify (including augment) the existing mitigation, monitoring, or reporting measures (after consulting

with AAC regarding the practicability of the modifications) if doing so creates a reasonable likelihood of more effectively accomplishing the goals of the mitigation and monitoring set forth in the preamble for these regulations:

(i) Possible sources of data that could contribute to the decision to modify the mitigation, monitoring, or reporting measures in an LOA:

(A) Results from AAC's monitoring from the previous year(s);

(B) Results from other marine mammal and/or sound research or studies; and

(C) Any information that reveals marine mammals may have been taken in a manner, extent or number not authorized by these regulations or subsequent LOAs.

(ii) If, through adaptive management, the modifications to the mitigation, monitoring, or reporting measures are substantial, NMFS will publish a notice of proposed LOA in the **Federal Register** and solicit public comment.

(2) Emergencies—If NMFS determines that an emergency exists that poses a significant risk to the well-being of the species or stocks of marine mammals specified in §§ 217.70(b) and 217.72(a), an LOA may be modified without prior notice or opportunity for public comment. Notice would be published in the **Federal Register** within 30 days of the action.

[FR Doc. 2017-00621 Filed 1-18-17; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No.: 161118999-7008-01]

RIN 0648-BG46

Fisheries of the Northeastern United States; Atlantic Sea Scallop Fishery; Framework Adjustment 28

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to approve and implement measures included in Framework Adjustment 28 to the Atlantic Sea Scallop Fishery Management Plan, which the New England Fishery Management Council adopted and submitted to NMFS for approval. The purpose of Framework 28

is to prevent overfishing, improve yield-per-recruit, and improve the overall management of the Atlantic sea scallop fishery. Framework 28 would: Set specifications for the scallop fishery for fishing year 2017; revise the way we allocate catch to the limited access general category individual fishing quota fleet to reflect spatial management of the scallop fishery; and implement a 50-bushel shell stock possession limit for limited access vessels inshore of the days-at-sea demarcation line north of 42°20' N. lat.

DATES: Comments must be received by February 7, 2017.

ADDRESSES: The Council has prepared a draft environmental assessment (EA) for this action that describes the proposed measures and other considered alternatives and analyzes of the impacts of the proposed measures and alternatives. The Council submitted a decision draft of the framework to NMFS that includes the draft EA, a description of the Council's preferred alternatives, the Council's rationale for selecting each alternative, and an Initial Regulatory Flexibility Analysis (IRFA). Copies of the decision draft of the framework, the draft EA, and the IRFA, are available upon request from Thomas A. Nies, Executive Director, New England Fishery Management Council, 50 Water Street, Newburyport, MA 01950.

You may submit comments on this document, identified by NOAA–NMFS–2016–0155, by either of the following methods:

- **Electronic Submission:** Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to www.regulations.gov/#/docketDetail;D=NOAA-NMFS-2015-0155, click the “Comment Now!” icon, complete the required fields, and enter or attach your comments.

- **Mail:** John K. Bullard, Regional Administrator, NMFS, Greater Atlantic Regional Fisheries Office, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope, “Comments on Scallop Framework 28 Proposed Rule.”

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on www.regulations.gov without change. All personal identifying

information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter “N/A” in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Travis Ford, Fishery Policy Analyst, 978–281–9233.

SUPPLEMENTARY INFORMATION:

Background

The scallop fishery's management unit ranges from the shorelines of Maine through North Carolina to the outer boundary of the Exclusive Economic Zone. The Scallop Fishery Management Plan (FMP), established in 1982, includes a number of amendments and framework adjustments that have revised and refined the fishery's management. The Council sets scallop fishery specifications through specification or framework adjustments that occur annually or biennially. The Council adopted Framework 28 on November 17, 2016, and submitted the framework and draft EA to NMFS on December 21, 2016, for review and approval. This action includes catch, effort, and quota allocations and adjustments to the rotational area management program for fishing year 2017.

Framework 28 specifies measures for fishing year 2017, and includes default fishing year 2018 measures that will go into place should the next specifications-setting action be delayed beyond the start of fishing year 2018. NMFS will implement Framework 28, if approved, after the start of fishing year 2017; 2017 default allocation measures will go into place on March 1, 2017. The Council has reviewed the Framework 28 proposed rule regulations as drafted by NMFS and deemed them to be necessary and appropriate as specified in section 303(c) of the Magnuson–Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

Specification of Scallop Overfishing Limit (OFL), Acceptable Biological Catch (ABC), Annual Catch Limits (ACLs), Annual Catch Targets (ACTs), Annual Projected Landings (APLs) and Set-Asides for the 2017 Fishing Year and Default Specifications for Fishing Year 2018

The Council set the proposed OFL based on a fishing mortality rate (F) of

0.48, equivalent to the overfishing F threshold updated through the 2014 assessment. The Council's Scientific and Statistical Committee recommended a scallop fishery ABC for the 2017 and 2018 fishing years of 103 million lb (46,737 mt) and 95 million lb (43,142 mt), respectively, after accounting for discards and incidental mortality. The Council based the proposed ABC and the equivalent total ACL for each fishing year on an F of 0.38, which is the F associated with a 25-percent probability of exceeding the OFL. The Scientific and Statistical Committee will reevaluate an ABC for 2018 when the Council develops the next framework adjustment in 2017.

Table 1 outlines the proposed scallop fishery catch limits. After deducting the incidental target total allowable catch (TAC), the research set-aside (RSA), and the observer set-aside, the remaining ACL available to the fishery is allocated according to the following fleet proportions established in Amendment 11 to the FMP (72 FR 20090; April 14, 2008): 94.5 percent allocated to the limited access scallop fleet (*i.e.*, the larger “trip boat” fleet); 5 percent allocated to the limited access general category (LAGC) individual fishing quota (IFQ) fleet (*i.e.*, the smaller “day boat” fleet); and the remaining 0.5 percent allocated to limited access scallop vessels that also have LAGC IFQ permits. Amendment 15 to the FMP (76 FR 43746; July 21, 2011) specified that no buffers to account for management uncertainty are necessary in setting the LAGC ACLs, meaning that the LAGC ACL would equal the LAGC ACT. To help ensure that allocation of potential catch to the LAGC IFQ fleet is more consistent with allocations to the limited access fleet and the concept of spatial management, this action proposes to distinguish the ACL from APL in setting allocations (for DAS, trip allocations, and IFQs) for each fleet, as shown in Table 1. The purpose and basis for this change, affecting the LAGC IFQ fleets mainly, is described in more detail in “LAGC Measures” section below. For the limited access fleet, the management uncertainty buffer is based on the F associated with a 75-percent probability of remaining below the F associated with ABC/ACL, which, using the updated Fs applied to the ABC/ACL, now results in an F of 0.34.

TABLE 1—SCALLOP CATCH LIMITS (mt) FOR FISHING YEARS 2017 AND 2018 FOR THE LIMITED ACCESS AND LAGC IFQ FLEETS

| Catch limits | 2017 (mt) | 2018 (mt)* |
|--|--------------|---------------|
| Overfishing Limit | 75,485 | 69,678 |
| Acceptable Biological Catch/ACL (discards removed) | 46,737 | 43,142 |
| Incidental Catch | 23 | 23 |
| Research Set-Aside (RSA) | 567 | 567 |
| Observer Set-Aside | 467 | 431 |
| ACL for fishery | 45,680 | 42,121 |
| Limited Access ACL | 43,167 | 39,804 |
| LAGC Total ACL | 2,512 | 2,317 |
| LAGC IFQ ACL (5% of ACL) | 2,284 | 2,106 |
| Limited Access with LAGC IFQ ACL (0.5% of ACL) | 228 | 211 |
| Limited Access ACT | 38,623 | 35,614 |
| APL | 20,516 | (*) |
| Limited Access Projected Landings (94.5% of APL) | 19,388 | (*) |
| Total IFQ Annual Allocation (5.5% of APL) | 1,129 | ** 846 |
| LAGC IFQ Annual Allocation (5% of APL) | 1,026 | ** 769 |
| Limited Access with LAGC IFQ Annual Allocation (0.5% of APL) | 103 | ** 77 |

* The catch limits for the 2018 fishing year are subject to change through a future specifications action or framework adjustment. This includes the setting of an APL for 2018 that will be based on the 2017 annual scallop surveys.

** As a precautionary measure, the 2018 IFQ annual allocations are set at 75% of the 2017 IFQ Annual Allocations.

This action would deduct 1.25 million lb (567 mt) of scallops annually for 2017 and 2018 from the ABC and set it aside as the Scallop RSA to fund scallop research and to compensate participating vessels through the sale of scallops harvested under RSA projects. As of March 1, 2017, this set-aside would be available for harvest by RSA-funded projects in open areas. Framework 28 would allow RSA to be harvested from the Mid-Atlantic Access Area (MAAA) once this action is approved and implemented, but would prevent RSA harvesting from access areas under 2018 default measures. Of this 1.25 million lb (567 mt) allocation, NMFS has already allocated 63,204 lb (28.7 mt) to previously-funded multi-year projects as part of the 2016 RSA awards process. NMFS is reviewing proposals submitted for consideration of 2017 RSA awards and will be selecting projects for funding in the near future.

This action would also set aside 1 percent of the ABC for the industry-funded observer program to help defray the cost to scallop vessels that carry an observer. The observer set-asides for fishing years 2017 and 2018 are 467 mt and 431 mt, respectively. The Council may adjust the 2018 observer set-aside when it develops specific, non-default measures for 2018.

Open Area Days-at-Sea (DAS) Allocations

This action would implement vessel-specific DAS allocations for each of the three limited access scallop DAS permit categories (*i.e.*, full-time, part-time, and occasional) for 2017 and 2018 (Table 2). Proposed 2017 DAS allocations are

lower than those allocated to the LA fleet in 2016 (34.55 DAS for full-time, 13.82 DAS for part-time, and 2.88 DAS for occasional vessels). Framework 28 would set 2018 DAS allocations at 75 percent of fishing year 2017 DAS allocations as a precautionary measure. This is to avoid over-allocating DAS to the fleet in the event that the 2018 specifications action, if delayed past the start of the 2018 fishing year, estimates that DAS should be less than currently projected. The proposed allocations in Table 2 exclude any DAS deductions that are required if the limited access scallop fleet exceeded its 2016 sub-ACL. In addition, these DAS values take into account a 0.14–DAS reduction necessary to compensate for a measure implemented in Framework Adjustment 26 to the FMP (80 FR 22119; April 21, 2015) that allows vessels to transit to ports south of 39° N. lat. while not on DAS. The proposed DAS also include a 4.7 percent increase because the 2017 fishing year will be 13 months long to account for the change in the start of the fishing year (from March 1 to April 1) implemented through Amendment 19 to the Scallop FMP (81 FR 76516; November 3, 2016).

TABLE 2—SCALLOP OPEN AREA DAS ALLOCATIONS FOR 2017 AND 2018

| Permit category | 2017 | 2018 (Default) |
|------------------|-------|-------------------|
| Full-Time | 30.41 | 21.75 |
| Part-Time | 12.16 | 8.69 |
| Occasional | 2.54 | 1.91 |

Because NMFS is likely to implement Framework 28, if approved, after March

1, 2017, full-time, part-time, and occasional vessels will receive 34.55, 13.82, and 2.88 DAS, respectively, on March 1, 2017, as default allocations. These allocations would be reduced as soon as we implement Framework 28, if approved.

Limited Access Allocations and Trip Possession Limits for Scallop Access Areas

For fishing year 2017 and the start of 2018, Framework 28 would keep the MAAA open as an access area and would also open the Nantucket Lightship Access Area (NLS) and Closed Area 2 Access Area (CA2). Closed Area 1 would remain closed. In addition, this action proposes to open the Elephant Trunk Closed Area and allow full-time vessels to choose to fish up to 18,000 lb (8,165 kg) of their 36,000-lb (16,330 kg) MAAA-allocation in this area. Because of the flexible trip option for the Elephant Trunk area, this action proposes to rename the area Elephant Trunk Flex Access Area (ETFA) for 2017. The Council approved this flexible trip option to reduce the fishing pressure on both the MAAA and the ETFA and to protect small scallops in the ETFA while still providing the option to fish in the area. There are sections of the ETFA where there is a mix of harvestable scallops and small scallops. Framework 28 also proposes a seasonal closure of the ETFA, from July 1 through September 30, to help reduce the discard mortality of small scallops during the warmest months of the year.

Table 3 proposes the limited access full-time allocations for all of the access areas, which could be taken in as many

trips as needed, so long as the vessels do not exceed the possession limit (also in Table 3) on each trip.

TABLE 3—PROPOSED SCALLOP ACCESS AREA FULL-TIME LIMITED ACCESS VESSEL POUNDAGE ALLOCATIONS AND TRIP POSSESSION LIMITS FOR 2016 AND 2017

| Rotational access area | Possession limits | 2017 allocation | 2018 allocation (default) |
|------------------------|----------------------------|-----------------------------|---------------------------|
| CA2 | 18,000 lb (8,165 kg) | 18,000 lb (8,165 kg) | |
| NLS | | 18,000 lb (8,165 kg). | |
| MAAA | | 18,000 lb (8,165 kg) | 18,000 lb (8,165 kg) |
| ETFA | | 18,000 lb (8,165 kg)* | No flex option |
| Total | | 72,000 lb (32,660 kg) | 18,000 lb (8,165 kg). |

* ETFA allocation can be landed from either the ETFA or the MAAA.

For the 2017 fishing year only, a part-time limited access vessel would be allocated a total of 28,800 lb (13,064 kg) with a trip possession limit of 14,400 lb per trip (6,532 kg per trip). Of the 28,800-lb (13,064-kg) allocation, 14,400 lb (6,532 kg) would be allocated exclusively to the MAAA. The remaining 14,400 lb (6,532 kg) could be harvested and landed either from the MAAA or any one other available access area, (CA2, NLS, or ETFA). However, if a vessel chooses to harvest and land the remaining 14,400 lb (6,532 kg) from the ETFA and does not harvest up to the full allocation on a trip, it would only be allowed to land the remaining pounds either from the ETFA or the MAAA. For the 2018 fishing year, part-time limited access vessels would be allocated 14,400 lb (6,532 kg) in the MAAA only with a trip possession limit of 14,400 lb per trip (6,532 kg per trip).

For the 2017 fishing year only, an occasional limited access vessel would be allocated 6,000 lb (2,722 kg) with a trip possession limit of 6,000 lb per trip (2,722 kg per trip). Occasional vessels would be able to harvest 6,000 lb (2,722 kg) allocation from only one available access area (CA2, NLS, MAAA, or ETFA). For the 2018 fishing year, occasional limited access vessels would be allocated 6,000 lb (2,722 kg) in the MAAA only with a trip possession limit of 6,000 lb per trip (2,722 kg per trip).

Limited Access Vessels' One-for-One Area Access Allocation Exchanges

Framework 26 changed the way we allocate access area effort to the limited access fleet from trip allocations (2 trips with an 18,000-lb (8,165-kg) possession limit in an area) to landings allocations (36,000 lb (16,330 kg) of landings with an 18,000-lb (8,165-kg) possession limit in an area). However, Framework 26 did not address trip exchanges because it only opened a single access area. This action clarifies that the owner of a vessel issued a limited access scallop permit may exchange unharvested

scallop pounds allocated into one access area for another vessel's unharvested scallop pounds allocated into another Scallop Access Area. These exchanges may only be made for the amount of the current trip possession limit (18,000-lb (8,165-kg)). In addition, these exchanges would be made only between vessels with the same permit category: A full-time vessel may not exchange allocations with a part-time vessel, and vice versa.

In fishing year 2017, each limited access full-time vessel would be allocated 18,000 lb (8,165 kg) that may be landed from either the ETFA or the MAAA (flex allocation). Such flex allocation could be exchanged in full only for another access area allocation, but only the flex allocation could be landed from the ETFA. For example, if a Vessel A exchanges 18,000 lb (8,165 kg) of flex allocation for 18,000 lb (8,165 kg) of MAAA allocation with Vessel B, Vessel A would no longer be allowed to land allocation from the ETFA based on its MAAA allocation, but Vessel B could land up to 36,000 lb (16,330 kg) from the ETFA and/or the MAAA, combined.

Prohibition on Possessing Greater Than 50 Bushels of Shell Stock for Limited Access Vessels Inshore of the DAS Demarcation Line North of 42°20' N. Lat

This action proposes a 50-bushel shell stock possession limit inshore of the DAS demarcation line for limited access vessels fishing north of 42°20' N. lat. Framework Adjustment 14 to the Scallop FMP (66 FR 21639; April 26, 2001) implemented a 50-bushel possession limit for shell stock south of 42°20' N. lat. for limited access vessels inshore of the DAS demarcation line. This action would extend the restriction to all Federal waters for limited access vessels. This possession limit is intended to prevent limited access vessels from shucking scallops off the DAS clock. Vessels fishing exclusively north of 42°20' N. lat. were exempt from this possession limit to allow a limited

fishery to continue by some vessels that traditionally landed in-shell scallops in this area. Since Framework 14, there has been very little limited access effort north of 42°20' N. lat. However, in the spring of 2016, there was a sharp increase in limited access activity in this area. During this increase in activity there were reports of vessels possessing greater than 50 bushels of shell stock inside of the VMS demarcation line for the purpose of shucking scallops off the DAS clock. This is a conservation and management concern because DAS allocations are set using landings per unit effort (LPUE). The LPUE calculation assumes that vessels are shucking scallops on the DAS clock. Given the recent increase in limited access effort in this area, this action proposes to extend the 50-bushel possession limit for shell stock for limited access vessels to all Federal waters.

LAGC Measures

1. *LAGC IFQ Fleet Allocation Based on Spatial Management.* This action would change the way the LAGC IFQ allocations would be set from a direct percentage of the ACL to a percentage of the APL. The purpose of this change is to help ensure that the allocation of potential catch between the fleets is more consistent with the concept of spatial management by allocating catch to the LAGC IFQ fleet based on harvestable scallops instead of total biomass. Amendment 11 to the Scallop FMP (73 FR 20089; April 14, 2008) split the total scallop catch between the limited access and LAGC IFQ fleets (94.5 percent to the limited access fleet and 5.5 percent to the LAGC IFQ fleet). Using the current method of determining catch for each fleet, however, the LAGC IFQ fleet would effectively be allocated about 11.4 percent of total projected landings. The reason for this allocation is that, currently, ACLs in the scallop fishery are based on the overall biomass of

scallops, while projected landings are limited to the harvestable scallop biomass in areas that are open to the fishery in a given year (*i.e.*, harvestable scallops only in the open area and open access areas). Since Amendment 15 to the Scallop FMP (76 FR 43746; July 21, 2011), the LAGC IFQ allocation (sub-ACL) has been equal to 5.5 percent of the ACL (5 percent for LAGC IFQ vessels and 0.5 percent for LAGC IFQ vessels that also have a limited access scallop permit), while the limited access allocation has been based on projected landings for the fishing year, taking into account only the scallops available to the fishery. The allocation of 94.5 percent of the scallop ACL for the limited access fleet served as a threshold that, if exceeded, would trigger accountability measures for the limited access fleet. As a result of the difference in allocation, the allocation to the limited access fleet is spatially explicit, while the LAGC IFQ allocation is not. In recent years, due to increasing biomass in closed areas included in ACL calculations, projected landings (excluding biomass in closed areas) have been substantially less than ACL. Since the LAGC IFQ fleets' allocations are based on the stock-wide ACL, the fleets have been allocated an increasing percentage of projected landings (greater than 5.5 percent).

Allocating the LAGC IFQ fleets' catch based on projected catch also has less potential to cause harm to the scallop biomass where these vessels fish. LAGC IFQ fleets are constrained by the available access areas and open areas defined in the Scallop FMP because regulations confine the fleets generally to nearshore dredge exemption areas. In addition, because of the size of the vessels in the LAGC IFQ fleet, and the 600-lb (272.2-kg) trip limit, harvest is more concentrated in near-shore areas. With an allocation based on stockwide ACL (including closed areas), the vessels could catch more scallops in the areas where the vessels are confined to than the areas might be able to handle biologically. Allocation based on projected landings of scallops available through area rotation reduces this risk.

Choosing to allocate based on 5.5 percent of the projected catch would result in an approximate 45 percent cut in the allocation from the current method of allocation (*status quo*) for 2017 (2.49 million lb (1,129 mt) based on projected catch compared to 5.5 million lb (2,512 mt) based on stockwide ACL). The Council supported this measure, despite this large cut in the allocation, because the concept of spatial management for the LAGC IFQ fishery has support across both the

limited access and the LAGC IFQ fleets and because it reduces the risk of LAGC IFQ allocations resulting in higher realized F rates in certain areas than predicted in the model. The Council felt that the intent of Amendment 11 was to limit the LAGC IFQ fleet harvest to 5.5 percent of the actual landings, not 5.5 percent of the ACL.

2. ACL and IFQ allocation for LAGC vessels with IFQ permits. For LAGC vessels with IFQ permits, this action implements a 2,284-mt ACL for 2017 and a default ACL of 2,106 mt for 2018 (see Table 1). These sub-ACLs have no associated regulatory or management requirements, but provide a ceiling on overall landings by the LAGC IFQ fleets. The annual allocation to the LAGC IFQ-only fleet for fishing years 2017 and 2018 based on APL would be 1,026 mt and 769 mt, respectively (see Table 1). The 2017 allocation includes a 4.7-percent increase because the 2017 fishing year will be 13 months long to account for the change in the start of the fishing year (from March 1 to April 1) implemented through Amendment 19 to the Scallop FMP.

Because Framework 28 is likely to go into effect after the March 1 start of fishing year 2017, the default 2017 IFQ allocations will go into place automatically on March 1, 2017. This action implements IFQ allocations that are less than the default allocations. NMFS will send a letter to IFQ permit holders providing both default March 1, 2017, IFQ allocations and Framework 28 IFQ allocations so that vessel owners know what mid-year adjustments would occur should Framework 28 be approved.

3. ACL and IFQ allocation for Limited Access Scallop Vessels with IFQ Permits. For limited access scallop vessels with IFQ permits, this action implements a 228-mt ACL for 2017 and a default 211-mt ACL for 2018 (see Table 1). As explained above, this action would change the way the Council and NMFS calculate IFQ allocations by applying each vessel's IFQ contribution percentage to this fleet's percentage (*i.e.*, 0.5 percent) of the projected landings. The annual allocation to limited access vessels with IFQ permits for fishing years 2017 and 2018 would be 103 mt and 77 mt, respectively (see Table 1). The 2017 allocation includes a 4.7 percent increase because the 2017 fishing year will be 13 months long to account for the change in the start of the fishing year (from March 1 to April 1) implemented through Amendment 19 to the Scallop FMP.

4. LAGC IFQ Trip Allocations for Scallop Access Areas. Framework 28 would allocate LAGC IFQ vessels a

fleetwide number of trips in the NLS, MAAA, and ETFA for fishing year 2017 and default fishing year 2018 trips in the MAAA (see Table 4). The total number of trips for both areas combined (2,230) for fishing year 2017 is equivalent to the 5.5 percent of total catch from access areas. This action would not allocate any LAGC IFQ trips into CA2 because many of these vessels do not fish in that area due to its distance from shore. Because the IFQ vessels would not be able to access CA2, the Council proposes in Framework 28 to shift those trips that would have been allocated to CA2 to other access areas closer to shore, so that LAGC IFQ vessels would have the opportunity to utilize their access area trips. This action would allocate 558 trips that would have been allocated to CA2 into NLS (279 trips), MAAA (139), and ETFA (139).

TABLE 4—LAGC IFQ TRIP ALLOCATIONS FOR SCALLOP ACCESS AREAS

| Access area | 2017 | 2018 (default) |
|-------------|-------|----------------|
| NLS | 836 | |
| MAAA | 697 | 558 |
| ETFA | 697 | |
| Total | 2,230 | 558 |

5. Northern Gulf of Maine (NGOM) TAC. This action proposes a 95,000-lb (43,091 kg) annual NGOM TAC for fishing years 2017 and 2018. During the 2016 fishing year there was a 21,629-lb (9,811-kg) overage of the NGOM TAC. This triggers a pound-for-pound deduction in 2017 to account for the overage. Therefore, the 2017 NGOM TAC would be 73,371 lb (33,281 kg) to account for the overage.

6. Scallop Incidental Catch Target TAC. This action proposes a 50,000-lb (22,680-kg) scallop incidental catch target TAC for fishing years 2017 and 2018 to account for mortality from this component of the fishery, and to ensure that F targets are not exceeded. The Council and NMFS may adjust this target TAC in a future action if vessels catch more scallops under the incidental target TAC than predicted.

RSA Harvest Restrictions

This action proposes that vessels participating in RSA projects would be prohibited from harvesting RSA compensation from CA2, NLS, and ETFA during the 2017 fishing year to control F, reduce impacts on flatfish, and reduce impacts on high densities of scallops with growth potential. Further, this action proposes to prohibit the harvest of RSA compensation from the

NGOM to control the F in the area. During the 2017 fishing year, all RSA compensation fishing must take place in either the open area, excluding the NGOM, or the MAAA. In addition, Framework 28 would prohibit the harvest of RSA from any access areas under default 2018 measures. At the start of 2018, RSA compensation could only be harvested from open areas. The Council would re-evaluate this measure in the action that would set final 2018 specifications.

Regulatory Corrections Under Regional Administrator Authority

This proposed rule includes a revision to the regulatory text to address a typographical error in the regulations. NMFS proposes this change consistent with section 305(d) of the MSA which provides that the Secretary of Commerce may promulgate regulations necessary to ensure that amendments to an FMP are carried out in accordance with the FMP and the MSA. This revision corrects the error at § 648.14(i)(4)(i)(G).

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Steven Act, the NMFS Assistant Administrator has made a preliminary determination that this proposed rule is consistent with the FMP, other provisions of the Magnuson-Steven Act, and other applicable law. In making the final determination, NMFS will consider the data, views, and comments received during the public comment period.

This proposed rule does not contain policies with federalism implications under Executive Order 13132.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

An IRFA has been prepared, as required by section 603 of the Regulatory Flexibility Act (RFA). The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. The IRFA consists of Framework 28 analyses, the draft IRFA, and the preamble to this proposed rule.

Description of the Reasons Why Action by the Agency Is Being Considered and Statement of the Objectives of, and Legal Basis for, This Proposed Rule

This action proposes the management measures and specifications for the

Atlantic sea scallop fishery for 2017, with 2018 default measures. A description of the action, why it is being considered, and the legal basis for this action are contained in Framework 28 and the preamble of this proposed rule and are not repeated here.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule

This action contains no new collection-of-information, reporting, or recordkeeping requirements.

Federal Rules Which May Duplicate, Overlap or Conflict With This Proposed Rule

The proposed regulations do not create overlapping regulations with any state regulations or other federal laws.

Description and Estimate of Number of Small Entities to Which the Rule Would Apply

The proposed regulations would affect all vessels with limited access and LAGC scallop permits. Framework 28 provides extensive information on the number and size of vessels and small businesses that would be affected by the proposed regulations, by port and state (see **ADDRESSES**). Fishing year 2015 data were used for this analysis because these data are the most recent complete data set for a fishing year. There were 313 vessels that obtained full-time limited access permits in 2015, including 250 dredge, 52 small-dredge, and 11 scallop trawl permits. In the same year, there were also 34 part-time limited access permits in the sea scallop fishery. No vessels were issued occasional scallop permits. NMFS issued 217 LAGC IFQ permits in 2015, and 119 of these vessels actively fished for scallops that year. The remaining permits likely leased out scallop IFQ allocations with their permits in Confirmation of Permit History.

The RFA defines a small business in shellfish fishery as a firm that is independently owned and operated with receipts of less than \$11 million annually (see NMFS final rule revising the small business size standard for commercial fishing, 80 FR 81194, December 29, 2015). Individually-permitted vessels may hold permits for several fisheries, harvesting species of fish that are regulated by several

different fishery management plans, even beyond those impacted by the proposed action. Furthermore, multiple permitted vessels and/or permits may be owned by entities with various personal and business affiliations. For the purposes of this analysis, “ownership entities” are defined as those entities with common ownership as listed on the permit application. Only permits with identical ownership are categorized as an “ownership entity.” For example, if five permits have the same seven persons listed as co-owners on their permit applications, those seven persons would form one “ownership entity,” that holds those five permits. If two of those seven owners also co-own additional vessels, that ownership arrangement would be considered a separate “ownership entity” for the purpose of this analysis.

On June 1 of each year, ownership entities are identified based on a list of all permits for the most recent complete calendar year. The current ownership dataset is based on the calendar year 2015 permits and contains average gross sales associated with those permits for calendar years 2013 through 2015. Matching the potentially impacted 2015 fishing year permits described above (limited access and LAGC IFQ) to calendar year 2015 ownership data results in 154 distinct ownership entities for the limited access fleet and 87 distinct ownership entities for the LAGC IFQ fleet. Of these, and based on the Small Business Administration guidelines, 141 of the limited access distinct ownership entities and 84 of the LAGC IFQ entities are categorized as small. The remaining 13 of the limited access and 3 of the LAGC IFQ entities are categorized as large entities, all of which are shellfish businesses.

Description of Significant Alternatives to the Proposed Action Which Accomplish the Stated Objectives of Applicable Statutes and Which Minimize Any Significant Economic Impact on Small Entities

Framework 28 has several specification alternatives with different open area DAS and access area allocations in addition to the “No Action” alternative (ALT1). Table 5 provides a description of these alternatives.

TABLE 5—FRAMEWORK 28 PROJECTIONS WITH ALTERNATIVE SPECIFICATIONS

| Alternatives | Effort and catch limits |
|---|---|
| ALT1—No Action—Default measures set in Framework 27 | 34.55 open area DAS, 1 MAAA trip, LAGC IFQ allocation = 4.5 mill. lb. |
| ALT2—Basic Run—IFQ allocations = 5.5% of ACL | 30 DAS, LAGC IFQ allocation = 5.5 mill. lb. |

TABLE 5—FRAMEWORK 28 PROJECTIONS WITH ALTERNATIVE SPECIFICATIONS—Continued

| Alternatives | Effort and catch limits |
|---|---|
| ALT3—Basic Run—IFQ Allocations = 5.5% of Projected landings (Same for Basic Run + ETFA at 30 DAS). | 30 DAS, LAGC IFQ allocation = 2.6 mill. lb. |
| ALT4—Basic Run with Open area F = 0.4, IFQ Allocations = 5.5% of Projected landings (Same for Basic Run + ETFA at F = 0.4). | 27.56 DAS, LAGC IFQ allocation = 2.5 mill. lb. |
| ALT5 (Preferred)—Basic Run with NLS extension + ETFA (F = 0.44), IFQ Allocations = 5.5% of projected landings. | 29.20 DAS, LAGC IFQ allocation = 2.4 mill. lb. |
| ALT6—ETFA—IFQ Allocations = 5.5% of Projected landings | 30 DAS, LAGC IFQ allocation = 2.6 mill. lb. |
| ALT7—ETFA—IFQ Allocations = 5.5% of ACL | 30 DAS, LAGC IFQ allocation = 5.5 mill. |
| SQ—Status Quo scenario | 34.55 open area DAS, 3 MAAA trips, LAGC IFQ allocation = 4.5 mill.lb. |

The estimated revenues and net revenue for the limited access scallop vessels and small business entities under all alternatives to the proposed action are expected to be higher than the No Action alternative and status quo levels in the short-term as well as in the long-term. The differences in terms of revenue and net revenue per limited access vessel of these specification alternatives are not significantly different than that of the proposed action.

The economic impacts of the status quo (5.5 percent of the ACL) and allocation based on spatial management (5.5 percent of the projected landings) alternatives are different for the LAGC IFQ vessels. The status quo management alternative would provide considerably higher allocations to the LAGC IFQ fleets (*i.e.*, 4.1 million lb (1,860 mt) versus 2.3 million lb (1,043 mt) under the proposed action. Therefore, the status quo management alternative would have positive economic impacts on the LAGC IFQ vessels while the proposed action would have negative impacts in 2017 compared to status quo, as summarized above and analyzed in Section 5.4.4.1 of the Framework 28 document. However, the Council chose not to recommend the status quo because, under the status quo method of allocation, the share of IFQ fishery in total landings would be over 11.4 percent of the total landings, which would be inconsistent with the intent of Amendment 11.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Recordkeeping and reporting requirements.

Dated: January 6, 2017.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 648 is proposed to be amended as follows:

PART 648—FISHERIES OF THE NORTHEAST UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 648.14:

- a. Revise paragraphs (i)(1)(viii), (i)(2)(iii)(B), and (i)(2)(vi)(B);
- b. Add paragraph (i)(2)(vi)(C); and
- c. Revise paragraphs (i)(3)(v)(E) and (i)(4)(i)(G).

The revisions and additions read as follows:

§ 648.14 Prohibitions.

* * * * *

(i) * * *

(1) * * *

(viii) *Scallop research.* (A) Fail to comply with any of the provisions specified in § 648.56.

(B) Fish for scallops in, or possess or land scallops from, the NGOM on a scallop research set-aside compensation trip as described in § 648.56(d).

* * * * *

(2) * * *

(iii) * * *

(B) Fish for, possess, or land more than 50 bu (17.62 hL) of in-shell scallops inside the VMS Demarcation Line on or by a vessel, except as provided in the state waters exemption, as specified in § 648.54.

* * * * *

(vi) * * *

(B) Transit the Closed Area II Rotational Area or the Closed Area II Extension Rotational Area, as defined § 648.60(d) and (e), respectively, or the Elephant Trunk Flex Rotational Area, as defined in § 648.60(b), unless there is a compelling safety reason for transiting the area and the vessel's fishing gear is stowed and not available for immediate use as defined in § 648.2.

(C) Fish for, possess, or land scallops in or from the Elephant Trunk Flex Access Area in excess of the vessel's total Elephant Trunk Flex Access Area specific allocation as specified in § 648.59(b)(3)(i)(B)(1)(ii) or the amount permitted to be landed from the

Elephant Trunk Flex Access Area as allowed under trip exchanges specified in § 648.59(b)(3)(ii)(A) and (B).

* * * * *

(3) * * *

(v) * * *

(E) Transit the Elephant Trunk Flex Rotational Area, Closed Area II Rotational Area, or the Closed Area II Extension Rotational Area, as defined § 648.60(b), (d), and (e), respectively, unless there is a compelling safety reason for transiting the area and the vessel's fishing gear is stowed and not available for immediate use as defined in § 648.2.

* * * * *

(4) * * *

(i) * * *

(G) Fish for, possess, or land more than 40 lb (18.1 kg) of shucked scallops, or 5 bu (1.76 hL) of in-shell scallops shoreward of the VMS Demarcation Line, or 10 bu (3.52 hL) of in-shell scallops seaward of the VMS Demarcation Line, when the vessel is not declared into the IFQ scallop fishery, unless the vessel is fishing in compliance with all of the requirements of the State waters exemption program, specified at § 648.54.

* * * * *

■ 3. In § 648.52, revise paragraph (e) to read as follows:

§ 648.52 Possession and landing limits.

* * * * *

(e) Owners or operators of vessels issued limited access permits are prohibited from fishing for, possessing, or landing per trip more than 50 bu (17.6 hL) of in-shell scallops shoreward of the VMS Demarcation Line, unless when fishing under the state waters exemption specified under § 648.54.

* * * * *

■ 4. In § 648.53:

- a. Revise the section heading, paragraph (a)(3), and the heading of paragraph (a)(6);
- b. Add paragraph (a)(6)(iii); and
- c. Revise paragraphs (a)(8), (b)(3), the heading of paragraph (h), (h)(2) introductory text, and (h)(2)(i).

The additions and revisions read as follows:

§ 648.53 Overfishing limit (OFL), acceptable biological catch (ABC), annual catch limits (ACL), annual catch targets (ACT), annual projected landings (APL), DAS allocations, and individual fishing quotas (IFQ).

(a) * * *

(3) *Overall ABC/ACL and APL*—(i) *Overall ABC/ACL.* The overall ABC for sea scallop fishery shall be the catch level that has an associated F that has a 75-percent probability of remaining below the F associated with OFL. The overall ACL shall be equal to the ABC for the scallop fishery, minus discards (an estimate of both incidental and discard mortality). The ABC/ACL, after the discards and deductions specified in

paragraph (a)(4) of this section are removed, shall be divided as sub-ACLs between limited access vessels, limited access vessels that are fishing under a LAGC permit, and LAGC vessels as defined in paragraphs (a)(5) and (6) of this section, after the deductions outlined in paragraph (a)(4) of this section.

(ii) *APL.* The APL shall be equal to the combined projected landings by the limited access and LAGC IFQ fleets in both the open area and access areas, after set-asides (RSA and observer) and incidental landings are accounted for, for a given fishing year. Projected scallop landings are calculated by estimating the landings that will come from open and access area effort combined for both limited access and LAGC IFQ fleets. These projected

landings shall not exceed the overall ABC/ACL and ACT, as described in paragraph (a) of this section.

* * * * *

(6) *LAGC IFQ fleet sub-ACL, sub-ACT, and annual allocation* * * *

* * * * *

(iii) *LAGC IFQ fleet annual allocation.* The annual allocation for the LAGC IFQ fishery for vessels issued only a LAGC IFQ scallop permit shall be equal to 5 percent of the APL. The annual allocation for the LAGC IFQ fishery for vessels issued both a LAGC IFQ scallop permit and a limited access scallop permit shall be 0.5 percent of the APL.

* * * * *

(8) The following catch limits will be effective for the 2017 and 2018 fishing years:

SCALLOP FISHERY CATCH LIMITS

| Catch limits | 2017 (mt) | 2018 (mt) ¹ |
|--|--------------|---------------------------|
| Overfishing Limit | 75,485 | 69,678 |
| Acceptable Biological Catch/ACL (discards removed) | 46,737 | 43,142 |
| Incidental Catch | 23 | 23 |
| Research Set-Aside (RSA) | 567 | 567 |
| Observer Set-Aside | 467 | 431 |
| ACL for fishery | 45,680 | 42,121 |
| Limited Access ACL | 43,167 | 39,804 |
| LAGC Total ACL | 2,512 | 2,317 |
| LAGC IFQ ACL (5% of ACL) | 2,284 | 2,106 |
| Limited Access with LAGC IFQ ACL (0.5% of ACL) | 228 | 211 |
| Limited Access ACT | 38,623 | 35,614 |
| APL | 20,516 | (¹) |
| Limited Access Projected Landings (94.5% of APL) | 19,388 | (¹) |
| Total IFQ Annual Allocation (5.5% of APL) | 1,129 | ² 846 |
| LAGC IFQ Annual Allocation (5% of APL) | 1,026 | ² 769 |
| Limited Access with LAGC IFQ Annual Allocation (0.5% of APL) | 103 | ² 77 |

¹ The catch limits for the 2018 fishing year are subject to change through a future specifications action or framework adjustment. This includes the setting of an APL for 2018 that will be based on the 2017 annual scallop surveys. The 2018 default allocations for the limited access component are defined for DAS in paragraph (b)(3) of this section and for access areas in § 648.59(b)(3)(i)(B).

² As a precautionary measure, the 2018 IFQ annual allocations are set at 75% of the 2017 IFQ Annual Allocations.

(b) * * *

(3) The DAS allocations for limited access scallop vessels for fishing years 2017 and 2018 are as follows:

SCALLOP OPEN AREA DAS ALLOCATIONS

| Permit category | 2017 | 2018 ¹ |
|------------------|-------|-------------------|
| Full-Time | 30.41 | 21.75 |
| Part-Time | 12.16 | 8.69 |
| Occasional | 2.54 | 1.91 |

¹ The DAS allocations for the 2018 fishing year are subject to change through a future specifications action or framework adjustment. The 2018 DAS allocations are set at 75% of the 2017 allocation as a precautionary measure.

* * * * *

(h) *Annual IFQs* * * *

* * * * *

(2) *Calculation of IFQ.* The LAGC IFQ fleet annual allocation as defined in paragraph (a)(6)(iii) of this section, shall be used to determine the IFQ of each vessel issued an IFQ scallop permit. Each fishing year, the Regional Administrator shall provide the owner of a vessel issued an IFQ scallop permit issued pursuant to § 648.4(a)(2)(ii) with the scallop IFQ for the vessel for the upcoming fishing year.

(i) *IFQ.* The IFQ for an IFQ scallop vessel shall be the vessel's contribution percentage as specified in paragraph (h)(2)(iii) of this section and determined using the steps specified in paragraphs (h)(2)(ii) of this section, multiplied by the LAGC IFQ fleet annual allocation as defined in paragraph (a)(6)(iii) of this section.

* * * * *

■ 5. In § 648.59:

■ a. Revise paragraphs (a)(2), (a)(3), (b)(3)(i)(B), and (b)(3)(ii), and (e);

■ b. Remove and reserve paragraph (g)(3)(iv); and

■ c. Revise paragraph (g)(3)(v).

The additions and revisions read as follows:

§ 648.59 Sea Scallop Rotational Area Management Program and Access Area Program requirements.

(a) * * *

(2) *Transiting a Closed Scallop Rotational Area.* No vessel possessing scallops may enter or be in the area(s) specified in this section when those areas are closed, as specified through the specifications or framework adjustment processes defined in § 648.55, unless the vessel is transiting the area and the vessel's fishing gear is stowed and not available for immediate use as defined in § 648.2, or there is a

compelling safety reason to be in such areas without such gear being stowed. A vessel may only transit the Elephant Trunk Flex Rotational Area, the Closed Area II Scallop Rotational Area, or the Closed Area II Extension Scallop Rotational Area, as defined § 648.60(b), (d) and (e), respectively, if there is a compelling safety reason for transiting the area and the vessel's fishing gear is stowed and not available for immediate use as defined in § 648.2.

(3) *Transiting a Scallop Access Area.* Any sea scallop vessel that has not declared a trip into the Scallop Area Access Program may enter a Scallop Access Area, and possess scallops not

caught in the Scallop Access Areas, for transiting purposes only, provided the vessel's fishing gear is stowed and not available for immediate use as defined in § 648.2. Any scallop vessel that has declared a trip into the Scallop Area Access Program may not enter or be in another Scallop Access Area on the same trip except such vessel may transit another Scallop Access Area provided its gear is stowed and not available for immediate use as defined in § 648.2, or there is a compelling safety reason to be in such areas without such gear being stowed. A vessel may only transit the Elephant Trunk Flex Rotational Area,

Closed Area II Scallop Rotational Area, or the Closed Area II Extension Scallop Rotational Area, as defined in § 648.60(b), (d), and (e), respectively, if there is a compelling safety reason for transiting the area and the vessel's fishing gear is stowed and not available for immediate use as defined in § 648.2.

(b) * * *

(3) * * *

(i) * * *

(B) The following access area allocations and possession limits for limited access vessels shall be effective for the 2017 and 2018 fishing years:

(1) *Full-time vessels*—(i)

| Rotational access area | Possession limits | 2017 Allocation | 2018 Allocation (default) |
|---------------------------|----------------------------|--|--|
| Closed Area 2 | 18,000 lb (8,165 kg) | 18,000 lb (8,165 kg) | 18,000 lb (8,165 kg). No flex option. |
| Nantucket Lightship | | 18,000 lb (8,165 kg) | |
| Mid-Atlantic | | 18,000 lb (8,165 kg) | |
| Elephant Trunk Flex | | ¹ 18,000 lb (8,165 kg) | |
| Total | | 72,000 lb (32,660 kg) | 18,000 lb (8,165 kg). |

¹ Elephant Trunk Flex Access Area allocation can be landed from either the Elephant Trunk Flex Access Area or the Mid-Atlantic Access Area, as described in paragraph (B)(1)(ii) of this section.

(ii) *Elephant Trunk Flex Access Area allocations.* Subject to the seasonal restriction specified in § 648.60(b)(2), for the 2017 fishing year only, a full-time vessel may choose to land up to 18,000 lb (8,165 kg) of the Mid-Atlantic Rotational Access Area allocation from the Elephant Trunk Flex Access Area, which shall be known as an *Elephant Trunk Flex Access Area allocation*. For example, Vessel A could take a trip in to the Elephant Trunk Flex Access Area and land 18,000 lb (8,165 kg) from that area on one trip, leaving the vessel with 18,000 lb (8,165 kg) of the Mid-Atlantic Rotational Access Area allocation; or, alternatively, the vessel could take a trip in to the Elephant Trunk Flex Access Area and land 15,000 lb (6,804 kg), leaving the vessel with 21,000 lb (9,525 kg) of Mid-Atlantic Access Area allocation, and, 3,000 lb (1,361 kg) of flex allocation which could be landed from the Elephant Trunk Flex Access Area on another trip.

(iii) For the 2018 fishing year, full-time limited access vessels are allocated 18,000 lb (8,165 kg) in the Mid-Atlantic Access Area only with a trip possession limit of 18,000 lb (8,165 kg).

(2) *Part-time vessels.* (i) For the 2017 fishing year only, a part-time limited access vessel is allocated a total of 28,800 lb (13,064 kg) with a trip possession limit of 14,400 lb per trip (6,532 kg per trip). Of the 28,800-lb (13,064-kg) allocation, 14,400 lb (6,532 kg) are allocated exclusively to the Mid-Atlantic Access Area. The remaining

14,400 lb (6,532 kg) can be landed either from the Mid-Atlantic Access Area or any one other available access area, (Closed Area 2, Nantucket Lightship, or Elephant Trunk Flex Access Areas). However, if a vessel chooses to land the remaining 14,400 lb (6,532 kg) from the Elephant Trunk Flex Access Area and does not land up to the full allocation on a trip, it may only land the remaining pounds either from the Elephant Trunk Flex Access Areas or the Mid-Atlantic Access Area.

(ii) For the 2018 fishing year, part-time limited access vessels are allocated 14,400 lb (6,532 kg) in the Mid-Atlantic Access Area only with a trip possession limit of 14,400 lb per trip (6,532 kg per trip).

(3) *Occasional vessels.* (i) For the 2017 fishing year only, an occasional limited access vessel is allocated 6,000 lb (2,722 kg) with a trip possession limit at 6,000 lb per trip (2,722 kg per trip).

Occasional vessels may harvest 6,000 lb (2,722 kg) allocation from only one available access area (Closed Area 2, Nantucket Lightship, Mid-Atlantic, or Elephant Trunk Flex Access Areas).

(ii) For the 2018 fishing year, occasional limited access vessels are allocated 6,000 lb (2,722 kg) in the Mid-Atlantic Access Area only with a trip possession limit of 6,000 lb per trip (2,722 kg per trip).

(ii) *Limited access vessels' one-for-one area access allocation exchanges.* (A) The owner of a vessel issued a limited access scallop permit may exchange

unharvested scallop pounds allocated into one access area for another vessel's unharvested scallop pounds allocated into another Scallop Access Area. These exchanges may only be made for the amount of the current trip possession limit, as specified in paragraph (b)(3)(i)(B) of this section. For example, if the access area trip possession limit for full-time vessels is 18,000 lb (8,165 kg), a full-time vessel may exchange no more or less than 18,000 lb (8,165 kg), from one access area for no more or less than 18,000 lb (8,165 kg) allocated to another vessel for another access area. In addition, these exchanges may be made only between vessels with the same permit category: A full-time vessel may not exchange allocations with a part-time vessel, and vice versa. Vessel owners must request these exchanges by submitting a completed Access Area Allocation Exchange Form at least 15 days before the date on which the applicant desires the exchange to be effective. Exchange forms are available from the Regional Administrator upon request. Each vessel owner involved in an exchange is required to submit a completed Access Area Allocation Form. The Regional Administrator shall review the records for each vessel to confirm that each vessel has enough unharvested allocation remaining in a given access area to exchange. The exchange is not effective until the vessel owner(s) receive a confirmation in writing from the Regional Administrator

that the allocation exchange has been made effective. A vessel owner may exchange equal allocations up to the current possession limit between two or more vessels under his/her ownership. A vessel owner holding a Confirmation of Permit History is not eligible to exchange allocations between another vessel and the vessel for which a Confirmation of Permit History has been issued.

(B) *Flex allocation exchanges.* In fishing year 2017, each limited access full-time vessel is allocated 18,000 lb (8,165 kg) that may be landed from either the Elephant Trunk Flex Access Area or the Mid-Atlantic Access Area (flex allocation). Such flex allocation may be exchanged in full only for another access area allocation, but only the flex allocation may be landed from the Elephant Trunk Flex Access Area. For example, if a Vessel A exchanges 18,000 lb (8,165 kg) of flex allocation for 18,000 lb (8,165 kg) of Mid-Atlantic Access Area allocation with Vessel B, Vessel A would no longer be allowed to land allocation from the Elephant Trunk Flex Access Area based on its Mid-Atlantic Access Area allocation, but Vessel B could land up to 36,000 lb (16,330 kg) from the Elephant Trunk Flex Access Area and/or the Mid-Atlantic Access Area, combined.

* * * * *

(e) *Sea Scallop Research Set-Aside Harvest in Scallop Access Areas.* Unless otherwise specified, RSA may be harvested in any access area that is open

in a given fishing year, as specified through a specifications action or framework adjustment and pursuant to § 648.56. The amount of scallops that can be harvested in each access area by vessels participating in approved RSA projects shall be determined through the RSA application review and approval process. The access areas open for RSA harvest for fishing years 2017 and 2018 are:

- (1) 2017: Mid-Atlantic Access Area
- (2) 2018: No access areas

* * * * *

(g) * * *

(3) * * *

(v) The following LAGC IFQ access area allocations will be effective for the 2017 and 2018 fishing years:

| Scallop access area | 2017 | 2018 ¹ |
|---------------------------|------|-------------------|
| Mid-Atlantic | 697 | 558 |
| Elephant Trunk Flex | 697 | 0 |
| Nantucket Lightship | 836 | 0 |

¹ The LAGC IFQ access area trip allocations for the 2018 fishing year are subject to change through a future specifications action or framework adjustment.

* * * * *

■ 6. In § 648.60, revise paragraph (b) to read as follows:

§ 648.60 Sea scallop rotational areas.

* * * * *

(b) *Elephant Trunk Flex Rotational Area.* (1) The Elephant Trunk Flex Rotational Area is defined by straight lines connecting the following points in the order stated (copies of a chart

depicting this area are available from the Regional Administrator upon request).

| Point | Latitude | Longitude |
|--------------|-----------|-----------|
| ETFA 1 | 38°50' N. | 74°20' W. |
| ETFA 2 | 38°50' N. | 73°40' W. |
| ETFA 3 | 38°40' N. | 73°40' W. |
| ETFA 4 | 38°40' N. | 73°50' W. |
| ETFA 5 | 38°30' N. | 73°50' W. |
| ETFA 6 | 38°30' N. | 74°20' W. |
| ETFA 1 | 38°50' N. | 74°20' W. |

(2) *Season.* A vessel issued a scallop permit may not fish for, possess, or land scallops in or from the area known as the Elephant Trunk Flex Rotational Area, defined in paragraph (b)(1) of this section, during the period of July 1 through September 30 of each year the Elephant Trunk Flex Rotational Area is open to scallop vessels, unless transiting pursuant to § 648.59(a).

* * * * *

■ 7. In § 648.62, revise paragraph (b)(1) to read as follows:

§ 648.62 Northern Gulf of Maine (NGOM) management program.

* * * * *

(b) * * *

(1) *NGOM annual hard TACs.* The annual hard TAC for the NGOM is 73,371 lb (33,281 kg) for the 2017 fishing year and 95,000 lb (43,091 kg) for the 2018 fishing year.

* * * * *

[FR Doc. 2017-00517 Filed 1-18-17; 8:45 am]

BILLING CODE 3510-22-P

Notices

Federal Register

Vol. 82, No. 12

Thursday, January 19, 2017

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

Notice of Intent To Grant Exclusive License

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice of intent.

SUMMARY: Notice is hereby given that the U.S. Department of Agriculture, Agricultural Research Service, intends to grant to BioWorks, Inc. of Victor, New York, an exclusive license to U.S. Patent No. 9,320,283, "TRICHODERMA ASPERELLUM TO REMEDIATE PHYTOPHTHORA RAMORUM-INFESTED SOIL", issued on April 26, 2016.

DATES: Comments must be received on or before February 21, 2017.

ADDRESSES: Send comments to: USDA, ARS, Office of Technology Transfer, 5601 Sunnyside Avenue, Rm. 4-1174, Beltsville, Maryland 20705-5131.

FOR FURTHER INFORMATION CONTACT: Mojdeh Bahar of the Office of Technology Transfer at the Beltsville address given above; telephone: 301-504-5989.

SUPPLEMENTARY INFORMATION: The Federal Government's patent rights in this invention are assigned to the United States of America, as represented by the Secretary of Agriculture. It is in the public interest to so license this invention as BioWorks, Inc. of Victor, New York has submitted a complete and sufficient application for a license. The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within thirty (30) days from the date of this published Notice, the Agricultural Research Service receives written evidence and argument which establishes that the grant of the license

would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Mojdeh Bahar,

Assistant Administrator.

[FR Doc. 2017-01173 Filed 1-18-17; 8:45 am]

BILLING CODE 3410-03-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2016-0093]

Addition of Moldova to the List of Regions Affected by African Swine Fever

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that we have added Moldova to the Animal and Plant Health Inspection Service (APHIS) list maintained on the APHIS Web site of regions considered affected with African swine fever (ASF). We are taking this action because of the confirmation of ASF in Moldova.

DATES: *Effective Date:* The addition of Moldova to the APHIS list of regions considered affected with ASF is effective retroactively to October 4, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. Donald Link, Microbiologist/Import Risk Analyst, National Import Export Services, VS, 920 Main Campus Drive, Suite 200, Raleigh, NC 27606; (919) 855-7731; *Donald.B.Link@aphis.usda.gov*.

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation of specified animals and animal products to prevent the introduction into the United States of various animal diseases, including rinderpest, foot-and-mouth disease, bovine spongiform encephalopathy, swine vesicular disease, classical swine fever, and African swine fever (ASF). These are dangerous and destructive diseases of ruminants and swine.

Sections 94.8 and 94.17 of part 94 of the regulations contain requirements governing the importation into the United States of pork and pork products from regions of the world where ASF

exists or is reasonably believed to exist and imposes restrictions on the importation of pork and pork products into the United States from those regions. ASF is a highly contagious disease of wild and domestic swine that can spread rapidly in swine populations with extremely high rates of morbidity and mortality. A list of regions where ASF exists or is reasonably believed to exist is maintained on the Animal and Plant Health Inspection Service (APHIS) Web site at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/ct_animal_disease_status.

APHIS receives notice of ASF outbreaks from veterinary officials of the exporting country, from the World Organization for Animal Health (OIE), or from other publically available sources the Administrator determines to be reliable. In a report dated October 4, 2016, the veterinary authorities of Moldova reported to the OIE confirmation of an ASF outbreak in the Donduseni District of Moldova.

Although Moldova does not currently export pork or pork products to the United States, APHIS has determined that it is necessary to impose restrictions on the importation of pork and pork products from Moldova into the United States. Therefore, in response to this outbreak, APHIS added Moldova to the list of regions where ASF exists or is reasonably believed to exist.

As a result, pork and pork products from Moldova are subject to APHIS import restrictions designed to mitigate the risk of ASF introduction into the United States. These restrictions are effective retroactively to October 4, 2016.

Authority: 7 U.S.C. 450, 7701-7772, 7781-7786, and 8301-8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 12th day of January 2017.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017-01270 Filed 1-18-17; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0032]

Notice of Decision To Authorize the Importation of Fresh Star Apple Fruit From Vietnam Into the Continental United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our decision to authorize the importation into the continental United States of fresh star apple fruit from Vietnam. Based on the findings of a pest risk analysis, which we made available to the public for review and comment through a previous notice, we have determined that the application of one or more designated phytosanitary measures will be sufficient to mitigate the risks of introducing or disseminating plant pests or noxious weeds via the importation of fresh star apple fruit from Vietnam.

DATES: Effective January 19, 2017.

FOR FURTHER INFORMATION CONTACT: Mr. Tony Román, Senior Regulatory Policy Specialist, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737–1231; (301) 851–2242.

SUPPLEMENTARY INFORMATION: Under the regulations in “Subpart-Fruits and Vegetables” (7 CFR 319.56–1 through 319.56–76, referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture prohibits or restricts the importation of fruits and vegetables into the United States from certain parts of the world to prevent plant pests from being introduced into and spread within the United States.

Section 319.56–4 of the regulations contains a performance-based process for approving the importation of commodities that, based on the findings of a pest risk analysis (PRA), can be safely imported subject to one or more of the designated phytosanitary measures listed in paragraph (b) of that section. Under that process, APHIS publishes a notice in the **Federal Register** announcing the availability of the PRA that evaluates the risks associated with the importation of a particular fruit or vegetable. Following the close of the 60-day comment period, APHIS may begin issuing permits for importation of the fruit or vegetable subject to the identified designated

measures if: (1) No comments were received on the PRA; (2) the comments on the PRA revealed that no changes to the PRA were necessary; or (3) changes to the PRA were made in response to public comments, but the changes did not affect the overall conclusions of the analysis and the Administrator’s determination of risk.

In accordance with that process, we published a notice¹ in the **Federal Register** on July 19, 2016 (81 FR 46886, Docket No. APHIS–2016–0032), in which we announced the availability, for review and comment, of a PRA that evaluated the risks associated with the importation into the continental United States of fresh star apple fruit (*Chrysophyllum cainito*) from Vietnam. The PRA consisted of a risk assessment identifying pests of quarantine significance that could follow the pathway of importation of fresh star apple fruit from Vietnam into the continental United States and a risk management document identifying phytosanitary measures to be applied to that commodity to mitigate the pest risk.

We solicited comments on the notice for 60 days ending September 19, 2016. We received one comment by that date, from a manufacturing company.

One measure identified in the PRA is that all consignments of fresh star fruit from Vietnam imported into the continental United States will be required to be treated with irradiation prior to arrival in the United States. The commenter argued that the fresh star fruit should also be allowed to be treated after its arrival in the United States.

While it is true that the phytosanitary treatment regulations in 7 CFR 305.9(a)(1) state that, where certified irradiation facilities are available, an approved irradiation treatment may be conducted for any imported regulated article either prior to shipment to the United States or in the United States, this is a general statement of the types of treatment APHIS deems allowable. The particulars of any treatment are examined on an individual basis as part of a country’s market access request. In their request, the national plant protection organization (NPPO) of Vietnam specifically stipulated that fresh star fruit be subject to a pre-clearance program within Vietnam. In considering this request, APHIS determined that Vietnam possesses sufficient infrastructure to meet an in-country treatment requirement.

¹ To view the notice, the comments received, and the PRA, go to <http://www.regulations.gov/#/docketDetail;D=APHIS-2016-0032>.

The PRA also indicates that the fruit must be individually wrapped in plastic prior to shipment to reduce the risk of post-treatment reinfestation. The commenter observed that the PRA does not specify why fruits will be required to be packaged in this manner rather than using insect-proof cartons as described in 7 CFR 305.9(f)(2)(i)(A). The commenter argued that the fresh star fruit should be packed in insect-proof cartons rather than individually wrapped in keeping with the regulations.

Individually wrapping fruit is an effective phytosanitary mitigation measure, which takes the place of insect-proof cartons. This measure was specifically proposed by the NPPO of Vietnam in its market access request. Its phytosanitary efficacy was considered as part of the PRA conducted by APHIS. We determined that such individual wrapping provides equal phytosanitary protection to insect-proofing cartons and pallets.

Therefore, in accordance with the regulations in § 319.56–4(c)(2)(ii), we are announcing our decision to authorize the importation into the continental United States of fresh star apple fruit from Vietnam subject to the following phytosanitary measures:

- The fresh star apple fruit must be imported as commercial consignments only;
- Each consignment of fresh star apple fruit must be accompanied by a phytosanitary certificate issued by the NPPO of Vietnam;
- Each consignment of fresh star apple fruit must be treated in accordance with 7 CFR part 305; and
- Each consignment of fresh star apple fruit is subject to inspection upon arrival at the port of entry to the United States.

These conditions will be listed in the Fruits and Vegetables Import Requirements database (available at <https://www.aphis.usda.gov/favir/>). In addition to these specific measures, fresh star apple fruit from Vietnam will be subject to the general requirements listed in § 319.56–3 that are applicable to the importation of all fruits and vegetables.

Authority: 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 12th day of January 2017.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017–01267 Filed 1–18–17; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE**Farm Service Agency****Information Collection Request; Direct Loan Servicing—Regular****AGENCY:** Farm Service Agency, USDA.**ACTION:** Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Farm Service Agency (FSA) is requesting comments from all interested individuals and organizations on an extension with a revision of a currently approved information collection that supports Direct Loan Servicing-Regular programs. The information is used to determine borrower compliance with loan agreements, assist the borrower in achieving business goals, and regular servicing of the loan account such as graduation, subordination, partial release, and use of proceeds.

DATES: We will consider comments that we receive by March 20, 2017.

ADDRESSES: We invite you to submit comments on this notice. In your comments, include date, volume, and page number, and the OMB control number and the title of the information collection of this issue of the **Federal Register**. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to: www.regulations.gov. Follow the online instructions for submitting comments.
- *Mail:* J. Lee Nault, Loan Specialist, USDA/FSA/FLP, STOP 0523, 1400 Independence Avenue SW., Washington, DC 20250-0503.

You may also send comments to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. Copies of the information collection may be requested by contacting J. Lee Nault at the above address.

FOR FURTHER INFORMATION CONTACT:

J. Lee Nault, (202) 720-6834.

SUPPLEMENTARY INFORMATION:

Title: (7 CFR part 765) Farm Loan Programs—Direct Loan Servicing—Regular.

OMB Number: 0560-0236.

Expiration Date: 05/31/2017.

Type of Request: Extension with a revision.

Abstract: FSA's Farm Loan Programs provide loans to family farmers to purchase real estate and equipment, and finance agricultural production. Direct Loan Servicing—Regular, as specified in 7 CFR part 765, provides the requirements related to routine servicing actions associated with direct loans. FSA is required to actively

supervise its borrowers and provide credit counseling, management advice and financial guidance. Additionally, FSA must document that credit is not available to the borrower from commercial credit sources in order to maintain eligibility for assistance. Information collections established in the regulation are necessary for FSA to monitor and account for loan security, including proceeds derived from the sale of security, and to process a borrower's request for subordination or partial release of security. Borrowers are required to provide financial information to determine graduation eligibility based on commercial lender standards provided to FSA.

FSA is requesting OMB approval on the estimated numbers, which are being provided currently in this request. The burden hours have been increased by 5,968 hours while the annual responses have reduced by 6,531.

For the following estimated total annual burden on respondents, the formula used to calculate the total burden hours is the estimated average time per responses multiplied by the estimated total annual of responses.

Estimate of Average Time to Respond: Public reporting burden for collecting information under this notice is estimated to average 0.84752 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The average travel time, which is included in the total annual burden, is estimated to be 1 hour per respondent.

Type of Respondents: Business or other for profits and farms.

Estimated Number of Respondents: 54,524.

Estimated Average Number of Responses per Respondent: 1.78621.

Estimated Total Annual Responses: 97,391.

Estimated Average Time per Response: 0.84752.

Estimated Total Annual Burden on Respondents: 82,541 hours.

We are requesting comments on all aspects of this information collection to help us to:

- (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (2) Evaluate the accuracy of the agency's estimate of burden of the collection of information including the validity of the methodology and assumptions used;

(3) Evaluate the quality, utility and clarity of the information technology; and

(4) Minimize the burden of the information collection on those who respond through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses where provided, will be made a matter of public record. Comments will be summarized and included in the request for OMB approval.

Val Dolcini,*Administrator, Farm Service Agency.*

[FR Doc. 2017-01071 Filed 1-18-17; 8:45 am]

BILLING CODE 3410-05-P**DEPARTMENT OF AGRICULTURE****Farm Service Agency****Information Collection Request; Guaranteed Farm Loan Program****AGENCY:** Farm Service Agency, USDA.**ACTION:** Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Farm Service Agency (FSA) is requesting comments from all interested individuals and organizations on an extension with a revision of a currently approved information collection associated with the Guaranteed Farm Loan Program. The collected information is needed to make and service loans guaranteed by FSA to eligible farmers and ranchers by commercial lenders and nontraditional lenders. FSA is also requesting approval to merge the information collection for the EZ Guarantee Program and the Micro Lender Program (MLP) (0560-0288) into the Guaranteed Farm Loan Program.

DATES: We will consider comments that we receive by March 20, 2017.

ADDRESSES: We invite you to submit comments on this notice. In your comments, include date, volume, and page number of this issue of the **Federal Register**. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to: www.regulations.gov. Follow the online instructions for submitting comments.
- *Mail:* Trent Rogers, Senior Loan Specialist, USDA, FSA, Stop 0522, 1400 Independence Avenue SW., Washington, DC 20250.

You may also send comments to the Desk Officer for Agriculture, Office of

Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. Copies of the information collection may be requested by contacting Trent Rogers at the above addresses.

FOR FURTHER INFORMATION CONTACT: Trent Rogers, Senior Loan Specialist, (202) 720-3889.

SUPPLEMENTARY INFORMATION:

Description of Information Collection

Title: Guaranteed Farm Loans.

OMB Number: 0560-0155.

Expiration Date of Approval: 05/31/2017.

Type of Request: Extension with a revision.

Abstract: This information collection is needed to effectively administer the FSA guaranteed farm loan programs. The information is collected by the FSA loan official in consultation with participating lenders. The basic objective of the guaranteed loan program is to provide credit to applicants who are unable to obtain credit from lending institutions without a guarantee. The reporting requirements imposed on the public by the regulations at 7 CFR part 762 and 763 are necessary to administer the guaranteed loan program in accordance with statutory requirements of the Consolidated Farm and Rural Development Act and are consistent with commonly performed lending practices. Collection of information after loans are made is necessary to protect the Government's financial interest.

The estimated total annual burden hours are amended due to the EZ Guarantee Program and the Micro Lender Program (MLP), which reduced the information collection requirements. Therefore, the burden hours are being provided currently in this request for OMB approval. The annual responses have been reduced by 23,764 while the burden hours reduced by 33,340 hours in the request.

For the following estimated total annual burden on respondents, the formula used to calculate the total burden hours is the estimated average time per responses multiplied by the estimated total annual of responses.

Estimate of Average Time to Respond: Public reporting burden for collecting information under this notice is estimated to average 0.9989 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The average travel time, which is included in the total annual

burden, is estimated to be 1 hour per respondent.

Type of Respondents: Businesses or other for-profits and Farms.

Estimated Number of Respondents: 14,585.

Estimated Average Number of Responses Per Respondent: 15.308.

Estimated Total Annual Responses: 220,213.

Estimated Average Time per Response: 0.9989.

Estimated Total Annual Burden on Respondents: 220,213 hours.

We are requesting comments on all aspects of this information collection to help us to:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of burden of the collection of information including the validity of the methodology and assumptions used;

(3) Evaluate the quality, utility and clarity of the information technology; and

(4) Minimize the burden of the information collection on those who respond through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses where provided, will be made a matter of public record. Comments will be summarized and included in the request for OMB approval.

Val Dolcini,

Administrator, Farm Service Agency.

[FR Doc. 2017-01072 Filed 1-18-17; 8:45 am]

BILLING CODE 3410-05-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2016-0049]

Codex Alimentarius Commission: Meeting of the Codex Committee on Food Additives

AGENCY: Office of the Deputy Under Secretary for Food Safety, USDA.

ACTION: Notice of public meeting and request.

SUMMARY: The Office of Food Safety, U.S. Department of Agriculture (USDA), and the Food and Drug Administration (FDA), U.S. Department of Health and

Human Services are sponsoring a public meeting on February 21, 2017, from 9:00 a.m. to 12:00 noon. The objective of the public meeting is to provide information and receive public comments on agenda items and draft United States (U.S.) positions discussed at the 49th Session of the Codex Committee on Food Additives (CCFA) of the Codex Alimentarius Commission (Codex), taking place in Macao SAR, China March 20-24, 2017. The USDA Office of Food Safety and FDA recognize the importance of providing interested parties the opportunity to obtain background information on the 49th Session of the CCFA and to address items on the agenda.

DATES: The public meeting is scheduled for Tuesday, February 21, 2017, from 9:00 a.m. to 12:00 p.m.

ADDRESSES: The public meeting will take place in Rooms 1A-001 and 1A-002, The Food and Drug Administration (FDA), Harvey Wiley Federal Building, 5001 Campus Drive, College Park, MD 20740.

Documents related to the 49th Session of the CCFA will be accessible via the Internet at the following address: <http://www.codexalimentarius.org/meetings-reports/en/>.

The U.S. Delegate to the 49th Session of the CCFA, Paul Honigfort, invites interested U.S. parties to submit their comments electronically to the following email address: ccfa@fda.hhs.gov.

Registration: Attendees may register by emailing ccfa@fda.hhs.gov by February 14, 2017. Early registration is encouraged because it will expedite entry into the building and its parking area. If you require parking, please include the vehicle make and tag number when you register. Because the meeting will be held in a Federal building, you should also bring photo identification and plan for adequate time to pass through security screening systems. Attendees that are not able to attend the meeting in-person but wish to participate may do so by phone. Those wishing to participate by phone should request the call-in number and conference code when they register for the meeting.

For further information about the 49th Session of the CCFA contact: Paul Honigfort, Ph.D., Consumer Safety Officer, Division of Food Contact Notifications, Office of Food Additive Safety, U.S. Food and Drug Administration 5001 Campus Drive, College Park, MD 20740, Telephone: (240) 402-1206, Fax: (301) 436-2965, email: Paul.Honigfort@fda.hhs.gov.

FOR FURTHER INFORMATION ABOUT THE PUBLIC MEETING CONTACT: Daniel E.

Folmer, Ph.D., Review Chemist, Division of Petition Review, Office of Food Additive Safety, CFSAN/FDA HFS-265, 5001 Campus Drive, College Park, MD 20740, Telephone: (240) 402-1269, Fax: (301) 436-2972, email: daniel.folmer@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**Background**

Codex was established in 1963 by two United Nations organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO).

Through adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, Codex seeks to protect the health of consumers and ensure that fair practices are used in trade.

The CCFA establishes or endorses permitted maximum levels for individual food additives; prepares priority lists of food additives for risk assessment by the Joint FAO/WHO Expert Committee on Food Additives (JECFA); assigns functional classes and International Numbering System (INS) numbers to individual food additives; recommends specifications of identity and purity for food additives for adoption by Codex; considers methods of analysis for the determination of additives in food; and considers and elaborates standards or codes for related subjects such as labeling of food additives when sold as such. The CCFA is hosted by China.

Issues To Be Discussed at the Public Meeting

The following items on the agenda for the 49th Session of the CCFA will be discussed during the public meeting:

- Matters Referred by the Codex Alimentarius Commission and other subsidiary bodies
- Matters of Interest arising from FAO/WHO and from the 82nd Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)
- Proposed draft Specifications for Identity and Purity of Food Additives arising from the 82nd JECFA Meeting
- Endorsement and/or Revision of Maximum Levels for Food Additives and Processing Aids in Codex Standards
- Alignment of the food additive provisions of commodity standards: Report of the EWG on Alignment
- General Standard for Food Additives (GSFA): Outstanding provisions from the 48th session of CCFA; provisions

for benzoates in FC 14.1.4; provisions in FC 5.0 and 5.1; provisions associated with Note 22; provisions in FC 01.1.1, 01.1.1.1, 01.1.3 and 01.1.4 (Report of the EWG on the GSFA)

- General Standard for Food Additives (GSFA): Use levels for adipic acid (INS 355) in various food categories (replies to CL 2016/9-FA)
- General Standard for Food Additives (GSFA): Proposals for new and/or revision of food additive provisions (replies to CL 2016/8-FA, point 4 (a), 4(b) & 4 (c))
- Discussion paper on the use of food additives in the production of wine
- Proposed draft revision to the International Numbering System (INS) for Food Additives (CAC/GL 36-1989)
- Proposals for additions and changes to the Priority List of Substances proposed for evaluation by JECFA (replies to CL 2016/13-FA)
- Discussion paper on the management of CCFA work
- Other Business and Future Work

Each issue listed will be fully described in documents distributed, or to be distributed, by the Codex Secretariat prior to the meeting. Members of the public may access these documents at <http://www.fao.org/fao-who-codexalimentarius/meetings-reports/detail/en/?meeting=CCFA&session=49>.

Public Meeting

At the February 21, 2017 public meeting, draft U.S. positions on the agenda items will be described and discussed, and attendees will have the opportunity to pose questions and offer comments. Written comments may be offered at the meeting or sent to the U.S. Delegate for the 49th Session of the CCFA, Paul Honigfort, Ph.D. at the following address: ccfa@fda.hhs.gov. Written comments should state that they relate to activities of the 49th Session of the CCFA.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it online through the FSIS Web page located at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/federal-register-notices>.

FSIS will also make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of

information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free email subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. Through the Listserv and Web page, FSIS is able to provide information to a much broader and more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/us-codex-alimentarius/committees-and-task-forces/mailling-list/CT_Index.

Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250-9410.

Fax: (202) 690-7442.

Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotope, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Dated: January 12, 2016.

Mary Frances Lowe,

U.S. Manager for Codex Alimentarius.

[FR Doc. 2017-01108 Filed 1-18-17; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Forest Service

Coconino and Tonto National Forests; Arizona; Fossil Creek Wild and Scenic River Comprehensive River Management Plan and Environmental Impact Statement

AGENCY: Forest Service, USDA.

ACTION: Revised notice of intent to extend the scoping period for the Fossil Creek Wild and Scenic River Environmental Impact Statement and Comprehensive River Management Plan.

SUMMARY: The Coconino and Tonto national forests published a Notice of Intent in the **Federal Register** on November 29, 2016 for the Fossil Creek Wild and Scenic River Environmental Impact Statement and Comprehensive River Management Plan. This notice extends the comment period to January 27, 2017.

DATES: Comments concerning the scope of the analysis must be received by January 27, 2017. The draft environmental impact statement is expected in summer 2017, and the final environmental impact statement is expected in spring 2018.

ADDRESSES: Send written comments via email to comments-southwestern-coconino-redrock@fs.fed.us (include "Fossil Creek CRMP" in the subject line); via mail to Coconino National Forest, Attention: Fossil Creek CRMP, P.O. Box 20429, Sedona, AZ 86341; via facsimile to (928) 203-7539; or in person at the Red Rock Ranger District Office, 8375 State Route 179, Sedona, AZ 86351.

FOR FURTHER INFORMATION CONTACT:

Contact Marcos Roybal, Fossil Creek Project Coordinator, by email at maroybal@fs.fed.us or by phone at (928) 203-2915. For information about the project, including proposed alternatives and other project documents, visit <http://tinyurl.com/FossilCreekCRMP>. Hard copy documents may be requested from the phone number above.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1 (800) 877-8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

The purpose of the project is to prepare a CRMP for the Fossil Creek Wild and Scenic River to meet the requirements of Section 3(d)(1) of the WSRA. The CRMP is needed to provide for the protection or enhancement of Fossil Creek's water quality, free-flowing condition, and its ORVs, and to fulfill WSRA Section 3(b) requirements to establish river corridor boundaries and recreation and wild segment classifications.

Since the decommissioning of a historic hydropower dam in 2005, public use dramatically increased as visitors sought to explore the heavily publicized Arizona landscape. Recreational use during the high-use season (June–September), for example, increased from an estimated 20,000 visitors in 2006 to approximately 80,000 visitors by 2013, with thousands turned away daily at the entrance barricades due to overcrowding. River values that need protection from impacts of recreational use include water quality, recreation, geology, Western Apache traditional and contemporary cultural values, and biological values (especially the high diversity of fish and wildlife species). Impacts have resulted from uncontrolled dispersed camping, creation of unapproved camp sites, creation of unplanned trail systems, excessive littering, and human waste near the creek. Monitoring since 2011 indicates there are increasing impacts to upland vegetation that is habitat for wildlife species; damage to heritage sites; and unsafe conditions for visitors, Forest Service personnel and emergency responders. In April 2016, an interim management reservation system was successfully implemented to reduce the daily capacity of visitors during the high-use season; this interim management reservation system will remain in place until the CRMP's completion.

Proposed Action

The Coconino and Tonto National Forests propose to establish a CRMP to guide management of the designated 17-mile Fossil Creek Wild and Scenic River corridor and to protect or enhance the area's outstandingly remarkable values. Within a range of alternatives, the proposed action is designated to include the most flexibility to increase capacity and recreation infrastructure—maximizing recreation opportunities in the future—while providing protection for sensitive river and tribal values at the same time through both a management plan and site-specific actions. Project actions would address

recreation capacity, corridor access, recreation facilities, services, and public health and safety.

During all or part of the year, a reservation system would manage visitor use by limiting the number of people at one time (PAOT) in the river corridor. The initial PAOT in the river corridor would be set at the current 2016 reservation management level—approximately 154 vehicles and 780 PAOT, including administrative use. Over time, if appropriate, adaptive management would increase capacity to a permitted maximum of approximately 338 vehicles and 1,705 PAOT if infrastructure is built, management capacity allows, and visitor behavior promotes sustainable river value protection. The proposed action also includes the following potential elements:

- Existing recreation sites would be expanded, particularly at the Irving site.
- Additional trails would be developed to link recreation sites and provide a greater variety of opportunities for a different hiking levels.
- A portion of Forest Road 708 would become a motorized trail.
- A limited amount of camping would be allowed at designated sites.
- Opportunities for outfitters/guides and concessionaries would be provided.
- Limited or no waterplay would exist at some creek locations due to cultural or natural resource issues.
- Some system routes would be closed or decommissioned, and other restoration actions would occur.

The existing Coconino and Tonto Forest Plans would be programmatically amended under the 2012 Planning Rule to incorporate management direction for the Fossil Creek WSR corridor. The proposed amendments would add, replace, delete or revise (as needed) direction for the management of the Wild and Scenic River corridor.

Possible Alternatives

A range of alternatives to the proposed action, including a no action alternative and three additional action alternatives, are being considered. The no action alternative (Alternative A) represents no change (a CRMP would not be established) and serves as the baseline for comparison of the effects of the action alternatives. The four action alternatives, which are based on extensive public engagement that has occurred since 2010, include: Alternative B (Enhanced Protections), Alternative C (Non-motorized Experience), Alternative D (Motorized Use and Refugia), and Alternative E (Long-term Adaptive Management—

Proposed Action). More detailed descriptions of the proposed action and alternatives can be found online at <http://tinyurl.com/FossilCreekCRMP> or be requested through the contact information provided above.

Lead and Cooperating Agencies

Arizona Game and Fish Department has cooperating agency status in order to assist the Coconino and the Tonto National Forests in the preparation of the Fossil Creek Wild and Scenic River CRMP and EIS.

Responsible Official

Laura Jo West, the Forest Supervisor on the Coconino National Forest, is the responsible official.

Nature of Decision To Be Made

Given the purpose and need of the project, the Coconino Forest Supervisor will review the proposed action, other alternatives, and the effects analysis in the EIS in order to determine: (1) Which alternative, or combination of alternatives, should be implemented; (2) what actions will be taken to protect and enhance the river's water quality, free-flowing condition and its ORVs, as required by WSRA; (3) the location and extent of infrastructure development, restoration activities, and changes in permitted visitor capacity; (4) the design features, mitigation measures and monitoring requirements; and, (5) consistency with the forest plans in place at the time of the decision and the need for amendments.

Preliminary Issues

Since 2010, public involvement regarding management of the Fossil Creek Wild and Scenic River has informed key issues and the alternatives that have been developed. Three key issues have arisen: (1) Recreation opportunities and recreational impacts on natural and cultural resources; (2) the level of recreation development; and (3) public health and safety. These issues form the basis for the alternatives presented in this Notice.

Scoping Process

The Notice of Intent published on November 29, 2016 initiated the scoping process, which guides the development of the environmental impact statement. Several scoping meetings have been held, and interested parties should check the Fossil Creek CRMP Web page at <http://tinyurl.com/FossilCreekCRMP> for information about these meetings. This revised Notice of Intent extends the scoping period to January 27, 2017.

This project is subject to the objection process pursuant to 36 CFR 218 and is

not being authorized under the Healthy Forest Restoration Act (HFRA). As such, those who provide specific written comments during designated comment periods in accordance with 36 CFR 218.5 will be eligible to participate in the objection process. Issues raised in objections must be based on previously submitted timely, specific written comments regarding the proposed project unless new information arises after designated opportunities (36 CFR 218.7). Several previous scoping periods have occurred since 2010, and provide standing to object under 36 CFR 218 to those who commented during designated comment periods.

It is important that reviewers provide their comments at such times and in such manner that they are useful to the agency's preparation of the environmental impact statement. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions.

Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered, but will not be eligible for objection per 36 CFR 218.5.

Dated: January 12, 2017.

Laura Jo West,

Coconino National Forest Supervisor.

[FR Doc. 2017-01191 Filed 1-18-17; 8:45 am]

BILLING CODE 3411-15-P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Connecticut Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA), that a briefing meeting of the Connecticut Advisory Committee to the Commission will convene at 9:30 a.m. (EST) on Tuesday, February 7, 2017, in the Old Judiciary Room of the Capitol Building, 210 Capitol Avenue, Hartford, CT 06106.

DATES: Tuesday, February 7, 2017 (EST). at 9:30 a.m.—Briefing Meeting and Public Session

ADDRESSES: Old Judiciary Room of the Capitol Building, 210 Capitol Avenue, Hartford, CT 06106.

FOR FURTHER INFORMATION CONTACT: Barbara Delaviez at ero@usccr.gov, or 202-376-7533.

SUPPLEMENTARY INFORMATION: The purpose of the briefing meeting is to examine the issue of solitary confinement in Connecticut correctional facilities. The Committee will hear from elected officials, correction officials, advocates, former inmates, and family members of incarcerated prisoners. The public is invited to the meeting and encouraged to address the committee following the presentations.

If other persons who plan to attend the meeting require other accommodations, please contact Evelyn Bohor at ebohor@usccr.gov at the Eastern Regional Office at least ten (10) working days before the scheduled date of the meeting.

Time will be set aside at the end of the briefing so that members of the public may address the Committee after the formal presentations have been completed. Persons interested in the issue are also invited to submit written comments; the comments must be received in the regional office by Tuesday, March 7, 2017. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, faxed to (202) 376-7548, or emailed to Evelyn Bohor at ebohor@usccr.gov. Persons who desire additional information may contact the Eastern Regional Office at (202) 376-7533.

Records and documents discussed during the meeting will be available for public viewing as they become available at <http://facadatabase.gov/committee/meetings.aspx?cid=239> and clicking on the "Meeting Details" and "Documents" links. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, www.usccr.gov, or to contact the Eastern Regional Office at the above phone number, email or street address.

Tentative Agenda

Welcome and Introductions

David J. McGuire, Chair, Connecticut Advisory Committee

Opening Statement

David J. McGuire, Chair, Connecticut Advisory Committee

Briefing Meeting

Panel I—Elected Officials and
Correction Officials

Panel II—Professors, Advocates, and
former inmates and family members
of prisoners.

Dated: January 12, 2016.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2017–01127 Filed 1–18–17; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Economic Development Administration

**Notice of Petitions by Firms for
Determination of Eligibility To Apply
for Trade Adjustment Assistance**

AGENCY: Economic Development
Administration, Department of
Commerce.

ACTION: Notice and Opportunity for
Public Comment.

Pursuant to Section 251 of the Trade
Act 1974, as amended (19 U.S.C. 2341

et seq.), the Economic Development
Administration (EDA) has received
petitions for certification of eligibility to
apply for Trade Adjustment Assistance
from the firms listed below.
Accordingly, EDA has initiated
investigations to determine whether
increased imports into the United States
of articles like or directly competitive
with those produced by each of these
firms contributed importantly to the
total or partial separation of the firm's
workers, or threat thereof, and to a
decrease in sales or production of each
petitioning firm.

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE
[1/1/2017 through 1/12/2017]

| Firm name | Firm address | Date accepted for investigation | /Product(s) |
|--|--|------------------------------------|---|
| M. Lizen Manufacturing Company | 2625 Federal Signal Drive, University Park, IL 60484. | 1/11/2017 | The firm manufactures precision metal stampings and springs. |
| Brad Foote Gear Works, Inc. | 3250 South Central Avenue, Cicero, IL 60804. | 1/12/2017 | The firm manufactures precision-ma- chined metal gears. |
| Golden Hill Enterprises, d/b/a Golden Hill Studios. | 4123 Golden Hill Road, Great Valley, NY 14741. | 1/12/2017 | The firm manufactures hand painted glassware. |
| Guidry's Catfish, Inc. | 1093 Henderson Highway, Breau Bridge, LA 70517. | 1/12/2017 | The firm processes seafood. |

Any party having a substantial
interest in these proceedings may
request a public hearing on the matter.
A written request for a hearing must be
submitted to the Trade Adjustment
Assistance for Firms Division, Room
71030, Economic Development
Administration, U.S. Department of
Commerce, Washington, DC 20230, no
later than ten (10) calendar days
following publication of this notice.

Please follow the requirements set
forth in EDA's regulations at 13 CFR
315.9 for procedures to request a public
hearing. The Catalog of Federal
Domestic Assistance official number
and title for the program under which
these petitions are submitted is 11.313,
Trade Adjustment Assistance for Firms.

Miriam Kearse,

Lead Program Analyst.

[FR Doc. 2017–01134 Filed 1–18–17; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–65–2016]

**Foreign-Trade Zone (FTZ) 158—
Vicksburg/Jackson, Mississippi;
Authorization of Limited Production
Activity; MTD Consumer Group, Inc.
(Lawn and Garden Equipment);
Verona, Mississippi**

On September 13, 2016, MTD
Consumer Group, Inc., submitted a
notification of proposed production
activity to the Foreign-Trade Zones
(FTZ) Board for its facility within FTZ
158—Site 17, in Verona, Mississippi.
The notification was processed in
accordance with the regulations of the
FTZ Board (15 CFR part 400), including
notice in the **Federal Register** inviting
public comment (81 FR 68404, October
4, 2016). The FTZ Board has determined
that further review of part of the
proposed activity is warranted at this
time. The production activity described
in the notification is authorized on a
limited basis, subject to the FTZ Act and
the Board's regulations, including
Section 400.14, and further subject to a
restriction requiring that foreign-status
textile grass catcher bags be admitted in
domestic/duty-paid status (19 CFR
146.43).

Dated: January 11, 2017.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2017–01213 Filed 1–18–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–63–2016]

**Foreign-Trade Zone (FTZ) 177—
Evansville, Indiana; Authorization of
Production Activity; Best Chairs, Inc.
d/b/a Best Home Furnishings
(Upholstered Furniture); Ferdinand,
Cannelton and Paoli, Indiana**

On September 14, 2016, Best Chairs,
Inc. d/b/a Best Home Furnishings
submitted a notification of proposed
production activity to the Foreign-Trade
Zones (FTZ) Board for its facility within
FTZ 177—Sites 5, 6, and 7, in
Ferdinand, Cannelton and Paoli,
Indiana.

The notification was processed in
accordance with the regulations of the
FTZ Board (15 CFR part 400), including
notice in the **Federal Register** inviting
public comment (81 FR 65626,
September 23, 2016). The FTZ Board
has determined that no further review of
the activity is warranted at this time.
The production activity described in the
notification is authorized, subject to the

FTZ Act and the Board's regulations, including Section 400.14, and subject to a restriction requiring that foreign status upholstery leather be admitted to the zone in privileged foreign status (19 CFR 146.41).

Dated: January 12, 2017.

Andrew McGilvray,
Executive Secretary.

[FR Doc. 2017-01207 Filed 1-18-17; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 2025]

Foreign-Trade Zone 168; Application Requesting Expansion/Reorganization; Dallas/Fort Worth, Texas Area

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a-81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Metroplex International Trade Development Corporation, grantee of Foreign-Trade Zone 168, submitted an application to the Board for authority to reorganize/expand FTZ 168 to include proposed Site 9 in Coppell, Texas and to remove 101 acres from existing Site 8 in Gainesville, Texas, adjacent to the Dallas/Fort Worth Customs and Border Protection port of entry (B-52-2013, docketed May 23, 2013);

Whereas, notice inviting public comment has been given in the **Federal Register** (78 FR 32238-32239, May 29, 2013) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiners' report, and finds that the requirements of the FTZ Act and the Board's regulations would be satisfied with regard to the proposed removal of acreage at Site 8 and to the designation of a subzone for the use of Samsung Electronics America, Inc. (SEA) within proposed Site 9 (but not with regard to the approval of FTZ designation for the remaining portion(s) of proposed Site 9) upon submission by the applicant of documentary evidence of having reestablished its corporate existence and a definitive map(s) and acreage figure for the portion(s) of proposed Site 9 to be designated as the subzone for the use of SEA;

Now, therefore, the Board hereby orders:

The Board's Executive Secretary is authorized to finalize designation of a

subzone for the use of SEA and the requested removal of acreage from Site 8 upon the applicant's submission to the Executive Secretary of documentary evidence of the applicant's having reestablished its corporate existence and a definitive map(s) and acreage figure for the portion(s) of proposed Site 9 to be designated as the subzone for the use of SEA. This action is subject to the FTZ Act and the Board's regulations, including Section 400.13.

Signed at Washington, DC, this 12th day of January 2017.

Paul Piquado,

Assistant Secretary of Commerce for Enforcement and Compliance, Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 2017-01219 Filed 1-18-17; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B-06-2017]

Foreign-Trade Zone (FTZ) 20—Norfolk, Virginia; Notification of Proposed Production Activity; STIHL Incorporated (Outdoor Power Products Manufacturing); Virginia Beach, Virginia

STIHL Incorporated (STIHL) submitted a notification of proposed production activity to the FTZ Board for its facilities in Virginia Beach, Virginia within FTZ Subzone 20E. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on December 23, 2016.

STIHL already has authority to produce outdoor power products within Subzone 20E. The current request would add an additional foreign status component to the scope of authority. Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific foreign-status component described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt STIHL from customs duty payments on the foreign-status materials/components used in export production. On its domestic sales, STIHL would be able to choose the duty rates during customs entry procedures that apply to the blowers, trimmers, sprayers, cutters, cultivators and chain saws (duty rate free to 4.7%) for the foreign-status component noted below and in the existing scope of authority. Customs duties also could possibly be deferred or reduced on foreign-status

production equipment. The additional component sourced from abroad is lithium ion batteries (duty rate 3.4%).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is February 28, 2017.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230-0002, and in the "Reading Room" section of the Board's Web site, which is accessible via www.trade.gov/ftz.

For further information, contact Christopher Kemp at Christopher.Kemp@trade.gov or (202) 482-0862.

Dated: January 11, 2017.

Andrew McGilvray,
Executive Secretary.

[FR Doc. 2017-01209 Filed 1-18-17; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-943; C-570-944]

Certain Oil Country Tubular Goods From the People's Republic of China: Notice of Court Decision Not in Harmony With Final Scope Ruling and Notice of Amended Final Scope Ruling Pursuant to Court Decision

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is notifying the public that the Court of International Trade's (CIT's or the Court's) final judgment in this case is not in harmony with the Department's final scope ruling. Therefore, the Department finds that neither the plain language of the scope nor an analysis of the scope language using the criteria outlined in the Department's regulations support a finding that seamless unfinished oil country tubular goods (OCTG) (*i.e.*, green tubes) manufactured in the People's Republic of China (the PRC), and subsequently finished in a third country, are covered by the scope of the antidumping and countervailing duty orders.

DATES: Effective December 3, 2016.

FOR FURTHER INFORMATION CONTACT: John Drury, AD/CVD Operations, Office VI, Enforcement and Compliance,

International Trade Administration,
U.S. Department of Commerce, 1401
Constitution Avenue NW., Washington,
DC 20230; telephone: (202) 482-0195.

SUPPLEMENTARY INFORMATION:

Background

On February 7, 2014, the Department issued the *Bell Supply Scope Ruling*,¹ in which it determined that green tubes that are finished in third countries are covered under the scope of the *Orders* based on an analysis of the factors under 19 CFR 351.225(k)(1).² Bell Supply Company, LLC (Bell Supply) challenged the Department's final ruling before the CIT. On July 9, 2015, the Court issued its opinion on the *Bell Supply Scope Ruling*, remanding the Department's determination back to the agency for further analysis,³ as discussed in further detail in the *Final Remand Results*.⁴ The Department issued a redetermination on remand, under protest, which continued to find that the merchandise in question was within the scope of the *Orders*.⁵ On April 27, 2016, the Court issued its opinion on the *First Remand Results*, again remanding the Department's determination for further analysis.⁶ Specifically, the Court found that the language of the *Orders* does not necessarily include OCTG finished in third countries, even if processed using green tubes sourced from the PRC.⁷ The Court stated that the evidence on which the Department relied to make its determination (*i.e.*, the petition and the injury analysis by the International Trade Commission) “does not support” the Department's conclusion that the merchandise in question is

within the scope.⁸ The Court further stated that “{a}bsent additional evidence from the descriptions of the merchandise found in the (k)(1) sources, Commerce was required to proceed to the next step of its interpretive analysis and evaluate the factors under 19 CFR 351.225(k)(2).”⁹ The Court also stated that, in the event that the Department was unable to find that the scope of the *Orders* covers the merchandise at issue under 19 CFR 351.225(k)(2), the Department was free to employ a circumvention analysis pursuant to 19 CFR 351.225(h) and section 781(b) of the Tariff Act of 1930, as amended (the Act).¹⁰

Accordingly, the Department issued the *Final Remand Results*. Consistent with the Court's instructions in *Bell Supply II*, the Department determined that neither the plain language of the scope nor an analysis of the scope language using the criteria outlined in 19 CFR 351.225(k)(1) supported a finding that green tubes manufactured in the PRC, and subsequently finished in a third country, are covered by the scope of the *Orders*.¹¹ Additionally, the Department determined that, because the factors under 19 CFR 351.225(k)(2) did not indicate whether OCTG finished in third countries fell within the *Orders*, green tubes from the PRC that are subsequently heat-treated in third countries are not within the scope of the *Orders*.¹² Finally, the Department also determined information on the record did not support a finding that merchandise produced by Citra Tubindo, a producer of finished OCTG in Indonesia who used unfinished green tubes produced in the PRC, circumvented the *Orders*.¹³

In *Bell Supply III*, the Court sustained the Department's *Final Remand Results* in its entirety.¹⁴

Timken Notice

In its decision in *Timken*,¹⁵ as clarified by *Diamond Sawblades*,¹⁶ the United States Court of Appeals for the Federal Circuit (CAFC) held that, pursuant to sections 516A(c) and (e) of the Act, the Department must publish a notice of a court decision that is not “in

harmony” with a Department determination and must suspend liquidation of entries pending a “conclusive” court decision. The CIT's November 23, 2016, judgment in *Bell Supply III*, sustaining the Department's decision in the *Final Remand Results* that unfinished green tubes further processed in third countries into finished OCTG are not covered by the scope of the *Orders* and that merchandise processed in Indonesia into finished OCTG by Citra Tubindo, using unfinished green tubes produced in the PRC, does not constitute circumvention of the *Orders*, constitutes a final decision of the court that is not in harmony with the *Bell Supply Scope Ruling*. This notice is published in fulfillment of the publication requirements of *Timken*. Accordingly, the Department will continue the suspension of liquidation of the oil country tubular goods at issue pending expiration of the period to appeal or, if appealed, pending a final and conclusive court decision.

Amended Final Scope Ruling

Because there is now a final court decision with respect to the *Bell Supply Scope Ruling*, the Department is amending its final scope ruling. The Department finds that the scope of the *Orders* does not cover the products addressed in the *Bell Supply Scope Ruling*. The Department will instruct U.S. Customs and Border Protection (CBP) that the cash deposit rate will be zero percent for the OCTG finished in Indonesia using unfinished green tubes manufactured in the PRC. In the event that the CIT's ruling is not appealed, or if appealed, upheld by the CAFC, the Department will instruct CBP to liquidate entries of the OCTG at issue without regard to antidumping and/or countervailing duties, and to lift suspension of liquidation of such entries.

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(e)(1), 751(a)(1), and 777(i)(1) of the Act.

Dated: January 11, 2017.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2017-01166 Filed 1-18-17; 8:45 am]

BILLING CODE 3510-DS-P

¹ See Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, “Final Scope Ruling on Green Tubes Manufactured in the People's Republic of China and Finished in Countries Other than the United States and the People's Republic of China” (February 7, 2014) (*Bell Supply Scope Ruling*).

² See *Certain Oil Country Tubular Goods from the People's Republic of China: Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order*, 75 FR 3203 (January 20, 2010) and *Certain Oil Country Tubular Goods from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order*, 75 FR 28551 (May 21, 2010) (together, *Orders*).

³ See *Bell Supply Co. v. United States*, Court No. 14-00066, Slip Op. 15-73 (CIT 2015) (*Bell Supply I*).

⁴ See *Final Results of Second Redetermination Pursuant to Remand*, dated August 11, 2016 (*Final Remand Results*) at 2-5.

⁵ See *Final Results of Redetermination Pursuant to Remand*, dated November 9, 2015 (*First Remand Results*).

⁶ See *Bell Supply Co. v. United States*, Court No. 14-00066, Slip Op. 16-41 (CIT 2016) (*Bell Supply II*).

⁷ *Id.* at 13.

⁸ *Id.* at 28.

⁹ *Id.* at 33.

¹⁰ *Id.* at 38-39.

¹¹ See *Final Remand Results* at 14-15.

¹² *Id.* at 15-19.

¹³ *Id.* at 33-34.

¹⁴ See *Bell Supply Co. v. United States*, Court No. 14-00066, Slip Op. 16-109 (CIT 2016) (*Bell Supply III*) at 16.

¹⁵ See *Timken Co. v. United States*, 893 F.2d 337 (Fed. Cir. 1990) (*Timken*), at 341.

¹⁶ See *Diamond Sawblades Mfrs. Coalition v. United States*, 626 F.3d 1374 (Fed. Cir. 20 10) (*Diamond Sawblades*).

DEPARTMENT OF COMMERCE**International Trade Administration****United States Travel and Tourism Advisory Board: Meeting of the United States Travel and Tourism Advisory Board**

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an Open Meeting.

SUMMARY: The United States Travel and Tourism Advisory Board (Board) will hold an open meeting via teleconference on Wednesday, February 1, 2017. The Board was re-chartered in August 2015 and advises the Secretary of Commerce on matters relating to the U.S. travel and tourism industry. The purpose of the meeting is for Board members to deliberate a letter to the Secretary with an overview of the Board and its activities to date under the current charter term. The final agenda will be posted on the Department of Commerce Web site for the Board at <http://trade.gov/ttab>, at least one week in advance of the meeting.

DATES: Wednesday, February 1, 2017 3:00 p.m.–3:30 p.m. EST. The deadline for members of the public to register, including requests for auxiliary aids, or to submit written comments for dissemination prior to the meeting, is 5:00 p.m. EST on January 25, 2017.

ADDRESSES: The meeting will be held by conference call. The call-in number and passcode will be provided by email to registrants. Requests to register (including for auxiliary aids) and any written comments should be submitted to: U.S. Travel and Tourism Advisory Board, U.S. Department of Commerce, M–800, 1300 Pennsylvania Avenue NW., Washington, DC 20230, OACIO@trade.gov. Members of the public are encouraged to submit registration requests and written comments via email to ensure timely receipt.

FOR FURTHER INFORMATION CONTACT: Joe Holecko, the United States Travel and Tourism Advisory Board, M–800, 1300 Pennsylvania Avenue NW., Washington, DC 20230, telephone: 202–482–4783, email: OACIO@trade.gov.

SUPPLEMENTARY INFORMATION:

Background: The Board advises the Secretary of Commerce on matters relating to the U.S. travel and tourism industry.

Public Participation: The meeting will be open to the public and will be accessible to people with disabilities. All guests are required to register in advance by the deadline identified under the DATES caption. Requests for

auxiliary aids must be submitted by the registration deadline. Last minute requests will be accepted, but may not be possible to fill. Any member of the public may submit pertinent written comments concerning the Board's affairs at any time before or after the meeting. Comments may be submitted to Joe Holecko at the contact information indicated above. To be considered during the meeting, comments must be received no later than 5:00 p.m. EST on Wednesday, January 25, 2017, to ensure transmission to the Board prior to the meeting. Comments received after that date and time will be distributed to the members but may not be considered on the call. Copies of Board meeting minutes will be available within 90 days of the meeting.

Joe Holecko,

Executive Secretary, United States Travel and Tourism Advisory Board.

[FR Doc. 2017–01062 Filed 1–18–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE**International Trade Administration****Proposed Information Collection; Comment Request; Information Collection for Self-Certification to the Swiss-U.S. Privacy Shield Framework**

AGENCY: International Trade Administration (ITA).

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before March 20, 2017.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at jjessup@doc.gov).

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the information collection instrument and instructions should be directed to David Ritchie, Department of Commerce, International Trade Administration, Room 20001, 1401 Constitution Avenue NW., Washington, DC, (or via the Internet at privacyshield@trade.gov, and tel. 202–482–1512).

SUPPLEMENTARY INFORMATION:**I. Abstract**

The United States and Switzerland share the goal of enhancing privacy protection for their citizens, but take different approaches to protecting personal data. Given those differences, the Department of Commerce (DOC) developed the Swiss-U.S. Privacy Shield Framework (Privacy Shield) in consultation with the Swiss Administration, as well as with industry and other stakeholders, to provide organizations in the United States with a reliable mechanism for personal data transfers to the United States from Switzerland while ensuring the protection of the data as required by Swiss law.

On January 12, 2017, the Swiss Administration deemed the Privacy Shield Framework adequate to enable data transfers under Swiss law. To provide organizations the time needed to review the Privacy Shield Principles and the commitment that they entail, the DOC will begin accepting self-certification submissions from organizations on April 12, 2017. More information on the Privacy Shield is available at: <https://www.privacyshield.gov/welcome>.

The DOC has issued the Privacy Shield Principles under its statutory authority to foster, promote, and develop international commerce (15 U.S.C. 1512). The International Administration (ITA) administers and supervises the Privacy Shield, including by maintaining and making publicly available an authoritative list of U.S. organizations that have self-certified to the DOC. U.S. organizations submit information to ITA to self-certify their compliance with Privacy Shield.

U.S. organizations considering self-certifying to the Privacy Shield should review the Privacy Shield Framework. In summary, in order to enter the Privacy Shield, an organization must (a) be subject to the investigatory and enforcement powers of the Federal Trade Commission (FTC), the Department of Transportation, or another statutory body that will effectively ensure compliance with the Principles; (b) publicly declare its commitment to comply with the Principles; (c) publicly disclose its privacy policies in line with the Principles; and (d) fully implement them.

Self-certification to the DOC is voluntary; however, an organization's failure to comply with the Principles after its self-certification is enforceable under Section 5 of the Federal Trade Commission Act prohibiting unfair and

deceptive acts in or affecting commerce (15 U.S.C. 45(a)) or other laws or regulations prohibiting such acts.

In order to rely on the Privacy Shield for transfers of personal data from Switzerland, an organization must self-certify its adherence to the Principles to the DOC, be placed by ITA on the Privacy Shield List, and remain on the Privacy Shield List. To self-certify for the Privacy Shield, an organization must provide to the DOC a self-certification submission that contains the information specified in the Privacy Shield Principles. The Privacy Shield self-certification form would be the means by which an organization would provide the relevant information to ITA.

ITA has committed to follow up with organizations that have been removed from the Privacy Shield List. ITA will send questionnaires to organizations that fail to complete the annual certification or who have withdrawn from the Privacy Shield to verify whether they will return, delete, or continue to apply the Principles to the personal information that they received while they participated in the Privacy Shield, and if personal information will be retained, verify who within the organization will serve as an ongoing point of contact for Privacy Shield-related questions.

In addition, ITA has committed to conduct compliance reviews on an ongoing basis, including through sending detailed questionnaires to participating organizations. In particular, such compliance reviews shall take place when: (a) The DOC has received specific non-frivolous complaints about an organization's compliance with the Principles, (b) an organization does not respond satisfactorily to inquiries by the DOC for information relating to the Privacy Shield, or (c) there is credible evidence that an organization does not comply with its commitments under the Privacy Shield.

The proposed information collection for the Swiss-U.S. Privacy Shield Framework is substantially similar to the previously approved information collection for the EU-U.S. Privacy Shield Framework (OMB Control Number: 0625-0276).

II. Method of Collection

The Privacy Shield self-certification is submitted electronically by organizations through the DOC's Privacy Shield Web site (<https://www.privacyshield.gov/>). It is anticipated that the Privacy Shield questionnaires and the corresponding responses provided by organizations would be conveyed electronically via

email or through the DOC's Privacy Shield Web site.

III. Data

OMB Control Number: None.

Form Number(s): None.

Type of Review: Regular submission.

Affected Public: primarily businesses or other for-profit organizations.

Estimated Number of Respondents: 2,700.

Estimated Time per Response: 38 minutes.

Estimated Total Annual Burden Hours: 2,215.

Estimated Total Annual Cost to Public: \$2,118,150.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Sheleen Dumas,

PRA Departmental Lead, Office of the Chief Information Officer.

[FR Doc. 2017-01156 Filed 1-18-17; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XF168

Whaling Provisions; Aboriginal Subsistence Whaling Quotas

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; notification of quota for bowhead whales.

SUMMARY: NMFS notifies the public of the aboriginal subsistence whaling quota for bowhead whales that it has assigned to the Alaska Eskimo Whaling

Commission (AEWC), and of limitations on the use of the quota deriving from regulations of the International Whaling Commission (IWC). For 2017, the quota is 75 bowhead whales struck. This quota and other applicable limitations govern the harvest of bowhead whales by members of the AEWC.

DATES: Effective January 19, 2017.

ADDRESSES: Office for International Affairs and Seafood Inspection, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT:

Carolyn Doherty, (301) 427-8385.

SUPPLEMENTARY INFORMATION: Aboriginal subsistence whaling in the United States is governed by the Whaling Convention Act (WCA) (16 U.S.C. 916 *et seq.*). Under the WCA, IWC regulations shall generally become effective with respect to all persons and vessels subject to the jurisdiction of the United States, within 90 days of notification from the IWC Secretariat of an amendment to the IWC Schedule (16 U.S.C. 916k). Regulations that implement the WCA, found at 50 CFR 230.6, require the Secretary of Commerce (Secretary) to publish, at least annually, aboriginal subsistence whaling quotas and any other limitations on aboriginal subsistence whaling deriving from regulations of the IWC.

At the 64th Annual Meeting of the IWC, the Commission set catch limits for aboriginal subsistence use of bowhead whales from the Bering-Chukchi-Beaufort Seas stock. The bowhead catch limits were based on a joint request by the United States and the Russian Federation, accompanied by documentation concerning the needs of two Native groups: Alaska Eskimos and Chukotka Natives in the Russian Far East.

The IWC set a 6-year block catch limit of 336 bowhead whales landed. For each of the years 2013 through 2018, the number of bowhead whales struck may not exceed 67, except that any unused portion of a strike quota from any prior year may be carried forward. No more than 15 strikes may be added to the strike quota for any one year. At the end of the 2016 harvest, there were 15 unused strikes available for carry-forward, so the combined strike quota set by the IWC for 2017 is 82 (67 + 15).

An arrangement between the United States and the Russian Federation ensures that the total quota of bowhead whales landed and struck in 2017 will not exceed the limits set by the IWC. Under this arrangement, the Russian natives may use no more than seven

strikes, and the Alaska Eskimos may use no more than 75 strikes.

Through its cooperative agreement with the AEW, NOAA has assigned 75 strikes to the Alaska Eskimos. The AEW will in turn allocate these strikes among the 11 villages whose cultural and subsistence needs have been documented, and will ensure that its hunters use no more than 75 strikes.

Other Limitations

The IWC regulations, as well as the NOAA regulation at 50 CFR 230.4(c), forbid the taking of calves or any whale accompanied by a calf.

NOAA regulations (at 50 CFR 230.4) contain a number of other prohibitions relating to aboriginal subsistence whaling, some of which are summarized here:

- Only licensed whaling captains or crew under the control of those captains may engage in whaling.
- Captains and crew must follow the provisions of the relevant cooperative agreement between NOAA and a Native American whaling organization.
- The aboriginal hunters must have adequate crew, supplies, and equipment to engage in an efficient operation.
- Crew may not receive money for participating in the hunt.
- No person may sell or offer for sale whale products from whales taken in the hunt, except for authentic articles of Native American handicrafts.
- Captains may not continue to whale after the relevant quota is taken, after the season has been closed, or if their licenses have been suspended. They may not engage in whaling in a wasteful manner.

Dated: January 13, 2017.

John Henderschedt,

Director, Office for International Affairs and Seafood Inspection, National Marine Fisheries Service.

[FR Doc. 2017-01241 Filed 1-18-17; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Number: PR17-15-000.

Applicants: Columbia Gas of Maryland, Inc.

Description: Tariff filing per 284.123(b), (e)/: CMD SOC to be effective 1/1/2017; Filing Type: 980.

Filed Date: 1/5/2017.

Accession Number: 201701055071.

Comments/Protests Due: 5 p.m. ET 1/26/17.

Docket Number: PR17-16-000.

Applicants: Columbia Gas of Ohio, Inc.

Description: Tariff filing per 284.123(b), (e)/: COH SOC to be effective 12/30/2016; Filing Type: 980.

Filed Date: 1/6/2017.

Accession Number: 201701065044.

Comments/Protests Due: 5 p.m. ET 1/27/17.

Docket Number: RP17-325-000.

Applicants: Northern Natural Gas Company.

Description: § 4(d) Rate Filing: 20161219 FDD Cycle Quantity Increase to be effective 6/1/2017.

Filed Date: 1/5/17.

Accession Number: 20170105-5083.

Comments Due: 5 p.m. ET 1/17/17.

Docket Number: RP17-326-000.

Applicants: Elba Express Company, L.L.C.

Description: § 4(d) Rate Filing: Shell Phase I Negotiated Rate to be effective 2/10/2017.

Filed Date: 1/5/17.

Accession Number: 20170105-5136.

Comments Due: 5 p.m. ET 1/17/17.

Docket Number: RP17-327-000.

Applicants: Rockies Express Pipeline LLC.

Description: § 4(d) Rate Filing: Neg Rate 2017-01-05 BP to be effective 1/6/2017.

Filed Date: 1/5/17.

Accession Number: 20170105-5170.

Comments Due: 5 p.m. ET 1/17/17.

Docket Number: RP17-328-000.

Applicants: Dominion Carolina Gas Transmission, LLC.

Description: § 4(d) Rate Filing: DCGT—Web site Notification to be effective 2/6/2017.

Filed Date: 1/6/17.

Accession Number: 20170106-5098.

Comments Due: 5 p.m. ET 1/18/17.

Docket Number: RP17-329-000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: Negotiated Rate Agreement—Castleton 510984 to be effective 1/8/2017.

Filed Date: 1/6/17.

Accession Number: 20170106-5133.

Comments Due: 5 p.m. ET 1/18/17.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but

intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Number: RP16-1179-002.

Applicants: Equitrans, L.P.

Description: Compliance filing Negotiated Rate Service Agreement—Revised EQT Energy OVC Agreement to be effective 10/1/2016.

Filed Date: 12/21/16.

Accession Number: 20161221-5081.

Comments Due: 5 p.m. ET 1/13/17.

Docket Number: RP17-197-002.

Applicants: Dominion Cove Point LNG, LP.

Description: Compliance filing DCP—2016 Section 4 General Rate Case Compliance to be effective 1/1/2017.

Filed Date: 1/5/17.

Accession Number: 20170105-5086.

Comments Due: 5 p.m. ET 1/17/17.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: January 9, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017-01190 Filed 1-18-17; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP17-50-000.

Applicants: Columbia Gulf Transmission, LLC.

Description: Report Filing: Columbia Gulf Section 5 Settlement Refund Report.

Filed Date: 1/10/17.

Accession Number: 20170110-5055.

Comments Due: 5 p.m. ET 1/23/17.

Docket Numbers: RP17-332-000.

Applicants: Equitrans, L.P.

Description: § 4(d) Rate Filing; Right of First Refusal Update to be effective 2/11/2017.

Filed Date: 1/11/17.

Accession Number: 20170111-5019.

Comments Due: 5 p.m. ET 1/23/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: January 11, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017-01132 Filed 1-18-17; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP15-499-001; CP15-499-000]

Texas Eastern Transmission, LP; Notice of Amendment to Application

Take notice that on December 30, 2016, Texas Eastern Transmission, LP (Texas Eastern), 5400 Westheimer Court, Houston, Texas 77056, filed an amendment to its application in Docket No. CP15-499-000, pursuant to section 7(c) of the Natural Gas Act (NGA) and Part 157 of the Commission's regulations for its proposed South Texas Expansion Project (Project). Specifically, Texas Eastern requests, in addition to the authorizations requested in the previous application, authorization to (i) construct, install, own, operate, and maintain new gas release measurement equipment and associated enclosures at its existing Vidor and Mont Belvieu Compressor Stations in Orange and Chambers Counties, Texas, respectively, and at its proposed Petronila Compressor Station in Nueces County, Texas, new gas coolers at its existing

Blessing Compressor Station in Matagorda County, Texas, and a new tie-in to Pomelo Connector at Texas Eastern's proposed Petronila Compressor Station; (ii) acquire, by lease, 400,000 dekatherms per day (Dth/d) of capacity on Pomelo Connector, LLC's proposed pipeline; (iii) change the Project's targeted in-service date from May 1, 2017 to October 1, 2018; (iv) change the Project's capacity from 400,000 Dth/d to 396,000 Dth/d; and (v) remove from the Project's scope the meter and regulating station at the proposed Petronila Compressor Station. Texas Eastern further proposes to amend its incremental project recourse rate and to modify its Exhibit K, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing may be viewed on the web at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at FERCOnlineSupport@ferc.gov or call toll-free, (866) 208-3676 or TTY, (202) 502-8659.

Any questions concerning these applications may be directed to Berk Donaldson, General Manager, Rates & Certificates, Texas Eastern Transmission, LP, P.O. Box 1642, Houston, Texas 77251-1642, by telephone at (713) 627-4488, or by fax at (713) 627-5947.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental analysis (EA) and place it into the Commission's public record (eLibrary) for this proceeding, or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888

First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 5 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Comment Date: 5:00 p.m. Eastern Time on February 2, 2017.

Dated: January 12, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017-01136 Filed 1-18-17; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16-17-000; EL16-18-000]

City of West Memphis, Arkansas; Conway Corporation; Notice of Filing

Take notice that on January 12, 2016, Midcontinent Independent System Operator, Inc. submitted tariff filing per: Refund Report to be effective N/A, pursuant to the Federal Energy Regulatory Commission's (Commission) Order issued on October 4, 2016.¹

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at <http://www.ferc.gov>, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email FERCOnlineSupport@ferc.gov, or call

(866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Comment Date: 5:00 p.m. Eastern Time on February 2, 2017.

Dated: January 12, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017-01137 Filed 1-18-17; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Number: ER17-405-000, ER17-406-000.

Applicants: American Electric Power Service Corporation, PJM Interconnection, L.L.C.

Description: Supplement to November 22 PJM Interconnection, L.L.C. rate filing.

Filed Date: 1/9/17.

Accession Number: 20170109-5351.

Comments Due: 5 p.m. ET 1/30/17.

Docket Number: ER17-779-000.

Applicants: California Independent System Operator Corporation.

Description: Compliance filing: 2017-01-11 Petition for Limited Waiver of RAAIM Advisory Period to be effective N/A.

Filed Date: 1/11/17.

Accession Number: 20170111-5148.

Comments Due: 5 p.m. ET 1/23/17.

Docket Number: ER17-781-000.

Applicants: NorthWestern Corporation.

Description: Notice of Cancellation of Multiple Inactive Service Agreements and Rate Schedules of NorthWestern Corporation.

Filed Date: 1/11/17.

Accession Number: 20170111-5169.

Comments Due: 5 p.m. ET 2/1/17.

Docket Number: ER17-782-000.

Applicants: New York Independent System Operator, Inc.

Description: Order No. 825 Compliance Filing of New York Independent System Operator, Inc.

Filed Date: 1/11/17.

Accession Number: 20170111-5173.

Comments Due: 5 p.m. ET 2/1/17.

Docket Number: ER17-783-000.

Applicants: Wabash Valley Power Association, Inc.

Description: § 205(d) Rate Filing: Revisions to Formulary Rate Tariff to be effective 3/12/2017.

Filed Date: 1/12/17.

Accession Number: 20170112-5055.

Comments Due: 5 p.m. ET 2/2/17.

Docket Number: ER17-784-000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Queue Position AB2-010/AB2-011, Original Service Agreement No. 4601 to be effective 12/13/2016.

Filed Date: 1/12/17.

Accession Number: 20170112-5120.

Comments Due: 5 p.m. ET 2/2/17.

Docket Number: ER17-785-000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: Amended LGIA AltaGas Sonoran Energy Inc. to be effective 3/14/2017.

Filed Date: 1/12/17.

Accession Number: 20170112-5143.

Comments Due: 5 p.m. ET 2/2/17.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: January 12, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017-01135 Filed 1-18-17; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL17-34-000]

Alcoa Corporation; Notice of Petition for Declaratory Order

Take notice that on December 22, 2016, pursuant to section 385.207(a)(4) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207(a) (2016), and sections 366(b)(1), 366.3(d), and 366.4(b)(3) of Commission's regulations under the Public Utility Holding Company Act of

¹ City of West Memphis, Arkansas and Conway Corporation, 157 FERC ¶ 61,005 (2016).

2005 (PUHCA 2005), Alcoa Corporation (Petitioner) filed a petition for declaratory order requesting that the Commission grant their petition and declare them exempt from the Commission's regulations under PUHCA 2005, all as more fully explained in the petition.

Any person desiring to intervene or to protest in this proceeding must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email FERCOnlineSupport@ferc.gov, or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Comment Date: 5:00 p.m. Eastern time on February 2, 2017.

Dated: January 12, 2017.

Kimberly D. Bose,
Secretary.

[FR Doc. 2017-01139 Filed 1-18-17; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2611-084]

Hydro Kennebec, LLC; Notice of Application To Extend Interim Species Protection Plan for Three Years and Soliciting Comments, Motions To Intervene and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

- a. *Application Type:* Amendment of License.
- b. *Project No:* 2611-084.
- c. *Date Filed:* December 23, 2016.
- d. *Applicant:* Hydro Kennebec, LLC.
- e. *Name of Project:* Hydro Kennebec.
- f. *Location:* The project is located on the Kennebec River in Kennebec and Somerset counties, Maine.
- g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a-825r.
- h. *Applicant Contact:* Kelly Maloney, Hydro Kennebec LLC, 150 Main Street, Lewiston, ME 04340, (207) 755-5605.
- i. *FERC Contact:* Mr. Mark Pawlowski 202-502-6052, mark.pawlowski@ferc.gov.
- j. *Deadline for filing comments, motions to intervene, and protests:* February 13, 2017.

All documents may be filed electronically via the Internet. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at <http://www.ferc.gov/docs-filing/efiling.asp>. If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and seven copies should be mailed to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments.

Please include the project number, P-2611-084, on any comments, motions, or protests filed.

k. *Description of Request:* Hydro Kennebec, LLC, licensee for the Hydro Kennebec Project, seeks Commission approval to extend the expiration date of its approved Interim Species Passage Plan (ISPP). The Commission approved the ISPP on February 28, 2013, with an expiration date of December 31, 2016. Hydro Kennebec, LLC wants to keep the plan in effect for three more years so that it expires on December 31, 2019

(the same date approved ISPPs expire for the Lockwood, Shawmut, and Weston Projects, which are also located on the Kennebec River).

l. *Locations of the Application:* A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208-3676 (toll free), or (202) 502-8659 (TTY). A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title "COMMENTS," "PROTESTS," or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource

agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: January 12, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017-01140 Filed 1-18-17; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2007-0268; FRL-9958-50-OW]

Revision to the PAG Manual: Protective Action Guide (PAG) for Drinking Water After a Radiological Incident

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: As part of its mission to protect human health and the environment, the Environmental Protection Agency publishes protective action guides (PAGs) to help federal, state, local and tribal emergency response officials make radiation protection decisions during emergencies. EPA, in coordination with a multi-agency working group within the Federal Radiological Preparedness Coordinating Committee, recently updated its guidance manual on this topic, titled "Protective Action Guides and Planning Guidance for Radiological Incidents" (referred to herein as the PAG Manual). On December 8, 2016, EPA announced availability of the updated 2016 PAG Manual in the **Federal Register**. In this document, EPA is announcing that it has amended Chapter 4 of the 2016 PAG Manual to incorporate guidance for radiation protection decisions concerning drinking water. The drinking water PAG is not binding and does not in any way affect regulatory requirements or enforcement of the Safe Drinking Water Act (SDWA), including maximum contaminant limits (MCLs) for radionuclides established by regulation under the SDWA. The drinking water PAG is guidance only and is intended for use by federal, state and local emergency management officials in the unlikely event of significant radiological contamination incidents, such as a disaster at a nuclear power plant, a

radiological dispersal device or an improvised nuclear device, and for a duration which may last for weeks to months but not longer than one year. The dose levels reflected in the drinking water PAG provide a level of protection against cancer risks for a short-term (weeks to months but not longer than a year), similar to that provided by EPA's MCLs for radionuclides (which are calculated based on 70 years of exposure). The revised drinking water PAG is available for use upon publication of this document in the **Federal Register**, at www.regulations.gov, under ID No. EPA-HQ-OAR-2007-0268.

FOR FURTHER INFORMATION CONTACT:

Samuel Hernandez, Standards and Risk Management Division, Office of Ground Water and Drinking Water, Mail Code 4607M, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: (202) 564-1735; email: hernandez.samuel@epa.gov.

SUPPLEMENTARY INFORMATION:

A. How can I get copies of the PAG Manual and supporting information?

Docket: EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2007-0268. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the Air and Radiation Docket in the EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC 20004. The Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Docket's Public Reading Room is (202) 566-1744 and the telephone number for the Air and Radiation Docket is (202) 566-1742. In accordance with normal EPA docket procedures, if copies of any docket materials are requested, a reasonable fee may be charged for photocopying.

Electronic access: The PAG Manual in electronic form suitable for printing, as well as related guidelines and further information, can be found on the PAGs' Web site at <http://www.epa.gov/radiation/protective-action-guides-pags>.

B. What authority does EPA have to provide Protective Action Guidance?

The historical and legal basis of EPA's role in the PAG Manual begins with the Reorganization Plan No. 3 of 1970, in which the Administrator of the EPA assumed all the functions of the Federal Radiation Council (FRC), including the charge to "... advise the President with respect to radiation matters,

directly or indirectly affecting health, including guidance for all federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with [s]tates." (Reorg. Plan No. 3 of 1970, section 2(a) (7), 6(a) (2); § 274.h of the Atomic Energy Act of 1954, as amended (AEA), codified at 42 U.S.C. 2021(h)). Recognizing this role, the Federal Emergency Management Agency (FEMA) directed EPA, in its Radiological Emergency Planning and Preparedness Regulations, to "establish Protective Action Guides (PAGs) for all aspects of radiological emergency planning in coordination with appropriate federal agencies." (44 CFR 351.22(a)). FEMA also tasked EPA with preparing "guidance for state and local governments on implementing PAGs, including recommendations on protective actions which can be taken to mitigate the potential radiation dose to the population." (44 CFR 351.22(b)). All of this information was to "be presented in the Environmental Protection Agency (EPA) 'Manual of Protective Action Guides and Protective Actions for Nuclear Incidents.'" (44 CFR 351.22(b)).

Additionally, section 2021(h) charged the Administrator with performing "such other functions as the President may assign to him [or her] by Executive Order." Executive Order 12656 states that the Administrator shall "[d]evelop, for national security emergencies, guidance on acceptable emergency levels of nuclear radiation. . . ." (Executive Order No. 12656, section 1601(2)). EPA's role in PAGs development was recognized by the *National Response Framework, Nuclear/Radiological Incident Annex* of June 2008.

C. What is the PAG Manual: Protective action guides and planning guidance for radiological incidents?

The PAG Manual provides federal, state and local emergency management officials with guidance for responding to radiological emergencies. A protective action guide is the projected dose to an individual from a release of radioactive material at which a specific protective action to reduce or avoid that dose is recommended. Emergency management officials use PAGs for making decisions regarding actions to protect the public from exposure to radiation during an emergency. Such actions include, but are not limited to, evacuation, shelter-in-place, temporary relocation and food restrictions.

Development of the PAGs was based on the following essential principles, which also apply to the selection of any protective action during an incident:

- Prevent acute effects.
- Balance protection with other important factors and ensure that actions result in more benefit than harm.

- Reduce risk of chronic effects.

The PAG Manual is not a legally binding regulation or standard and does not supersede any environmental laws. This guidance does not address or impact site cleanups occurring under other statutory authorities such as the EPA's Superfund program, the Nuclear Regulatory Commission's (NRC) decommissioning program, or other federal or state cleanup programs. As indicated by the use of non-mandatory language such as "may," "should" and "can," the PAG Manual only provides recommendations and does not confer any legal rights or impose any legally binding requirements upon any member of the public, states or any other federal agency. Rather, the PAG Manual recommends projected radiation doses at which specific actions may be warranted in order to reduce or avoid that dose. The PAG Manual is designed to provide flexibility to be more or less restrictive as deemed appropriate by decision makers based on the unique characteristics of the incident and the local situation.

D. How did EPA respond to public comments on the proposed Draft Protective Action Guide for Drinking Water?

PAGs do not represent "acceptable" routine exposure in the way that regulatory standards such as maximum contaminant levels do. PAGs are guidance levels to support emergency decision making by response authorities to avoid unnecessary radiation exposure. Development and implementation of PAGs is always guided by three basic principles: Prevent acute effects, balance protection with other important factors and ensure that actions result in more benefit than harm, and reduce risk of chronic effects.

On June 10, 2016, EPA published a **Federal Register** document requesting public comments on the proposed drinking water PAG and the guidance for advance planning (81 FR 37589). EPA sought specific comments and feedback on the appropriateness of the drinking water PAG and possible implementation challenges associated with the two-tiered approach. In addition, EPA asked whether a single-tier drinking water PAG should be considered rather than using the tiered approach.

In response, EPA received over 60,000 comment letters from members of the public, state and local emergency

response and health organizations, environmental advocates, industry associations and other stakeholders. Most of the comment letters expressed concerns with the proposed guidance. Commenters wrote that the proposed guidance could weaken the regulatory requirements of the Safe Drinking Water Act. In addition, environmental advocacy organizations indicated that the drinking water PAG dose levels were too high and insufficient to be protective of human health, and asked EPA to withdraw the proposed guidance and, in its place, use the National Primary Drinking Water Regulations for Radionuclides as the basis for any emergency response measures regarding drinking water.

Commenters also asserted that the proposed drinking water PAG did not conform to the National Environmental Policy Act (NEPA) as well as other regulations dealing with cleanup and waste management of radioactive contaminants. Commenters expressed doubts regarding the duration that the drinking water PAG would be implemented after an incident, claiming that the drinking water PAG could be in place for timeframes exceeding one year.

In response to comments, EPA has amended the drinking water guidance to emphasize, with regards to the scope of the drinking water PAG recommendations, that they are only intended to apply to nationally significant radiological contamination incidents, such as a disaster at a nuclear power plant, a radiological dispersal device or an improvised nuclear device, and for a duration that may last for weeks to months but not longer than one year.

Some commenters expressed concerns that PAGs would weaken drinking water standards and regulations. Environmental regulations or standards are legal limits designed to minimize health effects from everyday exposure to low levels of radiation over long periods. The PAG levels are guidance for emergency situations; they do not supplant any standards or regulations, nor do they affect the stringency or enforcement of any standards or regulations. The PAG levels are intended to be used only in an emergency when radiation levels have already exceeded environmental standards. The PAG levels trigger public safety measures to minimize radiation exposures during an emergency.

To develop guidance on drinking water considerations, EPA based its assessment on assumptions limiting exposures to a one-year timeframe. EPA expects that the responsible party for

any drinking water system adversely impacted during a radiation incident will take action to return to compliance with Safe Drinking Water Act levels as soon as practicable.

The National Primary Drinking Water Regulations establish regulatory limits designed to minimize health effects from everyday exposure to low levels of radiation over long periods; those limits are not changing with this action. Emergency guides are temporary measures to minimize risk while enabling distribution of limited resources during an emergency response.

Estimated risk of excess cancer cases for lifetime exposure (70 years) to beta emitting radioactive contaminants in drinking water at 4 mrem/yr (the MCL) generally falls in a range of risks deemed acceptable by EPA. Estimated risks associated for a shorter (one-year) exposure to radioactivity in drinking water at the proposed PAG levels fall within a similar risk range.

The drinking water PAG meets NEPA policy goals because it is based on analyses, documentation and review procedures that are functionally equivalent to NEPA. "Activities for the development of federal radiation regulations and guidance in accordance with the Atomic Energy Act of 1954 are functionally equivalent to NEPA" (63 FR 58045, October 29, 1998).

Commenters questioned whether the EPA considered cumulative effects in developing the drinking water PAG. In developing the PAG Manual, EPA considered the potential for cumulative exposure from multiple exposure pathways including: plume inhalation, immersion, ground shine, drinking water ingestions and food, among others. However, EPA has determined that for implementation purposes, it is impractical to compartmentalize joint protective actions, since allocations of dose to different segments of the population based on individual exposure routes will depend on site-specific circumstances and are impossible to quantify. While the PAGs for the various pathways are separate, emergency management officials should consider all relevant exposure routes when making protective action decisions in an emergency. In addition, incident-specific factors like geographical location, ongoing weather, the isotopes released and population affected should be considered after a contamination event, and specific exposure routes should be identified to allow different types of protective actions to be aimed at the specific risks to be avoided.

Several commenters from state emergency management agencies and radiation control programs expressed support for EPA's proposal, stating that the guidance was well developed and technically sound; and that the incorporation of the drinking water PAG into the PAG Manual is a critical aspect of a coordinated emergency response after a radiation contamination incident.

Some commenters suggested that while they support the incorporation of the drinking water PAG, they believe the proposed PAG was too conservative and that EPA should consider establishing the PAG in the 2,000 to 10,000 mrem range.

EPA believes that the drinking water PAG should be consistent with and within the range of currently available guidance for other exposure pathways during the intermediate phase. Also, when possible, the drinking water PAG recommendations should be based on an additional level of protection to sensitive life-stages. For short-term incidents, as explained in the PAG Manual, it is appropriate to have a 500 mrem PAG level for drinking water for the general population and a lower-tier PAG level of 100 mrem for persons at sensitive life-stages, including pregnant women, nursing women, and children 15 years old and under. This approach of setting a two-tier level of protection incorporates suggestions submitted by commenters regarding the adequate consideration of children and sensitive subpopulations.

There is an abundance of caution built into the derivation of the drinking water PAG through a variety of assumptions, including conservative dose-response modeling; selection of the most sensitive life stages to derive the PAG for children through age 15 years; and, the assumption of no decay of isotopes over the calculated one-year exposure period, which may be appropriate in some situations. This action ensures that the protective measures it recommends are appropriate for all members of the public, including sensitive subpopulations.

E. What is the timeframe for implementation of this PAG Manual?

Emergency management and radiation protection organizations that use the PAGs in their emergency plans are encouraged to incorporate this updated guidance as soon as possible. This may entail training, as well as the update of plans and procedures. Outreach and technical training will be conducted by EPA, the Federal Radiological Monitoring and Assessment Center and interagency partners of the PAG Subcommittee. FEMA expects certain

organizations associated with nuclear power plant operations to use the PAG Manual in developing their emergency management plans. FEMA plans to begin using the new PAG Manual during their evaluation of offsite response organizations around nuclear power facilities 12 months after the publication of this document in the **Federal Register**.

For further information and related guidelines, see the EPA Web site: <http://www.epa.gov/radiation/protective-action-guides-pags>. Keywords include: drinking water, radiation, radiological incident, emergency and protective action guide.

Dated: January 10, 2017.

Joel Beauvais,

Deputy Assistant Administrator, Office of Water.

[FR Doc. 2017-01230 Filed 1-18-17; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2014-0534; FRL-9958-62-OAR]

California State Nonroad Engine Pollution Control Standards; Commercial Harbor Craft Regulations; Notice of Decision

AGENCY: Environmental Protection Agency.

ACTION: Notice of decision.

SUMMARY: The Environmental Protection Agency ("EPA") is granting the California Air Resources Board ("CARB") its request for an authorization of its amendments to its Commercial Harbor Craft regulations ("CHC Amendments"). EPA is also confirming that certain CHC amendments are within the scope of a prior EPA authorization. CARB's CHC Amendments primarily subject diesel-fueled engines on crew and supply, barge and dredge vessels to the in-use engine emission requirements of the original CHC regulations; allow CARB or EPA Tier 2 or higher tier certified off-road ("nonroad") engines to be used as auxiliary or propulsion engines in both new and in-use CHC vessels; and clarify requirements and address certain issues that have arisen during CARB's implementation of the original CHC regulations. This decision is issued under the authority of the Clean Air Act ("CAA" or "Act").

DATES: Petitions for review must be filed by March 20, 2017.

ADDRESSES: EPA has established a docket for this action under Docket ID

EPA-HQ-OAR-2014-0534. All documents relied upon in making this decision, including those submitted to EPA by CARB, are contained in the public docket. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the Air and Radiation Docket in the EPA Headquarters Library, EPA West Building, Room 3334, located at 1301 Constitution Avenue NW., Washington, DC. The Public Reading Room is open to the public on all federal government working days from 8:30 a.m. to 4:30 p.m.; generally, it is open Monday through Friday, excluding holidays. The telephone number for the Reading Room is (202) 566-1744. The Air and Radiation Docket and Information Center's Web site is <http://www.epa.gov/oar/docket.html>. The electronic mail (email) address for the Air and Radiation Docket is: a-and-r-Docket@epa.gov, the telephone number is (202) 566-1742, and the fax number is (202) 566-9744. An electronic version of the public docket is available through the federal government's electronic public docket and comment system. You may access EPA dockets at <http://www.regulations.gov>. After opening the www.regulations.gov Web site, enter EPA-HQ-OAR-2014-0534 in the "Enter Keyword or ID" fill-in box to view documents in the record. Although a part of the official docket, the public docket does not include Confidential Business Information ("CBI") or other information whose disclosure is restricted by statute.

EPA's Office of Transportation and Air Quality ("OTAQ") maintains a Web page that contains general information on its review of California waiver requests. Included on that page are links to prior waiver **Federal Register** notices, some of which are cited in today's notice. The page can be accessed at <http://www.epa.gov/otaq/cafr.htm>.

FOR FURTHER INFORMATION CONTACT: David Dickinson, Attorney-Advisor, Transportation Climate Division, Office of Transportation and Air Quality, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue (6405J), NW., Washington, DC 20460. Telephone: (202) 343-9256. Fax: (202) 343-2800. Email: Dickinson.David@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

EPA granted an authorization for California's initial set of CHC regulations on December 5, 2011.¹ California's initial CHC regulations

¹ 76 FR 77521 (December 5, 2011).

established emission standards, requirements related to the control of emissions, and enforcement provisions. The requirements are applicable to diesel propulsion and auxiliary engines on new and in-use commercial harbor craft, with some exceptions. Commercial harbor craft include a variety of different types of vessels, including ferries, excursion vessels, tugboats, towboats, and commercial and charter fishing boats. The initial CHC regulations established in-use emission limits for in-use ferries, excursion vessels, tugboats, and towboats equipped with federal Tier 0 and Tier 1 propulsion and auxiliary marine engines. Owners and operators of these vessels were required to upgrade the engines to meet emission limits equal to or cleaner than federal Tier 2 or Tier 3 marine engine certification standards, according to a compliance schedule that was also set forth in the regulations. The compliance schedule was based on the model year of the original engine ("in-use engine model year"), its hours of operation, and the vessel's home port location. The CHC regulations apply separately to new and in-use engines used on harbor craft.²

In a letter dated May 28, 2014, CARB submitted to EPA its request pursuant to section 209(e) of the CAA, regarding authorization of its amendments to California's CHC regulations to reduce emissions from diesel engines on commercial harbor craft ("CHC Amendments").³ The CARB Board approved the CHC Amendments on June 24, 2010 (by Resolution 10-26).⁴

The CHC Amendments set forth a variety of in-use requirements, including extending the applicability of the CHC regulations to in-use crew and supply, barge, and dredge vessels that are equipped with federal Tier 0 and Tier 1 propulsion and auxiliary marine engines that operate within the Regulated California Waters.⁵ The CHC

Amendments also eliminate certain exemptions for CHC engines that had been registered in CARB's portable equipment registration program ("PERP") or permitted by local air pollution districts, and now subject such engines to the CHC regulations. In addition, the CHC Amendments clarify and define "swing engines" as replacement engines that are maintained at dockside locations and require such engines to comply with the CHC regulation's in-use engine requirements. The original CHC regulations required replacement engines for in-use CHC vessels to be certified to current EPA model year engines standards. CARB found this requirement could present difficulties for in-use CHC vessels in certain situations. Therefore, the CHC Amendments allow an owner or operator to use a non-current-year certified replacement engine under certain circumstances. In addition, the CHC Amendments allow the use of existing engines in a fleet to replace an older engine otherwise subject to the in-use requirements (the existing engine becomes subject to the in-use compliance date that applied to the engine being replaced). The CHC Amendments also expand the compliance extension options to fleets of three or more vessels.

CARB's CHC Amendments also include requirements that are applicable to both new and in-use engines. The original CHC regulation provided that new or in-use diesel propulsion or auxiliary engines for in-use harbor craft could not be sold, offered for sale, leased, rented, or acquired unless the engines were certified to at least federal Tier 2 or Tier 3 marine emission standards for a new engine of the same power rating and displacement in effect at the time of the aforementioned actions. The amendments now provide compliance flexibility to CHC owners or operators with the option of using EPA or CARB Tier 2 or higher tier certified off-road engines provided the engine or vessel manufacturer has complied with the provisions of 40 CFR 1042.605, which establishes requirements for marinized land-based engines.

A. California's Authorization Request

California requested that EPA perform two types of review. First, CARB

use engine compliance was required. The compliance schedule was based on the in-use engine model year, hours of operation, and the vessel's home port location. The amendments establish compliance schedules applicable to crew and supply vessel engines and a separate set of compliance schedules applicable to both barge and dredge vessel engines that are based solely on the in-use engine model year and annual hours of operation.

requested an EPA determination that certain provisions of the CHC Amendments are within the scope of a prior authorization issued by EPA, or in the alternative, merit full authorization ("Within-the-Scope Amendments"). CARB includes as part of the Within-the-Scope Amendments: The provisions allowing use of EPA or CARB certified off-road CI engines to comply with the new and in-use requirements for propulsion and/or auxiliary engines; the amendments that subject CHC engines registered and permitted by local air pollution districts prior to January 1, 2009, CHC auxiliary engines registered to CARB's PERP prior to January 1, 2009, and CHC auxiliary engines not permanently affixed to the vessel and registered in PERP on or after January 1, 2009 to the CHC Regulation; and the amendments that clarify swing engines are replacement engines subject to the CHC regulation's in-use requirements, along with the exemptions for replacement engines in in-use CHC vessels, the allowance of the use of existing engines to replace an older engine subject to in-use requirements, and the expansion of the availability of compliance extensions for CHC vessel fleets.

Second, CARB requests full authorization for amendments that establish new requirements ("Full Authorization Amendments"). The Full Authorization Amendments pertain to the new provisions establishing in-use requirements applicable to crew and supply, barge, and dredge vessels. The amendments extend the applicability of the previous requirement that specified categories of CHC vessels (ferries, excursions vessels tugboats, towboats, push boats, and multipurpose harbor craft) to meet emission limits equal to or cleaner than federal Tier 2 or Tier 3 new marine engine emission standards, as applicable and in effect for the year that in-use engine compliance is required under the compliance schedule set forth within the regulation.

B. Clean Air Act Nonroad Engine and Vehicle Authorizations

Section 209(e)(1) of the Act permanently preempts any state, or political subdivision thereof, from adopting or attempting to enforce any standard or other requirement relating to the control of emissions for certain new nonroad engines or vehicles.⁶ For

² The regulations are codified at title 13, California Code of Regulations (CCR), section 2229.5 and title 17, CCR section 93118.5.

³ Letter and attached memo from Richard Corey, CARB to Gina McCarthy, EPA dated May 28, 2014 ("Waiver Support Document"), EPA-HQ-OAR-2014-0534-0002.

⁴ CARB Resolution 10-26, June 24, 2010, EPA-HQ-OAR-2014-0534-0008.

⁵ Regulated California Waters include all California inland waters, all California estuarine waters, and all waters within a zone 24 nautical miles seaward of the California coastline, except for specified areas along the Southern California coastline, Title 17 CCR 93118.5(d)(68). The original CHC regulations required owners or operators of in-use ferries, excursion vessels, and tugboats equipped with Tier 0 and Tier 1 propulsion and auxiliary marine engines to meet equal to or cleaner than federal Tier 2 or Tier 3 new marine engine certification standards in effect for the year that in-

⁶ States are expressly preempted from adopting or attempting to enforce any standard or other requirement relating to the control of emissions from new nonroad engines which are used in construction equipment or vehicles or used in farm equipment or vehicles and which are smaller than

all other nonroad engines, states generally are preempted from adopting and enforcing standards and other requirements relating to the control of emissions. Section 209(e)(2), however, requires the Administrator, after notice and opportunity for public hearing, to authorize California to adopt and enforce standards and other requirements relating to the control of emissions from such vehicles or engines if California determines that California standards will be, in the aggregate, at least as protective of public health and welfare as applicable Federal standards. However, EPA shall not grant such authorization if it finds that (1) the determination of California is arbitrary and capricious; (2) California does not need such California standards to meet compelling and extraordinary conditions; or (3) California standards and accompanying enforcement procedures are not consistent with [CAA section 209].⁷

On July 20, 1994, EPA promulgated a rule interpreting the three criteria set forth in section 209(e)(2)(A) that EPA must consider before granting any California authorization request for nonroad engine or vehicle emission standards.⁸ EPA revised these regulations in 1997.⁹ As stated in the preamble to the 1994 rule, EPA historically has interpreted the consistency inquiry under the third criterion, outlined above and set forth in section 209(e)(2)(A)(iii), to require, at minimum, that California standards and

enforcement procedures be consistent with section 209(a), section 209(e)(1), and section 209(b)(1)(C) of the Act.¹⁰

In order to be consistent with section 209(a), California's nonroad standards and enforcement procedures must not apply to new motor vehicles or new motor vehicle engines. To be consistent with section 209(e)(1), California's nonroad standards and enforcement procedures must not attempt to regulate engine categories that are permanently preempted from state regulation. To determine consistency with section 209(b)(1)(C), EPA typically reviews nonroad authorization requests under the same "consistency" criteria that are applied to motor vehicle waiver requests under section 209(b)(1)(C). That provision provides that the Administrator shall not grant California a motor vehicle waiver if she finds that California "standards and accompanying enforcement procedures are not consistent with section 202(a)" of the Act. Previous decisions granting waivers and authorizations have noted that state standards and enforcement procedures will be found to be inconsistent with section 202(a) if (1) there is inadequate lead time to permit the development of the necessary technology, giving appropriate consideration to the cost of compliance within that time,¹¹ or (2) the federal and state testing procedures impose inconsistent certification requirements.¹²

In light of the similar language in sections 209(b) and 209(e)(2)(A), EPA has reviewed California's requests for authorization of nonroad vehicle or engine standards under section 209(e)(2)(A) using the same principles that it has historically applied in reviewing requests for waivers of preemption for new motor vehicle or new motor vehicle engine standards under section 209(b).¹³ These principles include, among other things, that EPA should limit its inquiry to the three specific authorization criteria identified in section 209(e)(2)(A),¹⁴ and that EPA should give substantial deference to the policy judgments California has made in adopting its regulations. In previous waiver decisions, EPA has stated that Congress intended EPA's review of

California's decision-making be narrow. EPA has rejected arguments that are not specified in the statute as grounds for denying a waiver:

The law makes it clear that the waiver requests cannot be denied unless the specific findings designated in the statute can properly be made. The issue of whether a proposed California requirement is likely to result in only marginal improvement in California air quality not commensurate with its costs or is otherwise an arguably unwise exercise of regulatory power is not legally pertinent to my decision under section 209, so long as the California requirement is consistent with section 202(a) and is more stringent than applicable Federal requirements in the sense that it may result in some further reduction in air pollution in California.¹⁵

This principle of narrow EPA review has been upheld by the U.S. Court of Appeals for the District of Columbia Circuit.¹⁶ Thus, EPA's consideration of all the evidence submitted concerning an authorization decision is circumscribed by its relevance to those questions that may be considered under section 209(e)(2)(A).

B. Within-the-Scope Determinations

If California amends regulations that were previously authorized by EPA, California may ask EPA to determine that the amendments are within the scope of the earlier authorization. A within-the-scope determination for such amendments is permissible without a full authorization if three conditions are met. First, the amended regulations must not undermine California's previous determination that its standards, in the aggregate, are as protective of public health and welfare as applicable federal standards. Second, the amended regulations must not affect consistency with section 209 of the Act, following the same criteria discussed above in the context of full authorizations. Third, the amended regulations must not raise any "new issues" affecting EPA's prior authorizations.¹⁷

¹⁵ "Waiver of Application of Clean Air Act to California State Standards," 36 FR 17458 (Aug. 31, 1971). Note that the more stringent standard expressed here, in 1971, was superseded by the 1977 amendments to section 209, which established that California must determine that its standards are, in the aggregate, at least as protective of public health and welfare as applicable Federal standards. In the 1990 amendments to section 209, Congress established section 209(e) and similar language in section 209(e)(1)(i) pertaining to California's nonroad emission standards which California must determine to be, in the aggregate, at least as protective of public health and welfare as applicable federal standards.

¹⁶ See, e.g., *Motor and Equip. Mfrs. Assoc. v. EPA*, 627 F.2d 1095 (D.C. Cir. 1979) ("MEMA I").

¹⁷ See "California State Motor Vehicle Pollution Control Standards; Amendments Within the Scope

175 horsepower. Such express preemption under section 209(e)(1) of the Act also applies to new locomotives or new engines used in locomotives. CAA § 209(e)(1), 42 U.S.C. 7543(e)(1)(A).

⁷ EPA's review of California regulations under section 209 is not a broad review of the reasonableness of the regulations or its compatibility with all other laws. Sections 209(b) and 209(e) of the Clean Air Act limit EPA's authority to deny California requests for waivers and authorizations to the three criteria listed therein. As a result, EPA has consistently refrained from denying California's requests for waivers and authorizations based on any other criteria. In instances where the U.S. Court of Appeals has reviewed EPA decisions declining to deny waiver requests based on criteria not found in section 209(b), the Court has upheld and agreed with EPA's determination. See *Motor and Equipment Manufacturers Ass'n v. Nichols*, 142 F.3d 449, 462–63, 466–67 (D.C. Cir. 1998); *Motor and Equipment Manufacturers Ass'n v. EPA*, 627 F.2d 1095, 1111, 1114–20 (D.C. Cir. 1979). See also 78 FR 58090, 58120 (September 20, 2013).

⁸ See "Air Pollution Control; Preemption of State Regulation for Nonroad Engine and Vehicle Standards," 59 FR 36969 (July 20, 1994).

⁹ See "Control of Air Pollution: Emission Standards for New Nonroad Compression-Ignition Engines at or Above 37 Kilowatts; Preemption of State Regulation for Nonroad Engine and Vehicle Standards; Amendments to Rules," 62 FR 67733 (December 30, 1997). The applicable regulations are now found in 40 CFR part 1074, subpart B, section 1074.105.

¹⁰ 59 FR 36969 (July 20, 1994). EPA has interpreted 209(b)(1)(C) in the context of section 209(b) motor vehicle waivers.

¹¹ H. Rep. No. 728, 90th Cong., 1st Sess. 21 (1967).

¹² S. Rep. No. 403, 90th Cong., 1st Sess. 32 (1967).

¹³ See *Engine Manufacturers Association v. EPA*, 88 F.3d 1075, 1087 (D.C. Cir. 1996): "... EPA was within the bounds of permissible construction in analogizing § 209(e) on nonroad sources to § 209(a) on motor vehicles."

¹⁴ See EPA's Final 209(e) rulemaking at 59 FR 36969, 36983 (July 20, 1994).

C. Deference to California

In previous waiver and authorization decisions, EPA has recognized that the intent of Congress in creating a limited review based on the section 209(b)(1) criteria was to ensure that the federal government did not second-guess state policy choices. As the agency explained in one prior waiver decision:

It is worth noting . . . I would feel constrained to approve a California approach to the problem which I might also feel unable to adopt at the federal level in my own capacity as a regulator. The whole approach of the Clean Air Act is to force the development of new types of emission control technology where that is needed by compelling the industry to “catch up” to some degree with newly promulgated standards. Such an approach . . . may be attended with costs, in the shape of reduced product offering, or price or fuel economy penalties, and by risks that a wider number of vehicle classes may not be able to complete their development work in time. Since a balancing of these risks and costs against the potential benefits from reduced emissions is a central policy decision for any regulatory agency under the statutory scheme outlined above, I believe I am required to give very substantial deference to California’s judgments on this score.¹⁸

Similarly, EPA has stated that the text, structure, and history of the California waiver provision clearly indicate both a congressional intent and appropriate EPA practice of leaving the decision on “ambiguous and controversial matters of public policy” to California’s judgment.¹⁹ This interpretation is supported by relevant discussion in the House Committee Report for the 1977 amendments to the Clean Air Act.²⁰ Congress had the opportunity through the 1977 amendments to restrict the preexisting waiver provision, but elected instead to expand California’s flexibility to adopt a complete program of motor vehicle emission controls. The report explains that the amendment is intended to ratify and strengthen the preexisting California waiver provision and to affirm the underlying intent of that provision, that is, to afford California the broadest possible discretion in selecting the best means to protect the health of its citizens and the public welfare.²¹

D. Burden and Standard of Proof

As the U.S. Court of Appeals for the D.C. Circuit has made clear in *MEMA I*,

opponents of a waiver request by California bear the burden of showing that the statutory criteria for a denial of the request have been met:

[T]he language of the statute and its legislative history indicate that California’s regulations, and California’s determinations that they must comply with the statute, when presented to the Administrator are presumed to satisfy the waiver requirements and that the burden of proving otherwise is on whoever attacks them. California must present its regulations and findings at the hearing and thereafter the parties opposing the waiver request bear the burden of persuading the Administrator that the waiver request should be denied.²²

The same logic applies to authorization requests. The Administrator’s burden, on the other hand, is to make a reasonable evaluation of the information in the record in coming to the waiver decision. As the court in *MEMA I* stated: “here, too, if the Administrator ignores evidence demonstrating that the waiver should not be granted, or if he seeks to overcome that evidence with unsupported assumptions of his own, he runs the risk of having his waiver decision set aside as ‘arbitrary and capricious.’”²³ Therefore, the Administrator’s burden is to act “reasonably.”²⁴

With regard to the standard of proof, the court in *MEMA I* explained that the Administrator’s role in a section 209 proceeding is to:

[. . .] consider all evidence that passes the threshold test of materiality and . . . thereafter assess such material evidence against a standard of proof to determine whether the parties favoring a denial of the waiver have shown that the factual circumstances exist in which Congress intended a denial of the waiver.²⁵

With regard to the protectiveness finding, the court upheld the Administrator’s position that, to deny a waiver, there must be “clear and compelling evidence” to show that proposed enforcement procedures undermine the protectiveness of California’s standards.²⁶ The court noted that this standard of proof also accords with the congressional intent to provide California with the broadest possible discretion in setting regulations it finds protective of the public health and welfare.²⁷

With respect to the consistency finding, the court did not articulate a standard of proof applicable to all

proceedings, but found that the opponents of the waiver were unable to meet their burden of proof even if the standard were a mere preponderance of the evidence. EPA’s past waiver decisions have consistently made clear that: “[E]ven in the two areas concededly reserved for Federal judgment by this legislation—the existence of ‘compelling and extraordinary’ conditions and whether the standards are technologically feasible—Congress intended that the standards of EPA review of the State decision to be a narrow one.”²⁸

E. EPA’s Administrative Process in Consideration of California’s Commercial Harbor Craft Regulations

Upon review of CARB’s request, EPA offered an opportunity for a public hearing, and requested written comment on issues relevant to a full section 209(e) authorization analysis, by publication of a **Federal Register** notice on November 24, 2014.²⁹ Specifically, we requested comment on: (a) Whether CARB’s determination that its standards, in the aggregate, are at least as protective of public health and welfare as applicable federal standards is arbitrary and capricious, (b) whether California needs such standards to meet compelling and extraordinary conditions, and (c) whether California’s standards and accompanying enforcement procedures are consistent with section 209 of the Act. In addition, EPA requested comment on issues relevant to a within-the-scope analysis for any CARB amendments that may merit confirmation of being within the scope of EPA’s prior authorization of the CHC regulation.

EPA did not receive a request for hearing and therefore no hearing was held. EPA did not receive any written comments. EPA’s evaluation is based on the record, which includes CARB’s authorization request and accompanying documents.

II. Discussion

A. Within-the-Scope Analysis

We initially evaluate California’s Within-the-Scope Amendments by application of our traditional within-the-scope analysis, as CARB requested. If we determine that CARB’s request does not meet the requirements for a within-the-scope determination, we then evaluate the request based on a full authorization analysis. In determining whether amendments can be viewed as

of Previous Waiver of Federal Preemption,” 46 FR 36742 (July 15, 1981).

¹⁸ 40 FR 23102, 23103–23104 (May 28, 1975).

¹⁹ *Id.* at 23104; 58 FR 4166 (January 13, 1993).

²⁰ *MEMA I*, 627 F.2d at 1110 (citing H.R. Rep. No. 294, 95th Cong., 1st Sess. 301–302 (1977)).

²¹ *Id.*

²² *MEMA I*, *supra* note 17, at 1121.

²³ *Id.* at 1126.

²⁴ *Id.* at 1126.

²⁵ *Id.* at 1122.

²⁶ *Id.*

²⁷ *Id.*

²⁸ See, e.g., “California State Motor Vehicle Pollution Control Standards; Waiver of Federal Preemption,” 40 FR 23102 (May 28, 1975), at 23103.

²⁹ 79 FR 69482 (November 24, 2014).

within the scope of previous authorizations, EPA looks at whether CARB's revisions have been limited to making minor technical amendments to previously waived regulations or modifying the regulations in order to provide manufacturers with additional compliance flexibilities without significantly reducing the overall stringency of the requirements.

EPA sought comment on a range of issues, including those applicable to a within-the-scope analysis as well as those applicable to a full authorization analysis. No party submitted a comment that California's Within-the-Scope Amendments require a full authorization analysis. Given the lack of comments on this issue, and EPA's assessment of the nature of the amendments, EPA will evaluate California's Within-the-Scope Amendments by application of our traditional within-the-scope analysis, as CARB requested.

EPA can confirm that amended regulations are within the scope of a previously granted waiver of preemption if three conditions are met. First, the amended regulations must not undermine California's determination that its standards, in the aggregate, are as protective of public health and welfare as applicable federal standards. Second, the amended regulations must not affect consistency with section 202(a) of the Act. Third, the amended regulations must not raise any "new issues" affecting EPA's prior authorizations.

B. Full Authorization Analysis

As noted above, CARB's authorization request also included the Full Authorization Amendments. EPA must grant an authorization of the Full Authorization Amendments unless the Administrator finds: (1) California's determination that its standards will be, in the aggregate, as protective of public health and welfare as applicable federal standards is arbitrary and capricious; (2) California does not need such California standards to meet compelling and extraordinary conditions; or (3) California's standards and accompanying enforcement procedures are not consistent with this section.

EPA's evaluation of the CHC Amendments, including the Within-the-Scope Amendments and Full Authorization Amendments, is set forth below. Because of the similarity of the within-the-scope criteria and the full authorization criteria, a discussion of both sets of the respective amendments take place within each authorization criterion. To the extent that the criteria are applied uniquely, or that additional

criteria apply under either the within-the-scope analysis or the full authorization analysis, such application is also addressed below.

C. California's Protectiveness Determination

Section 209(e)(2)(i) of the Act instructs that EPA cannot grant an authorization if the agency finds that CARB was arbitrary and capricious in its determination that its standards are, in the aggregate, at least as protective of public health and welfare as applicable federal standards. CARB's Board made a protectiveness determination in Resolution 10–26, finding that "the California emission standards and other requirements related to the control of emissions in the amended regulation are, in the aggregate, at least as protective of public health and welfare than applicable federal standards."³⁰ CARB asserts that EPA has no basis to find that the CARB Board's determination is arbitrary or capricious.³¹ CARB points out that because the California and federal emission standards and test procedures for off-road CI engines are essentially aligned, and because California and federal off-road CI emission standards are generally more stringent than the equivalent federal marine engine emission standards, that EPA has no basis to find that the option to use the off-road CI engines would cause the CHC Amendments to be less protective.³² With respect to in-use engines, CARB maintains there is no question that the option of using EPA or CARB Tier 2 or higher tier certified off-road CI engines to meet the CHC regulation's in-use requirements are more stringent than applicable federal regulations, given that EPA is not authorized to regulate in-use off-road engines.³³ In addition, CARB notes that the Within-the-Scope Amendments do not undermine the protectiveness determination made by EPA in granting the initially authorized CHC regulation. As explained above, CARB adopted the Within-the-Scope Amendments to accommodate implementation and compliance issues that have arisen under the original CHC regulations. Given that EPA has no authority to regulate in-use engines, CARB notes that it is indisputable that its in-use provisions are more stringent than non-

existent "applicable" federal requirements.

After evaluating the materials submitted by CARB, and since EPA has not adopted any standards or requirements for in-use CHC engines and based on the lack of any comments submitted to the record, I cannot find that California's Within-the-Scope Amendments undermine California's previous determination that its standards, in the aggregate, are at least as protective of public health and welfare as applicable federal standards. Thus I cannot deny CARB's within-the-scope request based on this criterion. Similarly, with regard to the Full Authorization Amendments I cannot make a finding that CARB's protectiveness determination is arbitrary and capricious and thus I cannot deny CARB's Full Authorization Amendments based on this criterion.

D. Need for California Standards To Meet Compelling and Extraordinary Conditions

Section 209(e)(2)(ii) of the Act instructs that EPA cannot grant an authorization if the agency finds that California "does not need such California standards to meet compelling and extraordinary conditions." EPA's inquiry under this second criterion (found both in paragraph 209(b)(1)(B) and 209(e)(2)(A)(ii)) has been to determine whether California needs its own mobile source pollution program (*i.e.* set of standards) for the relevant class or category of vehicles or engines (*e.g.*, on-highway mobile source or nonroad mobile source) to meet compelling and extraordinary conditions, and not whether the specific standards that are the subject of the authorization or waiver request are necessary to meet such conditions.³⁴

California has asserted its longstanding position that the State continues to need its own nonroad engine program to meet serious air pollution problems.³⁵ CARB notes that "California, and particularly the South Coast and San Joaquin Valley Air Basins, continue to experience some of the worst air quality in the nation and continue to be in non-attainment with national ambient air quality standards for PM_{2.5} and ozone. The unique geographical and climatic conditions, and the tremendous growth in on and off-road vehicle population and use that moved Congress to authorize California to establish separate on-road motor vehicle standards in 1967 and off-road

³⁰ CARB Resolution 10–26, EPA–HQ–OAR–201–0534–0008.

³¹ CARB Support Document at 7–8.

³² *Id.* at 11. In addition, EPA's existing regulations for new marine diesel engines also allow the use of certified off-road land-based engines in marine vessels.

³³ *Id.* at 12.

³⁴ See 74 FR 32744, 32761 (July 8, 2009); 49 FR 18887–18890 (May 3, 1984).

³⁵ See Waiver Support Document at p. 18.

engine standards in 1990 still exists today.³⁶

There has been no evidence submitted to indicate that California's compelling and extraordinary conditions do not continue to exist. California, including the South Coast and the San Joaquin Valley air basins, continues to experience some of the worst air quality in the nation and continues to be in non-attainment with national ambient air quality standards for fine particulate matter (PM_{2.5}) and ozone.³⁷ In addition, EPA is not aware of any other information that would suggest that California no longer needs its nonroad emission program.

Therefore, based on the record of this request and absence of comments or other information to the contrary, I cannot find that California does not continue to need such state standards, including the CHC regulations, to address the "compelling and extraordinary conditions" underlying the state's air pollution problems. I have determined that I cannot deny California authorization for its Full Authorization Amendments under section 209(e)(2)(A)(ii). As noted above, EPA's within-the-scope analysis (that is applicable to the Within-the-Scope Amendments) does not require an assessment of section 209(e)(2)(A)(ii).

E. Consistency With Section 209 of the Clean Air Act

Section 209(e)(2)(A)(iii) of the Act instructs that EPA cannot grant an authorization if California's standards and enforcement procedures are not consistent with "this section." As described above, EPA's section 209(e) rule states that the Administrator shall not grant authorization to California if she finds (among other tests) that the "California standards and accompanying enforcement procedures are not consistent with section 209." EPA has interpreted this requirement to mean that California standards and accompanying enforcement procedures (under both the full authorization and the within-the-scope analysis) must be consistent with at least sections 209(a),

209(e)(1), and 209(b)(1)(C), as EPA has interpreted this last subsection in the context of motor vehicle waivers. Thus, this can be viewed as a three-pronged test.

1. Consistency With Section 209(a) and 209(e)(1)

To be consistent with section 209(a) of the Clean Air Act, California's commercial harbor craft regulations must not apply to new motor vehicles or new motor vehicle engines. California's commercial harbor craft regulations apply to nonroad marine vessels and engines, not on-highway motor vehicles or engines. CARB states that the new vessel requirements regulate new diesel engines, and apply only to nonroad engines that are neither new motor vehicles nor new motor vehicle engines. No commenter presented otherwise; therefore, I cannot deny California's request on the basis that California's commercial harbor craft regulations are not consistent with section 209(a).

To be consistent with section 209(e)(1) of the Clean Air Act, California's commercial harbor craft regulations must not affect new farming or construction vehicles or engines that are below 175 horsepower, or new locomotives or their engines. CARB represents that commercial harbor craft engines are not used in locomotives and are not primarily used in farm and construction equipment vehicles. No commenter presented otherwise and EPA is otherwise not aware of any information to the contrary; therefore, I cannot deny California's request on the basis that California's commercial harbor craft requirements are not consistent with section 209(e)(1).

2. Consistency With Section 209(b)(1)(C)

The requirement that California's standards be consistent with section 209(b)(1)(C) of the Clean Air Act effectively requires consistency with section 202(a) of the Act. California standards are inconsistent with section 202(a) of the Act if there is inadequate lead-time to permit the development of technology necessary to meet those requirements, giving appropriate consideration to the cost of compliance within that time. California's accompanying enforcement procedures would also be inconsistent with section 202(a) if the federal and California test procedures were not consistent. The scope of EPA's review of whether California's action is consistent with section 202(a) is narrow. The determination is limited to whether those opposed to the authorization or waiver have met their burden of

establishing that California's standards are technologically infeasible, or that California's test procedures impose requirements inconsistent with the federal test procedure.³⁸

Congress has stated that the consistency requirement of section 202(a) relates to technological feasibility.³⁹ Section 202(a)(2) states, in part, that any regulation promulgated under its authority "shall take effect after such period as the Administrator finds necessary to permit the development and application of the requisite technology, giving appropriate consideration to the cost of compliance within such period." Section 202(a) thus requires the Administrator to first determine whether adequate technology already exists; or if it does not, whether there is adequate time to develop and apply the technology before the standards go into effect. The latter scenario also requires the Administrator to decide whether the cost of developing and applying the technology within that time is feasible. Previous EPA waivers are in accord with this position.⁴⁰

As described above, the Full Authorization Amendments require in-use Tier 0 and Tier 1 propulsion and auxiliary marine engines on crew and supply, barge, and dredge vessels to meet emission limits equal to or cleaner than federal Tier 2 or Tier 3 new marine engine certification standards in effect for the year that in-use engine compliance is required (based on the model year of the in-use engine and annual hours of operation). Vessel owners are provided the same compliance options that were available to owners of Tier 0 and Tier 1 marine engines in the initial CHC regulations: (1) Replacing an in-use engine with a new marine engine certified to applicable Tier 2 or Tier 3 marine standards, (2) demonstrating that the in-use marine engine already meets the most stringent Tier 2 or Tier 3 marine standards in effect for new engines of similar power rating and displacement, (e.g., utilizing engine rebuild kits or aftertreatment technologies), (3) demonstrating that an in-use marine engine has not and will not operate more than a specified number of hours per calendar year (300 hours for crew and supply vessel engines or 80 hours for barge and dredge vessel engines), or (4) using the flexibility provided through the exemptions and compliance extensions of the regulation. CARB

³⁶ *Id.* See 74 FR 32744, 32762–32763 (July 8, 2009); 79 FR 6584, 6588–6590 (February 4, 2014).

³⁷ 74 FR 32744, 32762–63 (July 8, 2009), 76 FR 77515, 77518 (December 13, 2011), 81 FR 95982 (December 29, 2016). EPA continually evaluates the air quality conditions in the United States, including California. California continues to experience some of the worst air quality in the country and continues to be in nonattainment with National Ambient Air Quality Standards for fine particulate matter and ozone, see "Notice of Availability of the Environmental Protection Agency's Preliminary Interstate Ozone Transport Modeling Data for the 2015 Ozone National Ambient Air Quality Standard (NAAQS)" at EPA–HQ–OAR–2016–0751.

³⁸ *MEMA I*, 627, F.2d at 1126.

³⁹ H.R. Rep. No. 95–294, 95th Cong., 1st Sess. 301 (1977).

⁴⁰ See, e.g., 49 FR 1887, 1895 (May 3, 1984); 43 FR 32182, 32183 (July 25, 1978); 41 FR 44209, 44213 (October 7, 1976).

notes “In granting California the authorization for the original CHC regulation, EPA stated that ‘no party objected to CARB’s demonstration that [compliance] technologies are in existence and are being used in actual operation,’ and also found no issue of incompatibility between California and federal test procedures.”⁴¹ CARB also notes that the CHC Amendments now provide owners or operators the additional compliance flexibility option of using CARB or EPA Tier 2 or higher tier certified off-road CI engines to meet the requirements for auxiliary or propulsion engines, so owners or operators may also elect to comply with the amended in-use requirements by replacing an in-use engine with a new off-road engine, or by demonstrating that an existing in-use engine meets CARB or EPA Tier 2 or Tier 3 off-road CI engines standards (e.g., through utilization of engine rebuild kits or aftertreatment technologies).

CARB maintains that the Within-the-Scope Amendments present no issue regarding technical feasibility or inconsistent test procedures as the amendments only maintain or relax the stringency of the original CHC regulation’s in-use requirements.

EPA did not receive any comments suggesting that California’s commercial harbor craft regulations are technologically infeasible.

Therefore, based on the record before us, I cannot find that the CHC Amendments are technologically infeasible or otherwise inconsistent with section 202(a). Therefore, I cannot deny CARB’s authorization request for the Full Authorization Amendments and likewise cannot deny the within-the-scope request for the Within-the-Scope Amendments based on the section 202(a) criterion.

F. New Issues

EPA has stated in the past that if California promulgates amendments that raise new issues affecting previously granted waivers or authorizations, we would not confirm that those amendments are within the scope of previous authorizations.⁴² I do not believe that the Within-the-Scope Amendments raise any new issues with respect to our prior granting of the authorization. Moreover, EPA did not receive any comments that CARB’s CHC Amendments raised new issues affecting the previously granted

authorization. Therefore, I cannot find that CARB’s Within-the-Scope Amendments raise new issues and consequently cannot deny CARB’s request based on this criterion.

III. Decision

After evaluating California’s CHC Amendments and CARB’s submissions for EPA review as described above, I am taking the following actions. First, I am granting an authorization for the Full Authorization Amendments. Second, I confirm that the Within-the-Scope Amendments are within-the-scope of EPA’s previous authorization.

This decision will affect not only persons in California, but also manufacturers and/or owners/operators nationwide who must comply with California’s requirements. In addition, because other states may adopt California’s standards for which a section 209(e)(2)(A) authorization has been granted if certain criteria are met, this decision would also affect those states and those persons in such states. See CAA section 209(e)(2)(B). For these reasons, EPA determines and finds that this is a final action of national applicability, and also a final action of nationwide scope or effect for purposes of section 307(b)(1) of the Act. Pursuant to section 307(b)(1) of the Act, judicial review of this final action may be sought only in the United States Court of Appeals for the District of Columbia Circuit. Petitions for review must be filed by March 20, 2017. Judicial review of this final action may not be obtained in subsequent enforcement proceedings, pursuant to section 307(b)(2) of the Act.

IV. Statutory and Executive Order Reviews

As with past authorization and waiver decisions, this action is not a rule as defined by Executive Order 12866. Therefore, it is exempt from review by the Office of Management and Budget as required for rules and regulations by Executive Order 12866.

In addition, this action is not a rule as defined in the Regulatory Flexibility Act, 5 U.S.C. 601(2). Therefore, EPA has not prepared a supporting regulatory flexibility analysis addressing the impact of this action on small business entities.

Further, the Congressional Review Act, 5 U.S.C. 801, *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule for purposes of 5 U.S.C. 804(3).

Dated: January 11, 2017.

Gina McCarthy,
Administrator.

[FR Doc. 2017–01261 Filed 1–18–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2016–0745; FRL–9958–54–OECA]

Inquiry To Learn Whether Businesses Assert Business Confidentiality Claims Regarding Waste Import and Export

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for comment.

SUMMARY: The Environmental Protection Agency (EPA) receives from time to time Freedom of Information Act (FOIA) requests for documentation received or issued by EPA or data contained in EPA database systems pertaining to the export and import of Resource Conservation and Recovery Act (RCRA) hazardous waste from/to the United States, the export of cathode ray tubes (CRTs) and spent lead acid batteries (SLABs) from the United States, and the export and import of RCRA universal waste from/to the United States. These documents and data may identify or reference multiple parties, and describe transactions involving the movement of specified materials in which the parties propose to participate or have participated. The purpose of this notice is to inform “affected businesses” about the documents or data sought by these types of FOIA requests in order to provide the businesses with the opportunity to assert claims that any of the information sought that pertains to them is entitled to treatment as confidential business information (CBI), and to send comments to EPA supporting their claims for such treatment. Certain businesses, however, do not meet the definition of “affected business,” and are not covered by today’s notice. They consist of any business that actually submitted to EPA any document at issue pursuant to applicable RCRA regulatory requirements and did not assert a CBI claim as to information that pertains to that business in connection with the document at the time of its submission; they have waived their right to do so at a later time. Nevertheless, other businesses identified or referenced in the documents that were submitted to EPA by the submitting business may have a right to assert a CBI claim concerning information that pertains to

⁴¹ Waiver Support Document at 19 (citing EPA’s authorization at 76 FR 77521, 77527 (December 13, 2011)).

⁴² See, e.g., 78 FR 38970 (June 28, 2013), 75 FR 8056 (February 23, 2010), and 70 FR 22034 (April 28, 2005).

them and may do so in response to this notice.

DATES: Comments must be received on or before February 21, 2017. The period for submission of comments may be extended if, before the comments are due, you make a request for an extension of the comment period and it is approved by the EPA legal office. Except in extraordinary circumstances, the EPA legal office will not approve such an extension without the consent of any person whose request for release of the information under the FOIA is pending.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OECA-2016-0745, by one of the following methods:

- <http://www.regulations.gov>: Follow the on-line instructions for submitting comments.

- Email: kreisler.eva@epa.gov.

- Address: Eva Kreisler, International Compliance Assurance Division, Office of Federal Activities, Office of Enforcement and Compliance Assurance, Environmental Protection Agency, Mailcode: 2254A, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

Instructions: Direct your comments to Docket ID No. EPA-HQ-OECA-2016-0745. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or email. Instructions about how to submit comments claimed as CBI are given later in this notice.

The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through <http://www.regulations.gov>, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment. Please include your name and other contact information with any disk

or CD-ROM you submit by mail. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the HQ EPA Docket Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the docket for this notice is (202) 566-1752.

FOR FURTHER INFORMATION CONTACT: Eva Kreisler, International Compliance Assurance Division, Office of Federal Activities, Office of Enforcement and Compliance Assurance, Environmental Protection Agency, Mailcode: 2254A, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564-8186; email address: kreisler.eva@epa.gov.

SUPPLEMENTARY INFORMATION: Today's notice relates to any documents or data in the following areas: (1) Export of Resource Conservation and Recovery Act (RCRA) hazardous waste, during calendar year 2016 or before, under 40 CFR part 262, subparts E and H; (2) import of RCRA hazardous waste, during calendar year 2016 or before, under 40 CFR part 262, subparts F and H; (3) transit of RCRA hazardous waste, during calendar year 2016 or before, under 40 CFR part 262, subpart H, through the United States and foreign countries; (4) export of cathode ray tubes, during calendar year 2016 or before, under 40 CFR part 261, subpart E; (5) exports of non-crushed spent lead acid batteries with intact casings, during calendar year 2016 or before, under 40 CFR part 266 subpart G; (6) export and import of RCRA universal waste, during calendar year 2016 or before, under 40

CFR part 273, subparts B, C, D, and F; (7) submissions from transporters, during calendar year 2016 or before, under 40 CFR part 263, or from treatment, storage or disposal facilities under 40 CFR parts 264 and 265, related to exports or imports of hazardous waste which occurred during calendar year 2016 or before, including receiving facility notices under 40 CFR 264.12(a)(1) and 265.12(a)(1) and import consent documentation under 40 CFR 264.71(a)(3) and 265.71(a)(3).

I. General Information

EPA has previously published notices similar to this one in the **Federal Register**, the latest one being at 81 FR 7788, February 16, 2016, that address issues similar to those raised by today's notice. The Agency did not receive any comments on the previous notices. Since the publication of the February 16, 2016, **Federal Register** notice, the Agency has continued to receive FOIA requests for documents and data contained in EPA's database related to hazardous waste exports and imports.

II. Issues Covered by This Notice

Specifically, EPA receives FOIA requests from time to time for documentation or data related to hazardous waste exports and imports that may identify or reference multiple parties, and that describe transactions involving the movement of specified materials in which the parties propose to participate or have participated. This notice informs "affected businesses,"¹ which could include, among others, "transporters,"² and "consignees,"³ of the requests for information in EPA database systems and/or contained in one or more of the following documents: (1) Documents related to the export of Resource Conservation and Recovery Act (RCRA) hazardous waste, during calendar year 2016 or before, under 40 CFR part 262, subparts E and H, including but not limited to the "notification of intent to export,"⁴ "manifests,"⁵ "annual reports,"⁶ "EPA acknowledgements of consent,"⁷ "any subsequent communication withdrawing a prior consent or

¹ The term "affected business" is defined at 40 CFR 2.201(d), and is set forth in this notice, below.

² The term "transporter" is defined at 40 CFR 260.10.

³ The term "consignee" is defined, for different purposes, at 40 CFR 262.51 and 262.81(c).

⁴ The term "notification of intent to export" is described at 40 CFR 262.53.

⁵ The term "manifest" is defined at 40 CFR 260.10.

⁶ The term "annual reports" is described at 40 CFR 262.56.

⁷ The term "EPA acknowledgement of consent" is defined at 40 CFR 262.51.

objection,”⁸ “responses that neither consent nor object,” “exception reports,”⁹ “transit notifications,”¹⁰ and “renotifications”;¹¹ (2) documents related to the import of hazardous waste, during calendar year 2016 or before, under 40 CFR part 262, subparts F and H, including but not limited to notifications of intent to import hazardous waste into the U.S. from foreign countries; (3) documents related to the transit of hazardous waste, during calendar year 2016 or before, under 40 CFR part 262, subpart H, including notifications from U.S. exporters of intent to transit through foreign countries, or notifications from foreign countries of intent to transit through the U.S.; (4) documents related to the export of cathode ray tubes (CRTs), during calendar year 2016 or before, under 40 CFR part 261, subpart E, including but not limited to notifications of intent to export CRTs; (5) documents related to the export of non-crushed spent lead acid batteries (SLABs) with intact casings, during calendar year 2016 or before, under 40 CFR part 266 subpart G, including but not limited to notifications of intent to export SLABs; (6) submissions from transporters under 40 CFR part 263, or from treatment, storage or disposal facilities under 40 CFR parts 264 and 265, related to exports or imports of hazardous waste which occurred during calendar year 2016 or before, including receiving facility notices under 40 CFR 264.12(a)(1) and 265.12(a)(1) and import consent documentation under 40 CFR 264.71(a)(3) and 265.71(a)(3); and (7) documents related to the export and import of RCRA “universal waste”¹² under 40 CFR part 273, subparts B, C, D, and F.

Certain businesses, however, do not meet the definition of “affected business,” and are not covered by today’s notice. They consist of any business that actually submitted information responsive to a FOIA request, under the authority of 40 CFR parts 260 through 266 and 268, and did not assert a claim of business confidentiality covering any of that information at the time of submission. As set forth in the RCRA regulations at 40 CFR 260.2(b), “if no such [business

confidentiality] claim accompanies the information when it is received by EPA, it may be made available to the public without further notice to the person submitting it.” Thus, for purposes of this notice and as a general matter under 40 CFR 260.2(b), a business that submitted to EPA the documents at issue, pursuant to applicable regulatory requirements, and that failed to assert a claim as to information that pertains to it at the time of submission, cannot later make a business confidentiality claim.¹³ Nevertheless, other businesses identified or referenced in the same documents that were submitted to EPA by the submitting business may have a right to assert a CBI claim concerning information that pertains to them and may do so in response to this notice.

In addition, EPA may develop its own documents and organize into its database systems information that was originally contained in documents from submitting businesses relating to exports and imports of hazardous waste. If a submitting business fails to assert a CBI claim for the documents it submits to EPA at the time of submission, not only does it waive its right to claim CBI for those documents, but it also waives its right to claim CBI for information in EPA’s documents or databases that is based on or derived from the documents that were originally submitted by that business.¹⁴

In accordance with 40 CFR 2.204(c) and (e), this notice inquires whether any affected business asserts a claim that any of the requested information constitutes CBI, and affords such business an opportunity to comment to EPA on the issue. This notice also informs affected businesses that, if a claim is made, EPA would determine under 40 CFR part 2, subpart B, whether any of the requested information is entitled to business confidential treatment.

1. Affected Businesses

EPA’s FOIA regulations at 40 CFR 2.204(c)(1) require an EPA office that is responsible for responding to a FOIA request for the release of business information (“EPA office”) to determine which businesses, if any, are affected businesses. “Affected business” is

defined at 40 CFR 2.201(d) as: With reference to an item of business information, a business which has asserted (and not waived or withdrawn) a business confidentiality claim covering the information, or a business which could be expected to make such a claim if it were aware that disclosure of the information to the public was proposed.

2. The Purposes of This Notice

This notice encompasses two distinct steps in the process of communication with affected businesses prior to EPA’s making a final determination concerning the business confidentiality of the information at issue: the preliminary inquiry and the notice of opportunity to comment.

a. Inquiry To Learn Whether Affected Businesses (Other Than Those Businesses That Previously Asserted a CBI Claim) Assert Claims Covering Any of the Requested Information

Section 2.204(c)(2)(i) provides, in relevant part: If the examination conducted under paragraph (c)(1) of § 2.204 discloses the existence of any business which, although it has not asserted a claim, might be expected to assert a claim if it knew EPA proposed to disclose the information, the EPA office shall contact a responsible official of each such business to learn whether the business asserts a claim covering the information.

b. Notice of Opportunity To Submit Comments

Sections 2.204(d)(1)(i) and 2.204(e)(1) of Title 40 of the Code of Federal Regulations require that written notice be provided to businesses that have made claims of business confidentiality for any of the information at issue, stating that EPA is determining under 40 CFR part 2, subpart B, whether the information is entitled to business confidential treatment, and affording each business an opportunity to comment as to the reasons why it believes that the information deserves business confidential treatment.

3. The Use of Publication in the Federal Register

Section 2.204(e)(1) of Title 40 of the Code of Federal Regulations requires that this type of notice be furnished by certified mail (return receipt requested), by personal delivery, or by other means which allows verification of the fact and date of receipt. EPA, however, has determined that in the present circumstances the use of a **Federal Register** notice is a practical and efficient way to contact affected

⁸ The requirement to forward to the exporter “any subsequent communication withdrawing a prior consent or objection” is found at 42 U.S.C. 6938(e).

⁹ The term “exception reports” is described at 40 CFR 262.55.

¹⁰ The term “transit notifications” is described at 40 CFR 262.53(e).

¹¹ The term “renotifications” is described at 40 CFR 262.53(c).

¹² The term “universal waste” is defined at 40 CFR 273.9.

¹³ However, businesses having submitted information to EPA relating to the export and import of RCRA universal waste are not subject to 40 CFR 260.2(b) since they submitted information in accordance with 40 CFR part 273, and not parts 260 through 266 and 268, as set forth in 40 CFR 260.2(b). They are therefore affected businesses that could make a claim of CBI at the time of submission or in response to this notice.

¹⁴ With the exception, noted above, of the submission of information relating to the export and import of RCRA universal waste.

businesses and to furnish the notice of opportunity to submit comments. The Agency's decision to follow this course was made in recognition of the administrative difficulty and impracticality of directly contacting potentially thousands of individual businesses.

4. *Submission of Your Response in the English Language*

All responses to this notice must be in the English language.

5. *The Effect of Failure To Respond to This Notice*

In accordance with 40 CFR 2.204(e)(1) and 2.205(d)(1), EPA will construe your failure to furnish timely comments in response to this notice as a waiver of your business's claim(s) of business confidentiality for any information in the types of documents identified in this notice.

6. *What To Include in Your Comments*

If you believe that any of the information contained in the types of documents which are described in this notice and which are currently, or may become, subject to FOIA requests, is entitled to business confidential treatment, please specify which portions of the information you consider business confidential. Information not specifically identified as subject to a business confidentiality claim may be disclosed to the requestor without further notice to you.

For each item or class of information that you identify as being subject to your claim, please answer the following questions, giving as much detail as possible:

1. For what period of time do you request that the information be maintained as business confidential, *e.g.*, until a certain date, until the occurrence of a specified event, or permanently? If the occurrence of a specific event will eliminate the need for business confidentiality, please specify that event.

2. Information submitted to EPA becomes stale over time. Why should the information you claim as business confidential be protected for the time period specified in your answer to question no. 1?

3. What measures have you taken to protect the information claimed as business confidential? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose the information further? If so, why should the information still be considered business confidential?

4. Is the information contained in any publicly available material such as the Internet, publicly available data bases, promotional publications, annual reports, or articles? Is there any means by which a member of the public could obtain access to the information? Is the information of a kind that you would customarily not release to the public?

5. Has any governmental body made a determination as to the business confidentiality of the information? If so, please attach a copy of the determination.

6. For each category of information claimed as business confidential, explain with specificity why and how release of the information is likely to cause substantial harm to your competitive position. Explain the specific nature of those harmful effects, why they should be viewed as substantial, and the causal relationship between disclosure and such harmful effects. How could your competitors make use of this information to your detriment?

7. Do you assert that the information is submitted on a voluntary or a mandatory basis? Please explain the reason for your assertion. If the business asserts that the information is voluntarily submitted information, please explain whether and why disclosure of the information would tend to lessen the availability to EPA of similar information in the future.

8. Any other issue you deem relevant. Please note that you bear the burden of substantiating your business confidentiality claim. Conclusory allegations will be given little or no weight in the determination. If you wish to claim any of the information in your response as business confidential, you must mark the response "BUSINESS CONFIDENTIAL" or with a similar designation, and must bracket all text so claimed. Information so designated will be disclosed by EPA only to the extent allowed by, and by means of, the procedures set forth in, 40 CFR part 2, subpart B. If you fail to claim the information as business confidential, it may be made available to the requestor without further notice to you.

III. **What should I consider as I prepare my comments for EPA?**

1. Submitting CBI. Do not submit this information to EPA through <http://www.regulations.gov> or email. Please submit this information by mail to the address identified in the **ADDRESSES** section of today's notice for inclusion in the non-public CBI docket. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that

you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. Information so marked will not be disclosed except in accordance with the procedures set forth in 40 CFR part 2, subpart B. In addition to the submission of one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket.

2. **Tips for Preparing Your Comments.** When submitting comments, remember to:

- Identify the notice by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Describe any assumptions and provide any technical information and/or data that you used.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Make sure to submit your comments by the comment period deadline identified.

Dated: January 4, 2017.

Robert Tomiak,

Director, Office of Federal Activities.

[FR Doc. 2017-01101 Filed 1-18-17; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-OAR-2016-0596; FRL-9958-48-OAR]

RIN 2060-AT22

Response to December 9, 2013, Clean Air Act Section 176A Petition From Connecticut, Delaware, Maryland, Massachusetts, New Hampshire, New York, Pennsylvania, Rhode Island and Vermont

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed action on petition.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to deny the Clean Air Act (CAA or Act) petition filed on December 9, 2013 (and amended on December 17, 2013), by the states of Connecticut, Delaware, Maryland, Massachusetts, New Hampshire, New York, Pennsylvania, Rhode Island and Vermont. The petition requested that the EPA add the states of

Illinois, Indiana, Kentucky, Michigan, North Carolina, Ohio, Tennessee, West Virginia and Virginia to the Ozone Transport Region (OTR). As a result of this denial, the geographic scope or requirements of the OTR will remain unchanged.

DATES: *Comments.* Comments must be received on or before February 21, 2017.

Public Hearing. If anyone contacts us requesting to speak at a public hearing by January 30, 2017, we will hold a public hearing. Additional information about the hearing would be published in a subsequent **Federal Register** notice. For updates and additional information on a public hearing, please check the EPA's Web site for this notice at <https://www.epa.gov/implementation-2008-national-ambient-air-quality-standards-naaqs-ozone-state>.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2016-0596, at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e., on the Web, Cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: Questions concerning this proposed notice should be directed to Ms. Gobeail McKinley, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Air Quality Policy Division, Mail code C539-01, Research Triangle Park, NC 27711, telephone (919) 541-5246; email at mckinley.gobeail@epa.gov.

To request a public hearing or information pertaining to a public hearing on this document, contact Ms. Pamela Long, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Air Quality

Policy Division, (C504-01), Research Triangle Park, NC 27711; telephone number (919) 541-0641; fax number (919) 541-5509; email at: long.pam@epa.gov (preferred method of contact).

SUPPLEMENTARY INFORMATION:

I. General Information

Throughout this document wherever "we," "us," or "our" is used, we mean the U.S. EPA.

The information in this Supplementary Information section of this preamble is organized as follows:

- I. General Information
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 - B. What acronyms, abbreviations and units are used in this preamble?
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- IV. The EPA's Proposed Decision on the CAA Section 176A Petition
 - A. The CAA Good Neighbor Provisions
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I. General Information

A. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this document will be posted at <https://www.epa.gov/implementation-2008-national-ambient-air-quality-standards-naaqs-ozone-state>.

B. What acronyms, abbreviations and units are used in this preamble?

APA Administrative Procedures Act
CAA or Act Clean Air Act
CFR Code of Federal Regulations
CH₄ Methane
D.C. Circuit United States Court of Appeals for the District of Columbia Circuit
EGU Electric Generating Unit
EPA U.S. Environmental Protection Agency
FIP Federal Implementation Plan
FR Federal Register
NAAQS National Ambient Air Quality Standard
NEI National Emissions Inventory
NESHAP National Emission Standard for Hazardous Air Pollutants
NO_x Nitrogen Oxides

NSPS New Source Performance Standard
NSR New Source Review
OMB Office of Management and Budget
OTAG Ozone Transport Assessment Group
OTC Ozone Transport Commission
OTR Ozone Transport Region
PM Particulate Matter
RACT Reasonably Available Control Technology
SIP State Implementation Plan
SO₂ Sulfur Dioxide
UMRA Unfunded Mandates Reform Act
VOC Volatile Organic Compound

II. Executive Summary of the EPA's Proposed Decision on the CAA Section 176A Petition

The EPA is proposing to deny a petition filed pursuant to CAA section 176A(a) that requests the states of Illinois, Indiana, Kentucky, Michigan, North Carolina, Ohio, Tennessee, West Virginia and Virginia¹ (the upwind states) be added to the OTR, which was established pursuant to section 184 of the CAA. The petitioning states of Connecticut, Delaware, Maryland, Massachusetts, New Hampshire, New York, Pennsylvania, Rhode Island and Vermont (the petitioning states, downwind states, or petitioners) submitted a technical analysis intended to demonstrate that these nine upwind states significantly contribute to violations of the 2008 ozone national ambient air quality standard (NAAQS) in one or more of the current OTR states.

Section 176A(a) of the CAA provides the Administrator with the authority to develop interstate transport regions for particular pollutants where the Administrator determines that interstate transport of air pollutants from one or more states contributes significantly to violations of air quality standards in other states. The creation of such an interstate transport region requires the establishment of a transport commission with representatives from each state that make recommendations for the mitigation of the interstate pollution. Congress created one such transport region by statute in CAA section 184(a) in 1990 in order to address the interstate transport of ozone pollution, referred to as the OTR. The statute establishes certain minimum control requirements that apply to sources of emissions in each state in the OTR intended to address transported ozone pollution and provides the Ozone Transport Commission (OTC), comprised of representatives of each state in the OTR, with the authority to recommend

¹ The parts of northern Virginia included in the Washington, DC Consolidated Metropolitan Statistical Area are already in the OTR. The petition seeks to add the remainder of the state of Virginia to the OTR as well.

additional controls within the region. The downwind states' petition seeks to expand the OTR to include additional states and would thereby subject sources in those states to the requirements applicable in the OTR.

The CAA provides other provisions for addressing the interstate transport of ozone pollution besides sections 176A and 184. In particular, the Act includes a specific provision addressing how the EPA and the states are to mitigate the specific sources of emissions that contribute to interstate ozone pollution transport. Section 110(a)(2)(D)(i)(I) of the CAA, also referred to as the "good neighbor" provision, requires that states develop state implementation plans (SIPs) to prohibit emissions that will "contribute significantly to nonattainment in, or interfere with maintenance by, any other state" with respect to a NAAQS. Pursuant to this provision, states have the primary responsibility for reducing the interstate transport of pollutants, including ozone. Should the states fail to fulfill this responsibility, the EPA is obligated to develop federal implementation plans (FIPs) to ensure that appropriate emissions reductions are achieved and that the air quality standards downwind are attained and maintained. The CAA also contains a provision in section 126(b) that permits states and political subdivisions to petition the Administrator for a finding that any major source or group of stationary sources emits in violation of the prohibition in the good neighbor provision. In response to such a finding, the EPA may promulgate additional limits on such sources, and these limits must then be included in a state's good neighbor SIP pursuant to CAA section 110(a)(2)(D)(ii). This provision provides a means for the EPA to mediate disputes between the states regarding the compliance of specific sources with the requirements of the good neighbor provision. As described in detail later in this document, states and the EPA have historically used their authority under CAA sections 110(a)(2)(D)(i)(I) and section 126 to develop SIPs and FIPs that target specific sources of ozone precursor emissions to address interstate ozone transport across the U.S., including with respect to air quality concerns stemming from interstate transport of ozone within the OTR.

Pursuant to these and other CAA authorities, the EPA and states within and outside the OTR have taken significant actions independently and in collaboration for many years to address ozone pollution problems by reducing precursor emissions (*i.e.*, nitrogen

oxides (NO_x) and volatile organic compounds (VOC)) that contribute to the formation of ozone. The EPA and states have promulgated a number of rules that have already or are expected in the future to result in reductions in ozone concentrations that will help areas attain the 2008 ozone NAAQS. Several of these rules were developed specifically to address the interstate transport of ozone pollution. With respect to the 2008 ozone NAAQS, the EPA recently promulgated FIPs to address the requirements of CAA section 110(a)(2)(D)(i)(I) to specifically address interstate transport of ozone pollution in the eastern U.S. from power plants during the ozone season.² Other rules reduce ozone precursor emissions to address other ozone pollution challenges (*e.g.*, ozone attainment demonstrations) and impact the interstate transport of ozone pollution as a co-benefit. Further, several other state and federal air quality regulations reduce emissions of other air pollutants, such as rules targeted to reduce air toxics from industrial boilers, which often also result in the reduction of ozone precursors (*e.g.*, NO_x) and thereby reduce interstate ozone transport as a co-pollutant benefit.

Section 176A of the CAA provides the Administrator with discretion to determine whether to establish a new transport region or expand an existing transport region. The EPA has reviewed the request of the petitioners in light of the control requirements that apply to sources located in states now included in the OTR and that would apply to states if they were added and the other statutory authorities provided for addressing the interstate transport of ozone pollution. The EPA proposes to deny the CAA section 176A petition to add states to the OTR for the purpose of addressing the interstate ozone transport problem with respect to the 2008 ozone NAAQS. The EPA believes that, based on the reasons fully described in Section IV of this document, other CAA provisions (*e.g.*, CAA sections 110 or 126) provide a better alternative pathway for states and the EPA to develop a targeted remedy to address interstate ozone transport that focuses on the precursor pollutants and sources most effective at addressing the nature of the downwind air quality problems identified by the petitioning states. The states and the EPA have historically and effectively reduced ozone and the interstate transport of ozone pollution using these CAA authorities to

implement necessary emissions reductions. For purposes of addressing interstate transport of ozone with respect to the 2008 ozone NAAQS, the EPA believes that continuing its longstanding and effective utilization of the existing and expected control programs under the CAA's mandatory good neighbor provision embodied in CAA section 110(a)(2)(D)(i)(I) is a more effective means of addressing regional ozone pollution transport with respect to the 2008 ozone NAAQS for the areas within the OTR that must attain the NAAQS. Thus, the EPA believes that regulation pursuant to these other CAA authorities together with the implementation of existing EPA and state rules expected to further reduce precursor pollutant emissions that contribute to the interstate transport of ozone are the more effective means for addressing the interstate ozone transport problem with respect to the 2008 ozone NAAQS. Accordingly, the EPA is proposing to deny the CAA section 176A petition filed by the petitioning states. This proposed denial is specific to the 2008 ozone NAAQS, but the EPA notes that under different circumstances the OTR provisions have been an effective tool for air quality management, and could be similarly effective in the future. The EPA requests comment on the proposed denial of the petition based on the EPA's preferred approach to addressing interstate transport with respect to the 2008 ozone NAAQS pursuant to these other CAA authorities.

III. Background and Legal Authority

A. Ozone and Public Health

Ground-level ozone causes a variety of negative effects on human health, vegetation, and ecosystems. In humans, acute and chronic exposure to ozone is associated with premature mortality and a number of morbidity effects, such as asthma exacerbation. In ecosystems, ozone exposure causes visible foliar injury, decreases plant growth, and affects ecosystem community composition. Ground-level ozone is not emitted directly into the air, but is a secondary air pollutant created by chemical reactions between NO_x, carbon monoxide (CO), methane (CH₄), and non-methane VOCs in the presence of sunlight. Emissions from electric generating utilities (EGUs), industrial facilities, motor vehicles, gasoline vapors, and chemical solvents are some of the major anthropogenic sources of ozone precursors. The potential for ground-level ozone formation increases during periods with warmer temperatures and stagnant air masses;

² See 81 FR 74504, October 26, 2016, Cross-State Air Pollution Rule Update for the 2008 Ozone NAAQS.

therefore ozone levels are generally higher during the summer months.³ Ground-level ozone concentrations and temperature are highly correlated in the eastern U.S. with observed ozone increases of 2–3 parts per billion (ppb) per degree Celsius reported.⁴ Increased temperatures may also increase emissions of volatile man-made and biogenic organics and can indirectly increase anthropogenic NO_x emissions as well (e.g., through increased electricity generation to power air conditioning).

Precursor emissions can be transported downwind directly or, after transformation in the atmosphere, as ozone. Studies have established that ozone formation, atmospheric residence, and transport occurs on a regional scale (i.e., hundreds of miles) over much of the eastern U.S., with elevated concentrations occurring in rural as well as metropolitan areas. As a result of ozone transport, in any given location, ozone pollution levels are impacted by a combination of local emissions and emissions from upwind sources. The transport of ozone pollution across state borders compounds the difficulty for downwind states in meeting the health-and-welfare based NAAQS. Numerous observational studies have demonstrated the transport of ozone and its precursors and the impact of upwind emissions on high concentrations of ozone pollution.

While substantial progress has been made in reducing ozone in many urban areas, regional-scale ozone transport is still an important component of peak ozone concentrations during the summer ozone season. Model assessments have looked at impacts on peak ozone concentrations after potential emission reduction scenarios for NO_x and VOCs for NO_x-limited and VOC-limited areas. For example, one study⁵ concluded that NO_x emission reductions strategies would be effective in lowering ozone mixing ratios in urban areas and another study showed NO_x reductions would reduce peak ozone concentrations in non-attainment areas in the Mid-Atlantic (i.e., a 10

percent reduction in electric generating unit (EGU) and non-EGU NO_x emissions would result in approximately a 6 ppb reduction in peak ozone concentrations in Washington, DC).⁶

On March 12, 2008, the EPA promulgated a revision to the NAAQS, lowering both the primary and secondary standards to 75 ppb.⁷ On October 1, 2015, the EPA strengthened the ground-level ozone NAAQS, based on extensive scientific evidence about ozone's effects on public health and welfare.⁸ This document does not address any CAA requirements with respect to the 2015 ozone NAAQS.

B. Sections 176A and 184 of the CAA and the OTR Process

Subpart 1 of part D of title I of the CAA provides provisions governing general plan requirements for designated nonattainment areas. This subpart includes provisions providing for the development of transport regions to address the interstate transport of pollutants that contribute to NAAQS violations. In particular, section 176A(a) of the CAA provides that, on the EPA's own motion or by a petition from the Governor of any state, whenever the EPA has reason to believe that the interstate transport of air pollutants from one or more states contributes significantly to a violation of the NAAQS in one or more other states, the EPA may establish, by rule, a transport region for such pollutant that includes such states. The provision further provides that the EPA may add any state or portion of a state to any transport region whenever the Administrator has reason to believe that the interstate transport of air pollutants from such state significantly contributes to a violation of the standard in the transport region.

Section 176A(b) of the CAA provides that when the EPA establishes a transport region, the Administrator shall establish an associated transport commission, comprised of (at a minimum) the following: Governor or designee of each state, the EPA Administrator or designee, the Regional EPA Administrator and an air pollution control official appointed by the Governor of each state. The purpose of the transport commission is to assess the degree of interstate transport throughout the transport region and

assess control strategies to mitigate the interstate transport.

Subpart 2 of part D of title I of the CAA provides provisions governing additional plan requirements for designated ozone nonattainment areas. Consistent with CAA section 176A found in subpart 1, subpart 2 included specific provisions focused on the interstate transport of ozone. In particular, CAA section 184(a) established a single transport region for ozone—the OTR—comprised of the states of Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont and the Consolidated Metropolitan Statistical Area that includes the District of Columbia and certain parts of northern Virginia.

Section 184(b) of the CAA established certain control requirements that each state in the OTR is required to implement within the state and which require certain controls on sources of NO_x and VOCs statewide. These include the following. Section 184(b)(1)(A) of the CAA requires OTR states to include in their SIPs enhanced vehicle inspection and maintenance (I/M) programs.⁹ Section 184(b)(2) of the CAA requires SIPs to subject major sources of VOCs in ozone transport regions to the same requirements that apply to major sources in designated ozone nonattainment areas classified as moderate, regardless of whether the source is located in a nonattainment area. Thus, the state must adopt rules to apply the nonattainment new source review (NSR) (pursuant to CAA section 173) and reasonably available control technology (RACT) (pursuant to CAA section 182(b)(2)) provisions for major VOC sources statewide. Section 184(b)(2) of the CAA further provides that, for purposes of implementing these requirements, a major stationary source shall be defined as any source that emits or has the potential to emit at least 50 tons per year of VOCs. Under CAA section 184(b)(2) states must also implement Stage II vapor recovery programs, incremental to Onboard Refueling Vapor Recovery achievements, or measures that achieve comparable emissions reductions for both attainment and nonattainment areas.¹⁰ These programs are required to be implemented statewide in any state

³ Rasmussen, D.J. et al. (2011) Ground-level ozone-temperature relationship in the eastern US: A monthly climatology for evaluating chemistry-climate models. *Atmospheric Environment* 47: 142–153.

⁴ Bloomer, B.J., J.W. Stehr, C.A. Piety, R.J. Salawitch, and R.R. Dickerson (2009), Observed relationships of ozone air pollution with temperature and emissions, *Geophysical Research Letters*, 36, L09803.

⁵ Jiang, G.; Fast, J.D. (2004) Modeling the effects of VOC and NO_x emission sources on ozone formation in Houston during the TexAQs 2000 field campaign. *Atmospheric Environment* 38: 5071–5085.

⁶ Liao, K. et al. (2013) Impacts of interstate transport of pollutants on high ozone events over the Mid-Atlantic U.S. *Atmospheric Environment* 84, 100–112.

⁷ See National Ambient Air Quality Standards for Ozone, Final Rule, 73 FR 16436 (March 27, 2008).

⁸ See National Ambient Air Quality Standards for Ozone, Final Rule, 80 FR 65292 (October 26, 2015).

⁹ Enhanced vehicle inspection and maintenance programs are required in metropolitan statistical areas in the OTR with a 1990 Census population of 100,000 or more regardless of ozone attainment status.

¹⁰ See 72 FR 28772, May 16, 2012, Air Quality: Widespread Use for Onboard Refueling Vapor Recovery and Stage II Waiver.

included within the OTR, not just in areas designated as nonattainment.

Section 182(f) of the CAA requires states to apply the same requirements to major stationary sources of NO_x as are applied to major stationary sources of VOCs under subpart 2. Thus, the same NNSR and RACT requirements that apply to major stationary sources of VOC in the OTR also apply to major stationary sources of NO_x.¹¹ While NO_x emissions are necessary for the formation of ozone in the lower atmosphere, a local decrease in NO_x emissions can, in some cases, increase local ozone concentrations, creating potential “NO_x disbenefits.” Accordingly, CAA section 182(f) provides for an exemption of the NO_x requirements where the Administrator determines that such NO_x reductions would not contribute to the attainment of the NAAQS in a particular area. Areas granted a NO_x exemption under CAA section 182(f) may be exempt from certain requirements of the EPA’s motor vehicle I/M regulations and from certain federal requirements of general and transportation conformity.¹²

Additionally, under CAA section 184(c), the OTC may, based on a majority vote of the Governors on the Commission, recommend additional control measures not specified in the statute to be applied within all or part of the OTR if necessary to bring any areas in the OTR into attainment by the applicable attainment dates. If EPA approves such a recommendation, under CAA section 184(c)(5) the Administrator must declare each state’s implementation plan inadequate and it must order the states to include the approved control measures in their revised plans pursuant to CAA section 110(k)(5) for the state to meet the requirements of CAA section 110(a)(2)(D). If a CAA section 110(k)(5) finding is issued, states have 1 year to revise their SIPs to include the approved measures.

States included in the OTR by virtue of CAA section 184(b)(1) were required to submit SIPs to the EPA addressing these requirements within 2 years of the 1990 CAA Amendments, or by November 15, 1992. Section 184(b)(1) of the CAA further provides that if states are later added to the OTR pursuant to CAA section 176A(a)(1), such states

must submit SIPs addressing these requirements within 9 months after inclusion in the OTR.

C. Legal Standard for This Action

Section 176A(a)(1) of the CAA states that the Administrator *may* add a state to a transport region if the Administrator has reason to believe that emissions from the state significantly contribute to a violation of the NAAQS within the transport region. For the reasons discussed in this section, the use of the discretionary term “may” in CAA section 176A(a) means that the Administrator may exercise reasonable discretion in implementing the requirements of the CAA with respect to interstate pollution by determining whether or not to approve or deny a CAA section 176A petition.

The Administrator’s discretion pursuant to CAA section 176A(a) has been affirmed by the U.S. District Court for the District of Columbia Circuit (D.C. Circuit). In *Michigan v. EPA*, plaintiffs challenged whether the EPA may exercise its authority pursuant to CAA sections 110(k)(5) and 110(a)(2)(D) of the statute to address interstate transport without first forming a transport commission pursuant to CAA section 176A(b). 213 F.3d 663, 672 (2000). The D.C. Circuit held that the agency shall only establish a transport commission “if the agency exercises its discretion to create a transport region pursuant to section 176A(a).” *Id.* The court explained that “EPA can address interstate transport apart from convening a 176A/184 transport commission as subsection (a) provides that EPA ‘may’ establish a transport region” *Id.* Thus, the court held that the statute clearly provides that the discretion to create a transport region rests with the Administrator. So, too, does the discretion to add states to or remove states from a transport commission.

Several courts have held that the use of similarly non-mandatory language such as that found in CAA section 176A confers discretion on the agency to grant or deny a petition so long as it is supported by a “reasonable explanation.” For example, in *Massachusetts v. Environmental Protection Agency*, the Supreme Court was considering whether the EPA’s denial of a petition to regulate greenhouse gases under CAA section 202(a)(1) was reasonable. 549 U.S. 497 (2007). Section 202(a)(1) of the CAA states that the Administrator “shall by regulation prescribe (and from time to time revise) . . . standards applicable to the emission of any air pollutant from any class or classes of new motor

vehicles or new motor vehicle engines, which in his judgment cause, or contribute to, air pollution which may reasonably be anticipated to endanger public health or welfare.” The EPA denied the petition, reasoning that the Act does not authorize the agency to issue mandatory regulations to address global climate change. *Id.* at 500. The Court concluded that the EPA has statutory authority to regulate emissions of greenhouse gases, and that the phrases “from time to time” and “in his judgment” conferred discretion on the Administrator to determine whether to promulgate an endangerment finding. Thus, “[u]nder the clear terms of the Clean Air Act, EPA can avoid taking further action . . . if it provides some reasonable explanation as to why it cannot or will not exercise its discretion.” *Id.* at 533. The Supreme Court confirmed that the review of an agency’s denial of a petition for rulemaking is very narrow: “Refusals to promulgate rules are . . . susceptible to judicial review, though such review is extremely limited and highly deferential.” *Id.* at 527–28 (quotations omitted). Further, the court explained that the EPA’s reason should conform to the authorizing statute, and that the agency could avoid taking further regulatory action if it provides some reasonable explanation as to why it cannot or will not exercise its discretion. *Id.* at 533 (citations omitted).

Consistent with *Massachusetts*, the D.C. Circuit has held that agencies have the discretion to determine how to best allocate resources in order to prioritize regulatory actions in a way that best achieve the objectives of the authorizing statute. In *Defenders of Wildlife v. Gutierrez*, the court rejected a challenge to the National Marine Fisheries Service’s (NMFS) denial of a petition for emergency rulemaking to impose speed restrictions to protect the right whale from boating traffic pursuant to section 553(e) of the Endangered Species Act, which requires agencies to “give an interested person the right to petition for the issuance, amendment, or repeal of a rule.” 532 F.3d 913 (D.C. Cir. 2008). The NMFS denied the petition on the grounds that imposing such restrictions would divert resources from, and delay development of, a more comprehensive strategy for protecting the whale population. *Id.* at 916. The court determined that NMFS’s explanation for the denial was a reasonable decision to focus its resources on a comprehensive strategy, which in light of the information before the NMFS at the time, was reasoned and adequately supported by the record. *Id.*

¹¹ See 57 FR 55622 (Nitrogen Oxides Supplement to the General Preamble, published November 25, 1992).

¹² As stated in the EPA’s I/M (November 5, 1992; 57 FR 52950) and conformity rules (60 FR 57179 for transportation rules and 58 FR 63214 for general rules), certain NO_x requirements in those rules do not apply where the EPA grants an area-wide exemption under CAA section 182(f).

Similarly, in *WildEarth Guardians v. EPA*, the court reviewed the EPA's denial of a petition to list coal mines for regulation under CAA section 111(b)(1)(A). 751 F.3d 651 (D.C. Cir. 2014). Section 110(b)(1)(A) of the CAA provides that, as a means of developing standards of performance for new stationary sources, the EPA shall, by a date certain publish "(and from time to time thereafter shall revise) a list of categories of stationary sources." (emphasis added) The provision provides that the Administrator "shall include a category of sources in such list if in his judgment it causes, or contributes significantly to, air pollution which may reasonably be anticipated to endanger public health and welfare." The EPA denied the petition, explaining that it must prioritize its actions in light of limited resources and ongoing budget uncertainties, and that denial of the petition was not a determination as to whether coal mines should be regulated as a source of air pollutants. 751 F.3d at 650. The EPA also noted as part of its denial that it might in the future initiate a rulemaking to do so. The D.C. Circuit held that the language in CAA section 111(b)(1)(A)—"from time to time" and "in his judgment"—means that the Administrator may exercise reasonable discretion in determining when to add new sources to the list of regulated pollutants, and that such language afforded agency officials discretion to prioritize sources that are the most significant threats to public health to ensure effective administration of the agency's regulatory agenda. *Id.* at 651.

In each of these cases previously discussed, the acting agency has been entitled to broad discretion to act on a pending petition so long as the agency provided a reasoned explanation. Notably, as each of these decisions focused on the case-specific circumstances relied upon by the acting agency to deny the pending petition, the courts did not speak to whether the agency might reach a different conclusion under different circumstances. Like the statutory provisions evaluated by the courts in these cases, the term "may" in CAA section 176A(a) means that the Administrator is permitted to exercise reasonable discretion in determining when to add new states to a transport region. While the Administrator must adequately explain the facts and policy concerns she relied on in acting on the petition and conform such reasons with the authorizing statute, review of such a decision is highly deferential. Thus, the agency is entitled to broad

discretion when determining whether to grant or deny such a petition.

D. The CAA Section 176A Petition and Related Correspondence

On December 9, 2013, the states of Connecticut, Delaware, Maryland, Massachusetts, New Hampshire, New York, Rhode Island and Vermont submitted a petition under CAA section 176A requesting that the EPA add to the OTR the states of Illinois, Indiana, Kentucky, Michigan, North Carolina, Ohio, Tennessee, West Virginia and the portion of Virginia currently not within the OTR. On December 17, 2013, the petition was amended to add the state of Pennsylvania as an additional state petitioner.

The petitioning states submitted a technical analysis which the petitioning states contend demonstrates that the nine named upwind states significantly contribute to violations of the 2008 ozone NAAQS in the OTR. The petitioning states acknowledge and include data used to support rulemakings promulgated by the EPA that addressed interstate transport with respect to both the 2008 ozone NAAQS and prior ozone NAAQS in order to further support their request. Moreover, the petitioners identified those areas that are designated nonattainment with respect to the 2008 ozone NAAQS within and outside the OTR and conducted a linear extrapolation to predict that certain areas will continue to be in nonattainment or will have difficulty maintaining attainment of the NAAQS after the EPA's 2008 ozone NAAQS final area designations in 2012. The petitioning states' 2018 modeling showed that, with on-the-way OTR measures, areas within the OTR and non-OTR would continue to have problems attaining the 2008 ozone NAAQS. Lastly, their 2020 modeling showed that with a 58 percent NO_x and 3 percent VOC emissions reduction over the eastern U.S., there would only be one area in New Jersey that could have trouble maintaining the NAAQS.

The petitioners further note that the OTR states have adopted and implemented numerous and increasingly stringent controls on sources of VOCs and NO_x that may not currently be required for sources in the upwind states. Petitioners contend that expansion of the OTR to include these upwind states will help the petitioning states attain the 2008 ozone NAAQS. The petitioning states include two case studies that identify the types of measures adopted throughout the current OTR including mobile source and stationary source control measures that have been enacted to minimize

emissions of NO_x and VOCs. The petitioners contend that the expansion of the OTR is warranted so that the downwind states and the upwind states can work together to address interstate ozone transport for the 2008 ozone NAAQS. Also, the petitioners assert that without immediate expansion of the OTR, attainment of the 2008 ozone NAAQS in many areas in the U.S. will remain elusive.

At the time the petition was submitted, the EPA's most recent effort to address the interstate transport of ozone pollution was subject to litigation in the D.C. Circuit. As discussed in more detail later in this document, the EPA issued the Cross-State Air Pollution Rule (CSAPR) pursuant to section 110(a)(2)(D)(i)(I) of the CAA in order to address interstate transport with respect to the 1997 ozone NAAQS as well as the 1997 and 2006 fine particulate matter (PM_{2.5}) NAAQS. 76 FR 48208 (August 8, 2011). On August 21, 2012, the D.C. Circuit issued a decision in *EME Homer City Generation, L.P. v. EPA*, 696 F.3d 7 (D.C. Cir. 2012), vacating CSAPR based on several holdings that would have limited the EPA's authority pursuant to section 110(a)(2)(D)(i)(I). The petitioners subsequently submitted the section 176A petition. Thereafter, on April 29, 2014, the Supreme Court issued a decision reversing the D.C. Circuit's decision and upholding the EPA's interpretation of its authority pursuant to CAA section 110. *EPA v. EME Homer City Generation, L.P.*, 134 S. Ct. 1584 (2014).

Since the petition was submitted, the EPA has received correspondence from both the upwind states and the petitioning states regarding the EPA's pending action on the petition. On February 14, 2014, the EPA received a letter from the environmental commissioners and directors representing the states of Illinois, Ohio, Indiana, Tennessee, Kentucky, Virginia, Michigan, West Virginia and North Carolina (in collaboration with LADCO) disagreeing with the basis for the petition and requesting that the EPA deny the petition. On May 29, 2015, the EPA received a letter from the Midwest Ozone Group urging that the EPA consider recent air quality, on-the-books measures between now and 2018 and other related information prior to any action on the petition. On July 7, 2015, the EPA received a letter from state representatives from the states of Ohio, Kentucky, Indiana, West Virginia, North Carolina and Michigan communicating the progress of the voluntary dialogue called the State Collaborative on Ozone Transport (SCOOT) that according to the letter, resulted in commitments, from

utilities in the upwind states to operate NO_x controls during the summer of 2015. The upwind states believed that the requests from some Northeast states to sign a memorandum of understanding to require additional emission control and reporting requirements from facilities and place such requirements into SIPs to be unnecessary and requested that the CAA section 176A petition be withdrawn by the petitioning states or denied by the EPA given the forecasted air quality improvements and declining ozone trends. On October 30, 2015, the EPA received a letter from environmental commissioners (or their designated representatives) from the petitioning states that provided an update on the SCOOT process and responded to the July 7, 2015, letter expressing a need for federally enforceable commitments from states to operate existing controls.

On April 6, 2016, the EPA received a letter from the petitioning states requesting immediate action to grant the CAA section 176A petition. The letter acknowledged the EPA's recent proposal to update the CSAPR to address interstate transport for the 2008 ozone NAAQS and urged the EPA to grant the petition because the proposed rulemaking would only partially address ozone transport problems in the eastern U.S. Further, the letter noted that granting the petition will also facilitate efforts to attain the 2015 ozone NAAQS, as well as future updates to the ozone NAAQS. On May 16, 2016, the EPA received a letter from the upwind states of Ohio, Kentucky, Indiana, West Virginia and Michigan requesting that the EPA deny the petition, claiming that the technical information used to support the petition was not comparable to current air quality and noting the EPA's proposed transport rule to address the 2008 ozone NAAQS. These communications can be found in the docket for this action.

IV. The EPA's Proposed Decision on the CAA Section 176A Petition

This section describes the basis for the EPA's proposed denial of this CAA section 176A petition. Section IV.A of this document describes the alternative authorities provided by the CAA for addressing the interstate transport of ozone pollution and the flexibilities those provisions provide. Section IV.B of this document describes EPA's historical use of these authorities to address the interstate transport of ozone pollution and the advantages of those rulemakings for addressing current ozone nonattainment problems. Section IV.C of this document describes other measures that have achieved, and will

continue to achieve, significant reductions in emissions of NO_x and VOCs resulting in lower levels of transported ozone pollution that impact downwind attainment and maintenance of the 2008 ozone NAAQS. Finally, Section IV.D of this document describes the EPA's rationale, based on these considerations, for proposing to deny this CAA section 176A petition.

As explained more fully later, the EPA believes an expansion of the OTR is unnecessary at this time and would not be the most efficient way to address the remaining interstate transport issues for the 2008 ozone NAAQS in states currently included in the OTR. Additional local and regional ozone precursor emissions reductions are expected in the coming years from already on-the-books rules (*see* Sections IV. B and C of this document for more details) and as described elsewhere in this document, the EPA has the authority through other CAA provisions (including CAA sections 110 and 126) to develop a more effective remedy to address the particular pollutants and sources for this air quality situation.

A. The CAA Good Neighbor Provisions

The CAA provision that states and the EPA have used most for addressing interstate transport is section 110(a)(2)(D)(i)(I), often referred to as the "good neighbor" or "interstate transport" provision, requires states to prohibit certain emissions from in-state sources if such emissions impact the air quality in downwind states. Specifically, in keeping with the CAA's structure of shared state and federal regulatory responsibility, CAA section 110(a)(2)(D)(i)(I) requires all states, within 3 years of promulgation of a new or revised NAAQS, to submit SIPs that contain adequate provisions prohibiting any source or other type of emissions activity within the state from emitting any air pollutant in amounts which will contribute significantly to nonattainment in, or interfere with maintenance by, any other state with respect to any NAAQS. Thus, each state is required to submit a SIP that demonstrates the state is adequately controlling sources of emissions that would impact downwind states' air quality relative to the NAAQS in violation of the good neighbor provision.

Once a state submits a good neighbor SIP, the EPA must evaluate the SIP to determine whether it meets the statutory criteria of the good neighbor provision, and then approve or disapprove, in whole or in part, the state's submission in accordance with CAA section 110(k)(3). In the event that a state does

not submit a required SIP addressing the good neighbor provision, the EPA publishes in the **Federal Register** a "finding of failure to submit" that a state has failed to make the required SIP submission. If the EPA disapproves a state's SIP submission or if the EPA issues a finding of failure to submit, then the action triggers the EPA's obligations under section 110(c) of the CAA, to promulgate a FIP within 2 years, unless the state corrects the deficiency, and the EPA approves the plan or plan revision before the EPA promulgates a FIP. Thus, in the event that a state does not address the good neighbor provision requirements in a SIP submission, the statute provides that the EPA must address the requirements in the state's stead.

Section 110(k)(5) of the CAA also provides a means for the EPA to reopen previously approved SIPs, including good neighbor SIPs, if the EPA determines that an approved SIP is substantially inadequate to attain or maintain the NAAQS, to adequately mitigate interstate pollutant transport, or to otherwise comply with requirements of the CAA. The EPA can use its authority under CAA section 110(k)(5) to call for re-submission of the SIP to correct the inadequacies under CAA 110(a)(2)(D)(i)(I), and if the state fails to make the required submission, the EPA can promulgate a FIP under CAA section 110(c) to address the inadequacies.

Finally, section 126 of the CAA provides states with an additional opportunity to bring to the EPA's attention specific instances where a source or a group of sources in a specific state may be emitting in excess of what the good neighbor provision would allow. Section 126(b) of the CAA provides that any state or political subdivision may petition the Administrator of the EPA to find that any major source or group of stationary sources in upwind states emits or would emit any air pollutant in violation of the prohibition of CAA section 110(a)(2)(D)(i).¹³ Petitions submitted pursuant to this section are referred to as CAA section 126 petitions. Section 126(c) of the CAA explains the impact of such a finding and establishes the conditions under which continued operation of a source subject to such a finding may be permitted. Specifically,

¹³ The text of CAA section 126 codified in the U.S. Code cross references CAA section 110(a)(2)(D)(ii) instead of CAA section 110(a)(2)(D)(i). The courts have confirmed that this is a scrivener's error and the correct cross reference is to CAA section 110(a)(2)(D)(i). *See Appalachian Power Co. v. EPA*, 249 F.3d 1032, 1040–44 (D.C. Cir. 2001).

CAA section 126(c) provides that it would be a violation of section 126 of the Act and of the applicable SIP: (1) For any major proposed new or modified source subject to a CAA section 126 finding to be constructed or operate in violation of the good neighbor prohibition of CAA section 110(a)(2)(D)(i); or (2) for any major existing source for which such a finding has been made to operate more than 3 months after the date of the finding. The statute, however, also gives the Administrator discretion to permit the continued operation of a source beyond 3 months if the source complies with emission limitations and compliance schedules provided by the EPA to bring about compliance with the requirements contained in CAA sections 110(a)(2)(D)(i) and 126 as expeditiously as practicable but no later than 3 years from the date of the finding. Where the EPA provides such limitations and compliance schedules, it promulgates these as a revision to the upwind state's good neighbor SIP, and CAA section 110(a)(2)(D)(ii) further requires that good neighbor SIPs ensure compliance with these limitations and compliance schedules.¹⁴

The flexibility provided by these statutory provisions is different from that provided by the requirements imposed upon states in the OTR. With limited exceptions described previously, states in the OTR must impose a uniform set of requirements on sources within each state. While the OTR states may impose additional requirements with the consent of the OTC and the EPA, the states generally must comply with the minimum requirements imposed by the statute. The good neighbor provision, by contrast, provides both the states and the EPA with the flexibility to develop a remedy targeted at a particular air quality problem, including the flexibility to tailor the remedy to address the particular precursor pollutants and sources that would most effectively address the downwind air quality problem. As described later, the EPA has previously promulgated four interstate transport rulemakings pursuant to these authorities in order to quantify the specific emission reductions required in certain eastern

states in order to comply with the requirements of CAA section 110(a)(2)(D)(i)(I) with respect to downwind nonattainment and maintenance concerns with respect to the NAAQS for ozone and PM_{2.5}. In Section IV.B. of this document, the EPA describes the importance of these transport rules as they relate to regional ozone pollution transport.

B. The EPA's Interstate Transport Rulemakings Under the Good Neighbor Provision

In order to address the regional transport of ozone pursuant to the CAA's good neighbor provision under section 110(a)(2)(D)(i)(I), the EPA has promulgated four regional interstate transport rules focusing on the reduction of NO_x emissions, as the primary meaningful precursor to address regional ozone, from certain sources located in states in the eastern half of the U.S.^{15 16} States and the EPA have implemented the emission reductions required by these rulemakings pursuant to the various authorities for implementing the good neighbor provision, including CAA sections 110(a)(1), 110(c), 110(k)(5) and 126.

In each of these rulemakings, the EPA identified those sources and pollutants that were most effective in addressing the particular air quality problem identified through the course of the EPA's analysis. This allowed the EPA to craft targeted remedies that provided efficient and effective means of addressing the particular air quality problem. In each of the regional transport rules, the EPA analysis has continued to demonstrate that NO_x is the ozone precursor that is most effective to reduce when addressing regional transport of ozone in the eastern U.S. The EPA has also focused each rule on those sources that can most cost-effectively reduce emissions of NO_x, such as EGUs and, in one rule, certain large non-EGUs. These rulemakings demonstrate that the EPA has used and is continuing to use its authority under CAA section 110(a)(2)(D)(i)(I) to target those sources and precursors that most efficiently address the particular interstate ozone transport problem. Accordingly, the EPA believes that it is unnecessary to

include additional states, and sources within those states, in OTR in order to address the current nonattainment situation for the 2008 ozone NAAQS in the petitioning states. Prior to the EPA's promulgation of some of those federal transport rules, the EPA worked with states and provided guidance to help states submit approvable good neighbor SIPs to address the CAA good neighbor provision. States have the first responsibility to address these CAA requirements pursuant to section 110(a)(1), and the EPA issued those transport rules only after states had the opportunity to address their CAA interstate transport obligation. While some states have state-developed and EPA-approved good neighbor SIPs, other states are covered by EPA-issued FIPs.

1. NO_x SIP Call

Through a 2-year effort (starting in 1995 and ending in 1997) known as the Ozone Transport Assessment Group (OTAG), the EPA worked in partnership with the 37 eastern-most states and the District of Columbia, industry representatives, and environmental groups to address the interstate transport of ozone pollution. OTAG identified and evaluated flexible and cost-effective strategies for reducing long-range transport of ozone and ozone precursors. Based on the OTAG process, the EPA engaged in a rulemaking to promulgate a final action commonly referred to as the NO_x SIP Call in order to address the requirements of the good neighbor provision (CAA section 110(a)(2)(D)(i)(I)) with respect to the 1979 1-hour ozone NAAQS and the 1997 8-hour ozone NAAQS. 63 FR 57356 (October 27, 1998). The rule required 22 eastern states and the District of Columbia to amend their SIPs and limit NO_x emissions that contribute to ozone nonattainment. The rule set a NO_x ozone season emission budget for each covered state, essentially a cap on all ozone season NO_x emissions in the state. Covered states were given the option to participate in a regional allowance trading program, known as the NO_x Budget Trading Program (NBP) in order to achieve most of the necessary emissions reductions.

Through the OTAG process, the states concluded that widespread NO_x reductions were necessary to enable areas to attain and maintain the ozone NAAQS.¹⁷ The OTAG's recommendations identified control

¹⁴ The EPA has received, but not yet acted upon, several CAA section 126 petitions from a number of the petitioning states regarding the contribution of specific EGUs to interstate ozone transport with respect to the 2008 and 2015 ozone NAAQS. Petitions have been submitted by Delaware, Maryland, and Connecticut. The list of EGUs identified in one or more of these petitions includes EGUs operating in Pennsylvania, West Virginia, Ohio, Kentucky, and Indiana.

¹⁵ For purposes of these rulemakings, the western U.S. (or the West) consists of the 11 western contiguous states of Arizona, California, Colorado, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington and Wyoming.

¹⁶ Two of these rulemakings also addressed the reduction of NO_x and SO₂ emissions for the purposes of addressing the interstate transport of particulate matter pollution pursuant to the good neighbor provision.

¹⁷ See 62 FR 60320, November 7, 1997, Notice of proposed rulemaking, Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone.

measures for states to achieve additional reductions in emissions of NO_x but did not identify such measures for VOC, beyond the EPA's promulgation of national VOC measures, at that time. The OTAG Regional and Urban Scale Modeling and Air Quality Analysis Work Groups reached the following relevant conclusions (with which the EPA agreed): Regional NO_x emissions reductions are effective in producing ozone benefits; the more NO_x emissions reduced, the greater the benefit to air quality; and VOC controls are effective in reducing ozone locally and are most advantageous to urban nonattainment areas. The EPA concluded in its rulemaking that, "a regional strategy focusing on NO_x reductions across a broad portion of the region will help mitigate the ozone problem in many areas of the East." 63 FR 57381. The EPA did not propose any new SIP requirements for VOC reductions for the purpose of reducing the interstate transport of ozone, however, the agency suggested that states may consider additional reductions in VOC emissions as they develop local attainment plans.

In order to quantify necessary NO_x emission reductions, the EPA developed statewide NO_x emissions budgets based on recommendations from OTAG on how to cost-effectively reduce emissions from utilities and other sources of NO_x. Thus, the EPA established NO_x emission budgets based on the conclusion that EGUs and large non-EGU point sources could cost-effectively achieve emissions reductions by the implementation of controls costing \$2,000 per ton of NO_x emissions reduced, including controls such as selective catalytic reduction (SCR) and selective non-catalytic reduction (SNCR) that could be required on a number of units in the OTAG region. Although the NO_x SIP Call did not specify which sources must reduce NO_x, consistent with OTAG's recommendations, the EPA encouraged states to consider controls on EGUs and large non-EGU point sources under an allowance trading program as a cost effective strategy for complying with the NO_x emissions budgets.

At the time the NO_x SIP Call was finalized, the EPA had already approved good neighbor SIPs for many states with respect to the 1-hour ozone standard. Accordingly, the EPA initiated a SIP call pursuant to CAA section 110(k)(5) requiring states covered by the rule to amend their SIPs in order to limit NO_x emissions that significantly contribute to ozone nonattainment in other states consistent with the budgets finalized in the rule.

In parallel with issuing the SIP call, the EPA reviewed petitions submitted pursuant to CAA section 126(b) by eight states requesting that the EPA find that stationary sources in upwind states contribute significantly to ozone nonattainment in the petitioning states. Because the section 126 petitions raised many of the same issues as those being addressed in NO_x SIP call, the EPA coordinated its response to the CAA section 126 petitions with the NO_x SIP Call rulemaking. The EPA issued findings that NO_x emissions in twelve states and the District of Columbia contribute significantly to nonattainment of the 1-hour ozone NAAQS in three downwind states, but the EPA determined that it was appropriate to postpone CAA section 126 findings pending the resolution of the NO_x SIP call process. 64 FR 28250 (May 25, 1999). Accordingly, the EPA issued a rule providing that the findings would automatically be deemed made with regard to sources from a given state should that state fail to submit a SIP revision as required by the NO_x SIP Call. The rulemaking further established the NBP as the remedy that would apply pursuant to CAA section 126(c) for any state subject to such a finding.

The D.C. Circuit subsequently issued two orders affecting implementation of the NO_x SIP Call: (1) An order remanding the 1997 8-hour ozone standard to the EPA, *American Trucking Ass'n v. EPA*, 175 F.3d 1027, *reh'g granted in part and denied in part*, 195 F.3d 4 (D.C. Cir.1999), *rev'd in part sub nom. Whitman v. American Trucking Ass'n*, 531 U.S. 457, 121 S.Ct. 903 (2001), and (2) an order staying the NO_x SIP Call deadline pending further litigation, *Michigan v. EPA*, No. 98–1497 (D.C. Cir. May 25, 1999) (order granting stay in part). In response to these court decisions, the EPA took two actions. First, the EPA indefinitely stayed the technical determinations of the prior section 126 action as they applied to the 8-hour ozone NAAQS, pending further developments in the litigation. 65 FR 2674, 2685 (January 18, 2000). Second, with respect to the 1-hour standard, the EPA made the requested findings of significant contributions, granting the relevant portions of the section 126 petitions. *Id.* at 2684–85. The EPA further imposed the NBP on affected sources as the remedy pursuant to section 126(c). *Id.* at 2686.

Ultimately, the NO_x SIP Call was largely upheld by the D.C. Circuit in *Michigan v. EPA*, 213 F.3d 663 (D.C. Cir. 2000), *cert. denied*, 532 U.S. 904

(2001).¹⁸ States chose to use the NBP to achieve the majority of the NO_x reductions required by the NO_x SIP Call. Subsequent rules have required additional reductions from certain sources regulated by the NO_x SIP Call, but the rules have not replaced the NO_x SIP Call reduction requirements and the rule remains in effect.

2. Clean Air Interstate Rule (CAIR)

The CAIR was published in May 2005 and addressed both the 1997 PM_{2.5} and the 1997 ozone standards under the good neighbor provision. 70 FR 25162 (May 12, 2005). CAIR required SIP revisions in 28 eastern states and the District of Columbia to ensure that certain emissions of sulfur dioxide (SO₂) and/or NO_x—important precursors of regionally transported PM_{2.5} (SO₂ and NO_x) and ozone (NO_x)—were prohibited.

The rule set statewide emission budgets for large EGUs that reduced emissions of annual SO₂ and annual NO_x (particulate matter precursors) and summertime NO_x (ozone precursor). As in the NO_x SIP Call, the EPA identified reductions in NO_x emissions as the most efficient and effective way to achieve the greatest reduction of interstate ozone pollution. *Id.* at 25185–8, 25195. The EPA also determined that emissions reductions from EGUs were the most cost-effective and efficient means of achieving necessary NO_x emissions reductions. 70 FR 25173. As in the NO_x SIP Call, affected states were given the option to participate in a regional allowance trading program to satisfy their SIP obligations.

When the EPA promulgated the final CAIR, the EPA also issued a national rule finding that certain states had failed to submit SIPs to address the requirements of CAA section 110(a)(2)(D)(i) with respect to the 1997 PM_{2.5} and the 1997 ozone NAAQS by the CAA deadline for those standards of July 2000. 70 FR 21147. The findings of failure to submit triggered a 2-year clock for the EPA to issue FIPs to address the good neighbor provision with respect to those standards, and the EPA subsequently promulgated FIPs to ensure that the emission reductions required by CAIR would be achieved on schedule. 71 FR 25328 (April 28, 2006). Upon review, the D.C. Circuit determined that CAIR was "fundamentally flawed," and the rule was remanded to the EPA to be replaced "from the ground up." *North Carolina v.*

¹⁸ The EPA's January 18, 2000, action on the CAA section 126 petitions was also challenged and upheld by the D.C. Circuit in *Appalachian Power Company v. EPA*, 249 F.3d 1032 (2001).

EPA, 531 F.3d 896, 929 (D.C. Cir. 2008), *modified on reh'g*, 550 F.3d 1176.

3. CSAPR

In response to the court's remand of CAIR, on July 6, 2011, the EPA promulgated CSAPR, which requires certain states to significantly improve air quality by reducing power plant emissions that contribute to ozone and/or fine particle pollution in other states. CSAPR requires sources in a total of 28 states to reduce annual SO₂ emissions, annual NO_x emissions and/or ozone season NO_x emissions to assist in attaining the 1997 ozone and PM_{2.5} and 2006 PM_{2.5} NAAQS. 76 FR 48208. The EPA found that each CSAPR state had failed to submit a complete SIP or the EPA disapproved a submitted SIP for the relevant NAAQS. To accomplish implementation aligned with the applicable NAAQS attainment deadlines, the EPA promulgated FIPs for each affected state which require affected sources to participate in the regional allowance trading program to achieve the necessary emission reductions. These states have the option of replacing each FIP with a SIP that could achieve the same emissions reductions in other ways.

CSAPR set emissions budgets for certain states according to the applicable NAAQS—annual NO_x and annual SO₂ budgets for PM_{2.5}, and ozone season NO_x budgets for ozone—to eliminate a state's significant contribution or interference with maintenance of a NAAQS in other states. With respect to the ozone NAAQS, the EPA determined that NO_x emissions had the most meaningful interstate impacts based on air quality modeling that examined upwind state emissions of all ozone precursors (including VOCs and NO_x). 75 FR 45230 (August 2, 2010) and 76 FR 48222. Moreover, the EPA noted that the other recent assessments of ozone, for example those conducted for the Regulatory Impact Analysis for the ozone standards in 2008, continue to show the importance of NO_x emissions on ozone transport. 75 FR 45236. Accordingly, the EPA quantified NO_x emissions budgets for each affected state by quantifying the emissions reductions achievable by applying cost-effective controls to EGUs. 76 FR 48256. The EPA determined that controls at other sources were generally not available at similar cost levels.

The timing of CSAPR's implementation was affected by a number of court actions. CSAPR was the subject to nearly four years of litigation in both the D.C. Circuit and the Supreme Court. CSAPR was generally

upheld by the courts, but for the remand of certain state budgets, and implementation of the trading programs began in 2015. See *EPA v. EME Homer City Generation, L.P.*, 134 S. Ct. 1584 (2014); *EME Homer City Generation, L.P. v. EPA*, 795 F.3d 118 (D.C. Cir. 2015).

4. The CSAPR Update To Address the 2008 Ozone NAAQS

On October 26, 2016, the EPA published an update to CSAPR intended to respond to the D.C. Circuit's remand of certain NO_x ozone season budgets from the original CSAPR and to address the good neighbor provision with respect to the 2008 ozone NAAQS. 81 FR 74504 (CSAPR Update). The CSAPR Update requires 22 states to reduce ozone season NO_x emissions that significantly contribute to nonattainment or interfere with maintenance of the 2008 ozone NAAQS in certain downwind states. The EPA found that each CSAPR state had failed to submit a complete SIP or the EPA disapproved a submitted SIP for the 2008 ozone NAAQS. To accomplish implementation aligned with the applicable attainment deadline for the 2008 ozone NAAQS, the EPA promulgated FIPs for each of the 22 states covered by CSAPR Update which require affected sources to participate in the regional allowance trading program to achieve the necessary emission reductions beginning with the 2017 ozone season.

The CSAPR Update analysis found that emissions from eight of the nine states named in the section 176A petition, in addition to a number of other states, were linked to downwind projected nonattainment and/or maintenance receptors, in the eastern U.S., in 2017 with respect to the 2008 ozone NAAQS. 81 FR 74506, 74538–39. For one state named in the CAA section 176A petition, North Carolina, the EPA determined in the CSAPR Update that the state was not linked to any downwind receptors and, therefore, will not significantly contribute to nonattainment or interfere with maintenance of the 2008 ozone NAAQS in any other state pursuant to the good neighbor provision. 81 FR 74506, 74537–38.

For those states linked to downwind air quality problems, the EPA evaluated timely and cost-effective emissions reductions achievable in each state in order to quantify the amount of emissions constituting each state's significant contribution to nonattainment and interference with maintenance of the standard pursuant to the good neighbor provision. The EPA

focused its analysis on: (1) Emissions reductions achievable by 2017 in order to assist downwind states with meeting the applicable attainment deadline for the 2008 ozone NAAQS (81 FR 74521), (2) reductions in only NO_x emissions, consistent with past ozone transport rules (81 FR 74514), and (3) achievable, cost effective NO_x emissions reductions from EGUs. The EPA, therefore, calculated emissions budgets for each affected state based on the cost-effective NO_x emissions reductions achievable from EGUs by the 2017 ozone season.

The EPA concluded that the emissions reductions achieved by implementation of the budgets constitute a portion of most affected states' significant contribution to nonattainment or interference with maintenance of the 2008 ozone NAAQS at these downwind receptors. 81 FR 74508, 74522.¹⁹ However, because downwind air quality problems were projected to remain after implementation of the quantified emissions reductions, the EPA could not determine that it had fully quantified the affected states' emissions reduction obligations pursuant to the good neighbor provision to the extent upwind states remain linked to the downwind receptors and further emission reductions from EGUs and non-EGUs could be available. In order to determine the level of NO_x control stringency necessary to quantify those emissions reductions that fully constitute each state's significant contribution to downwind nonattainment or interference with maintenance, the EPA explained in promulgating the final CSAPR Update that it must evaluate further emission reductions from EGU and non-EGU strategies that can be implemented on longer timeframes. The CSAPR Update represents a significant first step by the EPA to quantify states' emission reduction obligations under the good neighbor provision for the 2008 ozone NAAQS. Even though the CSAPR Update did not fully address upwind states' emission reduction obligation pursuant to the good neighbor provision, the implementation of the emissions budgets quantified in that rule will help to resolve a number of projected air quality problems in the Philadelphia, Pennsylvania, Jefferson County, Kentucky and Hamilton County, Ohio areas and will help make progress to reduce upwind

¹⁹For one state named in the CAA section 176A petition, Tennessee, the EPA determined that the emissions reductions required by the CSAPR Update would fully address the state's significant contribution to nonattainment and interference with maintenance of the 2008 ozone NAAQS in other states.

contributions to high ozone levels in Baltimore, Maryland, and the New York City area (including parts of Connecticut and New Jersey).

The EPA is continuing the work necessary to address its remaining obligation to promulgate FIPs fully addressing the good neighbor provision with respect to the 2008 ozone NAAQS for 21 states. The EPA intends to continue to collect information and undertake analyses to evaluate potential future emission reductions from non-EGUs and EGUs that may be necessary to fully quantify each state's interstate transport obligations for the 2008 ozone NAAQS in a future action.²⁰ The EPA expects to continue to fulfill its obligation to promulgate FIPs fully addressing interstate transport with respect to the 2008 ozone NAAQS consistent with the authority and flexibility provided by the good neighbor provision to tailor a remedy based on those sources and precursor pollutants (*i.e.*, NO_x) that can most effectively address the downwind air quality problems identified by the EPA's analysis.

C. Additional Rules That Reduce NO_x and VOC Emissions

In addition to the significant efforts to implement the good neighbor provision for the 2008 and prior ozone NAAQS described in Section IV.B of this document, there are numerous federal and state emission reduction rules that have already been adopted which have resulted or will result in the further reduction of ozone precursor emissions, including emissions from states named in the section 176A petition. Many of these rules directly require sources to achieve reductions of NO_x, VOC, or both, and others require actions that will indirectly result in such reductions. As a result of these emissions reductions, the interstate transport of ozone has been and will continue to be reduced over time.

The majority of man-made NO_x and VOC emissions that contribute to ozone formation in the U.S. comes from the following sectors: on-road and nonroad mobile sources, industrial processes

(including solvents), consumer and commercial products, and the electric power industry. In 2014, the most recent year for which the National Emissions Inventory (NEI) is available, on-road and nonroad mobile sources accounted for about 56 percent of annual NO_x emissions; and the electric power industry (EGUs) accounted for about 13 percent. With respect to VOCs, industrial processes (including solvents) accounted for about 48 percent of manmade VOC emissions; and mobile sources accounted for about 27 percent.^{21 22}

The EPA establishes emissions standards under various CAA authorities for numerous classes of automobile, truck, bus, motorcycle, earth mover, aircraft, and locomotive engines, and for the fuels used to power these engines. The pollutant reduction benefits from new engine standards increase each year as older and more-polluting vehicles and engines are replaced with newer, cleaner models. The benefits from fuel programs generally begin as soon as a new fuel is available. Further, the ongoing emission reductions from mobile source federal programs such as those listed previously will provide for substantial emissions reductions well into the future, and will complement state and local efforts to attain the 2008 ozone NAAQS.

There are several existing national rules that continue to achieve emission reductions through 2025 and beyond with more protective emission standards for on-road vehicles that include: Control of Air Pollution from Motor Vehicles: Tier 3 Motor Vehicle Emission and Fuel Standards;²³ Control of Air Pollution from New Motor Vehicles: Tier 2 Motor Vehicle Emissions Standards and Gasoline Sulfur Control Requirements;²⁴ Control of Air Pollution from New Motor Vehicles: Heavy-Duty Engine and Vehicle Standards and Highway Diesel Fuel Sulfur Control Requirements;²⁵ Model Year 2017 and Later Light-Duty Vehicle Greenhouse Gas Emissions and Corporate Average Fuel Economy Standards;²⁶ Model Year 2012–2016 Light-Duty Vehicle Greenhouse Gas Emission Standards and Corporate

Average Fuel Economy Standards;²⁷ Greenhouse Gas Emissions and Fuel Efficiency Standards for Medium- and Heavy-Duty Engines and Vehicles—Phase 2;²⁸ Phase 1 Greenhouse Gas Emissions Standards and Fuel Efficiency Standards for Medium- and Heavy-Duty Engines and Vehicles²⁹ and Control of Hazardous Air Pollutants from Mobile Sources.³⁰

Similarly, already adopted regulations for non-road engines and equipment that will achieve further reductions include: Control of Emissions of Air Pollution from Nonroad Diesel Engines and Fuel;³¹ Republication for Control of Emissions of Air Pollution from Locomotive Engines and Marine Compression-Ignition Engines Less Than 30 Liters per Cylinder;³² Control of Emissions from New Marine Compression-Ignition Engines at or Above 30 Liters per Cylinder;³³ the International Maritime Organization's Emission Control Area to Reduce Emissions from Ships in the U.S. Caribbean; Control of Air Pollution From Aircraft and Aircraft Engines;³⁴ Emission Standards and Test Procedures; Control of Emissions from Nonroad Large Spark-Ignition Engines, and Recreational Engines (Marine and Land-Based);³⁵ and Control of Emissions from Nonroad Spark-Ignition Engines and Equipment.³⁶

Similarly, a number of already-adopted stationary source rules will drive further regional reductions in ozone precursor emissions, including: boiler maximum achievable control technology standards under CAA section 112 and the Mercury and Air Toxics Standards. These rules target specific sources and have the co-benefit of reducing ozone precursors which also reduce interstate ozone pollution transport. For example, the measures to address Regional Haze best available retrofit technology determinations often include power plant pollution controls that can achieve NO_x reductions of at least 80 to 90 percent from a particular source.

Other existing rules that will achieve NO_x and VOC emissions reductions include: New Source Performance Standards (NSPS) for reciprocating internal combustion engines; NSPS for gas turbines; NSPS for process heaters;

²⁰ Moreover, in support of this effort, on December 28, 2016, the EPA shared updated preliminary modeling information providing air quality projections for areas in the contiguous U.S. for the 2015 ozone NAAQS, which the EPA anticipates will assist states with the development of SIPs. See, "Notice of Availability of the Environmental Protection Agency's Preliminary Interstate Ozone Transport Modeling Data for the 2015 Ozone National Ambient Air Quality Standard (NAAQS)" available at: <https://www.epa.gov/airmarkets/notice-data-availability-preliminary-interstate-ozone-transport-modeling-data-2015-ozone>.

²¹ The VOC percentages are for manmade VOCs only. Emissions from natural sources, such as trees, also comprise around 70 percent of total VOC emissions nationally, with a higher proportion during the ozone season and in areas with more vegetative cover.

²² For more information, see the "2014 NEI Summary Spreadsheet" in the docket.

²³ 81 FR 23414 (April 28, 2014).

²⁴ 65 FR 6698 (February 10, 2000).

²⁵ 66 FR 5002 (January 18, 2001).

²⁶ 77 FR 62624 (October 15, 2012).

²⁷ 75 FR 25324, (May 7, 2010).

²⁸ 81 FR 73478, (October 25, 2016).

²⁹ 76 FR 57106, (September 15, 2011).

³⁰ 72 FR 8428, (February 26, 2007).

³¹ 69 FR 38958, (June 29, 2004).

³² 73 FR 37096, (June 30, 2008).

³³ 75 FR 22896, (April 30, 2010).

³⁴ 77 FR 36342, (June 18, 2012).

³⁵ 67 FR 68242, (November 8, 2002).

³⁶ 73 FR 59034, (October 8, 2008).

Hospital/Medical/Infectious Waste Incinerators: New Source Performance Standards and Emission Guidelines: Final Rule Amendments; and NO_x Emission Standard for New Commercial Aircraft Engines. The EPA's regulations for commercial, industrial and solid waste incinerators set standards for NO_x and several air toxics for all commercial incinerators, as required under CAA section 129. Air toxics rules for industrial boilers will yield co-benefit NO_x reductions as a result of tune-ups and energy efficiency measures, especially from boilers that burn coal.

The EPA expects existing federal and state rules, and also those that may be promulgated in the future, will have the co-benefit of reducing ozone precursor emissions even if they do not directly address interstate transport of ozone pollution. These rules will result in reductions in ozone concentrations that will help areas attain the 2008 ozone NAAQS. For example, the Regional Haze Rule requires states to revise their regional haze SIPs³⁷ to assess whether additional measures are necessary for continued visibility progress. On December 14, 2016, the EPA signed a final rule that could influence state regional haze plans to include measures to further reduce NO_x in light of its role as a visibility impairing pollutant.³⁸ Further, to address interstate transport with respect to the 2015 ozone NAAQS, states are required to submit additional SIPs addressing the good neighbor provision by October 2018. Measures designed to address the interstate transport of ozone with respect to the 2015 standard will necessarily assist with addressing interstate transport with respect to the less-stringent 2008 standard. Lastly, in response to actions such as the 2012 PM_{2.5} SIP Requirements Rule and nonattainment designations under the 2010 primary SO₂ NAAQS, many states will be submitting SIPs that reduce pollution, some of which reduce ozone precursor emissions as a co-benefit.

As a result of the rules and programs listed previously, various other state programs and efforts, and wider economic trends, ozone levels across the nation and the OTR have been declining. Ozone levels across the nation are expected to further decline

over the next several years due to emissions controls already in place. The EPA's emissions projections in support of the 2015 ozone NAAQS modeling show declining emissions of NO_x and VOCs between 2017 and 2025. In the states comprising the OTR plus the nine upwind states named in the CAA section 176A petition, total NO_x emissions over the upcoming 7-year period (2017–2025) are expected to decline by almost 20 percent on average and VOC emissions are expected to decline by more than 10 percent on average over the same period.

D. Rationale for the Proposed Decision on the CAA 176A Petition

The EPA is proposing to deny the CAA section 176A petition because we believe that the statute provides other, more effective means of addressing the impact of interstate ozone transport on the states within the OTR with respect to the 2008 ozone NAAQS. As described in Section IV of this document, the statute provides several provisions that allow states and the EPA to address interstate ozone transport with a remedy better tailored to the nature of the air quality problem, focusing on those precursor emissions and sources that most directly impact downwind ozone nonattainment and maintenance problems and which can be controlled most cost-effectively. The EPA and states are actively using these provisions, as demonstrated by the numerous federal and state measures that have reduced, and will continue to reduce, the VOC and NO_x emissions that contribute to ozone formation and the interstate transport of ozone pollution. The EPA does not believe that it is necessary to add more states to the OTR at this time in order to effectively address transported pollution in the OTR relative to the 2008 ozone NAAQS.

While the Act contains several provisions, both mandatory and discretionary, to address interstate pollution transport, the EPA's decision whether to grant or deny a CAA section 176A petition to expand an existing transport region is discretionary. Section 176A of the CAA states that the Administrator *may* add any state or portion of a state to an existing transport region whenever the Administrator has reason to believe that the interstate transport of air pollutants from such state significantly contributes to a violation of the standard in the transport region. The EPA does not dispute that certain named upwind states in the petition might significantly contribute to violations of the 2008 ozone NAAQS in one or more downwind states. However, the EPA believes that it can

fully and more effectively address the upwind states' impacts on downwind ozone air quality through the good neighbor provision and the various statutory provisions that provide for its implementation. The EPA has already taken steps to address interstate transport with respect to the 2008 ozone NAAQS through the promulgation of the CSAPR Update, which reduces emissions in the 2017 ozone season and beyond. The EPA used the authority of CAA sections 110(a)(2)(D)(i)(I) and 110(c) to tailor a remedy focused on the precursor pollutant most likely to improve ozone levels (currently NO_x) and those sources that can most cost-effectively reduce emissions (*i.e.*, EGUs). The EPA further implemented the remedy through an allowance trading program that achieves necessary emission reductions while providing sources with the flexibility to implement the control strategies of their choice.

We believe that the continued use of the authority provided by the good neighbor provision to address the interstate transport of ozone pollution plus other regulations that are already in place will permit the states and EPA to achieve necessary additional reductions to address the 2008 ozone NAAQS without the need to implement the additional requirements that inclusion in the OTR would entail. As described in Section IV.A and B of this document, this approach to address the interstate transport of ozone is a proven, efficient, and cost-effective means of addressing downwind air quality concerns that the agency has employed and refined over nearly two decades. However, the EPA notes that the addition of states to the OTR pursuant to the section 176A authority—and the additional planning requirements that would entail—could be given consideration as an appropriate means to address the interstate transport requirements of the CAA should the agency depart from its current approach to addressing these requirements.

As described in this document, the CAA provides the agency with the authority to mitigate the specific sources that contribute to interstate pollution through the approval of SIPs or promulgation of FIPs to satisfy the requirements of the good neighbor provision, CAA section 110(a)(2)(D)(i)(I), and through the related petition process under section 126. This authority gives the EPA and states numerous potential policy approaches to address interstate pollution transport of ozone, and the EPA has consistently and repeatedly used its authority under CAA section 110(a)(2)(D)(i)(I) to approve state plans

³⁷ The EPA extended the due date to 2021, but is not changing dates for the implementation of further pollution reductions needed to address regional haze, which are required over the 2018–2028 time frame. See <https://www.epa.gov/visibility/final-rulemaking-amendments-regulatory-requirements-state-regional-haze-plans>.

³⁸ See https://www.epa.gov/sites/production/files/2016-12/documents/regional_haze_2060-as55_final_preamble_rule_final_12-14-16_disclaimer_0.pdf.

for reducing ozone transport or to promulgate its own federal implementation plan to specifically target the sources of ozone transport both within and outside the OTR. The NO_x SIP call, CAIR, CSAPR, CSAPR Update and numerous individual SIP approvals demonstrate that the EPA has a long history of using its section 110 authority to specifically address interstate pollution transport in a targeted way that is tailored to a specific NAAQS and set of pollution sources which are the primary contributors to interstate pollution transport. As described in Section IV.B of this document, using the authority of the good neighbor provision has allowed the EPA to focus its efforts on pollution sources that are responsible for the largest contributions to ozone transport and that can cost-effectively reduce emissions, and also enables the agency to focus on NO_x as the primary driver of long range ozone transport—an approach the courts have found to be a reasonable means of addressing interstate ozone transport. *EPA v. EME Homer City Generation, L.P.*, 134 S. Ct. at 1607 (affirming as “efficient and equitable” the EPA’s use of cost to apportion emission reduction responsibility pursuant to the good neighbor provision); *Michigan v. EPA*, 213 F.3d at 688 (“EPA reasonably concluded that long-range ozone transport can only be addressed adequately through NO_x reductions”).

As explained previously, it does not appear that adding states to an OTR under CAA section 176A will afford the states and EPA with the flexibility to focus on specific sources and ozone precursor emissions tailored to address the downwind state’s current air quality and needed remedy to achieve attainment of the 2008 NAAQS. The statute prescribes a specific set of controls for a variety of sources to control emissions of both VOCs and NO_x. CAA section 110(a)(2)(D)(i)(I) on the other hand permits the EPA and the regulated community the flexibility to focus controls on specific sources and pollutants that most efficiently address the air quality problem being targeted. The EPA determined in the CSAPR Update that regional NO_x emissions reductions from upwind states are the most effective means for providing ozone benefits to an area in the OTR currently violating the 2008 ozone NAAQS, and that NO_x reductions can be most efficiently achieved by focusing on those sources that can cost-effectively reduce emissions. Accordingly, the EPA does not believe that the requirements imposed upon

states added to the OTR would be the most effective means of addressing any remaining interstate transport concerns with respect to the 2008 ozone NAAQS.

The implementation of controls within the OTR, when combined with the numerous federal and state emission reduction programs that have already been adopted that have resulted in the reduction of ozone precursor emissions either directly or as a co-benefit of those regulations, have helped to significantly reduce ozone levels. These programs will continue to reduce ozone precursor emissions and ozone concentrations both within and outside of the OTR over many years to come. However, the EPA believes the most efficient way to address the current 2008 ozone NAAQS nonattainment and interstate transport problems is to continue to rely on the ability to flexibly target the necessary reductions through this combination of targeted programs such as the implementation of the CSAPR Update Rule, the further utilization of the CSAPR framework, development of local attainment plans, and consideration of additional emissions limitations resulting from action on CAA section 126 petitions.

As discussed in Section III.C. of this document, CAA section 176A provides that the Administrator may exercise reasonable discretion in administering the agency’s regulatory agenda by determining whether or not to approve or deny a section 176A petition, so long as the EPA’s action is supported by a reasonable interpretation within the context of the statute. The EPA has reviewed the request of the petitioners to add additional states to the OTR in light of required control strategies for ozone transport regions and the other statutory tools available to the agency and states to address the interstate transport of ozone pollution. The agency believes that continuing its longstanding and effective use of the existing and expected control programs under the CAA’s mandatory good neighbor provision embodied in section 110(a)(2)(D)(i)(I), including implementation of the CSAPR Update beginning in 2017 and technical work now underway to establish a full remedy for the 2008 NAAQS as well as to implement the good neighbor provision for the more stringent 2015 NAAQS, is a more effective approach for addressing regional interstate ozone transport problems relative to the 2008 ozone standard.

The EPA is proposing to deny the petitioning states’ request to add additional states to the OTR for the purpose of addressing interstate transport of the 2008 ozone NAAQS at

this time. The agency will instead continue to use other authorities available within the CAA in order to address the long range interstate transport of ozone pollution. This document is specific to the 2008 ozone NAAQS, but the EPA notes that under different circumstances the OTR provisions have been an effective tool for air quality management, and could be similarly effective in the future for addressing interstate transport of ozone pollution. Accordingly, nothing in this document should be read to limit states’ ability to file a different petition under 176A or to prejudice the outcome of such a petition if filed. The EPA requests comment on the proposed denial of the petition based on the EPA’s preferred approach to addressing interstate transport with respect to the 2008 ozone NAAQS pursuant to these other CAA authorities.³⁹

V. Judicial Review and Determinations Under Section 307(b)(1) of the CAA

Section 307(b)(1) of the CAA indicates which Federal Courts of Appeal have venue for petitions of review of final actions by the EPA. This section provides, in part, that petitions for review must be filed in the Court of Appeals for the District of Columbia Circuit if (i) the agency action consists of “nationally applicable regulations promulgated, or final action taken, by the Administrator,” or (ii) such action is locally or regionally applicable, if “such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator finds and publishes that such action is based on such a determination.” The EPA finds that any final action related to this document is “nationally applicable” and of “nationwide scope and effect” within the meaning of CAA section 307(b)(1). Through this document, the EPA interprets section 176A of the CAA, a provision which has nationwide applicability. In addition, this document is a response to a petition which would, if granted, extend

³⁹ The EPA’s proposal as to the pending section 176A petition is focused on the appropriate mechanism to address interstate transport issues relative to the 2008 ozone NAAQS rather than the scope of remaining air quality problems or the level of controls necessary to address any such problems. Comment on any determinations made in prior rulemaking actions to identify downwind air quality problems relative to the ozone NAAQS or to quantify upwind state emission reduction obligations relative to those air quality problems, including the EPA’s decision to focus on certain precursor emissions or sources, are not within the scope of this proposal. To the extent the EPA evaluates these issues in a future rulemaking to address remaining air quality problems relative to the 2008 ozone NAAQS, comments will be welcomed in the context of that rulemaking.

regulatory requirements to nine states in multiple different circuits, and if denied could impact the 13 states within the ozone transport region established in CAA section 184. This proposed action also discusses at length prior EPA action and analyses concerning the transport of pollutants between the different states under CAA section 110. For these reasons, the Administrator determines that, when finalized, this action is of nationwide scope and effect for purposes of section 307(b)(1). Thus, pursuant to CAA section 307(b) any petitions for review of any final action regarding this document would be filed in the Court of Appeals for the District of Columbia Circuit within 60 days from the date any final action is published in the **Federal Register**.

VI. Statutory Authority

42 U.S.C. 7401 *et seq.*

Dated: January 11, 2017.

Gina McCarthy,
Administrator.

[FR Doc. 2017-01097 Filed 1-18-17; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2017-0026; FRL-9958-34]

Statutory Requirements for Substantiation of Confidential Business Information (CBI) Claims Under the Toxic Substances Control Act (TSCA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In June 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act amended the Toxic Substances Control Act (TSCA). EPA is announcing an interpretation of TSCA section 14 concerning confidential business information (CBI) claims for information submitted to EPA. EPA interprets the revised TSCA section 14(c)(3) as requiring substantiation of non-exempt CBI claims at the time the information claimed as CBI is submitted to EPA.

FOR FURTHER INFORMATION CONTACT:

For general information contact: Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

For technical information contact: Scott M. Sherlock, Attorney Advisor, Environmental Assistance Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-8257; email address: sherlock.scott@epa.gov.

DATES: This action is effective on March 20, 2017.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This announcement is directed to the public in general. It may, however, be of particular interest to you if you manufacture (defined by statute to include import) and/or process chemicals covered by TSCA (15 U.S.C. 2601 *et seq.*). This may include businesses identified by the North American Industrial Classification System (NAICS) codes 325 and 32411. Because this action is directed to the general public and other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be interested in this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get copies of this document and other related information?

1. *Docket.* EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPPT-2017-0026. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave. NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification,

pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

2. *Other related information.* For information about EPA's programs to evaluate new and existing chemicals and their potential risks and the amended TSCA, go to <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>.

II. What action is the Agency taking?

The amended TSCA provides new requirements relating to the assertion, substantiation and review of CBI claims. EPA is interpreting the revised TSCA section 14(c)(3) as requiring substantiation of all CBI claims at the time the information claimed as CBI is submitted to EPA, except for claims for information subject to TSCA section 14(c)(2).

This action facilitates the Agency's implementation of TSCA section 14(g) to review all CBI claims for chemical identity, with limited exceptions, as well as to review a representative sample of at least 25% of other non-exempt claims.

III. What is the Agency's authority for taking this action?

EPA has determined that TSCA section 14(c)(3), 15 U.S.C. 2613(c)(3), requires an affected business to substantiate all TSCA CBI claims, except for information subject to TSCA section 14(c)(2), at the time the affected business submits the claimed information to EPA.

TSCA section 14(c)(1)(a) requires an affected business to assert a claim for protection from disclosure concurrent with submission of the information in accordance with existing or future rules. TSCA section 14(c)(3) in turn requires an affected business submitting a claim to protect information from disclosure to substantiate the claim, also in accordance with existing or future rules. The language of TSCA section 14(c)(3) is as follows:

“(3) Substantiation requirements. Except as provided in paragraph (2), a person asserting a claim to protect information from disclosure under this section shall substantiate the claim, in accordance with such rules as the Administrator has promulgated or may promulgate pursuant to this section.”

EPA interprets TSCA section 14(c)(3) to require substantiation for all TSCA CBI claims, except for information

within TSCA section 14(c)(2). That is the clear import of the language, “a person asserting a claim to protect information from disclosure under this section shall substantiate the claim . . .” While the final clause requires that submissions be in accordance with EPA rules, EPA interprets this provision as addressing the form and manner of a submission, not as making the substantiation requirement conditional upon a future EPA rulemaking. In the future, EPA may promulgate regulations governing the form and manner of substantiating CBI claims for those submissions addressed by this action. Nonetheless, EPA considers the statutory substantiation requirement to be in place as of the effective date of this action.

EPA’s interpretation is supported by legislative history for the recent amendments to TSCA. Both the Senate and House intended to require substantiation of CBI claims. See S. Rpt. 114–67 (observing, on page 5, that “section 14 [of pre-amendment TSCA] and EPA’s implementation of it has been criticized for failing to require . . . up-front substantiation of confidentiality claims,” and, on page 22, stating that, under the Senate bill, “all new claims for protection of information not presumed to be protected from disclosure must be substantiated by the claimant”); H. Rpt. 114–176 at 29 (a confidentiality claim must “include . . . a justification for each claim of confidentiality”); Senate Environment and Public Works Committee summary: “Reforming the Toxic Substances Control Act” at 3 (http://www.epw.senate.gov/public/_cache/files/aa2ac4d1-15bb-4e71-9588-909d49bdcff2/tscareform-marketing-packet-5.19-final.pdf). (“The legislation promotes additional transparency by requiring up-front substantiation of claims to protect confidential commercial information. . . .”) EPA’s interpretation also is supported by TSCA section 14(i)(2), which provides that, “nothing in this chapter” prevents EPA from requiring substantiation before the effective date of rules that may be promulgated after June 22, 2016, the date on which the amendments to TSCA were enacted.

It might be maintained that TSCA section 14(c)(3) does not impose a substantiation requirement, but merely authorizes EPA to promulgate rules requiring substantiation. Alternatively, it might be maintained that the section does impose a substantiation requirement, but that the requirement must be effectuated through EPA rulemaking.

The first reading does not effectuate the legislative intent to require substantiation. In addition, the provision is not worded as a mere grant of authority. Numerous other provisions of TSCA—both of the pre-amended statute and of the Lautenberg amendments—demonstrate that Congress used more straightforward language when it intended simply to grant EPA rulemaking or other authority (e.g., TSCA section 14(f)(1) (“The Administrator may require any person . . . to reassert and substantiate or re-substantiate” an existing claim under certain circumstances); TSCA section 4(a)(2) (“The Administrator may, by rule, order, or consent agreement . . . require the development of new information”). Finally, TSCA section 14(c)(1) already authorizes EPA to promulgate rules governing the assertion of CBI claims. This paragraph provides authority for EPA to promulgate rules requiring substantiation, and EPA in fact promulgated a number of rules requiring substantiation under similarly worded authority in pre-amendment TSCA section 14(c)(1). See, e.g., 40 CFR 711.30(b)(1), requiring up-front substantiation for chemical identity claims for Chemical Data Reporting under part 711. To interpret TSCA section 14(c)(3) as merely providing authority to require substantiation, where that authority already exists in TSCA section 14(c)(1), would arguably give TSCA section 14(c)(3) no effect at all.

The second reading amounts to a revision of the legislative text. TSCA section 14(c)(3) does not require EPA to undertake rulemaking; it merely acknowledges that EPA “may” do so. Unless this “may” were read as “shall”, EPA would be under no obligation to promulgate the rules required to carry out the objective of requiring substantiation. Here again, numerous other provisions of TSCA demonstrate that Congress used clear language—and included deadlines—when it intended to require EPA to promulgate regulations (e.g., TSCA section 6(b)(1)(A) (“Not later than 1 year after June 22, 2016, the Administrator shall establish, by rule, a risk-based screening process. . . .”).

Having determined that TSCA section 14(c)(3) requires substantiation of all non-exempt TSCA CBI claims, EPA believes the provision is best interpreted as requiring substantiation *concurrent with the submission*. This is the natural reading of the requirement that “a person asserting a claim . . . shall substantiate the claim.” By analogy, TSCA section 14(c)(5)—another

requirement newly added by the Lautenberg amendments—provides that a claimant “shall certify that the statement required to assert a [confidentiality] claim . . . and any information required to substantiate a claim . . . are true and correct.” While this provision does not explicitly state that the certification must accompany the submission, it is reasonable to conclude that Congress intended that result. Moreover, a requirement to substantiate CBI claims at some unspecified time would not create any meaningful self-executing requirement, because there would be no point in time at which an affected business could be found not to have complied.

Reading the law as requiring substantiation concurrent with the CBI claim also comports with the legislative history. In addition to the history cited earlier in this document, the Senate Report, on p. 5, noted stakeholder concerns that, under pre-amendment TSCA, the lack of a requirement for up-front substantiation resulted in “an over-abundance of CBI claims, some of which may not be legitimate.” Interpreting TSCA section 14(c)(3) as requiring substantiation of a CBI claim concurrent with the claim’s submission best effectuates the expressed intent of Congress.

This interpretation is consistent with the requirement in TSCA section 14(g)(1) that EPA review most confidentiality claims for chemical identity and at least 25% of claims for other types of non-exempt information within 90 days after the receipt of the claim. An approach under which substantiations were submitted at some point after assertion of CBI claims would significantly reduce (and has already significantly reduced) the short period for such CBI reviews. To date, for each review, the Agency must contact each affected business, request the submission of a substantiation, and allow a period of time for the affected business to submit the substantiation. Since timely substantiation provides critical information for completing CBI reviews, it is reasonable to conclude that Congress intended for claims to be substantiated at the time the CBI claim is asserted.

When the amendments to TSCA became law on June 22, 2016, EPA published initial Questions and Answers (Q and A’s) in an effort to respond to the inquiries and requests concerning EPA’s views on the new law. EPA needed to issue guidance to the public as quickly as possible on a broad range of matters under the amendments, since the amendments became effective

upon signature. In the Q and A's on TSCA section 14, EPA stated that the Agency was using existing authorities to obtain CBI substantiations and that the Agency may revise CBI substantiation requirements for specific types of information submissions by subsequent rulemaking. Since the time the Q and A's were developed, EPA has heard the views of a number of stakeholders and has had the opportunity to more fully review the statute and legislative history and to evaluate the operational considerations associated with the interpretation of TSCA section 14(c)(3).

Operationally, given the large volume of CBI claims, including those that the Agency has already received and those that the Agency expects to receive in the future, it is administratively efficient to interpret the statute as requiring up-front substantiation, which necessarily saves the Agency the time and resources that would otherwise be spent in attempting to contact the affected business. Up-front substantiation will also significantly enhance EPA's ability to meet the review deadlines in TSCA section 14(g). Further, requiring substantiation concurrent with submission will mitigate any need for an affected business to request an extension to substantiate a CBI claim. Additionally, requiring the affected business to provide justification at the time of submission may help limit unwarranted claims of CBI. Based on this further review, for the reasons stated above, EPA has concluded that the provision is best read as creating a requirement to substantiate non-exempt TSCA CBI claims concurrent with their submission.

IV. Implementation

Existing EPA confidentiality rules at 40 CFR part 2, section 2.204(e), provide substantiation questions that the Agency may specifically request answers to, pursuant to the procedures in those regulations. While those specific questions are not dictated by the self-executing substantiation requirement in TSCA section 14(c)(3), EPA suggests that companies look to those questions for guidance as to how to fulfill the TSCA section 14(c)(3) substantiation requirement for information that is not currently subject to an existing regulatory up-front substantiation requirement. The answers to those questions typically form the basis of EPA final confidentiality determinations, and substantiations that do not address those questions might not provide sufficient information to uphold a determination, pursuant to TSCA section 14(g)(1), that information claimed as CBI is eligible for

confidential protection. For information that is currently subject to a regulatory up-front substantiation requirement (for example, chemical identity CBI claims in the Chemical Data Reporting rule, under 40 CFR 711.30), the terms of that requirement, including the substantiation questions required, will continue to govern the substantiation.

EPA has revised its Web pages on CBI to assist compliance with this interpretation of TSCA section 14. The Web pages list the substantiation questions from 40 CFR 2.204(e) and provide information on substantiation exemptions and on how the substantiations should be directed to the Agency.

Because EPA is providing this interpretation of TSCA section 14(c)(3) for the first time in this document, the Agency is setting different procedures for those who have submitted or will submit information claimed as CBI under TSCA before the effective date of this action, *i.e.*, March 20, 2017, and those who submit information claimed as CBI afterwards.

A. TSCA Submissions Filed on or After March 20, 2017

Those submissions containing information claimed as CBI filed on or after the effective-date of this action (*i.e.*, March 20, 2017) must provide a substantiation for all information claimed as confidential, other than information exempt from substantiation pursuant to TSCA section 14(c)(2). Any non-exempt CBI claim that is submitted without a substantiation will be considered deficient, and EPA will send a notice of deficiency to the affected business. The notice will inform the affected business that it must submit its substantiation within 30 calendar days in order to remedy its deficient CBI claim. The notice letter will also inform the affected business that if a timely substantiation has not been received by EPA within 30 days of receipt of the letter, then any CBI claims not substantiated will be considered withdrawn, and the information may be made public with no further notice to the affected business.

B. TSCA Submissions Filed Between June 22, 2016 and March 20, 2017

Those submissions containing information claimed as CBI filed between June 22, 2016 and March 20, 2017, must provide a substantiation for all information claimed as confidential, other than information exempt from substantiation pursuant to TSCA section 14(c)(2). The Agency is giving submitters until September 18, 2017 to provide substantiations and direct them

to the Agency. If a substantiation has already been provided to EPA with the submission or in response to a substantiation request, no additional substantiation need be filed for the same information. Be aware, however, that if some non-exempt information claimed as confidential in a particular submission has already been substantiated and some has not, the unsubstantiated information claimed as CBI in the submission must still be substantiated by September 18, 2017. The CBI claims, and the substantiations, may then be reviewed consistent with the provisions of TSCA, its implementing regulations and in accordance with the Agency procedures set forth in 40 CFR part 2. Once September 18, 2017 has passed, if no substantiation has been received for a claim, then EPA will provide the affected business 30 days' notice and a final opportunity to substantiate. The notice will inform the affected business that any CBI claims not substantiated at the end of the 30 days will be considered withdrawn, and the information may be made public with no further notice to the affected business.

EPA's electronic reporting systems for TSCA submissions have been modified to require substantiations for non-exempt CBI claims in submissions filed on or after March 20, 2017. Any new paper TSCA submissions that are directed to the Agency after that date must include substantiations for all non-exempt CBI claims at the time of submission.

For electronic submissions made using EPA's Central Data Exchange (CDX) during the period from June 22, 2016 to March 20, 2017 that were not substantiated, affected businesses must provide substantiation for CBI claims using the amendment processes for the particular submission type. Information on electronic reporting, including how to make amendments, can be found at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/electronic-reporting-requirements-certain-information>.

For any paper TSCA submissions that were submitted to the Agency during the period from June 22, 2016 to March 20, 2017, the affected business must submit substantiations for any non-exempt CBI claims that have not yet been substantiated. Submit these substantiations to: TSCA Confidential Business Information Center (7407M), WJC East; Room 6428; Attn: TSCA CBI Substantiations. U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460-0001.

Courier Deliveries should be directed to:

U.S. EPA, Office of Pollution Prevention and Toxics, Confidential Business Information Center (CBIC), Attn: TSCA CBI Substantiations, 1201 Constitution Avenue NW., WJC East; Room 6428 Washington, DC 20004–3302, (202) 564–8930.

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Authority: 15 U.S.C. 2601 *et seq.*

Dated: January 13, 2017.

James J. Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2017–01235 Filed 1–18–17; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2013–0024; FRL–9958–64–OAR]

California State Nonroad Engine Pollution Control Standards; In-Use Diesel-Fueled Transport Refrigeration Units (TRUs) and TRU Generator Sets and Facilities Where TRUs Operate; Notice of Decision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of decision.

SUMMARY: The Environmental Protection Agency (“EPA”) is granting the California Air Resources Board (“CARB”) request for authorization of amendments to its Airborne Toxic Control Measure for In-Use Diesel-Fueled Transport Refrigeration Units (“TRU”) and TRU Generator Sets and Facilities Where TRUs Operate (together “2011 TRU Amendments”). EPA’s decision also confirms that certain of the 2011 TRU amendments are within the scope of prior EPA authorizations. The 2011 TRU Amendments primarily provide owners of TRU engines with certain flexibilities; clarify recordkeeping requirements for certain types of TRU engines; establish requirements for businesses that arrange, hire, contract, or dispatch the transport of goods in TRU-equipped trucks, trailers, or containers; and address other issues that arose during the initial implementation of the regulation. This decision is issued under the authority of the Clean Air Act (“CAA” or “Act”).

DATES: Petitions for review must be filed by March 20, 2017.

ADDRESSES: EPA has established a docket for this Notice of Decision under Docket ID EPA–HQ–OAR–2015–0224. All documents relied upon in making this decision, including those submitted to EPA by CARB, are contained in the public docket. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the Air and Radiation Docket in the EPA Headquarters Library, EPA West Building, Room 3334, located at 1301 Constitution Avenue NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m.; Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744. The Air and Radiation Docket and Information Center’s Web site is <http://www.epa.gov/oar/docket.html>. The email address for the Air and Radiation Docket is: a-and-r-Docket@epa.gov, the telephone number is (202) 566–1742, and the fax number is (202) 566–9744. An electronic version of the public docket is available through the federal government’s electronic public docket and comment system. You may access EPA dockets at <http://www.regulations.gov>. After opening the www.regulations.gov Web site, enter EPA–HQ–OAR–2015–0224 in the “Enter Keyword or ID” fill-in box to view documents in the record. Although a part of the official docket, the public docket does not include Confidential Business Information (“CBI”) or other information whose disclosure is restricted by statute.

EPA’s Office of Transportation and Air Quality (“OTAQ”) maintains a Web page that contains general information on its review of California waiver and authorization requests. Included on that page are links to prior waiver **Federal Register** notices, some of which are cited in today’s notice; the page can be accessed at <http://www.epa.gov/otaq/cafr.htm>.

FOR FURTHER INFORMATION CONTACT:

David Dickinson, Attorney-Advisor, Transportation and Climate Division, Office of Transportation and Air Quality, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., (6405J), Washington, DC 20460. Telephone: (202) 343–9256. Fax: (202) 343–2804. Email: dickinson.david@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

EPA granted an authorization for California’s initial set of TRU

regulations on January 9, 2009.¹ EPA also granted a within-the-scope authorization for amendments to the TRU regulations, adopted in 2010, on June 28, 2013.² The TRU regulations establish in-use performance standards for diesel-fueled TRUs and TRU generator sets which operate in California, and facilities where TRUs operate. The TRU regulations are contained in an Airborne Toxic Control Measure (“ATCM”) adopted by CARB to reduce the general public’s exposure to diesel particulate matter (“PM”), other toxic airborne contaminants and air pollutants generated by TRUs and reduce near source risk at facilities where TRUs congregate. TRUs are refrigeration systems powered by internal combustion engines which control the environment of temperature-sensitive products that are transported in semi-trailer vans, truck vans, “reefer” railcars or shipping containers. The engines in TRUs do not propel the vehicle, but are used strictly to power the refrigeration system. These TRU engines are nonroad engines and vary in horsepower (“hp”) generally from 7 hp to 36 hp.

By letter dated March 2, 2015, CARB submitted a request to EPA for authorization of amendments to its TRU regulations³ pursuant to section 209(e) of the CAA.⁴ The 2011 TRU Amendments were adopted by CARB on October 21, 2011, and became operative state law on October 15, 2012.⁵ The 2011 TRU Amendments provide owners of 2001 through 2003 model year (MY) TRU engines that complied with applicable Low-Emission TRU (“LETRU”) in-use performance standards by specified compliance deadlines a one- or two-year extension from the more stringent Ultra-Low Emission (“ULETRU”) in-use performance standards. The amendments also clarify manual recordkeeping requirements for electric standby-equipped TRUs and ultimately require automated electronic tracking system requirements for such TRUs and establish requirements for businesses that arrange, hire, contract, or dispatch the transport of goods in TRU-equipped trucks, trailers or containers. A more

¹ 74 FR 3030 (January 16, 2009).

² 78 FR 38970 (June 28, 2013).

³ 13 California Code of Regulations (CCR), sections 2111, 2112, Appendix A therein, 2139, 2147, 2440, 2441, 2442, 2443.1, 2443.2, 2443.3, 2444.1, 2444.2, 2445.1, 2445.2, 2447, 2474 and 2448.

⁴ “Clean Air Act § 209(e)(2) Authorization Support Document submitted by the California Air Resources Board, March 2, 2015,” at EPA–HQ–OAR–2015–0224–0002 (Authorization Support Document).

⁵ *Id.*, Attachment 13.

detailed description of the 2011 Amendments is presented below in the context of which amendments CARB seeks within-the-scope conformation and those amendments for which CARB seeks a full authorization.

A. California's Authorization Request

California requested EPA perform two types of review. First, CARB requested an EPA determination that certain provisions of the 2011 amendments are within the scope of the prior authorizations, or in the alternative, merit full authorization ("Within-the-Scope Amendments"). The Within-the-Scope Amendments provide owners of 2003 and older MY TRUs an extension of the ULETRU compliance date if the TRUs complied with the LETRU standard by specified dates. Such TRU engines that are 2001 MY and older are given an extension to December 31, 2016 for the ULETRU deadline, 2002 MY TRUs are given a new deadline of December 31, 2017, and 2003 MY TRUs are given a new deadline of December 31, 2018. The Within-the-Scope Amendments also provide up to a one-year extension of the compliance dates if owners demonstrate that compliant technology is unavailable or is delayed due to financing, delivery, or installation and provides other flexibilities based upon certain requirements. In addition, the Within-the-Scope Amendments provide a host of new or clarified exemptions including: (1) Clarification that non-operational TRUs are generally exempt from compliance with the performance standards, but are still prohibited from being sold, rented or leased to a person that could reasonably be expected to operate such TRUs in California; (2) a limited exemption for TRU-equipped trucks and trailers used by mobile catering companies to feed emergency responders, such as firefighters (such engines are subject to registration and other requirements); (3) an exemption for non-compliant, non-operational TRUs on refrigerated railcars that travel through California based on CARB's Executive Officer approval under certain contingencies; and (4) an exemption for railway carriers from the owner/operator requirements for TRUs not owned by the railway carrier. Lastly, the Within-the-Scope Amendments clarify that the in-use performance standards and associated compliance deadlines are to be based on the year the TRU unit itself was manufactured (including the potential for a prior model year TRU engine to be installed in limited circumstances), instead of

basing the compliance deadline on the model year of the TRU engine.⁶

Second, CARB requested full authorization for amendments that revise standards or establish new requirements ("Full Authorization Amendments"). These provisions include amendments that require new replacement engines to meet more stringent requirements (based on the new replacement engine's model year or effective model year) than the original TRU engines. The Full Authorization Amendments also provide that to the extent TRUs now may be repowered with rebuilt engines such rebuilt engines must meet more stringent emission standards than the standards of the original engine, and provided the engines are rebuilt by engine rebuilders in compliance with federal and state engine rebuilding requirements for off-road compression ignition engines.⁷ CARB's TRU regulations allow TRU owners to utilize hybrid electric, hybrid cryogenic, and electric-standby ("E/S") equipped TRUs as an "Alternative technology" compliance option, which requires such TRUs to be operated in a manner that eliminates diesel engine operations at the facilities where the TRUs operate. The Full Authorization Amendments establish new recordkeeping requirements that will require the application of hardware to monitor the engine hour usage of the TRUs along with other automated monitoring, recordkeeping and reporting requirements. In addition, the TRU regulations now cover business entities that arrange, hire, contract for, or dispatch the transport of perishable goods in TRU-equipped trucks, trailers, shipping containers, or railcars. Lastly, the Full Authorization Amendments create new disclosure requirements for TRU original equipment manufacturers that are primarily designed to address engine emission labels on new replacement engines and new flexibility engines, as well as disclosure requirements for dealers and repair shops in order that the ARBER registration information is supplied to the end-user.

⁶ See CARB's Authorization Support Document. CARB's Within-the-Scope Amendments also include those provisions referenced at page 11 (allowance of California TRU dealers to acquire non-compliant TRUs under certain conditions), pages 13–14 (clarification on the prohibition of selling non-compliant TRUs), page 15 (allowance of the use of unique identification numbers instead of a CARB identification number), and page 16 (clarification of the registration requirements and consistency with current CARB Equipment Registration ("ARBER") system screens).

⁷ 40 CFR 89.130 and 1068.120 and Cal. Code Regs. Tit. 13., section 2423(l), respectively.

B. Clean Air Act Nonroad Engine and Vehicle Authorizations

Section 209(e)(1) of the Act permanently preempts any state, or political subdivision thereof, from adopting or attempting to enforce any standard or other requirement relating to the control of emissions for certain new nonroad engines or vehicles.⁸ For all other nonroad engines, states generally are preempted from adopting and enforcing standards and other requirements relating to the control of emissions. Section 209(e)(2), however, requires the Administrator, after notice and opportunity for public hearing, to authorize California to adopt and enforce standards and other requirements relating to the control of emissions from such vehicles or engines if California determines that California standards will be, in the aggregate, at least as protective of public health and welfare as applicable Federal standards. However, EPA shall not grant such authorization if it finds that (1) the determination of California is arbitrary and capricious; (2) California does not need such California standards to meet compelling and extraordinary conditions; or (3) California standards and accompanying enforcement procedures are not consistent with [CAA section 209].⁹

On July 20, 1994, EPA promulgated a rule interpreting the three criteria set forth in section 209(e)(2)(A) that EPA must consider before granting any California authorization request for nonroad engine or vehicle emission standards.¹⁰ EPA revised these

⁸ States are expressly preempted from adopting or attempting to enforce any standard or other requirement relating to the control of emissions from new nonroad engines which are used in construction equipment or vehicles or used in farm equipment or vehicles and which are smaller than 175 horsepower. Such express preemption under section 209(e)(1) of the Act also applies to new locomotives or new engines used in locomotives. CAA § 209(e)(1), 42 U.S.C. 7543(e)(1)(A).

⁹ EPA's review of California regulations under section 209 is not a broad review of the reasonableness of the regulations or its compatibility with all other laws. Sections 209(b) and 209(e) of the Clean Air Act limit EPA's authority to deny California requests for waivers and authorizations to the three criteria listed therein. As a result, EPA has consistently refrained from denying California's requests for waivers and authorizations based on any other criteria. In instances where the U.S. Court of Appeals has reviewed EPA decisions declining to deny waiver requests based on criteria not found in section 209(b), the Court has upheld and agreed with EPA's determination. See *Motor and Equipment Manufacturers Ass'n v. Nichols*, 142 F.3d 449, 462–63, 466–67 (D.C. Cir. 1998), *Motor and Equipment Manufacturers Ass'n v. EPA*, 627 F.2d 1095, 1111, 1114–20 (D.C. Cir. 1979). See also 78 FR 58090, 58120 (September 20, 2013).

¹⁰ See "Air Pollution Control; Preemption of State Regulation for Nonroad Engine and Vehicle Standards," 59 FR 36969 (July 20, 1994).

regulations in 1997.¹¹ As stated in the preamble to the 1994 rule, EPA historically has interpreted the consistency inquiry under the third criterion, outlined above and set forth in section 209(e)(2)(A)(iii), to require, at minimum, that California standards and enforcement procedures be consistent with section 209(a), section 209(e)(1), and section 209(b)(1)(C) of the Act.¹²

In order to be consistent with section 209(a), California's nonroad standards and enforcement procedures must not apply to new motor vehicles or new motor vehicle engines. To be consistent with section 209(e)(1), California's nonroad standards and enforcement procedures must not attempt to regulate engine categories that are permanently preempted from state regulation. To determine consistency with section 209(b)(1)(C), EPA typically reviews nonroad authorization requests under the same "consistency" criteria that are applied to motor vehicle waiver requests under section 209(b)(1)(C). That provision provides that the Administrator shall not grant California a motor vehicle waiver she finds that California "standards and accompanying enforcement procedures are not consistent with section 202(a)" of the Act. Previous decisions granting waivers and authorizations have noted that state standards and enforcement procedures will be found to be inconsistent with section 202(a) if (1) there is inadequate lead time to permit the development of the necessary technology, giving appropriate consideration to the cost of compliance within that time,¹³ or (2) the federal and state testing procedures impose inconsistent certification requirements.¹⁴

In light of the similar language in sections 209(b) and 209(e)(2)(A), EPA has reviewed California's requests for authorization of nonroad vehicle or engine standards under section 209(e)(2)(A) using the same principles that it has historically applied in reviewing requests for waivers of preemption for new motor vehicle or new motor vehicle engine standards

under section 209(b).¹⁵ These principles include, among other things, that EPA should limit its inquiry to the three specific authorization criteria identified in section 209(e)(2)(A),¹⁶ and that EPA should give substantial deference to the policy judgments California has made in adopting its regulations. In previous waiver decisions, EPA has stated that Congress intended EPA's review of California's decision-making be narrow. EPA has rejected arguments that are not specified in the statute as grounds for denying a waiver:

The law makes it clear that the waiver requests cannot be denied unless the specific findings designated in the statute can properly be made. The issue of whether a proposed California requirement is likely to result in only marginal improvement in California air quality not commensurate with its costs or is otherwise an arguably unwise exercise of regulatory power is not legally pertinent to my decision under section 209, so long as the California requirement is consistent with section 202(a) and is more stringent than applicable Federal requirements in the sense that it may result in some further reduction in air pollution in California.¹⁷

This principle of narrow EPA review has been upheld by the U.S. Court of Appeals for the District of Columbia Circuit.¹⁸ Thus, EPA's consideration of all the evidence submitted concerning an authorization decision is circumscribed by its relevance to those questions that may be considered under section 209(e)(2)(A).

C. Within-the-Scope Determinations

If California amends regulations that have been previously authorized by EPA, California may ask EPA to determine that the amendments are within the scope of the earlier authorization. A within-the-scope determination for such amendments is permissible without a full authorization

review if three conditions are met. First, the amended regulations must not undermine California's previous determination that its standards, in the aggregate, are as protective of public health and welfare as applicable federal standards. Second, the amended regulations must not affect consistency with section 209 of the Act, following the same criteria discussed above in the context of full authorizations. Third, the amended regulations must not raise any new issues affecting EPA's prior waiver or authorization decisions.¹⁹

D. Deference to California

In previous waiver decisions, EPA has recognized that the intent of Congress in creating a limited review based on the section 209(b)(1) criteria was to ensure that the federal government did not second-guess state policy choices. As the agency explained in one prior waiver decision:

It is worth noting * * * I would feel constrained to approve a California approach to the problem which I might also feel unable to adopt at the federal level in my own capacity as a regulator. The whole approach of the Clean Air Act is to force the development of new types of emission control technology where that is needed by compelling the industry to "catch up" to some degree with newly promulgated standards. Such an approach * * * may be attended with costs, in the shape of reduced product offering, or price or fuel economy penalties, and by risks that a wider number of vehicle classes may not be able to complete their development work in time. Since a balancing of these risks and costs against the potential benefits from reduced emissions is a central policy decision for any regulatory agency under the statutory scheme outlined above, I believe I am required to give very substantial deference to California's judgments on this score.²⁰

Similarly, EPA has stated that the text, structure, and history of the California waiver provision clearly indicate both a congressional intent and appropriate EPA practice of leaving the decision on "ambiguous and controversial matters of public policy" to California's judgment.²¹ This interpretation is supported by relevant discussion in the House Committee Report for the 1977 amendments to the Clean Air Act.²² Congress had the opportunity through the 1977 amendments to restrict the preexisting waiver provision, but elected instead to

¹¹ See "Control of Air Pollution: Emission Standards for New Nonroad Compression-Ignition Engines at or Above 37 Kilowatts; Preemption of State Regulation for Nonroad Engine and Vehicle Standards; Amendments to Rules," 62 FR 67733 (December 30, 1997). The applicable regulations are now found in 40 CFR part 1074, subpart B, section 1074.105.

¹² 59 FR 36969 (July 20, 1994). EPA has interpreted 209(b)(1)(C) in the context of section 209(b) motor vehicle waivers.

¹³ H. Rep. No. 728, 90th Cong., 1st Sess. 21 (1967).

¹⁴ S. Rep. No. 403, 90th Cong., 1st Sess. 32 (1967).

¹⁵ See *Engine Manufacturers Association v. EPA*, 88 F.3d 1075, 1087 (D.C. Cir. 1996): "... EPA was within the bounds of permissible construction in analogizing § 209(e) on nonroad sources to § 209(a) on motor vehicles."

¹⁶ See EPA's Final 209(e) rulemaking at 59 FR 36969, 36983 (July 20, 1994).

¹⁷ "Waiver of Application of Clean Air Act to California State Standards," 36 FR 17458 (Aug. 31, 1971). Note that the more stringent standard expressed here, in 1971, was superseded by the 1977 amendments to section 209, which established that California must determine that its standards are, in the aggregate, at least as protective of public health and welfare as applicable Federal standards. In the 1990 amendments to section 209, Congress established section 209(e) and similar language in section 209(e)(1)(i) pertaining to California's nonroad emission standards which California must determine to be, in the aggregate, at least as protective of public health and welfare as applicable federal standards.

¹⁸ See, e.g., *Motor and Equip. Mfrs Assoc. v. EPA*, 627 F.2d 1095 (D.C. Cir. 1979) ("MEMA I").

¹⁹ See "California State Motor Vehicle Pollution Control Standards; Amendments Within the Scope of Previous Waiver of Federal Preemption," 46 FR 36742 (July 15, 1981).

²⁰ 40 FR 23102, 23103–23104 (May 28, 1975).

²¹ *Id.* at 23104; 58 FR 4166 (January 13, 1993).

²² MEMA I, 627 F.2d at 1110 (citing H.R. Rep. No. 294, 95th Cong., 1st Sess. 301–302 (1977)).

expand California's flexibility to adopt a complete program of motor vehicle emission controls. The report explains that the amendment is intended to ratify and strengthen the preexisting California waiver provision and to affirm the underlying intent of that provision, that is, to afford California the broadest possible discretion in selecting the best means to protect the health of its citizens and the public welfare.²³

E. Burden and Standard of Proof

As the U.S. Court of Appeals for the D.C. Circuit has made clear in *MEMA I*, opponents of a California waiver request bear the burden of showing that the statutory criteria for a denial of the request have been met:

[T]he language of the statute and its legislative history indicate that California's regulations, and California's determinations that they must comply with the statute, when presented to the Administrator are presumed to satisfy the waiver requirements and that the burden of proving otherwise is on whoever attacks them. California must present its regulations and findings at the hearing and thereafter the parties opposing the waiver request bear the burden of persuading the Administrator that the waiver request should be denied.²⁴

The Administrator's burden, on the other hand, is to make a reasonable evaluation of the information in the record in coming to the waiver decision. As the court in *MEMA I* stated: "here, too, if the Administrator ignores evidence demonstrating that the waiver should not be granted, or if he seeks to overcome that evidence with unsupported assumptions of his own, he runs the risk of having his waiver decision set aside as 'arbitrary and capricious.'" ²⁵ Therefore, the Administrator's burden is to act "reasonably."²⁶

With regard to the standard of proof, the court in *MEMA I* explained that the Administrator's role in a section 209 proceeding is to:

[. . .] consider all evidence that passes the threshold test of materiality and * * * thereafter assess such material evidence against a standard of proof to determine whether the parties favoring a denial of the waiver have shown that the factual circumstances exist in which Congress intended a denial of the waiver.²⁷

In that decision, the court considered the standards of proof under section 209 for the two findings related to granting a waiver for an "accompanying

enforcement procedure." Those findings involve: (1) Whether the enforcement procedures impact California's prior protectiveness determination for the associated standards, and (2) whether the procedures are consistent with section 202(a). The principles set forth by the court, however, are similarly applicable to an EPA review of a request for a waiver of preemption for a standard. The court instructed that "the standard of proof must take account of the nature of the risk of error involved in any given decision, and it therefore varies with the finding involved. We need not decide how this standard operates in every waiver decision."²⁸

With regard to the protectiveness finding, the court upheld the Administrator's position that, to deny a waiver, there must be "clear and compelling evidence" to show that proposed enforcement procedures undermine the protectiveness of California's standards.²⁹ The court noted that this standard of proof also accords with the congressional intent to provide California with the broadest possible discretion in setting regulations it finds protective of the public health and welfare.³⁰

With respect to the consistency finding, the court did not articulate a standard of proof applicable to all proceedings, but found that the opponents of the waiver were unable to meet their burden of proof even if the standard were a mere preponderance of the evidence. Although *MEMA I* did not explicitly consider what the standards of proof would be under section 209 concerning a waiver request for "standards," as compared to a waiver request for accompanying enforcement procedures, there is nothing in the opinion to suggest that the court's analysis would not apply with equal force to such determinations. EPA's past waiver decisions have consistently made clear that: "[E]ven in the two areas concededly reserved for Federal judgment by this legislation—the existence of 'compelling and extraordinary' conditions and whether the standards are technologically feasible—Congress intended that the standards of EPA review of the State decision to be a narrow one."³¹

F. EPA's Administrative Process in Consideration of California's Request for Authorization of the 2011 TRU Amendments

The CAA directs EPA to offer an opportunity for public hearing on authorization requests from California. On November 17, 2015, EPA published a **Federal Register** notice announcing an opportunity for written comment and offering a public hearing on California's request for authorization of the 2011 TRU Amendments.³² The request for comments specifically included, but was not limited to, the following issues.

First, EPA requested comment on whether the 2011 amendments for which CARB requested a within-the-scope determination should be considered under a within-the-scope analysis. We specifically requested comment on whether the Within-the-Scope Amendments (1) undermine California's previous determination that its standards, in the aggregate, are at least as protective of public health and welfare as comparable federal standards, (2) affect the consistency of California's requirement with section 209 of the Act, or (3) raise any other new issue affecting EPA's previous authorization determinations.

Second, EPA requested comment on whether the Within-the-Scope Amendments would satisfy the criteria for full authorization if they do not meet the criteria for within-the-scope analysis.

Third, EPA sought comment on whether the Full Authorization Amendments, for which CARB requested full authorization, satisfy the full authorization criteria. We specifically requested comment on whether (1) California's protectiveness determination (*i.e.*, that California standards will be, in the aggregate, as protective of public health and welfare as applicable federal standards) is arbitrary and capricious, (2) California does not need such standards to meet compelling and extraordinary conditions, or (3) the California standards and accompanying enforcement procedures are not consistent with section 209 of the Act.

EPA received no request for a public hearing. Consequently, EPA did not hold a public hearing. EPA received one written comment and a response comment from CARB, discussed below.

II. Discussion

A. Within-The-Scope Analysis

We initially evaluate California's Within-the-Scope Amendments by

²³ *Id.*

²⁴ *MEMA I*, at 1121.

²⁵ *Id.* at 1126.

²⁶ *Id.* at 1126.

²⁷ *Id.* at 1122.

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ See, e.g., "California State Motor Vehicle Pollution Control Standards; Waiver of Federal Preemption," 40 FR 23102 (May 28, 1975), at 23103.

³² 80 FR 71791 (November 17, 2015).

application of our traditional within-the-scope analysis, as CARB requested. If we determine that CARB's request does not meet the requirements for a within-the-scope determination, we then evaluate the request based on a full authorization analysis. In determining whether amendments can be viewed as within the scope of previous waivers, EPA looks at whether CARB's revision has been limited to making minor technical amendments to previously waived regulations or modifying the regulations in order to provide manufacturers with additional compliance flexibilities without significantly reducing the overall stringency of the requirements. The Within-the-Scope Amendments at issue in this request provide for certain compliance extensions and certain exemptions from the TRU in-use performance standards. The Within-the-Scope Amendments also clarify pre-existing requirements.

EPA sought comment on a range of issues, including those applicable to a within-the-scope analysis as well as those applicable to a full authorization analysis. No party submitted a comment that California's Within-the-Scope Amendments require a full authorization analysis. Given the lack of comments on this issue, and EPA's assessment of the nature of the amendments, EPA will evaluate California's Within-the-Scope Amendments by application of our traditional within-the-scope analysis, as CARB requested.

EPA can confirm that amended regulations are within the scope of a previously granted waiver of preemption if three conditions are met. First, the amended regulations must not undermine California's determination that its standards, in the aggregate, are as protective of public health and welfare as applicable federal standards. Second, the amended regulations must not affect consistency with section 202(a) of the Act. Third, the amended regulations must not raise any "new issues" affecting EPA's prior authorizations.

B. Full Authorization Analysis

As noted above, CARB's authorization request also included the Full Authorization Amendments. EPA must grant an authorization of the Full Authorization Amendments unless the Administrator finds: (1) California's determination that its standards will be, in the aggregate, as protective of public health and welfare as applicable federal standards is arbitrary and capricious; (2) California does not need such California standards to meet compelling and

extraordinary conditions; or (3) California's standards and accompanying enforcement procedures are not consistent with this section.

EPA's evaluation of the 2011 TRU Amendments, including the Within-the-Scope Amendments and Full Authorization Amendments, is set forth below. Because of the similarity of the within-the-scope criteria and the full authorization criteria, a discussion of both sets of respective amendments take place within each authorization criterion. To the extent that the criteria are applied uniquely, or that additional criteria apply under either the within-the-scope analysis or the full authorization analysis, such application is also addressed below.

1. California's Protectiveness Determination

In its March 2, 2015 letter requesting a within-the-scope determination, CARB stated that in approving the amendments to the TRU ATCM, the Board approved Resolution 11–35.³³ The Board expressly declared “. . . that the Board hereby determines that pursuant to Title II, section 209(e)(2) of the federal Clean Air Act, as amended in 1990, that the emission standards and other requirements related to the control of emissions adopted as part of the amendments to the TRU ATCM are, in the aggregate, at least as protective of public health and welfare as applicable federal standards.”³⁴ CARB noted that EPA cannot find CARB's determination to be arbitrary and capricious for the reason that EPA does not have comparable federal emission standards that regulate in-use TRUs and TRU engines.

After evaluating the materials submitted by CARB, and since EPA has not adopted any standards or requirements for in-use TRU systems or engines, and based on no comments submitted to the record, I cannot find that California's TRU amendments undermine California's previous determination that its standards, in the aggregate, are at least as protective of public health and welfare as applicable federal standards. Thus I cannot deny CARB's within-the-scope request based on this criterion. Similarly, with regard to the Full Authorization Amendments I cannot make a finding that CARB's protectiveness determination is arbitrary and capricious and thus I cannot deny CARB's Full Authorization Amendments based on this criterion.

³³ See Authorization Support Document at 18–19. See also EPA–HQ–OAR–2015–0224–0002, Attachment 6.

³⁴ *Id.*

2. Whether the Standards Are Necessary To Meet Compelling and Extraordinary Conditions

Section 209(e)(2)(A)(ii) instructs that EPA cannot grant an authorization if the Agency finds that California “does not need such California standards to meet compelling and extraordinary conditions” EPA's inquiry under this second criterion (found both in paragraphs 209(b)(1)(B) and 209(e)(2)(A)(ii)) has been to determine whether California needs its own mobile source pollution program (*i.e.* set of standards) for the relevant class or category of vehicles or engines to meet compelling and extraordinary conditions, and not whether the specific standards that are the subject of the authorization or waiver request are necessary to meet such conditions.³⁵

EPA does not examine the section 209(e)(2)(A)(ii) criterion in the context of within-the-scope requests since the original regulations (that received a previous authorization from EPA) have already been evaluated under this criterion. However, should CARB adopt amendments that require a full authorization assessment (*e.g.* the addition of more stringent emission standards, etc.) then EPA believes it is appropriate to reevaluate whether California continues to demonstrate the need for its own mobile source program. EPA's assessment of the Full Authorization Amendments under this criterion is set forth below.

California has asserted its longstanding position that the State continues to need its own nonroad engine program to meet serious air pollution problems.³⁶ The relevant inquiry under section 209(e)(2)(A)(ii) is whether California needs its own emission control program to meet compelling and extraordinary conditions, not whether any given standard is necessary to meet such conditions.³⁷

There has been no evidence submitted to indicate that California's compelling and extraordinary conditions do not continue to exist. California, including the South Coast and the San Joaquin Valley air basins, continues to experience some of the worst air quality in the nation and continues to be in non-attainment with national ambient

³⁵ See 74 FR 32744, 32761 (July 8, 2009); 49 FR 18887, 18889–18890 (May 3, 1984).

³⁶ See Authorization Support Document at 23, “In adopting Resolution 11–35, the Board confirmed CARB's longstanding position that California continues to need its own nonroad engine program to meet serious air pollution problems.”

³⁷ *Id.*

air quality standards for fine particulate matter (PM_{2.5}) and ozone.³⁸

We received no contrary evidence or comments contesting California's longstanding determination that its TRU ATCM program is needed to address the state's compelling and extraordinary conditions, nor did we receive any suggestion that CARB's nonroad program is not still necessary. In addition, EPA is not aware of any other information that would suggest that California no longer needs its nonroad emission program. Therefore, based on the record of this request and absence of comments or other information to the contrary, I cannot find that California does not continue to need such state standards, including the 2011 TRU Amendments, to address the "compelling and extraordinary conditions" underlying the state's air pollution problems.

3. Consistency With Section 209 of the Clean Air Act

Section 209(e)(2)(A)(iii) of the Act instructs that EPA cannot grant an authorization if California's standards and enforcement procedures are not consistent with "this section." As described above, EPA's section 209(e) rule states that the Administrator shall not grant authorization to California if she finds (among other tests) that the "California standards and accompanying enforcement procedures are not consistent with section 209." EPA has interpreted the requirement to mean that California standards and accompanying enforcement procedures must be consistent with at least section 209(a), section 209(e)(1), and section 209(b)(1)(C), as EPA has interpreted this last subsection in the context of motor vehicle waivers.³⁹ Thus, this can be viewed as a three-pronged test.

a. Consistency With Section 209(a) and 209(e)(1)

Section 209(a) of the Clean Air Act prohibits states or any political subdivisions of states from setting emission standards for new motor vehicles or new motor vehicle engines. Section 209(a) is modified in turn by

section 209(b) which allows California to set such standards if other statutory requirements are met. To find a standard to be inconsistent with section 209(a) for purposes of section 209(e)(2)(A)(iii), EPA must find that the standard in question actually regulates new motor vehicles or new motor vehicle engines.

To be consistent with section 209(e)(1) of the Clean Air Act, California's standards or other requirements relating to the control of emissions must not relate to new engines which are used in farm or construction equipment or vehicles and which are smaller than 175 horsepower (hp), and new locomotives or new engines used in locomotives.

In its authorization request, CARB states that in granting an authorization for the initial TRU ATCM regulation, EPA found that the TRU ATCM was consistent with CAA sections 209(a) and 209(e)(1) because the ATCM did not apply to new motor vehicles and engines or to new engines under 175 hp used in farm and construction vehicles or equipment or to new locomotives or locomotive engines.⁴⁰ CARB notes that the 2011 TRU Amendments likewise do not apply to the above categories of preempted mobile sources and thus EPA cannot find that such amendments are inconsistent with section 209(a) and 209(e)(1). No commenter argued the contrary or otherwise asserted that the 2011 TRU Amendments are not consistent with section 209(a) and 209(e)(1) and EPA is otherwise not aware of such evidence.

Therefore, I cannot deny California's request on the basis that 2011 TRU Amendments are not consistent with section 209(a) and section 209(e)(1).

b. Consistency With Section 209(b)(1)(C)

The requirement that California's standards be consistent with section 209(b)(1)(C) of the Clean Air Act effectively requires consistency with section 202(a) of the Act. To determine this consistency, EPA has applied to California nonroad standards the same test it has used previously for California motor vehicle standards; namely, state standards are inconsistent with section 202(a) of the Act if there is inadequate lead-time to permit the development of technology necessary to meet those requirements, giving appropriate consideration to the cost of compliance within that timeframe. California's accompanying enforcement procedures would also be inconsistent with section 202(a) if federal and California test

procedures conflicted. The scope of EPA's review of whether California's action is consistent with section 202(a) is narrow. The determination is limited to whether those opposed to the authorization or waiver have met their burden of establishing that California's standards are technologically infeasible, or that California's test procedures impose requirements inconsistent with the federal test procedures.⁴¹

The legislative history of section 209 (including the "consistency with section 202(a)" requirement in 209(b)(1)(C)) indicates that this provision is intended to relate to technological feasibility.⁴² Section 202(a)(2) states, in relevant part, that any regulation promulgated under its authority "shall take effect after such period as the Administrator finds necessary to permit the development and application of the requisite technology, giving appropriate consideration to the cost of compliance within such period." Section 202(a) thus requires the Administrator to first determine whether adequate technology already exists; or if it does not, whether there is adequate time to develop and apply the technology before the standards go into effect. The latter scenario also requires the Administrator to decide whether the cost of developing and applying the technology within that time is feasible. Previous EPA waivers are in accord with this position.⁴³

With regard to the Within-the-Scope Amendments, CARB notes that the amendments are designed to provide owners with greater flexibility to comply with the existing TRU ATCM's in-use requirements. The amendments were not the result of non-existing technologies according to CARB, but rather that the Board determined that special considerations were necessary to accommodate TRU owners during implementation of the rule, including the availability of certain diesel emission control devices or the availability of cleaner Tier 4 standard engines in the later model years. With regard to the amendments that specify requirements for repowering TRUs with new replacement engines and the allowance for owners to repower TRUs with rebuilt engines, CARB notes that these amendments do not modify the pre-existing compliance dates that EPA previously authorized and EPA has previously addressed rebuilding

³⁸ 74 FR 32744, 32762–63 (July 8, 2009), 76 FR 77515, 77518 (December 13, 2011), 81 FR 95982 (December 29, 2016). EPA continually evaluates the air quality conditions in the United States, including California. California continues to experience some of the worst air quality in the country and continues to be in nonattainment with National Ambient Air Quality Standards for fine particulate matter and ozone, see "Notice of Availability of the Environmental Protection Agency's Preliminary Interstate Ozone Transport Modeling Data for the 2015 Ozone National Ambient Air Quality Standard (NAAQS)" at EPA-HQ-OAR–2016–0751.

³⁹ See 59 FR 36969 (July 20, 1994).

⁴⁰ See Authorization Support Document at page 19.

⁴¹ *MEMA I*, 627, F.2d at 1126.

⁴² H.R. Rep. No. 95–294, 95th Cong., 1st Sess. 301 (1977).

⁴³ See, e.g., 49 FR 1887, 1895 (May 3, 1984); 43 FR 32182, 32183 (July 25, 1978); 41 FR 44209, 44213 (October 7, 1976).

requirements.⁴⁴ CARB also notes that several of its Full Authorization Amendments help ensure that the TRU ATCM is effectively implemented and enforced, and therefore constitute “accompanying enforcement provisions” (“AEPs”).⁴⁵ CARB notes that the AEPs that pertain to new automated monitoring, recordkeeping and reporting requirements for E/S, hybrid-electric, and hybrid cryogenic TRUs present no issues regarding technical feasibility. CARB maintains that the technology needed to comply with the reporting requirements already exists and the GPS tracking systems are already being used and are capable of wirelessly transmitting reports and data.⁴⁶

EPA received comment acknowledging that the technology for data collection and record reporting currently exists, but that additional development will be necessary to ensure that the technology will provide the necessary information for reporting purposes while also providing the necessary security and safeguards to protect proprietary information of both the original equipment manufacturers (“OEMs”) and the equipment owner.⁴⁷ This commenter also requested further definition of “stationary location” as well as seeking an increase in the 5 minute requirement to 15 minutes.⁴⁸ CARB responds by noting that the commenter acknowledges that the technology needed to comply with the automated monitoring, recordkeeping and reporting requirements currently exists and that the commenter fails to specify and provide any evidence of the types of proprietary information that is at issue and how such potential information is included in what information must be reported to CARB. CARB also notes that the Alternative

Technology TRUs are subject to reporting requirements that include the address of each stationary location where such a TRU was operated longer than five minutes. CARB states that “Thermo King does not describe why or how the current 5-minute stationary requirement may be causing confusion and/or false stationary readings. Furthermore, Thermo King has presented no evidence to support its argument that the five-minute requirement will result in confusion or erroneous readings.”⁴⁹

As noted above, EPA’s determination is limited to whether those opposed to the authorization or waiver have met their burden of establishing that California’s standards are technologically infeasible. I agree that the Within-the-Scope Amendments are designed to relax (*i.e.* extend the compliance deadlines in limited circumstances and provide additional exemptions) and clarify existing TRU ATCM requirements and therefore provide additional flexibility to regulated parties. EPA also did not receive any comments arguing that the Within-the-Scope Amendments were technologically infeasible. With regard to the Full Authorization Amendments I find that CARB has presented sufficient information to demonstrate that the technology needed to meet the applicable requirements already exists. To the extent that comments were raised concerning Alternative Technology TRUs and associated reporting requirements, the commenter raising such concerns has failed to meet their burden of proof in demonstrating why such requirements are technologically infeasible. As such, the record does not support a finding that the 2011 TRU Amendments are inconsistent with Section 202(a).

4. New Issues

EPA has stated in the past that if California promulgates amendments that raise new issues affecting previously granted waivers or authorizations, we would not confirm that those amendments are within the scope of previous authorizations.⁵⁰ I do not believe that the Within-the-Scope Amendments that extend the compliance dates under certain circumstances, provide new or clarify existing exemptions from the TRU in-use performance standards, and provide clarifications to CARB’s existing TRU ATCM raise any new issues with respect

to our prior granting of the authorization. Moreover, EPA did not receive any comments that CARB’s TRU Amendments raised new issues affecting the previously granted authorization. Therefore, I cannot find that CARB’s Within-the-Scope Amendments raise new issues and consequently, cannot deny CARB’s request based on this criterion.

III. Decision

After evaluating CARB’s 2011 TRU Amendments described above, EPA is taking the following actions. First, I am granting an authorization for the Full Authorization Amendments. Second, I confirm that the Within-the-Scope Amendments are within the scope of the previous EPA authorizations.

This decision will affect persons not only in California, but also manufacturers and/or owners/operators nationwide who must comply with California’s requirements. In addition, because other states may adopt California’s standards for which a section 209(e)(2)(A) authorization has been granted if certain criteria are met, this decision would also affect those states and those persons in such states. See CAA section 209(e)(2)(B). For these reasons, EPA determines and finds that this is a final action of national applicability, and also a final action of nationwide scope or effect for purposes of section 307(b)(1) of the Act. Pursuant to section 307(b)(1) of the Act, judicial review of this final action may be sought only in the United States Court of Appeals for the District of Columbia Circuit. Petitions for review must be filed by March 20, 2017. Judicial review of this final action may not be obtained in subsequent enforcement proceedings, pursuant to section 307(b)(2) of the Act.

IV. Statutory and Executive Order Reviews

As with past authorization and waiver decisions, this action is not a rule as defined by Executive Order 12866. Therefore, it is exempt from review by the Office of Management and Budget as required for rules and regulations by Executive Order 12866.

In addition, this action is not a rule as defined in the Regulatory Flexibility Act, 5 U.S.C. 601(2). Therefore, EPA has not prepared a supporting regulatory flexibility analysis addressing the impact of this action on small business entities.

Further, the Congressional Review Act, 5 U.S.C. 801, *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule for purposes of 5 U.S.C. 804(3).

⁴⁴ See 74 FR 3030 (January 16, 2009), Authorization Support Document at 22.

⁴⁵ See Authorization Support Document at 25. Section 209(e)(2)(A)(iii) requires that both standards and accompanying enforcement procedures be consistent with section 202(a). AEPs are not mentioned elsewhere in section 209(e). AEPs are general procedures or other requirements designed to ensure that the levels of emission reductions sought by the standards are achieved, *see MEMA I* at 1113.

⁴⁶ See Authorization Support Document at 27.

⁴⁷ See comment submitted by Thermo King, EPA-HQ-OAR-2015-0224-0003.

⁴⁸ *Id.* Thermo King also raises a series of questions regarding the electronic tracking system requirements that CARB has addressed in its supplemental comments at EPA-HQ-OAR-2015-0224-0004 (“CARB Supplemental Comments”). EPA agrees with CARB that questions about whether the definition and requirements of the electronic tracking system apply to OEMs and “free access” are questions that do not fall under EPA’s review given the limited statutory criteria for authorization review.

⁴⁹ CARB Supplemental Comments at 7–8.

⁵⁰ See, e.g., 78 FR 38970 (June 28, 2013), 75 FR 8056 (February 23, 2010), and 70 FR 22034 (April 28, 2005).

Dated: January 11, 2017.

Gina McCarthy,
Administrator.

[FR Doc. 2017-01225 Filed 1-18-17; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OGC-2017-0030; FRL-9958-55-OGC]

Proposed Settlement Agreement, Clean Air Act Petition for Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement agreement; request for public comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act, as amended (“CAA”), notice is hereby given of a proposed settlement agreement to address a lawsuit filed by Sierra Club in the United States Court of Appeals for the District of Columbia Circuit: *Sierra Club v. EPA*, No. 16-1158 (D.C. Cir.). On May 27, 2016, Sierra Club filed a petition for judicial review of the final action taken by EPA under the CAA titled “Revisions to Ambient Monitoring Quality Assurance and Other Requirements” (“final action”) at 81 FR 17,248 (Mar. 28, 2016). The proposed settlement agreement would resolve Sierra Club’s lawsuit upon EPA’s issuance of two nonbinding guidance documents recommending public notification practices concerning the submission and approval of ambient air monitoring network plans.

DATES: Written comments on the proposed settlement agreement must be received by February 21, 2017.

ADDRESSES: Submit your comments, identified by Docket ID number EPA-HQ-OGC-2017-0030, online at www.regulations.gov. For comments submitted at www.regulations.gov, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from www.regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (“CBI”) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment

contents located outside of the primary submission (i.e. on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the “For Further Information Contact” section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT:

Jonathan Skinner-Thompson, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone: (202) 564-0291; fax number (202) 564-5603; email address: skinner-thompson.jonathan@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Additional Information About the Proposed Settlement Agreement

Sierra Club filed a petition for review of EPA’s final action titled “Revisions to Ambient Monitoring Quality Assurance and Other Requirements” (“final action”) at 81 FR 17,248 (Mar. 28, 2016). In the final action, EPA revised requirements pertaining to public inspection of proposed annual monitoring network plans under 40 CFR 58.10.

Under the terms of the proposed settlement agreement, Sierra Club would agree to dismiss its case with prejudice upon EPA’s issuance of two nonbinding guidance documents. The first guidance document would be issued to state and local monitoring agencies and would make public inspection recommendations concerning proposed monitoring plans. The second guidance document would be issued to EPA regional offices and would make recommendations for stakeholder notification of submitted monitoring plan approvals and disapprovals. The United States also would agree to make a payment in settlement of Sierra Club’s claim for fees and costs. Please review the settlement agreement for additional details, available in the public docket at EPA-HQ-OGC-2017-0030.

For a period of 30 days following the date of publication of this notice, the Agency will receive written comments relating to the proposed settlement agreement from persons who were not named as parties or intervenors to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the proposed settlement agreement if the comments disclose facts or considerations that

indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Unless EPA or the Department of Justice determines that consent to the agreement should be withdrawn or withheld, the terms of the agreement will be affirmed.

II. Additional information about commenting on the proposed settlement agreement.

A. How can I get a copy of the proposed settlement agreement?

The official public docket for this action under Docket ID No. EPA-HQ-OGC-2017-0030 contains a copy of the proposed settlement agreement. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OEI Docket is (202) 566-1752.

An electronic version of the public docket is available through www.regulations.gov. You may use the www.regulations.gov to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select “search”.

It is important to note that EPA’s policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing online at www.regulations.gov without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. Information claimed as CBI and other information whose disclosure is restricted by statute is not included in the official public docket or in the electronic public docket. EPA’s policy is that copyrighted material, including copyrighted material contained in a public comment, will not be placed in EPA’s electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the EPA Docket Center.

B. How and to whom do I submit comments?

You may submit comments as provided in the **ADDRESSES** section. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment and with any disk or CD ROM you submit. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the www.regulations.gov Web site to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an "anonymous access" system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment. In contrast to EPA's electronic public docket, EPA's electronic mail (email) system is not an "anonymous access" system. If you send an email comment directly to the Docket without going through www.regulations.gov, your email address is automatically captured and included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

Dated: January 11, 2017.

Lorie J. Schmidt,

Associate General Counsel.

[FR Doc. 2017-01099 Filed 1-18-17; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-R06-OW-2017-0017; FRL-9958-31-Region 6]

Proposed Reissuance of the NPDES General Permit for Facilities Related to Oil and Gas Extraction in the Territorial Seas of Texas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability for comment.

SUMMARY: The Director of the Water Division, Environmental Protection Agency (EPA) Region 6 today proposes to reissue the National Pollutant Discharge Elimination System (NPDES) general permit for the Territorial Seas of Texas (No. TXG260000) for discharges from existing and new dischargers and New Sources in the Offshore Subcategory of the Oil and Gas Extraction Point Source Category as authorized by section 402 of the Clean Water Act, 33 U.S.C. 1342. The permit will supersede the previous general permit (TXG260000) issued on February 8, 2012 and published in the **Federal Register** at 77 FR 8855. This permit renewal authorizes discharges from exploration, development, and production facilities located in and discharging to the territorial seas off Texas.

Comment: Submit your comments, identified by Docket ID No. EPA-R06-OW-2017-0017 to the *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

DATES: Comments must be received by March 6, 2017.

FOR FURTHER INFORMATION CONTACT: Ms. Evelyn Rosborough, Region 6, U.S. Environmental Protection Agency, 1445 Ross Avenue, Dallas, Texas 75202-2733. Telephone: (214) 665-7515. Email: rosborough.evelyn@epa.gov.

A complete draft permit and a fact sheet more fully explaining the proposal may be obtained from Ms. Rosborough. In addition, the Agency's current administrative record on the proposal is available for examination at the Region's Dallas offices during normal working hours after providing Ms. Rosborough 24 hours advance notice. A copy of the proposed permit, fact sheet, and this **Federal Register** Notice may be found on the EPA Region 6 Web site at: <https://www3.epa.gov/region6/water/npdes/genpermit/index.htm>.

SUPPLEMENTARY INFORMATION: EPA intends to use the proposed reissued permit to regulate discharges from oil and gas extraction facilities located in the territorial seas off Texas. To obtain discharge authorization, operators of such facilities must submit a new Notice of Intent (NOI). To determine whether your (facility, company, business, organization, etc.) is regulated by this action, you should carefully examine the applicability criteria in Part I, Section A.2 of the permit. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section above. The proposed permit contains limitations conforming to EPA's Oil and Gas Extraction, Offshore Subcategory Effluent Limitation Guidelines at 40 CFR part 435 and additional requirements assuring that regulated discharges will not cause unreasonable degradation of the marine environment, as required by section 403(c) of the Clean Water Act. Limitations and conditions are also included to ensure compliance with State Water Quality Standards. Specific information on the derivation of those limitations and conditions is contained in the fact sheet. Specifically, the draft permit proposes to prohibit the discharge of drilling fluids, drill cuttings and produced sand. Produced water discharges are limited for oil and grease, 7-day chronic toxicity, and 48-hour acute toxicity. In addition to limits on oil and grease, the proposed permit includes a prohibition of the discharge of priority pollutants except in trace amounts in well treatment, completion, and workover fluids. A limit of "No Free Oil" is proposed for miscellaneous discharges, such as non-contact cooling water and

ballast water, and on deck drainage discharges. Discharges of seawater and freshwater which have been used to pressure test existing pipelines and piping, to which treatment chemicals have been added, are proposed to be subject to limitations on free oil, concentration of treatment chemicals, and acute toxicity. New facilities withdrawing cooling water greater than 2 million gallons per day (MGD) are required to have the best technology available for minimizing fish/shellfish impingement mortality and entrainment caused by cooling water intake structures. Pursuant to the electronic reporting rule published in the **Federal Register** (80 FR 64063), a new electronic reporting requirement is added to the proposed permit.

Other Legal Requirements

State certification under section 401 of the CWA; consistency with the Texas Coastal Management Program; and compliance with National Environmental Policy Act, Endangered Species Act, Magnuson-Stevens Fishery Conservation and Management Act, Historic Preservation Act, Paperwork Reduction Act, and Regulatory Flexibility Act requirements are discussed in the fact sheet to the proposed permit.

Dated: December 28, 2016.

William K. Honker,

Director, Water Division, EPA Region 6.

[FR Doc. 2017-01082 Filed 1-18-17; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OW-2015-0828; FRL-9958-68-OW]

Final National Pollutant Discharge Elimination System (NPDES) General Permit for Stormwater Discharges From Construction Activities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final permit issuance.

SUMMARY: All ten EPA Regions today are issuing the 2017 National Pollutant Discharge Elimination System (NPDES) general permit for stormwater discharges from construction activities to waters of the United States, also referred to as the “2017 Construction General Permit (CGP).” The 2017 CGP replaces the existing general permit (the “2012 CGP”) covering stormwater discharges from construction activities that expires on February 16, 2017. EPA is issuing this permit for five (5) years, during which time the permit will make available coverage to eligible operators in all areas of the country where EPA is the NPDES permitting authority. This **Federal Register** notice describes the 2017 CGP in general and provides a summary of the significant changes from the 2012 CGP.

DATES: The 2017 CGP will become effective on February 16, 2017. This effective date will provide dischargers with the immediate opportunity to comply with Clean Water Act requirements in light of the expiration of the 2012 CGP at midnight on February 16, 2017. In accordance with 40 CFR part 23, specifically 23.2, this permit shall be considered issued for the purpose of judicial review on January 25, 2017. Under section 509(b) of the Clean Water Act, judicial review of this general permit can be requested by filing a petition for review in the United States Court of Appeals within 120 days after the permit is considered issued. Under section 509(b)(2) of the Clean Water Act, this permit may not be challenged later in civil or criminal proceedings to enforce this permit. In addition, this permit may not be challenged in any other agency proceedings. Deadlines for submittal of notices of intent are provided in Part 1.4.3 of the permit. The permit also provides additional dates for compliance with the terms of the permit.

FOR FURTHER INFORMATION CONTACT: For further information on the permit, contact the appropriate EPA Regional office listed in Section I.C of this notice, or Emily Halter, EPA Headquarters, Office of Water, Office of Wastewater Management at tel.: 202-564-3324 or email: halter.emily@epa.gov.

SUPPLEMENTARY INFORMATION: This section is organized as follows:

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I. General Information

A. Does this action apply to me?

1. Entities Covered by This Permit

This permit covers the following entities, as categorized in the North American Industry Classification System (NAICS):

TABLE 1—ENTITIES COVERED BY THIS PERMIT

| Category | Examples of affected entities | North American Industry Classification System (NAICS) code |
|----------------|--|--|
| Industry | Construction site operators disturbing one (1) or more acres of land, or less than one (1) acre but part of a larger common plan of development or sale if the larger common plan will ultimately disturb one (1) acre or more, and performing the following activities: | |
| | Construction of Buildings | 236 |
| | Heavy and Civil Engineering Construction | 237 |

EPA does not intend the preceding table to be exhaustive, but provides it as a guide for readers regarding the types of activities that EPA is now aware of that could potentially be affected by this action. Other types of entities not listed in the table could also be affected. To determine whether your site is covered by this action, you should carefully examine the definition of “construction activity” and “small construction activity” in existing EPA regulations at 40 CFR 122.26(b)(14)(x) and 122.26(b)(15), respectively. If you have questions regarding the applicability of this action to a particular entity, consult one of the persons listed for technical information in the preceding **FOR FURTHER INFORMATION CONTACT** section.

2. Construction Projects for Which Operators Are Eligible for Permit Coverage

Coverage under this permit is available to operators of eligible projects located in those areas where EPA is the permitting authority. A list of eligible areas is included in Appendix B of the permit. Eligibility for permit coverage is limited to operators of “new sites,” operators of “existing sites,” “new operators of permitted sites,” and operators of “emergency-related projects.” A “new site” is a site where construction activities commenced on or after February 16, 2017. An “existing site” is a site where construction activities commenced prior to February 16, 2017. A “new operator of a permitted site” is an operator that through transfer of ownership and/or operation replaces the operator of an already permitted construction site that is either a “new site” or an “existing site.” An “emergency-related project” is a project initiated in response to a public emergency (*e.g., mud slides, earthquake, extreme flooding conditions, disruption in essential public services*), for which the related work requires immediate authorization to avoid imminent endangerment to human health or the environment, or to reestablish public services.

3. Geographic Coverage

This permit makes coverage available to eligible operators for stormwater discharges from construction activities that occur in areas not covered by an approved state NPDES program. The areas of geographic coverage of this permit are listed in Appendix B, and include the states of New Hampshire, Massachusetts, New Mexico, and Idaho as well as most Indian country lands, and areas in selected states operated by a federal operator. Permit coverage is also available to eligible operators in

Puerto Rico, the District of Columbia, and the Pacific Island territories, among others.

B. How can I get copies of these documents and other related information?

1. *Docket.* EPA has established an official public docket for this action under Docket ID No. EPA-HQ-OW-2015-0828. The official public docket is the collection of materials that is available for public viewing at the Water Docket in the EPA Docket Center, (EPA/DC) WJC West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC 20460. Although all documents in the docket are listed in an index, some information is not publicly available, *i.e.*, Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Publicly available docket materials are available in hard copy at the EPA Docket Center Public Reading Room, open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744 and the telephone number for the Water Docket is (202) 566-2426.

2. *Electronic Access.* You may access this **Federal Register** notice electronically through the United States government on-line source for Federal regulations at <http://www.regulations.gov>.

Electronic versions of this permit and fact sheet are available on EPA’s NPDES Web site at <https://www.epa.gov/npdes/stormwater-discharges-construction-activities>.

An electronic version of the public docket is available through the EPA’s electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.regulations.gov> to view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. For additional information about EPA’s public docket, visit the EPA Docket Center homepage at <https://www.epa.gov/dockets>. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the Docket Facility identified in Section I.B.1.

C. Who are the EPA regional contacts for this permit?

For EPA Region 1, contact Suzanne Warner at tel.: (617) 918-1383 or email at warner.suzanne@epa.gov.

For EPA Region 2, contact Stephen Venezia at tel.: (212) 637-3856 or email at venezia.stephen@epa.gov, or for

Puerto Rico, contact Sergio Bosques at tel.: (787) 977-5838 or email at bosques.sergio@epa.gov.

For EPA Region 3, contact Carissa Moncavage at tel.: (215) 814-5798 or email at moncavage.carissa@epa.gov.

For EPA Region 4, contact Michael Mitchell at tel.: (404) 562-9303 or email at mitchell.michael@epa.gov.

For EPA Region 5, contact Brian Bell at tel.: (312) 886-0981 or email at bell.brianc@epa.gov.

For EPA Region 6, contact Suzanna Perea at tel.: (214) 665-7217 or email at perea.suzanna@epa.gov.

For EPA Region 7, contact Mark Matthews at tel.: (913) 551-7635 or email at matthews.mark@epa.gov.

For EPA Region 8, contact Amy Clark at tel.: (303) 312-7014 or email at clark.amy@epa.gov.

For EPA Region 9, contact Eugene Bromley at tel.: (415) 972-3510 or email at bromley.eugene@epa.gov.

For EPA Region 10, contact Margaret McCauley at tel.: (206) 553-1772 or email at mccauley.margaret@epa.gov.

II. Background of Permit

The Clean Water Act (“CWA”) establishes a comprehensive program “to restore and maintain the chemical, physical, and biological integrity of the Nation’s waters.” 33 U.S.C. 1251(a). The CWA also includes the objective of attaining “water quality which provides for the protection and propagation of fish, shellfish and wildlife and * * * recreation in and on the water.” 33 U.S.C. 1251(a)(2). To achieve these goals, the CWA requires EPA to control discharges of pollutants from point sources through the issuance of NPDES permits.

The Water Quality Act of 1987 (WQA) added section 402(p) to the CWA, which directed EPA to develop a phased approach to regulate stormwater discharges under the NPDES program. 33 U.S.C. 1342(p). EPA published a final regulation in the **Federal Register**, often called the “Phase I Rule,” on November 16, 1990, establishing permit application requirements for, among other things, “storm water discharges associated with industrial activity.” See 55 FR 47990. EPA defines the term “storm water discharge associated with industrial activity” in a comprehensive manner to cover a wide variety of facilities. See *id.* Construction activities, including activities that are part of a larger common plan of development or sale, that ultimately disturb at least five acres of land and have point source discharges to waters of the U.S. were included in the definition of “industrial activity” pursuant to 40 CFR 122.26(b)(14)(x). The second rule

implementing section 402(p), often called the “Phase II Rule,” was published in the **Federal Register** on December 8, 1999. It requires NPDES permits for discharges from construction sites disturbing at least one acre but less than five acres, including sites that are part of a larger common plan of development or sale that will ultimately disturb at least one acre but less than five acres, pursuant to 40 CFR 122.26(b)(15)(i). See 64 FR 68722. EPA is issuing this permit under the statutory and regulatory authority cited above.

NPDES permits for construction stormwater discharges are required under Section 402(a)(1) of the CWA to include conditions to meet technology-based effluent limits established under Section 301 and, where applicable, Section 306. Effluent Limitations Guidelines (ELGs) and New Source Performance Standards (NSPS) are technology-based effluent limitations that are based on the degree of control that can be achieved using various levels of pollutant control technology as defined in Subchapter III of the CWA.

Once a new national standard is established in accordance with these sections, NPDES permits must incorporate limits based on such technology-based standards. See CWA sections 301 and 306, 33 U.S.C. 1311 and 1316, and 40 CFR 122.44(a)(1). On December 1, 2009, EPA published final regulations establishing technology-based ELGs and NSPSs for the Construction & Development (C&D) point source category, which became effective on February 1, 2010. See 40 CFR part 450, and 74 FR 62996 (December 1, 2009). The Construction & Development Rule, or “C&D rule,” was amended on March 6, 2014 to satisfy EPA’s agreements pursuant to a settlement of litigation that challenged the 2009 rule. See 79 FR 12661. All NPDES construction stormwater NPDES permits issued by EPA or states after this date must incorporate the requirements in the C&D rule.

III. Summary of the Final 2017 CGP

The final 2017 CGP is substantially similar to the 2012 CGP. It includes effluent limitations (*i.e., requirements for erosion and sediment and pollutant prevention controls*) and requirements for self-inspections, corrective actions, staff training, development of a stormwater pollution prevention plan (SWPPP), and permit conditions applicable to construction sites in specific states, Indian country lands, and territories. Additionally, the appendices provide forms for the submittal of a Notice of Intent (NOI),

Notice of Termination (NOT), Low Erosivity Waiver (LEW), as well as step-by-step procedures for determining eligibility with respect to the protection of threatened and endangered species and historic properties, and for complying with the permit’s natural buffer requirements.

A. Technology-Based Effluent Limits

As stated above, all NPDES construction permits issued by EPA or states after March 6, 2014 must incorporate the requirements in the C&D rule, as amended. The non-numeric effluent limitations in the C&D rule are designed to prevent the mobilization and discharge of sediment and sediment-bound pollutants, such as metals and nutrients, and to prevent or minimize exposure of stormwater to construction materials, debris, and other sources of pollutants on construction sites. In addition, these non-numeric effluent limitations reduce the generation of dissolved pollutants. Soil on construction sites can contain a variety of pollutants such as nutrients, pesticides, herbicides, and metals. These pollutants may be present naturally in the soil, such as arsenic or selenium, or they may have been contributed by previous activities on the site, such as agriculture or industrial activities. These pollutants, once mobilized by stormwater, can detach from the soil particles and become dissolved pollutants. Once dissolved, these pollutants would not be removed by down-slope sediment controls. Source control through minimization of soil erosion is therefore the most effective way of controlling the discharge of these pollutants.

The non-numeric effluent limits in the C&D rule, upon which the technology-based requirements in the permit are based, include the following:

- **Erosion and Sediment Controls**—Permittees are required to design, install and maintain effective erosion controls and sediment controls to minimize the discharge of pollutants. At a minimum, such controls must be designed, installed and maintained to:

1. Control stormwater volume and velocity to minimize soil erosion in order to minimize pollutant discharges;
2. Control stormwater discharges, including both peak flowrates and total stormwater volume, to minimize channel and streambank erosion and scour in the immediate vicinity of discharge points;
3. Minimize the amount of soil exposed during construction activity;
4. Minimize the disturbance of steep slopes;

5. Minimize sediment discharges from the site. The design, installation and maintenance of erosion and sediment controls must address factors such as the amount, frequency, intensity and duration of precipitation, the nature of resulting stormwater discharge, and soil characteristics, including the range of soil particle sizes expected to be present on the site;

6. Provide and maintain natural buffers around waters of the United States, direct stormwater to vegetated areas and maximize stormwater infiltration to reduce pollutant discharges, unless infeasible;

7. Minimize soil compaction. Minimizing soil compaction is not required where the intended function of a specific area of the site dictates that it be compacted; and

8. Unless infeasible, preserve topsoil. Preserving topsoil is not required where the intended function of a specific area of the site dictates that the topsoil be disturbed or removed.

- **Soil Stabilization Requirements**—Permittees are required to, at a minimum, initiate soil stabilization measures immediately whenever any clearing, grading, excavating or other earth disturbing activities have permanently ceased on any portion of the site, or temporarily ceased on any portion of the site and will not resume for a period exceeding 14 calendar days. In arid, semiarid, and drought-stricken areas where initiating vegetative stabilization measures immediately is infeasible, alternative stabilization measures must be employed as specified by the permitting authority. Stabilization must be completed within a period of time determined by the permitting authority. In limited circumstances, stabilization may not be required if the intended function of a specific area of the site necessitates that it remain disturbed.

- **Dewatering Requirements**—Permittees are required to minimize the discharge of pollutants from dewatering trenches and excavations. Discharges are prohibited unless managed by appropriate controls.

- **Pollution Prevention Measures**—Permittees are required to design, install, implement, and maintain effective pollution prevention measures to minimize the discharge of pollutants. At a minimum, such measures must be designed, installed, implemented and maintained to:

1. Minimize the discharge of pollutants from equipment and vehicle washing, wheel wash water, and other wash waters. Wash waters must be treated in a sediment basin or alternative control that provides

equivalent or better treatment prior to discharge;

2. Minimize the exposure of building materials, building products, construction wastes, trash, landscape materials, fertilizers, pesticides, herbicides, detergents, sanitary waste and other materials present on the site to precipitation and to stormwater. Minimization of exposure is not required in cases where the exposure to precipitation and to stormwater will not result in a discharge of pollutants, or where exposure of a specific material or product poses little risk of stormwater contamination (such as final products and materials intended for outdoor use); and

3. Minimize the discharge of pollutants from spills and leaks and implement chemical spill and leak prevention and response procedures.

• *Prohibited Discharges*—The following discharges from C&D sites are prohibited:

1. Wastewater from washout of concrete, unless managed by an appropriate control;

2. Wastewater from washout and cleanout of stucco, paint, form release oils, curing compounds and other construction materials;

3. Fuels, oils, or other pollutants used in vehicle and equipment operation and maintenance; and

4. Soaps or solvents used in vehicle and equipment washing.

• *Surface Outlets*—When discharging from basins and impoundments, permittees are required to utilize outlet structures that withdraw water from the surface, unless infeasible.

The fact sheet details how EPA has incorporated these requirements into the final 2017 CGP. The discussion in the fact sheet includes a summary of each provision and the agency's rationale for articulating the provision in this way.

B. Water Quality-Based Effluent Limits (WQBELs)

EPA's regulations at 40 CFR 122.44(d)(1) require permitting authorities to include additional or more stringent permit requirements when necessary to achieve water quality standards. The 2012 CGP contained several provisions to protect water quality and the 2017 CGP includes those same provisions. The permit includes a narrative WQBEL requiring that discharges be controlled as necessary to meet applicable water quality standards. Failure to control discharges in a manner that meets applicable water quality standards is a violation of the permit.

In addition to the narrative WQBEL, the permit contains related provisions that act together to further protect water quality. Many of these provisions were also included in the 2012 CGP. For example, the permit requires operators to implement stormwater control measures and to take corrective action in response to any exceedance of applicable water quality standards. To provide further protection, the permit also requires more stringent site inspection frequencies and stabilization deadlines for construction sites that discharge to sensitive waters, such as those waters that are impaired for sediment or nutrients, which are parameters typically associated with stormwater discharges from construction sites, or waters identified by a state, tribe, or EPA as requiring enhanced protection under antidegradation requirements. Additionally, EPA received CWA Section 401 certifications for the 2017 CGP. Some of these certifications include additional water quality-based conditions that are required by states, Indian country lands, and territories, that become legally binding permit limits and conditions in specific geographic areas where the permit is available.

A new water quality protection established in the 2017 CGP is a modified approach to site stabilization deadlines based on the concept of phasing construction disturbances, where sites that disturb more than five (5) acres total over the course of a construction project are required to stabilize within a more stringent timeframe if they do not limit disturbances to five (5) acres or less at any one time. This modified approach is summarized below and is discussed in more detail in the fact sheet.

C. Summary of Significant Permit Changes From the 2012 CGP

The 2017 CGP includes several new or modified requirements, which are summarized below and discussed in more detail in the fact sheet. The final 2017 CGP and the fact sheet can be found at <https://www.epa.gov/npdes/stormwater-discharges-construction-activities>.

1. *Streamlining of the permit*—EPA streamlined and simplified language throughout the 2017 CGP to present requirements in a generally more clear and readable manner. This structure should enhance the operators' understanding of and compliance with the permit's requirements. For example, EPA moved language that was not necessary in the permit into the relevant appendix or to the fact sheet. Although

the permit has been streamlined from prior permits, most of the requirements remain unchanged.

2. *Revisions consistent with the C&D ELG, as amended*—EPA made minor revisions to the technology-based effluent limits in the permit to incorporate the March 6, 2014 amendments to the Construction and Development Effluent Guidelines and Standards (the "C&D rule") at 40 CFR part 450 (see section III.A. of this notice on Technology-Based Effluent Limits). The 2012 CGP already incorporated the original C&D rule requirements and the 2017 CGP includes the necessary revisions to the language based on the rule amendments but does not add any new requirements. These revisions include clarifying the applicability of requirements to control erosion caused by discharges, providing additional details on areas where buffers are required, and clarifying requirements for soil stabilization, preservation of topsoil and pollution prevention measures.

3. *Authorized non-stormwater discharges*—Non-stormwater discharges of external building washdown waters containing hazardous substances, such as paint or caulk containing polychlorinated biphenyl (PCBs) are not authorized in the 2017 CGP. Non-stormwater discharges are required to comply with any applicable effluent limitation requirements in Parts 2 and 3 of the permit. Part 1.2.2.

4. *Notice of permit coverage*—Consistent with the 2012 CGP, operators must post a sign or other notice of permit coverage at a safe, publicly accessible location in close proximity to the construction site. In the 2017 CGP, this notice must also include information informing the public on how to contact EPA to obtain a copy of the SWPPP and how to contact EPA if stormwater pollution is observed in the discharge. EPA is requiring these additions to make the longstanding process of obtaining a SWPPP more readily known to the public and to improve transparency of the process to report possible violations. Part 1.5.

5. *Stockpiles and land clearing debris piles*—EPA changed the requirement for temporary stabilization for stockpiles or land clearing debris piles from "where practicable" to requiring cover or appropriate temporary stabilization for all inactive piles that will be unused for 14 or more days, consistent with the temporary stabilization deadlines in Part 2.2.14 of the 2017 CGP. EPA made this change to ensure pollutants are minimized from these piles, but is clarifying that the requirement only

applies where these piles are not actively being used. Part 2.2.5.

6. *Stabilization deadlines*—The 2017 CGP establishes a modified approach to the stabilization deadlines, which is based on the concept of phasing construction disturbances. Sites that disturb five (5) acres or less must complete stabilization within a 14-calendar day timeframe, which is the same timeframe that applied to sites in the 2012 CGP. For sites that disturb more than five (5) acres over the course of a construction project, operators can choose between completing stabilization within a 14-calendar day timeframe if they limit disturbances to five (5) acres or less at any one time, or within a 7-calendar day timeframe if they do not limit disturbances to five (5) acres or less at any one time. The intent of this approach is to provide an incentive to disturb less land at any given period of time by providing longer stabilization timeframes if the disturbance is kept below a threshold level. The deadline for sites discharging to sensitive waters remains unchanged (within 7 calendar days), and the exceptions for sites in arid, semi-arid, and drought-stricken areas and for operators affected by circumstances beyond their control also remain unchanged. Part 2.2.14.

7. *Construction and domestic waste*—The 2017 CGP requires operators to keep waste container lids closed when not in use and at the end of the business day for those containers that are actively used throughout the day, or, for waste containers that do not have lids, to provide cover or a similarly effective means to minimize the discharge of pollutants. EPA made this change to minimize the exposure of these waste materials to precipitation and stormwater, and to make the requirements for construction and domestic waste consistent with the cover requirements for most other types of materials and wastes in the CGP. Part 2.3.3.

8. *Discharge limitations for sites discharging to sensitive waters*—In order to ensure that discharges meet water quality standards, EPA added a requirement in the 2017 CGP to implement controls on sites discharging to polychlorinated biphenyl (PCB) impaired waters to minimize the exposure of building materials containing PCBs to precipitation and stormwater. This provision applies to the demolition of structures with at least 10,000 square feet of floor space built or renovated before January 1, 1980. EPA also added a requirement to document information about the demolition location and associated pollutants in the SWPPP. Part 3.2.

9. *Notice of Intent (NOI)*—In the 2017 CGP, EPA added three questions to the NOI form (Appendix J). These questions are:

- The type of construction site (select one or more of 9 options);
- A yes/no question asking if there is demolition of a structure with at least 10,000 square feet of floor space that was built or renovated before January 1, 1980; and
- A yes/no question asking whether the predevelopment land use was used for agriculture.

IV. Implementation Assistance

Following issuance of the 2017 CGP, EPA plans to provide further assistance to construction operators, state permitting authorities, and other interested parties on various aspects of this new permit. The following activities or documents are planned:

- *National Webcast*—EPA will host a webcast in February of 2017 that will provide an overview of the 2017 CGP and an opportunity for participants to ask questions. EPA anticipates offering more webcasts covering the same material or more specific aspects of the permit. The agency will announce details of all webcasts on the CGP Web site at <https://www.epa.gov/npdes/stormwater-discharges-construction-activities>.

- *Small Residential Lot SWPPP Template*—EPA will also be providing an updated template that small residential lot builders can use to develop a streamlined SWPPP that is consistent with the minimum requirements of the permit.

- *Inspection and Corrective Action Report Templates*—EPA will also be providing updated template forms that construction site operators can use to document inspections completed pursuant to the permit's requirements in Part 4 and in preparing corrective action reports pursuant to the permit's requirements in Part 5.

EPA will consider additional outreach to support the 2017 CGP based on the level of interest and demand.

V. Analysis of Economic Impacts

EPA expects the economic impact on entities that will likely seek coverage under this permit, including small businesses, to be minimal. A copy of EPA's economic analysis, titled "Cost Impact Analysis for the 2017 Construction General Permit (CGP)," is available in the docket for this permit. The economic impact analysis indicates that while there may be some incremental increase in the costs of complying with the 2017 CGP over the 2012 CGP, these costs will not have a

significant economic impact on a substantial number of small entities.

This analysis evaluates the cost implications of the key changes to the permit. Each change is examined in light of the 2012 CGP's requirements, where applicable. The objective of this examination is to show where or to what extent the 2017 CGP includes requirements that impose an incremental increase in costs on operators above and beyond costs that are already accounted for in the 2012 CGP, which incorporated the C&D rule and defines the baseline of costs to which operators are currently subject.

The C&D rule baseline costs estimate the cost of compliance for all construction activities required to obtain NPDES permit coverage to implement the stormwater controls required by the Effluent Limitations Guideline. While the C&D rule applies to permitted construction activities under the NPDES program nationwide, the 2017 CGP provides coverage to a sub-set of those activities in areas not covered by an approved state NPDES program, which accounts for approximately 5–6 percent of the construction stormwater permitted universe under the NPDES program.

Calculating the total cost of EPA's construction stormwater program under the 2017 CGP is challenging for several reasons. NPDES general permits, such as the CGP, are issued to no one operator in particular, with multiple operators obtaining coverage under the general permit after it is issued. Therefore, the 2017 CGP has an inherently unknown permitted universe at the time of permit issuance. EPA can estimate that approximately 25,000 operators will seek coverage under the 2017 CGP during its five-year life span, based on data from previous CGPs.

However, the total cost calculation is dependent on many other factors and assumptions that are difficult to estimate or extrapolate for the entire CGP permitted universe. Although many operators under the CGP share similar operations and discharge properties, the variables that would need to be accounted for in estimating the total cost of compliance vary widely across individual construction sites, for example, total area and duration that land is disturbed, slope, climate and precipitation patterns, soil type, topography, and previous land use. In addition, factors such as labor and material costs vary across the country. Given that EPA does not know and does not collect data on all of the specific operator characteristics necessary to make an accurate estimate, EPA is not able to estimate the total cost of

compliance with EPA's CGP at this time. EPA's practice instead is to calculate the incremental change in burden with each permit reissuance and, where applicable, provide estimates of some known costs that can be used to calculate the estimated total cost of a specific permit change.

Part 3.2 has a new requirement in the 2017 CGP for operators discharging to waters impaired for PCBs. Buildings and structures originating or remodeled between the years of 1950–1979 often contain PCBs in materials such as caulk and paint. Without proper controls, the demolition of such structures can cause PCBs to be released into the environment and discharged into waters of the U.S. during storm events. To address this concern, EPA has added a new provision that requires controls to be implemented to minimize exposure of PCB-containing building materials to precipitation and stormwater, and to ensure that such materials are disposed in compliance with applicable state, federal, and local laws. The requirement is limited to the demolition of buildings or structures with at least 10,000 square feet of floor space built or renovated before January 1, 1980 on sites that discharge to waters with known impairments for PCBs.

Over 4,500 water bodies are currently listed in the PCB-polluted category, making this the sixth-highest water pollution cause nationwide. This includes 81,610 miles of rivers and streams, 3,204,534 acres of lakes and ponds, and 400,094 square miles of bays and estuaries that are impaired for PCBs. EPA does not currently have data on the number of construction projects subject to EPA's CGP that involve demolition of a structure with at least 10,000 square feet of floor space built or renovated before January 1, 1980 on sites that discharge to waters impaired for PCBs. Therefore, at this time, EPA does not have an estimate for the number of operators that will be affected by this new requirement. However, EPA added a new question on the NOI form asking about the prevalence of demolition of a structure with at least 10,000 square feet of floor space that was built or renovated before January 1, 1980. When reissuing this permit, EPA will review the data submitted on the NOI forms as well as information on the implementation of this requirement, as necessary, to determine whether to revise the applicability of the requirement or associated cost impact analysis.

VI. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is a “significant regulatory action.” Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011) and any changes made in response to OMB recommendations have been documented in the docket for this action.

VII. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order (EO) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that the 2017 CGP will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because the requirements in the permit apply equally to all construction projects that disturb one or more acres in areas where EPA is the permitting authority, and the erosion and sediment control provisions increase the level of environmental protection for all affected populations.

VIII. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

In compliance with Executive Order 13175, EPA consulted with tribal officials to gain an understanding of and, where necessary, address the tribal implications of the permit. In the course of this consultation, EPA conducted the following activities:

- August 5, 2015—EPA mailed notification letters to all Tribal leaders, initiating consultation and coordination on the draft 2017 CGP. The consultation period was from August 17, 2015 to October 13, 2015.

- August 11, 2015—EPA presented a brief overview of the 2012 CGP and information regarding the upcoming consultation to the National Tribal Caucus.

- August 12, 2015—EPA presented a brief overview of the 2012 CGP and information regarding the upcoming consultation to the National Tribal Water Council.

- September 22, 2015—EPA held a consultation teleconference call; 18 Tribes were represented. EPA responded to the general questions raised on the call.

- On October 14, 2015, EPA received one set of comments from a Tribe in the State of Washington. EPA evaluated and considered the comments during the finalization of the 2017 CGP; EPA responded to the formal comments submitted in writing during the comment period in the Agency's final action.

- EPA will provide email notification to Tribes of today's final 2017 CGP.

EPA also notes that as part of the finalization of 2017 CGP, it completed the Section 401 certification procedures with all applicable tribes where the 2017 CGP applies (see Appendix B).

Authority: Clean Water Act, 33 U.S.C. 1251 *et seq.*

Dated: January 11, 2017.

Deborah Szaro,

Acting Regional Administrator, EPA Region 1.

Dated: January 11, 2017.

Javier Laureano,

Director, Clean Water Division, EPA Region 2.

Dated: January 11, 2017.

Jose C. Font,

Acting Director, Caribbean Environmental Protection Division, EPA Region 2.

Dated: January 11, 2017.

Dominique Lueckenhoff,

Acting Director, Water Protection Division, EPA Region 3.

Dated: January 11, 2017.

César A. Zapata,

Deputy Director, Water Protection Division, EPA Region 4.

Dated: January 11, 2017.

Christopher Korleski,

Director, Water Division, EPA Region 5.

Dated: January 11, 2017.

William K. Honker,

Director, Water Division, EPA Region 6.

Dated: January 11, 2017.

Karen Flournoy,

Director, Water, Wetlands, and Pesticides Division, EPA Region 7.

Dated: January 11, 2017.

Darcy O'Connor,

Assistant Regional Administrator, Office of Water Protection, EPA Region 8.

Dated: January 11, 2017.

Kristin Gullatt,

Deputy Director, Water Division, EPA Region 9.

Dated: January 11, 2017.

Daniel D. Opalski,

Director, Office of Water and Watersheds, EPA Region 10.

[FR Doc. 2017-01231 Filed 1-18-17; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2016-0181; FRL-9958-63-OAR]

California State Nonroad Engine Pollution Control Standards; Evaporative Emission Standards and Test Procedures for Off-Highway Recreational Vehicles (OHRVs); Notice of Decision

AGENCY: Environmental Protection Agency.

ACTION: Notice of decision.

SUMMARY: The Environmental Protection Agency ("EPA") is granting the California Air Resources Board ("CARB") its request for an authorization of its amendments to its Off-Highway Recreational Vehicle regulation ("OHRV Amendments"). The OHRV Amendments establish new evaporative emission standards and test procedures for 2018 and subsequent model year OHRVs. The California OHRV category encompasses a wide variety of vehicles, including off-road motorcycles, all-terrain vehicles ("ATVs"), off-road sport and utility vehicles, sand cars, and golf carts. This decision is issued under the authority of the Clean Air Act ("CAA" or "Act").

DATES: Petitions for review must be filed by March 20, 2017.

ADDRESSES: EPA has established a docket for this action under Docket ID EPA-HQ-OAR-2016-0181. All documents relied upon in making this decision, including those submitted to EPA by CARB, are contained in the public docket. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the Air and Radiation Docket in the EPA Headquarters Library, EPA West Building, Room 3334, located at 1301 Constitution Avenue NW., Washington, DC. The Public Reading Room is open to the public on all federal government working days from 8:30 a.m. to 4:30 p.m.; generally, it is open Monday through Friday, excluding holidays. The telephone number for the Reading Room

is (202) 566-1744. The Air and Radiation Docket and Information Center's Web site is <http://www.epa.gov/oar/docket.html>. The electronic mail (email) address for the Air and Radiation Docket is: a-and-r-Docket@epa.gov, the telephone number is (202) 566-1742, and the fax number is (202) 566-9744. An electronic version of the public docket is available through the federal government's electronic public docket and comment system. You may access EPA dockets at <http://www.regulations.gov>. After opening the www.regulations.gov Web site, enter EPA-HQ-OAR-2016-0181 in the "Enter Keyword or ID" fill-in box to view documents in the record. Although a part of the official docket, the public docket does not include Confidential Business Information ("CBI") or other information whose disclosure is restricted by statute.

EPA's Office of Transportation and Air Quality ("OTAQ") maintains a Web page that contains general information on its review of California waiver and authorization requests. Included on that page are links to prior waiver **Federal Register** notices, some of which are cited in today's notice. The page can be accessed at <http://www.epa.gov/otaq/cafr.htm>.

FOR FURTHER INFORMATION CONTACT:

David Dickinson, Attorney-Advisor, Transportation Climate Division, Office of Transportation and Air Quality, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, (6405J), NW., Washington, DC 20460. Telephone: (202) 343-9256. Fax: (202) 343-2800. Email: Dickinson.David@epa.gov.

I. Background

CARB first adopted exhaust emission standards and test procedures applicable to OHRVs and the engines used in OHRVs in 1994, and EPA authorized California to enforce such standards and test procedures in 1996.¹ CARB subsequently adopted amendments to the OHRV regulation in 1996, 1999, 2003, and 2007, and EPA determined those amendments either fell within the scope of previously granted authorizations or met the criteria for a new authorization.²

In 2002, EPA adopted regulations that established both exhaust and evaporative emission standards for nonroad recreational vehicles and engines, including off-road motorcycles

and ATVs.³ EPA's evaporative emission standards applied to 2008 and subsequent model year nonroad recreational vehicles, and established a fuel tank permeation limit of 1.5 grams per square meter per day (g/m²/day) and a fuel hose permeation limit of 15 g/m²/day. Correspondingly, CARB's 2007 amendments to their OHRV regulation set forth, among other provisions, evaporative emission standards for new 2008 and subsequent model year OHRVs that are identical to the federal evaporative emission standards for 2008 and subsequent model year nonroad vehicles. In 2014, CARB adopted the OHRV Amendments that establish a new test procedure and evaporative emission standard of 1.0 gram per day (g/day) of total organic gas (TOG) for a 3-day diurnal period.⁴

A. CARB's Authorization Request

In a letter dated February 26, 2016, CARB submitted to EPA its request pursuant to section 209(e) of the CAA, regarding authorization of its OHRV Amendments.⁵ The CARB Board approved the OHRV Amendments on July 25, 2013 (by Resolution 13-33).⁶ The OHRV Amendments were approved by California's Office of Administrative Law (OAL) on December 17, 2014 and became operative state law on April 1, 2015.

The OHRV Amendments differ from preexisting OHRV requirements because they impose a 1.0 g/day evaporative emissions standard for the complete OHRV fuel system. Previously the OHRV regulation only required fuel tanks and fuel hoses to meet specific permeation standards. The OHRV Amendments comprehensively address all potential sources of evaporative emissions, including running losses (evaporative emissions generated during vehicle operation), hot soak (evaporative emission generated directly after vehicle operation), and diurnal losses (evaporative emissions generated during long term storage). The OHRV

³ 67 FR 68242 (November 8, 2002). The terms "off-road" and "nonroad" are used interchangeably, generally CARB uses the term off-road and EPA uses the term nonroad.

⁴ CARB's regulatory text enacted by the OHRV Amendments (which EPA is authorizing by this action), is set forth in California Code of Regulations, Title 13, sections 2416, 2417, 2418, 2419, 2419.1, 2419.2, 3419.3, and 2419.4. A full description of the OHRV Amendments is found in CARB's Authorization Request Support Document, 2014 Amendments to Evaporative Emissions Control Requirements for Off Highway Recreational Vehicles, dated February 26, 2016 ("Authorization Request Support Document") at EPA-HQ-OAR-2016-0181-0002.

⁵ Authorization Request Support Document.

⁶ CARB Resolution 13-33, July 25, 2013, EPA-HQ-OAR-2016-0181-0006.

¹ 61 FR 69093 (December 3, 1996).

² 65 FR 69673 (November 20, 2000) [1996 amendments]; 79 FR 6584 (February 14, 2014) [1999, 2003, and 2007 amendments].

Amendments establish diurnal and fuel system leakage standards and associated test procedures for new 2018 and subsequent model year OHRVs. In addition, the OHRV Amendments establish durability test procedures and other test procedure provisions for preconditioning evaporative emission control systems and components, running loss and hot soak preconditioning tests, and test procedures for the 72-hour and steady-state diurnal tests. Finally, the OHRV Amendments include many of CARB's general compliance provisions, including among other provisions: Annual certification of the evaporative emission control systems, the applicability of the in-use recall provisions that CARB previously adopted for OHRVs in 1994, and emissions warranty requirements.⁷

B. Clean Air Act Nonroad Engine and Vehicle Authorizations

Section 209(e)(1) of the Act permanently preempts any state, or political subdivision thereof, from adopting or attempting to enforce any standard or other requirement relating to the control of emissions for certain new nonroad engines or vehicles.⁸ For all other nonroad engines, states generally are preempted from adopting and enforcing standards and other requirements relating to the control of emissions. Section 209(e)(2), however, requires the Administrator, after notice and opportunity for public hearing, to authorize California to adopt and enforce standards and other requirements relating to the control of emissions from such vehicles or engines if California determines that California standards will be, in the aggregate, at least as protective of public health and welfare as applicable Federal standards. However, EPA shall not grant such authorization if it finds that (1) the determination of California is arbitrary and capricious; (2) California does not need such California standards to meet compelling and extraordinary conditions; or (3) California standards and accompanying enforcement

procedures are not consistent with [CAA section 209].⁹

On July 20, 1994, EPA promulgated a rule interpreting the three criteria set forth in section 209(e)(2)(A) that EPA must consider before granting any California authorization request for nonroad engine or vehicle emission standards.¹⁰ EPA revised these regulations in 1997.¹¹ As stated in the preamble to the 1994 rule, EPA historically has interpreted the consistency inquiry under the third criterion, outlined above and set forth in section 209(e)(2)(A)(iii), to require, at minimum, that California standards and enforcement procedures be consistent with section 209(a), section 209(e)(1), and section 209(b)(1)(C) of the Act.¹²

In order to be consistent with section 209(a), California's nonroad standards and enforcement procedures must not apply to new motor vehicles or new motor vehicle engines. To be consistent with section 209(e)(1), California's nonroad standards and enforcement procedures must not attempt to regulate engine categories that are permanently preempted from state regulation. To determine consistency with section 209(b)(1)(C), EPA typically reviews nonroad authorization requests under the same "consistency" criteria that are applied to motor vehicle waiver requests under section 209(b)(1)(C). That provision provides that the Administrator shall not grant California a motor vehicle waiver if she finds that California "standards and accompanying enforcement procedures

are not consistent with section 202(a)" of the Act. Previous decisions granting waivers and authorizations have noted that state standards and enforcement procedures will be found to be inconsistent with section 202(a) if (1) there is inadequate lead time to permit the development of the necessary technology, giving appropriate consideration to the cost of compliance within that time,¹³ or (2) the federal and state testing procedures impose inconsistent certification requirements.¹⁴

In light of the similar language in sections 209(b) and 209(e)(2)(A), EPA has reviewed California's requests for authorization of nonroad vehicle or engine standards under section 209(e)(2)(A) using the same principles that it has historically applied in reviewing requests for waivers of preemption for new motor vehicle or new motor vehicle engine standards under section 209(b).¹⁵ These principles include, among other things, that EPA should limit its inquiry to the three specific authorization criteria identified in section 209(e)(2)(A),¹⁶ and that EPA should give substantial deference to the policy judgments California has made in adopting its regulations. In previous waiver decisions, EPA has stated that Congress intended EPA's review of California's decision-making be narrow. EPA has rejected arguments that are not specified in the statute as grounds for denying a waiver:

The law makes it clear that the waiver requests cannot be denied unless the specific findings designated in the statute can properly be made. The issue of whether a proposed California requirement is likely to result in only marginal improvement in California air quality not commensurate with its costs or is otherwise an arguably unwise exercise of regulatory power is not legally pertinent to my decision under section 209, so long as the California requirement is consistent with section 202(a) and is more stringent than applicable Federal requirements in the sense that it may result in some further reduction in air pollution in California.¹⁷

¹³ H. Rep. No. 728, 90th Cong., 1st Sess. 21 (1967).

¹⁴ S. Rep. No. 403, 90th Cong., 1st Sess. 32 (1967).

¹⁵ See *Engine Manufacturers Association v. EPA*, 88 F.3d 1075, 1087 (D.C. Cir. 1996): "... EPA was within the bounds of permissible construction in analogizing § 209(e) on nonroad sources to § 209(a) on motor vehicles."

¹⁶ See EPA's Final 209(e) rulemaking at 59 FR 36969, 36983 (July 20, 1994).

¹⁷ "Waiver of Application of Clean Air Act to California State Standards," 36 FR 17458 (Aug. 31, 1971). Note that the more stringent standard expressed here, in 1971, was superseded by the 1977 amendments to section 209, which established that California must determine that its standards are, in the aggregate, at least as protective of public

Continued

⁷ See Authorization Request Support Document at 8–10 for a complete list of provisions.

⁸ States are expressly preempted from adopting or attempting to enforce any standard or other requirement relating to the control of emissions from new nonroad engines which are used in construction equipment or vehicles or used in farm equipment or vehicles and which are smaller than 175 horsepower. Such express preemption under section 209(e)(1) of the Act also applies to new locomotives or new engines used in locomotives. CAA § 209(e)(1), 42 U.S.C. 7543(e)(1)(A).

⁹ EPA's review of California regulations under section 209 is not a broad review of the reasonableness of the regulations or its compatibility with all other laws. Sections 209(b) and 209(e) of the Clean Air Act limit EPA's authority to deny California requests for waivers and authorizations to the three criteria listed therein. As a result, EPA has consistently refrained from denying California's requests for waivers and authorizations based on any other criteria. In instances where the U.S. Court of Appeals has reviewed EPA decisions declining to deny waiver requests based on criteria not found in section 209(b), the Court has upheld and agreed with EPA's determination. See *Motor and Equipment Manufacturers Ass'n v. Nichols*, 142 F.3d 449, 462–63, 466–67 (D.C. Cir. 1998), *Motor and Equipment Manufacturers Ass'n v. EPA*, 627 F.2d 1095, 1111, 1114–20 (D.C. Cir. 1979). See also 78 FR 58090, 58120 (September 20, 2013).

¹⁰ See "Air Pollution Control; Preemption of State Regulation for Nonroad Engine and Vehicle Standards," 59 FR 36969 (July 20, 1994).

¹¹ See "Control of Air Pollution: Emission Standards for New Nonroad Compression-Ignition Engines at or Above 37 Kilowatts; Preemption of State Regulation for Nonroad Engine and Vehicle Standards; Amendments to Rules," 62 FR 67733 (December 30, 1997). The applicable regulations are now found in 40 CFR part 1074, subpart B, section 1074.105.

¹² 59 FR 36969 (July 20, 1994). EPA has interpreted 209(b)(1)(C) in the context of section 209(b) motor vehicle waivers.

This principle of narrow EPA review has been upheld by the U.S. Court of Appeals for the District of Columbia Circuit.¹⁸ Thus, EPA's consideration of all the evidence submitted concerning an authorization decision is circumscribed by its relevance to those questions that may be considered under section 209(e)(2)(A).

C. Deference to California

In previous waiver and authorization decisions, EPA has recognized that the intent of Congress in creating a limited review based on the section 209(b)(1) criteria was to ensure that the federal government did not second-guess state policy choices. As the agency explained in one prior waiver decision:

It is worth noting . . . I would feel constrained to approve a California approach to the problem which I might also feel unable to adopt at the federal level in my own capacity as a regulator. The whole approach of the Clean Air Act is to force the development of new types of emission control technology where that is needed by compelling the industry to "catch up" to some degree with newly promulgated standards. Such an approach . . . may be attended with costs, in the shape of reduced product offering, or price or fuel economy penalties, and by risks that a wider number of vehicle classes may not be able to complete their development work in time. Since a balancing of these risks and costs against the potential benefits from reduced emissions is a central policy decision for any regulatory agency under the statutory scheme outlined above, I believe I am required to give very substantial deference to California's judgments on this score.¹⁹

Similarly, EPA has stated that the text, structure, and history of the California waiver provision clearly indicate both a congressional intent and appropriate EPA practice of leaving the decision on "ambiguous and controversial matters of public policy" to California's judgment.²⁰ This interpretation is supported by relevant discussion in the House Committee Report for the 1977 amendments to the Clean Air Act.²¹ Congress had the opportunity through the 1977 amendments to restrict the preexisting

waiver provision, but elected instead to expand California's flexibility to adopt a complete program of motor vehicle emission controls. The report explains that the amendment is intended to ratify and strengthen the preexisting California waiver provision and to affirm the underlying intent of that provision, that is, to afford California the broadest possible discretion in selecting the best means to protect the health of its citizens and the public welfare.²²

D. Burden and Standard of Proof

As the U.S. Court of Appeals for the D.C. Circuit has made clear in *MEMA I*, opponents of a waiver request by California bear the burden of showing that the statutory criteria for a denial of the request have been met:

[T]he language of the statute and its legislative history indicate that California's regulations, and California's determinations that they must comply with the statute, when presented to the Administrator are presumed to satisfy the waiver requirements and that the burden of proving otherwise is on whoever attacks them. California must present its regulations and findings at the hearing and thereafter the parties opposing the waiver request bear the burden of persuading the Administrator that the waiver request should be denied.²³

The same logic applies to authorization requests. The Administrator's burden, on the other hand, is to make a reasonable evaluation of the information in the record in coming to the waiver decision. As the court in *MEMA I* stated: "here, too, if the Administrator ignores evidence demonstrating that the waiver should not be granted, or if he seeks to overcome that evidence with unsupported assumptions of his own, he runs the risk of having his waiver decision set aside as 'arbitrary and capricious.'" ²⁴ Therefore, the Administrator's burden is to act "reasonably."²⁵

With regard to the standard of proof, the court in *MEMA I* explained that the Administrator's role in a section 209 proceeding is to:

[. . .] consider all evidence that passes the threshold test of materiality and . . . thereafter assess such material evidence against a standard of proof to determine whether the parties favoring a denial of the waiver have shown that the factual circumstances exist in which Congress intended a denial of the waiver.²⁶

With regard to the protectiveness finding, the court upheld the Administrator's position that, to deny a waiver, there must be "clear and compelling evidence" to show that proposed enforcement procedures undermine the protectiveness of California's standards.²⁷ The court noted that this standard of proof also accords with the congressional intent to provide California with the broadest possible discretion in setting regulations it finds protective of the public health and welfare.²⁸

With respect to the consistency finding, the court did not articulate a standard of proof applicable to all proceedings, but found that the opponents of the waiver were unable to meet their burden of proof even if the standard were a mere preponderance of the evidence. EPA's past waiver decisions have consistently made clear that: "[E]ven in the two areas concededly reserved for Federal judgment by this legislation—the existence of 'compelling and extraordinary' conditions and whether the standards are technologically feasible—Congress intended that the standards of EPA review of the State decision to be a narrow one."²⁹

E. EPA's Administrative Process in Consideration of California's Commercial Harbor Craft Regulations

Upon review of CARB's request, EPA offered an opportunity for a public hearing, and requested written comment on issues relevant to a section 209(e)(2)(A) authorization analysis, by publication of a **Federal Register** notice on August 9, 2016.³⁰ Specifically, we requested comment on: (a) Whether CARB's determination that its standards, in the aggregate, are at least as protective of public health and welfare as applicable federal standards is arbitrary and capricious, (b) whether California needs such standards to meet compelling and extraordinary conditions, and (c) whether California's standards and accompanying enforcement procedures are consistent with section 209 of the Act.

EPA did not receive a request for hearing and therefore no hearing was held. EPA did not receive any written comments. EPA's evaluation is based on the record, which includes CARB's authorization request and accompanying documents.

health and welfare as applicable Federal standards. In the 1990 amendments to section 209, Congress established section 209(e) and similar language in section 209(e)(1)(i) pertaining to California's nonroad emission standards which California must determine to be, in the aggregate, at least as protective of public health and welfare as applicable federal standards.

¹⁸ See, e.g., *Motor and Equip. Mfrs. Assoc. v. EPA*, 627 F.2d 1095 (D.C. Cir. 1979) ("*MEMA I*"), *Ford Motor Co. v. EPA*, 606 F.2d 1293, 1300 (D.C. Cir. 1979).

¹⁹ 40 FR 23102, 23103–23104 (May 28, 1975).

²⁰ *Id.* at 23104; 58 FR 4166 (January 13, 1993).

²¹ *MEMA I*, 627 F.2d at 1110 (citing H.R. Rep. No. 294, 95th Cong., 1st Sess. 301–302 (1977)).

²² *Id.*

²³ *MEMA I*, *supra* note 17, at 1121.

²⁴ *Id.* at 1126.

²⁵ *Id.* at 1126.

²⁶ *Id.* at 1122.

²⁷ *Id.*

²⁸ *Id.*

²⁹ See, e.g., "California State Motor Vehicle Pollution Control Standards; Waiver of Federal Preemption," 40 FR 23102 (May 28, 1975), at 23103.

³⁰ 81 FR 52684 (August 9, 2014).

II. Discussion

A. California's Protectiveness Determination

Section 209(e)(2)(i) of the Act instructs that EPA cannot grant an authorization if the agency finds that CARB was arbitrary and capricious in its determination that its standards are, in the aggregate, at least as protective of public health and welfare as applicable federal standards. CARB's Board made a protectiveness determination in Resolution 13–33, declaring that “the Amendments approved for adoption herein will not cause California emission standards, in the aggregate, to be less protective of public health and welfare than applicable federal standards.”³¹ CARB asserts that EPA has no basis to find that the CARB Board's determination is arbitrary or capricious.³² CARB notes that EPA's existing evaporative emission standards for 2008 and subsequent model year nonroad recreational vehicles and engines solely consist of permeation evaporative emission standards applicable to fuel tanks and fuel hoses. Conversely, CARB notes that the OHRV Amendments provide for more comprehensive control of the evaporative emission system. CARB projects the OHRV Amendments will reduce OHRV evaporative emissions by over 70 percent as compared to current model-year vehicles, and are therefore clearly, in the aggregate, at least as protective of the public health and welfare as applicable federal standards.

After evaluating the materials submitted by CARB, and since EPA has not adopted any comparable standards or requirements for OHRVs, and based on the lack of any comments submitted to the record, I cannot find that CARB's protectiveness determination is arbitrary and capricious and thus I cannot deny CARB's authorization request based on this criterion.

B. Need for California Standards To Meet Compelling and Extraordinary Conditions

Section 209(e)(2)(A)(ii) of the Act instructs that EPA cannot grant an authorization if the agency finds that California “does not need such California standards to meet compelling and extraordinary conditions.” EPA's inquiry under this second criterion (found both in paragraph 209(b)(1)(B) and 209(e)(2)(A)(ii)) has been to determine whether California needs its own mobile source pollution program

(i.e. set of standards) for the relevant class or category of vehicles or engines (e.g., on-highway mobile source or nonroad mobile source) to meet compelling and extraordinary conditions, and not whether the specific standards that are the subject of the authorization or waiver request are necessary to meet such conditions.³³

California has asserted its longstanding position that the State continues to need its own nonroad engine program to meet serious air pollution problems.³⁴ CARB notes that “California, and particularly the South Coast and San Joaquin Valley Air Basins, continue to experience some of the worst air quality in the nation and continue to be in non-attainment with national ambient air quality standards for fine particulate matter (“PM_{2.5}”) and ozone. The unique geographical and climatic conditions, and the tremendous growth in on and off-road vehicle population and use that moved Congress to authorize California to establish separate on-road motor vehicle standards in 1967 and off-road engine standards in 1990 still exists today.”³⁵

There has been no evidence submitted to indicate that California's compelling and extraordinary conditions do not continue to exist. California, including the South Coast and the San Joaquin Valley air basins, continues to experience some of the worst air quality in the nation and continues to be in non-attainment with national ambient air quality standards for PM_{2.5} and ozone.³⁶ In addition, EPA is not aware of any other information that would suggest that California no longer needs its nonroad emission program.

Therefore, based on the record of this request and absence of comments or other information to the contrary, I cannot find that California does not continue to need such state standards, including the OHRV Amendments, to address the “compelling and extraordinary conditions” underlying

the state's air pollution problems. I have determined that I cannot deny California authorization for its OHRV Amendments based on the section 209(e)(2)(A)(ii) criterion.

C. Consistency With Section 209 of the Clean Air Act

Section 209(e)(2)(A)(iii) of the Act instructs that EPA cannot grant an authorization if California's standards and enforcement procedures are not consistent with “this section.” As described above, EPA's section 209(e) rule states that the Administrator shall not grant authorization to California if she finds (among other tests) that the “California standards and accompanying enforcement procedures are not consistent with section 209.” EPA has interpreted this requirement to mean that California standards and accompanying enforcement procedures must be consistent with at least sections 209(a), 209(e)(1), and 209(b)(1)(C), as EPA has interpreted this last subsection in the context of motor vehicle waivers. Thus, this can be viewed as a three-pronged test.

1. Consistency With Section 209(a) and 209(e)(1)

To be consistent with section 209(a) of the Clean Air Act, California's OHRV Amendments (and CARB's underlying OHRV regulation) must not apply to new motor vehicles or new motor vehicle engines. California's OHRV regulation applies to a wide variety of vehicles, including off-road motorcycles, ATVs, off-road sport and utility vehicles, sand cars, and golf carts. CARB states that the OHRV Amendments, much like the previously authorized OHRV regulation, do not apply to the categories of preempted mobile sources. No commenter presented otherwise, and EPA is not otherwise aware of any contrary evidence; therefore, EPA cannot deny California's request on the basis that California's OHRV regulation (including the OHRV Amendments) is not consistent with section 209(a).

To be consistent with section 209(e)(1) of the Clean Air Act, California's OHRV regulation must not affect new farming or construction vehicles or engines that are below 175 horsepower, or new locomotives or their engines. CARB presents that OHRV engines are not used in locomotives and are not primarily used in farm and construction equipment or vehicles. No commenter presented otherwise, and EPA is not otherwise aware of any contrary evidence; therefore, I cannot deny California's request on the basis that California's OHRV regulation

³¹ Authorization Request Support Document at 11.

³² *Id.* at 12.

³³ See 74 FR 32744, 32761 (July 8, 2009); 49 FR 18887–18890 (May 3, 1984).

³⁴ See *Authorization Request Support Document* at p. 12, referencing CARB Board Resolution 13–33.

³⁵ *Id.* See 74 FR 32744, 32762–32763 (July 8, 2009); 79 FR 6584, 6588–6590 (February 4, 2014).

³⁶ 74 FR 32744, 32762–63 (July 8, 2009), 76 FR 77515, 77518 (December 13, 2011), 81 FR 95982 (December 29, 2016). EPA continually evaluates the air quality conditions in the United States, including California. California continues to experience some of the worst air quality in the country and continues to be in nonattainment with National Ambient Air Quality Standards for fine particulate matter and ozone, see “Notice of Availability of the Environmental Protection Agency's Preliminary Interstate Ozone Transport Modeling Data for the 2015 Ozone National Ambient Air Quality Standard (NAAQS)” at EPA–HQ–OAR–2016–0751.

(including the OHRV Amendments) is not consistent with section 209(e)(1).

2. Consistency With Section 209(b)(1)(C)

The requirement that California's standards be consistent with section 209(b)(1)(C) of the Clean Air Act effectively requires consistency with section 202(a) of the Act. California standards are inconsistent with section 202(a) of the Act if there is inadequate lead-time to permit the development of technology necessary to meet those requirements, giving appropriate consideration to the cost of compliance within that time. California's accompanying enforcement procedures would also be inconsistent with section 202(a) if the federal and California test procedures were not consistent. The scope of EPA's review of whether California's action is consistent with section 202(a) is narrow. The determination is limited to whether those opposed to the authorization or waiver have met their burden of establishing that California's standards are technologically infeasible, or that California's test procedures impose requirements inconsistent with the federal test procedure.³⁷

Congress has stated that the consistency requirement of section 202(a) relates to technological feasibility.³⁸ Section 202(a)(2) states, in part, that any regulation promulgated under its authority "shall take effect after such period as the Administrator finds necessary to permit the development and application of the requisite technology, giving appropriate consideration to the cost of compliance within such period." Section 202(a) thus requires the Administrator to first determine whether adequate technology already exists; or if it does not, whether there is adequate time to develop and apply the technology before the standards go into effect. The latter scenario also requires the Administrator to decide whether the cost of developing and applying the technology within that time is feasible. Previous EPA waivers are in accord with this position.³⁹

CARB states that its Staff Report explains the technology needed to comply with the primary diurnal evaporative emission standards and that such technology clearly exists as it is being used by manufacturers of on-road mobile sources.⁴⁰ In addition, CARB

states that it received no comments indicating that the requirements to comply with the new evaporative emission standards was technically infeasible.⁴¹ As described in the Staff Report, CARB identified (but did not prescribe) technologies that have been successfully employed in the automotive sector and that are expected to be utilized in OHRVs. These technologies include: Low permeation materials to be utilized in fuel tanks and fuel lines, activated carbon canisters to control diurnal emissions by capturing hydrocarbons that would otherwise be vented when the fuel system heats up during engine operation or storage, pressure relief valves on the vent of the fuel tank, strategic placement or insulation of the fuel tank so the tank is not affected by large temperature increases, and improvements in connectors, carburetors and fuel injectors.⁴² CARB also identifies roll-over values presently used in on-road motorcycles to meet the fuel system leakage test and notes that the ATV fuel filler neck compatibility requirement presents no issue since the fuel pipe sealing specification is identical to on-road motor vehicles.⁴³

With regard to test procedure consistency, CARB states that the OHRV Amendments present no issue of incompatibility between California and federal test procedures since there are no analogous federal standards or associated test procedures applicable to 2018 and subsequent model year nonroad recreational vehicles and engines.⁴⁴

EPA did not receive any comments that suggests California's OHRV Amendments regulations are technologically infeasible. In addition, EPA believes that CARB has reasonably identified, within the lead time provided, the types of technologies that can be used to meet the OHRV Amendments. EPA is not otherwise aware of any evidence to suggest such technologies cannot be employed in the manner CARB has identified. In addition, EPA finds no basis to determine that CARB's test procedures are incompatible with federal test procedures given the lack of applicable federal evaporative emission standards and test procedures.

Therefore, based on the record before us, I cannot find that the OHRV Amendments are technologically

infeasible or otherwise inconsistent with section 202(a). Therefore, I cannot deny CARB's authorization based on the section 202(a) criterion.

III. Decision

After evaluating California's OHRV Amendments and CARB's submissions for EPA review as described above, I am granting an authorization for the OHRV Amendments.

This decision will affect not only persons in California, but also manufacturers and/or owners/operators nationwide who must comply with California's requirements. In addition, because other states may adopt California's standards for which a section 209(e)(2)(A) authorization has been granted if certain criteria are met, this decision would also affect those states and those persons in such states. See CAA section 209(e)(2)(B). For these reasons, EPA determines and finds that this is a final action of national applicability, and also a final action of nationwide scope or effect for purposes of section 307(b)(1) of the Act. Pursuant to section 307(b)(1) of the Act, judicial review of this final action may be sought only in the United States Court of Appeals for the District of Columbia Circuit. Petitions for review must be filed by March 20, 2017. Judicial review of this final action may not be obtained in subsequent enforcement proceedings, pursuant to section 307(b)(2) of the Act.

IV. Statutory and Executive Order Reviews

As with past authorization and waiver decisions, this action is not a rule as defined by Executive Order 12866. Therefore, it is exempt from review by the Office of Management and Budget as required for rules and regulations by Executive Order 12866.

In addition, this action is not a rule as defined in the Regulatory Flexibility Act, 5 U.S.C. 601(2). Therefore, EPA has not prepared a supporting regulatory flexibility analysis addressing the impact of this action on small business entities.

Further, the Congressional Review Act, 5 U.S.C. 801, *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule for purposes of 5 U.S.C. 804(3).

Dated: January 11, 2017.

Gina McCarthy,
Administrator.

[FR Doc. 2017-01259 Filed 1-18-17; 8:45 am]

BILLING CODE 6560-50-P

³⁷ *MEMA I*, 627, F.2d at 1126.

³⁸ H.R. Rep. No. 95-294, 95th Cong., 1st Sess. 301 (1977).

³⁹ See, e.g., 49 FR 1887, 1895 (May 3, 1984); 43 FR 32182, 32183 (July 25, 1978); 41 FR 44209, 44213 (October 7, 1976).

⁴⁰ Authorization Request Support Document at 14, citing "CARB Staff Report: Initial Statement of

Reasons for Proposed Regulation," dated June 5, 2013. EPA-HQ-OAR-2016-0181-0004.

⁴¹ *Id.*

⁴² *Id.* at 14-15.

⁴³ *Id.* at 15-16.

⁴⁴ *Id.* at 16-17.

ENVIRONMENTAL PROTECTION AGENCY**[EPA-HQ-OPPT-2017-0002; FRL-9958-33]****Risk Evaluation Scoping Efforts Under TSCA for Ten Chemical Substances; Notice of Public Meeting****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice.

SUMMARY: EPA will hold a public meeting to receive input and information to assist the Agency in its efforts to establish the scope of risk evaluations under development for the ten chemical substances designated on December 19, 2016 for risk evaluations pursuant to the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. In particular, EPA is providing the public an opportunity to identify information specifically related to the conditions of use for the ten chemical substances (*i.e.*, the circumstances under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of). EPA plans to use this information as it develops the scoping documents for the TSCA risk evaluations of the ten chemical substances; these scoping documents must be issued within six months of the **Federal Register** notice that designated the chemical substances for a TSCA risk evaluation (*i.e.*, for these ten chemical substances, the scoping documents must be issued by June 19, 2017).

DATES: *Meeting Date.* The meeting will be held on February 14, 2017 from 9:00 a.m. to 3:00 p.m.

To request accommodation of a disability, please contact the meeting logistics person listed under **FOR FURTHER INFORMATION CONTACT**, preferably by February 3, 2017, to give EPA as much time as possible to process your request.

Meeting Registration. You may register online (preferred) or in person at the meeting. To register online, for the meeting, go to: <https://tscachemicaluse.eventbrite.com>. Advance registration for the meeting must be completed no later than February 10, 2017. On-site registration will be permitted, but seating and speaking priority will be given to those who pre-register by the deadline.

Comments. EPA will hear oral comments at the meeting, and will accept written comments and materials submitted to the dockets on or before March 1, 2017. For further information

about participation and submitting materials, see Unit IV. under **SUPPLEMENTARY INFORMATION.**

ADDRESSES: *Meeting.* The meeting will be held at the Ronald Reagan Building and International Trade Center, in the Polaris Room, located at 1300 Pennsylvania Avenue Northwest, Washington, DC 20004. The meeting will also be available by remote access for registered participants.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Sheila Canavan, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 566-1978; email address: Canavan.sheila@epa.gov.

For meeting logistics or registration contact: Klara Zimmerman; telephone number: (301) 634-1722; email address: Klara_Zimmerman@abtassoc.com.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information***A. Does this action apply to me?*

You may be potentially affected by this action if you manufacture (defined under TSCA to include import), process, distribute in commerce, use or dispose of any of the ten chemical substances identified for risk evaluation in the **Federal Register** notice published on December 19, 2016, entitled “Designation of Ten Chemical Substances for Initial Risk Evaluations Under the Toxic Substances Control Act” (81 FR 91927). This action may be of particular interest to entities that are regulated under TSCA (*e.g.*, entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110, among others). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

B. How can I get copies of this document and other related information?

The docket for this meeting, identified by docket identification (ID) number EPA-HQ-OPPT-2017-0002, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William

Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

II. Background

EPA is required to conduct chemical risk evaluations under section 6(b) the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment. (15 U.S.C. 2605(b)(4)). Pursuant to TSCA section 6(b)(2)(A), EPA identified ten chemical substances for initial risk evaluations under TSCA in the **Federal Register** notice of December 19, 2016, entitled “Designation of Ten Chemical Substances for Initial Risk Evaluations Under the Toxic Substances Control Act” (81 FR 91927) (FRL-9956-47).

The first step in the risk evaluation process, as outlined in TSCA, is to issue a scoping document for each chemical substance within six months of its designation in the **Federal Register**. TSCA section 6(b)(4)(B) also directs EPA to establish, by a rulemaking promulgated within one year of enactment, a process for conducting risk evaluations, which includes the process for issuing scoping documents. The Agency expects to propose such a procedural rule shortly, which will be applicable to risk evaluations once finalized. However, TSCA directed EPA to concurrently ensure that risk evaluations were being conducted on ten chemical substances by December 19, 2016. As a result, EPA must publish scoping documents for these initial ten chemical substances by June 19, 2017, which is before the procedural rule is expected to be finalized. Accordingly, EPA’s scoping efforts for these ten substances will be based directly on the terms of TSCA section 6(b)(4)(D), and not the pending procedural rulemaking. Each completed scoping document will describe the scope of information about the chemical substance that the Agency expects to consider in the risk evaluation, including its conditions of use, hazards, and exposures, including to potentially exposed or susceptible subpopulations.

At the public meeting, EPA will provide an overview briefing to describe the information the Agency has

obtained thus far relating to the conditions of use for the ten chemical substances. To assist EPA in this scoping process, EPA is providing the public with an opportunity to identify information specifically related to the conditions of use (*i.e.*, the circumstances under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of). EPA plans to use this information as it develops scoping documents for the TSCA risk evaluations for the ten chemical substances.

In view of the statutory deadline to complete these ten risk evaluations, it will be difficult, and may not be possible, for EPA to adjust the scope of the evaluations following release of the scoping document under TSCA section 6(b)(4)(D). In addition, EPA notes that the scoping document is a foundation for determining the scope of preemption arising after final risk evaluations (TSCA section 18(a)(1)(B)). Thus, EPA requests that members of the public provide any available information relating to the scope of the risk evaluations at the February meeting or to the docket by March 1, 2017. EPA will likely not be able to accommodate information as to scope received after that time.

III. Meeting

A. Remote Access

The meeting will be accessible remotely for registered participants. Registered participants will receive information on how to connect remotely to the meeting prior to its start.

B. Public Participation at the Meeting

Anyone may register to attend the meeting as observers and may also register to provide oral comments on the day of the meeting. A registered speaker is encouraged to focus on issues directly relevant to the meeting's subject matter. Each speaker is allowed no more than 5 minutes to provide oral comments. To accommodate as many registered speakers as possible, speakers may present oral comments only, without visual aids or written material.

C. Submitting Written Materials

Anyone may submit written materials to the dockets described in Unit IV.C.

IV. How can I request to participate in this meeting?

A. Registration

To attend the meeting in person or to receive remote access, you must register no later than February 10, 2017, using

one of the methods described under **ADDRESSES**. While on-site registration will be available, seating will be on a first-come, first-served basis, with priority given to early registrants, until room capacity is reached. The Agency anticipates that approximately 125 people will be able to attend the meeting in person. For registrants not able to attend in person, the meeting will also provide remote access capabilities; registered participants will be provided information on how to connect to the meeting prior to its start.

B. Required Registration Information

Members of the public may register to attend as observers or speak if planning to offer oral comments during the scheduled public comment period. To register for the meeting online, you must provide your full name, organization or affiliation, and contact information to the on-line signup or to the meeting registration contact person listed under **FOR FURTHER INFORMATION CONTACT**. Do not submit any information in your request that is considered Confidential Business Information (CBI). Requests to participate in the meeting, identified by docket ID No. EPA-HQ-OPPT-2017-0002, must be received on or before February 10, 2017.

C. Risk Evaluation Dockets for the Ten Chemical Substances

You may also elect to provide information to EPA's dockets for the ten chemical substances for which risk evaluations have begun. EPA has established separate dockets for each of the ten chemical substances for risk evaluation to facilitate receipt of information which may be useful to the Agency's risk evaluations. As noted above, EPA is asking the public for assistance in identifying information specifically related to the conditions of use (*i.e.*, intended, known or reasonably foreseen uses) that would assist the Agency in identifying potential exposure scenarios (pathways, routes and populations). EPA is requesting that any such information be submitted by March 1, 2017.

1,4-Dioxane. Docket ID No.: EPA-HQ-OPPT-2016-0723.

1-Bromopropane. Docket ID No.: EPA-HQ-OPPT-2016-0741.

Asbestos. Docket ID No.: EPA-HQ-OPPT-2016-0736.

Carbon Tetrachloride. Docket ID No.: EPA-HQ-OPPT-2016-0733.

Cyclic Aliphatic Bromide Cluster (Hexabromocyclododecane or HBCD). Docket ID No.: EPA-HQ-OPPT-2016-0735.

Methylene Chloride. Docket ID No.: EPA-HQ-OPPT-2016-0742.

N-Methylpyrrolidone (NMP). Docket ID No.: EPA-HQ-OPPT-2016-0743.

Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e']diisoquinoline-1,3,8,10(2H,9H)-tetrone). Docket ID No.: EPA-HQ-OPPT-2016-0725.

Trichloroethylene (TCE). Docket ID No.: EPA-HQ-OPPT-2016-0737.

Tetrachloroethylene (also known as Perchloroethylene). Docket ID No.: EPA-HQ-OPPT-2016-0732.

Information can be submitted by one of the following methods:

Online using the Federal eRulemaking Portal: <http://www.regulations.gov>.

Follow the online instructions for submitting information or comments. Once submitted, this information cannot be edited or withdrawn. EPA may publish any information received to its public docket. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written statement or information. The written information should include discussion of all points you wish to make. Learn more about CBI or multimedia submissions, and general guidance on making effective comments or providing useful information by visiting EPA's Web site at <https://www.epa.gov/dockets/commenting-epa-dockets>.

Mail: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460-0001.

Hand Delivery: To make special arrangements for hand delivery or delivery of boxed information, please follow instructions at <http://www.epa.gov/dockets/contacts.html>.

Authority: 15 U.S.C. 2605.

Dated: January 12, 2017.

James J. Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2017-01236 Filed 1-18-17; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OW-2016-0686; FRL-9958-49-OW]

Request for Nominations for Peer Reviewers and for Public Comment on Peer Review Materials To Inform the Derivation of a Water Concentration Value for Lead in Drinking Water

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for nominations for peer reviewers and request for public comment.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the release of materials for public comment that relate to the expert external peer review of documents intended to support the EPA's Safe Drinking Water Act assessment of lead in drinking water. EPA invites the public to nominate scientific experts to be considered as peer reviewers for the contract-managed peer review. Nominations of peer review candidates will be accepted by EPA's contractor, Eastern Research Group, Inc. (ERG). EPA also requests public comment on the draft report entitled "Proposed Modeling Approaches for a Health Based Benchmark for Lead in Drinking Water" and the draft charge questions for the expert peer review panel. These materials will be reviewed by an expert peer review panel and public comments will be made available to the peer reviewers for consideration in their review.

DATES: The nominations for expert peer review candidates must be received by ERG on or before February 21, 2017. Comments on the draft lead modeling report and draft peer review panel charge questions must be received by EPA on or before March 6, 2017.

ADDRESSES: Any interested person or organization may nominate scientific experts to be considered as peer reviewers. Nominations should be submitted to ERG no later than February 21, 2017 by one of the following methods:

- *Email:* peerreview@erg.com (subject line: Lead in Drinking Water Peer Review)
- *Mail:* Eastern Research Group, Inc. (ERG), 110 Hartwell Avenue, Lexington, MA 02421, ATTN: Laurie Waite (must arrive by nomination deadline).

Nominations should include all nominee information outlined in section III of the **SUPPLEMENTARY INFORMATION** section of this document.

Submit your comments on the draft lead modeling report and draft charge, identified by Docket ID No. EPA-HQ-OW-2016-0686, to the Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is

restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment content located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT:

Questions concerning nominations of expert peer reviewers should be directed to Eastern Research Group, Inc. (ERG), 110 Hartwell Avenue, Lexington, MA 02421; by email at peerreview@erg.com (subject line: Lead in Drinking Water Peer Review); or by phone: (781) 674-7362 (ask for Laurie Waite).

For additional information concerning the draft lead modeling report and draft peer review charge questions, please contact Erik Helm at the U.S. Environmental Protection Agency, Office of Ground Water and Drinking Water, Standards and Risk Management Division, (Mail Code 4607M), 1200 Pennsylvania Avenue NW., Washington, DC 20460; by phone: 202-566-1049; or by email: helm.erik@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Information on EPA's Lead in Drinking Water Modeling

EPA's Office of Ground Water and Drinking Water is in the process of considering National Primary Drinking Water Regulations for Lead and Copper: Regulatory Revisions (LCR) to improve public health protection by making changes to rule requirements under the Safe Drinking Water Act (SDWA). EPA has engaged with stakeholder groups and the public to inform revisions to the LCR. As part of this work, the EPA's National Drinking Water Advisory Committee (NDWAC) Lead and Copper Rule Working Group was established to inform NDWAC advice to the Administrator on recommendations to strengthen public health protections of the Lead and Copper Rule. In December 2015, the NDWAC provided specific recommendations to the EPA Administrator for LCR revisions related to lead service line replacement, public education, corrosion control treatment, copper, tap sampling, and the establishment of a "household action level." The NDWAC recommended that

water systems be required to notify the consumer and the local public health agency if this level was exceeded, with the expectation that individuals and local health officials will use this information to take prompt actions at the household level to mitigate lead risks.

While EPA has not yet determined the specific role of a household action level in the revised LCR, the Agency has developed potential scientific modeling approaches to define the relationship between lead levels in drinking water and blood lead levels, particularly for sensitive life stages such as formula fed infants and children up to age seven. EPA is using the terminology "health based benchmark" to refer to this concept. EPA is conducting an expert peer review of alternative approaches to inform future consideration of a health based benchmark for the LCR revisions. The purpose of this review is to obtain feedback on various lead modeling methods that can be used to characterize the relationship between lead in drinking water and children's blood lead levels.

EPA has developed three approaches that model how lead in drinking water influences blood lead levels (BLLs) of children. All the approaches use the Integrated Exposure Uptake and Biokinetic (IEUBK) Model for Lead in Children. Approaches 1 and 2 assess the relationship between water lead concentration and potential BLLs at different points in the IEUBK predicted distribution of BLLs. Approach 3 uses EPA's Stochastic Human Exposure and Dose Simulation model for multimedia, multipathway chemicals (SHEDS-Multimedia), coupled with IEUBK, to determine the drinking water lead concentrations that would result in BLLs at particular percentiles of a simulated national distribution of BLLs for children at various ages.

II. How To Obtain the Draft Lead Modeling Report and the Draft Peer Review Charge Questions

EPA's draft lead modeling report entitled "Proposed Modeling Approaches for a Health Based Benchmark for Lead in Drinking Water" and the draft charge for the peer review panel are available electronically and can be accessed using the Public Docket at <http://www.regulations.gov> (Docket ID No. EPA-HQ-OW-2016-0686). All written comments must be submitted during the public comment period.

III. How To Submit Nominations for Peer Reviewers

Expertise sought: EPA is seeking candidates who are nationally and/or

internationally recognized scientific experts to serve as external peer reviewers for the draft report regarding approaches to modeling children's BLL associated with lead in drinking water. The review is not intended to provide EPA with advice on the public health implications of alternative BLLs. As such, EPA is seeking nominees who possess a strong background and demonstrated expertise in one or more of the following areas: (1) Physiologically Based Pharmacokinetic modeling, particularly with regard to lead; (2) environmental lead exposure analyses, particularly with regard probabilistic modeling.

Selection criteria: Selection criteria for individuals nominated to serve as external peer reviewers of the draft report include the following: (1) Demonstrated expertise through relevant peer reviewed publications; (2) professional accomplishments and recognition by professional societies; (3) demonstrated ability to work constructively and effectively in a committee setting; (4) absence of financial conflicts of interest; (5) no actual conflicts of interest or appearance of lack of impartiality; (6) willingness to commit adequate time for the thorough review of the draft report; and (7) availability to participate in-person in a one-day or two-day peer review meeting in the Washington, DC metro area, projected to occur in June 2017 (exact date will be published in the **Federal Register** at least 30 days prior to the external peer review meeting). Further logistical information regarding the external peer review meeting will be announced at a later date in the **Federal Register**.

Required nominee information: To receive full consideration, the following information should be submitted to ERG at peerreview@epa.gov (the subject line should read: Lead in Drinking Water Peer Review): (1) Contact information for the person making the nomination; (2) contact information for the nominee; (3) the disciplinary and specific areas of expertise of the nominee; (4) the nominee's curriculum vitae; and (5) a biographical sketch of the nominee indicating current position, educational background, past and current research activities, recent service on other advisory committees, peer review panels, editorial boards or professional organizations, sources of recent grant and/or contract support and other comments on the relevance of the nominee's expertise to this peer review topic. Compensation for non-federal peer reviewers will be provided by ERG.

Selection process: EPA's contractor, ERG, will notify nominees of selection

or non-selection. ERG may also conduct an independent search for candidates to assemble a balanced group representing the expertise needed to fully evaluate EPA's draft report, entitled "Proposed Modeling Approaches for a Health Based Benchmark for Lead in Drinking Water." ERG will consider and screen all nominees against the criteria previously listed. Following the screening process, ERG will narrow the list of potential reviewers to approximately 10–16 candidates. Prior to selecting the final peer reviewers, a **Federal Register** document will be published (exact date to be determined) to solicit comments on the interim list of candidates. In that document, the public will be requested to provide relevant information or documentation on the nominees within 30 days of the announcement of the interim list of candidates. Once ERG has considered the public comments on the interim list of candidates, ERG will select the final list of peer reviewers, based on who, collectively, will best provide expertise spanning the disciplines previously listed and (to the extent feasible) best provide a balance of perspectives.

Dated: January 10, 2017.

Joel Beauvais,

Deputy Assistant Administrator, Office of Water.

[FR Doc. 2017–01228 Filed 1–18–17; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9958–16–OLEM]

FY2017 Supplemental Funding for Brownfields Revolving Loan Fund (RLF) Grantees

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of the availability of funds.

SUMMARY: The Environmental Protection Agency (EPA) plans to make available approximately \$13 million to provide supplemental funds to Revolving Loan Fund (RLF) capitalization grants previously awarded competitively under section 104(k)(3) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). Brownfields Cleanup Revolving Loan Fund pilots awarded under section 104(d)(1) of CERCLA that have not transitioned to section 104(k)(3) grants are not eligible to apply for these funds. EPA will consider awarding supplemental funding only to RLF grantees who have demonstrated an

ability to deliver programmatic results by making at least one loan or subgrant. The award of these funds is based on the criteria described at CERCLA 104(k)(4)(A)(ii).

The Agency is now accepting requests for supplemental funding from RLF grantees. Requests for funding must be submitted to the appropriate EPA Regional Brownfields Coordinator (listed below) by March 1, 2017. Funding requests for hazardous substances and/or petroleum funding will be accepted. Specific information on submitting a request for RLF supplemental funding is described below and additional information may be obtained by contacting the EPA Regional Brownfields Coordinator.

DATES: This action is effective January 19, 2017.

ADDRESSES: A request for supplemental funding must be in the form of a letter addressed to the appropriate Regional Brownfields Coordinator (see listing below) with a copy to Pankaj Arora, arora.pankaj@epa.gov.

FOR FURTHER INFORMATION CONTACT: Pankaj Arora, U.S. EPA, (202) 566–1388 or the appropriate Brownfields Regional Coordinator.

SUPPLEMENTARY INFORMATION:

Background

The Small Business Liability Relief and Brownfields Revitalization Act added section 104(k) to CERCLA to authorize federal financial assistance for brownfields revitalization, including grants for assessment, cleanup and job training. Section 104(k) includes a provision for EPA to, among other things, award grants to eligible entities to capitalize Revolving Loan Funds and to provide loans and subgrants for brownfields cleanup. Section 104(k)(4)(A)(ii) authorizes EPA to make additional grant funds available to RLF grantees for any year after the year for which the initial grant is made (noncompetitive RLF supplemental funding) taking into consideration:

(I) The number of sites and number of communities that are addressed by the revolving loan fund;

(II) the demand for funding by eligible entities that have not previously received a grant under this subsection;

(III) the demonstrated ability of the eligible entity to use the revolving loan fund to enhance remediation and provide funds on a continuing basis; and

(IV) such other similar factors as the [Agency] considers appropriate to carry out this subsection.

Eligibility

In order to be considered for supplemental funding, grantees must demonstrate that they have significantly depleted funds (both EPA grant funding and any available pre- or post-closeout program income) and that they have a clear plan for quickly utilizing requested additional funds. Grantees must demonstrate that they have made at least one loan or subgrant prior to applying for this supplemental funding and have significantly depleted existing available funds. For FY2017, EPA defines "significantly depleted funds" as \$400,000 or less remaining unliquidated obligations from all of the EPA RLF grant funding and available pre- or post-closeout program income from all the open or closed EPA RLF grants. Additionally, the RLF recipient must have demonstrated a need for supplemental funding based on, among other factors, the number of sites that will be addressed; demonstrated the

ability to make loans and subgrants for cleanups that can be started and completed expeditiously (*i.e.*, "shovel-ready" projects) and will lead to redevelopment; demonstrated the existence of additional leveraged funds to complete the project in a timely manner and move quickly from cleanup to redevelopment, including the use of tax incentives such as new market tax credits, direct funding or other resources to advance the project to completion; demonstrated the ability to administer and revolve the capitalization funding in the RLF grant; demonstrated an ability to use the RLF grant to address funding gaps for cleanup; and demonstrated that they have provided a community benefit from past and potential loan(s) and/or subgrant(s). Special consideration may be given to those communities affected by plant closures or other economic disruptions; can demonstrate projects that have a clear prospect of aiding the

in-sourcing of manufacturing capacity and keeping and/or adding jobs, or otherwise creating jobs, in the affected area; or will benefit a community that has been identified as part of EPA's Cross Agency Strategy on Working to Make a Visible Difference in Communities. EPA encourages innovative approaches to maximizing revolving and leveraging with other funds, including use of grants funds as a loan loss guarantee, combining with other government or private sector lending resources. Applicants for supplemental funding must contact the appropriate Regional Brownfields Coordinator below to obtain information on the format for supplemental funding applications for their region. When requesting supplemental funding, applicants must specify whether they are seeking funding for sites contaminated by hazardous substances or petroleum. Applicants may request both types of funding.

REGIONAL CONTACTS

| Region | States | Address/phone number/email |
|---|---------------------------------|--|
| EPA Region 1, Frank Gardner, Gardner.Frank@epa.gov ... | CT, ME, MA, NH, RI, VT | 5 Post Office Square, Boston, MA 02109-3912, Phone (617) 918-1278, Fax (617) 918-0278. |
| EPA Region 2, Benny Hom, Hom.Benny@epa.gov | NJ, NY, PR, VI | 290 Broadway, 18th Floor, New York, NY 10007, Phone (212) 637-3964, Fax (212) 637-3083. |
| EPA Region 3, Tom Stolle, Stolle.Tom@epa.gov | DE, DC, MD, PA, VA, WV ... | 1650 Arch Street, Mail Code 3HS51, Philadelphia, Pennsylvania 19103-2029, Phone (215) 814-3129, Fax (215) 814-3015. |
| EPA Region 4, Wanda Jennings, Jennings.Wanda@epa.gov . | AL, FL, GA, KY, MS, NC, SC, TN. | Atlanta Federal Center, 61 Forsyth Street SW., 10th Fl., Atlanta, GA 30303-8960, Phone (404) 562-8682, Fax (404) 562-8761. |
| EPA Region 5, Keary Cragan, Cragan.Keary@epa.gov | IL, IN, MI, MN, OH, WI | 77 West Jackson Boulevard, Mail Code SB-5J, Chicago, Illinois 60604-3507, Phone (312) 353-5669, Fax (312) 886-7190. |
| EPA Region 6, Mary Kemp, Kemp.Mary@epa.gov | AR, LA, NM, OK, TX | 1445 Ross Avenue, Suite 1200 (6SF-PB), Dallas, Texas 75202-2733, Phone (214) 665-8358, Fax (214) 665-6660. |
| EPA Region 7, Susan Klein, R7_Brownfields@epa.gov | IA, KS, MO, NE | 11201 Renner Blvd., Lenexa, Kansas 66219, Phone (913) 551-7786, Fax (913) 551-8688. |
| EPA Region 8, Ted Lanzano, Lanzano.Ted@epa.gov | CO, MT, ND, SD, UT, WY ... | 1595 Wynkoop Street (EPR-B), Denver, CO 80202-1129, Phone (303) 312-6596, Fax (303) 312-6065. |
| EPA Region 9, Noemi Emeric-Ford, Emeric-Ford.Noemi@epa.gov . | AZ, CA, HI, NV, AS, GU | 75 Hawthorne Street, WST-8, San Francisco, CA 94105, Phone (213) 244-1821, Fax (415) 972-3364. |
| EPA Region 10, Susan Morales, Morales.Susan@epa.gov | AK, ID, OR, WA | 1200 Sixth Avenue, Suite 900, Mailstop: ECL-112 Seattle, WA 98101, Phone (206) 553-7299, Fax (206) 553-0124. |

Dated: January 3, 2017.

David R. Lloyd,

Director, Office of Brownfields and Land Revitalization, Office of Land and Emergency Management.

[FR Doc. 2017-00448 Filed 1-18-17; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

[WT Docket No. 17-17; DA 17-33]

Acumen Communications

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This document commences a hearing to determine whether Acumen

Communications (Acumen) is qualified to be and to remain a Federal Communications Commission (Commission) licensee, and as a consequence thereof, whether any or all of its licenses should be revoked, and whether any or all of the applications to which Acumen is a party should be denied. As discussed more fully below, based on the totality of the evidence, there are substantial and material questions of fact as to whether Acumen

repeatedly made misrepresentations to and lacked candor with the Commission in its submission of fifty applications in connection with various Wireless Radio Service authorizations.

DATES: Each party to the proceeding (except for the Chief, Enforcement Bureau), in person or by counsel, shall file with the Commission, by January 30, 2017, a written appearance stating that the party will appear on the date fixed for hearing and present evidence on the issues specified herein.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Pamela Kane, Special Counsel, Enforcement Bureau, (202) 418-2393.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order to Show Cause, Hearing Designation Order and Notice of Opportunity for Hearing (Order) in WT Docket No. 17-17, DA 17-33, adopted on January 9, 2017, and released on January 10, 2017. The full text of the Order is available for inspection and copying during regular business hours in the FCC Reference Center, 445 12th Street SW., Room CY-A257, Portals II, Washington, DC 20554. This document is available in alternative formats (computer diskette, large print, audio record, and Braille). Persons with disabilities who need documents in these formats may contact the FCC by email: FCC504@fcc.gov or phone: 202-418-0530 or TTY: 202-418-0432.

Synopsis

1. In this Order, the Commission commences a hearing proceeding before a Commission Administrative Law Judge to determine whether the pending applications of Acumen Communications should be granted, and whether Acumen's licenses should be revoked. Acumen represented to the Commission in fifty (50) license applications that no party directly or indirectly controlling Acumen has ever been convicted of a felony by any state or federal court. The information before us indicates that Hector Manuel Mosquera, a party directly or indirectly controlling Acumen, was convicted of a felony by a state court in California. The evidence further indicates that Mr. Mosquera signed Acumen's applications in which Acumen answered "N" to the felony question.

2. Accordingly, *it is ordered*, pursuant to sections 309(e), 312(a)(1), 312(a)(2), 312(a)(4), and 312(c) of the Act, 47 U.S.C. 309(e), 312(a)(1), 312(a)(2), 312(a)(4), and 312(c), that Acumen Communications shall show cause why

the authorizations for which it is the licensee set forth in Attachment A should not be revoked, and that the above-captioned applications filed by Acumen Communications are designated for hearing in a consolidated proceeding before an FCC

Administrative Law Judge, at a time and place to be specified in a subsequent Order, upon the following issues:

(a) To determine whether Hector Manuel Mosquera directly or indirectly controls Acumen.

(b) To determine whether Acumen engaged in misrepresentation and/or lack of candor in its applications with the Commission.

(c) To determine whether Acumen failed to amend its pending applications, in willful and/or repeated violation of section 1.65 of the Commission's rules.

(d) To determine, in light of the evidence adduced pursuant to the foregoing issues, whether Acumen is qualified to be and remain a Commission licensee.

(e) To determine, in light of the foregoing issues, whether the authorizations for which Acumen is the licensee should be revoked.

(f) To determine, in light of the foregoing issues, whether the captioned applications filed by or on behalf of Acumen should be granted.

3. *It is further ordered that*, in addition to the resolution of the foregoing issues, it shall be determined, pursuant to section 503(b)(1) of the Act, 47 U.S.C. 503(b)(1), whether an *order of forfeiture* should be issued against Acumen in an amount not to exceed the statutory limit for the willful and/or repeated violation of each rule section above for which the statute of limitations in section 503(b)(6) of the Act, 47 U.S.C. 503(b)(6), has not lapsed.

4. *It is further ordered that*, pursuant to section 312(c) of the Act and sections 1.91(c) and 1.221 of the rules, 47 U.S.C. 312(c) and 47 CFR 1.91(c) and 1.221, to avail itself of the opportunity to be heard and to present evidence at a hearing in this proceeding, Acumen, in person or by an attorney, *shall file* with the Commission, within 20 calendar days of the release of this Order, a written appearance stating that it will appear at the hearing and present evidence on the issues specified above.

5. *It is further ordered that*, pursuant to section 1.91 of the rules, 47 CFR 1.91, if Acumen fails to file a timely appearance, its right to a hearing shall be deemed to be waived. In the event the right to a hearing is waived, the Chief Administrative Law Judge (or presiding officer if one has been designated) shall, at the earliest

practicable date, issue an order reciting the events or circumstances constituting a waiver of hearing, terminating the hearing proceeding, and certifying the case to the Commission. In addition, pursuant to section 1.221 of the Commission's rules, 47 CFR 1.221, if any applicant to any of the captioned applications fails to file a timely written appearance, the captioned application shall be dismissed with prejudice for failure to prosecute.

6. *It is further ordered* that the Chief, Enforcement Bureau, shall be made a party to this proceeding without the need to file a written appearance.

7. *It is further ordered* that pursuant to section 312(d) of the Act, 47 U.S.C. 312(d), and section 1.91(d) of the Commission's rules, 47 CFR 1.91(d), the burden of proceeding with the introduction of evidence and the burden of proof shall be upon the Enforcement Bureau as to the issues at 15(a)-(e), above, and that, pursuant to section 309(e) of the Act, 47 U.S.C. 309(e), and section 1.254 of the Commission's rules, 47 CFR 1.254, the burden of proceeding with the introduction of evidence and the burden of proof shall be upon Acumen as to the issue at 15(f), above.

8. *It is further ordered* that Mobile Relay Associates shall be made a party to this hearing in its capacity as a petitioner to one or more of the captioned applications.

9. *It is further ordered* that a copy of this document, or a summary thereof, shall be published in the **Federal Register**.

Federal Communications Commission.

Scot Stone,

Deputy Chief, Mobility Division.

[FR Doc. 2017-01226 Filed 1-18-17; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

AGENCY: Federal Election Commission.

DATE AND TIME: Tuesday, January 24, 2017 at 10:00 a.m. and its continuation at the conclusion of the open meeting on January 25, 2017.

PLACE: 999 E Street NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 52 U.S.C. 30109.

Matters concerning participation in civil actions or proceedings or arbitration.

* * * * *

PERSON TO CONTACT FOR INFORMATION:

Judith Ingram, Press Officer, Telephone: (202) 694-1220.

Dayna C. Brown,

Acting Secretary and Clerk of the Commission.

[FR Doc. 2017-01428 Filed 1-17-17; 4:15 pm]

BILLING CODE 6715-01-P

FEDERAL HOUSING FINANCE AGENCY

[No. 2017-N-02]

Notice of Annual Adjustment of the Cap on Average Total Assets That Defines Community Financial Institutions

AGENCY: Federal Housing Finance Agency.

ACTION: Notice.

SUMMARY: The Federal Housing Finance Agency (FHFA) has adjusted the cap on average total assets that is used in determining whether a Federal Home Loan Bank (Bank) member qualifies as a "community financial institution" (CFI) to \$1,148,000,000, based on the annual percentage increase in the Consumer Price Index for all urban consumers (CPI-U), as published by the Department of Labor (DOL). These changes took effect on January 1, 2017.

FOR FURTHER INFORMATION CONTACT:

Kaitlin Hildner, Division of Federal Home Loan Bank Regulation, (202) 649-3329, Kaitlin.Hildner@fhfa.gov; or Eric M. Raudenbush, Associate General Counsel, (202) 649-3084, Eric.Raudenbush@fhfa.gov, (not toll-free numbers), Federal Housing Finance Agency, Constitution Center, 400 Seventh Street SW., Washington, DC 20219.

SUPPLEMENTARY INFORMATION:

I. Statutory and Regulatory Background

The Federal Home Loan Bank Act (Bank Act) confers upon insured depository institutions that meet the statutory definition of a CFI certain advantages over non-CFI insured depository institutions in qualifying for Bank membership, and in the purposes for which they may receive long-term advances and the collateral they may pledge to secure advances.¹ Section 2(10)(A) of the Bank Act and § 1263.1 of FHFA's regulations define a CFI as any Bank member the deposits of which are insured by the Federal Deposit Insurance Corporation and that has average total assets below the statutory

cap.² The Bank Act was amended in 2008 to set the statutory cap at \$1 billion and to require FHFA to adjust the cap annually to reflect the percentage increase in the CPI-U, as published by the DOL.³ For 2016, FHFA set the CFI asset cap at \$1,128,000,000, which reflected a 0.5 percent increase over 2015, based upon the increase in the CPI-U between 2014 and 2015.⁴

II. The CFI Asset Cap for 2017

As of January 1, 2017, FHFA has increased the CFI asset cap to \$1,148,000,000, which reflects a 1.7 percent increase in the unadjusted CPI-U from November 2015 to November 2016. Consistent with the practice of other Federal agencies, FHFA bases the annual adjustment to the CFI asset cap on the percentage increase in the CPI-U from November of the year prior to the preceding calendar year to November of the preceding calendar year, because the November figures represent the most recent available data as of January 1st of the current calendar year. The new CFI asset cap was obtained by applying the percentage increase in the CPI-U to the unrounded amount for the preceding year and rounding to the nearest million, as has been FHFA's practice for all previous adjustments.

In calculating the CFI asset cap, FHFA uses CPI-U data that have not been seasonally adjusted (*i.e.*, the data have not been adjusted to remove the estimated effect of price changes that normally occur at the same time and in about the same magnitude every year). The DOL encourages use of unadjusted CPI-U data in applying "escalation" provisions such as that governing the CFI asset cap, because the factors that are used to seasonally adjust the data are amended annually, and seasonally adjusted data that are published earlier are subject to revision for up to five years following their original release. Unadjusted data are not routinely subject to revision, and previously published unadjusted data are only corrected when significant calculation errors are discovered.

Dated: January 11, 2017.

Fred Graham,

Deputy Director, Division of Federal Home Loan Bank Regulation, Federal Housing Finance Agency.

[FR Doc. 2017-01104 Filed 1-18-17; 8:45 am]

BILLING CODE 8070-01-P

² See 12 U.S.C. 1422(10)(A); 12 CFR 1263.1.

³ See 12 U.S.C. 1422(10)(B); 12 CFR 1263.1 (defining the term *CFI asset cap*).

⁴ See 81 FR 9196 (Feb. 24, 2016).

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (www.fmc.gov) or by contacting the Office of Agreements at (202)-523-5793 or tradeanalysis@fmc.gov.

Agreement No.: 012181-001.

Title: HLAG/HSDG Latin America Slot Exchange Agreement.

Parties: Hapag-Lloyd AG and Hamburg Sud.

Filing Party: Wayne R. Rohde, Esquire; Cozen O'Connor; 1200 19th Street NW., Washington, DC 20036.

Synopsis: The amendment increases the amount of space to be exchanged, provides for limited, defined flexibility in the amount of space to be exchanged going forward, and eliminates restrictions on the movement of cargo to/from certain locations.

Agreement No.: 012454.

Title: MOL/NMCC/WLS/SCC Space Charter Agreement.

Parties: Mitsui O.S.K. Lines, Ltd., Nissan Motor Car Carrier Co., Ltd., and World Logistics Service (U.S.A.), Inc. (collectively "MOL"); and Siem Car Carriers A/S.

Filing Party: Eric C. Jeffrey, Esq.; Nixon Peabody; 799 9th Street NW., Suite 500, Washington, DC 20001.

Synopsis: The agreement authorizes the parties to charter space to one another on an as needed, as available, basis for the carriage of vehicles and other Ro-Ro cargo in the trades between the United States and all foreign countries.

By Order of the Federal Maritime Commission.

Dated: January 13, 2017.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2017-01242 Filed 1-18-17; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company

¹ See 12 U.S.C. 1424(a), 1430(a).

Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 14, 2017.

A. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291:

1. *Hazen Bancorporation, Inc.*, Hazen, North Dakota; to increase its ownership of North Star Holding Company, Inc., Jamestown, North Dakota, as a result of a stock redemption of North Star Holding Company, and thereby indirectly control Unison Bank, Jamestown, North Dakota.

2. *McIntosh County Bank Holding Company, Inc.*, Ashley, North Dakota; to increase its ownership of North Star Holding Company, Inc., Jamestown, North Dakota, as a result of a stock redemption of North Star Holding Company, and thereby indirectly acquire control Unison Bank, Jamestown, North Dakota.

Board of Governors of the Federal Reserve System, January 13, 2017.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2017-01200 Filed 1-18-17; 8:45 am]

BILLING CODE 6210-01-P

GENERAL SERVICES ADMINISTRATION

[Notice-ID-2016-03; Docket 2016-0002; Sequence No. 29]

Privacy Act of 1974; Notice of a New System of Records

AGENCY: General Services Administration (GSA).

ACTION: Notice of a new system of records.

SUMMARY: GSA proposes to establish a new system of records subject to the Privacy Act of 1974. The proposed system is a single sign-on platform to facilitate access to government services.

DATES: The system of records notice is effective upon its publication in today's **Federal Register**, with the exception of the routine uses which are effective February 21, 2017. Comments on the routine uses or other aspects of the system of records notice must be submitted by February 21, 2017.

ADDRESSES: Submit comments identified by "Notice-ID-2016-03, Notice of New System of Records" by any of the following methods:

- *Regulations.gov:* <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by searching for Notice-ID-2016-03, Notice of New System of Records. Select the link "Comment Now" that corresponds with "Notice-ID-2016-03, Notice of New System of Records." Follow the instructions provided on the screen. Please include your name, company name (if any), and "Notice-ID-2016-03, Notice of New System of Records" on your attached document.

- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/Notice-ID-2016-03, Notice of New System of Records.

FOR FURTHER INFORMATION CONTACT: Call the GSA Chief Privacy Officer at telephone 202-322-8246; or email gsa.privacyact@gsa.gov.

SUPPLEMENTARY INFORMATION: GSA proposes to establish a new system of records subject to the Privacy Act of 1974, 5 U.S.C. 552a. The proposed system is a single sign-on platform to facilitate access to government services. The previously published notice, at 81 FR 57912, on August 24, 2016, is being replaced. The system is a single, secure platform through which members of the public can log-in and access services from participating federal agencies (partner agencies). All federal agencies are eligible to participate, and those that do will be listed on the *Login.gov*

information page. The platform will use information given by the user to identity proof them including email address, password, name, date of birth, address, phone number, and social security number.

Identity proofing is the process of verifying that a person is who they say they are. Personally Identifiable Information (PII) must be collected from a *Login.gov* user to identity proof that user and then authenticate that user's identity at a Level of Assurance (LOA) required by a partner agency to grant access to its information, applications, programs, or records (for the purpose of this notice, "services"). *Login.gov* authenticates a user by validating that person is the owner of an account through a valid username, password, and the completion of the multi-factor authentication step, for example by providing the one-time password they receive by phone.

Login.gov operates at two levels of assurance: Level of Assurance 1 (LOA1) and Level of Assurance 3 (LOA3). A user will only be asked for information based on the LOA required by the partner agency to access a given service. For example, in order to access a service that requires LOA1, the user will only be asked to provide an email address, password and phone number, because that information suffices for LOA1. To access a service that requires LOA3, the user will be asked to provide the above information as well as full name, date of birth, home address and Social Security Number. These two sets of PII comprise the user's LOA1 or LOA3 "account information," respectively.

Login.gov will collect and maintain a user's LOA1 account information, and if required, LOA3 account information. *Login.gov* will verify a user's identity at LOA3 by providing the user's LOA3 account information to a third party identity proofing service. Third party identity proofing services used by *Login.gov* may employ a variety of verification techniques, including, but not limited to, verifying a user's financial information or information from a user's government-issued identification.

The identity proofing process between *Login.gov* and a third party identity proofing service takes place within *Login.gov* after the user provides the information required by that third party identity proofing service. However, *Login.gov* does not retain a user's response(s) to any question(s) posed by a third party identity proofing service during the proofing process.

Once a user is proofed at LOA1, that user's account information will be assigned a meaningless, but unique,

number (MBUN) to identify the user in *Login.gov*. The user's MBUN (and the minimum set of user account information needed to allow access to the partner agency's service) will be provided to the partner agency only after the user gives permission to send that information.

The information in *Login.gov* is contributed voluntarily by the user and cannot be accessed, used, or disclosed by GSA without consent of the user, except as provided in this notice. A partner agency may add its own unique identifier to the user's *Login.gov* account information for the purpose of identifying the user on subsequent attempts to access that agency's services.

Login.gov follows National Institute of Standards and Technology (NIST) Special Publication 800-63-2, "Electronic Authentication Guideline" and will employ third party identity proofing services, proofing using government data sources, including government-issued identification.

Richard Speidel,

Chief Privacy Officer, Office of the Deputy Chief Information Officer, General Services Administration.

SYSTEM NAME AND NUMBER:

Login.gov, GSA/TTS-1.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

The system is owned and maintained by GSA, housed in secure datacenters in continental United States. Contact the System Manager listed below for additional information.

SYSTEM MANAGER:

Joel Minton, Director, *Login.gov*, General Services Administration, 1800 F Street NW., Washington, DC 20405. <https://www.Login.gov>.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

E-Government Act of 2002 (Pub. L. 107-347, 44 U.S.C. 3501 note), 6 U.S.C. 1523 (b)(1)(A)-(E), and 40 U.S.C. 501.

PURPOSE(S) OF THE SYSTEM:

The purpose of the system is to provide a single, secure platform through which members of the public can log-in and access services from partner agencies, and to increase user security by facilitating identity proofing and authentication as necessary in order to access specific government services.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Anyone with an email account and access to a phone is able to create an

account at any time. Individuals in this system of records are members of the public seeking electronic access to a service from a participating Federal agency (partner agency), including anyone attempting to authenticate and/or identity proof for the purpose of obtaining a credential to electronically access a partner agency's services. All federal agencies are eligible to participate, and those that do will be listed on the *Login.gov* information page.

CATEGORIES OF RECORDS IN THE SYSTEM:

The information collected by *Login.gov* is necessary to perform identity proofing at the partner agency's required level of assurance (LOA). A user's account information is only retained as necessary to manage the user's credential. The only information a user must provide to identity proof at LOA1 is an email address, password and phone number. For LOA3 identity proofing, the above information is collected, as well as the user's name, address, birth date, Social Security number.

If a third party identity proofing service is unable to proof the user based on the user's LOA3 account information, *Login.gov* may request additional information from the user. However, any additional questions from the third party identity proofing service and the user's responses will not be retained by *Login.gov* after the user logs off.

Each third party identity proofing service will send information back to *Login.gov* about its attempt to identity proof the user including: Transaction ID; pass/fail indicator; date/time of transaction; and codes associated with the transaction data.

Each partner agency whose services the user accesses via *Login.gov* may add its own unique identifier to that user's account information.

RECORD SOURCE CATEGORIES:

The sources for information in the system are the individual *Login.gov* users. Each third party identity proofing service will provide transaction details about its attempt to identity proof a user and each partner agency whose services the user accesses via *Login.gov* may provide its own unique identifier to that user's account information.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information

contained in this system may be disclosed to authorized entities, as is determined to be relevant and necessary, outside GSA as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

a. To the Department of Justice or other Federal agency conducting litigation or in proceedings before any court, adjudicative or administrative body, when: (a) GSA or any component thereof, or (b) any employee of GSA in his/her official capacity, or (c) any employee of GSA in his/her individual capacity where DOJ or GSA has agreed to represent the employee, or (d) the United States or any agency thereof, is a party to the litigation or has an interest in such litigation, and GSA determines that the records are both relevant and necessary to the litigation.

b. To NIST-compliant third party identity proofing services, as necessary to identity proof an individual for access to a service at the required level of assurance.

c. To an appropriate Federal, State, tribal, local, international, or foreign law enforcement agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, where a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations and such disclosure is proper and consistent with the official duties of the person making the disclosure.

d. To a Member of Congress or his or her staff in response to a request made on behalf of and at the request of the individual who is the subject of the record.

e. To the Office of Management and Budget (OMB) and the Government Accountability Office (GAO) in accordance with their responsibilities for evaluation or oversight of Federal programs.

f. To an expert, consultant, or contractor of GSA in the performance of a Federal duty to which the information is relevant.

g. To the National Archives and Records Administration (NARA) for records management purposes.

h. To appropriate agencies, entities, and persons when (1) GSA suspects or has confirmed that there has been a breach of the system of records; (2) GSA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, GSA (including its information systems, programs and operations), the Federal Government, or national security; and (3) the disclosure made to such

agencies, entities, and persons is reasonably necessary to assist in connection with GSA's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

i. To another Federal agency or Federal entity, when GSA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

All records are stored electronically in a database. User account information is encrypted in transit and at rest.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

The user's email address and phone number, which are part of LOA1 account information, can be retrieved using *Login.gov* developed software with system access. When the user provides their password or recovery code, the system retrieves that user's LOA1 account information (email, password, and phone number) or LOA3 account information (full name, date of birth, home address and Social Security Number) using a search of the email addresses in the system. However, each user's LOA3 account information is encrypted such that neither the system nor system operators can retrieve it without the user providing their password or recovery code.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

System records will be retained and disposed of in accordance with NARA's General Records Schedule (GRS) Transmittal 26, section 3.2 "System access records" covering user profiles, log-in files, password files, audit trail files and extracts, system usage files, and cost-back files used to assess charges for system use. The guidance instructs, "Destroy 6 years after password is altered or user account is terminated, but longer retention is authorized if required for business use."

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records in the system are protected from unauthorized access and misuse through various administrative, technical and physical security

measures. Technical security measures within GSA include restrictions on computer access to authorized individuals, required use of strong passwords that are frequently changed and regular review of security procedures and best practices to enhance security. Access to the *Login.gov* database is maintained behind an industry-standard firewall and information in the database is encrypted. As noted above, neither the system nor the system operators can retrieve the user's LOA3 account information without the user supplying a password or recovery code.

RECORD ACCESS PROCEDURES:

Individuals or users wishing to access their own records may do so by providing their email address, password, and a multi-factor authentication token (e.g. a one-time password or code sent to the user's phone) to *Login.gov*, or by contacting the system administrator at the above address.

CONTESTING RECORD PROCEDURES:

Users can modify, or amend, any of their user account information by accessing it in their account. Users that want access to partner agency records, or to contest the contents of those records, need to make a request with that agency.

NOTIFICATION PROCEDURE:

Users create their account information and, thereafter, access it by providing their email address, password, and a multi-factor authentication token (e.g. a one-time password or code sent to the user's phone). Inquiries can be made via the Web site at <https://Login.gov/> or at the above address under 'System Manager and Address'.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This notice replaces the previously published notice at 81 FR 57912, on August 24, 2016.

[FR Doc. 2017-01174 Filed 1-18-17; 8:45 am]

BILLING CODE 6820-34-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-17-0739; Docket No. CDC-2016-0114]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuous information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comments on the CDC Chronic Disease Management Information System (CDMIS). The Management Information System is a central repository for the work plans of state oral health programs. This includes their goals, objectives, performance milestones, indicators, oral health program performance activities and budget information.

DATES: Written comments must be received on or before March 20, 2017.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0114 by any of the following methods:

- *Federal eRulemaking Portal:* *Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *Regulations.gov*, including any personal information provided. For access to the docket to read background documents or comments received, go to *Regulations.gov*.

Please note: All public comments should be submitted through the Federal eRulemaking portal (*Regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of

the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology

and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

CDC Oral Health Management Information System (OMB Control Number 0920-0739, expires 5/31/2017)—Revision—Division of Oral Health (DOH), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC Division of Oral Health (DOH) works with state health departments to improve the oral health of the nation. Targeted efforts include building and/or maintaining effective public health capacity for the implementation, evaluation, and dissemination of evidence-based practices in oral disease prevention and advancement of oral health. Through a cooperative agreement program (Program Announcement DP13-1307), DOH has provided funding to 21 states over a five-year period, in which 3 are basic level awardees and 18 are enhanced level. The current cooperative agreement went into effect in September 2013 and builds on previously funded collaborations involving DOH and state programs.

DOH is currently approved to collect annual progress and activity reports from state-based oral health programs. Historically, an electronic reporting system has been in place since 2007 and was enhanced in 2008 to capture information about grantees' success stories. This system, formerly known as the Management Overview for Logistics, Analysis, and Reporting (MOLAR)

system was retired in 2013-14. The new cooperative agreement, DP13-1307, was transitioned to the enhanced CDMIS platform in Fiscal Year (FY) 2013 to align with the CDC Funding Opportunity Announcement (FOA) redesign required for all domestic, non-research FOAs. The redesign emphasized evaluation, performance measurement, and outcomes. The information collected in CDMIS improved CDC's ability to disseminate information about successful public health approaches that can be replicated or adapted for use in other states.

The initial data for DP13-1307 was entered into CDMIS when the cooperative agreement began. Subsequently, only annual progress reports are required for basic and enhanced level awardees. This has resulted in no changes in how the information is collected as well as a reduction in the burden of information required by awardees. The estimated burden for system maintenance and annual reporting is three hours for basic level awardees and nine hours for enhanced level.

The revised method provides a more accurate depiction of burden per respondent in comparison to the method presented in previous OMB requests for approval, which were based on a long-term average burden per response. Even though reports will be submitted to CDC annually, states may enter updates into the MIS at any time. CDC uses all information collected to monitor awardee activities and to provide any technical assistance or follow-up support that may be needed.

OMB approval is requested for three years. Participation in the progress reporting system is a condition of the award for all funded state oral health programs.

All information will be collected electronically and there are no costs to respondents other than their time. The total estimated annualized burden hours are 171.

ESTIMATED ANNUALIZED BURDEN OF HOURS

| Type of respondents | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hrs.) | Total burden (in hrs.) |
|---------------------------------------|------------------------------|-----------------------|------------------------------------|---------------------------------------|------------------------|
| Program Awardees Basic Level | Annual Progress Report | 3 | 1 | 3 | 9 |
| Program Awardees Enhanced Level | Annual Progress Report | 18 | 1 | 9 | 162 |
| Total | | | | | 171 |

Leroy A. Richardson,
*Chief, Information Collection Review, Office
 Office of Scientific Integrity, Office of the
 Associate Director for Science Office of the
 Director, Centers for Disease Control and
 Prevention.*

[FR Doc. 2017-01185 Filed 1-18-17; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for
Occupational Safety and Health
(NIOSH), Centers for Disease Control
and Prevention, Department of Health
and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a
decision to designate a class of
employees from the Pantex Plant in
Amarillo, Texas, as an addition to the
Special Exposure Cohort (SEC) under
the Energy Employees Occupational
Illness Compensation Program Act of
2000.

FOR FURTHER INFORMATION CONTACT:

Stuart L. Hinnefeld, Director, Division
of Compensation Analysis and Support,
NIOSH, 1090 Tusculum Avenue,
MS C-46, Cincinnati, OH 45226-1938,
Telephone 1-877-222-7570.
Information requests can also be
submitted by email to DCAS@CDC.GOV.

SUPPLEMENTARY INFORMATION:

Authority: 42 U.S.C. 7384q(b). 42 U.S.C.
7384l(14)(C).

On January 4, 2017, as provided for
under 42 U.S.C. 7384l(14)(C), the
Secretary of HHS designated the
following class of employees as an
addition to the SEC:

All employees of the Department of
Energy, its predecessor agencies, and their
contractors and subcontractors who worked
at the Pantex Plant in Amarillo, Texas,
during the period from January 1, 1951,
through December 31, 1957, for a number of
work days aggregating at least 250 work days,
occurring either solely under this
employment or in combination with work
days within the parameters established for
one or more other classes of employees in the
Special Exposure Cohort.

This designation will become
effective on February 3, 2017, unless
Congress provides otherwise prior to the
effective date. After this effective date,
HHS will publish a notice in the
Federal Register reporting the addition
of this class to the SEC or the result of
any provision by Congress regarding the

decision by HHS to add the class to the
SEC.

Frank Hearl

*Chief of Staff, National Institute for
Occupational Safety and Health.*

[FR Doc. 2017-01109 Filed 1-18-17; 8:45 am]

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Health Statistics (NCHS) Confidentiality Pledge Revision Notice

AGENCY: Centers for Disease Control and
Prevention (CDC), Department of Health
and Human Services (HHS).

ACTION: General notice—notice of
revision of confidentiality pledges
under the Confidential Information
Protection and Statistical Efficiency Act.

SUMMARY: Under 44 U.S.C. 3506(e) and
44 U.S.C. 3501, CDC's National Center
for Health Statistics (NCHS) is
announcing revisions to the
confidentiality pledge(s) it provides to
its respondents under the Confidential
Information Protection and Statistical
Efficiency Act (44 U.S.C. 3501)
(CIPSEA). These revisions are required
by the passage and implementation of
provisions of the Federal Cybersecurity
Enhancement Act of 2015 (H.R. 2029,
Division N, Title II, Subtitle B, Sec.
223), which permit and require the
Secretary of the Department of
Homeland Security (DHS) to provide
Federal civilian agencies' information
technology systems with cybersecurity
protection for their Internet traffic. More
details on this announcement are
presented in the **SUPPLEMENTARY
INFORMATION** section below.

DATES: These revisions become effective
January 19, 2017.

ADDRESSES: Questions about this notice
should be addressed to the Information
Collection Review Office, Centers for
Disease Control and Prevention, 1600
Clifton Road NE., MS-D74, Atlanta,
Georgia 30329.

FOR FURTHER INFORMATION CONTACT:

Leroy A. Richardson by telephone at
404-639-7570 (this is not a toll-free
number); by email omb@cdc.gov, or by
mail Information Collection Review
Office, Centers for Disease Control and
Prevention, 1600 Clifton Road NE., MS-
D74, Atlanta, Georgia 30329. Because of
delays in the receipt of regular mail
related to security screening,
respondents are encouraged to use
electronic communications.

SUPPLEMENTARY INFORMATION: Federal
statistics provide key information that
the Nation uses to measure its
performance and make informed
choices about budgets, employment,
health, investments, taxes, and a host of
other significant topics. The
overwhelming majority of Federal
surveys are conducted on a voluntary
basis. Respondents, ranging from
businesses to households to institutions,
may choose whether or not to provide
the requested information. Many of the
most valuable Federal statistics come
from surveys that ask for highly
sensitive information such as
proprietary business data from
companies or particularly personal
information or practices from
individuals. The CDC's National Center
for Health Statistics (NCHS) protects all
data collected under its authority under
the confidentiality provisions of section
308(d) of the Public Health Service Act
(42 U.S.C. 242m). Strong and trusted
confidentiality and exclusively
statistical use pledges under the
Confidential Information Protection and
Statistical Efficiency Act (CIPSEA) and
similar statistical confidentiality
pledges are effective and necessary in
honoring the trust that businesses,
individuals, and institutions, by their
responses, place in statistical agencies.

Under CIPSEA and similar statistical
confidentiality protection statutes, many
Federal statistical agencies make
statutory pledges that the information
respondents provide will be seen only
by statistical agency personnel or their
sworn agents, and will be used only for
statistical purposes. CIPSEA and similar
statutes protect the confidentiality of
information that agencies collect solely
for statistical purposes and under a
pledge of confidentiality. These acts
protect such statistical information from
administrative, law enforcement,
taxation, regulatory, or any other non-
statistical use and immunize the
information submitted to statistical
agencies from legal process. Moreover,
many of these statutes carry criminal
penalties of a Class E felony (fines up to
\$250,000, or up to five years in prison,
or both) for conviction of a knowing and
willful unauthorized disclosure of
covered information.

As part of the Consolidated
Appropriations Act for Fiscal Year 2016
signed on December 17, 2015, the
Congress included the Federal
Cybersecurity Enhancement Act of 2015
(H.R. 2029, Division N, Title II, Subtitle
B, Sec. 223). This Act, among other
provisions, permits and requires the
Secretary of the Department of
Homeland Security (DHS) to provide
Federal civilian agencies' information

technology systems with cybersecurity protection for their Internet traffic. The technology currently used to provide this protection against cyber malware is known as Einstein 3A; it electronically searches Internet traffic in and out of Federal civilian agencies in real time for malware signatures.

When such a signature is found, the Internet packets that contain the malware signature are shunted aside for further inspection by DHS personnel. Because it is possible that such packets entering or leaving a statistical agency's information technology system may contain a small portion of confidential statistical data, statistical agencies can no longer promise their respondents that their responses will be seen only by statistical agency personnel or their sworn agents. However, they can promise, in accordance with provisions of the Federal Cybersecurity Enhancement Act of 2015, that such monitoring can be used only to protect information and information systems from cybersecurity risks, thereby, in effect, providing stronger protection to the integrity of the respondents' submissions.

Consequently, with the passage of the Federal Cybersecurity Enhancement Act of 2015, the Federal statistical community has an opportunity to welcome the further protection of its confidential data offered by DHS' Einstein 3A cybersecurity protection program. The DHS cybersecurity program's objective is to protect Federal civilian information systems from malicious malware attacks. The Federal

statistical system's objective is to ensure that the DHS Secretary performs those essential duties in a manner that honors the Government's statutory promises to the public to protect their confidential data. Given that the Department of Homeland Security is not a Federal statistical agency, both DHS and the Federal statistical system have been successfully engaged in finding a way to balance both objectives and achieve these mutually reinforcing objectives.

However, many current CIPSEA and similar statistical confidentiality pledges promise that respondents' data will be seen only by statistical agency personnel or their sworn agents. Since it is possible that DHS personnel could see some portion of those confidential data in the course of examining the suspicious Internet packets identified by Einstein 3A sensors, statistical agencies need to revise their confidentiality pledges to reflect this process change.

Therefore, NCHS is providing this notice to alert the public to these confidentiality pledge revisions in an efficient and coordinated fashion. Below is a table listing NCHS's current Paperwork Reduction Act (PRA) OMB Control numbers and information collection titles and their associated revised confidentiality pledge(s) for the Information Collections whose confidentiality pledges will change to reflect the statutory implementation of DHS' Einstein 3A monitoring for cybersecurity protection purposes.

The following NCHS statistical confidentiality pledge will now apply to the Information Collections whose

Paperwork Reduction Act Office of Management and Budget numbers and titles are listed below.

We take your privacy very seriously. All information that relates to or describes identifiable characteristics of individuals, a practice, or an establishment will be used only for statistical purposes. NCHS staff, contractors, and agents will not disclose or release responses in identifiable form without the consent of the individual or establishment in accordance with section 308(d) of the Public Health Service Act (42 U.S.C. 242m) and the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA, Title 5 of Public Law 107–347). In accordance with CIPSEA, every NCHS employee, contractor, and agent has taken an oath and is subject to a jail term of up to five years, a fine of up to \$250,000, or both if he or she willfully discloses ANY identifiable information about you. In addition, NCHS complies with the Federal Cybersecurity Enhancement Act of 2015. This law requires the federal government to protect federal computer networks by using computer security programs to identify cybersecurity risks like hacking, internet attacks, and other security weaknesses. If information sent through government networks triggers a cyber threat indicator, the information may be intercepted and reviewed for cyber threats by computer network experts working for, or on behalf of the government.

NCHS'S CURRENT OMB CONTROL NUMBERS

| OMB control No. | Title of information collection |
|-----------------|--|
| 0920–0119 | National Ambulatory Medical Care Survey Supplement on Culturally and Linguistically Appropriate Services (NAMCS CLAS). |
| 0920–0212 | National Hospital Care Survey. |
| 0920–0213 | NCHS: National Vital Statistics Report Forms. |
| 0920–0214 | National Health Interview Survey. |
| 0920–0215 | Application Form and Related Forms for the Operation of the National Death Index. |
| 0920–0217 | NCHS Application for Vital Statistics Training Form. |
| 0920–0222 | NCHS Questionnaire Design Research Laboratory. |
| 0920–0234 | National Ambulatory Medical Care Survey (NAMCS). |
| 0920–0278 | National Hospital Ambulatory Medical Care Survey. |
| 0920–0314 | National Survey of Family Growth. |
| 0920–0729 | Customer Surveys Generic Clearance for the National Center for Health Statistics. |
| 0920–0943 | Data Collection for the Residential Care Community and Adult Day Services Center Components of the National Study of Long-term Care Providers. |
| 0920–0950 | National Health and Nutrition Examination Survey. |
| 0920–1015 | The National Ambulatory Medical Care Survey (NAMCS) National Electronic Health Record Survey (NEHRS). |
| 0920–1030 | Developmental Studies to Improve the National Health Care Surveys. |
| 0920–1063 | NAMCS Supplement of Primary Care Policies (NSPCP) for Managing Patients with High Blood Pressure, High Cholesterol, or Diabetes. |

Leroy A. Richardson,
*Chief, Information, Collection Review Office,
 Office of Scientific Integrity, Office of the
 Associate Director for Science, Office of the
 Director, Centers for Disease Control and
 Prevention.*

[FR Doc. 2017-01186 Filed 1-18-17; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a decision to designate a class of employees from Area IV of the Santa Susana Field Laboratory in Ventura County, California, as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000.

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, NIOSH, 1090 Tusculum Avenue, MS C-46, Cincinnati, OH 45226-1938, Telephone 1-877-222-7570. Information requests can also be submitted by email to DCAS@CDC.GOV.

SUPPLEMENTARY INFORMATION:

Authority: 42 U.S.C. 7384q(b). 42 U.S.C. 7384l(14)(C).

On January 6, 2017, as provided for under 42 U.S.C. 7384l(14)(C), the Secretary of HHS designated the following class of employees as an addition to the SEC:

All employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked in any area at Area IV of the Santa Susana Field Laboratory in Ventura County, California, from January 1, 1965, through December 31, 1988, for a number of work days aggregating at least 250 work days, occurring either solely under this employment or in combination with work days within the parameters established for one or more other classes of employees included in the Special Exposure Cohort.

This designation will become effective on February 5, 2017, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of

any provision by Congress regarding the decision by HHS to add the class to the SEC.

Frank Hearl,
*Chief of Staff, National Institute for
 Occupational Safety and Health.*

[FR Doc. 2017-01110 Filed 1-18-17; 8:45 am]

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10142]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by February 21, 2017.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 OR, Email: OIRA_submission@omb.eop.gov.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); *Use:* We require that Medicare Advantage organizations and Prescription Drug Plans complete the BPT as part of the annual bidding process. During this process, organizations prepare their proposed actuarial bid pricing for the upcoming contract year and submit them to us for review and approval. The purpose of the BPT is to collect the actuarial pricing information for each plan. The BPT calculates the plan's bid, enrollee premiums, and payment rates. We publish beneficiary premium information using a variety of formats (www.medicare.gov, the Medicare & You handbook, Summary of Benefits marketing information) for the purpose of beneficiary education and

enrollment. *Form Number:* CMS–10142 (OMB control number: 0938–0944); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 555; *Total Annual Responses:* 4,995; *Total Annual Hours:* 149,850. (For policy questions regarding this collection contact Rachel Shevland at 410–786–3026.)

Dated: January 13, 2017.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office
of Strategic Operations and Regulatory
Affairs.

[FR Doc. 2017–01204 Filed 1–18–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10120 and CMS–
10501]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare &
Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by March 20, 2017.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and

recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT:
Reports Clearance Office at (410) 786–
1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10120 1932(a) State Plan Amendment Template, State Plan Requirements and Supporting Regulations

CMS–10501 Healthcare Fraud Prevention Partnership (HFPP): Data Sharing and Information Exchange

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of

information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* 1932(a) State Plan Amendment Template, State Plan Requirements and Supporting Regulations; *Use:* Section 1932(a)(1)(A) of the Social Security Act (the Act) grants states the authority to enroll Medicaid beneficiaries on a mandatory basis into managed care entities and primary care case managers. Under this authority, a state can amend its Medicaid state plan to require certain categories of Medicaid beneficiaries to enroll in managed care entities without being out of compliance with section 1902 of the Act on state-wideness (42 CFR 431.50), freedom of choice (42 CFR 431.51) or comparability (42 CFR 440.230). The template may be used by states to modify their state plans if they choose to implement the provisions of section 1932(a)(1)(A); *Form Number:* CMS–10120 (OMB control number: 0938–0933); *Frequency:* Once and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 12; *Total Annual Hours:* 70. (For policy questions regarding this collection contact Debbie Anderson at 410–786–5545.)

2. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Healthcare Fraud Prevention Partnership (HFPP): Data Sharing and Information Exchange; *Use:* Section 1128C(a)(2) of the Social Security Act (42 U.S.C. 1320a–7c(a)(2)) authorizes the Secretary and the Attorney General to consult, and arrange for the sharing of data with, representatives of health plans for purposes of establishing a Fraud and Abuse Control Program as specified in Section 1128(C)(a)(1) of the Social Security Act. The result of this authority has been the establishment of the Healthcare Fraud Prevention Partnership (HFPP). The HFPP was officially established by a Charter in the fall of 2012 and signed by HHS Secretary Sibelius and US Attorney General Holder. Data sharing within the HFPP primarily focuses on conducting studies for the purpose of combatting fraud, waste, and abuse. These studies are intended to target specific

vulnerabilities within the payment systems in both the public and private healthcare sectors. The HFPP and its committees design and develop studies in coordination with the TTP. The core function of the TTP is to manage and execute the HFPP studies within the HFPP. Specifically, the TTP collects and consolidates partner (both public and private) study-related data in order to share information among the HFPP pertaining to analytical tools and techniques; study analysis; successful anti-fraud practices, trends and vulnerabilities; and reports that maintain the confidentiality of its source data.

Please note that on December 16, 2016 (81 FR 91175), a notice published in the **Federal Register** for the HFPP. However, the incorrect abstract published with the notice. In addition, it was identified under the incorrect CMS number. We are republishing this notice with the correct abstract and form number. In addition, the 60-day notice and comment will commence with the publication of this new notice. *Form Number*: CMS-10501 (OMB control number: 0938-1251); *Frequency*: Occasionally; *Affected Public*: Private sector (Business or other for-profits); *Number of Respondents*: 20; *Total Annual Responses*: 20; *Total Annual Hours*: 360. (For policy questions regarding this collection contact Marnie Dorsey at 410-786-5942.)

Dated: January 13, 2017.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017-01205 Filed 1-18-17; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3339-N]

Medicare Program; Meeting of the Medicare Evidence Development and Coverage Advisory Committee—March 22, 2017

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces that a public meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) (“Committee”) will be held on Wednesday, March 22, 2017. This meeting will specifically focus on

obtaining the MEDCAC’s recommendations regarding what health outcomes in studies for heart failure treatment technologies should be of interest to CMS. This meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)).

DATES:

Meeting Date: The public meeting will be held on Wednesday, March 22, 2017 from 7:30 a.m. until 4:30 p.m., Eastern Daylight Time (EDT).

Deadline for Submission of Written Comments: Written comments must be received at the address specified in the **ADDRESSES** section of this notice by 5:00 p.m., Eastern Standard Time (EST), Tuesday, February 21, 2017. Once submitted, all comments are final.

Deadlines for Speaker Registration and Presentation Materials: The deadline to register to be a speaker and to submit PowerPoint presentation materials and writings that will be used in support of an oral presentation is 5:00 p.m., EST on Tuesday, February 21, 2017. Speakers may register by phone or via email by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Presentation materials must be received at the address specified in the **ADDRESSES** section of this notice.

Deadline for All Other Attendees Registration: Individuals may register online at <http://www.cms.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3> or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by 5:00 p.m. EDT, Wednesday, March 15, 2017.

We will be broadcasting the meeting live via Webcast at <http://www.cms.gov/live/>.

Deadline for Submitting a Request for Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to contact the Executive Secretary as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice no later than 5:00 p.m., EST Friday, March 3, 2017.

ADDRESSES:

Meeting Location: The meeting will be held in the main auditorium of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244.

Submission of Presentations and Comments: Presentation materials and written comments that will be presented at the meeting must be submitted via email to MedCACpresentations@

cms.hhs.gov or by regular mail to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice.

FOR FURTHER INFORMATION CONTACT:

Maria Ellis, Executive Secretary for MEDCAC, Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality, Coverage and Analysis Group, S3-02-01, 7500 Security Boulevard, Baltimore, MD 21244 or contact Ms. Ellis by phone (410-786-0309) or via email at Maria.Ellis@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

MEDCAC, formerly known as the Medicare Coverage Advisory Committee (MCAC), is advisory in nature, with all final coverage decisions resting with CMS. MEDCAC is used to supplement CMS’ internal expertise. Accordingly, the advice rendered by the MEDCAC is most useful when it results from a process of full scientific inquiry and thoughtful discussion, in an open forum, with careful framing of recommendations and clear identification of the basis of those recommendations. MEDCAC members are valued for their background, education, and expertise in a wide variety of scientific, clinical, and other related fields. (For more information on MCAC, see the MEDCAC Charter (<http://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/medcaccharter.pdf>) and the CMS Guidance Document, *Factors CMS Considers in Referring Topics to the MEDCAC* (<http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=10>)).

II. Meeting Topic and Format

This notice announces the Wednesday, March 22, 2017, public meeting of the Committee. During this meeting, the Committee will discuss recommendations regarding what health outcomes in studies for heart failure treatment technologies should be of interest to CMS. Background information about this topic, including panel materials, is available at <http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAAA&>. We will no longer be providing paper copies of the handouts for the meeting. Electronic copies of all the meeting materials will be on the CMS Web site no later than 2 business days before the meeting. We encourage the participation of organizations with expertise in what

health outcomes in studies for heart failure treatment technologies should be of interest to CMS. This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, we may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 27, 2017. Your comments should focus on issues specific to the list of topics that we have proposed to the Committee. The list of research topics to be discussed at the meeting will be available on the following Web site prior to the meeting: <http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=AAAAAAAAAAAA&>. We require that you declare at the meeting whether you have any financial involvement with manufacturers (or their competitors) of any items or services being discussed. Speakers presenting at the MEDCAC meeting should include a full disclosure slide as their second slide in their presentation for financial interests (for example, type of financial association—consultant, research support, advisory board, and an indication of level, such as minor association <\$10,000 or major association >\$10,000) as well as intellectual conflicts of interest (for example, involvement in a federal or nonfederal advisory committee that has discussed the issue) that may pertain in any way to the subject of this meeting. If you are representing an organization, we require that you also disclose conflict of interest information for that organization. If you do not have a PowerPoint presentation, you will need to present the full disclosure information requested previously at the beginning of your statement to the Committee.

The Committee will deliberate openly on the topics under consideration. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topics under consideration. At the conclusion of the day, the members will vote and the Committee will make its recommendation(s) to CMS.

III. Registration Instructions

CMS' Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register online at <http://www.cms.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3> or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your state-issued driver's license), address, organization, telephone number(s), fax number, and email address. You will receive a registration confirmation with instructions for your arrival at the CMS complex or you will be notified that the seating capacity has been reached.

IV. Security, Building, and Parking Guidelines

This meeting will be held in a federal government building; therefore, federal security measures are applicable. The Real ID Act, enacted in 2005, establishes minimum standards for the issuance of state-issued driver's licenses and identification (ID) cards. It prohibits Federal agencies from accepting an official driver's license or ID card from a state unless the Department of Homeland Security determines that the state meets these standards. Beginning October 2015, photo IDs (such as a valid driver's license) issued by a state or territory not in compliance with the Real ID Act will not be accepted as identification to enter Federal buildings. Visitors from these states/territories will need to provide alternative proof of identification (such as a valid passport) to gain entrance into CMS buildings. The current list of states from which a Federal agency may accept driver's licenses for an official purpose is found at <http://www.dhs.gov/real-id-enforcement-brief>. We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Inspection, via metal detector or other applicable means, of all persons

entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

V. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Authority: 5 U.S.C. App. 2, section 10(a).

Dated: January 10, 2017.

Kate Goodrich,

Director, Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

[FR Doc. 2017-01043 Filed 1-18-17; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0394]

Regulation of Intentionally Altered Genomic DNA in Animals; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #187 entitled "Regulation of Intentionally Altered Genomic DNA in Animals." This draft guidance revises GFI #187 entitled "Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs" (current GFI #187). Current GFI #187 clarifies FDA's requirements

and recommendations for producers and developers of genetically engineered (GE) animals and their products. It describes how the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) apply with respect to GE animals. This draft revision of current GFI #187 expands the scope of the guidance to include animals intentionally altered through use of genome editing techniques. The draft revised GFI #187 now applies to “those animals whose genomes have been intentionally altered using modern molecular technologies.” The Agency is seeking comment on the draft revised GFI #187, including the nomenclature that best describes these animals and on any existing empirical evidence indicating that certain types of genome editing may pose minimal risk.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 19, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of

Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2008-D-0394 for “Regulation of Intentionally Altered Genomic DNA in Animals.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets

Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Laura R. Epstein, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-796-8558, laura.epstein@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability, for public comment, of draft revised GFI #187 entitled “Regulation of Intentionally Altered Genomic DNA in Animals.” This draft guidance revises current GFI #187 entitled “Regulation of Genetically Engineered Animals Containing Heritable recombinant DNA Constructs” to expand the scope of the guidance to address animals intentionally altered through use of genome editing techniques. FDA is also requesting comment on nomenclature and on whether certain types of genome editing may pose minimal risk. Before finalizing the draft revised guidance, the agency intends to modify its regulatory approach if it receives evidence demonstrating low risk.

In the *National Strategy for Modernizing the Regulatory System for Biotechnology Products* (the *Strategy*; released by the White House Office of Science and Technology Policy on September 16, 2016),¹ FDA noted its intent to clarify its policy on the regulation of products derived from genome editing techniques, including, as appropriate, identifying and/or updating relevant existing guidance documents. FDA also stated, as an example, its intent to update GFI #187, “Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs,” to clarify how developers of animals produced using emerging technologies (e.g., genome editing) may meet applicable statutory and regulatory requirements. FDA is issuing this draft revised guidance for public comment consistent with this commitment in the *Strategy* document. Under the Coordinated Framework for the

¹ https://www.whitehouse.gov/sites/default/files/microsites/ostp/biotech_national_strategy_final.pdf.

Regulation of Biotechnology, we intend to work cooperatively with other relevant agencies that may also be considering their policies or approaches related to genome editing applications within their jurisdictions. As we finalize the draft revised guidance, we will be consistent with the principles for the regulation of biotechnology products articulated in the 2017 Update to the Coordinated Framework (https://www.whitehouse.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf) and the goals and objectives of the July 2015 EOP memorandum (https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf).

A. Key Draft Revisions

Draft revised GFI #187 is intended to clarify that, unless otherwise excluded,² the altered genomic DNA in an animal (referred to in this document as “animals with intentionally altered genomic DNA”) that is intended to affect the structure or function of the body of the animal or, in some cases, to diagnose, cure, mitigate, treat, or prevent disease in the animal, meets the drug definition in section 201(g) of the FD&C Act. For the purposes of draft revised GFI #187, “altered genomic DNA” refers to the portion of an animal’s genome that has been intentionally altered. Such intentional alterations may be made, for example, through the use of “nucleases” or “genome editing technologies,” including engineered nuclease/nucleotide complexes such as zinc finger nucleases (ZFN), transcription activator-like effector nucleases (TALENs), and the clustered regulatory interspersed short palindromic repeats (CRISPR) associated systems.

Similar to current GFI #187, draft revised GFI #187 is intended to clarify FDA’s requirements and recommendations for producers and developers of animals with intentionally altered genomic DNA. Current GFI #187 and draft revised GFI #187 describe how the new animal drug provisions of the FD&C Act apply with respect to the

intentionally altered genomic DNA of such animals.

Animals may have intentional genomic alterations that are heritable or non-heritable (e.g., those alterations intended to be used as gene therapy). Although much of draft revised GFI #187 is relevant to non-heritable intentional genomic alterations, and FDA intends to regulate non-heritable intentional genomic alterations in much the same way as described in this draft revised guidance, this draft revised guidance primarily addresses animals whose genomes have been intentionally altered for heritable purposes.

B. Additional Issues for Consideration and Comment

FDA requests comment on draft revised GFI #187. In particular, we request comments on two major categories of questions.

1. In the first, we seek the public’s input on how to refer to these animals. In the past, FDA has used the term “genetically engineered” to refer to animals containing recombinant DNA constructs intended to alter the structure or function of the body of the animal. For this draft revised guidance, we have used the phrase “animals whose genomes have been altered intentionally.” Other terms that could be used include “genome edited animals,” “intentionally altered animals,” or expanding the term “genetically engineered” to include the deliberate modification of the characteristics of an organism by manipulating its genetic material. The public is encouraged to suggest other phrases that are accurate and inclusive.

2. The second set of questions for which we seek public input is on whether there is any existing empirical evidence demonstrating that certain types of genome editing may pose minimal risk, with particular emphasis on the following:

a. Are there categories of animals whose genomes have been intentionally altered for which specific empirical evidence indicates that there are no significant target animal, user safety, food safety, or environmental risks? If so, what is that evidence?

b. Are there categories of animals whose genomes have been intentionally altered for which empirical evidence exists to demonstrate that genome editing is durable on a genotypic and phenotypic level and would continue to be durable over the lifetime of a particular product? If so, what is that evidence?

c. Is there empirical evidence to demonstrate that there are degrees of introduced changes (e.g., insertions or

deletions of any size or single nucleotide substitutions) that are likely to pose less risk than other changes? If so, what is that evidence?

d. Is there empirical evidence that indicates that the degree of taxonomic relationship between the introduced gene and the recipient animal influences the health of that recipient animal or the extent to which the trait is expressed? If so, what is that evidence?

We noted in current GFI #187 that we might issue a separate guidance on the regulation of GE animals bearing non-heritable alterations. Draft revised GFI #187 removes references to this and other guidance documents that we intend to develop in the future. This was not done to indicate that we no longer intend to issue such guidance documents. In light of changing priorities over time, we may issue other guidance documents before developing those identified in current GFI #187, and therefore decided we should not indicate in the text of the revised guidance any additional guidance documents that we may develop in the future.

Current GFI #187 states, “FDA is discussing with other agencies the best approach for oversight of GE insects. Future guidance may be developed to address them.” Draft revised GFI #187 eliminates this language. As indicated in the *Strategy*, FDA, EPA, and USDA intend to “continue to examine their regulatory structures with the goal of clarifying how the U.S. Federal Government will regulate genetically engineered insects in an integrated and coordinated fashion to cover the full range of potential products.” FDA is continuing to work with EPA and USDA, and will address this issue through action(s) separate from this draft revision to current GFI #187. Elsewhere in this issue of the **Federal Register**, we have published a notice announcing the availability of a draft guidance for industry on regulation of mosquito-related products.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on Regulation of Intentionally Altered Genomic DNA in Animals. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

² In Draft Guidance for Industry #236, “Regulation of Mosquito-Related Products,” FDA has proposed to clarify that the phrase “articles (other than food) intended to affect the structure or any function of the body of man or other animals” does not include articles intended to prevent, destroy, repel, or mitigate mosquitoes for population control purposes. Instead, such products are pesticides regulated by the Environmental Protection Agency (EPA) (<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM533600.pdf>).

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information have been approved under OMB Control Nos. 0910–0032, 0910–0045, 0910–0117, and 0910–0284.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: January 11, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–00839 Filed 1–18–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Psychopharmacologic Drugs Advisory Committee; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The meeting of the Psychopharmacologic Drugs Advisory Committee scheduled for February 16, 2017, is cancelled. This meeting was announced in the **Federal Register** of December 27, 2016 (81 FR 95147). The meeting is no longer needed.

FOR FURTHER INFORMATION CONTACT:

Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: PDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting.

Dated: January 11, 2017.

Janice M. Soreth,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2017–01170 Filed 1–18–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–4389]

Genome Editing in New Plant Varieties Used for Foods; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the establishment of a docket to receive comments on the use of genome editing techniques to produce new plant varieties that are used for human or animal food. We invite comment on specific questions contained in this document related to foods derived from such genome edited plant varieties. FDA is taking this action to help inform our thinking about foods derived from new plant varieties produced using genome editing techniques.

DATES: Submit either electronic or written comments by April 19, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2016–N–4389 for “Genome Editing in New Plant Varieties Used For Foods; Request for Comments.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments

received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding human food issues: Jason Dietz, Center for Food Safety and Applied Nutrition (HFS-205), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2282. *Regarding animal food issues:* Kathleen Jones, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5938.

SUPPLEMENTARY INFORMATION:

I. Background

Use of Genome Editing Techniques To Produce New Plant Varieties Used for Human or Animal Food

Recently, new technologies have emerged that are intended to alter the genomes of various organisms, including plants. FDA is aware that these technologies make it easier for plant developers to produce new plant varieties with targeted genetic modifications. Using deoxyribonucleic acid (DNA) sequence information from a plant, plant breeders can make targeted changes to a plant's DNA sequence to alter expression of traits in the plant. These new methods include processes using targeted nucleases (clustered regulatory interspersed short palindromic repeat associated nucleases, zinc-finger nucleases, meganucleases, and transcription activator-like effector nucleases or targeted oligonucleotides (oligonucleotide-directed mutagenesis) intended to modify a plant's DNA sequence by insertion, deletion, or substitution of nucleotides at a specific site in a plant's genome. The process of producing these targeted DNA sequence alterations is often referred to as "genome editing."

In the *National Strategy for Modernizing the Regulatory System for Biotechnology Products* (the *Strategy*; released by the White House Office of Science and Technology Policy on September 16, 2016),¹ FDA noted its intent to clarify its policy for the regulation of products derived from genome editing techniques, including, as appropriate, identifying and/or updating relevant existing guidance documents. Consistent with this

commitment in the *Strategy* document, FDA is opening this docket to inform its thinking on foods derived from plants produced using genome editing techniques. FDA also looks forward to receiving the results from the study being conducted by the National Academies of Sciences, Engineering, and Medicine entitled "*Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System*" commissioned under the Update to the Coordinated Framework for Regulation of Biotechnology, available at <http://nas-sites.org/biotech/>. As we consider this issue, we intend for our actions to be guided by the principles for the regulation of biotechnology products articulated in the 2017 Update to the Coordinated Framework (https://www.whitehouse.gov/sites/default/files/microsites/ostp/2017_coordinated_framework_update.pdf) and the goals and objectives of the July 2015 EOP memorandum (https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf).

Producers of foods from plant varieties developed using genome editing techniques, like all food producers, have an obligation under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to ensure that the foods they offer consumers are safe and in compliance with applicable legal requirements (57 FR 22984 at 22985), available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm>. The FD&C Act gives FDA broad authority to initiate legal action against a food that is adulterated or misbranded within the meaning of the statute (id.). In 1992, FDA issued a statement of policy (57 FR 22984) that discussed scientific issues and provided guidance relevant to the safety assessment of foods derived from new plant varieties derived by traditional methods, tissue culture methods, and recombinant DNA methods (57 FR 22984 at 22991). The guidance provided in the 1992 policy has helped to ensure that developers of new plant varieties make market entry decisions consistent with the FD&C Act. FDA also explained that we have long regarded it to be a prudent practice for producers of foods using new technologies to work cooperatively with us to ensure that the new products are safe and comply with applicable legal requirements (57 FR 22984 at 22991). Over the past 20 years, developers have

routinely consulted FDA about the safety and legality of foods from new genetically engineered plant varieties prior to marketing. These consultations have relied on the objective characteristics of foods to consider their safety and legality prior to marketing. This process has worked well and has helped developers ensure that all safety and other legal issues are satisfactorily addressed prior to market entry of foods derived from these new varieties. FDA intends to continue offering consultations for developers of new plant varieties, including those produced using genome editing, in order to help developers ensure that applicable safety and legal questions are resolved prior to market. In addition to the information we anticipate gathering from developers in the course of consultations, we recognize that developers, researchers, and other stakeholders may have valuable factual information and data about foods derived from new plant varieties produced using genome editing, which can help inform FDA's thinking for these specific products. Therefore, we invite comment in this notice.

II. Additional Issues for Consideration and Invitation for Comment: Genome Editing in Plants

To help inform our thinking on foods derived from new plant varieties produced using genome editing, we invite comment on the following questions:

1. In what ways are the food safety risks associated with human and animal foods from genome edited plants the same as or different from those associated with other plant development methods (e.g., hybridization, chemical or radiation-induced mutagenesis and non-targeted genetic modifications using in vitro recombinant DNA technologies)? Please provide data and/or information to support your view.

- To what extent is the scientific knowledge of and experience with current new plant varieties (such as those developed with in vitro recombinant DNA technologies that have gone through the voluntary consultation process) relevant to the safety assessment and regulatory status of food from new plant varieties produced using genome editing? Is there additional scientific knowledge that would be relevant specifically to the safety assessment and regulatory status of new plant varieties produced using genome editing? Please provide data and/or information to support your view.

¹ https://www.whitehouse.gov/sites/default/files/microsites/ostp/biotech_national_strategy_final.pdf.

2. Are there categories of genome edited plant varieties for which there are scientific bases to conclude that foods from such categories are unlikely to present food safety risks different from or greater than those for traditional plant breeding? Similarly, are there categories of genome edited plant varieties for which the regulatory status of the food derived from such plant varieties can be said to be no different from that of traditionally-bred plants? If there are such categories, is there a basis upon which to determine that there would be no reason to include them in any voluntary premarket consultation process? If so, please describe the characteristics of such categories (including, for example, information about the types of phenotypes and modifications (insertions, deletions or substitutions) achieved through genome editing) and provide data and/or information for why plant varieties in these categories are unlikely to present food safety risks or regulatory status questions. Regulatory status questions may include, for example, whether food from the new plant variety contains an unapproved food or color additive such that premarket review and approval is required (see sections 409 and 721 of the FD&C Act). As another example, if food from the new plant variety has a different nutritional profile from food from traditionally-bred plants, then certain labeling may be required to disclose a material change in the food.

a. If such categories exist, how do plant developers ensure the safety of foods from new plant varieties in these categories? For example, how are safety assessments of foods from these varieties accomplished, and what data and information are or should be considered in such assessments?

b. If certain categories of genome edited plants do not raise questions of safety or regulatory status, should there nevertheless be a mechanism separate from the voluntary premarket consultation process through which plant developers may voluntarily notify FDA about their intent to market a food derived from a genome edited new plant variety that falls within these categories? If so, what process should plant developers use to notify FDA? What kind of information should be included in such a notification to FDA?

c. Given that genome editing techniques can give rise to a broad range of plant modifications, from simple gene deletions to totally novel genes, and that some such modifications can be achieved through traditional breeding, please discuss the basis upon which to determine that there would or would not be a reason to include, in any

voluntary premarket consultation process, foods from genome edited crops with modifications that could have been achieved through traditional breeding.

3. Are there categories of genome edited plant varieties for which there are scientific bases to conclude that foods from these categories are more likely than traditionally-bred plants to present food safety risks? If so, please describe the characteristics of these categories (including, for example, information about the types of phenotypes and modifications (insertions, deletions or substitutions) achieved through genome editing) and provide data and/or information to support why plant varieties in these categories are more likely to present food safety risks than traditionally-bred plants.

4. What steps can we take to help small firms, including those who may be considering using genome editing to produce new plant varieties for use in human or animal food, to engage with FDA about any questions related to food safety or the regulatory status of foods from their new plant varieties? Please provide supporting data and other information to support your comments and responses to this question.

Dated: January 11, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-00840 Filed 1-18-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0084]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Program for Medical Devices (Medical Product Safety Network)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for

public comment in response to the notice. This notice solicits comments on the Adverse Event Program for Medical Devices (Medical Product Safety Network (MedSun)).

DATES: Submit either electronic or written comments on the collection of information by March 20, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-N-0084 for "Adverse Event Program for Medical Devices (Medical Product Safety Network (MedSun))." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

<http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Adverse Event Program for Medical Devices (Medical Product Safety Network (MedSun))—OMB Control Number 0910–0471—Extension

Under section 519 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360i) authorizes FDA to require (1) manufacturers to report medical device-related deaths, serious injuries, and malfunctions; and (2) user facilities to report device-related deaths directly to manufacturers and FDA and serious injuries to the manufacturer. Section 213 of the Food

and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) amended section 519(b) of the FD&C Act relating to mandatory reporting by user facilities of deaths, serious injuries, and serious illnesses associated with the use of medical devices. This amendment legislated the replacement of universal user facility reporting by a system that is limited to a “subset of user facilities that constitutes a representative profile of user reports” for device-related deaths and serious injuries. This amendment is reflected in section 519(b)(5)(A) of the FD&C Act. This legislation provides FDA with the opportunity to design and implement a national surveillance network, composed of well-trained clinical facilities, to provide high-quality data on medical devices in clinical use. This system is called MedSun.

FDA is seeking OMB clearance to continue to use electronic data collection to obtain the information on Form FDA 3500A (approved under OMB control number 0910–0291) related to medical devices and tissue products from the user facilities participating in MedSun, to obtain a demographic profile of the facilities, and for additional questions which will permit FDA to better understand the cause of reported adverse events. Participation in the program is voluntary and includes approximately 250 facilities.

In addition to collecting data on the electronic adverse event report form, MedSun collects additional information from participating sites about reported problems emerging from the MedSun hospitals. This data collection is also voluntary and is collected on the same Web site as the report information.

The burden estimate is based on the number of facilities participating in MedSun (250). FDA estimates an average of 15 reports per site annually. This estimate is based on MedSun working to promote reporting in general from the sites, as well as promoting reporting from specific parts of the hospitals, such as the pediatric intensive care units, the electrophysiology laboratories, and the hospital laboratories.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| Activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|-------------------------------|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Adverse event reporting | 250 | 15 | 3,750 | 0.75 (45 minutes) | 2,813 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: January 13, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-01187 Filed 1-18-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-1307]

Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers; Draft Guidance for Industry and Review Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry and review staff entitled “Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers.” This draft guidance provides answers to common questions regarding the communication of health care economic information (HCEI) about approved prescription drugs by medical product manufacturers, packers, distributors, and their representatives (firms) to payors, formulary committees, or other similar entities with knowledge and expertise in the area of health care economic analysis (collectively referred to as payors). This draft guidance also provides answers to common questions about firms’ communications regarding investigational drugs and devices (investigational products) to payors before FDA approval or clearance of such products. The Agency is issuing this draft guidance to explain FDA’s current thinking on frequently asked questions regarding such communications in order to provide clarity for firms and payors.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 19, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2016-D-1307 for “Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS

CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002; the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this draft guidance document.

FOR FURTHER INFORMATION CONTACT: Elaine Hu Cunningham, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3203, Silver Spring, MD 20993-0002, 301-

796–1200; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; Paul Gadiock, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5448, Silver Spring, MD 20993–0002, 301–796–5736; or Kristin Davis, Office of the Commissioner, 10903 New Hampshire Ave., Bldg. 32, Rm. 4252, Silver Spring, MD 20993–0002, 301–796–0418.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and review staff entitled “Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers.” This draft guidance provides answers to common questions regarding firms’ communications of HCEI about their approved prescription drugs to payors. This draft guidance also addresses common questions relating to firms’ dissemination of information about investigational products to payors before FDA approval or clearance of such products. For purposes of this draft guidance, the term “payors” collectively refers to payors, formulary committees, or other similar entities with knowledge and expertise in the area of health care economic analysis that are responsible for making drug selection, formulary management, and/or coverage and reimbursement decisions on a population basis regarding drugs and/or devices for health care organizations, which may include entities such as integrated health care delivery networks, hospitals, and hospital systems.

FDA is aware that payors seek a range of information on effectiveness, safety, and cost-effectiveness of approved drugs, including information from firms, to help support their drug selection, formulary management, and/or coverage and reimbursement decisions on a population basis. This information may differ from and may be in addition to the information FDA reviews in order to make drug approval decisions. Because coverage and reimbursement decisions by payors impact a large number of patients, FDA believes it is essential that HCEI provided by firms to payors about their approved drugs be truthful and non-misleading.

With respect to HCEI regarding approved drugs, section 502(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(a)), as amended by section 114 of the Food and Drug

Administration Modernization Act of 1997 (Pub. L. 105–115) and section 3037 of the 21st Century Cures Act (Pub. L. 114–255), includes a provision regarding communication of HCEI about such drugs to payors. Section 502(a) indicates that HCEI provided to payors carrying out their responsibilities for the selection of drugs for coverage or reimbursement shall not be considered to be false or misleading if the HCEI relates to an FDA-approved indication for the drug, is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the FDA-approved labeling for the drug. Section III.A of this draft guidance provides FDA’s current thinking on key concepts in section 502(a) and recommendations for how firms can communicate HCEI about approved drugs to payors in accordance with this section to help ensure that payors have information needed to make informed drug selection, formulary management, and/or coverage and reimbursement decisions and to help ensure that the information is not false or misleading. Section III.A also discusses how FDA’s requirements for submission of promotional materials apply to HCEI about approved drugs disseminated by firms to payors. If a firm disseminates HCEI about an approved drug in accordance with this draft guidance, when finalized, FDA does not intend to consider such information false or misleading. In addition, FDA does not intend to use HCEI about approved drugs disseminated consistent with this draft guidance, when finalized, as providing evidence of a new intended use.

FDA also recognizes that due in part to their need, in some situations, to plan for and make coverage and reimbursement decisions far in advance of the effective date of such decisions, payors are also interested in receiving information from drug and device firms about medical products that are not yet approved or cleared by FDA for any use (referred to in this draft guidance as investigational products). Section III.B discusses FDA’s thinking with respect to communication by firms to payors of information about investigational products. As with HCEI about approved prescription drugs, it is essential that information provided by firms about their investigational products be truthful and non-misleading. Therefore, section III.B also lays out a series of recommendations to help achieve these goals.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance for industry entitled “Medical Product Communications That Are Consistent With the Food and Drug Administration-Required Labeling—Questions and Answers.” The guidance provides information for medical product firms about how FDA evaluates their medical product communications, including their promotional materials, that present information that is not contained in the FDA-required labeling for the product but that may be consistent with the FDA-required labeling for the product.

In addition, FDA is announcing in this issue of the **Federal Register** that it is reopening the comment period for the notice of public hearing that appeared in the **Federal Register** of September 1, 2016, concerning manufacturer communications regarding unapproved uses of approved or cleared medical products. The comment period will be reopened for 90 days, until *January 19, 2017*. As announced in the notice of public hearing, FDA is engaged in a comprehensive review of its regulations and policies governing communications by firms about unapproved uses of approved or cleared medical products, and the comments it receives will inform FDA’s policy development in this area.

FDA will consider the feedback it receives in all three of these dockets as the Agency continues to review its policies on firm communications about medical products, and interested persons may wish to review the documents FDA has issued in all three dockets before submitting comments to any of the relevant dockets.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the current thinking of FDA on certain commonly asked questions regarding firms’ communications with payors. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests

or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Drug Manufacturer Communications of Health Care Economic Information to Payors Under FD&C Act Section 502(a); Drug and Device Manufacturer Communications With Payors Regarding Investigational Products.

Description of Respondents: For information that should be included when HCEI is disseminated to payors, respondents to this collection of information are firms that manufacture prescription human drug products, including biological products; for information that should be included with communications with payors about investigational products, respondents to this collection of information are firms that manufacture prescription human drug products, including biological products, and medical devices.

Burden Estimate: This draft guidance includes recommendations regarding

information that firms should include in HCEI for prescription drugs if they choose to disseminate such materials ("HCEI materials") to payors, in accordance with section 502(a). Specifically, FDA recommends that various aspects of study design and methodology of an economic analysis (*i.e.*, type of analysis, modeling technique, patient population, perspective/viewpoint, treatment comparator, time horizon, outcome measures, cost estimates, and assumptions); factors that limit generalizability of an economic analysis; limitations to an economic analysis; and sensitivity analyses, if applicable, be included in HCEI materials disseminated to payors to allow for informed decision-making and to help ensure that the HCEI is not false or misleading.

Furthermore, FDA recommends that firms include other information when disseminating HCEI materials, as applicable, to provide a balanced and complete presentation. Such information includes a statement of the FDA-approved indication of the drug and a copy of the most current FDA-approved labeling. Under section 502(a), firms must also include a conspicuous and prominent statement to describe any material differences between the HCEI and the FDA-approved labeling. HCEI materials should also disclose whether certain studies or data sources were omitted from an economic analysis and how such selective inclusion of studies or data sources may alter the conclusions presented in the analysis. Moreover, FDA recommends that HCEI materials disclose important risk information associated with the approved use of the drug, and pursuant to section 502(a), must disclose any additional risk information related to assumptions that vary from the approved labeling. Finally, HCEI materials should disclose potential financial or affiliation biases to the extent reasonably known by firms at the time of dissemination.

If firms choose to make communications to payors about investigational products, FDA

recommends that firms include a clear statement with their communications that the product is under investigation and that the safety or effectiveness of the product has not been established. In addition, FDA recommends providing information related to the stage of product development (*e.g.*, the phase of clinical trial in which a product is being studied and how it relates to the overall product development plan). Moreover, FDA recommends that firms provide followup information to payors if previously communicated information becomes outdated as a result of significant changes or as a result of new information regarding the product or its review status.

Based on the post-marketing submissions of promotional materials using Form FDA 2253 received in calendar year (CY) 2015 for prescription drugs, FDA estimates that approximately 400 firms will disseminate 4,000 distinct HCEI materials annually. FDA estimates that it will take firms approximately 20 hours to compile and draft the information that this draft guidance recommends should be included if they choose to disseminate HCEI materials to payors.

Based on the number of prescription drugs and devices approved/cleared in CY 2015, FDA estimates that approximately 520 firms will prepare 1,040 distinct communications of information to payors about their investigational products annually. FDA estimates that it will take firms approximately 0.5 hours to compile and draft the information that this draft guidance recommends should be provided with communications to payors about investigational products. In addition, FDA estimates that approximately half of the firms will spend approximately 2 hours to compile and provide 520 distinct communications of followup information regarding previously communicated information to payors about their investigational products annually.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

| Type of information | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Recommended information to be included when firms choose to disseminate HCEI materials to payors about prescription drugs under section 502(a). | 400 | 10 | 4,000 | 20 | 80,000 |
| Recommended information to be included when firms choose to disseminate pre-approval communications about investigational drugs or devices to payors. | 520 | 2 | 1,040 | 0.5 (30 minutes) | 520 |

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

| Type of information | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|--|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Follow up information to payors regarding previously communicated information about investigational drugs and devices. | 260 | 2 | 520 | 2 | 1,040 |
| Total | | | | | 81,560 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 314.81(b)(3)(i) (Form FDA 2253) have been approved under OMB control number 0910–0001.

III. Other Issues for Consideration

Although section 502(a) is specific to approved drugs and section III.A of this draft guidance addresses firms' communications of HCEI to payors only about approved drugs, FDA is interested in whether similar principles to those outlined in that section should apply to firms' communications of HCEI to payors about approved/cleared devices or whether different principles should be considered. FDA is specifically interested in identifying principles that, if applied to communications of HCEI about approved/cleared devices, could help ensure that such information is truthful and non-misleading and aids payors in making informed selection and/or coverage and reimbursement decisions about these products. FDA is interested in comments from interested parties on any of the topics addressed in this draft guidance and specifically requests comments from interested parties on the extent to which the principles provided in section III.A could be applicable to communications of HCEI about approved/cleared devices. To the extent that interested parties believe that different considerations should apply to medical devices or that guidance is needed on additional issues with respect to medical device firms' communications of HCEI about approved/cleared medical devices to payors, FDA is interested in input on those topics as well.

FDA is also seeking comments from interested parties regarding communications of HCEI about animal drugs. Although FDA recognizes that the audience for HCEI about animal drugs may be different from that identified in section III.A as a result of differences in how payment decisions are made for animal drugs, FDA is interested in learning the extent to

which the principles provided in section III.A could be applicable to communications of HCEI about animal drugs with appropriate audiences for such information. To the extent that commenters believe that different considerations should apply to animal drugs or that guidance is needed on additional issues with respect to animal drug firms' communications of HCEI about approved new animal drugs to appropriate audiences, FDA is interested in input on those topics as well.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>, or <https://www.regulations.gov>.

Dated: January 6, 2017.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–01011 Filed 1–18–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0595]

Advice About Eating Fish, From the Environmental Protection Agency and Food and Drug Administration; Revised Fish Advice; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: In June 2014, the Food and Drug Administration (FDA) and the U.S. Environmental Protection Agency (EPA) (the Agencies) jointly released a draft

update to a March 2004 document entitled “What You Need to Know About Mercury in Fish and Shellfish.” FDA and EPA are now announcing revised fish advice that contains advice and supplemental questions and answers for those who want to understand the advice in greater detail.

FOR FURTHER INFORMATION CONTACT:

FDA: William R. Jones, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1422, William.Jones@fda.hhs.gov; **EPA:** Lisa Larimer, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., MS 4305T, Washington, DC 20460, 202–566–1017, Larimer.Lisa@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2014 (79 FR 33559), FDA, in coordination with EPA, announced the availability of the draft updated fish advice, entitled “Fish: What Pregnant Women and Parents Should Know” (the notice), and made the draft updated advice available for public comment. The draft fish advice was intended to update advice previously published by EPA and FDA in March 2004 (Ref. 1), to make it consistent with the 2010 Dietary Guidelines for Americans and to modify the wording and organization of the 2004 advice to enhance the likelihood that it would be followed by the target audience. The 2004 advice on fish consumption itself was preceded by earlier recommendations published by FDA in September 1994 and revised in May 1995 (http://www.fda.gov/ohrms/dockets/ac/02/briefing/3872_advisory%207.pdf), followed by separate, but simultaneously issued, FDA and EPA fish consumption advice in 2001. FDA's 2001 advice addressed commercial fish; EPA's 2001 advice addressed locally caught fish. The 2014 notice announcing the availability of the draft updated fish advice stated that the comment period would be open until 30 days after the last transcript became available from either the FDA Risk

Communication Advisory Committee (RCAC) meeting to be held on the draft advice or any other public meeting that the Agencies chose to hold on the draft advice (79 FR 33559). The notice also stated that the date for closure of public comment would be published in a future notice in the **Federal Register** (id.).

The RCAC meeting was held on November 3 and 4, 2014, and the transcript of the meeting became available on December 2, 2014. The meeting addressed the draft updated fish advice in great detail and included presentations by the Agencies on both the substance and the presentation of the draft updated fish advice, and included presentations by invited experts in risk communications. The meeting also provided members of the public with an opportunity to express their views to the RCAC and to officials of the Agencies who were in attendance. FDA and EPA concluded that the thoroughness of this public meeting, in addition to the public comments received and still to be received, removed the need for additional public meetings, and announced in the **Federal Register** that the comment period for the draft updated advice would be closed on March 26, 2015 (80 FR 9732). The transcript from the RCAC meeting is available electronically at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM425352.pdf> and <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials>. A summary table of joint responses from FDA and EPA to the comments we received on the draft updated fish advice is available in the docket (Ref. 2). The comments themselves are also available in the Docket.

In August 2016, an external peer review of FDA-EPA's method for categorizing species of fish into consumption categories was conducted at the request of FDA and EPA. Information on the external peer review and FDA's and EPA's responses to the peer review are available at <http://www.fda.gov/fishadvice> (and also on FDA's Completed Peer Reviews page at <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>) (Refs. 3 and 4). Fish and shellfish (referred to collectively in this notice as "fish") provide protein, are low in saturated fat, are rich in many micronutrients, and provide certain omega-3 fatty acids (Ref. 5). However, as a result of natural processes and human activity, fish also contain mercury in the

form of methylmercury. Methylmercury can adversely affect the central nervous system, particularly the developing brain of the fetus. After a careful review and consideration of the RCAC transcript, the comments received on the draft updated fish advice (Ref. 2), and the peer review, EPA and FDA are issuing revised fish advice.

The 2004 advice was issued to help individuals in the target population limit their exposure to mercury while still obtaining the health benefits of fish consumption. The 2004 advice recommended avoiding four types of commercially available fish that have the highest average mercury concentrations: Tilefish, shark, swordfish, and king mackerel. The advice further recommended that women in the target population eat up to—but not exceed—12 ounces per week of most other types of commercially available fish. It recommended limiting consumption of one species, white (albacore) tuna, to no more than 6 ounces per week. For local fish caught by family and friends, the advice recommended following locally posted fish advisories regarding safe catch. Where no such advice exists, it recommends limiting consumption of locally caught fish to 6 ounces per week and eating no other fish that week.

While the 2004 advice encourages fish consumption as part of a healthy diet, it does not encourage consumption of a minimum amount of fish. In June 2014, FDA and EPA issued the draft updated advice to encourage women who are pregnant or breastfeeding to consume 8 to 12 ounces of a variety of fish per week to maximize the potential benefits that fish could provide. The Agencies also proposed to modify the wording and organization of the 2004 advice in order to enhance the likelihood that it will be followed by the target audience.

II. What is in the revised fish advice?

The revised fish advice is designed to encourage women who are pregnant and breastfeeding to consume 8 to 12 ounces of a variety of fish per week, and it includes further modified wording and organization to further enhance the likelihood that it will be followed by the target audience. The revised fish advice includes a chart and supplemental questions and answers. The chart provides recommendations for how often the target audience (pregnant women, women who might become pregnant, breastfeeding women, and young children) should eat more than 60 different fish, based on mercury concentrations.

FDA and EPA used sampling data from FDA and, to a limited extent, from

the U.S. National Marine Fisheries Service as the source for mercury amounts in fish (Ref. 6), with support from other sources (Refs. 7 through 12). The revised fish advice makes the following recommendations for the target audience:

- *Eat 2 to 3 servings a week of a variety of fish.* The revised fish advice translates the consumption target of 8 to 12 ounces of a variety of fish per week into 2 to 3 servings a week of a variety of fish, with a typical adult serving as 4 ounces. The chart in the revised fish advice shows which fish the target audience can eat 2 to 3 servings a week.

- *Eat 1 serving a week of some fish.* Since 2004, the advice has recommended limiting albacore ("white") tuna to 1 serving a week (or 6 ounces per week). The revised fish advice adds 18 fish with similar mercury concentrations to the list of fish to eat 1 serving a week.

- *Avoid certain fish with the highest mercury concentrations.* Since 1994, the advice has recommended limiting or avoiding shark and swordfish. In 2001, tilefish and king mackerel were added to this list of recommended fish to avoid. This revised fish advice adds marlin, orange roughy, and bigeye tuna, which have similar mercury concentrations. The revised fish advice recommends avoiding tilefish only from the Gulf of Mexico, consistent with the draft updated fish advice. Data on tilefish from the Atlantic Ocean indicate that these fish have much lower levels of mercury on average (Ref. 6).

- *Check for advisories for fish caught by family and friends and where no advisory exists, limit eating those fish to one serving a week and do not eat other fish that week.* The revised fish advice retains the recommendations included in the 2004 advice for fish caught by family and friends. There are waters where there may have been little or no monitoring and, therefore, the extent of potential mercury contamination is unknown. Fish caught for recreation or subsistence can contain higher levels of mercury than commercially available species.

III. How does the revised fish advice differ from the draft updated fish advice?

The revised fish advice presents the recommended consumption for more than 60 fish in a color-coded chart. The fish are presented in categories of "Best Choices," those which the target audience can eat 2 to 3 servings a week; "Good Choices," which the target audience can eat 1 serving a week; and "Choices to Avoid." See Ref. 13 for a description of how FDA and EPA

decided which fish went in each category. The draft updated fish advice recommended eating 8 to 12 ounces of a variety of fish per week and choosing fish lower in mercury, but it only mentioned 7 of those fish (salmon, shrimp, pollock, tuna (light canned), tilapia, catfish, and cod). The revised fish advice also retains the recommendation to eat a variety of fish. The revised fish advice adds 18 fish that the target audience can eat 1 serving a week (see "Good Choices" category in the revised fish advice). The draft updated fish advice included only white (albacore tuna) as a fish to limit to 6 ounces per week. Another change between the draft updated advice and the revised fish advice is that the revised fish advice adds marlin, orange roughy, and bigeye tuna to the list of fish that the target audience should avoid eating (see "Choices to Avoid" category in the revised fish advice). These fish were added because they have comparable mercury levels to fish included in the draft updated advice as fish that should be avoided (*i.e.*, shark, swordfish, tilefish from the Gulf of Mexico, and king mackerel).

The Agencies reorganized the questions and answers (Qs and As) into topic areas, simplified the responses, and added new questions as a result of comments received during the comment period. The chart includes a link to two fish advice Web sites (<http://www.fda.gov/fishadvice>) and <http://www.epa.gov/fishadvice>), images to show serving size, and is designed to make it clear and easy to read for display at point of sale, doctors' offices and elsewhere. The Web site contains the advice and the Qs and As. Educational and outreach materials will be added to the Web site as they are developed.

IV. What comments were received and how does the revised fish advice reflect them?

FDA and EPA received over 200 comments from States, industry, academia, various organizations, and concerned individuals. The comments covered a range of topics from the scientific basis of the advice to communication. There was a wide range of opinions expressed in the comments, not all of which were relevant to the advice. The majority of the comments pertained to the clarity and effectiveness of how the advice was presented. In response to comments, the Agencies revised the presentation of the advice, as discussed in part III of this document. Other comments suggested a more restrictive set of consumption recommendations or disagreed with

setting consumption thresholds for specific species of fish or for any but the species highest in mercury. After reviewing the comments, FDA and EPA adopted an approach in which fish species are separated into three categories based on average measured mercury content ("Best Choices," "Good Choices," and "Choices to Avoid"). An evaluation of available information led the Agencies to recommend eating 2 to 3 servings a week for some fish and 1 serving a week for others. The advice to eat 2 to 3 servings of a variety of fish a week is consistent with the recommendation in the 2015–2020 Dietary Guidelines for Americans that women who are pregnant or breastfeeding consume at least 8 and up to 12 ounces of a variety of fish lower in mercury per week. Consuming 8 to 12 ounces of fish per week while pregnant or breastfeeding would be a significant dietary change for most women. In a survey of over 1,200 pregnant women conducted by FDA in 2005, median fish consumption was 1.8 ounces per week (Ref. 14).

The approach in the revised fish advice differs from that taken in the draft updated fish advice not only in that it categorizes more than 60 fish types, but also in its analytical basis. In categorizing the fish species for recommended consumption, the revised fish advice compares the reference dose (RfD) developed by EPA (Ref. 15) to the predicted exposure from the consumption of different fish species. Because the RfD is a rate of exposure that a person can experience over a lifetime without appreciable risk of harm and includes a 10-fold uncertainty factor to allow for variability among individuals and groups, this was a highly protective approach for determining which fish belong in each category. Specifically, the RfD for mercury is protective of neurodevelopmental effects from a critical window of development for a fetus during pregnancy. We believe the new approach is more protective of public health. This new approach is also consistent with a number of the comments received, and the external peer review conducted.

V. What did the peer reviewers say and how did FDA and EPA respond?

Overall, the reviewers agreed upon the necessity of mercury fish advice for pregnant women, those trying to get pregnant, and children, to encourage fish consumption while helping to avoid mercury. The reviewers were generally supportive of the technical information and methodology used to support the scientific basis for the fish

consumption recommendations. The reviewers made suggestions to improve clarity, transparency, and presentation, and to enhance the scientific underpinnings of the fish advice. The reviewers suggested supplementing FDA's data on mercury levels in seafood with other published sources to support the fish categorization for species with small sample sizes and/or large variability in mercury levels. The reviewers also provided various suggestions of where additional details could be added to aid the reader and support the conclusions. FDA and EPA implemented many of the reviewers' recommendations. A report of the FDA–EPA response to the peer review is available at <http://www.fda.gov/fishadvice> (and also on FDA's Completed Peer Reviews page at <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>) (Ref. 4).

VI. How can I access the documents?

The revised fish advice and supplemental questions and answers are available electronically at <http://www.fda.gov/fishadvice> and <http://www.epa.gov/fishadvice>.

VII. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. "What You Need to Know About Mercury in Fish and Shellfish; 2004 EPA and FDA Advice for: Women Who Might Become Pregnant, Women Who are Pregnant, Nursing Mothers, Young Children," available at <http://www.fda.gov/food/foodborneillnesscontaminants/buystoresservesafefood/ucm110591.htm>.
2. Summary Table of Responses to Public Comments on EPA's and FDA's Draft Updated Advice About Eating Fish (Docket No. FDA–2014–N–0595).
3. External Peer Review of FDA/EPA's "Technical Information on the Development of Fish Consumption Advice," available at <http://www.fda.gov/fishadvice> and <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>.
4. FDA and EPA's Response to External Peer

Review on the FDA-EPA's Technical Information on the Development of Fish Consumption Advice, available at <http://www.fda.gov/fishadvice> and <http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/ucm079120.htm>.

5. Institute of Medicine, Committee on Nutrient Relationships in Seafood: "Selections to Balance Benefits and Risks," (2007). Seafood Choices, Balancing Benefits and Risks. The National Academies Press, Washington, DC.
6. "Mercury Levels in Commercial Fish and Shellfish 1990–2010," available at <http://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm115644.htm>.
7. Karimi, R., Fitzgerald, T.P., and Fisher, N.S. (2012). "A Quantitative Synthesis of Mercury in Commercial Seafood and Implications for Exposure in the United States." *Environ Health Perspect* 120, 1512–1519, available at <http://ehp.niehs.nih.gov/1205122/>.
8. U.S. Environmental Protection Agency (U.S. EPA) 2003. Mercury in Marine Life Database. Office of Wetlands, Oceans and Watersheds, available at https://cfpub.epa.gov/si/si_public_record_Report.cfm?dirEntryId=58213.
9. U.S. Environmental Protection Agency. (U.S. EPA) (2016). National Coastal Assessment (NCA): Northeast 2000–2006 Summary Data, available at <https://archive.epa.gov/emap/archive-emap/web/html/index-124.html>.
10. U.S. Environmental Protection Agency (U.S. EPA). (2016). National Coastal Condition Assessment (NCCA) Office of Water & Office of Research Development, EPA 841–R–15–006, Washington, DC. 2010 Results, available at <https://www.epa.gov/national-aquatic-resource-surveys/national-coastal-condition-assessment-2010-results>.
11. Health Canada, (2007) Human Health Risk Assessment of Mercury in Fish and Health Benefits of Fish Consumption, Bureau of Chemical Safety Food Directorate Health Products and Food Branch, Ottawa, Ontario, Canada.
12. Cladis, D.P., Kleiner, A.C., and Santerre, C.R. (2014). "Mercury Content in Commercially Available Finfish in the United States." *J Food Prot* 77, 1361–1366, available at <http://www.ncbi.nlm.nih.gov/pubmed/25198598>.
13. FDA-EPA Fish Advice: Technical Information, available at <http://www.fda.gov/fishadvice>.
14. Lando, A.M., S.B. Fein, and C.J. Choinière, "Awareness of Methylmercury in Fish and Fish Consumption Among Pregnant and Postpartum Women of Childbearing Age in the United States," *Environmental Research*, vol. 116, pp. 85–92, 2012.
15. U.S. Environmental Protection Agency's Integrated Risk Information System (IRIS), available at <http://www.epa.gov/iris/subst/0073.htm>.

Dated: January 11, 2017.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–01073 Filed 1–18–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–4482]

Regulation of Mosquito-Related Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #236 entitled "Regulation of Mosquito-Related Products." This draft guidance provides information regarding regulatory oversight of mosquito-related products, defined as those articles for use in or on mosquitoes. We are clarifying circumstances under which such products are regulated by FDA as new animal drugs under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and other circumstances under which such products are regulated by the Environmental Protection Agency (EPA) as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 21, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any

confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–D–4482 for "Regulation of Mosquito-Related Products." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can

provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Laura R. Epstein, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-796-8558, Laura.Epstein@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry (GFI) #236 entitled “Regulation of Mosquito-Related Products.” This draft guidance provides information for industry and other stakeholders regarding regulatory oversight of mosquito-related products, defined as those articles for use in or on mosquitoes. Given the public health implications of mosquito control, FDA is providing this draft guidance to clarify the regulatory oversight of mosquito-related products, including but not limited to those produced through biotechnology. This guidance is important in light of the public health urgency of countering the spread of mosquito-borne disease, such as that caused by the Zika virus. Vector control is a critical element of the effort to combat the spread of mosquito-borne disease. Novel mosquito control technologies have gained greater

attention as an element of this effort; however, there has been some confusion with respect to FDA’s and EPA’s respective jurisdiction over such mosquito-related products. We are clarifying circumstances under which such products are regulated by FDA as new animal drugs under the FD&C Act and other circumstances under which such products are regulated by the EPA as pesticides under FIFRA. FDA is clarifying that the phrase “articles (other than food) intended to affect the structure or any function of the body of man or other animals” in the FD&C Act’s drug definition (21 U.S.C. 321(g)(1)(C)) does not include articles intended to function as pesticides by preventing, destroying, repelling, or mitigating mosquitoes for population control purposes. FDA believes that this interpretation is consistent with congressional intent and provides a rational approach for dividing responsibilities between FDA and EPA in regulating mosquito-related products.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on Regulation of Mosquito-Related Products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <https://www.regulations.gov>.

Dated: January 11, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-00838 Filed 1-18-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-2285]

Medical Product Communications That Are Consistent With the Food and Drug Administration-Required Labeling—Questions and Answers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers.” This draft guidance provides information for manufacturers, packers, and distributors and their representatives (collectively “firms”) of drugs and medical devices for humans, including those that are licensed as biological products, and animal drugs (collectively “medical products”), about how FDA evaluates their medical product communications, including their promotional materials, that present information that is not contained in the FDA-required labeling for the product but that may be consistent with the FDA-required labeling for the product. The Agency is issuing this draft guidance to explain FDA’s current thinking on commonly asked questions regarding such communications in order to provide clarity for firms.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 19, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a

third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-2285 for "Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers; Draft Guidance for Industry; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your

name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002; Division of Small Manufacturers, International and Consumer Assistance, Office of Communication, Education and Radiation Programs, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002; or to Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Kristin Davis, Office of Policy, Office of the Commissioner, 10903 New Hampshire Ave., Bldg. 32, Rm. 4252, Silver Spring, MD 20993-0002, 301-796-0418; or Catherine Gray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3203, Silver Spring, MD 20993-0002, 301-796-1200; or Stephen Ripley, Center for

Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911; or Angela Krueger, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1666, Silver Spring, MD 20993-0002, 301-796-6380; or Thomas Moskal, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. (HFV-1), Rockville, MD 20855, 240-402-6251.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers." This draft guidance provides information for firms about how FDA evaluates their medical product communications, including their promotional materials, that present information that is not contained in the FDA-required labeling¹ for the product but that may be consistent with the FDA-required labeling for the product.

FDA determines whether a medical product is safe and effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling submitted to FDA with the product's marketing application or submission (and for devices, also during the classification process). In making this determination, FDA evaluates whether the conditions of use in the proposed labeling are supported by the required levels and types of evidence of safety and effectiveness and whether the benefits of using the product under those specific conditions of use outweigh the risks of the product. After FDA approves or clears a medical product, the FDA-required labeling sets forth the conditions of use under which the product has been shown to meet the relevant standard for marketing, and it provides directions and information on how to use the product safely and effectively under those conditions.

Medical product firms have expressed interest in communicating, including in promotional materials, data and

¹ As used in the draft guidance, the term FDA-required labeling includes the labeling reviewed and approved by FDA as part of the medical product marketing application review process. For products not subject to premarket approval, but instead subject to premarket notification requirements or exempt from premarket review, the term also includes the labeling relied on to provide adequate directions for use and other information required to appear on the label or in labeling.

information that are not contained in their products' FDA-required labeling but concern the approved/cleared uses of the products. We are aware that firms have questions about how FDA determines when such communications are consistent with the FDA-required labeling, and how they are viewed by FDA.

The draft guidance describes FDA's thinking on these topics. As explained in the draft guidance, a firm's communication of information that is not contained in the product's FDA-required labeling, but that is determined to be consistent with the FDA-required labeling, is not alone considered evidence of a new intended use. However, even if a communication is consistent with the FDA-required labeling, the representations or suggestions made about the product would misbrand the product and could subject firms to enforcement action if the representations or suggestions are false or misleading. Accordingly, the draft guidance both describes FDA's thinking on the types of information that are consistent with the FDA-required labeling and provides general recommendations for how this information can be conveyed in a truthful and non-misleading way. The draft guidance also provides some examples to illustrate these concepts. The recommendations provided in the draft guidance to help ensure that communications are not false or misleading are specific to communications that are consistent with the FDA-required labeling; communication of information that is not consistent with the FDA-required labeling is outside the scope of these recommendations.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance for industry entitled "Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers." This draft guidance provides answers to common questions regarding firms' communications of health care economic information about their approved prescription drugs to payers and similar entities. This draft guidance also addresses common questions relating to firms' dissemination of information about investigational products to payers before FDA approval or clearance of such products.

In addition, FDA is announcing in this issue of the **Federal Register** that it is reopening the comment period for the notice of public hearing that appeared in the **Federal Register** of September 1, 2016, concerning manufacturer

communications regarding unapproved uses of approved or cleared medical products. The comment period will be reopened for 90 days, until April 19, 2017. As announced in the notice of public hearing, FDA is engaged in a comprehensive review of its regulations and policies governing communications by firms about unapproved uses of approved or cleared medical products, and the comments it receives will inform FDA's policy development in this area.

FDA will consider the feedback it receives in all three of these dockets as the Agency continues to review its policies on firm communications about medical products, and interested persons may wish to review the documents FDA has issued in all three dockets before submitting comments to any of the relevant dockets.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on certain commonly asked questions regarding firms' communications for their medical products that may be consistent with the FDA-required labeling. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's

estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Recommended Content of Medical Product Communications That Are Consistent With the FDA-Required Labeling.

Description of Respondents:

Respondents to the proposed collection of information are manufacturers, packers, and distributors and their representatives (firms) of human drugs and devices, including those licensed as biological products, and animal drugs.

Burden Estimate: The draft guidance includes Third-Party Disclosure recommendations regarding information that firms should include in communications that contain information not found in the FDA-required labeling for their medical products but that are consistent with the FDA-required labeling (as explained in the draft guidance) if they choose to publically disseminate such materials.

Specifically, FDA recommends that various aspects of study design and methodology for studies relied on in such communications be disclosed to provide material contextual information (e.g., type of study, study objectives, product dosage/use regimens, control(s) used, patient population studied), and that material limitations related to the study design, methodology, and results also be disclosed in a clear and prominent manner to help ensure that the communications are not false or misleading.

Furthermore, FDA recommends that firms accurately characterize and contextualize the relevant information about the product, including by disclosing unfavorable or inconsistent findings. FDA also recommends that firms disclose material contextual information from the FDA-required labeling in these communications, such as data and information from studies in the FDA-required labeling that are relevant to the data or information presented in the communication (e.g., if a communication provides post-market information about the types and rates of occurrence of adverse events that have been observed in practice, the communication should also include information from the FDA-required labeling about the types and rates of occurrence of adverse reactions

observed in clinical trials to provide context).

According to FDA data, approximately 162,000 FDA-regulated promotional materials are prepared by approximately 500 firms annually. Of these materials, we estimate approximately 5 percent contain unique presentations of information consistent with FDA-required labeling, as that term is described in the draft guidance, submitted by approximately 64 percent

(or 324) of the firms. Anticipating the number of these FDA-regulated promotional materials will soon increase to 6 percent, we estimate the 324 firms will prepare and disseminate annually 9,720 FDA-regulated promotional materials that contain unique presentations of information that is consistent with FDA-required labeling, as that term is described in the draft guidance, and that therefore are recommended to include the proposed

third party disclosures. Based on our experience reviewing FDA-regulated promotional materials for medical products, we estimate it will take respondents approximately 4 hours per unique presentation to prepare and incorporate the disclosures recommended in the draft guidance, if they choose to disseminate this information.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

| Type of information | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure | Total hours |
|---|-----------------------|--------------------------------------|--------------------------|-------------------------------|-------------|
| Recommended information to be included when firms choose to disseminate communications that are consistent with the FDA-required labeling | 324 | 30 | 9,720 | 4 | 38,880 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>, <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>, or <https://www.regulations.gov>.

Dated: January 6, 2017.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-01012 Filed 1-18-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Ryan White HIV/ AIDS Program: Allocation and Expenditure Forms

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public

comment on proposed data collection projects, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than March 20, 2017.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N-39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Ryan White HIV/AIDS Program: Allocation and Expenditure Forms.

OMB No. 0915-0318—Revision.

Abstract: HRSA's HIV/AIDS Bureau (HAB) administers the Ryan White HIV/AIDS Program authorized under Title XXVI of the Public Health Service Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009. The Ryan White HIV/AIDS Program Allocation and Expenditure Reports (A&E Reports), in conjunction with the Consolidated List of Contractors (CLC), enables HRSA to monitor and track the use of grant funds for compliance with

program and grants policies and requirements under the statute. By regulation, recipients are required to submit financial reports annually to HRSA and the A&E Reports and the CLC are HAB's mechanism to implement that requirement. Recipients funded under Parts A, B, C, and D of the Ryan White HIV/AIDS Program (codified under Title XXVI of the Public Health Service Act) are required to report financial data to HRSA at the beginning (Allocations Report) and at the end of their grant cycle (Expenditures Report). Recipients funded under Parts A and B are required to report information about their service provider contracts in the CLC.

The forms will continue to require recipients to report on how funds are allocated and spent on core medical and non-core services for persons living with HIV, and on various program components, such as administration, planning and evaluation, and quality management. The A & E Reports are identical in the types of information they collect. However, the first report tracks the allocation of the award at the beginning of the grant cycle and the second report tracks actual expenditures (including carryover dollars) at the end of the grant cycle. The CLC form identifies a recipient's contracts with service providers for the current grant year, the contract amount, and the types of services being provided.

Need and Proposed Use of the Information: Accurate allocation, expenditure, and service contract records of the recipients receiving Ryan White HIV/AIDS Program funding are critical to the implementation of the law and thus are necessary for HRSA to fulfill its responsibilities. The primary

purposes of these forms are to provide information on the number of grant dollars spent on various services and program components and oversee compliance with the intent of Congressional appropriations in a timely manner. In addition to meeting the goal of accountability to the Congress, clients, and the general public, information collected on these reports is critical for HRSA, state and local grantees, and individual providers

to evaluate the effectiveness of these programs.

Likely Respondents: Ryan White HIV/AIDS Program recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose

of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

| Form name | Number of respondents | Number of responses per respondent | Total responses | Average burden per response (in hours) | Total burden hours |
|----------------------------------|-----------------------|------------------------------------|-----------------|--|--------------------|
| Part A Allocations Report | 52 | 1 | 52 | 4 | 208 |
| Part A Expenditures Report | 52 | 1 | 52 | 4 | 208 |
| Part A CLC | 52 | 1 | 52 | 2 | 104 |
| Part B Allocations Report | 54 | 1 | 54 | 6 | 324 |
| Part B Expenditures Report | 54 | 1 | 54 | 6 | 324 |
| Part B CLC | 54 | 1 | 54 | 2 | 108 |
| Part C Allocations Report | 346 | 1 | 346 | 4 | 1,384 |
| Part C Expenditures Report | 346 | 1 | 346 | 4 | 1,384 |
| Part D Allocations Report | 116 | 1 | 116 | 4 | 464 |
| Part D Expenditures Report | 116 | 1 | 116 | 4 | 464 |
| Total | | | 1,294 | | 4,972 |

Note: Recipients are required to fill out an allocation report, expenditure report, and CLC for each Ryan White HIV/AIDS Program award received.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2017-01220 Filed 1-18-17; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Evaluation of the Maternal and Child Health Bureau's Autism CARES Act Initiative

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than February 21, 2017.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A), the Paperwork Reduction Act of 1995.

Information Collection Request Title: Evaluation of the Maternal and Child Health Bureau's Autism CARES Act Initiative OMB No. 0915-0335, Revision.

Abstract: In response to the growing need for research and resources devoted to autism spectrum disorder (ASD) and other developmental disabilities (DDs), the U.S. Congress passed the Combating Autism Act in 2006 (Pub. L. 109-416); it was reauthorized by the Combating Autism Reauthorization Act of 2011 (Pub. L. 112-32) and the Autism CARES (Collaboration, Accountability, Research, Education, and Support) Act of 2014 (Pub. L. 113-157). Through Autism CARES, HRSA is tasked with increasing awareness of ASD and other DDs, reducing barriers to screening and diagnosis, promoting evidence-based interventions, and training health care professionals in the use of valid and reliable diagnostic tools. To address these goals, HRSA awards grants to various programs through the Maternal and Child Health Bureau (MCHB).

Need and Proposed Use of the Information: The purpose of this information collection is to describe the accomplishments of MCHB's grant programs in implementing the provisions of the Autism CARES Act. This ICR is a revision to an existing package; this study is the third

evaluation of MCHB's Autism CARES activities and employs similar data collection methodologies to the prior studies. Grantee interviews remain the primary form of data collection, but the research team has made minor adjustments to the data collection processes. Changes include adjusting the interview protocols to improve flow and clarify questions, and planning for more than one respondent to attend interviews in instances where the principal investigator requests support.

Likely Respondents: Grantees funded by HRSA under the Autism CARES Act. The grantees are from these MCHB

programs: Leadership Education in Neurodevelopmental Disabilities (LEND) Training Program; Developmental-Behavioral Pediatrics (DBP) Training Program; State Implementation Program; State Innovation in Care Integration Program; Research Network Program; Research Program; Interdisciplinary Technical Assistance Center (ITAC); and the State Public Health Autism Center (SPHARC) Resource Center.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information

requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN

| Grant program/form name | Number of respondents | Number of responses per respondent | Total responses | Average burden per response (in hours) | Total burden hours |
|---|-----------------------|------------------------------------|-----------------|--|--------------------|
| LEND Interview Protocol | 53 | 2 | 106 | 1 | 106 |
| DBP Interview Protocol | 10 | 2 | 20 | 1 | 20 |
| State Implementation Program Interview Protocol | 9 | 2 | 18 | 1 | 18 |
| State Innovation in Care Integration State Grantees | 4 | 1 | 4 | 1 | 4 |
| Research Network Interview Protocol | 5 | 2 | 10 | 1 | 10 |
| Research Program R40 Interview Protocol | 10 | 1 | 10 | 1.5 | 15 |
| Research Network Questionnaire | 5 | 1 | 5 | 1 | 5 |
| Resource Center: ITAC Interview Protocol | 1 | 2 | 2 | 1 | 2 |
| Resource Center: SPHARC Interview Protocol | 1 | 2 | 2 | 1 | 2 |
| Total | 98 | | 177 | | 182 |

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2017-01206 Filed 1-18-17; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of Meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given about a meeting of the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC). This meeting will be open to the public but advance registration is required. Information regarding the ACHDNC can be found at <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/>.

DATE: The meeting will be held on February 9, 2017, from 9:00 a.m. to 5:00 p.m. EST.

ADDRESSES: This meeting will be a webinar. The public can join the meeting by registering in advance. The registration link is available at <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/>. The registration deadline is February 6, 2017, 11:59 p.m. Eastern Time.

FOR FURTHER INFORMATION CONTACT:

Anyone requesting information regarding the ACHDNC should contact Alaina Harris, Maternal and Child Health Bureau (MCHB), HRSA, Room 18W66, 5600 Fishers Lane, Rockville, Maryland 20857; email: aharris@hrsa.gov.

SUPPLEMENTARY INFORMATION: ACHDNC, as authorized by the Public Health Service Act (PHS), Title XI, § 1111 (42 U.S.C. 300b-10), was established to advise the Secretary of HHS about the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. In addition, ACHDNC recommendations regarding additional conditions/inherited

disorders for screening that have been adopted by the Secretary are included in the Recommended Uniform Screening Panel and constitute part of the comprehensive guidelines supported by HRSA. Pursuant to section 2713 of the PHS, codified at 42 U.S.C. 300gg-13, non-grandfathered health plans are required to cover screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (*i.e.*, policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

ACHDNC will hear presentations and discussions on topics related to newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. ACHDNC will also hear updates from the Laboratory Standards and Procedures workgroup, Follow-up and Treatment workgroup, and Education and Training workgroup. Agenda items are subject to changes as priorities indicate. ACHDNC will not be voting on a proposed addition of a condition to the Recommended Uniform Screening Panel. The detailed meeting

agenda, and any changes to the start and end times, will be available 2 days prior to the meeting on the ACHDNC Web site: <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/>.

Members of the public may submit written and/or present oral comments at the meeting. All comments are part of the official ACHDNC record. Advance registration is required to submit written comments and/or present oral comments. Written comments must be submitted by February 6, 2017, 11:59 p.m. EST to be included in the February meeting briefing book. Written comments should identify the individual's name, address, email, telephone number, professional or business affiliation, type of expertise (i.e., parent, researcher, clinician, public health, etc.), and the topic/subject matter of comments.

Individuals who wish to provide oral comments must register by February 6, 2017, 11:59 p.m. EST. To ensure that all individuals who have registered to make oral comments can be accommodated, time may be allocated per speaker. Individuals who are associated with groups or have similar interests may be requested to combine their comments and present them through a single representative. No audiovisual presentations are permitted. For additional information or questions on public comments, please contact Alaina Harris, MCHB, HRSA; email: aharris@hrsa.gov.

Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Alaina Harris at aharris@hrsa.gov at least 10 days prior to the meeting.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2017-01198 Filed 1-18-17; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection

Activities: Proposed Collection: Public Comment Request; Ryan White HIV/AIDS Program Part F Dental Services Report

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than March 20, 2017.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in pursuant to Section 3506(c)(2)(A), the Paperwork Reduction Act of 1995.

Information Collection Request Title: Ryan White HIV/AIDS Program Part F Dental Services Report.

OMB No. 0915-0151—Extension

Abstract: The Dental Reimbursement Program (DRP) and the Community Based Dental Partnership Program (CBDPP) under Part F of the Ryan White HIV/AIDS Program (RWHAP) offer funding to accredited dental education programs. This funding supports the education and training of oral health providers in HIV oral health care and the provision of oral health services for people eligible for the RWHAP and living with HIV. Institutions eligible for the RWHAP are accredited schools of dentistry and other accredited dental education programs, such as dental hygiene programs or those sponsored by a school of dentistry, a hospital, or a public or private institution that offers postdoctoral training in the specialties of dentistry, advanced education in general dentistry, or a dental general practice residency. Schools and programs use the Dental Services Report to apply for funding of non-reimbursed costs incurred in providing oral health care to patients living with HIV and to report annual program data. Awards are authorized under section 2692(b) of the Public Health Service Act (42 U.S.C.

300ff-111(b)). The Dental Services Report collects data for DRP on patient demographics, oral health services, funding, and training. It also requires applicants to provide narrative descriptions of their services and facilities, as well as their links and collaboration with community-based providers of oral health services.

Need and Proposed Use of the Information: The primary purpose of collecting this information annually is to verify applicant eligibility and determine reimbursement amounts for DRP applicants, as well as to document the program accomplishments of CBDPP grant recipients. This information also allows HRSA to learn about (1) the extent of the involvement of dental schools and programs in treating patients with HIV, (2) the number and characteristics of clients who receive RWHAP-supported oral health services, (3) the types and frequency of the provision of these services, (4) the non-reimbursed costs of oral health care provided to patients living with HIV, and (5) the scope of grant recipients' community-based collaborations and training of providers. Information collected in the Dental Services Report is critical for HRSA, state and local grantees, and individual providers to help assess the status of existing HIV-related health service delivery systems.

Likely Respondents: Accredited schools of dentistry and other accredited dental education programs, such as dental hygiene programs or those sponsored by a school of dentistry, a hospital, or a public or private institution that offers postdoctoral training in the specialties of dentistry, advanced education in general dentistry, or a dental general practice residency.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

| Form name | Type of respondent | Number of respondents | Number of responses per respondent | Total responses | Average burden per response (in hours) | Total burden hours |
|------------------------------|--------------------|-----------------------|------------------------------------|-----------------|--|--------------------|
| Dental Services Report | DRP | 56 | 1 | 56 | 45 | 2,520 |
| | CBDPP | 12 | 1 | 12 | 35 | 420 |
| Total | | 68 | | 68 | | 2,940 |

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2017-01218 Filed 1-18-17; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: 0937-0198-60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans

to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for extending the use of the approved information collection assigned OMB control number 0937-0198, which expires on May 31, 2017. Prior to submitting the ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before March 20, 2017.

ADDRESSES: Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690-5683 or email *Sherrette.funn@hhs.gov*.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier 0937-0198-60D for reference.

Proposed Project: Public Health Service Polices on Research Misconduct (42 CFR part 93)—OMB No 0937-0198-Extension—Office of Resource Integrity.

Abstract: This is a request to extend the currently approved collection, OMB No 0937-0198, which involves two forms: PHS-6349 and PHS-6315. The purpose of the Institutional Assurance and Annual Report on Possible Research Misconduct form (PHS-6349) is to provide data on the amount of research misconduct activity occurring in

institutions conducting PHS-supported research, as well as providing an annual assurance that those institutions have established and will follow administrative policies and procedures for responding to allegations of research misconduct that comply with the Public Health Service (PHS) Regulations on Research Misconduct (42 CFR part 93). The purpose of the Assurance of Compliance by Sub-Award Recipients form (PHS-6315) is to establish a similar assurance of compliance with 42 CFR part 93 for sub-awardee institutions, as well as provide data on the amount of research misconduct activity occurring in those sub-awardee institutions. Research misconduct is defined as receipt of an allegation of research misconduct and/or the conduct of an inquiry and/or investigation into such allegations. These data enable the ORI to monitor institutional compliance with the PHS regulation.

Summary of the information collection: Lastly, the forms will be used to respond to congressional requests for information to prevent misuse of Federal funds and to protect the public interest.

Need and Proposed Use of the Information: Public Health Service Polices on Research Misconduct (42 CFR part 93)—OMB No 0937-0198-Extension—Office of Research Integrity.

ESTIMATED ANNUALIZED BURDEN TABLE

| Forms (if necessary) | Type of respondent | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|----------------------|-------------------------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| PHS-6349 | Awardee Institutions | 5435 | 1 | 10/60 | 906 |
| PHS-6315 | Sub-award Institution's | 200 | 1 | 5/60 | 17 |
| Total | | | | | 923 |

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the

use of automated collection techniques or other forms of information

technology to minimize the information collection burden.

Terry S. Clark,

Asst. Information Collection Clearance Officer.

[FR Doc. 2017-01106 Filed 1-18-17; 8:45 am]

BILLING CODE 4150-31-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier 4040-0018; 60-day Notice]

Agency Information Collection Request. 60-Day Public Comment Request, Grants.gov

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, *Grants.gov* (EGOV), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to

minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, email your request, including your address, phone number, OMB number, to Ed.Calimag@hhs.gov, or call the Reports Clearance Office on (202) 690-7569. Send written comments and recommendations for the proposed information collections within 60 days of this notice directly to the *Grants.gov*.

Proposed Project

SF-428 Tangible Personal Property Report

Reinstatement without change and 3 Year Extension and assignment as a Common Form.

Office: Grants.gov

Abstract: Reporting on the status of Federally owned property, including disposition, is necessitated in 2 CFR part 215, the "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations", and the "Uniform Administrative Requirements for Grants and Agreements with State and Local

Governments", Additionally, Public Law 106-107, the Federal Financial Assistance Management Improvement Act requires that agencies "simplify Federal financial assistance application and reporting requirements." 31 U.S.C. 6101, Section 3.

Agencies are currently using a variety of forms to account for both Federally owned and grantee owned equipment and property. During the public consultation process mandated by Public Law 106-107, grant recipients requested a standard form to help them submit appropriate property information when required. The Public Law 106-107 Post Awards Subgroup developed a new standard form, the Tangible Personal Property Report, for submission of the required data. The form consists of the cover sheet (SF-428), three attachments to be used as required: Annual Report, SF-428-A; Final Report, SF-428-B; Disposition Request/Report, SF-428-C and a Supplemental Sheet, SF-428S to provide detailed individual item information when required. We are requesting a three-year clearance of this collection and that it be designated as a Common Form.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

| Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|--|-----------------------|------------------------------------|--|--------------------|
| SF-428 Tangible Personal Property Report | 2000 | 1 | 1 | 2000 |
| Total | 2000 | | | 2000 |

Terry S. Clark,

Asst Information Collection Clearance Officer.

[FR Doc. 2017-01182 Filed 1-18-17; 8:45 am]

BILLING CODE 4151-AE-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OMHA-1602-N]

Medicare Program; Administrative Law Judge Hearing Program for Medicare Claim and Entitlement Appeals; Quarterly Listing of Program Issuances—October Through December 2016

AGENCY: Office of Medicare Hearings and Appeals (OMHA), HHS.

ACTION: Notice.

SUMMARY: This quarterly notice lists the OMHA Case Processing Manual (OCPM) manual instructions that were published

from October through December, 2016. This manual standardizes the day-to-day procedures for carrying out adjudicative functions, in accordance with applicable statutes, regulations and OMHA directives, and gives OMHA staff direction for processing appeals at the OMHA level of adjudication.

FOR FURTHER INFORMATION CONTACT:

Amanda Axeen, by telephone at (571) 777-2705, or by email at amanda.axeen@hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Medicare Hearings and Appeals (OMHA), a staff division within the Office of the Secretary of the U.S. Department of Health and Human Services (HHS), administers the nationwide Administrative Law Judge hearing program for Medicare claim, organization and coverage determination, and entitlement appeals under sections 1869, 1155,

1876(c)(5)(B), 1852(g)(5), and 1860D-4(h) of the Social Security Act (the Act). OMHA ensures that Medicare beneficiaries and the providers and suppliers that furnish items or services to Medicare beneficiaries, as well as Medicare Advantage Organizations (MAOs), Medicaid State Agencies, and applicable plans have a fair and impartial forum to address disagreements with Medicare coverage and payment determinations made by Medicare contractors, MAOs, or Part D Plan Sponsors (PDPs), and determinations related to Medicare eligibility and entitlement, Part B late enrollment penalty, and income-related monthly adjustment amounts (IRMAA) made by the Social Security Administration (SSA).

The Medicare claim, organization and coverage determination appeals processes consist of four levels of administrative review, and a fifth level of review with the Federal district

courts after administrative remedies under HHS regulations have been exhausted. The first two levels of review are administered by the Centers for Medicare & Medicaid Services (CMS) and conducted by Medicare contractors for claim appeals, by MAOs and an independent review entity for Part C organization determination appeals, or by PDPs and an independent review entity for Part D coverage determination appeals. The third level of review is administered by OMHA and conducted by Administrative Law Judges. The fourth level of review is administered by the HHS Departmental Appeals Board (DAB) and conducted by the Medicare Appeals Council. In addition, OMHA and the DAB administer the second and third levels of appeal, respectively, for Medicare eligibility, entitlement, Part B late enrollment penalty, and IRMAA reconsiderations made by SSA; a fourth level of review with the Federal district courts is available after administrative remedies within SSA and HHS have been exhausted.

Sections 1869, 1155, 1876(c)(5)(B), 1852(g)(5), and 1860D-4(h) of the Act are implemented through the regulations at 42 CFR part 405 subparts I and J; part 417, subpart Q; part 422, subpart M; part 423, subparts M and U; and part 478, subpart B. As noted above, OMHA administers the nationwide Administrative Law Judge hearing program in accordance with these statutes and applicable regulations. As part of that effort, OMHA is establishing a manual, the OMHA Case Processing Manual (OCPM). Through the OCPM, the OMHA Chief Administrative Law Judge establishes the day-to-day procedures for carrying out adjudicative functions, in accordance with applicable statutes, regulations and OMHA directives. The OCPM provides direction for processing appeals at the OMHA level of adjudication for Medicare Part A and B claims; Part C organization determinations; Part D coverage determinations; and SSA eligibility and entitlement, Part B late enrollment penalty, and IRMAA determinations.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides the specific updates to the OCPM that have occurred in the 3-month period. A hyperlink to the available chapters on

the OMHA Web site is provided below. The OMHA Web site contains the most current, up-to-date chapters and revisions to chapters, and will be available earlier than we publish our quarterly notice. We believe the OMHA Web site list provides more timely access to the current OCPM chapters for those involved in the Medicare claim, organization and coverage determination and entitlement appeals processes. We also believe the Web site offers the public a more convenient tool for real time access to current OCPM provisions. In addition, OMHA has a listserv to which the public can subscribe to receive immediate notification of any updates to the OMHA Web site. This listserv avoids the need to check the OMHA Web site, as update notifications are sent to subscribers as they occur. If accessing the OMHA Web site proves to be difficult, the contact person listed above can provide the information.

III. How To Use the Notice

This notice lists the OCPM chapters and subjects published during the quarter covered by the notice so the reader may determine whether any are of particular interest. We expect this notice to be used in concert with future published notices. The OCPM can be accessed at http://www.hhs.gov/omha/OMHA_Case_Processing_Manual/index.html.

IV. OCPM Releases for October Through December 2016

The OCPM is used by OMHA adjudicators and staff to administer the OMHA program. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, and OMHA directives.

The following is a list and description of new or revised OCPM provisions and the subject matter. For future quarterly notices, we will list only the specific updates to the list of manual provisions that have occurred in the covered 3-month period. This information is available on our Web site at http://www.hhs.gov/omha/OMHA_Case_Processing_Manual/index.html.

OCPM Division I: General Matters

Chapter 6, CMS and CMS Contractor Roles. We corrected a misdirected link to the CMS Medicare Administrative Contractors Web site (<https://www.cms.gov/medicare/medicare-contracting/medicare-administrative-contractors/medicareadministrative-contractors.html>) in the table in Section I-6-1 of this chapter.

OCPM Division II: Part A/B Claim Determinations

Chapter 3, Procedural Screening. The table in Section II-3-4 A of this chapter was updated to include the minimum amounts in controversy (AICs) required for an Administrative Law Judge hearing for calendar years through 2017.

OCPM Division III: Part C Organization Determinations

Chapter 3, Procedural Screening. The table in Section III-3-4 A of this chapter was updated to include the minimum AICs required for an Administrative Law Judge hearing for calendar years through 2017.

OCPM Division IV: Part D Organization Determinations

Chapter 3, Procedural Screening. The table in Section IV-3-4 A of this chapter was updated to include the minimum AICs required for an Administrative Law Judge hearing for calendar years through 2017.

OCPM Division V: SSA Determinations

Chapter 3, Procedural Screening. The table in Section V-3-4 A of this chapter was updated to include the minimum AICs required for an Administrative Law Judge hearing for calendar years through 2017.

Dated: January 6, 2017.

Jason M. Green,
Chief Advisor, Office of Medicare Hearings and Appeals.

[FR Doc. 2017-01181 Filed 1-18-17; 8:45 am]

BILLING CODE 4152-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; Review of the Consortium on Alcohol and Neurodevelopment in Adolescence (NCANDA) RFA AA 17-003, 004 & 005.

Date: February 27, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, North Bethesda, MD.

Contact Person: Beata Buzas, Ph.D., Scientific Review Officer, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, Room 2081, Rockville, MD 20852, 301-443-0800, bbuzas@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards, National Institutes of Health, HHS) February 23, 2017.

Dated: January 12, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017-01116 Filed 1-18-17; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Initial Review Group; Genome Research Review Committee.

Date: March 2, 2017.

Time: 11:30 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, 3rd Floor Conference Room, 5635

Fishers Lane, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Ken D. Nakamura, Ph.D., Scientific Review Officer, Office of Scientific Review, National Human Genome Research Institute, National Institutes of Health, Bethesda, MD 20892, 301-402-0838.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: January 12, 2017.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017-01113 Filed 1-18-17; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute Amended; Notice of Meeting

Notice is hereby given of a change in the meeting of the National Heart, Lung, and Blood Institute Special Emphasis Panel, January 24, 2017, 02:00 p.m. to January 24, 2017, 04:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on December 29, 2016, 81FR96028.

Dr. Sunnarborg's January 24, 2017, teleconference has been rescheduled to January 30, 2017, 09:30 a.m. to January 30, 2017, 11:00 a.m. The meeting is closed to the public.

January 12, 2017.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017-01115 Filed 1-18-17; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,

and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group; Obstetrics and Maternal-Fetal Biology Subcommittee.

Date: February 28, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Peter Zelazowski, Ph.D., Scientific Review Officer, National Institutes of Health, NICHD, SRB, 6710B Rockledge Drive, Bethesda, MD 20892, 301-435-6902, Peter.Zelazowski@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: January 12, 2017.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017-01118 Filed 1-18-17; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications/contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications/contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Microbiome.

Date: February 28, 2017.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room

6W032, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Bratin K. Saha, Ph.D., Scientific Review Officer, Program Coordination and Referral Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W556, Rockville, MD 20892–9750, 240–276–6411 sahab@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Cancer Tissue Engineering Collaborative: Enabling Biomimetic Tissue—Engineered Technologies for Cancer Research (U01).
Date: March 3, 2017.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W030, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Jun Fang, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W246, Rockville, MD 20892–9750, 240–276–7975, jfang@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis; Panel NCI R21 Meeting.

Date: March 6, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Shakeel Ahmad, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W102, Rockville, MD 20892–9750, 240–276–6349, ahmads@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Provocative Question 9.

Date: March 6, 2017.

Time: 12:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W606, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Timothy C. Meeker, MD, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W606, Rockville, MD 20892–9750, 240–276–6464, meekert@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Outstanding Investigator Award II.

Date: March 9–10, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Caterina Bianco, MD, Ph.D., Scientific Review Officer, Research

Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W116, Rockville, MD 20892–9750, 240–276–6459, biancoc@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Small Cell Lung Cancer Consortium.

Date: March 13, 2017.

Time: 12:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W606, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Timothy C. Meeker, MD, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W606, Rockville, MD 20892–9750, 240–276–6464, meekert@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; Core Infrastructure and Methodological Research for Cancer Epidemiology Cohorts.

Date: March 14, 2017.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Tushar Deb, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W624, Rockville, MD 20892–9750, 240–276–6132, tushar.deb@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel; U01 NCI Review Meeting.

Date: March 23, 2017.

Time: 12:30 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W238, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Byeong-Chel Lee, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W238, Rockville, MD 20892–9750, 240–276–7755, byeong-chel.lee@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 12, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–01112 Filed 1–18–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; NIAMS SBIR Peer Review.

Date: February 7, 2017.

Time: 10:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Democracy Boulevard, Suite 824, Bethesda, MD 20892 (IAM/Teleconference).

Contact Person: Yin Liu, Ph.D., MD, Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, NIH, 6701 Democracy Boulevard, Suite 824, Bethesda, MD 20892, 301–496–0505, liuy@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: January 12, 2017.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–01117 Filed 1–18–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Mental Health.

The meeting will be closed to the public as indicated below in accordance

with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE OF MENTAL HEALTH, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute of Mental Health.

Date: January 31–February 1, 2017.

Time: January 31, 2017, 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Porter Neuroscience Research Center, GE 620/630/640, Building 35A Convent Drive, Bethesda, MD 20892.

Time: February 01, 2017, 9:00 a.m. to 2:40 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Porter Neuroscience Research Center, GE 620/630/640, Building 35A Convent Drive, Bethesda, MD 20892.

Contact Person: Jennifer E. Mehren, Ph.D., Scientific Advisor, Division of Intramural Research Programs, National Institute of Mental Health, NIH, 35A Convent Drive, Room GE 412, Bethesda, MD 20892–3747, 301–496–3501, mehrenj@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: January 12, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–01119 Filed 1–18–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,

and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; NHLBI Pulmonary Hypertension Review.

Date: February 9, 2017.

Time: 8:30 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: YingYing Li-Smerin, MD, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7184, Bethesda, MD 20892–7924, 301–435–0277, lismerin@nhlbi.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 12, 2017.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–01114 Filed 1–18–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 15–326: Imaging—Science Track Award For Research Transition (I/Start) R03.

Date: February 7, 2017.

Time: 12:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Yvonne Bennett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5199, MSC 7846, Bethesda, MD 20892, 301–379–3793, bennetty@csr.nih.gov.

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Basic Mechanisms of Cancer Therapeutics Study Section.

Date: February 13–14, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

Contact Person: Lambratu Rahman Sesay, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, 301–451–3493, rahman-sesay@csr.nih.gov.

Name of Committee: Digestive, Kidney and Urological Systems Integrated Review Group; Xenobiotic and Nutrient Disposition and Action Study Section.

Date: February 15, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC.

Contact Person: Martha Garcia, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2186, Bethesda, MD 20892, 301–435–1243, garciamc@nih.gov.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Instrumentation and Systems Development Study Section.

Date: February 15–16, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: JW New Orleans Marriott, 614 Canal Street, New Orleans, LA 70130.

Contact Person: Kathryn Kalasinsky, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5158, MSC 7806, Bethesda, MD 20892, 301–402–1074, kalasinskyks@mail.nih.gov.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Somatosensory and Chemosensory Systems Study Section.

Date: February 15–16, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Long Beach, 701 W Ocean Boulevard, Long Beach, CA 90831.

Contact Person: M Catherine Bennett, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7846, Bethesda, MD 20892, 301–435–1766, bennettc3@csr.nih.gov.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Biomaterials and Biointerfaces Study Section.

Date: February 15–16, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: New Orleans Marriott, 555 Canal Street, New Orleans, LA 70130.

Contact Person: Joseph D Mosca, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5158, MSC 7808, Bethesda, MD 20892, (301) 408–9465, moscajos@csr.nih.gov.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Societal and Ethical Issues in Research Study Section.

Date: February 15, 2017.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting)

Contact Person: Karin F Helmers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3148, MSC 7770, Bethesda, MD 20892, (301) 254–9975, helmersk@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393 h; 93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 12, 2017.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–01111 Filed 1–18–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke; Neurological Sciences and Disorders B.

Date: February 23–24, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Lorien Hotel and Spa, 1600 King Street, Alexandria, VA 22314.

Contact Person: Birgit Neuhuber, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529 neuhuber@ninds.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: January 12, 2017.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–01120 Filed 1–18–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Refugee Resettlement; Statement of Organization, Functions, and Delegations of Authority

AGENCY: Administration for Children and Families, HHS.

ACTION: Notice.

SUMMARY: Statement of Organizations, Functions, and Delegations of Authority. The Administration for Children and Families (ACF) has reorganized the Office of Refugee Resettlement (ORR). Based on internal evaluation and feedback from external stakeholders related to making ORR programs more efficient, responsive, and better organized to meet ORR's statutory obligations, this reorganization aims to increase efficiencies and better align organizational structures with programmatic requirements and to increase the effectiveness of all ORR programs. To accomplish those goals, this reorganization realigns ORR's four current programmatic divisions to create two dedicated program offices, the Refugee Programs and the Unaccompanied Children Programs. Within the Unaccompanied Children Programs, it renames the Division of Children's Services to the Division of Unaccompanied Children Operations and creates two new divisions, the Division of Planning and Logistics, and the Division of Unaccompanied Children's Health. It also renames the Division of Policy to the Division of Policy and Procedures and changes the

Budget Team to the Division of Strategic Planning, Budget, and Analysis.

FOR FURTHER INFORMATION CONTACT:

Robert Carey, Office of Refugee Resettlement, 330 C Street SW., Washington, DC 20201, (202) 401–4556.

This notice amends Part K of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), Administration for Children and Families (ACF), as follows: Chapter KR, Office of Refugee Resettlement, as last amended by 80 FR 33269–33270, June 11, 2015.

I. Under Chapter KR, Office of Refugee Resettlement, delete KR.10 Organization in its entirety and replace with the following:

KR.10 Organization. The Office of Refugee Resettlement (ORR) is headed by a Director who reports directly to the Assistant Secretary for Children and Families. The Office is organized as follows:

Office of the Director (KRA)
Division of Policy and Procedures (KRA1)
Division of Strategic Planning, Budget and Analysis (KRA2)
Refugee Programs (KRB)
Division of Refugee Assistance (KRB1)
Division of Refugee Services (KRB2)
Division of Refugee Health (KRB3)
Unaccompanied Children Programs (KRC)
Division of Unaccompanied Children Operations (KRC1)
Division of Planning and Logistics (KRC2)
Division of Health for Unaccompanied Children (KRC3)

II. Under Chapter KR, Office of Refugee Resettlement, delete KR.20 Functions in its entirety and replace with the following:

KR.20 Function. A. The Office of the Director reports directly to the Assistant Secretary for Children and Families and is responsible for carrying ORR's mission and providing guidance and general supervision to the components of ORR. The Office provides direction in the development of program policy and budget and in the formulation of salaries and expense budgets. Staff also provide administrative and personnel support services.

The Office of the Director coordinates with the lead refugee and entrant program offices of other Federal departments; provides leadership in representing refugee and entrant programs, policies and administration to a variety of governmental entities and other public and private interests; and, acts as the coordinator of the total refugee and entrant resettlement effort

for ACF and the Department. The Office oversees the care and custody of unaccompanied alien children, grants specific consent for those who wish to invoke the jurisdiction of a state court for a dependency order to seek Special Immigrant Juvenile (SIJ) status, and makes determinations of eligibility for the Unaccompanied Refugee Minors (URM) Program. The Office of the Director develops guidance, legislative proposals, and routine interpretations of policy. The Office of the Director also provides management and administrative services for the office, including the coordination of human resources activities. Within the Office of the Director, the Chief of Staff assists and advises the Director in implementing strategic initiatives and management priorities, and oversees communications for the office, including responses to media requests, congressional inquiries, and stakeholder engagement.

The Division of Policy and Procedures assesses and evaluates ORR programs and their legal authorities and proactively recommends policy development, legislative proposals, and operational and management actions to comply with statutory parameters as they relate to each of the program areas. The Division advises the ORR Director, deputies, division directors, and staff on a wide range of significant and sensitive policy-related matters and strategies for attaining ORR policy objectives including reviewing proposed legislation and assisting with responding to Congressional inquiries. The Division identifies major emerging legislative and policy issues, assesses impacts, develops policy options and strategies, and implements policy initiatives, including the drafting of policies, guidance and regulations. The Division consults with the ORR operating divisions in the creation and clearance of procedures, consistent with established regulations, policies and guidance, and implements training on policies and procedures for ORR staff. The Division of Policy and Procedures develops clearance and informational memoranda, briefing materials and summary statements for ORR, ACF, and department leadership on complex and sensitive ORR matters. The Division collaborates with the ORR operating divisions and regional staff to clarify and enhance existing policies and guidance, particularly in areas where the work of two or more divisions overlap. The Division of Policy and Procedures serves as the ORR point of contact for other ACF and HHS offices related to legal and evaluation issues,

such as OGC, OLAB, GAO, and OIG. The Division represents ORR on interagency working groups and collaborates with both government and private sector leaders on ORR policy-related issues and developments.

The Division of Strategic Planning, Budget and Analysis leads ORR in the development, tracking, and implementation of strategic goals and performs budget, data analysis, and compliance functions for the office. The Division prepares annual budget estimates and related materials and performs allocation and tracking of funds for all programs. The Division performs analysis on the changing needs of the populations served by ORR programs, provides leadership to identify data needs and sources, and formulates data and reporting requirements. The Division also leads the office in the development of strategic goals and objectives and ensures that policies and operational and management activities are designed to achieve ORR, ACF and department goals. The Division develops and maintains standard monitoring procedures for the office and ensures the regular monitoring of ORR grant funds.

B. The Refugee Programs are responsible for carrying out programs that provide assistance to refugees, asylees, Cuban and Haitian entrants, and certain Amerasians and victims of severe forms of trafficking in persons. The Refugee Programs oversee the movement of children into the Unaccompanied Refugee Minor (URM) program. The Refugee Programs consist of the Division of Refugee Assistance, the Division of Refugee Services, and the Division of Refugee Health. The Refugee Programs collect and maintain data related to the populations served. The Deputy Director reports directly to the Director of ORR.

The Division of Refugee Assistance represents ORR in coordinating services and capacity for refugees in a manner that helps refugees become employed and economically self-sufficient soon after their arrival in the United States. The Division monitors and provides technical assistance to the State-administered domestic assistance programs and Wilson/Fish projects. The Division works closely with each State in designing a resettlement program specific to the needs of incoming populations. The Division develops guidance and procedures for their implementation; manages special initiatives to increase refugee self-sufficiency such as through State funded discretionary grants or pilot programs. The Division also assists

public and private agencies on data reporting and the resolution of reporting problems. The Division develops and supports the flow of information on refugee profiles and community resources in support of effective placement at the State and local level. The Division works closely with the Department of State to ensure effective and seamless orientation from overseas to local resettlement community. The Division manages the effective allocation of formula social services and targeted assistance in support of newly arriving populations. The Division tracks all State costs related to refugee assistance.

The Division of Refugee Services manages effective refugee resettlement through the programmatic implementation of grants, contracts and special initiatives, such as the Match Grant Program. The Division oversees and monitors most ORR discretionary grants; recommends grantee allocation; coordinates with the grants management office to review the financial expenditures under discretionary grant programs; provides data in support of apportionment requests; and, provides technical assistance on discretionary grants operations. The Division coordinates and provides liaison with the Department and other Federal agencies on discretionary grant operational issues and other activities as specified by the Director or required by Congressional mandate. The Division responds to unanticipated refugee and entrant arrivals or significant increases in arrivals to communities where adequate or appropriate services do not exist through supplemental initiatives. The Division works to promote economic independence among refugees through social services, educational services, and intensive case management and community development initiatives.

The Division of Refugee Health provides direction for assuring that refugees are provided medical assistance and mental health services through the State-administered programs and alternative programs. The Division ensures the quality of medical screening and initial medical treatment of refugees through its administration of grant programs, technical assistance, and interagency agreements in support of comprehensive medical and mental health services. The Division also supports mental health services to victims of torture. The Division works closely with State Refugee Health Coordinators in the planning and provision of medical and mental health services to meet the individual needs of incoming populations. The Division

tracks all state costs related to refugee medical assistance and screening.

C. The Unaccompanied Children Programs are directly responsible for providing services to unaccompanied children who are referred to ORR for care pending immigration status, or identified as victims of trafficking. The Unaccompanied Children Programs consists of the Division of Unaccompanied Children Operations, the Division of Planning and Logistics, and the Division of Unaccompanied Children's Health. Unaccompanied Children Programs staff ensures that services are administered in a manner that supports child welfare standards of care and services and complete regular monitoring of service provision. The Deputy Director reports directly to the Director of ORR.

The Division of Operations implements intake and placement decisions for all unaccompanied alien children. The Division supports specialized care through grants and contracts, and also conducts monitoring and inspections of facilities and placement locations in which unaccompanied children reside. The Division also maintains statistical information and data on each child and any actions concerning the child while the child is under ORR's care. The Division ensures consideration of the child's best interest in care and custody decisions. The Division coordinates all decisions related to sponsor reunification, background checks, home assessments, follow-up services, medical assessment and treatment, and repatriation. The Division administers the pro bono legal services and child advocate program and compiles a State-by-State list of professionals or entities qualified to provide the children with a guardian and attorney representational services. The Division also supports grants for services provided to children after their release from ORR care.

The Division of Planning and Logistics oversees the development of a comprehensive annual plan to ensure that Unaccompanied Children Programs are able to accommodate the number of referrals of children to ORR care. The Division prepares plans for anticipated shelter capacity and staffing needs. The Division leads coordination with other federal agencies and management of grants and contracts. If ORR requires temporary shelters to care for unaccompanied children, the Division leads the operational and logistical support for those shelters.

The Division of Health for Unaccompanied Children oversees the provision of health and medical services to unaccompanied children in ORR

care. The Division reviews and approves orders for complex medical procedures and reviews test results for certain medical ailments. The Division also ensures reporting of public health information to the appropriate public health authorities.

III. Continuation of Policy. Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to organizational components affected by this notice within ACF, heretofore issued and in effect on this date of this reorganization are continued in full force and effect.

IV. Delegation of Authority. Pending further delegation, directives or orders by the Director of ORR, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

V. Funds, Personnel, and Equipment. Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies, and other resources.

This realignment is effective January 19, 2017.

Date: December 30, 2016.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2017-00301 Filed 1-18-17; 8:45 am]

BILLING CODE 4184-34-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Protecting Our Infants Act Report to Congress

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment, in the Department of Health and Human Services (HHS) announces the opening of a docket to obtain public comment on a report to Congress in response to the Projecting Our Infants Act of 2015 (POIA) (Pub. L. 114-91). The POIA mandated HHS to: Conduct a review of planning and coordination activities related to prenatal opioid exposure and neonatal abstinence

syndrome; develop recommendations for the identification, prevention, and treatment of prenatal opioid exposure and neonatal abstinence syndrome; and develop a strategy to address gaps, overlap, and duplication among Federal programs and Federal coordination efforts to address neonatal abstinence syndrome. The POIA further mandates that public comment be sought regarding the proposed strategy and incorporated as appropriate.

DATES: *Comment Close Date:* To be assured consideration, comments on the must be received at one of the addresses provided below, no later than February 21, 2017 at 5:00 p.m. EST.

ADDRESSES: You may submit comments identified by Docket No. [SAMHSA-2016-0004] by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Electronically:* You may submit electronic comments to: POIAcomments@samhsa.hhs.gov.

- *By regular mail:* You may mail written comments to the following address ONLY: Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment, 5600 Fishers Lane, Room 13E49, Rockville, MD 20852 Attn: Docket No. [SAMHSA-2016-0004]. Please allow sufficient time for mailed comments to be received before the close of the comment period.

- *By express or overnight mail:* You may send written comments to the following address ONLY: Substance Abuse and Mental Health Services Administration, Attention: Melinda Campopiano, 5600 Fishers Lane, 13E49, Rockville, MD 20852 Attn: Docket No. [SAMHSA-2016-0004].

- *By hand or courier:* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following address prior to the close of the comment period: For delivery in Rockville, MD: Substance Abuse and Mental Health Services Administration, Attention: Melinda Campopiano, 5600 Fishers Lane, 13E49, Rockville, MD 20852. To deliver your comments to the Rockville address, call telephone number (240) 276-2701 in advance to schedule your delivery with one of our staff members.

Instructions: To avoid duplication, please submit only one copy of your comments by only one method. All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to <http://www.regulations.gov>, including any

personal information provided. For access to the report or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Melinda Campopiano, MD, Chief Medical Officer, Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, 13E49, Rockville, MD 20852. Email: POIAcomments@samhsa.hhs.gov. Phone: (240)276-2701.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. Comments received by the deadline will be available for public inspection at the Substance Abuse and Mental Health Service Administration, 5600 Fishers Lane, 13E49, Rockville, MD 20852, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, call (240) 276-2701.

Background: The POIA mandated HHS to: (1) Conduct a review of planning and coordination activities related to prenatal opioid exposure and neonatal abstinence syndrome (Section 2(a) of the Act); (2) develop recommendations for the identification, prevention, and treatment of prenatal opioid exposure and neonatal abstinence syndrome (Section 3 of the Act); and (3) develop a strategy to address gaps, overlap, and duplication among Federal programs and Federal coordination efforts to address neonatal abstinence syndrome (Section 2(b) of the Act). The POIA is available at: <https://www.congress.gov/bill/114th-congress/senate-bill/799>.

In response to this Act, this report provides background information on prenatal opioid exposure and neonatal abstinence syndrome (Part 1), summarizes HHS activities related to prenatal opioid exposure and neonatal abstinence syndrome (Part 2), presents clinical and programmatic evidence and recommendations for preventing and treating neonatal abstinence syndrome (Part 3), and presents a strategy to address the identified gaps, challenges, and recommendations (Part 4).

Public comment is sought for “Part 4: Strategy to Protect Our Infants” (Section 2(b) of the Act) and comments will be incorporated into the strategy as appropriate. The final strategy will be posted on an HHS Web site by May 25, 2017.

Supporting and Related Material in the Docket: The information provided includes:

(1) The Report

Summer King,
Statistician.

[FR Doc. 2017-01180 Filed 1-18-17; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4291-DR; Docket ID FEMA-2016-0001]

Virginia; Amendment No. 4 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the Commonwealth of Virginia (FEMA-4291-DR), dated November 2, 2016, and related determinations.

DATES: Effective December 19, 2016.

FOR FURTHER INFORMATION CONTACT:

Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the Commonwealth of Virginia is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of November 2, 2016.

The independent city of Hampton for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2017-01096 Filed 1-18-17; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2016-0002; Internal Agency Docket No. FEMA-B-1668]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Title 44, Part 65 of the Code of Federal Regulations (44 CFR part 65). The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will become effective on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and

Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at www.msc.fema.gov for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646-7659, or (email) patrick.sacbibit@fema.dhs.gov; or visit the FEMA Map Information eXchange (FMIX) online at www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean

that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at www.msc.fema.gov for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: December 21, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Online location of letter of map revision | Effective date of modification | Community No. |
|------------------|---|--|--|---|--------------------------------|---------------|
| Alabama: | | | | | | |
| Jefferson | City of Birmingham (16-04-6488P). | The Honorable William A. Bell, Sr., Mayor, City of Birmingham, 710 20th Street North, 3rd Floor, Birmingham, AL 35203. | City Hall, 710 20th Street North, 3rd Floor, Birmingham, AL 35203. | http://www.msc.fema.gov/lomc | Feb. 21, 2017 | 010116 |
| Jefferson | Unincorporated areas of Jefferson County (16-04-6488P). | The Honorable James A. Stephens, Chairman, Jefferson County Commission, 716 Richard Arrington Jr. Boulevard North, Birmingham, AL 35203. | Jefferson County Land Development Department, 716 Richard Arrington Jr. Boulevard North, Birmingham, AL 35203. | http://www.msc.fema.gov/lomc | Feb. 21, 2017 | 010217 |
| Colorado: | | | | | | |
| Mesa | City of Grand Junction (16-08-0727P). | Mr. Greg Caton, Manager, City of Grand Junction, 250 North 5th Street, Grand Junction, CO 81501. | City Hall, 250 North 5th Street, Grand Junction, CO 81501. | http://www.msc.fema.gov/lomc | Mar. 6, 2017 | 080117 |
| Mesa | Unincorporated areas of Mesa County (16-08-0612P). | The Honorable John Justman, Chairman, Mesa County Board of Commissioners, 544 Rood Avenue, 3rd Floor, Grand Junction, CO 81501. | Mesa County Central Services Department, 200 South Spruce Street, Grand Junction, CO 81501. | http://www.msc.fema.gov/lomc | Mar. 9, 2017 | 080115 |
| Mesa | Unincorporated areas of Mesa County (16-08-0727P). | The Honorable John Justman, Chairman, Mesa County Board of Commissioners, 544 Rood Avenue, 3rd Floor, Grand Junction, CO 81501. | Mesa County Central Services Department, 200 South Spruce Street, Grand Junction, CO 81501. | http://www.msc.fema.gov/lomc | Mar. 6, 2017 | 080115 |
| Florida: | | | | | | |
| Broward | City of Hallandale Beach (16-04-8271P). | The Honorable Joy Cooper, Mayor, City of Hallandale Beach, 400 South Federal Highway, Hallandale Beach, FL 33009. | Development Services Department, 400 South Federal Highway, Hallandale Beach, FL 33009. | http://www.msc.fema.gov/lomc | Mar. 20, 2017 | 125110 |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Online location of letter of map revision | Effective date of modification | Community No. |
|---------------------------------|--|--|--|---|--------------------------------|---------------|
| Broward | City of Hollywood (16-04-8271P). | The Honorable Peter Bober, Mayor, City of Hollywood, P.O. Box 229045, Hollywood, FL 33022. | City Hall, 2600 Hollywood Boulevard, Hollywood, FL 33020. | http://www.msc.fema.gov/lomc | Mar. 20, 2017 | 125113 |
| Broward | Unincorporated areas of Broward County (16-04-8271P). | The Honorable Marty Kiar, Mayor, Broward County Board of Commissioners, 115 South Andrews Avenue, Room 421, Fort Lauderdale, FL 33301. | Broward County Environmental Licensing and Building Permitting Division, 1 North University Drive, Plantation, FL 33324. | http://www.msc.fema.gov/lomc | Mar. 20, 2017 | 125093 |
| Collier | City of Naples (16-04-7943P). | The Honorable Bill Barnett, Mayor, City of Naples, 735 8th Street South, Naples, FL 34102. | Building Department, 295 Riverside Circle, Naples, FL 34102. | http://www.msc.fema.gov/lomc | Mar. 8, 2017 | 125130 |
| Collier | Unincorporated areas of Collier County (16-04-8239P). | The Honorable Donna Fiala, Chair, Collier County Board of Commissioners, 3299 Tamiami Trail East, Suite 303, Naples, FL 34112. | Collier County Administration Department, 3301 East Tamiami Trail, Building F, 1st Floor, Naples, FL 34112. | http://www.msc.fema.gov/lomc | Mar. 9, 2017 | 120067 |
| Lee | Unincorporated areas of Lee County (16-04-4523P). | The Honorable Frank Mann, Chairman, Lee County Board of Commissioners, 2120 Main Street, Fort Myers, FL 33901. | Lee County Community Development Department, 1500 Monroe Street, Fort Myers, FL 33901. | http://www.msc.fema.gov/lomc | Mar. 3, 2017 | 125124 |
| Miami-Dade | City of Miami (16-04-6380P). | The Honorable Tomás P. Regalado, Mayor, City of Miami, 3500 Pan American Drive, Miami, FL 33133. | Building Department, 444 Southwest 2nd Avenue, 4th Floor, Miami, FL 33130. | http://www.msc.fema.gov/lomc | Mar. 8, 2017 | 120650 |
| Miami-Dade | City of Miami (16-04-7155P). | The Honorable Tomás P. Regalado, Mayor, City of Miami, 3500 Pan American Drive, Miami, FL 33133. | Building Department, 444 Southwest 2nd Avenue, 4th Floor, Miami, FL 33130. | http://www.msc.fema.gov/lomc | Mar. 3, 2017 | 120650 |
| Monroe | Unincorporated areas of Monroe County (16-04-7782P). | The Honorable Heather Carruthers, Mayor, Monroe County Board of Commissioners, 500 Whitehead Street, Suite 102, Key West, FL 33040. | Monroe County Building Department, 2798 Overseas Highway, Marathon, FL 33050. | http://www.msc.fema.gov/lomc | Mar. 8, 2017 | 125129 |
| Orange | City of Orlando (16-04-5226P). | The Honorable Buddy Dyer, Mayor, City of Orlando, 400 South Orange Avenue, Orlando, FL 32802. | Public Works Department, 400 South Orange Avenue, Orlando, FL 32802. | http://www.msc.fema.gov/lomc | Mar. 10, 2017 | 120186 |
| Sarasota | Unincorporated areas of Sarasota County (16-04-4948P). | The Honorable Alan Maio, Chairman, Sarasota County Board of Commissioners, 1660 Ringling Boulevard, Sarasota, FL 34236. | Sarasota County Development Services Department, 1001 Sarasota Center Boulevard, Sarasota, FL 34240. | http://www.msc.fema.gov/lomc | Mar. 20, 2017 | 125144 |
| Maryland: Garrett .. | Unincorporated areas of Garrett County (16-03-2576P). | Mr. Kevin G. Null, Garrett County Administrator, 203 South 4th Street, Room 207, Oakland, MD 21550. | Garrett County Department of Permits and Inspection Services, 203 South 4th Street, Room 208, Oakland, MD 21550. | http://www.msc.fema.gov/lomc | Mar. 10, 2017 | 240034 |
| Massachusetts: Norfolk | City of Quincy (16-01-0647P). | The Honorable Thomas P. Koch, Mayor, City of Quincy, 1305 Hancock Street, Quincy, MA 02169. | Department of Public Works, 55 Sea Street, Quincy, MA 02169. | http://www.msc.fema.gov/lomc | Mar. 1, 2017 | 255219 |
| Norfolk | City of Quincy (16-01-2803P). | The Honorable Thomas P. Koch, Mayor, City of Quincy, 1305 Hancock Street, Quincy, MA 02169. | Department of Public Works, 55 Sea Street, Quincy, MA 02169. | http://www.msc.fema.gov/lomc | Mar. 13, 2017 | 255219 |
| New Mexico: Bernalillo | City of Albuquerque (16-06-1689P). | The Honorable Richard J. Berry, Mayor, City of Albuquerque, P.O. Box 1293, Albuquerque, NM 87103. | Planning Development and Building Services Division, 600 2nd Street Northwest, Albuquerque, NM 87102. | http://www.msc.fema.gov/lomc | Feb. 27, 2017 | 350002 |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Online location of letter of map revision | Effective date of modification | Community No. |
|-------------------------------|--|---|---|---|--------------------------------|---------------|
| Bernalillo | City of Albuquerque (16-06-2885P). | The Honorable Richard J. Berry, Mayor, City of Albuquerque, P.O. Box 1293, Albuquerque, NM 87103. | Planning Development and Building Services Division, 600 2nd Street Northwest, Albuquerque, NM 87102. | http://www.msc.fema.gov/lomc | Mar. 7, 2017 | 350002 |
| Bernalillo | Unincorporated areas of Bernalillo County (16-06-1689P). | The Honorable Art De La Cruz, Chairman, Bernalillo County Board of Commissioners, 1 Civic Plaza Northwest, Albuquerque, NM 87102. | Bernalillo County Public Works Division, 2400 Broadway Southeast, Albuquerque, NM 87102. | http://www.msc.fema.gov/lomc | Feb. 27, 2017 | 350001 |
| Taos | Town of Taos (16-06-2418P). | The Honorable Daniel R. Barrone, Mayor, Town of Taos, 400 Camino De La Placita, Taos, NM 87571. | Planning, Zoning and Community Development Department, 400 Camino De La Placita, Taos, NM 87571. | http://www.msc.fema.gov/lomc | Mar. 17, 2017 | 350002 |
| Taos | Unincorporated areas of Taos County (16-06-2418P). | Mr. Leandro Cordova, Manager, Taos County, 105 Albright Street, Taos, NM 87571. | Taos County Planning Department, 105 Albright Street, Taos, NM 87571. | http://www.msc.fema.gov/lomc | Mar. 17, 2017 | 350078 |
| North Carolina: Craven | City of Havelock (16-04-6818P). | The Honorable William Lewis, Mayor, City of Havelock, P.O. Box 368, Havelock, NC 28532. | Planning and Inspections Department, 1 Governmental Avenue, Havelock, NC 28532. | http://www.msc.fema.gov/lomc | Feb. 23, 2017 | 370265 |
| Craven | Unincorporated areas of Craven County (16-04-6818P). | The Honorable George S. Liner, Chairman, Craven County Board of Commissioners, 406 Crave Street, New Bern, NC 28560. | Craven County Planning and Community Development Department, 2828 Neuse Boulevard, New Bern, NC 28562. | http://www.msc.fema.gov/lomc | Feb. 23, 2017 | 370072 |
| Pennsylvania: Lancaster | Township of Conestoga (16-03-2652P). | The Honorable Craig C. Eshleman, Chairman, Township of Conestoga Board of Supervisors, 3959 Main Street, Conestoga, PA 17516. | Township Municipal Building, 3959 Main Street, Conestoga, PA 17516. | http://www.msc.fema.gov/lomc | Mar. 13, 2017 | 420544 |
| Lancaster | Township of Drumore (16-03-2652P). | The Honorable Kolin D. McCauley, Chairman, Township of Drumore Board of Supervisors, 1675 Furniss Road, Drumore, PA 17518. | Township Municipal Building, 1675 Furniss Road, Drumore, PA 17518. | http://www.msc.fema.gov/lomc | Mar. 13, 2017 | 421766 |
| South Dakota: Hughes | City of Pierre (16-08-0334P). | The Honorable Laurie Gill, Mayor, City of Pierre, 222 East Dakota Avenue, Pierre, SD 57501. | Department of Public Works, 222 East Dakota Avenue, Pierre, SD 57501. | http://www.msc.fema.gov/lomc | Mar. 21, 2017 | 460040 |
| Pennington | City of Rapid City (16-08-0803P). | The Honorable Steve Allender, Mayor, City of Rapid City, 300 6th Street, Rapid City, SD 57701. | Public Works and Engineering Services Department, 300 6th Street, Rapid City, SD 57701. | http://www.msc.fema.gov/lomc | Feb. 23, 2017 | 465420 |
| Pennington | City of Rapid City (16-08-0818P). | The Honorable Steve Allender, Mayor, City of Rapid City, 300 6th Street, Rapid City, SD 57701. | Public Works and Engineering Services Department, 300 6th Street, Rapid City, SD 57701. | http://www.msc.fema.gov/lomc | Feb. 27, 2017 | 465420 |
| Tennessee: Shelby | Town of Collierville (16-04-7778P). | The Honorable Stan Joyner, Jr., Mayor, Town of Collierville, 500 Poplar View Parkway, Collierville, TN 38017. | Development Department, 500 Poplar View Parkway, Collierville, TN 38017. | http://www.msc.fema.gov/lomc | Mar. 3, 2017 | 470263 |
| Texas: Bexar | Unincorporated areas of Bexar County (16-06-2426P). | The Honorable Nelson W. Wolff, Bexar County Judge, 101 West Nueva Street, 10th Floor, San Antonio, TX 78205. | Bexar County Public Works Department, 233 North Pecos-La Trinidad Street, Suite 420, San Antonio, TX 78207. | http://www.msc.fema.gov/lomc | Dec. 27, 2016 | 480035 |
| Collin | City of McKinney (16-06-1541P). | The Honorable Brian Loughmiller, Mayor, City of McKinney, P.O. Box 517, McKinney, TX 75070. | Engineering Department, 221 North Tennessee Street, McKinney, TX 75069. | http://www.msc.fema.gov/lomc | Mar. 13, 2017 | 480135 |
| Collin | City of Wylie (16-06-1916P). | The Honorable Eric Hogue, Mayor, City of Wylie, 300 Country Club Road, Building 100, Wylie, TX 75098. | City Hall, 300 Country Club Road, Building 100, Wylie, TX 75098. | http://www.msc.fema.gov/lomc | Feb. 23, 2017 | 480759 |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Online location of letter of map revision | Effective date of modification | Community No. |
|-------------------------|--|---|---|---|--------------------------------|---------------|
| Hays | Unincorporated areas of Hays County (16-06-2633P). | The Honorable Bert Cobb, M.D., Hays County Judge, 111 East San Antonio Street, Suite 300, San Marcos, TX 78666. | Hays County Development Services Department, 2171 Yarrington Road, San Marcos, TX 78666. | http://www.msc.fema.gov/lomc | Mar. 9, 2017 | 480321 |
| Hidalgo | City of McAllen (16-06-2547P). | The Honorable James E. Darling, Mayor, City of McAllen, P.O. Box 220, McAllen, TX 78505. | Development Engineering Department, 311 North 15th Street, McAllen, TX 78501. | http://www.msc.fema.gov/lomc | Feb. 21, 2017 | 480343 |
| Rockwall | City of Heath (16-06-1549P). | The Honorable Brian Berry, Mayor, City of Heath, 200 Laurence Drive, Heath, TX 75032. | City Hall, 200 Laurence Drive, Heath, TX 75032. | http://www.msc.fema.gov/lomc | Mar. 13, 2017 | 480545 |
| Williamson | Unincorporated areas of Williamson County (16-06-0501P). | The Honorable Dan A. Gattis, Williamson County Judge, 710 South Main Street, Suite 101, Georgetown, TX 78626. | Williamson County Engineering Department, 3151 Southeast Inner Loop, Suite B, Georgetown, TX 78626. | http://www.msc.fema.gov/lomc | Mar. 2, 2017 | 481079 |
| Utah: Morgan | City of Morgan City (16-08-1130P). | The Honorable Ray Little, Mayor, City of Morgan City, P.O. Box 1085, Morgan City, UT 84050. | Building Department, 90 West Young Street, Morgan City, UT 84050. | http://www.msc.fema.gov/lomc | Feb. 27, 2017 | 490093 |
| Wyoming: Sublette | Town of Pinedale (16-08-0579P). | The Honorable Robert M. Jones, Mayor, Town of Pinedale, 61 Pinedale South Road, Pinedale, WY 82941. | Town Hall, 61 Pinedale South Road, Pinedale, WY 82941. | http://www.msc.fema.gov/lomc | Feb. 21, 2017 | 560049 |
| Sublette | Unincorporated areas of Sublette County (16-08-0579P). | The Honorable Andy Nelson, Chairman, Sublette County Board of Commissioners, 21 South Tyler Avenue, Pinedale, WY 82941. | Sublette County Courthouse, 21 South Tyler Avenue, Pinedale, WY 82941. | http://www.msc.fema.gov/lomc | Feb. 21, 2017 | 560048 |

[FR Doc. 2017-01098 Filed 1-18-17; 8:45 am]

BILLING CODE 9110-12-P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency****[Docket ID: FEMA-2017-0004; OMB No. 1660-0046]****Agency Information Collection Activities: Proposed Collection; Comment Request; Emergency Management Institute (EMI) Independent Study Course Enrollment Application and Test Answer Sheet****AGENCY:** Federal Emergency Management Agency, DHS.**ACTION:** Notice.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a revision of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning enrollment for

students and score assessments for FEMA's Independent Study Program.

DATES: Comments must be submitted on or before March 20, 2017.

ADDRESSES: To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:

(1) *Online.* Submit comments at www.regulations.gov under Docket ID FEMA-2017-0004. Follow the instructions for submitting comments.

(2) *Mail.* Submit written comments to Docket Manager, Office of Chief Counsel, DHS/FEMA, 500 C Street SW., 8NE, Washington, DC 20472-3100.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at <http://www.regulations.gov>, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the link in the footer of www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Mark Magers, Instructional Systems Specialist, FEMA, PNP—Emergency Management Institute, at 301-447-1038.

You may contact the Information Management Division for copies of the proposed collection of information at email address: FEMA-Information-Collections-Management@fema.dhs.gov.

SUPPLEMENTARY INFORMATION: FEMA's Emergency Management Institute (EMI) provides a wide variety of training to emergency management personnel throughout the country. The EMI Independent Study (IS) Program is part of the FEMA training program authorized under section 611(f) of the Robert T. Stafford Disaster Relief and Emergency Act, Public Law 93-288 as amended. These courses are offered online by EMI. The IS Program provides valuable training to Federal, State, local and Tribal emergency management personnel and the general citizenry of the United States without having to attend a resident course at EMI, or at a State-sponsored course. The IS program also includes a course on the National Incident Management System (NIMS). NIMS is our nation's incident management system. Homeland Security Presidential Directive 5, "Management of Domestic Incidents," requires the adoption of NIMS by all Federal departments and agencies. This directive also requires that Federal preparedness assistance funding for States, Territories, local jurisdictions

and Tribal entities be dependent on being NIMS compliant.

Collection of Information

Title: Emergency Management Institute (EMI) Independent Study Course Enrollment Application and Test Answer Sheet.

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660-0046.

FEMA Forms: FEMA Form 064-0-9, Emergency Management Institute (EMI) Independent Study Course Enrollment Application.

Abstract: The IS program office collects data from FEMA Form 064-0-9 to create and update student records and provide students with credit for training completion. The system also allows FEMA to track completions and failures of course exams. The data on the electronic form will be encrypted and sent to the server to be parsed into the Independent Study database.

Affected Public: Individuals and households, business or other for-profit, not for profit institutions, Farms, Federal government, State, local or Tribal government.

Number of Respondents: 689,980.

Number of Responses: 2,069,940.

Estimated Total Annual Burden

Hours: 1,034,970 hours.

Estimated Cost: The estimated annual cost to respondents for the hour burden is \$25,211,869. There are no annual costs to respondents' operations and maintenance costs for technical services. There are no annual start-up or capital costs. The cost to the Federal Government is \$260,893.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Dated: January 13, 2017.

Richard W. Mattison,

Records Management Program Chief, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2017-01283 Filed 1-18-17; 8:45 am]

BILLING CODE 9111-72-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2016-0002; Internal Agency Docket No. FEMA-B-1663]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before April 19, 2017.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at www.msc.fema.gov for comparison.

You may submit comments, identified by Docket No. FEMA-B-1663, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646-7659, or (email) patrick.sacbibit@fema.dhs.gov.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646-7659, or (email) patrick.sacbibit@fema.dhs.gov; or visit the FEMA Map Information eXchange (FMIX) online at www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been

engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at http://floodsrp.org/pdfs/srp_fact_sheet.pdf.

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection

at both the online location and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at www.msc.fema.gov for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

February 23, 2017.

Dated: December 21, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

I. Watershed-based studies:

Community

Community map repository address

Upper Saline Watershed

Maps Available for Inspection Online at: <http://www.fema.gov/preliminaryfloodhazarddata>

Saline County, Arkansas and Incorporated Areas

| | |
|---|--|
| City of Alexander | Municipal Complex, 15605 Alexander Road, Alexander, AR 72002. |
| City of Benton | Municipal Complex, 114 South East Street, Benton, AR 72015. |
| City of Bryant | Public Safety Building, 312 Roya Lane, Bryant, AR 72022. |
| City of Haskell | City Hall, 2520 Highway 229, Haskell, AR 72015. |
| City of Shannon Hills | City Hall, 10401 High Road East, Shannon Hills, AR 72103. |
| City of Traskwood | Community Center, 212 Main Street, Traskwood, AR 72167. |
| Town of Bauxite | City Hall, 6055 Stanley Circle, Bauxite, AR 72011. |
| Unincorporated Areas of Saline County | Saline County Complex, 215 North Main Street, Suite 7, Benton, AR 72015. |

Lower Sabine Watershed

Maps Available for Inspection Online at: <http://www.fema.gov/preliminaryfloodhazarddata>

Vernon Parish, Louisiana and Incorporated Areas

| | |
|---|---|
| City of Leesville | City Hall, 101 West Lee Street, Leesville, LA 71446. |
| Town of Hornbeck | Town Hall, 939 Hammond Street, Hornbeck, LA 71439. |
| Town of New Llano | City Hall, 109 Stanton Street, New Llano, LA 71461. |
| Unincorporated Areas of Vernon Parish | Vernon Parish Public Works Department, 602 Alexandria Highway, Leesville, LA 71446. |
| Village of Anacoco | Village Hall, 4973 Main Street, Anacoco, LA 71403. |

[FR Doc. 2017-01100 Filed 1-18-17; 8:45 am]

BILLING CODE 9110-12-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2016-0002; Internal Agency Docket No. FEMA-B-1662]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood

Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR). The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will become effective on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at www.msc.fema.gov for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646-7659, or (email) patrick.sacbibit@fema.dhs.gov; or visit the FEMA Map Information eXchange (FMIX) online at www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or

pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at www.msc.fema.gov for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: December 21, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Online location of letter of map revision | Effective date of modification | Community No. |
|------------------|--|--|--|---|--------------------------------|---------------|
| Arizona: | | | | | | |
| Maricopa | City of Peoria (16-09-0861P). | The Honorable Cathy Carlat, Mayor, City of Peoria, 8401 West Monroe Street, Peoria, AZ 85345. | Engineering Department, 9875 North 85th Avenue, Peoria, AZ 85345. | http://www.msc.fema.gov/lomc | Feb. 17, 2017 | 040050 |
| Maricopa | City of Peoria (16-09-0867P). | The Honorable Cathy Carlat, Mayor, City of Peoria, 8401 West Monroe Street, Peoria, AZ 85345. | Engineering Department, 9875 North 85th Avenue, Peoria, AZ 85345. | http://www.msc.fema.gov/lomc | Feb. 17, 2017 | 040050 |
| Maricopa | City of Phoenix (15-09-2235P). | The Honorable Greg Stanton, Mayor, City of Phoenix, 200 West Washington Street, Phoenix, AZ 85003. | Street Transportation Department, 200 West Washington Street, 5th Floor, Phoenix, AZ 85003. | http://www.msc.fema.gov/lomc | Feb. 10, 2017 | 040051 |
| Maricopa | Town of Gilbert (16-09-1926P). | The Honorable John Lewis, Mayor, Town of Gilbert, 50 East Civic Center Drive, Gilbert, AZ 85296. | Town Hall, 90 East Civic Center Drive, Gilbert, AZ 85296. | http://www.msc.fema.gov/lomc | Feb. 17, 2017 | 040044 |
| Maricopa | Unincorporated Areas of Maricopa County (15-09-2235P). | The Honorable Clint L. Hickman, Chairman, Board of Supervisors, Maricopa County, 301 West Jefferson Street, 10th Floor, Phoenix, AZ 85003. | Flood Control District of Maricopa County, 2801 West Durango Street, Phoenix, AZ 85009. | http://www.msc.fema.gov/lomc | Feb. 10, 2017 | 040037 |
| Maricopa | Unincorporated Areas of Maricopa County (16-09-1926P). | The Honorable Clint L. Hickman, Chairman, Board of Supervisors, Maricopa County, 301 West Jefferson Street, 10th Floor, Phoenix, AZ 85003. | Flood Control District of Maricopa County, 2801 West Durango Street, Phoenix, AZ 85009. | http://www.msc.fema.gov/lomc | Feb. 17, 2017 | 040037 |
| Pima | Unincorporated Areas of Pima County (16-09-1661P). | The Honorable Sharon Bronson, Chair, Board of Supervisors, Pima County, 130 West Congress Street, 11th Floor, Tucson, AZ 85701. | Pima County Regional Flood Control District, 201 North Stone Avenue 9th Floor, Tucson, AZ 85701. | http://www.msc.fema.gov/lomc | Feb. 3, 2017 | 040073 |
| Yavapai | Town of Chino Valley (16-09-0142P). | The Honorable Chris Marley, Mayor, Town of Chino Valley, Town Hall, 202 North State Route 89, Chino Valley, AZ 86323. | Public Works Department, 1982 Voss Drive, Chino Valley, AZ 86323. | http://www.msc.fema.gov/lomc | Jan. 27, 2017 | 040094 |
| California: | | | | | | |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Online location of letter of map revision | Effective date of modification | Community No. |
|---------------------|---|---|--|---|--------------------------------|---------------|
| Santa Clara | City of San Jose (16-09-1141P). | The Honorable Sam Liccardo, Mayor, City of San Jose, 200 East Santa Clara Street, 18th Floor, San Jose, CA 95113. | Department of Public Works, 200 East Santa Clara Street, 3rd Floor, San Jose, CA 95113. | http://www.msc.fema.gov/lomc | Jan. 19, 2017 | 060349 |
| Yolo | Unincorporated Areas of Yolo County (16-09-2472P). | The Honorable Jim Provenza, Chairman, Board of Supervisors, Yolo County, 625 Court Street, Room 204, Woodland, CA 95695. | Department of Planning and Public Works, 292 West Beamer Street, Woodland, CA 95695. | http://www.msc.fema.gov/lomc | Feb. 13, 2017 | 060423 |
| Illinois: | | | | | | |
| Adams | Unincorporated Areas of Adams County (16-05-1107P). | The Honorable Les Post, Chairman, Adams County Board, County Courthouse, 101 North 54th Street, Quincy, IL 62305. | Adams County Court-house, 101 North 54th Street, Quincy, IL 62305. | http://www.msc.fema.gov/lomc | Jan. 3, 2017 | 170001 |
| Cass | Unincorporated Areas of Cass County (15-05-2462P). | The Honorable Dave Parish, Chairman, Cass County Board, 100 East Springfield Street, Virginia, IL 62691. | County Courthouse, 100 East Springfield Street, Virginia, IL 62691. | http://www.msc.fema.gov/lomc | Jan. 27, 2017 | 170810 |
| Cass | Village of Ashland (15-05-2462P). | The Honorable Terry S. Blakeman, Village President, Village of Ashland, 101 North Yates Street, Ashland, IL 62612. | Village Hall, 101 North Yates Street, Ashland, IL 62612. | http://www.msc.fema.gov/lomc | Jan 27, 2017 | 171025 |
| Cook | City of Countryside (15-05-6492P). | The Honorable Sean R. McDermott, Mayor, City of Countryside, 5550 East Avenue, Countryside, IL 60525. | Building Department, 5550 East Avenue, Countryside, IL 60525. | http://www.msc.fema.gov/lomc | Dec. 30, 2016 | 170079 |
| Cook | Unincorporated Areas of Cook County (15-05-6492P). | The Honorable Toni Preckwinkle, President, Cook County Board, 118 North Clark Street, Room 537, Chicago, IL 60602. | Cook County, Building and Zoning, Department, 69 West Washington, Street, 21st Floor, Chicago, IL 60602. | http://www.msc.fema.gov/lomc | Dec. 30, 2016 | 170054 |
| Cook | Village of La Grange (15-05-6492P). | The Honorable Thomas E. Livingston, Village President, Village, of La Grange, 53 South La Grange Road, La Grange, IL 60525. | Village Hall, 53 South La Grange Road, La Grange, IL 60525. | http://www.msc.fema.gov/lomc | Dec. 30, 2016 | 170114 |
| Kane | Village of Campton Hills (16-05-6021P). | The Honorable Harry Blecker, Village President, Village of Campton Hills, 40W270 LaFox Road, Suite B, Campton Hills, IL 60175. | Village Hall, 40W270 LaFox Road, Suite B, Campton Hills, IL 60175. | http://www.msc.fema.gov/lomc | Feb. 10, 2017 | 171396 |
| Kansas: Johnson .. | City of Overland Park (16-07-1180P). | The Honorable Carl Gerlach, Mayor, City of Overland Park, 8500 Santa Fe Drive, Overland Park, KS, 66212. | City Hall, 8500 Santa Fe Drive, Overland Park, KS 66212. | http://www.msc.fema.gov/lomc | Jan. 4, 2017 | 200174 |
| Kentucky: Jefferson | Louisville-Jefferson County Metro Government (16-04-6581P). | The Honorable Greg Fischer, Mayor, Louisville Jefferson County Metro, Metro Hall, 527 West Jefferson Street, 4th Floor, Louisville, KY 40202. | Louisville-Jefferson County Metropolitan Sewer District, 700 West Liberty Street, Louisville, KY 40203. | http://www.msc.fema.gov/lomc | Jan. 9, 2017 | 210120 |
| Missouri: | | | | | | |
| Greene | City of Springfield (16-07-1495P). | The Honorable Bob Stephens, Mayor, City of Springfield, Springfield City Hall, 840 Boonville Avenue, Springfield, MO 65802. | City Hall, 840 Boonville Avenue, Springfield, MO 65802. | http://www.msc.fema.gov/lomc | Feb. 15, 2017 | 290149 |
| Greene | Unincorporated Areas of Greene County (16-07-1495P). | Mr. Robert Cortin, Greene County Presiding Commissioner, Greene County Commission Offices, 933 North Robberson Avenue, Springfield, MO 65802. | Greene County Court-house, 840 Boonville Avenue, Springfield, MO 65802. | http://www.msc.fema.gov/lomc | Feb. 15, 2017 | 290782 |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Online location of letter of map revision | Effective date of modification | Community No. |
|-------------------------|---|---|--|---|--------------------------------|---------------|
| Nevada: Clark | Unincorporated Areas of Clark County (16-09-1844P). | The Honorable Steve Sisolak, Chairman, Board of Supervisors, 500 South Grand Central Parkway, 6th Floor, Las Vegas, NV 89106. | Office of The Director of Public Works, 500 South Grand Central Parkway, Las Vegas, NV 89155. | http://www.msc.fema.gov/lomc | Jan. 5, 2017 | 320003 |
| New York: Suffolk | Town of Southold (16-02-1018P). | The Honorable Scott A. Russell, Town Supervisor, Town of Southold, 53095 Main Road, Southold, NY 11971. | Town Hall, 53095 Route 25, Southold, NY 11971. | http://www.msc.fema.gov/lomc | Feb. 17, 2017 | 360813 |
| Ulster | Town of Saugerties (16-02-1922P). | The Honorable Gregory Helsmoortel, Town Supervisor, Town of Saugerties, 4 High Street, Saugerties, NY 12477. | Town of Saugerties, Town Hall, 4 High Street, Saugerties, NY 12477. | http://www.msc.fema.gov/lomc | April 5, 2017 | 360863 |
| Oregon: Benton | City of Corvallis (16-10-0653P). | The Honorable Biff Traber, Mayor, City of Corvallis, 501 Southwest Madison Avenue, Corvallis, OR 97339. | Planning Department, 501 Southwest Madison Avenue, Corvallis, OR 97333. | http://www.msc.fema.gov/lomc | Jan. 17, 2017 | 410009 |
| Jackson | Unincorporated Areas of Jackson County (16-10-0825P). | The Honorable Rick Dyer, Commissioner, Jackson County, 10 South Oakdale Avenue, Room 214, Medford, OR 97501. | Jackson County Roads, Parks and Planning Services, 10 South Oakdale Avenue, Medford, OR 97501. | http://www.msc.fema.gov/lomc | Dec. 27, 2016 | 415589 |
| Texas: Dallas | City of Mesquite (16-06-2265P). | The Honorable Stan Pickett, Mayor, City of Mesquite, 757 North Galloway Avenue, Mesquite, TX 75185. | City Engineering Services, 1515 North Galloway Avenue, Mesquite, TX 75185. | http://www.msc.fema.gov/lomc | Jan. 5, 2017 | 485490 |
| Travis | City of Manor (16-06-1785P). | The Honorable Rita G. Jonse, Mayor, City of Manor, 105 East Eggleston Street, Manor, TX 78653. | City Hall, 201 East Parson Street, Manor, TX 78653. | http://www.msc.fema.gov/lomc | Jan. 9, 2017 | 481027 |
| Travis | Unincorporated Areas of Travis County (16-06-1785P). | The Honorable Sarah Eckhardt, Travis County Judge, 700 Lavaca, Suite 2.300, Austin, TX 78767. | Transportation and Natural Resources, 700 Lavaca Street, 5th Floor, Austin, TX 78767. | http://www.msc.fema.gov/lomc | Jan. 9, 2017 | 481026 |
| Washington DC | District of Columbia (16-03-2068P). | The Honorable Muriel Bowser, Mayor, District of Columbia, John A. Wilson Building, 1350 Pennsylvania Avenue Northwest, Suite 316, Washington, DC 20004. | Department of Environment, 51 North Street, Northeast, Suite 5020 Washington, DC 20002. | http://www.msc.fema.gov/lomc | Feb. 9, 2017 | 110001 |
| Washington: King | City of Auburn (16-10-1206P). | The Honorable Nancy Backus, Mayor, City of Auburn, 25 West Main Street, Auburn, WA 98001. | City Hall, 25 West Main Street, Auburn, WA 98001. | http://www.msc.fema.gov/lomc | Mar. 8, 2017 | 530073 |
| King | City of Pacific (16-10-1206P). | The Honorable Leanne Guier, Mayor, City of Pacific, 100 3rd Avenue Southeast, Pacific, WA 98047. | City Hall, 100 3rd Avenue Southeast, Pacific, WA 98047. | http://www.msc.fema.gov/lomc | Mar. 8, 2017 | 530086 |
| Wisconsin: Dane | City of Monona (16-05-3951P). | The Honorable Bob Miller, Mayor, City of Monona, 5211 Schluter Road, Monona, WI 53716. | City Hall, 5211 Schluter Road, Monona, WI 53716. | http://www.msc.fema.gov/lomc | Dec. 30, 2016 | 550088 |
| Eau Claire | City of Eau Claire (16-05-5442P). | The Honorable Kerry Kincaid, President, City Council, 4441 South Lowes Creek Road, Eau Claire, WI 54701. | City Hall, 203 South Farwell Street, 3rd Floor, Eau Claire, WI 54701. | http://www.msc.fema.gov/lomc | Feb. 14, 2017 | 550128 |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Online location of letter of map revision | Effective date of modification | Community No. |
|------------------|---|--|---|---|--------------------------------|---------------|
| Jackson | Unincorporated Areas of Jackson County (16-05-4012P). | The Honorable Ray Ransom, Chairperson, Jackson County Board, Jackson County Court-house, 307 Main Street, Black River Falls, WI 54615. | Jackson County Court-house, 307 Main Street, Black River Falls, WI 54615. | http://www.msc.fema.gov/lomc | Feb. 9, 2017 | 550583 |

[FR Doc. 2017-01262 Filed 1-18-17; 8:45 am]

BILLING CODE 9110-12-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2016-0002; Internal Agency Docket No. FEMA-B-1667]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before April 19, 2017.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for

inspection at both the online location and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at www.msc.fema.gov for comparison.

You may submit comments, identified by Docket No. FEMA-B-1667, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646-7659, or (email) patrick.sacbibit@fema.dhs.gov.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646-7659, or (email) patrick.sacbibit@fema.dhs.gov; or visit the FEMA Map Information eXchange (FMIX) online at www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are

provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at http://floodsrp.org/pdfs/srp_fact_sheet.pdf.

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at www.msc.fema.gov for comparison. (Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: December 21, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

I. Non-watershed-based studies:

| Community | Community map repository address |
|--|---|
| City and Borough of Sitka, Alaska | |
| Maps Available for Inspection Online at: http://www.fema.gov/preliminaryfloodhazarddata | |
| Project: 14–10–0598S Preliminary Date: June 30, 2016 | |
| City and Borough of Sitka | 100 Lincoln Street, Sitka, AK 99835. |
| Kossuth County, Iowa and Incorporated Areas | |
| Maps Available for Inspection Online at: http://www.fema.gov/preliminaryfloodhazarddata | |
| Project: 16–07–0204S Preliminary Date: June 30, 2016 | |
| City of Algona | City Hall, 112 West Call Street, Algona, IA 50511. |
| City of Bancroft | City Hall, 105 East Ramsey Street, Bancroft, IA 50517. |
| City of Fenton | City Hall, 611 Maple Street, Fenton, IA 50539. |
| City of Lakota | City Hall, 204 3rd Street, Lakota, IA 50451. |
| City of Titonka | City Hall, 543 Dieckman Street Northeast, Titonka, IA 50480. |
| City of Wesley | City Hall, 105 2nd Street South, Wesley, IA 50483. |
| City of Whittemore | City Hall, 315 4th Street, Whittemore, IA 50598. |
| Unincorporated Areas of Kossuth County | Kossuth County Courthouse, 114 West State Street, Algona, IA 50511. |
| Fillmore County, Minnesota and Incorporated Areas | |
| Maps Available for Inspection Online at: http://www.fema.gov/preliminaryfloodhazarddata | |
| Project: 12–05–8948S Preliminary Dates: June 30, 2011 and April 29, 2016 | |
| City of Chatfield | City Hall, 21 Second Street Southeast, Chatfield, MN 55923. |
| City of Lanesboro | City Hall, 202 Parkway Avenue South, Lanesboro, MN 55949. |
| City of Mabel | City Hall, 207 North Main Street, Mabel, MN 55954. |
| City of Ostrander | City Hall, 414 Main Street, Ostrander, MN 55961. |
| City of Peterson | City Hall, 118 Fillmore Street, Peterson, MN 55962. |
| City of Preston | City Hall, 210 Fillmore Street West, Preston, MN 55965. |
| City of Rushford | City Hall, 101 North Mill Street, Rushford, MN 55971. |
| City of Rushford Village | City Hall, 43038 State Highway 30 West, Rushford Village, MN 55971. |
| City of Spring Valley | City Hall, 201 South Broadway, Spring Valley, MN 55975. |
| City of Whalan | City Hall, 905 Bench Street, Whalan, MN 55949. |
| Unincorporated Areas of Fillmore County | Fillmore County Courthouse, 101 Fillmore Street, Preston, MN 55965. |

[FR Doc. 2017–01264 Filed 1–18–17; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA–4285–DR; Docket ID FEMA–2016–0001]

North Carolina; Amendment No. 16 to Notice of a Major Disaster Declaration**AGENCY:** Federal Emergency Management Agency, DHS.**ACTION:** Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of North Carolina (FEMA–4285–DR), dated October 10, 2016, and related determinations.

DATES: Effective December 23, 2016.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency

Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of North Carolina is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of October 10, 2016.

Warren County for Public Assistance, including direct federal assistance. The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,
Administrator, Federal Emergency Management Agency.

[FR Doc. 2017–01095 Filed 1–18–17; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency**

[Docket ID FEMA–2016–0002; Internal Agency Docket No. FEMA–B–1665]

Changes in Flood Hazard Determinations**AGENCY:** Federal Emergency Management Agency, DHS.**ACTION:** Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone

designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR). The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will become effective on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each

community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at www.msc.fema.gov for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646-7659, or (email) patrick.sacibit@fema.dhs.gov; or visit the FEMA Map Information eXchange (FMIX) online at www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at www.msc.fema.gov for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: December 21, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Online location of letter of map revision | Effective date of modification | Community No. |
|------------------|--|--|--|---|--------------------------------|---------------|
| Arkansas: | | | | | | |
| Crawford | City of Van Buren (16-06-1669P). | The Honorable Bob Freeman, Mayor, City of Van Buren, 1003 Broadway Street, Van Buren, AR 72956. | Public Works Department, 1003 Broadway Street, Van Buren, AR 72956. | http://www.msc.fema.gov/lomc | Jan. 26, 2017 | 050053 |
| Crawford | Unincorporated areas of Crawford County (16-06-1669P). | The Honorable John Hall, Crawford County Judge, 300 Main Street, Room 4, Van Buren, AR 72956. | Crawford County Department of Emergency Management, 1820 Chestnut Street, Van Buren, AR 72956. | http://www.msc.fema.gov/lomc | Jan. 26, 2017 | 050428 |
| Colorado: | | | | | | |
| Adams | City of Thornton (16-08-0136P). | The Honorable Heidi Williams, Mayor, City of Thornton, 9500 Civic Center Drive, Thornton, CO 80229. | Engineering Services Division, 12450 Washington Street, Thornton, CO 80241. | http://www.msc.fema.gov/lomc | Feb. 10, 2017 | 080007 |
| Adams | City of Westminster (16-08-0417P). | The Honorable Herb Atchison, Mayor, City of Westminster, 4800 West 92nd Avenue, Westminster, CO 80031. | Engineering Division, 4800 West 92nd Avenue, Westminster, CO 80031. | http://www.msc.fema.gov/lomc | Feb. 10, 2017 | 080008 |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Online location of letter of map revision | Effective date of modification | Community No. |
|---------------------------------|--|--|--|---|--------------------------------|---------------|
| Adams | Unincorporated areas of Adams County (16-08-0136P). | The Honorable Steve O'Dorisio, Chairman, Adams County Board of Commissioners, 4430 South Adams County Parkway, Brighton, CO 80601. | Adams County Development and Engineering Services Department, 4430 South Adams County Parkway, Brighton, CO 80601. | http://www.msc.fema.gov/lomc | Feb. 10, 2017 | 080001 |
| El Paso | City of Colorado Springs (16-08-0694P). | The Honorable John Suthers, Mayor, City of Colorado Springs, 30 South Nevada Avenue, Colorado Springs, CO, 80903. | Pikes Peak Regional Building, 2880 International Circle, Colorado Springs, CO, 80903. | http://www.msc.fema.gov/lomc | Feb. 22, 2017 | 080060 |
| Jefferson | City of Westminster (16-08-0792P). | The Honorable Herb Atchison, Mayor, City of Westminster, 4800 West 92nd Avenue, Westminster, CO 80031. | Engineering Division, 4800 West 92nd Avenue, Westminster, CO 80031. | http://www.msc.fema.gov/lomc | Feb. 17, 2017 | 080008 |
| Delaware: New Castle. | Unincorporated areas of New Castle County (16-03-2184P). | The Honorable Thomas Gordon, New Castle County Executive, 87 Reads Way, New Castle, DE 19720. | New Castle County Department of Land Use, 87 Reads Way, New Castle, DE 19720. | http://www.msc.fema.gov/lomc | Jan. 30, 2017 | 105085 |
| Florida: Lake | City of Groveland (16-04-3023P). | The Honorable Tim Loucks, Mayor, City of Groveland, 156 South Lake Avenue, Groveland, FL 34736. | City Hall, 156 South Lake Avenue, Groveland, FL 34736. | http://www.msc.fema.gov/lomc | Feb. 3, 2017 | 120135 |
| Lake | Unincorporated areas of Lake County (16-04-3023P). | The Honorable Sean Parks, Chairman, Lake County Board of Commissioners, 315 West Main Street, Tavares, FL 32778. | Lake County Public Works Department, 323 North Sinclair Avenue, Tavares, FL 32778. | http://www.msc.fema.gov/lomc | Feb. 3, 2017 | 120421 |
| Manatee | City of Bradenton Beach (16-04-5422P). | The Honorable William Shearon, Mayor, City of Bradenton Beach, 107 Gulf Drive North, Bradenton Beach, FL 34217. | Public Works, Planning and Development Department, 107 Gulf Drive North, Bradenton Beach, FL 34217. | http://www.msc.fema.gov/lomc | Mar. 1, 2017 | 125091 |
| Osceola | Unincorporated areas of Osceola County (16-04-5214P). | The Honorable Viviana Janer, Chair, Osceola County Board of Commissioners, 1 Courthouse Square, Suite 4700, Kissimmee, FL 34741. | Osceola County Development Review Department, 1 Courthouse Square, Suite 1400, Kissimmee, FL 34741. | http://www.msc.fema.gov/lomc | Feb. 10, 2017 | 120189 |
| St. Johns | Unincorporated areas of St. Johns County (16-04-4101P). | The Honorable Jeb Smith, Chairman, St. Johns County Board of Commissioners, 500 San Sebastian View, St. Augustine, FL 32084. | St. Johns County Building Services Division, 4040 Lewis Speedway, St. Augustine, FL 32084. | http://www.msc.fema.gov/lomc | Jan. 31, 2017 | 125147 |
| Seminole | City of Oviedo (16-04-3084P). | The Honorable Dominic Persampiere, Mayor, City of Oviedo, 400 Alexandria Boulevard, Oviedo, FL 32765. | Engineering Department, 400 Alexandria Boulevard, Oviedo, FL 32765. | http://www.msc.fema.gov/lomc | Feb. 8, 2017 | 120293 |
| Seminole | Unincorporated areas of Seminole County (16-04-3084P). | The Honorable John Huran, Chairman, Seminole County Board of Commissioners, 1101 East 1st Street, Sanford, FL 32771. | Seminole County Development Review Division, 1101 East 1st Street, Sanford, FL 32771. | http://www.msc.fema.gov/lomc | Feb. 8, 2017 | 120289 |
| Massachusetts: Barnstable | Town of Sandwich (16-01-1204P). | The Honorable Susan James, Chair, Town of Sandwich Board of Selectmen, 130 Main Street, Sandwich, MA 02563. | Building Department, 16 Jan Sebastian Drive, Sandwich, MA 02563. | http://www.msc.fema.gov/lomc | Jan. 9, 2017 | 250012 |
| Plymouth | Town of Mattapoisett (16-01-2222P). | The Honorable R. Tyler Macallister, Chairman, Town of Mattapoisett Board of Selectmen, P.O. Box 435, Mattapoisett, MA 02739.. | Building Department, 16 Main Street, Mattapoisett, MA 02739. | http://www.msc.fema.gov/lomc | Feb. 17, 2017 | 255214 |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Online location of letter of map revision | Effective date of modification | Community No. |
|------------------------------|--|---|--|---|--------------------------------|---------------|
| Mississippi: Madison. | City of Ridgeland (16-04-1990P). | The Honorable Gene McGee, Mayor, City of Ridgeland, 304 Highway 51, Ridgeland, MS 39157. | City Hall, 304 Highway 51, Ridgeland, MS 39157. | http://www.msc.fema.gov/lomc | Feb. 10, 2017 | 280110 |
| New Mexico: Bernalillo | City of Albuquerque (16-06-0422P). | The Honorable Richard J. Berry, Mayor, City of Albuquerque, P.O. Box 1293, Albuquerque, NM 87102. | Development and Building Services Department, 600 2nd Street Northwest, Albuquerque, NM 87102. | http://www.msc.fema.gov/lomc | Feb. 16, 2017 | 350002 |
| Bernalillo | Unincorporated areas of Bernalillo County (16-06-0422P). | The Honorable Art De La Cruz, Chairman, Bernalillo County Board of Commissioners, 1 Civic Plaza Northwest, Albuquerque, NM 87102. | Bernalillo County Public Works Division, 2400 Broadway Boulevard Southeast, Albuquerque, NM 87102. | http://www.msc.fema.gov/lomc | Feb. 16, 2017 | 350001 |
| Dona Ana | Unincorporated areas of Dona Ana County (16-06-3875P). | The Honorable Wayne Hancock, Chairman, Dona Ana County Board of Commissioners, 845 North Motel Boulevard, Las Cruces, NM 88007. | Dona Ana County Flood Commission Department, 845 North Motel Boulevard, Las Cruces, NM 88007. | http://www.msc.fema.gov/lomc | Jan. 13, 2017 | 350012 |
| North Carolina: Mecklenburg. | Town of Pineville (16-04-3132P). | The Honorable John Edwards, Mayor, Town of Pineville, P.O. Box 249, Pineville, NC 28134. | Town Hall, 200 Dover Street, Pineville, NC 28134. | http://www.msc.fema.gov/lomc | Feb. 23, 2017 | 370160 |
| North Dakota: Burleigh. | City of Bismarck (16-08-0336P). | The Honorable Mike Seminary, Mayor, City of Bismarck, 221 North 5th Street, Bismarck, ND 58506. | City Hall, 221 North 5th Street, Bismarck, ND 58506. | http://www.msc.fema.gov/lomc | Feb. 10, 2017 | 380149 |
| Oklahoma: Oklahoma | City of Oklahoma City (16-06-2147P). | The Honorable Mick Cornett, Mayor, City of Oklahoma City, 200 North Walker Avenue, Oklahoma City, OK 73102. | Public Works Department, 420 West Main Street, Oklahoma City, OK 73102. | http://www.msc.fema.gov/lomc | Feb. 22, 2017 | 405378 |
| Payne | City of Perkins (16-06-2777P). | The Honorable Jason Shilling, Mayor, City of Perkins, P.O. Box 9, Perkins, OK 74059. | Floodplain Department, 110 North Main Street, Perkins, OK 74059. | http://www.msc.fema.gov/lomc | Jan. 27, 2017 | 400431 |
| Payne | Unincorporated areas of Payne County (16-06-2777P). | The Honorable Kent Bradley, Chairman, Payne County Board of Commissioners, 506 Expo Circle South, Stillwater, OK 74074. | Payne County Administrative Building, 315 West 6th Street, Suite 203, Stillwater, OK 74074. | http://www.msc.fema.gov/lomc | Jan. 27, 2017 | 400493 |
| Pottawatomie | City of Shawnee (16-06-2100P). | Mr. Justin Erickson, Manager, City of Shawnee, P.O. Box 1448, Shawnee, OK 74801. | City Hall, 16 West 9th Street, Shawnee, OK 74801. | http://www.msc.fema.gov/lomc | Feb. 15, 2017 | 400178 |
| Pennsylvania: Franklin. | Borough of Chambersburg (16-03-0980P). | The Honorable Allen B. Coffman, President, Borough of Chambersburg Council, 100 South 2nd Street, Chambersburg, PA 17201. | Borough Hall, 100 South 2nd Street, Chambersburg, PA 17201. | http://www.msc.fema.gov/lomc | Feb. 3, 2017 | 420469 |
| South Dakota: Aurora | City of Plankinton (16-08-0366P). | The Honorable Joe Staller, Mayor, City of Plankinton, P.O. Box 517, Plankinton, SD 57368. | City Hall, 102 South Main Street, Plankinton, SD 57368. | http://www.msc.fema.gov/lomc | Feb. 3, 2017 | 460001 |
| Aurora | Unincorporated areas of Aurora County (16-08-0366P). | The Honorable Jeff Sauvage, Chairman, Aurora County Commission, 401 North Main Street, Plankinton, SD 57368. | Aurora County Courthouse, 401 North Main Street, Plankinton, SD 57368. | http://www.msc.fema.gov/lomc | Feb. 3, 2017 | 460293 |
| Texas: Burnet | Unincorporated areas of Burnet County (16-06-1135P). | The Honorable James Oakley, Burnet County Judge, 220 South Pierce Street, Burnet, TX 78611. | Burnet County Environmental Services Department, 133 East Jackson Street, Burnet, TX 78611. | http://www.msc.fema.gov/lomc | Feb. 13, 2017 | 481209 |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Online location of letter of map revision | Effective date of modification | Community No. |
|---------------------------|--|--|---|---|--------------------------------|---------------|
| Collin | City of Wylie (16-06-0594P). | The Honorable Eric Hogue, Mayor, City of Wylie, 300 Country Club Road, Building 100, Wylie, TX 75098. | City Hall, 300 Country Club Road, Building 100, Wylie, TX 75098. | http://www.msc.fema.gov/lomc | Feb. 9, 2017 | 480759 |
| Collin | Town of Prosper (16-06-3608P). | The Honorable Ray Smith, Mayor, Town of Prosper, P.O. Box 307, Prosper, TX 75078. | Engineering Services Department, 407 East 1st Street, Prosper, TX 75078. | http://www.msc.fema.gov/lomc | Feb. 16, 2017 | 480141 |
| Dallas | City of Irving (16-06-2472P). | The Honorable Beth Van Duyn, Mayor, City of Irving, 825 West Irving Boulevard, Irving, TX 75060. | Capital Improvement Program Department, Engineering Section, 825 West Irving Boulevard, Irving, TX 75060. | http://www.msc.fema.gov/lomc | Feb. 21, 2017 | 480180 |
| Fort Bend | City of Katy (16-06-1376P). | The Honorable Fabol R. Hughes, Mayor, City of Katy, P.O. Box 617, Katy, TX 77493. | Public Works Department, 901 Avenue C, Katy, TX 77493. | http://www.msc.fema.gov/lomc | Feb. 14, 2017 | 480301 |
| Fort Bend | Unincorporated areas of Fort Bend County (16-06-1376P). | The Honorable Robert Hebert, Fort Bend County Judge, 401 Jackson Street, Richmond, TX 77469. | Fort Bend County Engineering Department, 301 Jackson Street, Richmond, TX 77469. | http://www.msc.fema.gov/lomc | Feb. 14, 2017 | 480228 |
| Fort Bend | Willow Fork Drainage District (16-06-1376P). | The Honorable Richard Ward, President, Willow Fork Drainage District, Board of Directors, 3200 Southwest Freeway, Suite 2600, Houston, TX 77027. | AECOM, 5444 Westheimer Road, Suite 400, Houston, TX 77027. | http://www.msc.fema.gov/lomc | Feb. 14, 2017 | 481603 |
| Harris | City of Houston (16-06-0816P). | The Honorable Sylvester Turner, Mayor, City of Houston, P.O. Box 1562, Houston, TX 77251. | Floodplain Management Department, 1002 Washington Avenue, 3rd Floor, Houston, TX 77002. | http://www.msc.fema.gov/lomc | Jan. 20, 2017 | 480296 |
| Harris | Unincorporated areas of Harris County (16-06-0816P). | The Honorable Edward M. Emmett, Harris County Judge, 1001 Preston Street, Suite 911, Houston, TX 77002. | Harris County Permit Office, 10555 Northwest Freeway, Suite 120, Houston, TX 77092. | http://www.msc.fema.gov/lomc | Jan. 20, 2017 | 480287 |
| Montgomery ... | City of Conroe (16-06-1340P). | The Honorable Toby Powell, Mayor, City of Conroe, P.O. Box 3066, Conroe, TX 77305. | Department of Public Works, 300 West Davis Street, Conroe, TX 77301. | http://www.msc.fema.gov/lomc | Feb. 17, 2017 | 480484 |
| Montgomery ... | City of Conroe (16-06-1603P). | The Honorable Toby Powell, Mayor, City of Conroe, P.O. Box 3066, Conroe, TX 77305. | Department of Public Works, 300 West Davis Street, Conroe, TX 77301. | http://www.msc.fema.gov/lomc | Jan. 11, 2017 | 480484 |
| Travis | City of Pflugerville (16-06-1416P). | The Honorable Jeff Coleman, Mayor, City of Pflugerville, P.O. Box 589, Pflugerville, TX 78691. | Development Services Department, 201-B East Pecan Street, Pflugerville, TX 78660. | http://www.msc.fema.gov/lomc | Feb. 21, 2017 | 481028 |
| Travis | Unincorporated areas of Travis County (16-06-1416P). | The Honorable Sarah Eckhardt, Travis County Judge, P.O. Box 1748, Austin, TX 78767. | Travis County Transportation and Natural Resources Department, 700 Lavaca Street, Austin, TX 78701. | http://www.msc.fema.gov/lomc | Feb. 21, 2017 | 481026 |
| Williamson | Unincorporated areas of Williamson County (16-06-1135P). | The Honorable Dan A. Gattis, Williamson County Judge, 710 South Main Street, Suite 101, Georgetown, TX 78626. | Williamson County Department of Infrastructure, 3151 Southeast Inner Loop, Suite B, Georgetown, TX 78626. | http://www.msc.fema.gov/lomc | Feb. 13, 2017 | 481079 |
| Utah: Iron | City of Cedar City (16-08-0339P). | The Honorable Maile Wilson, Mayor, City of Cedar City, 10 North Main Street, Cedar City, UT 84720. | City Hall, 10 North Main Street, Cedar City, UT 84720. | http://www.msc.fema.gov/lomc | Jan. 5, 2017 | 490074 |
| Virginia: Albemarle | Unincorporated areas of Albemarle County (16-03-1207P). | Mr. Thomas C. Foley, Albemarle County Executive, 401 McIntire Road, Charlottesville, VA, 22902. | Albemarle County Community Development/Engineering Department, 401 McIntire Road, Charlottesville, VA, 22902. | http://www.msc.fema.gov/lomc | Feb. 6, 2017 | 510006 |
| Independent City. | City of Charlottesville (16-03-1207P). | Mr. Maurice Jones, Manager, City of Charlottesville, P.O. Box 911, Charlottesville, VA 22902. | Neighborhood Development Services, 610 East Market Street, Charlottesville, VA 22902. | http://www.msc.fema.gov/lomc | Feb. 6, 2017 | 510033 |

[FR Doc. 2017-01302 Filed 1-18-17; 8:45 am]

BILLING CODE 9110-12-P

DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency**

[Docket ID FEMA-2016-0002; Internal Agency Docket No. FEMA-B-1666]

Proposed Flood Hazard Determinations**AGENCY:** Federal Emergency Management Agency, DHS.**ACTION:** Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before January 19, 2017.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for

inspection at both the online location and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at www.msc.fema.gov for comparison.

You may submit comments, identified by Docket No. FEMA-B-1666, to Rick Sacibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646-7659, or (email) patrick.sacibit@fema.dhs.gov.

FOR FURTHER INFORMATION CONTACT: Rick Sacibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW., Washington, DC 20472, (202) 646-7659, or (email) patrick.sacibit@fema.dhs.gov; or visit the FEMA Map Information eXchange (FMIX) online at www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at http://floodsrp.org/pdfs/srp_fact_sheet.pdf.

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at www.msc.fema.gov for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Dated: December 21, 2016.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

| Community | Community map repository address |
|--|--|
| Wateree Watershed | |
| Maps Available for Inspection Online at: http://www.fema.gov/preliminaryfloodhazarddata | |
| Fairfield County, South Carolina and Incorporated Areas | |
| Unincorporated Areas of Fairfield County | Fairfield County Planning, Building and Zoning Department, 117 South Congress Street, Winnsboro, SC 29180. |

| Community | Community map repository address |
|--|--|
| Kershaw County, South Carolina and Incorporated Areas | |
| City of Camden | City Hall, Building and Zoning Department, 1000 Lyttleton Street, Camden, SC 29020. |
| Unincorporated Areas of Kershaw County | Kershaw County Government Center, Planning and Zoning Department, 515 Walnut Street, Camden, SC 29020. |
| Lancaster County, South Carolina and Incorporated Areas | |
| Unincorporated Areas of Lancaster County | Lancaster County Administration Building, Zoning Department, 101 North Main Street, Lancaster, SC 29720. |
| Sumter County, South Carolina and Incorporated Areas | |
| City of Sumter | The Liberty Center, City-County Planning Department, 12 West Liberty Street, Sumter, SC 29150. |
| Unincorporated Areas of Sumter County | The Liberty Center, Sumter City-County Planning Department, 12 West Liberty Street, Sumter, SC 29150. |

[FR Doc. 2017-01266 Filed 1-18-17; 8:45 am]

BILLING CODE 9110-12-P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2016-0096]

Homeland Security Science and Technology Advisory Committee

AGENCY: Science and Technology Directorate, DHS.

ACTION: Committee Management; Notice of Federal Advisory Committee Meeting.

SUMMARY: The Homeland Security Science and Technology Advisory Committee (HSSTAC) will meet on February 16-17, 2017 in Washington, DC. The meeting will be an open session with both in-person and webinar participation.

DATES: The HSSTAC will meet in-person Thursday, February 16, 2017, from 1:30 p.m.-5:30 p.m. and Friday, February 17, 2017, from 9:00 a.m.-12:00 p.m.

Due to security requirements, screening pre-registration is required for this event. Please see the "REGISTRATION" section below.

The meeting may close early if the committee has completed its business.

ADDRESSES: Homeland Security, 1120 Vermont Ave. NW., 8th Floor, Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Michel Kareis, HSSTAC Designated Federal Official, S&T IAO STOP 0205, Department of Homeland Security, 245 Murray Lane, Washington, DC 20528-0205, 202-254-8778, (Office), 202-254-6176 (Fax) Michel.Kareis@hq.dhs.gov (Email).

SUPPLEMENTARY INFORMATION:

I. Background

Notice of this meeting is given under the Federal Advisory Committee Act (FACA), 5 U.S.C. appendix (Pub. L. 92-463). The committee addresses areas of interest and importance to the Under Secretary for Science and Technology (S&T), such as new developments in systems engineering, cyber-security, knowledge management and how best to leverage related technologies funded by other Federal agencies and by the private sector. It also advises the Under Secretary on policies, management processes, and organizational constructs as needed.

II. Registration

To pre-register for the virtual meeting (webinar) please send an email to: hsstac@hq.dhs.gov. The email should include the name(s), title, organization/affiliation, email address, and telephone number of those interested in attending. For information on services for individuals with disabilities or to request special assistance at the meeting, please contact Michel Kareis as soon as possible.

If you plan to attend the meeting in-person you must RSVP by February 15, 2017. To register, email hsstac@hq.dhs.gov with the following subject line: RSVP to HSSTAC Meeting. The email should include the name(s), title, organization/affiliation, email address, and telephone number of those interested in attending.

III. Public Comment

At the end of each open session, there will be a period for oral statements. Please note that the oral statement period may end before the time indicated, following the last call for oral statements. To register as a speaker, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

To facilitate public participation, we invite public comment on the issues to be considered by the committee as listed in the "Agenda" below. Written comments must be received by February 6, 2017. Please include the docket number (DHS-2016-0084) and submit via one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.
- **Email:** hsstac@hq.dhs.gov. Include the docket number in the subject line of the message.
- **Fax:** 202-254-6176.
- **Mail:** Michel Kareis, HSSTAC Executive Director, S&T IAO STOP 0205, Department of Homeland Security, 245 Murray Lane, Washington, DC 20528-0205.

Instructions: All submissions received must include the words "Department of Homeland Security" and the docket number. Comments received will be posted without alteration at <http://www.regulations.gov>.

Docket: For access to the docket to read the background documents or comments received by the HSSTAC, go to <http://www.regulations.gov> and enter the docket number into the search function: DHS-2016-0096.

Agenda: Day 1: This session will begin with updates from the subcommittees under HSSTAC. The Commercialization Subcommittee will present draft recommendations to the committee for discussion. The Social Media Working Group Subcommittee will present the results from the vote to accept the Best Practices document and the status of the new Federal Advisory Committee designation. The Internet of Things Smart Cities will present the final recommendations. And lastly, an update on the creation of a subcommittee on Quadrennial Homeland Security Review (QHSR) and

an update on tasking under the subcommittee will be provided. This session will be followed by questions from the public. There will be discussions on the Internet of Things draft guidance document for their Next Generation First Responder (NGFR) program and the HSSTAC FY17 planning updates followed by public comments to close out the day. *Day 2:* The morning session will begin with a meeting overview followed by sessions on Technology Scouting, Technology Transfer and Commercialization.

The sessions will focus discussion on the technology development lifecycle to include best practice recommendations on how to create situational awareness of new or emerging trends, technologies, capabilities and research; develop processes to efficiently use networks and partnerships to identify, locate, and evaluate existing or developing technologies, and identify methods that can be used to engage the commercial marketplace to support the development and ultimately the acquisition by homeland security stakeholders of new technologies while prioritizing the need to leverage limited resources and maximize impact. The day will end with questions and comments from the public.

Dated: January 12, 2017.

Michel Kareis,

Executive Director, Homeland Security Science and Technology Advisory Committee.

[FR Doc. 2017-01290 Filed 1-18-17; 8:45 am]

BILLING CODE 4410-10-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615-0029]

Agency Information Collection Activities: Application for Waiver of Grounds of Inadmissibility, Form I-601; Revision of a Currently Approved Collection.

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection notice was previously published in the **Federal**

Register on October 17, 2016, at 81 FR 71522, allowing for a 60-day public comment period. USCIS did receive 1 comment in connection with the 60-day notice.

DATES: The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until February 21, 2017. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be directed to the OMB USCIS Desk Officer via email at oira_submission@omb.eop.gov. Comments may also be submitted via fax at (202) 395-5806. (This is not a toll-free number.) All submissions received must include the agency name and the OMB Control Number [1615-0029].

You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make. For additional information please read the Privacy Act notice that is available via the link in the footer of <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, 20 Massachusetts Avenue NW., Washington, DC 20529-2140, Telephone number (202) 272-8377. (This is not a toll-free number; comments are not accepted via telephone message.) Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at <http://www.uscis.gov>, or call the USCIS National Customer Service Center at (800) 375-5283; TTY (800) 767-1833.

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: <http://www.regulations.gov> and enter USCIS-2007-0042 in the search box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including

whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection Request:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application for Waiver of Grounds of Inadmissibility.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I-601, USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* *Primary:* Individuals or households. Form I-601 is necessary for USCIS to determine whether the applicant is eligible for a waiver of inadmissibility under section 212 of the Act. Furthermore, this information collection is used by individuals who are seeking for Temporary Protected Status (TPS).

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I-601 is 20,194; the estimated hour burden per paper responses is 1.75 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 35,340 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is \$7,497,023.

Dated: January 12, 2017.

Samantha Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2017-01080 Filed 1-18-17; 8:45 am]

BILLING CODE 9111-97-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0045]

Agency Information Collection Activities: Petition by Entrepreneur To Remove Conditions on Permanent Resident Status, Form I–829; Revision of a Currently Approved Collection

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day Notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection notice was previously published in the **Federal Register** on October 4, 2016, at 81 FR 68445, allowing for a 60-day public comment period. USCIS received 2 comments in connection with the 60-day notice.

DATES: The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until February 21, 2017. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be directed to the OMB USCIS Desk Officer via email at oir_submission@omb.eop.gov. Comments may also be submitted via fax at (202) 395–5806. (This is not a toll-free number.) All submissions received must include the agency name and the OMB Control Number [1615–0045].

You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make. For additional information please read the Privacy Act notice that is available via the link in the footer of <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, Telephone number (202) 272–8377 (This is not a toll-free number; comments are not accepted via

telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at <http://www.uscis.gov>, or call the USCIS National Customer Service Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: <http://www.regulations.gov> and enter USCIS–2006–0009 in the search box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection:

(1) *Type of Information Collection Request:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Petition by Entrepreneur to Remove Conditions on Permanent Resident Status.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–829; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. Alien entrepreneurs admitted to the United States under section 203(b)(5) of the Immigration and Nationality Act (INA) are required to petition for removal of the conditional residence status imposed on them and

their accompanying spouse and children, within a 90-day period before the second anniversary of their conditional residence under section 216A of the INA.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–829 is 3,859 and the estimated hour burden per response is 3 hours. 3,859 respondents for biometrics processing at an estimated 1 hour and 10 minutes (1.17 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 16,092 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is \$487,199.

Dated: January 13, 2017.

Samantha Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2017–01221 Filed 1–18–17; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5967–N–01]

HUD Approval of Requests for Transfers of Multifamily Housing Project-Based Rental Assistance, HUD-Held or Insured Debt, and Income-Based Use Restrictions

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: This notice establishes the terms and conditions by which HUD will approve a request for the transfer of project-based rental assistance, debt held or insured by the Secretary, and statutorily required income-based use restrictions from one multifamily housing project to another (or between several such projects). The Department of Housing and Urban Development Appropriations Act, 2016 gives the Secretary the authority to approve transfer requests for fiscal years (FY) 2016 and 2017, provided that the Secretary publish a notice in the **Federal Register** establishing the terms and conditions for HUD approval of

such transfers no later than 30 days before such notice takes effect. In FY 2016, HUD continued to utilize the FY 2015 published criteria, which covered authority enacted for both FY 2015 and FY 2016. For FY 2017, HUD continues to utilize, without revision, the published FY 2015 criteria. HUD believes that criteria established and published in FY 2015, and cross-referenced in this notice, will continue to assist project owners to determine whether a transfer is feasible given the specific circumstances of their multifamily projects.

DATES: *Effective Date:* February 21, 2017.

FOR FURTHER INFORMATION CONTACT: Katherine Nzive, Director, Program Administration Office, Office of Asset Management and Portfolio Oversight of Multifamily Housing, Office of Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 6110, Washington, DC 20410; telephone number 202-402-3440 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800-877-8339.

SUPPLEMENTARY INFORMATION: Beginning with section 318 of the Department of Housing and Urban Development Appropriations Act, 2006 (Pub. L. 109-115, 119 Stat. 2396, approved November 30, 2005), HUD appropriations acts have contained a general provision authorizing the Secretary to approve requests from project owners for the transfer of certain rental assistance, debt, and income-based use restrictions between HUD-assisted projects. For fiscal year 2017, this transfer authority is provided under section 212 of the Consolidated Appropriations Act, 216 (Pub. L. 114-113, 129 Stat. 2889, approved December 18, 2015 (Section 212). Section 212(a) states that “[n]otwithstanding any other provision of law . . . the Secretary of Housing and Urban Development may authorize the transfer of some or all project-based assistance, debt held or insured by the Secretary and statutorily required low-income and very low-income use restrictions if any, associated with one or more multifamily housing project or projects to another multifamily housing project or projects.” Section 212(b) also allows for phased transfers of project-based assistance to accommodate the financing and other requirements related to rehabilitating or constructing the project or projects to which the assistance is transferred.

HUD approval of transfers is subject to the conditions enumerated in the

appropriations act for the applicable fiscal year. These statutory terms and conditions have, in general, been consistent from one appropriations act to the next. The statutory criteria for FY 2017 is enumerated in section 212(c), which provides as follows:

(c) The transfer authorized in subsection (a) is subject to the following conditions:

(1) NUMBER AND BEDROOM SIZE OF UNITS.—

(A) For occupied units in the transferring project: the number of low-income and very low-income units and the configuration (i.e. bedroom size) provided by the transferring project shall be no less than when transferred to the receiving project or projects and the net dollar amount of Federal assistance provided to the transferring project shall remain the same in the receiving project or projects.

(B) For unoccupied units in the transferring project: the Secretary may authorize a reduction in the number of dwelling units in the receiving project or projects to allow for a reconfiguration of bedroom sizes to meet current market demands, as determined by the Secretary and provided there is no increase in the project-based assistance budget authority.

(2) The transferring project shall, as determined by the Secretary, be either physically obsolete or economically nonviable.

(3) The receiving project or projects shall meet or exceed applicable physical standards established by the Secretary.

(4) The owner or mortgagor of the transferring project shall notify and consult with the tenants residing in the transferring project and provide a certification of approval by all appropriate local governmental officials.

(5) The tenants of the transferring project who remain eligible for assistance to be provided by the receiving project or projects shall not be required to vacate their units in the transferring project or projects until new units in the receiving project are available for occupancy.

(6) The Secretary determines that this transfer is in the best interest of the tenants.

(7) If either the transferring project or the receiving project or projects meets the condition specified in subsection (d)(2)(A),¹ any lien on the receiving project resulting from additional financing obtained by the owner shall be subordinate to any FHA-insured mortgage lien transferred to, or placed on, such project by the Secretary, except that the Secretary may waive this requirement upon determination that such a waiver is necessary to facilitate the financing of acquisition, construction, and/or rehabilitation of the receiving project or projects.

(8) If the transferring project meets the requirements of subsection (d)(2),² the owner or mortgagor of the receiving project or

¹ Subsection (d)(2)(A) pertains to housing that is subject to a mortgage insured under the National Housing Act (12 U.S.C. 1701 *et seq.*).

² Subsection (d)(2) defines the term “multifamily housing project.”

projects shall execute and record either a continuation of the existing use agreement or a new use agreement for the project where, in either case, any use restrictions in such agreement are of no lesser duration than the existing use restrictions.

(9) The transfer does not increase the cost (as defined in section 502 of the Congressional Budget Act of 1974, as amended) of any FHA-insured mortgage, except to the extent that appropriations are provided in advance for the amount of any such increased cost.

Section 212 (e)(1) requires that HUD publish by notice in the **Federal Register** the terms and conditions for HUD approval of transfers, no later than 30 days before such notice takes effect. This notice is being issued in accordance with the publication requirements of section 212(e)(1). In this **Federal Register** notice, HUD advises that the criteria for approval of transfers are unchanged from those in effect for fiscal years 2015 and 2016 and published in the **Federal Register** on March 31, 2015, at 80 FR 16963.³ For the convenience of the reader, the criteria can also be found in Microsoft Word format on HUD’s webpage at: http://portal.hud.gov/hudportal/HUD?src=/program_offices/housing/mfh/memos_letters.

This notice will become effective February 21, 2017. HUD will begin accepting requests for transfers pursuant to this notice on or after the effective date. For questions regarding the submission or status of a transfer request, interested parties should contact their local HUD Multifamily Regional Center or Satellite Office. The list of HUD Multifamily Regional Centers and Satellite Offices is available at: http://portal.hud.gov/hudportal/HUD?src=/program_offices/housing/mfh/hsgmfbus/aboutbuspcps.

Dated: January 12, 2017.

Edward L. Golding,

Principal Deputy Assistant Secretary for Housing.

[FR Doc. 2017-01260 Filed 1-18-17; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5981-D-02]

Redelegation of Authority to the Deputy Assistant Secretaries in the Office of Community Planning and Development

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

³ See <https://www.gpo.gov/fdsys/pkg/FR-2015-03-31/pdf/2015-06776.pdf>.

ACTION: Notice of Redlegation of Authority to Deputy Assistant Secretaries in Community Planning and Development.

SUMMARY: Section 7(d) of the Department of Housing and Urban Development Act, as amended, provides authority to the Secretary to delegate functions, powers, and duties as the Secretary deems necessary. By separate notice published in today's **Federal Register**, the Secretary of HUD delegates concurrent authority to the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development. In this notice, the Assistant Secretary of Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development redelegate to the Deputy Assistant Secretaries and other specified HUD officials all powers and authorities necessary to carry out Office of Community Planning and Development (CPD) programs, except for those powers and authorities specifically excluded.

DATES: *Effective Date:* January 10, 2017.

FOR FURTHER INFORMATION CONTACT: Cliff Taffet, General Deputy Assistant Secretary, Office of Community Planning and Development, Department of Housing and Urban Development, 451 7th Street SW., Room 7100, Washington, DC 20410-7000; telephone number 202-708-2690. This is not a toll-free number. For those needing assistance, this number may be accessed via TTY by calling the Federal Relay Service at 800-877-8339.

SUPPLEMENTARY INFORMATION:

Published elsewhere today in the **Federal Register** is a revised consolidated delegation of authority from the Secretary to the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development. This notice updates and revises redelegations of authority to Deputy Assistant Secretaries within the Office of Community Planning and Development. This notice supersedes all previous redelegations of authority by the Assistant Secretary for Community Planning and Development to CPD Deputy Assistant Secretaries and other specified HUD officials in CPD,

including a redelegation published on June 29, 2012 at 77 FR 38853. Also published elsewhere in today's **Federal Register** is a redelegation of authority from the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development to Directors and Deputy Directors of CPD in HUD Field Offices.

Section A. General Redlegation of Authority

1. Deputy Assistant Secretary for Grant Programs

Except those authorities specifically excluded, the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development redelegate to the Deputy Assistant Secretary for Grant Programs all powers and authorities necessary to carry out the following Community Planning and Development programs and matters:

a. Comprehensive Housing Affordability Strategies (CHAS), Title I of the Cranston-Gonzalez National Affordable Housing Act, Public Law 101-625, 104 Stat. 4079 (1990) (codified as amended at 42 U.S.C. 12701 *et seq.*); consolidated plans, 24 CFR part 91.

b. The HOME Investment Partnerships Act, Title II of the Cranston-Gonzalez National Affordable Housing Act, Public Law 101-625, 104 Stat. 4079 (1990) (codified as amended at 42 U.S.C. 12721 *et seq.*); 24 CFR part 92.

c. Housing Trust Fund (HTF), Section 1338 of the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, added by Section 1131 of Public Law 110-289, 122 Stat. 2654 (codified at 12 U.S.C. 4568).

d. Tax Credit Assistance Program (TCAP) as authorized under the HOME Investments Partnership Program heading of Division A, Title XII of American Recovery and Reinvestment Act of 2009, Public Law 111-5, 123 Stat. 115, 220-21.

e. Title I of the Housing and Community Development Act of 1974, Public Law 93-383, 88 Stat. 633 (codified as amended at 42 U.S.C. 5301 *et seq.*); 24 CFR part 570 including:

(1) Community Development Block Grant (CDBG) program;

(2) Section 108 Loan Guarantee program;

(3) Economic development grants pursuant to Section 108(q);

(4) Urban Development Action Grants
(5) Neighborhood Stabilization Programs Under Housing and Economic Recovery Act of 2008, Public Law 110-289, 122 Stat. 2850; Title XII of Division A of the American Recovery and Reinvestment Act of 2009, Public Law 111-5, 123 Stat. 115; and Section 1497 of the Wall Street Reform and Consumer Protection Act of 2010, Public Law 111-203, 124 Stat. 1376 (codified as amended at 42 U.S.C. 5301 note);

(6) CDBG Disaster Recovery Grants as provided for in annual and supplemental HUD appropriations acts; and

(7) Appalachian Regional Commission grants pursuant to section 214 of the Appalachian Regional Development Act of 1965, Public Law 89-4, 79 Stat. 5 (codified as amended at 40 U.S.C. 14507) and consistent with the CDBG program authorized under Title I of the Housing and Community Development Act of 1974, Public Law 93-383, 88 Stat. 633 (codified as amended at 42 U.S.C. 5301 *et seq.*).

f. Overall Departmental responsibility for policies, standards, procedures, and advisory materials for compliance with the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, Public Law 91-646, 84 Stat. 1894 (1971) (codified as amended at 42 U.S.C. 4601 *et seq.*); 49 CFR part 24 (except for the authority to exercise the Federal Agency waiver authority provided under 49 CFR 24.7).

g. Environment, overall Departmental responsibility for compliance with the National Environmental Policy Act of 1969 (NEPA), Public Law 91-190, 83 Stat. 852 (1970) (codified as amended at 42 U.S.C. 4321-4347), and the related laws and authorities cited in 24 CFR 50.4 and 58.5. The Director of the Office of Environment and Energy, within the Office of the Deputy Assistant Secretary for Grant Programs, is designated to serve as the Departmental Environmental Clearance Officer (DECO). The DECO serves as the Departmental lead in all federal initiatives that address NEPA and other federal environmental laws and authorities cited in 24 CFR 50.4 and 58.5 and as the Departmental signatory for environmental compliance MOUs with other federal agencies addressing compliance at the regional and national level.

h. Slum Clearance and Urban Renewal Program Under Title I of the Housing Act of 1949, Public Law 81-171, 63 Stat. 413 and any program that is superseded or inactive by, or inactive by reason of, Title I of the Housing and Community Development Act of 1974,

Public Law 93–383, 88 Stat. 633 (codified as amended at 42 U.S.C. 5316).

i. Rental Rehabilitation Program, United States Housing Act of 1937 § 17, Public Law 98–181, 97 Stat. 1196 (repealed 1990); 24 CFR part 511.

j. Section 312 Rehabilitation Loan Program, Housing Act of 1964 § 312, Public Law 88–560, 78 Stat. 769 (repealed 1990); 24 CFR part 510.

k. Homeownership Zone Initiative (HOZ) grants as provided for in section 205 of the Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 1997, Public Law 104–204, 110 Stat. 2874 (1996) and funded with recaptured Nehemiah grants authorized under Title VI of the Housing and Community Development Act of 1987, Pub. L. 100–242, 101 Stat. 1815 (1988) (codified at 12 U.S.C. 17151 note).

l. HOPE for Homeownership of Single-family Housing Program (HOPE 3), Title IV, Subtitle C of the Cranston-Gonzalez National Affordable Housing Act, Public Law 101–625, 104 Stat. 4079 (1990) (codified at 42 U.S.C. 12891).

m. New Communities Program, Section 413 of the Housing and Urban Development Act of 1968, Public Law 90–448, 82 Stat. 476 (repealed 1983), Section 726 of the Housing and Urban Development Act of 1970, Public Law 91–609 (repealed 1983), 84 Stat. 1784, Section 474 of the Housing and Urban-Rural Recovery Act of 1983, Public Law 98–181, 97 Stat. 1237 (codified at 12 U.S.C. 1701g–5b), and any other functions, powers and duties which may affect the liquidation of the New Communities program.

n. Technical assistance and capacity building awards authorized under any program or matter listed in Section A.1 and as provided for in annual and supplemental HUD appropriations acts (e.g., Consolidated Appropriations Act 2010, Pub. L. 111–117, 123 Stat. 3093 (2009)). Further, in the absence of the Deputy Assistant Secretary for Grant Programs, the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development redelegate to the Director of the Office of Block Grant Assistance all powers and authorities of the Assistant Secretary necessary to carry out programs and matters listed in of Section A.1. paragraphs e. and h. Further, in the absence of the Deputy Assistant Secretary for Grant Programs, the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for

Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development redelegate to the Director of the Office of Affordable Housing Programs all powers and authorities of the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development necessary to carry out programs and matters listed in Section A.1. paragraphs b, c, d, f, g, and k.

2. Deputy Assistant Secretary for Special Needs

Except those authorities specifically excluded, the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development redelegate to the Deputy Assistant Secretary for Special Needs all powers and authorities necessary to carry out the following Community Planning and Development programs and matters:

a. Title IV of the McKinney-Vento Homeless Assistance Act, Public Law 100–77, 101 Stat. 482 (1987) (codified as amended at 42 U.S.C. 11301 *et seq.*), including the following: Emergency Shelter Grants/Emergency Solutions Grants Program, 24 CFR part 576; Supportive Housing program, 24 CFR part 583; Shelter Plus Care program, 24 CFR part 582; Moderate Rehabilitation for Single Room Occupancy program, 24 CFR part 882, subpart H; Continuum of Care program, 24 CFR part 578; Rural Housing Stability Assistance program.

b. Base Closure, Base Closure Community Redevelopment and Homeless Assistance Act of 1994, Public Law 103–421, 108 Stat. 4352 (codified as amended at 10 U.S.C. 2687 note); 24 CFR part 586.

c. Homelessness Prevention and Rapid Re-Housing Program (HPRP), as authorized under the Homelessness Prevention Fund heading of Division A, Title XII of the American Recovery and Reinvestment Act of 2009, Public Law 111–5, 123 Stat. 115.

d. Title V of the McKinney-Vento Homeless Assistance Act, Public Law 100–77, 101 Stat. 482 (1987) (codified as amended 42 U.S.C. 11411 *et seq.*), 24 CFR part 581.

e. Veterans Homelessness Prevention Demonstration Program, as provided for in annual HUD appropriations act(s) (e.g., Omnibus Appropriations Act, 2009, Pub. L. 111–8, 123 Stat. 524 (2009)).

f. AIDS Housing Opportunity Act, Title VIII, Subtitle D of the Cranston-Gonzalez National Affordable Housing Act, Public Law 101–625, 104 Stat. 4079 (1990) (codified as amended at 42 U.S.C. 12901–12912); 24 CFR part 574.

Further, in the absence of the Deputy Assistant Secretary for Special Needs, the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development redelegate to the Director of the Office of Special Needs Programs all powers and authorities of the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development necessary to carry out programs and matters listed in Section A.2. paragraphs a., b., c., d., and e. Further, the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development redelegate to the Director of the Community Assistance Division the authority to sign notices of available properties and subsequent letters regarding the properties under Title V of the McKinney-Vento Homeless Assistance Act (codified as amended 42 U.S.C. 11411 *et seq.*). Further, in the absence of the Deputy Assistant Secretary for Special Needs, the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development redelegate to the Director of the Office of HIV/AIDS Housing all powers and authorities of the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development necessary to carry out programs and matters listed in Section A.2. paragraph f.

3. Deputy Assistant Secretary for Economic Development

Except those authorities specifically excluded, the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy

Assistant Secretary for Community Planning and Development redelegate to the Deputy Assistant Secretary for Economic Development all powers and authorities necessary to carry out the following Community Planning and Development programs and matters:

a. The Loan Guarantee Recovery Program under Section 4 of the Church Arson Prevention Act of 1996, Public Law 104–155, 110 Stat. 1392; 24 CFR part 573.

b. Neighborhood Initiatives grants specifically designated in annual HUD appropriations acts (e.g., Consolidated Appropriations Act 2010, Pub. L. 111–117, 123 Stat. 3034 (2009)).

c. Rural Innovation Fund grants as provided for in annual HUD appropriations act(s) (e.g., Consolidated Appropriations Act 2010, Pub. L. 111–117, 123 Stat. 3084 (2009)).

d. Rural Housing and Economic Development grants specifically designated originally in the Fiscal Year 1998 HUD Appropriations Act, Public Law 105–65, 111 Stat. 1344 1997, and subsequent annual HUD appropriations acts.

e. Self-Help Homeownership Opportunity Program (SHOP) under section 11 of the Housing Opportunity Program Extension Act of 1996, Public Law 104–120, 110 Stat. 834 (codified as amended at 42 U.S.C. 12805 note).

f. Pilot Program to Rehabilitate and Modify Homes of Disabled and Low-Income Veterans, as authorized under section 1079 of the Carl Levin and Howard P. “Buck” McKeon National Defense Authorization Act for Fiscal Year 2015, Public Law 113–291, 128 Stat. 3292, 3521–3524 (2014).

Further, in the absence of the Deputy Assistant Secretary for Economic Development, the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development redelegate to the Director of the Rural Housing and Economic Development Division all powers and authorities of the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development necessary to carry out programs and matters listed in Section A.3.

4. Deputy Assistant Secretary for Operations

Except those authorities specifically excluded, the Assistant Secretary for

Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development redelegate to the Deputy Assistant Secretary for Operations and the Director of Technical Assistance and Management all powers and authorities of the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development necessary to carry out the following Community Planning and Development programs and matters:

a. Technical Assistance and Capacity Building awards authorized under any program or matter delegated to the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development (e.g., section 107 of the Housing and Community Development Act of 1987, as amended and Section 4 Capacity Building for Community Development and Affordable Housing Grants program as authorized by Section 4 of the HUD Demonstration Act of 1993 (Pub. L. 103–120, 107 Stat. 1148, 42 U.S.C. 9816 note), as amended, and as provided for in annual and supplemental HUD appropriations acts (e.g., Consolidated Appropriations Act 2010, Pub. L. 111–117, 123 Stat. 3093 (2009)).

b. All programs consolidated in the Revolving Fund (Liquidating Programs) established pursuant to Title II of the Independent Offices Appropriations Act, Public Law 98–45, 97 Stat. 223 (1983) (codified at 12 U.S.C. 1701g–5), including all authority of the Assistant Secretary with respect to functions, administration and management of the Revolving Fund (Liquidating Programs). Only the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development are the responsible officials for allotments in the Revolving Fund (Liquidating Programs).

c. Economic Development Initiative grants, as provided for in annual HUD appropriations acts (e.g., Consolidated Appropriations Resolution, Fiscal Year 2003, Pub. L. 108–7, 117 Stat. 11 (2003)).

d. Grants for urban Empowerment Zones (EZ) as provided for in annual HUD appropriations acts (e.g., Consolidated Appropriations Resolution, Fiscal Year 2003, Pub. L. 108–7, 117 Stat. 11 (2003)).

e. Neighborhood Initiatives grants specifically designated in annual HUD appropriations acts (e.g., Consolidated Appropriations Act 2010, Pub. L. 111–117, 123 Stat. 3034 (2009)).

f. Rural Innovation Fund grants as provided for in annual HUD appropriations act(s) (e.g., Consolidated Appropriations Act 2010, Pub. L. 111–117, 123 Stat. 3084 (2009)).

g. The Renewal Communities (RC) Initiative as authorized under title 26, subtitle A, chapter 1, subchapter X of the Internal Revenue Code, as amended, 26 U.S.C. 1400E *et seq.*; 24 CFR part 599.

h. The urban Empowerment Zones (EZ), as authorized under title 26, subtitle A, chapter 1, subchapter U of the Internal Revenue Code (codified as amended at 26 U.S.C. 1391 *et seq.*); 24 CFR parts 597 and 598.

Section B. General Authority Excepted

The authority redelegated under Section A does not include:

1. The authority to issue or waive regulations covered by section 7(q) of the Department of Housing and Urban Development Act;

2. The authority to exercise the Federal Agency waiver authority provided under 49 CFR 24.7;

3. The authority to enter regulations or directives into Departmental clearance; or

4. Any authority not delegated to the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development under the Consolidated Delegation of Authority for Community Planning and Development. The Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, or the General Deputy Assistant Secretary for Community Planning and Development may revoke at any time this redelegation with respect to the programs and matters listed in Section A.

Section C. Authority To Further Redelegate

The authority redelegated in Section A may be further redelegated to employees of the Department.

Section D. Redelegations Superseded

This notice supersedes all prior redelegations of authority to Deputy Assistant Secretaries of Community Planning and Development, including the redelegation of authority published on June 29, 2012 at 77 FR 38853.

Section E. Actions Ratified

The Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development hereby ratify all actions previously taken by the Deputy Assistant Secretaries for Community Planning and Development, with respect to the programs and matters listed in Section A.

Authority: Section 7(d), Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: January 10, 2017.

Harriet Tregoning,

Principal Deputy Assistant Secretary for Community Planning and Development.

[FR Doc. 2017-01244 Filed 1-18-17; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5630-N-09]

Rental Assistance Demonstration: Revised Program Notice

AGENCY: Office of the Assistant Secretary for Public and Indian Housing and Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: On July 26, 2012, HUD announced through notice in the **Federal Register** the implementation of the statutorily authorized Rental Assistance Demonstration (RAD), which provides the opportunity to test the conversion of public housing and other HUD-assisted properties to long-term, project-based Section 8 rental assistance. The July 26, 2012, **Federal Register** notice also announced the availability of the program notice (PIH 2012-32), providing program instruction on HUD's Web site. On July 2, 2013, HUD issued a revised program notice (PIH 2012-32, REV-1). On April 26, 2015, HUD issued a further revised program notice (PIH 2012-32, REV-2). This **Federal Register** notice announces further revisions to RAD and solicits public comment on changed eligibility and selection criteria. It also announces

the posting of a further revised program notice (Revised Program Notice, PIH 2012-32/H 2017-03, REV-3). As provided by the RAD Statute, this notice addresses the requirement that the demonstration may proceed after publication of notice of its terms in the **Federal Register**. This notice summarizes the key changes made to PIH 2012-32/H 2017-03, REV-3. This notice also meets the RAD statutory requirement to publish at least 10 days before they may take effect, waivers and alternative requirements authorized by the statute, which does not prevent the demonstration, as modified, from proceeding immediately.

DATES: *Comment Due Date:* February 21, 2017.

Effective Dates: The Revised Program Notice, PIH 2012-32/H 2017-03, REV-3, other than those items listed as subject to notice and comment or new statutory or regulatory waivers or alternative requirements specified in this notice, is effective January 19, 2017.

The new statutory and regulatory waivers and alternative requirements are effective January 30, 2017.

The items listed as subject to notice and comment will be effective upon February 21, 2017. If HUD receives adverse comment that leads to reconsideration, HUD will notify the public in a new notice immediately upon the expiration of the comment period.

ADDRESSES: Interested persons are invited to submit comments electronically to rad@hud.gov no later than the comment due date.

FOR FURTHER INFORMATION CONTACT: To assure a timely response, please direct requests for further information electronically to the email address rad@hud.gov. Written requests may also be directed to the following address: Office of Public and Indian Housing—RAD Program; Department of Housing and Urban Development; 451 7th Street SW., Room 2000; Washington, DC 20410.

SUPPLEMENTARY INFORMATION:**I. Background**

RAD, authorized by the Consolidated and Further Continuing Appropriations Act, 2012 (Pub. L. 122-55, signed November 18, 2011) (2012 Appropriations Act), allows for the conversion of assistance under the public housing, Rent Supplement (Rent Supp), Rental Assistance (RAP), Moderate Rehabilitation (Mod Rehab), and Mod Rehab Single Room Occupancy (SRO) programs (collectively, “covered programs”) to long-term, renewable assistance under

Section 8.¹ The most recent version of the RAD program notice is PIH 2012-32, REV-2, located at https://portal.hud.gov/hudportal/documents/huddoc?id=PIHNotice_2012-32_062015.pdf.

II. Key Changes Made to RAD

The following highlights key changes to the RAD program that are included in the Revised Program Notice:

First Component (Public Housing Conversions)

1. Creating a new way in which public housing agencies (PHAs) can increase their RAD rents by relinquishing existing balances of replacement housing factor (RHF) funds or demolition and disposition transition funding (DDTF) (see section 1.5.A).

2. Eliminating the cap on the number of project-based voucher (PBV) units at a project (see section 1.6.A.2).

3. Improving the quality of information that must be provided to residents of properties undergoing conversion and requiring that PHAs submit responses to resident comments in connection with meetings held following the issuance of the Commitment to enter into a Housing Assistance Payments Contract (CHAP) (see section 1.8).

4. Extending the prohibition on re-screening to current public housing households that will reside in non-RAD PBV or non-RAD project-based rental assistance (PBRA) units placed in a project that contain RAD PBV or RAD PBRA units so as to facilitate the right to return to the assisted property (see sections 1.6.C.1 and 1.7.B.1).

5. Correcting the phase-in of rents for residents who may experience a rent increase as a result of conversion, in order to ensure a more even distribution across years (see sections 1.6.B.3 and 1.7.B.3).

6. Clarifying that a PHA is permitted to receive cash acquisition proceeds in excess of any seller take-back financing and that such proceeds must be used for Affordable Housing Purposes, a newly defined term (see section 1.4.7).

7. Establishing flexibility for requirements related to the Capital Needs Assessments, permitting certain

¹ The RAD statutory requirements were amended by the Consolidated Appropriations Act, 2014 (Pub. L. 113-76, signed January 17, 2014) (2014 Appropriations Act), the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235, signed December 16, 2014) (2015 Appropriations Act), and the Consolidated Appropriations Act, 2016 (Pub. L. 114-113, signed December 18, 2015) (2016 Appropriations Act). The statutory provisions of the 2012 Appropriations Act pertaining to RAD, as amended, are referred to as the RAD Statute in this notice.

exemptions when the assisted units are a small percentage of the total project (see section 1.4.A.1).

8. Requiring title reports to be submitted with the Financing Plan to avoid delays in closing (see section 1.15, Attachment 1A).

9. Modifying the maximum allowable developer fee, by excluding from the formula for larger transactions any acquisition payments made to the PHA, developer fee, and reserves (see section 1.14).

10. Establishing greater flexibility to underwrite to new loan products that have emerged in the market (see section 1.15, Attachment 2A).

11. Providing greater detail on the acceptable forms in which a public or non-profit entity can demonstrate ownership or control (see section 1.4.A.11).

12. Providing guidance on owners' responsibilities to treat lead-based paint hazards in the context of a RAD conversion (see section 1.4.A.15).

13. Encouraging PHAs and their partners to grant current workers whose employment positions may be eliminated during conversion the right of first refusal for new employment openings for which they are qualified (see section 1.4.A.16).

Second Component (Mod Rehab, Mod Rehab SRO, Rent Supp, RAP Conversions)

1. Eliminating the cap on the number of PBV units at a project (see section 2.5.C).

2. Permitting Mod Rehab conversions to PBRA to convert at comparable market rents, up to 110 percent of fair market rent (FMR) (see sections 2.6.C and D).

3. For Mod Rehab SRO conversions, authorizing the use of the efficiency FMR for SRO units, rather than 75 percent of the efficiency FMR, which is the existing SRO standard (see section 2.7).

4. Allowing all conversions to PBRA to achieve rents between 110 percent and 120 percent of FMR (up to the statutory maximum), if justified by comparable market rents and only in certain circumstances where preservation criteria have been met (see sections 3.6.C and D).

5. For conversions to PBRA, permitting the use of Small Area FMR (SAFMR) in the calculation of contract rent cap, with HUD approval (see sections 2.5 and 2.6).

III. Changes Subject to Notice and Comment

The Revised Program Notice makes changes to some of the selection and

eligibility criteria for conversions of public housing under the First Component. Pursuant to the RAD Statute, these changes must be made available for public comment before they are effective. Please submit all comments to rad@hud.gov. As indicated above, the following changes will be effective on February 21, 2017. If HUD receives adverse comment that leads to reconsideration, HUD will notify the public in a new notice immediately upon the expiration of the comment period.

The changes subject to notice and comment are:

1. Consolidating the selection priority categories for new applications into two buckets: (1) High investment applications and (2) all other applications (see section 1.11.C).

2. Allowing PHAs to submit a simple letter of interest, rather than an application, when a waiting list has formed. A letter of interest would serve to reserve a project or portfolio's position on the waiting list subject to future submission of a RAD Application (see section 1.9).

3. Making eligible an entire contiguous HOPE VI project that was developed in phases as long as the earliest phase is greater than ten years old (see section 1.3.H).

IV. New Waivers and Alternative Requirements

The RAD Statute provides that waivers and alternative requirements authorized under the First Component must be published by notice in the **Federal Register** no later than 10 days before the effective date of such notice. Under the Second Component of RAD, HUD is authorized to waive or alter the provisions of subparagraphs (C) and (D) of section 8(o)(13) of the United States Housing Act of 1937 (42 U.S.C. 1437f) (the 1937 Act).

HUD has previously published its waivers and alternative requirements for RAD, on July 26, 2012 (77 FR 43850), July 2, 2013 (78 FR 39759), and June 26, 2015 (80 FR 36830). This notice only includes waivers and alternative requirements not previously published or that have changed from previous publications. Although waivers or alternative requirements under the Second Component are not subject to a **Federal Register** publication requirement, the new Second Component waivers and alternative requirements are included in this notice as a matter of convenience.

The new waivers and alternative requirements are:

1. *Cap on PBV Units in a Project.*
Provisions affected: Section 8(o)(13)(D)

of the Act, and 24 CFR 983.56, 983.257(b), 983.262(a) and (d).
Alternative requirements: None. The previously imposed alternative requirements are waived, effectively eliminating any cap on the number of PBV units in a project undergoing conversion.

2. *Eligibility and Targeting of Tenants for Initial Occupancy.*
Provisions affected: 24 CFR 982.201 and 880.603(b).
Alternative requirements: Pursuant to the RAD Statute, at conversion, current households cannot be excluded from occupancy at the Covered Project based on any rescreening, income eligibility, or income targeting. Therefore, current households admitted into the PBV program following conversion of assistance at the property were not subject to the application of eligibility criteria for conditions that occurred prior to conversion of assistance but were subject to ongoing eligibility requirement for actions occurring after conversion. Once the grandfathered household moves out, the unit must be leased to an eligible family. MTW agencies may not alter this requirement. Further, so as to facilitate the right to return to the assisted property, this provision shall apply to current public housing residents of the Converting Project that will reside in non-RAD PBV units or non-RAD PBRA units placed in a project that contain RAD PBV units or RAD PBRA units. Such families and such contract units will otherwise be subject to all requirements of the applicable program, specifically 24 CFR 983 for non-RAD PBV units and the PBRA requirements governing the applicable contract for non-RAD PBRA units. Accordingly, HUD is waiving 24 CFR 982.201 and 880.603(b) for current public housing residents of the Converting Project that will reside in non-RAD PBV units or non-RAD PBRA units placed in a project that contain RAD PBV units or RAD PBRA units.

3. *Total Tenant Payment (TTP).*
Provisions affected: Section 3(a)(1) of the Act and 24 CFR 983.3 and 880.201.
Alternative requirements: If a resident's monthly rent increases by more than the greater of 10 percent or \$25 purely as a result of conversion, the rent increase will be phased in over 3 years or 5 years. Eligibility for the phase-in is to be determined at the Initial Certification which occurs at the time the household is converted to PBRA. A phase-in must not be applied after the household's Initial Certification. To implement the phase-in, HUD is specifying alternative requirements for section 3(a)(1) of the Act, as well as 24 CFR 880.201 (definition of "total tenant payment")

(TTP)) to the extent necessary to allow for the phase-in of tenant rent increases. A PHA must create a policy setting the length of the phase-in period at three years, five years, or a combination depending on circumstances. For example, a PHA may create a policy that uses a three-year phase-in for smaller increases in rent and a five-year phase-in for larger increases in rent. This policy must be in place at conversion and may not be modified after conversion.

The method described below explains the set percentage-based phase-in a Project Owner must follow according to the phase-in period established. For purposes of this section “Calculated Multifamily TTP” refers to the TTP calculated in accordance with regulations at 24 CFR 5.628 (not capped at Gross Rent) and the “most recently paid TTP” refers to the TTP recorded on the family’s most recent HUD Form 50059. If a family in a project converting from Public Housing to PBRA was paying a flat rent immediately prior to conversion, the PHA should use the flat rent amount to calculate the phase-in amount for Year 1, as illustrated below.

Three-Year Phase-in:

- Year 1: Any recertification (interim or annual) performed prior to the second annual recertification after conversion—33 percent of difference between most recently paid TTP or flat rent and the Calculated Multifamily TTP

- Year 2: Year 2 Annual Recertification (AR) and any Interim Recertification (IR) in prior to Year 3 AR—50 percent of difference between most recently paid TTP and Calculated Multifamily TTP

- Year 3: Year 3 AR and all subsequent recertifications—Year 3 AR and any IR in Year 3: Full Calculated Multifamily TTP²

Five-Year Phase-in

- Year 1: Any recertification (interim or annual) performed prior to the second annual recertification after conversion—20 percent of difference between most recently paid TTP or flat rent and the Calculated Multifamily TTP

- Year 2: Year 2 AR and any IR prior to Year 3 AR—25 percent of difference between most recently paid TTP and Calculated Multifamily TTP

- Year 3: Year 3 AR and any IR prior to Year 4 AR—33 percent of difference between most recently paid TTP and Calculated Multifamily TTP

- Year 4: Year 4 AR and any IR prior to Year 5 AR—50 percent of difference between most recently paid TTP and Calculated Multifamily TTP

- Year 5 AR and all subsequent recertifications—Full Calculated Multifamily TTP

Please Note: In either the three-year phase-in or the five-year phase-in, once Calculated Multifamily TTP is equal to or less than the previous TTP, the phase-in ends and tenants will pay full Calculated Multifamily TTP from that point forward.

4. *Mod Rehab SRO FMRs. Provision affected:* 24 CFR 888.113(f)(2).

Alternative requirements: The applicable FMR used for SRO units for initial and re-determined rents will be the zero bedroom (efficiency) FMR. Accordingly, HUD is waiving 24 CFR 888.113(f)(2) for Mod Rehab SRO units.

5. *Small Area FMRs for PBRA.*

Provision affected: 24 CFR 888.113(h). *Alternative requirements:* Projects converting assistance to PBRA under the Second Component may use a Small Area FMR for initial contract rent setting and when adjusting contract rents. Accordingly, HUD is waiving 24 CFR 888.113(h) for those projects.

V. Revised Program Notice Availability

The Revised Program Notice (PIH 2012–32/H 2017–03, REV–3) can be found on RAD’s Web site, www.hud.gov/RAD.

VI. Environmental Review

A Finding of No Significant Impact with respect to the environment was made in connection with HUD notice PIH 2012–32 issued on March 8, 2012, and in accordance with HUD regulations in 24 CFR part 50 that implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)). The Finding remains applicable to the Revised Program Notice and is available for public inspection during regular business hours in the Regulations Division, Office of General Counsel; Department of Housing and Urban Development; 451 7th Street SW., Room 10276; Washington, DC 20410–0500. Due to security measures at the HUD Headquarters building, please schedule an appointment to review the finding by calling the Regulations Division at 202–402–3055 (this is not a toll-free

number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8339.

Dated: January 12, 2017.

Nani A. Coloretti,
Deputy Secretary.

[FR Doc. 2017–01246 Filed 1–18–17; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5995–N–3]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT:

Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), call the toll-free Title V information line at 800–927–7588 or send an email to title5@hud.gov.

SUPPLEMENTARY INFORMATION:

In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless v. Veterans Administration*, No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to

² For example, where a resident’s most recently paid TTP is \$100, but the Calculated PBV TTP is \$200 and remains \$200 for the period of the resident’s occupancy, (*i.e.* no changes in income) the resident would continue to pay the same rent and utilities for which it was responsible prior to conversion. At the first recertification following conversion, the resident’s contribution would increase by 33% of \$100 to \$133. At the second AR, the resident’s contribution would increase by 50% of the \$66 differential to the standard TTP, increasing to \$166. At the third AR, the resident’s contribution would increase to \$200 and the resident would continue to pay the Calculated PBV TTP for the duration of their tenancy.

HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for "off-site use only" recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to: Ms. Theresa M. Ritta, Chief Real Property Branch, the Department of Health and Human Services, Room 12-07, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301)-443-2265 (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1-800-927-7588 or send an email to title5@hud.gov for detailed instructions, or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the

landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (e.g., acreage, floor plan, condition of property, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following address(es): GSA: Mr. Flavio Peres, General Services Administration, Office of Real Property Utilization and Disposal, 1800 F Street NW., Room 7040 Washington, DC 20405, (202)-501-0084; Navy: Ms. Nikki Hunt, Department of the Navy, Asset Management Division, Naval Facilities Engineering Command, Washington Navy Yard, 1330 Patterson Ave. SW., Suite 1000, Washington, DC 20374, (202)-685-9426; (These are not toll-free numbers).

Dated: January 12, 2017.

Brian P. Fitzmaurice,

Director, Division of Community Assistance, Office of Special Needs Assistance Programs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 01/20/2017

Suitable/Available Properties

LAND

North Carolina

OLF NAS Oceans (Parcel 025)

State Hwy 99

NAS NC

Landholding Agency: GSA

Property Number: 54201710001

Status: Surplus

GSA Number: 4-D-NC-0831-AH

Directions: Disposal Agency: GSA; Land

Holding Agency: Navy

Comments: 3.50 acres of land; contact GSA for more information.

OLF NAS Ocean (Parcel 010)

null

NAS NC

Landholding Agency: GSA

Property Number: 54201710002

Status: Surplus

GSA Number: 4-D-NC-0831-AF

Directions: Disposal Agency: GSA; Land

Holding Agency: Navy

Comments: 80 acres of land; this property is encumbered by a conservation easement that shall remain in effect for perpetuity; contact GSA for more information.

Unsuitable Properties

Land

California

Item 13B RESM 2008, CIVIL 172

1.97 acres

RPUID 165403

San Diego CA

Landholding Agency: Navy

Property Number: 77201710001

Status: Underutilized

Comments: public access denied and no alternative access without compromising national security.

Reasons: Secured Area

[FR Doc. 2017-01247 Filed 1-18-17; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5981-D-03]

Redelegation of Authority to Directors and Deputy Directors of Community Planning and Development in Field Offices

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice of redelegation of authority to field offices.

SUMMARY: Section 7(d) of the Department of Housing and Urban Development Act, as amended, provides authority to the Secretary to delegate functions, powers, and duties as the Secretary deems necessary. By separate notice published in today's **Federal Register**, the Secretary of HUD delegates concurrent authority to the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development. In this notice, the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development redelegate to the Directors and Deputy Directors of Community Planning and Development in HUD Field Offices all powers and authorities necessary to carry out Office of Community Planning and Development programs, except those powers and authorities specifically excluded.

DATES: *Effective Date:* January 10, 2017.

FOR FURTHER INFORMATION CONTACT: Cliff Taffet, General Deputy Assistant Secretary, Office of Community Planning and Development, Department of Housing and Urban Development, 451 7th Street SW., Room 7100, Washington, DC 20410-7000; telephone number 202-708-2690. This is not a toll-free number. For those needing assistance, this number may be accessed via TTY by calling the Federal Relay Service at 800-877-8339.

SUPPLEMENTARY INFORMATION: Published elsewhere in today's **Federal Register** is a revised consolidated delegation of authority from the Secretary of HUD to the Assistant Secretary for Community

Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development. This notice updates and revises redelegations of authority from the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development to CPD Directors and Deputy Directors in HUD Field Offices. This notice supersedes all previous redelegations of authority to CPD Directors and Deputy Directors in HUD Field Offices, including a redelegation published on June 29, 2012 at 77 FR 38851. Also published elsewhere in today's **Federal Register** is a redelegation of authority from the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development to the Deputy Assistant Secretaries in Community Planning and Development.

Section A. General Redelegation of Authority

Except those authorities specifically excluded, the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development redelegates to the Directors and Deputy Directors of Community Planning and Development in HUD Field Offices all powers and authorities of the Assistant Secretary necessary to carry out the following Community Planning and Development programs and matters:

1. Community Development Block Grants (CDBG), Section 108 Loan Guarantees, Neighborhood Stabilization Programs (NSP), CDBG Disaster Recovery Grants, and other programs covered by Title I of the Housing and Community Development Act of 1974, Public Law 93-383, 88 Stat. 633 (codified as amended at 42 U.S.C. 5301 *et seq.*); 24 CFR part 570. *Authority not redelegated:*

a. Terminate, reduce, or limit the availability of grant payments pursuant to section 111(a), 42 U.S.C. 5311.

b. Adjust entitlement and state grants pursuant to section 104(e), 42 U.S.C. 5304.

c. Determine basic grant amounts for metropolitan cities, urban counties, and

States pursuant to section 106, 42 U.S.C. 5306.

d. Reallocate funds pursuant to section 106(c) or (d), 42 U.S.C. 5306.

e. Determine the qualifications of localities for special consideration. This includes, but is not limited to, the determination of qualifications of counties as urban counties pursuant to section 102(a)(6), 42 U.S.C. 5302, the determination of what constitutes a city pursuant to section 102(a)(5), 42 U.S.C. 5302, and the determination of levels of physical and economic distress of cities and urban counties for eligibility for urban development action grants pursuant to section 119(b), 42 U.S.C. 5318.

f. Approve and disapprove applications, or amendments to applications, filed for loan guarantee or grant assistance, issue commitments or grant awards, execute grant agreements, or issue guarantees pursuant to section 108, 42 U.S.C. 5308.

2. Comprehensive Housing Affordability Strategies (CHAS), Title I of the Cranston-Gonzalez National Affordable Housing Act, Public Law 101-625, 104 Stat. 4079 (1990) (codified as amended at 42 U.S.C. 12701 *et seq.*); consolidated plans, 24 CFR part 91.

3. Emergency Shelter Grants/Emergency Solutions Grants program, Title IV, Subtitle B of the McKinney-Vento Homeless Assistance Act, Public Law 100-77, 101 Stat. 482 (1987) (codified as amended at 42 U.S.C. 11371 *et seq.*); 24 CFR part 576. *Authority not redelegated:*

a. Determine allocation amounts.

b. Approve built-in waivers or exceptions authorized under Title IV of the McKinney-Vento Homeless Assistance Act and applicable implementing regulations.

4. The HOME Investment Partnerships Act, Title II of the Cranston-Gonzalez National Affordable Housing Act (NAHA), Public Law 101-625, 104 Stat. 4094 (1990) (codified as amended at 42 U.S.C. 12721 *et seq.*); 24 CFR part 92. *Authority not redelegated:*

a. Determine allocation and reallocation amounts pursuant to section 217 of NAHA.

b. Revoke a jurisdiction's designation as a participating jurisdiction pursuant to section 216 of NAHA.

c. Effect remedies for noncompliance pursuant to section 223 of NAHA.

d. Approve a change in the number of units designated as HOME-assisted units during the period of affordability pursuant to 24 CFR 92.205(d).

e. Make a determination that a consortium does not have sufficient authority and administrative capability

to administer the HOME Program pursuant to 24 CFR 92.101(a)(3).

5. Housing Trust Fund (HTF), Section 1338 of the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, added by Section 1131 of Public Law 110-289, 122 Stat. 2654 (codified at 12 U.S.C. 4568). *Authority not redelegated:*

a. Determine allocations, adjustments, and reallocation amounts.

6. Homelessness Prevention and Rapid Re-Housing Program (HPRP) as authorized under the Homelessness Prevention Fund heading of Division A, Title XII of the American Recovery and Reinvestment Act of 2009, Public Law 111-5, 123 Stat. 115.

7. AIDS Housing Opportunity Act, Title VIII, Subtitle D of the Cranston-Gonzalez National Affordable Housing Act, Public Law 101-625, 104 Stat. 4079 (1990) (codified as amended at 42 U.S.C. 12901-12912); 24 CFR part 574. *Authority not redelegated:*

a. Determine allocations, adjustments, and reallocation amounts.

b. Revoke a jurisdiction's designation as an eligible state or eligible metropolitan statistical area for a formula allocation or as an eligible applicant for a nonformula allocation.

c. Suspend or terminate current awards in whole or in part, withhold further awards, and effect other legally available remedies pursuant to 24 CFR 200.338-200.342.

8. Title IV Subtitles C-F of the McKinney-Vento Homeless Assistance Act, Public Law 100-77, 101 Stat. 482 (1987) (codified as amended at 42 U.S.C. 11381 *et seq.*), including the following: Supportive Housing Program, 24 CFR part 583, Shelter Plus Care program, 24 CFR part 582, Moderate Rehabilitation for Single Room Occupancy program, 24 CFR part 882, subpart H, Continuum of Care program, 24 CFR part 578, and Rural Housing Stability Assistance program. *Authority not redelegated:*

a. Make funding decisions.

b. Approve built-in waivers or exceptions authorized under Title IV of the McKinney-Vento Homeless Assistance Act and applicable implementing regulations.

9. Economic Development Initiative grants, as provided for in annual HUD appropriations acts (e.g., Consolidated Appropriations Resolution, Fiscal Year 2003, Pub. L. 108-7, 117 Stat. 11 (2003)).

10. Neighborhood Initiatives grants specifically designated in annual HUD appropriations acts (e.g., Consolidated Appropriations Act 2010, Pub. L. 111-117, 123 Stat. 3034 (2009)).

11. Rural Innovation Fund grants as provided for in annual HUD

appropriations act(s) (e.g., Consolidated Appropriations Act 2010, Pub. L. 111–117, 123 Stat. 3084 (2009)).

12. The urban Empowerment Zones (EZ), as authorized under title 26, subtitle A, chapter 1, subchapter U of the Internal Revenue Code (codified as amended at 26 U.S.C. 1391 *et seq.*); 24 CFR parts 597 and 598. *Authority not redelegated:*

a. Approve or amend strategic plans or other state and local commitments, including boundary changes.

b. Revoke a designation, including issuing a warning letter pursuant to 24 CFR parts 597 and 598.

13. Responsibility for compliance with the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, Public Law 91–646, 84 Stat. 1894 (1971) (codified as amended at 42 U.S.C. 4601 *et seq.*); 49 CFR part 24 for programs covered by Section A of this redelegation. *Authority not redelegated:*

a. Exercise the Federal Agency waiver authority provided under 49 CFR 24.7.

14. Technical Assistance and Capacity Building awards authorized under any program or matter delegated under Section A (e.g., section 107 of the Housing and Community Development Act of 1987, Pub. L. 100–242, 101 Stat. 1815 (1988)) and as provided for in annual and supplemental HUD appropriations acts (e.g., Consolidated Appropriations Act 2010, Pub. L. 111–117, 123 Stat. 3093 (2009)).

15. Certain Community Planning and Development programs that are no longer authorized for funding (or future funding is not anticipated) but administration of the programs must continue until all Department responsibilities are discharged and finally terminated. These programs, as of June 2011, include the following:

a. Any program superseded by, or inactive by reason of, Title I of the Housing and Community Development Act of 1974, Public Law 93–383, 88 Stat. 633 (codified as amended at 42 U.S.C. 5316).

b. Grants for urban Empowerment Zones (EZ) as provided for in annual HUD appropriations acts (e.g., Consolidated Appropriations Resolution, Fiscal Year 2003, Pub. L. 108–7, 117 Stat. 11 (2003)).

c. HOPE for Homeownership of Single-family Housing Program (HOPE 3), Title IV, Subtitle C of the Cranston-Gonzalez National Affordable Housing Act, Public Law 101–625, 104 Stat. 4079 (1990) (codified at 42 U.S.C. 12891).

d. New Communities Program, Section 413 of the Housing and Urban Development Act of 1968, Public Law 90–448, 82 Stat. 476 (repealed 1983), Section 726 of the Housing and Urban

Development Act of 1970, Public Law 91–609 (repealed 1983), 84 Stat. 1784, Section 474 of the Housing and Urban-Rural Recovery Act of 1983, Public Law 98–181, 97 Stat. 1237 (codified at 12 U.S.C. 1701g–5b), and any other functions, powers and duties which may affect the liquidation of the New Communities program.

e. Rural Housing and Economic Development grants specifically designated originally in the Fiscal Year 1998 HUD Appropriations Act, Public Law 105–65, 111 Stat. 1344 (1997), and subsequent annual HUD appropriations acts.

f. Renewal Communities (RC), as authorized under Title 26, Subtitle A, Chapter 1, Subchapter X of the Internal Revenue Code (codified as amended at 26 U.S.C. 1400E *et seq.*); 24 CFR part 599.

g. All programs consolidated in the Revolving Fund (Liquidating Programs) established pursuant to Title II of the Independent Offices Appropriations Act, Public Law 98–45, 97 Stat. 223 (1983) (codified as amended at 12 U.S.C. 1701g–5) including all authority of the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development with respect to the functions, administration and management of the Revolving Fund (Liquidating Programs). Only the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development are the responsible official for allotments in the Revolving Fund (Liquidating Programs).

Section B. Limited Denial of Participation

Subject to the excepted authority in Section C, the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development redelegate to Directors and Deputy Directors of CPD in HUD Field Offices the authority to order a limited denial of participation sanction pursuant to HUD regulations at 2 CFR part 2424, with respect to the programs and matters listed in Section A; provided that the General Counsel, or such other official as may be designated by the General Counsel, must: (1) Concur in any proposed sanction under

2 CFR part 2424 before it is issued, and (2) concur in any proposed settlement of a sanction under 2 CFR part 2424.

Section C. General Authority Excepted

The authority redelegated under Section A does not include:

1. The authority to issue or waive regulations covered by section 7(q) of the Department of Housing and Urban Development Act (42 U.S.C. 3535(q));
2. The authority to sue and be sued;
3. The authority to effect remedies for noncompliance requiring notice and an opportunity for an administrative hearing;
4. The authority for allotments in the Revolving Fund (Liquidating Programs) under paragraph g of Section A; or
5. Any authority not delegated to the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development under the Consolidated Delegation of Authority for Community Planning and Development. The Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development may revoke at any time this redelegation with respect to the programs and matters listed in Section A and orders of limited denial of participation issued in accordance with Section B.

Section D. Authority To Further Redelegate

The authority redelegated in Sections A and B may not be further redelegated.

Section E. Redelegations Superseded

This notice supersedes all prior redelegations of authority to Directors and Deputy Directors of Community Planning and Development in HUD Field Offices, including the redelegation of authority published on June 29, 2012 at 77 FR 38851.

Section F. Actions Ratified

The Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary for Community Planning and Development hereby ratify all actions previously taken by the Directors and Deputy Directors of CPD in HUD Field Offices with respect to the programs and matters listed in Section A and orders of limited denial of

participation issued in accordance with Section B.

Authority: Section 7(d), Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: January 10, 2017.

Harriet Tregoning,

Principal Deputy Assistant, Secretary for Community Planning and Development.

[FR Doc. 2017-01238 Filed 1-18-17; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5981-D-01]

Consolidated Delegations of Authority for the Office of Community Planning and Development

AGENCY: Office of the Secretary, HUD.

ACTION: Notice of delegations of authority.

SUMMARY: This notice updates, clarifies, and consolidates delegations of authority from the Secretary of Housing and Urban Development to the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development and the General Deputy Assistant Secretary for Community Planning and Development.

DATES: *Effective Date:* January 10, 2017.

FOR FURTHER INFORMATION CONTACT: Cliff Taffet, General Deputy Assistant Secretary, Office of Community Planning and Development, Department of Housing and Urban Development, 451 7th Street SW., Room 7100, Washington, DC 20410-7000; telephone number 202-708-2690. This is not a toll-free number. For those needing assistance, this number may be accessed via TTY by calling the Federal Relay Service at 800-877-8339.

SUPPLEMENTARY INFORMATION: This notice updates, clarifies, and consolidates into one notice the authority delegated by the Secretary of Housing and Urban Development to the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development and the General Deputy Assistant Secretary for Community Planning and Development. This notice supersedes all previous delegations to the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development and the General Deputy Assistant Secretary for Community Planning and Development,

including the delegation published on April 20, 2015, at 80 FR 21747.

Section A. Authority Delegated

Only the Assistant Secretary for Community Planning and Development is delegated the authority to issue a final regulation or a Notice of Funding Availability (NOFA). The authority delegated herein to the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development, and the General Deputy Assistant Secretary includes the authority to waive regulations and statutes, but for the Principal Deputy Assistant Secretary and the General Deputy Assistant Secretary the authority to waive statutes is limited in Section B below. Except as provided in Section B, the Secretary of HUD delegates to the Assistant Secretary for Community Planning and Development, the Principal Deputy Assistant Secretary for Community Planning and Development and the General Deputy Assistant Secretary for Community Planning and Development the authority of the Secretary with respect to the programs and matters listed below:

1. The AIDS Housing Opportunity Act, Title VIII, Subtitle D of the Cranston-Gonzalez National Affordable Housing Act, Public Law 101-625, 104 Stat. 4079 (1990) (codified as amended at 42 U.S.C. 12901-12912); 24 CFR part 574.
2. The Base Closure Community Redevelopment and Homeless Assistance Act of 1994, Public Law 103-421, 108 Stat. 4346 (codified as amended at 10 U.S.C. 2687 note); 24 CFR part 586.
3. Capacity Building for Community Development and Affordability Housing grants, Section 4 of the HUD Demonstration Act of 1993, Public Law 103-120, 107 Stat. 1148 (codified as amended at 42 U.S.C. 9816 note).
4. Comprehensive Housing Affordability Strategies (CHAS), Title I of the Cranston-Gonzalez National Affordable Housing Act, Public Law 101-625, 104 Stat. 4079 (1990) (codified as amended at 42 U.S.C. 12701 *et seq.*); 24 CFR part 91.
5. Economic Development Initiative grants, as provided for in annual HUD appropriations acts (*e.g.*, the Consolidated Appropriations Resolution, Fiscal Year 2003, Public Law 108-7, 117 Stat. (2003)).
6. Urban Empowerment Zones (EZ), as authorized under Title 26, subtitle A, chapter 1, subchapter U of the Internal Revenue Code (codified as amended at

26 U.S.C. 1391 *et seq.*); 24 CFR parts 597 and 598.

7. The HOME Investment Partnerships Act, Title II of the Cranston-Gonzalez, National Affordable Housing Act, Public Law 101-625, 104 Stat. 4079 (1990) (codified as amended at 42 U.S.C. 12721 *et seq.*); 24 CFR part 92.

8. The Loan Guarantee Recovery Fund under Section 4 of the Church Arson Prevention Act of 1996, Public Law 104-155, 110 Stat. 1392; 24 CFR part 573.

9. Neighborhood Initiatives grants specifically designed in annual HUD appropriations acts (*e.g.*, the Consolidated Appropriations Act 2010, Pub. L. 111-117, 123 Stat. 3034 (2009)).

10. The Homelessness Prevention and Rapid Re-Housing Program (HPRP), as authorized under the Homelessness Prevention Fund heading of Division A, Title XII of the American Recovery and Reinvestment Act of 2009, Public Law 111-5, 123 Stat. 115.

11. The Housing Trust Fund (HTF), Section 1338 of the Federal Housing Enterprises Financial Safety and Soundness Act of 1992, added by Section 1131 of Public Law 110-289, 112 Stat. 2654 (codified at 12 U.S.C. 4568); 24 CFR part 93.

12. Rural Innovation Fund grants as provided for in annual HUD appropriations acts (*e.g.*, the Consolidated Appropriations Act 2010, Pub. L. 111-117, 123 Stat. 3084 (2009)).

13. The Tax Credit Assistance Program (TCAP), as authorized under the HOME Investments Partnerships Program heading of Division A, Title XII of the American Recovery and Reinvestment Act of 2009, Public Law 111-5, 123 Stat. 115, 220-21.

14. The Self-Help Homeownership Opportunity Program (SHOP) under section 11 of the Housing Opportunity Program Extension Act of 1996, Public Law 104-120, 110 Stat. 834 (codified as amended at 42 U.S.C. 12805 note).

15. Technical Assistance and Capacity Building awards authorized under any program or matter delegated under Section A (*e.g.*, Section 107 of the Housing and Community Development Act 1987, Pub. L. 100-242, 100 Stat. 1815 (1988)); and as provided for in annual and supplemental HUD appropriations acts (*e.g.*, the Consolidated Appropriations Act 2010, Pub. L. 111-117, 123 Stat. 3093 (2009)).

16. Title I of the Housing and Community Development Act of 1974, Public Law 93-383, 88 Stat. 633 (codified as amended at 42 U.S.C. 5301 *et seq.*); 24 CFR part 570, including the following:

a. The Community Development Block Grant (CDBG) program;

b. The Section 108 Loan Guarantee program;

c. Economic development grants pursuant to Section 108(q);

d. Neighborhood Stabilization programs under the Housing and Economic Recovery Act of 2008, Public Law 110–289, 122 Stat. 2850; Title XII of Division A of the American Recovery and Reinvestment Act of 2009, Public Law 111–5, 123 Stat. 115; and Section 1497 of the Wall Street Reform and Consumer Protection Act of 2010, Public Law 111–203, 124 Stat. 1376 (codified as amended at 42 U.S.C. 5301 note);

e. CDBG Disaster Recovery Grants as provided for in annual and supplemental HUD appropriations acts; and

f. Appalachian Regional Commission grants pursuant to Section 214 of the Appalachian Regional Development Act of 1965, Public Law 89–4, 79 Stat. 5 (codified as amended at 40 U.S.C. 14507) and consistent with the CDBG program authorized under Title I of the Housing and Community Development Act of 1974, Public Law 93–383, 88 Stat. 633 (codified as amended at 42 U.S.C. 5301 *et seq.*).

17. Title IV of the McKinney-Vento Homeless Assistance Act, Public Law 100–77, 101 Stat. 482 (1987) (codified as amended at 42 U.S.C. 5301 *et seq.*), including the following:

a. The Emergency Shelter Grants/Emergency Solutions Grants program, 24 CFR 576;

b. The Supportive Housing Program, 24 CFR part 583;

c. The Shelter Plus Care Program, 24 CFR part 582;

d. The Moderate Rehabilitation for Single Room Occupancy program 24 CFR part 882, subpart H;

e. The Continuum of Care program, 24 CFR part 578; and

f. The Rural Housing Stability Assistance program.

18. Title V of the McKinney-Vento Homeless Assistance Act, Public Law 100–77, 101 Stat. 482 (1987) (codified as amended at 42 U.S.C. 1411 *et seq.*), 24 CFR part 581.

19. The Veterans Homelessness Prevention Demonstration program as provided for in annual HUD appropriations acts (e.g., Omnibus Appropriations Act, 2009, Pub. L. 111–8, 123 Stat. 524 (2009)).

20. Overall departmental responsibility for rulemaking, policies, standards, procedures, and advisory materials for compliance with the Uniform Relocation Assistance and Real Property Acquisition Policies Act of

1970, Public Law 91–646, 84 Stat. 1894 (1971) (codified as amended at 42 U.S.C. 4601 *et seq.*); 49 CFR part 24. (For departmental programs, only the Assistant Secretary for Community Planning and Development is delegated the authority to exercise the federal waiver authority provided under 49 CFR 24.7).

21. Overall departmental responsibility for compliance with the National Environmental Policy Act of 1969, Public Law 91–190, 83 Stat. 852 (1970) (codified as amended at 42 U.S.C. 4321–4347), and the related laws and authorities cited in 24 CFR 50.4 and 58.5, including (with regard to the Assistant Secretary for Community Planning and Development) the authority to issue and to waive, or approve exceptions or establish criteria for exceptions from provisions of 24 CFR parts 50, 51, 55, and 58. The Assistant Secretary for Community Planning and Development's designee serves as the Departmental lead in all federal initiatives that address NEPA and other federal environmental laws and authorities cited in 24 CFR 50.4 and 58.5 and as the Departmental signatory for environmental compliance MOUs with other federal agencies addressing compliance at the regional and national level.

22. Certain Office of Community Planning and Development Programs that are no longer authorized for funding (or future funding is not anticipated), but whose administration must continue until all departmental responsibilities are discharged and finally terminated. These programs include the following:

a. The Slum Clearance and Urban Renewal program under Title I of the Housing Act of 1949, Public Law 81–171, 63 Stat. 413 and any program which is superseded by, or inactive by reason of Title I of the Housing and Community Development Act of 1974, Public Law 93–383, 88 Stat. 633 (codified as amended at 42 U.S.C. 5316);

b. Area-wide grants, inequities grants, disaster grants and the authority to concur in final approval actions regarding innovative grants under Section 107 of Title I of the Housing and Community Development Act of 1974, Public Law 93–383, 88 Stat. 633 (repealed 1981);

c. Urban Development Action grants under Title I of the Housing and Community Development Act of 1974, Public Law 93–383, 88 Stat. 633. (codified as amended at 42 U.S.C. 5318);

d. The Rental Rehabilitation Program, United States Housing Act of 1937, § 17, Public Law 98–181, 97 Stat. 1196;

e. The Section 312 Rehabilitation Loan Program, Housing Act of 1964, § 312 Public Law 88–560, 78 Stat. 769 (repealed 1990); 24 CFR part 510;

f. The Urban Homesteading Program, Housing and Community Development Act of 1974 § 810, Public Law 93–383, 88 Stat. 633 (repealed 1990);

g. Enterprise Zone Program under Title VII of the Housing and Community Development Act of 1987, Public Law 100–242, 100 Stat. 1815 (1988) (codified as amended at 42 U.S.C. 11501 *et seq.*);

h. Grant for Urban Empowerment Zones (EZ) as provided for in annual HUD appropriations acts (e.g., Consolidated Appropriations resolution, Fiscal Year 2003, Pub. L. 108–7, 117 Stat. 11 (2003));

i. HUD's Homeownership Zone initiative (HOZ) grants as provided for in Section 205 of the Department of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 1997, Public Law 104–204, 110 Stat. 2874 (1996) and funded with recaptured Nehemiah grants authorized under Title VI of the Housing and Community Development Act of 1987, Public Law 100–242, 101 Stat. 1815 (1988) (codified at 12 U.S.C. 1715l note);

j. The Innovative Homeless Initiatives Demonstration program under the HUD Demonstration Act of 1993, Public Law 103–120, 107 Stat. 1144;

k. The HOPE for Homeownership of Single-family Housing (HOPE 3) program, Title IV, Subtitle C of the Cranston-Gonzalez National Affordable Housing Act, Public Law 101–625, 104 Stat. 4079 (1990) (codified at 42 U.S.C. 12891);

l. New Communities Program, Section 413 of the Housing and Urban Development Act of 1968, Public Law 90–448, 82 Stat. 476 (repealed 1983), Section 726 of the Housing and Urban-Rural Recovery Act of 1983, Public Law 91–609 (repealed 1983), 84 Stat. 1784, Section 474 of the Housing and Urban-Rural Act of 1983, Public Law 98–181, 97 Stat. 1237 (codified at 12 U.S.C. 1710g–5b), and any other functions, powers, and duties that may affect the liquidation of the New Communities program;

m. Rural Housing and Economic Development grants specifically designed originally in the Fiscal Year 1998 HUD Appropriations Act, Public Law 105–65, 111 Stat. 1344 and subsequent annual HUD appropriations acts;

n. Renewal Communities (RC), as authorized under Title 26, subtitle A, chapter 1, subchapter X of the Internal Revenue Code (codified as amended at

26 U.S.C. 1400E *et seq.*); 24 CFR part 599;

o. All programs consolidated in the Revolving Fund (Liquidating Programs) established pursuant to Title II of the Independent Offices Appropriations Act, Public Law 98–45, 97 Stat. 223 (1983) (codified as amended at 12 U.S.C. 1701g-5), including all authority of the Secretary with respect to functions, administration, and management of the Revolving Fund (Liquidating Programs).

23. Suspensions, and/or limited denial of participations under 2 CFR part 2424 with the concurrence of the General Counsel, or such other official as may be designed by the General Counsel.

24. Pilot Program to Rehabilitate and Modify Homes of Disabled and Low-Income Veterans, as authorized under section 1079 of the Carl Levin and Howard P. “Buck” McKeon National Defense Authorization Act for Fiscal Year 2015, Public Law 113–291, 128 Stat. 3292, 3521–3524 (2014).

Section B. Authority Excepted

There is excepted from the authority delegated under Section A:

1. The power to sue and be sued;
2. Under Title I of the Housing and Community Development Act of 1974, Public Law 93–383, 88 Stat. 633 (codified as amended at 42 U.S.C. 5301 *et seq.*);

a. The power to administer the Indian Community Development Block Grant program, for which the authority has been delegated to the Assistant Secretary for Public and Indian Housing;

b. The power to administer section 107 programs delegated to the Assistant Secretary for Policy Development and Research;

c. The power to issue obligations for purchase by the Secretary of the Treasury under section 108(g) of the Housing and Community Development Act (42 U.S.C. 5308); and

d. The power and authority of the Secretary with respect to nondiscrimination under section 109 may be exercised only with the advice of the Assistant Secretary for Fair Housing Equal Opportunity.

3. For programs noted in Section A.22 of this delegation that are no longer authorized for funding;

a. The power to establish interest rates; and

b. The power to issue notes or obligations for purchase by the Secretary of the Treasury.

4. The authority delegated under Section A to the Principal Deputy Assistant Secretary and General Deputy Assistant Secretary does not include the

authority to waive the following statutes:

a. The authority under annual and supplemental HUD appropriations acts providing Community Development Block Grant funding for disaster recovery (*e.g.*, Pub. L. 113–2) to waive, or specify alternative requirements for, statutory requirements;

b. The authority under section 215(a)(6) of the Cranston-Gonzalez National Affordable Housing Act (42 U.S.C. 12745) to waive qualifying rents; and

c. The authority under section 858(b) of the Cranston-Gonzalez National Affordable Housing Act (42 U.S.C. 12907) to waive requirements for short-term supported housing and services.

Section C. Authority To Redelegate

The Assistant Secretary, the Principal Deputy Assistant Secretary and the General Deputy Assistant Secretary for Community Planning and Development are authorized to redelegate to employees of the Department any authority delegated under Section A. Redelegated authority to CPD Directors, Deputy Assistant Secretaries or other CPD program officials does not supersede the authority of the Assistant Secretary as designee of the Secretary.

Section D. Delegations Superseded

This notice supersedes all prior delegations of authority from the Secretary to the Assistant Secretary for Community Planning and Development, including the delegation published on April 20, 2015, at 80 FR 21747.

Authority: Section 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: January 10, 2017.

Julián Castro,
Secretary.

[FR Doc. 2017–01245 Filed 1–18–17; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5907–C–52]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Correction.

SUMMARY: HUD is republishing this notice to include all information that was inadvertently not included in the notice published on December 23, 2016 at 81 FR 94405.

FOR FURTHER INFORMATION CONTACT:

Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), call the toll-free Title V information line at 800–927–7588 or send an email to title5@hud.gov.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless v. Veterans Administration*, No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for “off-site use only” recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to: Ms. Theresa M. Ritta, Chief Real Property Branch, the Department of Health and Human Services, Room 12–07, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–2265 (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions

for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1-800-927-7588 or send an email to title5@hud.gov for detailed instructions, or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (e.g., acreage, floor plan, condition of property, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following address(es): *Agriculture*: Ms. Debra Kerr, Department of Agriculture, OPFM, Property Management Division, Agriculture South Building, 300 7th Street SW., Washington, DC 20024, (202) 720-8873; *Air Force*: Mr. Robert E. Moriarty, P.E., AFCEC/CI, 2261 Hughes Avenue, Ste. 155, JBSA Lackland TX 78236-9853, (315) 225-7384; *GSA*: Mr. Flavio Peres, General Services Administration, Office of Real Property Utilization and Disposal, 1800 F Street NW., Room 7040 Washington, DC 20405, (202) 501-0084; *Navy*: Ms. Nikki Hunt, Department of the Navy, Asset Management Division, Naval Facilities Engineering Command, Washington Navy Yard, 1330 Patterson Ave. SW., Suite 1000, Washington, DC 20374;

(202) 685-9426 (These are not toll-free numbers).

Dated: January 10, 2017.

Brian P. Fitzmaurice,

*Director, Division of Community Assistance,
Office of Special Needs Assistance Programs.*

**TITLE V, FEDERAL SURPLUS PROPERTY
PROGRAM FEDERAL REGISTER REPORT
FOR 12/23/2016**

Suitable/Available Properties

Building

Michigan

Raco Work Center
9200 South Ranger Road
Brimley MI 49715
Landholding Agency: Agriculture
Property Number: 15201640015
Status: Underutilized
Comments: Off-site removal only; 81+ yrs.
old; 442 sq. ft.; equipment/material storage;
roof needs replaced; lead based paint; no
future agency need; contact Agriculture for
more information.

Raco Work Center
9200 South Ranger Road
Brimley MI 49715
Landholding Agency: Agriculture
Property Number: 15201640016
Status: Underutilized
Comments: Off-site removal only; 82+ yrs.
old; 528 sq. ft.; equipment/material storage;
roof needs replaced; lead based paint; no
future agency need; contact Agriculture for
more information.

Moran Work Center
1790 W. Adolphus Street
Moran MI 49760
Landholding Agency: Agriculture
Property Number: 15201640017
Status: Underutilized
Comments: Off-site removal only; 45+ yrs.
old; 85 sq. ft.; tire storage; building needs
replacement; no future agency need;
contact Agriculture for more information.

Moran Work Center
1790 W. Adolphus Street
Moran MI 49760
Landholding Agency: Agriculture
Property Number: 15201640018
Status: Underutilized
Directions: Off-site removal only; 80+ yrs.;
2,240 sq. ft.; removal extremely difficult;
no future agency need; office/storage; poor
condition; lead base paint; roof needs to be
replaced;
Comments: Not ADA complaint; contact
Agriculture for more information.

Moran Work Center
1790 W. Adolphus Street
Moran MI 49760
Landholding Agency: Agriculture
Property Number: 15201640019
Status: Underutilized
Comments: Off-site removal only; 68+ yrs.
old; 1,160 sq. ft.; office/storage; poor
condition; lead based paint; roof needs to
be replaced; no future agency need; contact
Agriculture for more information.

Moran Work Center
1790 W. Adolphus Street
Moran MI 49760
Landholding Agency: Agriculture

Property Number: 15201640020

Status: Underutilized

Directions: Off-site removal only; 80+ yrs.
old; 300 sq. ft.; garage/fuel storage; no
future agency need; poor condition;
Comments: Roof needs to be replaced; lead
base paint; not ADA complaint; contact
Agriculture for more information.

Raco Work Center

Raco Fire Cache

Brimley MI 49715

Landholding Agency: Agriculture

Property Number: 15201640025

Status: Underutilized

Comments: Off-site removal only; 698 sq. ft.;
no future agency need; rehab needed; lead
present; contact Agriculture for more
information.

North Carolina

U.S. Army Reserve Center

1228 Carroll Street

Durham NC 27707

Landholding Agency: GSA

Property Number: 54201640006

Status: Excess

GSA Number: 4-D-NC-0832-AA

Directions: Disposal Agency: GSA;

Landholding Agency: COE

Comments: 58+ yrs. old; 15,000 sq. ft.;
training & education; 30+ mos. vacant; sits
on 5.45 acres of land; asbestos & lead
present; use restrictions may apply; contact
GSA for more information.

South Carolina

Orangeburg Memorial USARC

287 John C. Calhoun Drive

Orangeburg SC 29115

Landholding Agency: GSA

Property Number: 54201640007

Status: Excess

GSA Number: 4-D-SC-0638AA

Directions:

Disposal Agency: GSA; Landholding Agency:

Army 11,367 sf., masonry bldg.; 3,018 sf.,
masonry bldg., 1,500 sf., & 1,550 sf.
workshop bldg., 240 sf. shed

Comments: 57+ yrs. old; office/storage; sq. ft.
listed above; vacant 26+ mos., lead base
paint & asbestos present; sits on 2.62 acres
of land; contact GSA for more information.

Washington

White Pass Work Center

31381 Hwy. 12 located at MP 17

from 410/12 junction

Naches WA 98937

Landholding Agency: Agriculture

Property Number: 15201640021

Status: Unutilized

Directions: 0767200 1152(1110.005511; 1058

(1106.005511); 1151 (1109.005511); 1051

(1103.005511); 1053 (1105.005511); 1050

(1102.005511)

Comments: Off-site removal only; 57-81+
yrs. old; 1,000-3,444 sf.; residential;
removal extremely difficult; vacant 12
mos., no future agency need; appt. needed;
contact Agriculture for more information.

Suitable/Unavailable Properties

Building

Massachusetts

John A. Volpe National Transp.
Systems Center (Volpe Center)

55 Broadway
Cambridge MA
Landholding Agency: GSA
Property Number: 54201640008
Status: Excess
GSA Number: MA-0933-AA
Directions: Disposal Agency: GSA;
Landholding Agency: DOT; Bldg. 1
(211,654 sf.); bldg. 2 (21,970 sq.); bldg. 3
(67,977 sf.); bldg. 4 (46,899 sf.); 5 (13,856
sf.); bldg. 6 (12,934 sf.) 56+ yrs. old; sf.
listed above; property well maintained; sits
on 14 acres of land; property unavailable
due to an expressed federal need
Comments: Contact GSA for more
information.

Unsuitable Properties

Building

Alaska

Eielson Education Center
Eielson Air Force Base
Eielson AFB AK 99702
Landholding Agency: Air Force
Property Number: 18201640045
Status: Unutilized
Comments: Public access denied and no
alternative method to gain access without
compromising national security.
Reasons: Secured Area

California

Naval Air Facility Substation
Naval Air Weapons Station
China Lake CA 93555
Landholding Agency: Navy
Property Number: 77201640009
Status: Underutilized
Directions: (RPUID:153148)
Comments: Public access denied and no
alternative method to gain access without
compromising national security.
Reasons: Secured Area

North Carolina

OLF NAS Oceana (Parcel 013)
NAS Oceana
Oceana NC
Landholding Agency: GSA
Property Number: 54201640009
Status: Surplus
GSA Number: 4-D-NC-0831-AG
Directions:
Landholding Agency: Navy; Disposal
Agency: GSA
Comments: Friable asbestos; Documented
deficiencies: abandoned building; partially
collapsing; collapsed ceiling; clear threat to
physical safety
Reasons: Extensive deterioration;
Contamination

Washington

Lake Wenatchee Ranger Station
Compound
17420 N. Shore Drive
Leavenworth WA 98826
Landholding Agency: Agriculture
Property Number: 15201640022
Status: Excess
Directions: 0767200 1203 (1058.005511);
2071 (1077.005511); 2270 (1078.005511);
2274 (1067.005511); 2277 (1075.005511);
2372 (48216010700); 2671 (1084.005511)
Comments: Property located within floodway
which has not been correct or contained.

Reasons: Floodway
Airport Rec Storage #5282
Chiwawa Loop Rd
Leavenworth WA 98826
Landholding Agency: Agriculture
Property Number: 15201640024
Status: Excess
Directions:
(2189.005511) 0767200
Comments: Property located within floodway
which has not been correct or contained.
Reasons: Floodway
[FR Doc. 2017-00885 Filed 1-18-17; 8:45 am]
BILLING CODE 4210-67-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5858-N-04]

Announcement of the Housing Counseling Federal Advisory Committee Notice of Public Meeting

AGENCY: Office of the Assistant
Secretary for Housing—Federal Housing
Commissioner, Department of Housing
and Urban Development (HUD).
ACTION: Notice of Housing Counseling
Federal Advisory Committee (HCFAC)
public meeting.

SUMMARY: This gives notice of a Housing
Counseling Federal Advisory Committee
(HCFAC) meeting on Wednesday,
February 8, 2017, via conference phone,
and the proposed agenda. The meeting
is open to the public and is accessible
to individuals with disabilities.
DATES: The meeting will be held on
Wednesday, February 8, 2017 from
12:00 p.m. to 2:00 p.m. Eastern Daylight
Time (EDT) via conference phone.

FOR FURTHER INFORMATION CONTACT:
Marjorie George, Housing Program
Technical Specialist, Office of Housing
Counseling, U.S. Department of Housing
and Urban Development, 200 Jefferson
Avenue, Suite 300, Memphis, TN 38103;
telephone number (901) 544-4228 (this
is not a toll-free number). Persons who
have difficulty hearing or speaking may
access this number via TTY by calling
the toll-free Federal Relay Service at
(800) 877-8339. Individuals may also
email HCFACCommittee@hud.gov.

SUPPLEMENTARY INFORMATION: HUD is
convening the meeting of the HCFAC on
Wednesday, February 8, 2017 from
12:00 p.m. to 2:00 p.m. The meeting will
be held via conference phone. This
meeting notice is provided in
accordance with the Federal Advisory
Committee Act, 5. U.S.C. App. 10(a)(2).

Agenda—Housing Counseling Federal Advisory Committee Meeting— February 8, 2017

I. Approval of November 1, 2016
Meeting Minutes

II. Confirmation of HCFAC Objectives
III. Presentations by Creative Marketing
Resource
IV. Review of Quality Housing
Counseling
V. Planning for Future HCFAC Meetings
VI. Next Steps
VII. Adjourn

With advance registration, the public
is invited to attend this meeting via
teleconference. To register for this
meeting please access the below link:
[http://www.hud.gov/emarc/
index.cfm?fuseaction=emar.register
Event&eventId=2974&update=N](http://www.hud.gov/emarc/index.cfm?fuseaction=emar.registerEvent&eventId=2974&update=N).

The toll-free call-in number will be
provided once registration is confirmed.
Persons with hearing impairments may
also follow the discussion by first
calling the Federal Relay Service (FRS):
(800) 977-8339 and providing the FRS
operator with the conference call toll-
free number, which will be provided
upon registration.

Records and documents discussed
during the meeting, as well as other
information about the work of this
Committee, will be available for public
viewing as they become available at:
[http://www.facadatabase.gov/
committee/committee.aspx?cid=
2492&aid=77](http://www.facadatabase.gov/committee/committee.aspx?cid=2492&aid=77) by clicking on the
“Committee Meetings” link.

Dated: January 11, 2017.

Edward L. Golding,

*Principal Deputy Assistant Secretary, Office
of Housing/Federal Housing Administration.*

[FR Doc. 2017-01248 Filed 1-18-17; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R2-ES-2016-N199;
FXES11140200000F2-178--FF02ENEH00]

Notice of Intent To Prepare a Draft Environmental Impact Statement for a Proposed Habitat Conservation Plan for the Endangered American Burying Beetle for American Electric Power in Oklahoma, Arkansas, and Texas

AGENCY: Fish and Wildlife Service,
Interior.

ACTION: Notice of intent; announcement
of meetings; request for comments.

SUMMARY: We, the U.S. Fish and
Wildlife Service (Service), are notifying
the public that we intend to prepare a
draft environmental impact statement
(EIS) to evaluate the impacts of
alternatives relating to the proposed
issuance of an Endangered Species Act
(ESA) Incidental Take Permit (ITP) in
response to the American Electric Power

Habitat Conservation Plan (HCP). The ITP is needed to cover incidental take of the endangered American burying beetle (ABB) from activities associated with construction, operation, and/or maintenance of electric transmission and distribution lines or other associated infrastructure. American Electric Power (AEP) intends to apply for an ITP under the ESA and agrees to develop and implement the proposed HCP. We also are announcing the initiation of a public scoping process to engage Federal, Tribal, State, and local governments and the public in the identification of issues and concerns, potential impacts, and possible alternatives to the proposed action.

DATES: In order to be included in the analysis, all comments must be received or postmarked by February 21, 2017. See **SUPPLEMENTARY INFORMATION** regarding meeting dates.

ADDRESSES: Please provide comments in writing, by one of the following methods:

Email: OKES_HCP_EIS@fws.gov;
Facsimile: 918-581-7467, Attn: OKES HCP EIS; or

U.S. mail: Field Supervisor,
Oklahoma Ecological Services Field Office, U.S. Fish and Wildlife Service,
9014 E. 21st St., Tulsa, OK 74129.

Please specify that your information request or comments concern the AEP draft EIS/HCP (TE01909C).

See **SUPPLEMENTARY INFORMATION** regarding meeting locations.

FOR FURTHER INFORMATION CONTACT:

Jonna Polk, by U.S. mail at the U.S. Fish and Wildlife Service, Oklahoma Ecological Services Field Office, 9014 E. 21st St., Tulsa, OK 74129, or by phone at 918-581-7458. If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service at 800-877-8339.

SUPPLEMENTARY INFORMATION: We publish this notice in compliance with the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), and its implementing regulations (40 CFR 1501.7, 1506.6, and 1508.22), and section 10(c) of the Endangered Species Act of 1973 (the Act), as amended (16 U.S.C. 1539(c)). We intend to gather the information necessary to determine impacts and alternatives to support a decision regarding the potential issuance of an incidental take permit to AEP, and the implementation of the supporting draft habitat conservation plan (HCP).

Meeting Information

We will conduct four public scoping meetings within the 62-county proposed

covered area, which includes the ABB range: Tulsa, OK; McAlester, OK; Fort Smith, AR; and Texarkana, TX. Exact meeting locations and times will be announced in local newspapers and on Service Web sites at least 2 weeks prior to each event (Oklahoma Ecological Services Office Web site, <http://www.fws.gov/southwest/es/Oklahoma/>; Arkansas Ecological Services Office Web site, <https://www.fws.gov/arkansas-es/>; and Arlington, Texas, Ecological Services Office Web site, <https://www.fws.gov/southwest/es/ArlingtonTexas/>). The scoping meetings will provide the public with an opportunity to ask questions and discuss issues with Service staff regarding the EIS and provide written comments.

Persons needing reasonable accommodations in order to attend and participate in a public meeting should contact us at the address listed in **ADDRESSES** no later than 1 week before the relevant public meeting. Information regarding this proposed action is available in alternative formats upon request.

We will accept written comments at each meeting. You may also submit written comments to the Field Supervisor at the email or U.S. mail addresses in **ADDRESSES**.

Background

Section 9 of the ESA prohibits “take” of fish and wildlife species listed as endangered or threatened (16 U.S.C. 1531–1544). Under section 3 of the ESA, the term “take” means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct (16 U.S.C. 1532(19)). The term “harm” is further defined by regulation as an act that actually kills or injures wildlife. Such act may include significant habitat modification or degradation where it actually kills or injures wildlife by significantly impairing essential behavioral patterns, including breeding, feeding, or sheltering (50 CFR 17.3). The term “harass” is also further defined in the regulations as an intentional or negligent act or omission that creates the likelihood of injury to wildlife by annoying it to such an extent as to significantly disrupt normal behavioral patterns, which include, but are not limited to, breeding, feeding, or sheltering (50 CFR 17.3).

Under section 10(a)(1)(B) of the Act, the Secretary of the Interior may authorize the taking of federally listed species if such taking occurs incidental to otherwise legal activities and where a conservation plan has been developed under section 10(a)(2)(A) that describes:

(1) The impact that will likely result from such taking; (2) the steps an applicant will take to minimize and mitigate that take to the maximum extent practicable and the funding that will be available to implement such steps; (3) the alternative actions to such taking that an applicant considered and the reasons why such alternatives are not being utilized; and (4) other measures that the Service may require as being necessary or appropriate for the purposes of the plan. Issuance criteria under section 10(a)(2)(B) for an incidental take permit require the Service to find that: (1) The taking will be incidental to otherwise lawful activities; (2) an applicant will, to the maximum extent practicable, minimize and mitigate the impacts of such taking; (3) an applicant has ensured that adequate funding for the plan will be provided; (4) the taking will not appreciably reduce the likelihood of the survival and recovery of the species in the wild; and (5) the measures, if any, we require as necessary or appropriate for the purposes of the plan will be met. Regulations governing permits for endangered and threatened species are at 50 CFR 17.22 and 17.32, respectively.

Public Scoping

A primary purpose of the scoping process is to receive suggestions and information on the scope of issues and alternatives to consider when drafting the EIS, and to identify significant issues and reasonable alternatives related to the Service’s proposed action (issuance of the ITP under the AEP HCP). In order to ensure that we identify a range of issues and alternatives related to the proposed action, we invite comments and suggestions from all interested parties. We will conduct a review of this project according to the requirements of NEPA and its regulations, other relevant Federal laws, regulations, policies, and guidance, and our procedures for compliance with applicable regulations.

Once the draft EIS and draft HCP are completed, we will offer further opportunities for public comment on the content of these documents through additional public meetings and a 90-day public comment period.

Alternatives

No-Action Alternative

Under the no-action alternative, AEP would comply with the Act by avoiding impacts to (take of) the ABB where practicable. If take cannot be avoided and there is Federal involvement in the project (for example, a Federal permit, such as a Corps of Engineers section 404

Clean Water Act permit, authorization, or funding exists), AEP may receive take coverage through a biological opinion issued by the Service to the Federal action agency. If there is no Federal involvement in the project, AEP can apply for an incidental take permit from the Service. This approach is more time consuming and less efficient, because permits would need to be considered and processed one project at a time, which could result in an isolated, independent mitigation approach.

Proposed Alternative

The proposed action is issuance of an incidental take permit for the covered species during construction, operation, and/or maintenance of electric transmission and distribution lines or other associated infrastructure. The proposed HCP, which must meet the requirements in section 10(a)(2)(A) of the Act, would be developed in coordination with the Service and implemented by AEP. This alternative will allow for a comprehensive mitigation approach for authorized impacts and result in a more efficient and timely permit processing effort for the Service and AEP. Actions covered under the requested incidental take permit may include possible take of covered species associated with activities including, but not limited to, construction, operation, and/or maintenance of electric transmission and distribution lines or other associated infrastructure. The proposed permit submitted by American Energy Power provides coverage for a period of 30 years.

Sixty-two counties are in the proposed permit area, including Adair, Atoka, Bryan, Carter, Cherokee, Choctaw, Cleveland, Coal, Craig, Creek, Delaware, Garvin, Haskell, Hughes, Johnston, Kay, Latimer, Le Flore, Lincoln, Logan, Love, Marshall, Mayes, McClain, McCurtain, McIntosh, Murray, Muskogee, Noble, Nowata, Okfuskee, Oklahoma, Okmulgee, Osage, Ottawa, Pawnee, Payne, Pittsburg, Pontotoc, Pottawatomie, Pushmataha, Rogers, Seminole, Sequoyah, Tulsa, Wagoner, and Washington Counties in Oklahoma; Clark, Crawford, Franklin, Hempstead, Johnson, Little River, Logan, Miller, Sebastian, Scott, and Yell Counties in Arkansas; and Bowie, Fannin, Lamar, and Red River Counties in Texas. The species covered under the requested incidental take permit is the ABB. We will be evaluating whether the covered activities will impact other species and whether they should be included on the permit or if management practices can be implemented that are sufficient to

avoid take. These species and their legal status include:

- American alligator (*Alligator mississippiensis*)—Threatened (Similarity of Appearance)
- Arkansas fatmucket (*Lampsilis powellii*)—Threatened
- Arkansas River shiner (*Notropis girardi*)—Threatened, Arkansas R. Basin population, with Critical Habitat
- Gray bat (*Myotis grisescens*)—Endangered
- Harperella (*Ptilimnium nodosum*)—Endangered
- Indiana bat (*Myotis sodalis*)—Endangered
- Least tern (*Sterna antillarum* [now recognized as a subspecies *athalassos*])—Endangered, interior population
- Leopard darter (*Percina pantherina*)—Threatened with Critical Habitat
- Neosho madtom (*Noturus placidus*)—Threatened
- Neosho mucket (*Lampsilis rafinesqueana*)—Endangered with Critical Habitat
- Northern long-eared bat (*Myotis septentrionalis*)—Threatened
- Ouachita Rock pocketbook (*Arkansia wheeleri*)—Endangered
- Ozark big-eared bat (*Corynorhinus townsendii ingens*)—Endangered
- Ozark cavefish (*Amblyopsis rosae*)—Threatened
- Pink mucket (*Lampsilis abrupta*)—Endangered
- Piping plover (*Charadrius melodus*)—Threatened; except Great Lakes watershed population
- Rabbitsfoot (*Quadrula cylindrica cylindrica*)—Threatened with Critical Habitat
- Red-cockaded woodpecker (*Picoides borealis*)—Endangered
- Scaleshell mussel (*Leptodea leptodon*)—Endangered
- Spectaclecase (*Cumberlandia monodonta*)—Endangered
- Whooping crane (*Grus americana*)—Endangered; except in the experimental population area
- Winged mapleleaf (*Quadrula fragosa*)—Endangered; except where listed as experimental populations

We do not anticipate that covered activities will result in take of all these species, but we seek comments to help inform our evaluation.

We also will evaluate whether covered activities are likely to impact the bald eagle (*Haliaeetus leucocephalus*) and golden eagle (*Aquila chrysaetos*), protected under the Bald and Golden Eagle Protection Act (16 U.S.C. 668 *et seq.*).

Other Alternatives

We seek information regarding other reasonable alternatives during this scoping period and will evaluate the impacts associated with such alternatives in the draft EIS.

Public Availability of Comments

Written comments we receive become part of the public record associated with this action. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that the entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Comments and materials we receive, as well as supporting documentation we use in preparing the EIS, will be available for public inspection, by appointment, during normal business hours at the Service's Oklahoma Ecological Services Field Office in Tulsa, Oklahoma, (see **ADDRESSES**, above).

Benjamin N. Tuggle,

Regional Director, Southwest Region, U.S. Fish and Wildlife Service.

[FR Doc. 2017-01176 Filed 1-18-17; 8:45 am]

BILLING CODE 4333-15-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

**[FWS-R8-ES-2016-N187;
FXES111608M0000]**

Marine Mammals; Incidental Take During Specified Activities; Proposed Incidental Harassment Authorization

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of application and proposed incidental harassment authorization; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have received an application from the California Department of Fish and Wildlife, Central Region, for authorization to take small numbers of marine mammals by harassment incidental to construction activities as part of a tidal marsh restoration project within the Minhoto-Hester Marsh in Elkhorn Slough, Monterey County, California. In accordance with provisions of the Marine Mammal Protection Act of 1972,

as amended, we request comments on our proposed authorization for the applicant to take incidentally, by harassment, small numbers of southern sea otters (*Enhydra lutris nereis*) over the course of approximately 11 months beginning between January 2017 and June 2017. We anticipate no take by injury or death and include none in this proposed authorization, which would be for take by harassment only.

DATES: Comments and information must be received by February 21, 2017.

ADDRESSES: *Comment submission:* You may submit comments by any one of the following methods:

1. *U.S. mail or hand-delivery:* Steve Henry, Field Supervisor, Ventura Fish and Wildlife Office, 2493 Portola Road, Suite B, Ventura, CA 93003.

2. *Fax:* 805-644-3958, attention to Steve Henry, Field Supervisor.

3. *Electronic mail (email):* R8_SSO-IHA_Comment@fws.gov. Please include your name and U.S. mail address in your message.

Document availability: Electronic copies of the incidental harassment authorization request, the Marine Mammal Monitoring Plan, and other supporting materials, such as the list of references used in this notice, may be obtained by writing to the address specified above, telephoning the contact listed in **FOR FURTHER INFORMATION CONTACT**, or visiting the Internet at <http://www.fws.gov/ventura/endangered/species/info/ssoiha.html>. Documents cited in this notice may also be viewed, by appointment, during regular business hours, at the aforementioned U.S. mail address.

FOR FURTHER INFORMATION CONTACT: Lilian Carswell, Southern Sea Otter Recovery & Marine Conservation Coordinator, (805) 612-2793, or by email at Lilian_Carswell@fws.gov.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1371 (a)(5)(A) and (D)), authorize the Secretary of the Interior to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region, provided that we make certain findings and either issue regulations or, if the taking is limited to harassment, provide a notice of a proposed authorization to the public for review and comment.

We may grant authorization to incidentally take marine mammals if we

find that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses. As part of the authorization process, we prescribe permissible methods of taking and other means of effecting the least practicable impact on the species or stock and its habitat, and requirements pertaining to the monitoring and reporting of such takings.

The term “take,” as defined by the MMPA, means to harass, hunt, capture, or kill, or to attempt to harass, hunt, capture, or kill, any marine mammal. Harassment, as defined by the MMPA, means “any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [the MMPA calls this Level A harassment], or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [the MMPA calls this Level B harassment].”

The terms “negligible impact,” “small numbers,” and “unmitigable adverse impact” are defined in title 50 of the Code of Federal Regulations at 50 CFR 18.27, the Service’s regulations governing take of small numbers of marine mammals incidental to specified activities. “Negligible impact” is defined as “an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.” The term “small numbers” is also defined in the regulations as “a portion of a marine mammal species or stock whose taking would have a negligible impact on that species or stock.” However, we do not rely on that definition here, as it conflates the terms “small numbers” and “negligible impact,” which we recognize as two separate and distinct requirements. Instead, in our small numbers determination, we evaluate whether the number of marine mammals likely to be taken is small relative to the size of the overall population. “Unmitigable adverse impact” is defined as “an impact resulting from the specified activity (1) that is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by (i) causing the marine mammals to abandon or avoid hunting areas, (ii) directly displacing subsistence users, or (iii) placing physical barriers between the marine

mammals and the subsistence hunters; and (2) that cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.” The subsistence provision applies to northern sea otters (*Enhydra lutris kenyoni*) in Alaska but not to southern sea otters.

Summary of Request

On May 23, 2016, we received an application from the California Department of Fish and Wildlife, Central Region (CDFW), for authorization to take southern sea otters incidental to construction activities associated with a 47-acre tidal marsh restoration project within the Minhoto-Hester Marsh in Elkhorn Slough, Monterey County, California. The project would reduce tidal prism in Elkhorn Slough, reducing the potential for ongoing tidal scour and associated marsh loss. It would also improve marsh sustainability with sea level rise, as the restored marsh would be higher in the tidal frame and further from the drowning threshold, and marsh vegetation in the restored areas would accrete organic material that would help the restored marsh plain rise with sea level. The full Elkhorn Slough Tidal Marsh Restoration Project includes the anticipated restoration of 147 acres, but future phases are not part of this application because they would not likely occur for several years. If any future phase of the project would result in harassment of southern sea otters, another IHA would have to be requested and received prior to its implementation.

A detailed description of the proposed project is contained in the incidental harassment authorization request submitted to us by CDFW (ESA/ESNERR 2016). CDFW submitted revised versions of the application on July 26, 2016, August 24, 2016, August 29, 2016, and September 6, 2016. A final version, submitted on September 15, 2016, was determined to be adequate and complete. Work would begin between January 2017 and June 2017 and require approximately 11 months to complete. This period includes buffers for adverse weather and other conditions when work is not possible. Construction activities are expected to produce noise and visual disturbance that have the potential to result in behavioral harassment of southern sea otters. We are proposing to authorize take, by Level B harassment only, of southern sea otters as a result of the specified activity.

Description of the Activity

The proposed project would restore approximately 47 acres of tidal marsh within the Minhoto-Hester Marsh area and additional tidal marsh, upland ecotone, and native grassland in a buffer area, intended to absorb upland sediment and contaminants, between the remnant marsh and agricultural fields. Approximately 170,000 cubic yards of fill would be required to raise the marsh plain an average height of 2.4 feet, or 1.9 feet after 1 year of soil consolidation. The entire remnant marsh plain would be raised to an elevation that would allow emergent wetland vegetation to reestablish naturally and persist.

The buffer area would be graded to increase marsh area and to create a gently sloping ecotone band along the edge of the restored marsh. Excavation would widen the existing marsh by up to 150 feet and create a band of gentle slope on the hillside, fostering creation of a wider ecotone habitat. A 35-acre portion of the buffer area would be restored to native-dominated perennial grassland. A weed-resistant border of rhizomatous perennial plants would be planted between the grassland and ecotone. The remaining 6-acre portion of the buffer area would be used as a stockpile location for future restoration phases and would be revegetated with annual barley until future phases were complete, at which time it would be restored to native-dominated perennial grassland.

Remnant historic channels onsite would generally be left in place or filled and re-excavated in the same place. Smaller channels would be filled as needed for marsh access. As much of the existing tidal channel network would be maintained as feasible, and the post-project channel alignments would be similar to those under existing conditions. The density of channels (length of channel per acre of marsh) after restoration would be comparable to the density in natural reference marshes.

Low levees (less than 0.5 feet above the marsh plain) composed of fill material would be constructed along the larger channels to simulate natural channel levees. The project would re-create natural levee features along the sides of the main channel into the Minhoto-Hester area. Fill would be placed as close to the edge of the channel as possible to simulate the form and function of a natural channel bank. Borrow ditches that date from the times of historical wetland reclamation in these areas would be blocked or filled completely if fill is available after

raising the marsh plain. Blocking borrow ditches would route more flow through the natural channels and slightly increase hydraulic resistance, which may achieve benefits from reducing tidal prism and associated scour in the Elkhorn Slough system.

Construction sequencing would begin with water management and/or turbidity control measures constructed around the work areas prior to placing material on the marsh. Work areas on the remnant marsh plain would for the most part be isolated from the tides and dewatered to allow construction to occur in non-tidal conditions. Water control structures such as temporary berms would be utilized to isolate the fill placement area during the construction period. Existing berms would be used where possible. It is likely that the mouth of the restoration area could be closed with an earthen dam or an inflatable dam; however, a sheet pile wall at the mouth of the restoration area could be installed using vibratory hammering if the earthen and inflatable dam options proved to be infeasible. Tidal channels into work areas would be blocked. The isolated work areas would be drained using a combination of gravity and pumps. Water levels within the blocked areas would be managed to keep them mostly free of water (with some ponded areas remaining) to allow fill placement at all stages of the tides. Blocking of tidal channels would occur at low tide. Upon completion of sediment placement, the berms would be lowered to the target marsh elevation, reintroducing tidal inundation. Any blocked tidal channels would be re-excavated. After fill placement on the marsh, any temporary features, such as water management berms, sheet piles, and culverts, would be removed.

All material needed for the current phase of the project is onsite. Additional material may be delivered to the restoration areas by trucks if it becomes available. Construction crews and equipment would access the existing stockpile area and Minhoto Marsh from Dolan Road via existing roadways that were used for delivery of the existing sediment stockpile, located alongside existing agricultural fields. The Hester Marsh staging area may be accessed from Via Tanques Road.

Construction equipment would include haul trucks, heavy earthmoving equipment (such as bulldozers, backhoes, and loaders), and excavators to transport dry material out onto the marsh. A conveyor system could be used to transport material from a stockpile out to the marsh in lieu of bulldozers. In such cases, timber

matting would be temporarily placed on the marsh to provide a stable footing for the conveyors. A mobile radial stacker at the end of the conveyor belt would be rotated to spread the material.

a. Timing of Activity

Construction is anticipated to require approximately 11 months. The 11-month window would include 132 days of construction activity and (if needed) 4 days of vibratory pile driving, totaling 136 days of project activity. The 11-month window includes the time required for ecotone and grassland restoration work. Most work on the marsh plane would likely be completed within 6 to 8 months. The length of the construction period is based on the assumption that construction contractors would work between the hours of 5:00 a.m. to 6:00 p.m., Monday through Friday. However, some construction activity could also be required during these times on Saturdays. The proposed IHA would be valid for 1 year from the date of issuance, with project activities beginning between January 2017 and June 2017.

b. Geographic Location of Activity

The proposed project is located in the Elkhorn Slough estuary, a network of intertidal marshes, mudflats, and subtidal channels 90 miles south of San Francisco and 20 miles north of Monterey (see Figure 1–1 of ESA/ESNERR 2016). The Minhoto-Hester Marsh, where the proposed restoration work would occur, is a low-lying area within Elkhorn Slough consisting of subsided pickleweed (*Salicornia pacifica*) marsh, intertidal mudflats, tidal channels, and remnant levees. The project area is on land owned and managed by CDFW as part of the Elkhorn Slough National Estuarine Research Reserve (ESNERR) (see Figure 1–2 of ESA/ESNERR 2016). One Marine Protected Area (MPA), a State Marine Reserve, partially overlaps with the project area. Two additional MPAs are located within 1 mile of the project area. The Minhoto-Hester Marsh has multiple cross-levees and both natural and dredged channels, with a major dredged channel (exceeding 100 feet in width in some locations) that runs north to south through the remnant marsh.

Description of Marine Mammals in the Area of the Activity

Southern sea otters and Pacific harbor seals (*Phoca vitulina richardii*) are present in or near the project site. Pacific harbor seals are under the jurisdiction of the National Marine Fisheries Service (NMFS) and are

considered under a separate proposed IHA notice. Therefore, we do not address them further here. The only marine mammal species under the jurisdiction of the Service that occurs in the proposed project area is the southern sea otter.

Southern sea otters are listed as threatened under the Endangered Species Act of 1973, as amended (ESA) (42 FR 2965; January 14, 1977), and, because of their threatened status, are considered “depleted” under the MMPA. The State of California also recognizes the sea otter as a fully protected mammal (Fish and Game Code section 4700) and as a protected marine mammal (Fish and Game Code section 4500). All members of the sea otter population in California are descendants of a small group that survived the fur trade and persisted near Big Sur, California. Historically ranging from at least as far north as Oregon (Valentine et al. 2008) to Punta Abrejos, Baja California, Mexico, in the south, sea otters currently occur in only two areas of California. The mainland population ranges from San Mateo County to Santa Barbara County, and a translocated population exists at San Nicolas Island, Ventura County. The most recent (2016) California-wide index of abundance is 3,272 individuals (www.werc.usgs.gov/seaottercount). Additional general information on status and trends of the southern sea otter may be found in the stock assessment report, available at <http://www.fws.gov/ventura/endangered/species/info/sso.html>.

Sea otters occur in Elkhorn Slough year round. As many as 150 sea otters (mostly male) raft together in the harbor at the mouth of Elkhorn Slough, and more than 50 females and pups, and a few territorial males, utilize protected tidal creeks and adjacent waters further up the slough (Scoles et al. 2012). Sea otters occur in the harbor, in tidal channels, and where eelgrass (*Zostera marina*) is present. Seal Bend, which is located approximately 0.8 river miles west of the proposed project area, is an important area for sea otter activity due to the large patch of eelgrass present there. When not disturbed, sea otters also frequently come ashore to rest, interact, and groom (Scoles et al. 2012).

Sea otters use areas within the project footprint minimally (ESA/ESNERR 2016; USGS, Monterey Bay Aquarium, and ESNERR unpublished data). A maximum of two sea otters at any one time were observed within the project footprint during pre-project monitoring conducted in 2013 (Beck 2014). These animals were observed resting in water in area M3 of Minhoto Marsh (see

Figure 4–2 of ESA/ESNERR 2016) when tidal heights were approximately 4 feet or higher. The maximum length of time a sea otter was observed in M3 during any monitoring session was 1.5 hours (Beck 2014).

Up to 50 southern sea otters may be present in the area in and around Minhoto Marsh, Parsons Slough, Yampah Marsh, and the portion of Elkhorn Slough Channel that could be exposed to construction-related noise or disturbance (ESA/ESNERR 2016). Three main sea otter resting locations occur in these areas: One in the Parsons Slough Complex near the Avila Property and two near Yampah Island, southwest of the Union Pacific Railroad Bridge (see Figure 4–3 of ESA/ESNERR 2016; note that one marker is used to represent the two Yampah Island resting areas, which are located immediately to the west and east of its location on the map). Each of these areas consists of a territorial male and females with or without pups. Up to 35 sea otters were observed within the Parsons Slough Complex and Yampah Marsh during monitoring for an earlier project (ESNERR 2011). The closest area of concentrated sea otter activity to the project footprint is in Yampah Marsh, approximately 800 feet to the northeast (ESA/ESNERR 2016). The Yampah Marsh area is used heavily by females with and without pups for resting, hauling out, grooming, and (for females with pups) nursing (ESA 2016; USGS, Monterey Bay Aquarium, and ESNERR unpublished data).

Potential Impacts of the Proposed Action on Sea Otters

In this section we provide a qualitative discussion of the potential impacts of the proposed project. The “Estimated Take by Incidental Harassment” section later in this document includes a quantitative analysis of the number of individuals that may be taken by Level B harassment as a result of this activity. Sea otters that have been observed to use Minhoto Marsh would be prevented from accessing the area and would be displaced to other areas of Elkhorn Slough for the duration of the project. Sea otters using the marsh areas adjacent to the project site for resting and foraging would be exposed to construction noise and activity, which could deter them from using these areas and displace them to adjacent areas of Elkhorn Slough. If sheet pile (rather than an earthen dam or inflatable dam) is required to isolate the construction area from tidal waters, vibratory hammering would increase ambient noise levels at the site for 4 days. Noise generated by vibratory pile driving

could cause sea otters that forage or rest in the portion of the main channel adjacent to the restoration area to relocate temporarily to nearby areas. Behavioral changes resulting from disturbance could include startle responses, the interruption of resting behaviors (while in water or hauled out on pickleweed), and changes in foraging patterns. Impacts of the proposed project are limited to behavioral disturbance that may reach the threshold of Level B harassment. These impacts could result from airborne noise and visual disturbance caused by the presence of construction equipment and workers over a period of 11 months and (if sheet pile installation is required) from underwater noise caused by vibratory pile driving over a 4-day period.

Relatively little is known regarding the effects of noise on sea otters, but they have not been reported to be particularly sensitive to noise disturbance, especially in comparison to other marine mammals (Riedman 1983, 1984). Many marine mammals depend on acoustic cues for vital biological functions, such as orientation, communication, locating prey, and avoiding predators. However, sea otters are not known to use acoustic information to orient or to locate prey, nor are they known to communicate underwater. Ghaul and Reichmuth (2014) obtained aerial and underwater audiograms for a captive adult male sea otter and evaluated his hearing in the presence of noise. In air, the sea otter’s hearing was similar to that of a sea lion (*Zalophus californianus*) but less sensitive to high-frequency (greater than 22 kHz) and low-frequency (less than 2 kHz) sounds than terrestrial mustelids. Underwater, the sea otter’s hearing was less sensitive than that of sea lions and other pinnipeds, particularly at frequencies below 1 kHz. Critical ratios were more than 10 dB above those measured in pinnipeds, suggesting that sea otters have a relatively poor capacity to detect acoustic signals in noise.

Observed responses of wild sea otters to disturbance are highly variable, probably reflecting the level of noise and activity to which they have been exposed and become acclimated over time and the particular location and social or behavioral state of that individual (G. Bentall pers. comm. 2010). Sea otters appeared to be relatively undisturbed by pile driving activities in Elkhorn Slough during the construction of the Parsons Slough Sill (adjacent to the Minoto-Hester Marsh), with many showing no response to pile driving and generally reacting more strongly to passing vessels associated

with construction than to the sounds of machinery (ESNERR 2011). Sea otters in Elkhorn Slough are likely acclimated to loud noises, as they occupy an area near an active railroad track, which produces in-air sound levels comparable to those produced by the vibratory driving of H piles (ESNERR 2011). Approximately 15–20 trains pass through Elkhorn Slough each day within 400 feet of the easternmost portion of the project area (Vinnedge Environmental Consulting 2010). A vehicle dismantling and recycling yard is located approximately 300 feet from the project area.

The proposed construction activity may generate airborne noise above ambient levels or create a visual disturbance (during typical construction hours/workdays) for a period of 11 months. However, only work in the northern and eastern portions of Minhoto Marsh would be expected to disturb sea otters due to their proximity to the adjacent areas used by sea otters. Work in these portions of the marsh would likely be accomplished within approximately 6 months (132 construction days). Airborne noise produced by heavy earth-moving equipment such as backhoes and front-end loaders may produce sound levels of 80–90 dB re 20 μ Pa at 50 feet (Federal Highway Administration 2015). Vibratory driving of steel sheet piles, which may occur during 4 of the 136 total days of construction, is expected to produce maximum airborne sound levels of 97 dBA re 20 μ Pa at 33 feet and 90 dBA re 20 μ Pa at 98 feet (where dBA refers to dB with A-weighting designed to match the average frequency response of human hearing, which enables comparison of the intensity of noises with different frequency characteristics) (ESNERR 2011). Vibratory driving of sheet piles would generate underwater noise to which sea otters in the vicinity would be exposed while diving or performing other behaviors that cause immersion of the ears. However, because of acoustic shadowing due to the winding configuration of Elkhorn Slough, underwater sound transmission would be relatively limited. The likely extent of transmission of sound exceeding 120 dB re 1 μ Pa is pictured in Figure 6–4 of ESA/ESNERR (2016).

NMFS employs acoustic exposure criteria to define Level A harassment (injury) and Level B harassment (disturbance) resulting from sound for the marine mammal species under its jurisdiction. For underwater non-impulsive noise (which includes vibratory pile driving and removal), NMFS uses 219 dB re 1 μ Pa (cumulative 24-hour sound exposure level) as the threshold for Level A harassment of

otariid pinnipeds (*e.g.*, sea lions) (NMFS 2016) and 120 dB re 1 μ Pa (received level) as the threshold for Level B harassment. For airborne noise, NMFS uses 100 dB re 20 μ Pa (received level) as a guideline, but not formal threshold, for the onset of Level B harassment for pinnipeds other than harbor seals (79 FR 13991; March 12, 2014). NMFS does not have a guideline for the onset of Level A harassment of pinnipeds by airborne noise (A. Scholik-Schlomer, Office of Protected Resources, Marine Mammal and Sea Turtle Conservation Division, pers. comm. 2014). However, Southall et al. (2007) propose an injury criterion for sea lions exposed to airborne noise of 172.5 dB re 20 μ Pa.

In the absence of sufficient data on which to base noise exposure thresholds specific to sea otters, but in light of experimental evidence suggesting that the hearing sensitivities of sea lions and sea otters are generally comparable (although, as noted above, sea otter hearing appears to be less sensitive than sea lion hearing underwater), we use the thresholds, guidelines, and criteria applicable to sea lions as proxies. With regard to underwater noise, we use the thresholds adopted by NMFS for sea lions to evaluate whether noise exposure levels would constitute Level A or Level B harassment of sea otters. With regard to airborne noise, we use the guideline that NMFS uses for pinnipeds other than harbor seals to evaluate whether anticipated exposure levels resulting from this project would constitute Level B harassment of sea otters and the injury criterion proposed in Southall et al. (2007) for sea lions to evaluate whether the anticipated airborne noise exposures would constitute Level A harassment. Specifically, we use 219 dB re 1 μ Pa as the threshold for Level A harassment underwater and 120 dB re 1 μ Pa (for non-impulse sources) as the threshold for Level B harassment underwater. Similarly, we adopt for sea otters the 100 dB re 20 μ Pa guideline that NMFS uses for in-air Level B harassment of pinnipeds other than harbor seals. We use the Southall et al. (2007) criterion of 172.5 dB re 20 μ Pa for sea lions to approximate the airborne noise levels that may cause injury to sea otters. Given that sea otters are not known to use sound to communicate underwater, to orient, or to locate prey, and given sea otters' decreased sensitivity to underwater noise relative to that of sea lions, we acknowledge that these thresholds are likely highly conservative. As additional behavioral or other data on sea otter responses to sound become available, we may

determine that one or more of these thresholds are not applicable to sea otters.

Potential Effects of the Proposed Action on Sea Otter Habitat

Habitat within the project footprint would be inaccessible to sea otters for the duration of construction. However, these impacts would be minimal, as past surveys documented a maximum of two sea otters using this area. Construction activity would result in a slight increased risk of accidental water contamination from equipment refueling, fluid leakage, or maintenance activities within or near water bodies. Leaks or spills of petroleum hydrocarbon products found in construction equipment could have adverse effects on sea otters by contaminating their fur (interfering with thermoregulation) and through ingestion during grooming. Vibratory pile driving (if required by the project) would not be expected to alter the availability of prey species to sea otters in the waters or marshlands adjacent to the project site because these species are largely sessile benthic invertebrates. The proposed action would permanently alter habitat within the footprint of the construction area, but the restoration of salt marsh would benefit sea otters over the longer term by providing additional high-quality habitat within Elkhorn Slough for hauling out and foraging.

Potential Impacts on Subsistence Needs

The subsistence provision of the MMPA does not apply.

Mitigation Measures

CDFW has proposed the following measures to prevent Level A harassment (injury) and to reduce the extent of potential effects from Level B harassment (disturbance) to marine mammals.

1. A Service- and NMFS-approved biologist would conduct mandatory biological resources awareness training for construction personnel. The awareness training would be provided to all construction personnel to brief them on the need to avoid effects on marine mammals. If new construction personnel are added to the project, the contractor would ensure that the personnel receive the mandatory training before starting work.

2. A biological monitor approved by the Service and NMFS would monitor for marine mammal disturbance. Monitoring would occur at all times when work is occurring: (a) In water, (b) north of a line starting at 36°48'38.91 N. 121°45'08.03 W. and ending 36°48'38.91 N. 121°45'27.11 W., or (c) within 100

feet of tidal waters. When work is occurring in other areas, monitoring would be implemented for at least the first 3 days of construction. Monitoring would continue until there are 3 successive days of no observed disturbance, at which point monitoring would be suspended. Monitoring would resume when there is a significant change in activities or location of activities within the project area or if there is a gap in construction activities of more than 1 week. In these cases, monitoring would again be implemented for at least the first 3 days of construction and would not be suspended until there are 3 successive days of no observed disturbance. The biological monitor would have the authority to stop project activities if marine mammals approach or enter the exclusion zone. Biological monitoring would begin 0.5-hour before work begins and will continue until 0.5-hour after work is completed each day. Work would commence only with approval of the biological monitor to ensure that no marine mammals are present in the exclusion zone.

3. To reduce the risk of potentially startling marine mammals with a sudden intensive sound, the construction contractor would begin construction activities gradually each day by moving around the project area and starting tractors one at a time.

4. Biological monitors would have authority to stop construction at any time for the safety of any marine mammals.

5. In-water construction work would occur only during daylight hours when visual monitoring of marine mammals can be implemented. No in-water work would be conducted at night.

6. If sheet piles are used to isolate construction activities from tidal action, all piles would be installed using a vibratory pile driver, and an exclusion zone would be implemented. Because the area within which underwater sound pressure levels are expected to reach or exceed 190 dB re 1 μ Pa is less than a foot, the radius of the exclusion zone would be set at a minimum of 49 feet to prevent the injury of marine mammals from machinery. Pile extraction or driving would not commence (or re-commence following a shutdown) until marine mammals are not sighted within the exclusion zone for a 15-minute period. If a marine mammal enters the exclusion zone during sheet pile work, work would stop until the animal leaves the exclusion zone.

7. If marine mammals are present within the work area, they would be allowed to leave on their own volition.

If they are not leaving the work area on their own, coordination with NMFS or the Service (as appropriate) would occur to ensure a government official be present should an animal require flushing from within the footprint of the construction area.

8. Fuel storage and all fueling and equipment maintenance activities would be conducted at least 100 feet from subtidal and intertidal habitat.

Monitoring and Reporting

CDFW would follow a detailed monitoring plan developed in consultation with the Service and NMFS. A Service- and NMFS-approved biological monitor would monitor for marine mammal disturbance. Monitoring would occur as described in Mitigation Measure #2 above. Throughout construction activities that require a monitor, the biological monitor would maintain a log that documents numbers of marine mammals present before, during, and at the conclusion of daily activities. The monitor would record basic weather conditions and marine mammal behavior. A final report would be submitted to the Service and NMFS within 90 days of the conclusion of monitoring efforts. The report would detail the monitoring protocol, summarize the data recorded during monitoring, and contain an estimate of the number of marine mammals, by species, that may have been harassed.

Estimated Take by Incidental Harassment

Based on the proposed construction methodology and mitigation, including use of an exclusion zone, no Level A harassment of southern sea otters is anticipated as a result of the proposed project. Anticipated received noise levels would remain well below the thresholds established for Level A harassment. Behavioral harassment (Level B) could result from visual disturbance and in-air noise of 100 dB re 20 μ Pa or greater for a period of 132 days and (if pile driving is required by the project) visual disturbance, in-air noise of 100 dB re 20 μ Pa or greater, and underwater continuous noise of 120 dB re 1 μ Pa or greater for a period of 4 days.

In order to quantify take that may occur incidental to the specified activity, we determine the area that may be subject to project-related disturbance, estimate the number of sea otters likely to be present in that area, and multiply the number of sea otters by the number of days they could be disturbed during the project. Because airborne noise attenuates rapidly, and because of the distance of the project site from areas of

concentrated sea otter activity (the closest such area, Yampah Marsh, is approximately 800 feet away), it is likely that few sea otters will be exposed to noise levels exceeding the 100 dB re 20 μ Pa threshold. The area potentially subject to visual disturbance from construction activity is larger than and inclusive of the area potentially exposed to airborne sound exceeding the threshold for Level B harassment. Accordingly, we do not evaluate the number of sea otters exposed to airborne noise separately from the number of sea otters exposed to visual disturbance.

Vibratory pile driving (if required) would generate visual disturbance and in-air and underwater noise for a period of 4 days. The portion of Elkhorn Slough Channel that could be exposed to underwater noise of 120 dB re 1 μ Pa or greater during pile driving is pictured in Figure 6–4 of ESA/ESNERR (2016). An estimated 15 sea otters may use this portion of the channel for foraging or traveling from one location to another. The area that could potentially be affected by visual disturbance and in-air noise of 100 dB re 20 μ Pa or greater during pile driving includes Minhoto Marsh, Parsons Slough, and Yampah Marsh, which are utilized by an average of 35 sea otters (ESA/ESNERR 2016). Up to 50 sea otters may be present on land or in water and potentially affected by vibratory pile driving for 4 days, resulting in an estimated 200 instances of take.

After sheet piles are installed (or if an earthen dam or an inflatable dam is used instead), the project site would be isolated from aquatic areas, and sea otters would no longer be able to access the work area. At that time, sea otters outside of the work area would be subject to reduced levels of disturbance. An average of 10 sea otters per day (a subset of the 50 that may be affected by vibratory pile driving) could be affected by visual disturbance and in-air noise of 100 dB re 20 μ Pa or greater during the subsequent 132 days of construction work in the northern and eastern portions of the Minhoto Marsh, resulting in approximately 1,320 takes.

Findings

We propose the following findings regarding this action:

Negligible Impact

We find that any incidental take by harassment that is reasonably likely to result from the proposed project would not adversely affect the southern sea otter by means of effects on rates of recruitment or survival, and would, therefore, have no more than a negligible impact on the species or stock

(all southern sea otters are considered to belong to a single stock). In making this finding, we considered the best available scientific information, including: (1) The biological and behavioral characteristics of the species; (2) information on distribution and abundance of sea otters within the area of the proposed activity; (3) the potential sources of disturbance during the proposed activity; and (4) the potential response of sea otters to disturbance.

The estimated 200 potential takes (affecting up to 50 sea otters per day) during a total of 4 days of vibratory pile driving, if required by the project, and 1,320 potential takes (affecting up to 10 sea otters per day over a period of 132 days) during subsequent construction activity are expected to result in negligible impact for the following reasons: Received noise levels would remain well below the thresholds established for Level A harassment; sea otters do not appear to be particularly sensitive to noise (and often do not react visibly to it); and any behavioral reactions to noise or visual disturbance are expected to be temporary and of short duration. In particular, the estimate of the number of sea otters that could be harassed by exposure to project-related underwater sound based on the 120 dB threshold may overstate impacts because this threshold is sometimes at or even below the ambient noise level in certain locations. Additionally, disturbance resulting from project activities would affect only a small portion of the sea otter habitat available to and used by sea otters in Elkhorn Slough.

The mitigation measures outlined above are intended to minimize the number of sea otters that could be disturbed by the proposed activity. Any impacts to individuals are expected to be limited to Level B harassment of short duration. Responses of sea otters to disturbance would most likely be common behaviors such as diving and/or swimming away from the source of the disturbance. No take by injury or death is anticipated. Because any Level B harassment that occurs would be of short duration, and because no take by injury or death is anticipated, we find that the anticipated harassment caused by the proposed activities is not expected to adversely affect the species or stock through effects on annual rates of recruitment or survival.

Our finding of negligible impact applies to incidental take associated with the proposed activity as mitigated through this authorization process. This authorization establishes monitoring and reporting requirements to evaluate

the potential impacts of the authorized activities, as well as mitigation measures designed to minimize interactions with, and impacts to, sea otters.

Small Numbers

For small numbers take analysis, the statute and legislative history do not expressly require a specific type of numbers analysis, leaving the determination of “small” to the agency’s discretion. The sea otter population in California consists of approximately 3,272 animals. The number of sea otters that could potentially be taken by harassment in association with the proposed project, approximately 50 animals, is 1.5 percent of the population size. We find that the number of sea otters utilizing the affected area is small relative to the size of the population.

Impact on Subsistence

The subsistence provision of the MMPA does not apply to southern sea otters.

Endangered Species Act

The proposed activity will occur within the range of the southern sea otter, which is listed as threatened under the ESA. CDFW has requested a Pre-Construction Notification (PCN) under U.S. Army Corps of Engineers’ (Corps’) Nationwide Permit (NWP) 27 (USACE 2012). The Corps has initiated interagency consultation under section 7 of the ESA with the Service’s Ventura Fish and Wildlife Office. We will also complete intra-Service section 7 consultation on our proposed issuance of the IHA.

National Environmental Policy Act (NEPA)

The types of impacts associated with aquatic habitat restoration, establishment, and enhancement activities are described in NWP 27. The analyses in the NWP and the coordination undertaken prior to its issuance fulfill the requirements of NEPA (42 U.S.C. 4321 *et seq.*). The Service will review the Decision Document for NWP 27 and decide either to adopt it or to prepare its own NEPA document before making a determination on the issuance of an IHA. Our analysis will be completed prior to issuance or denial of the IHA and will be available at <http://www.fws.gov/ventura/endangered/species/info/sso.html>.

Government-To-Government Relations With Native American Tribal Governments

In accordance with the President’s memorandum of April 29, 1994, “Government-to-Government Relations with Native American Tribal Governments” (59 FR 22951), Executive Order 13175, Secretarial Order 3206, Department of the Interior Secretarial Order 3317 of December 1, 2011 (Tribal Consultation and Policy), the Department of the Interior’s manual at 512 DM 2, and the Native American Policy of the Service, January 20, 2016, we readily acknowledge our responsibility to communicate meaningfully with federally recognized Tribes on a Government-to-Government basis. We have evaluated possible effects on federally recognized Indian Tribes and have determined that there are no effects.

Proposed Authorization

The Service proposes to issue CDFW an IHA for the nonlethal, incidental, unintentional take by level B harassment of small numbers of southern sea otters while the applicant is completing the Minhoto-Hester Marsh Restoration Project in Elkhorn Slough, Monterey County, California. The 1-year authorization would begin on the date of issuance, with an anticipated project start date between January 2017 and June 2017. Authorization for incidental take beyond the 1-year period would require a request for renewal.

The final IHA would incorporate the mitigation, monitoring, and reporting requirements discussed in this proposal. The applicant would be responsible for following those requirements. This authorization would not allow the intentional taking of sea otters, nor take by injury or death.

If the level of activity exceeded that described by the applicant, or the level or nature of take exceeded those projected here, the Service would reevaluate its findings. The Secretary may modify, suspend, or revoke an authorization if the findings are not accurate or the mitigation, monitoring, and reporting requirements described in this notice are not being met.

Request for Public Comments

The Service requests that interested persons submit comments and information concerning this proposed IHA. For information on the references cited in this notice, see **ADDRESSES**.

Consistent with section 101(a)(5)(D)(iii) of the MMPA, we are opening the comment period on this proposed authorization for 30 days (see

DATES). We intend any final action resulting from this proposal to be as accurate and as effective as possible. Therefore, we request comments or suggestions on this proposed authorization.

We particularly seek comments concerning:

- Whether the proposed authorization, including the proposed activities, will have a negligible impact on the species or stock of the southern sea otter.
- Whether there are any additional provisions we may wish to consider for ensuring the conservation of the southern sea otter.

You may submit your comments and materials concerning this proposed authorization by one of the methods listed in **ADDRESSES**. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: We issue this notice under the authority of the MMPA (16 U.S.C. 1371 *et seq.*).

Dated: January 6, 2017.

Paul Souza,

Regional Director, Pacific Southwest Region.

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DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[17X.LLAKF02000. L16100000. DR0000. LXSS094L0000]

BLM Director's Response to the Alaska Governor's Appeal of the BLM Alaska State Director's Governor's Consistency Review Determination for the Eastern Interior Proposed Resource Management Plan and Final Environmental Impact Statement

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: This notice contains the Director of the Bureau of Land Management's (BLM) response to the Alaska Governor's appeal of the BLM Alaska State Director's response to the State of Alaska's Governor's consistency review letter for the Eastern Interior

Proposed Resource Management Plan (PRMP) and Final Environmental Impact Statement (FEIS). The BLM Director determined not to accept the recommendations of the Alaska Governor's consistency review letter.

FOR FURTHER INFORMATION CONTACT:

Leah Baker, Division Chief for Decision Support, Planning and NEPA, at 202-912-7282. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1-800-877-8339 to contact the above individual during normal business hours. FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: On July 29, 2016, the BLM released the PRMP and FEIS for the Eastern Interior Resource Management Plan in Alaska. In accordance with the regulations at 43 CFR 1610.3-2(e), the BLM submitted the PRMP and FEIS for a 60-day Governor's Consistency Review. On September 28, 2016, the Governor of Alaska submitted a Governor's Consistency Review letter to the BLM Alaska State Director asserting inconsistencies between the PRMP and State land use plans, programs, and policies.

After careful consideration of the concerns raised in the Governor's Consistency Review letter, the State Director decided not to adopt the recommendations made by the Governor. On October 12, 2016, the State Director sent a written response to the Governor describing the reasons for which the State Director believes that the PRMP is consistent with State land use plans, policies, and programs.

On November 8, 2016, the Governor appealed the BLM Alaska State Director's decision to not accept his recommendations to the BLM Director. In the Governor's appeal letter, the State of Alaska requested the BLM Director to reconsider the issues and recommendations raised in the Governor's Consistency Review letter. The BLM Director issued a final response to the Governor that declined to accept the recommendations of the Governor and affirmed the BLM State Director's decision. Pursuant to 43 CFR 1610.3-2(e), the basis for the BLM Director's determination on the Governor's appeal is published verbatim below.

"This letter addresses your appeal of the response provided by the Bureau of Land Management (BLM) Alaska State Director regarding your consistency review of the Eastern Interior Proposed Resource Management Plan and Final

Environmental Impact Statement (referred to hereafter as the PRMP or plan). The Governor's consistency review is an important part of the BLM land use planning process, and we appreciate the significant time and attention that you and your staff have committed to this effort.

The BLM developed the Eastern Interior PRMP with extensive local involvement. As a result of more than 15 months of public comment periods, we received 590 comments, including those from the State of Alaska, Chalkyitsik Village Council, Gwichyaa Zhee Gwich'in Tribal Government, miners from the Fortymile area, and industry groups. Of the total comments, 171 submissions were from rural Alaska residents who qualify as Federal subsistence users. All of these stakeholder groups provided important information about their current and anticipated future uses of the lands in the planning area.

I believe that this effort has led to the creation of a strong resource management plan that properly balances responsible development with the protection and conservation of subsistence use, important habitats for fish and wildlife, and other special values in the planning area. For example, the plan recommends opening more than one million acres of currently-withdrawn lands to mineral location, entry, and leasing, while also providing protection of priority habitats for caribou, Dall sheep, and other wildlife critical for subsistence use.

The applicable regulations at 43 CFR 1610.3-2(e) provide you with the opportunity to appeal the State Director's decision to not accept the recommendations you made in your consistency review letter. These regulations also guide my review of your appeal. In reviewing your appeal, I must first consider whether you have identified inconsistencies with State or local plans, policies, or programs. If such inconsistencies are identified, I then must consider whether your recommendations both address the inconsistencies and provide for a reasonable balance between the national interest and the State's interest.

In your consistency review letter, you identified three key issues that the Alaska State Director determined to be outside the scope of the Governor's consistency review: The PRMP is inconsistent with Federal statutes implementing the goals of the Alaska Statehood Act that protect the State's resource management responsibilities; the PRMP is inconsistent with previous BLM plans and the BLM's multiple use mandate; and the PRMP frustrates the

State and Federal governments' obligations under the Statehood Act and the Alaska Land Transfer Acceleration Act.

Your letter also stated that the PRMP is inconsistent with State land use plans, programs, and policies, which the State Director responded to in greater depth. While you raised multiple issues in both your consistency review and appeal letters, your overarching recommendation to address these issues was to revoke all Alaska Native Claims Settlement Act (ANCSA) 17(d)(1) withdrawals. Further, in your consistency review letter, you requested that recommendations for new mineral withdrawals be removed.

As described in this letter and supported by the State Director's response to your consistency letter, there is a strong national interest in protecting subsistence use and conserving important habitats for fish and wildlife. I find that the recommendations in your letter do not meet the standard for granting your appeal. I agree with the State Director that the issues dismissed in the response to your consistency review do not identify inconsistencies with State resource related plans, policies, or programs. Nevertheless, I have fully considered these issues as well as your responses to the State Director's findings. Below is my review of the issues and recommendations presented in your appeal letter.

1. The plan does not respect the congressional mandate in the Alaska National Interest Lands Conservation Act (ANILCA) to make multiple use lands not already designated as conservation system units available for intensive use, and instead applies layers of protective measures to buffer conservation system units within the planning area (e.g., the Fortymile Wild and Scenic River).

Upon review, I have determined that the PRMP is consistent with the provisions of ANILCA. As you are aware, ANILCA § 101(d) states that the designation and disposition of the public lands pursuant to this Act represent a proper balance between the reservation of national conservation system units and those public lands necessary and appropriate for more intensive use and designation, further stating that Congress believes the need for future legislation designating new conservation system units, new national conservation areas, or new national recreation areas, to be "obviated." The PRMP does not recommend designating any new conservation system units, national conservation areas, or national recreation areas, but rather recommends

revoking ANCSA 17(d)(1) withdrawals on a total of approximately 1.7 million acres in order to open these lands to mineral location entry and leasing, including 1.1 million acres of the Fortymile Subunit. While the PRMP does recommend new withdrawals under the Federal Land Policy and Management Act (FLPMA), this action is not precluded by ANILCA. Specifically, ANILCA (§ 1326(a)) outlines a process for withdrawing lands in Alaska, which indicates that Congress did envision the possibility of future withdrawals. Such withdrawals are consistent with ANILCA and Secretarial withdrawal authorities. The PRMP recommends only temporarily retaining the ANCSA 17(d)(1) withdrawals until new withdrawals under FLPMA can be enacted in these areas.

2. The plan relies on outdated ANCSA 17(d)(1) withdrawals to support restrictions on access, use, and resource development instead of recognizing that existing Federal and State environmental laws and regulations already protect resource values.

The BLM recognizes that Federal and State laws and regulations provide for the protection of resource values. FLPMA and its implementing regulations are included among these Federal laws. FLPMA mandates that the BLM manage on the basis of multiple use and sustained yield, and makes clear that the term "multiple use" does not mean that every use is appropriate for every acre of public land. Rather, the Secretary can "make the most judicious use of the land for some or all of these resources or related services over areas large enough to provide sufficient latitude for periodic adjustments in use . . ." (FLPMA § 103(c)).

In your appeal letter, you reference Article 8, Section 2 of the Alaska State Constitution, which states, "[t]he legislature shall provide for the utilization, development, and conservation of all natural resources belonging to the State, including land and waters, for the maximum benefit to the people." You also highlight similarities between State statutes and FLPMA, both of which provide for the balance of resource development and conservation. While section 102 of FLPMA expresses Congressional policy that public lands be managed in a manner which recognizes the Nation's need for domestic sources of minerals, that same section also references protection of the quality of scientific, scenic, historical, ecological, environmental, air and atmospheric, water resource, and archeological values, and FLPMA section 103(c)

expressly includes similar values in its definition of multiple use (including values such as "recreation . . . wildlife and fish, and natural scenic, scientific, and historical values").

The BLM also recognizes that all of the ANCSA 17(d)(1) withdrawals should not remain in place. As previously mentioned, the PRMP recommends revoking ANCSA 17(d)(1) withdrawals on approximately 1.7 million acres to open these lands for mineral entry. The PRMP recommends retaining certain portions of these withdrawals, but only until recommended withdrawals under FLPMA can be put in place. The PRMP also recommends eventual revocation of all ANCSA 17(d)(1) withdrawals to clean up the land record and remove duplicate withdrawals.

Your appeal states that the plan provides no explanation as to why existing laws and regulations provide insufficient protection for resource values. However, I find that the effects of the proposed alternative, including the rationale for these actions, are adequately analyzed and disclosed in the PRMP/FEIS. I concur with the determination in the PRMP that additional protections, such as FLPMA withdrawals to protect water quality and river values, are warranted.

3. The plan frustrates the State's ability to prioritize land selections and interferes with the State's ability to develop a resource-based economy.

While I have fully considered your concerns, I concur with the State Director's response that these statements do not identify inconsistencies with State plans, policies, or programs. In your appeal, you state that the PRMP impedes the State's ability to prioritize land selections. Based on analysis completed by BLM Alaska in June 2016, only an estimated 197,100 acres of the State's top three priorities of top-filed lands are encumbered solely by 17(d)(1) withdrawals on a statewide basis. Affected lands within the planning area would be even less. The State is currently over-selected on their land entitlement by 242 percent.

Further, in regards to the assertion that retaining 17(d)(1) withdrawals interferes with the State's ability to explore, locate, and define the mineral resource on large tracts of lands identified for selection, all State and Native-selected lands are segregated from mineral entry. Should 17(d)(1) withdrawals be revoked, the lands are not open to the staking of mining claims until the selections are relinquished, including State selections. Once a 17(d)(1) withdrawal is revoked and the State's top-filing attaches to a selection, the State's selection itself segregates the

land and makes it unavailable for mining claims, until such time as the selection is requested by the State and tentatively approved. For the reasons described throughout this letter, I do not think the plan will interfere with the State's ability to develop a resource-based economy, but that the PRMP will promote future opportunities for mineral exploration and development, where appropriate.

4. The plan does not provide sustainable opportunities for mineral exploration or development consistent with State area plans, including areas in the White Mountain National Recreation Area (NRA) that have high potential for rare earth elements.

In your consistency review and appeal letters, you assert that the PRMP preempts mineral exploration and development, and by doing so, the PRMP is inconsistent with State plans, policies, and programs. However, I concur with the State Director's finding that the PRMP is consistent with the State's plans, policies, and programs, including the State's policy to make mineral resources available for development. As noted in the State Director's response, the PRMP recommends revoking ANCSA 17(d)(1) withdrawals on 1.7 million acres to open lands to mineral location, entry, and leasing, including 1.1 million acres in the Fortymile Subunit, 4,000 acres in the White Mountains Subunit, 547,000 acres in the Draanjik (Upper Black River) Subunit adjacent to State and State-selected land, and 30,000 acres in the Steese Subunit adjacent to State land. These recommendations are consistent with making mineral resources available for mineral development.

Moreover, revoking the ANCSA 17(d)(1) withdrawals would not allow for new mining claims in the White Mountains NRA, as that area would remain withdrawn from the mining law by ANILCA. As noted in the response to comments on FEIS pp. 1520–1521, the PRMP recommends maintaining the ANILCA withdrawals for the Steese NCA and White Mountains NRA. It also recommends to the Secretary that the ANCSA 17(d)(1) withdrawals (Public Land Orders 5180 and 5179) be revoked as applied to these areas since they are duplicative of the ANILCA withdrawals and thus not necessary. Additionally, Public Land Order 5180 does not close the national conservation area to location of metalliferous mining claims (such as gold), so its protective effect is limited. Removing the 17(d)(1) withdrawals would clean up the public land record by removing duplicative

withdrawals, but it would not result in opening the lands to the mining law.

Your overarching recommendation is to revoke all ANCSA 17(d)(1) withdrawals, unconditionally. However, based on the foregoing, I find that the recommendations provided in your appeal letter do not meet the standard identified above for granting an appeal in accordance with 43 CFR 1610.3–2(e). Therefore, I affirm the Alaska State Director's response to your finding of inconsistency and respectfully deny your appeal. The reasons outlined above for my decision on your appeal will also be published in the **Federal Register** pursuant to the applicable BLM regulations.

Further, please note that the BLM gave due consideration to the State's concerns raised in the protest letter dated August 29, 2016. For a detailed response to these issues, many of which were raised in your consistency review letter, I refer you to the Director's Protest Resolution Report.

The BLM and the State of Alaska have a long history of working cooperatively on the development of resource management plans. I appreciate the resources and input that you and your staff have put into the process of developing the PRMP for the Eastern Interior planning area. As mentioned, I believe this plan balances responsible development with the protection and conservation of subsistence use, important habitats for fish and wildlife, and other special values. I look forward to our continued coordination as our teams work together to implement this plan."

Authority: 43 CFR 1610.3–2(e).

Kristin Bail,

Assistant Director, Resources and Planning.

[FR Doc. 2017–01199 Filed 1–18–17; 8:45 am]

BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

**[LLAZP02000.L54100000.FR0000.
LVCLA15A5240.241A; AZA–36488 and AZA–
36156]**

Notice of Realty Action: Application for Conveyance of Federally Owned Mineral Interests in Maricopa County, AZ

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) is processing an application under section 209 of the

Federal Land Policy and Management Act of 1976 (FLPMA) to convey the federally owned mineral interests in a 799.57-acre parcel of land, located in Maricopa County, Arizona, to the surface owner, REO Funding Solution IV, LLC. Publication of this notice temporarily segregates the federally owned mineral interests in the land covered by the application from all forms of appropriation under the public land laws, including the mining laws, for up to 2 years while the BLM processes the application.

DATES: Interested persons may submit written comments to the BLM at the address listed below on or before March 6, 2017.

ADDRESSES: Bureau of Land Management, Phoenix District Office, 21605 North 7th Avenue, Phoenix, AZ 85027. Detailed information concerning this action is available for review at this address.

FOR FURTHER INFORMATION CONTACT:

Benedict Parsons, Realty Specialist, at the address above, or by telephone at 623–580–5637, or email at bparsons@blm.gov. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 1–800–877–8339 to contact the above individual during business hours. The Service is available 24 hours a day, 7 days a week, to leave a message or question for the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The BLM is processing an application under section 209 of the Federal Land Policy and Management Act (FLPMA), 43 U.S.C. 1719(b), to convey the federally owned mineral interests that aggregate 799.57 acres, situated in Maricopa County, Arizona. The location of the federally owned mineral interest proposed for conveyance is intended to be identical in location as the privately owned surface interest of the applicant, and is described as follows.

AZA–036156

Gila and Salt River Meridian, Maricopa County, Arizona
T. 6 N., R 4 E.,

Parcel No. 1

A parcel of land situated in the southwest quarter of section 12, being more particularly described as follows:

COMMENCING at the southwest section corner of said section 12, which bears North 89°14'17" West, a distance of 2644.37 feet from the south ¼ section corner of said section 12;

THENCE South 89°14'17" East, along the south section line of said southwest ¼ of section 12, a distance of 330.55 feet to the point of beginning;

THENCE North 0°12'34" West, leaving said south section line, a distance of 1330.92 feet; THENCE South 88°54'41" East, a distance of 1198.47 feet;

THENCE South 0°08'53" East, a distance of 1324.06 feet to a point on said south section line of the southwest ¼;

THENCE North 89°14'17" West, along said south section line of the southwest ¼, a distance of 1196.92 feet to the point of beginning, containing 36.49 acres of land.

Parcel No. 2

A parcel of land situated in the south half of section 12, being more particularly described as follows:

COMMENCING at the southwest section corner of said section 12, which bears North 89°14'17" West, a distance of 2644.37 feet from the south ¼ section corner of said section 12;

THENCE South 89°14'17" East, along the south section line of said southwest ¼ of section 12, a distance of 1527.47 feet to the point beginning;

THENCE North 0°08'53" West, leaving said south section line, a distance of 1324.06 feet;

THENCE South 88°54'41" East, a distance of 1208.47 feet;

THENCE South 0°05'10" East, a distance of 1316.56 feet to a point on the south section line of the southeast ¼ of said Section 12;

THENCE North 89°36'43" West, along said south section line of the southeast ¼, a distance of 90.00 feet to the south ¼ section corner of said Section 12;

THENCE North 89°14'17" West, along the south section line of the southwest ¼ of said section 12, a distance of 1116.90 feet to the point of beginning, containing 36.60 acres of land.

Parcel No. 3

A parcel of land situated in the southeast ¼ of section 12, being more particularly described as follows:

COMMENCING at the south ¼ section corner of said section 12, which bears North 89°36'43" West, a distance of 2633.94 feet from the southeast section corner of said section 12;

THENCE South 89°36'43" East, along the south section line of the southeast ¼ of said section 12, a distance of 90.00 feet to the point of beginning;

THENCE North 00°05'10" West, leaving said south section line, a distance of 1316.56 feet;

THENCE South 88°54'51" East, a distance of 1232.04 feet to a point on the north and south center line of the southeast ¼ of said Section 12;

THENCE South 0°07'39" West, along said north and south center line of the southeast ¼ of said Section 12, a distance of 1301.46 feet to a point on said south section line of the southeast ¼;

THENCE North 89°36'43" West, along said south section line, a distance of 1226.97 feet to the point of beginning.

Excluding that portion within the Gift Lode Mining Claim, M.S. 4503, conveyed in U.S. Patent No. 1220768 dated June 23, 1961, and recorded in the records of Maricopa County, Arizona, at Docket 3753, Page 360, containing 35.35 acres of land.

Parcel No. 4

A parcel of land situated in the southwest ¼ of section 12, being more particularly described as follows:

COMMENCING at the southwest section corner of said section 12, which bears North 89°14'17" West, a distance of 2644.37 feet from the south ¼ section corner of said section 12;

THENCE South 89°14'17" East, along the south line of said southwest ¼ of section 12, a distance of 330.55 feet;

THENCE North 00°12'34" West, leaving said south section line, a distance of 1330.92 feet to the point of beginning;

THENCE North 00°12'34" West, a distance of 1330.92 feet to a point on the east and west center line of Section 12;

THENCE South 88°27'04" East, along said east and west center line, a distance of 1200.14 feet;

THENCE South 00°08'53" East, leaving said North line, a distance of 1321.24 feet;

THENCE North 88°54'41" West, a distance of 1198.47 feet to the point of beginning, containing 36.50 acres of land.

Parcel No. 5

A parcel of land situated in the south ½ of section 12, being more particularly described as follows:

COMMENCING at the southwest section corner of said section 12, which bears North 89°14'17" West, a distance of 2644.37 feet from the south ¼ section corner of said Section 12;

THENCE South 89°14'17" East, along the south section line of said southwest ¼ of section 12, a distance of 1527.47 feet;

THENCE North 0°08'53" West, leaving said south section line, a distance of 1324.06 feet to the point of beginning;

THENCE North 00°08'53" West, a distance of 1321.24 feet to a point on the east and west center line of said Section 12;

THENCE South 88°27'04" East, along said east and west center line, a distance of 1120.10 feet to the center ¼ section corner of section 12;

THENCE South 88°27'04" East, along the east and west center line of said Section 12, a distance of 90.04 feet;

THENCE South 00°05'10" East, a distance of 1311.49 feet;

THENCE North 88°54'41" West, a distance of 1208.47 feet to the point of beginning;

Excluding that portion within the Gift Lode Mining Claim, M.S. 4503, conveyed in U.S. Patent No. 1220768 dated June 23, 1961, and recorded in the records of Maricopa County, Arizona, at Docket 3753, Page 360, containing 35.46 acres of land.

Parcel No. 6

A parcel of land situated in the southeast ¼ of section 12, being more particularly described as follows:

COMMENCING at the south ¼ section corner of said section 12, which bears North 89°36'43" West, a distance of 2633.94 feet from the southeast section corner of said section 12;

THENCE South 89°36'43" East, along the south section line of the southeast ¼ of said section 12, a distance of 90.00 feet;

THENCE North 00°05'10" West, leaving said south section line, a distance of 1316.56 feet to the point of beginning;

THENCE North 00°05'10" West, a distance of 1311.49 feet to a point on the east and west center line of said Section 12;

THENCE South 88°27'04" East, along the said east and west center line, a distance of 1237.13 feet to a point on the north and south center line of the southeast ¼ of Section 12;

THENCE South 00°07'39" West, along said north and south center line, a distance of 1301.46 feet;

THENCE North 88°54'41" West, leaving said north and south center line, a distance of 1232.04 feet to the point of beginning;

Excluding that portion within the Gift Lode Mining Claim, M.S. 4503, conveyed by U.S. Patent No. 1220768 dated June 23, 1961, and recorded in the records of Maricopa County, Arizona, at Docket 3753, Page 360, containing 20.42 acres of land.

Parcel No. 7

A parcel of land situated in the northeast ¼ of section 12, being more particularly described as follows:

COMMENCING at the north ¼ section corner of said Section 12, which bears North 89°57'16" West, a distance of 2655.53 feet from the northeast section corner of said Section 12;

THENCE South 00°05'11" East, along the north and south center line of said section 12, a distance of 1150.23 feet to the point of beginning;

THENCE South 88°27'04" East, leaving said north and south center line, a distance of 1101.27 feet;

THENCE South 00°02'17" East, a distance of 1451.57 feet, to a point on the east and west center line of said section 12;

THENCE North 88°27'04" West, along said east and west center line, a distance of 1100.04 feet to the center ¼ section corner of said section 12;

THENCE North 00°05'11" West, along the north and south center line of said section 12, a distance of 1451.60 feet to the point of beginning;

Excluding that portion within the Gift Lode Mining Claim, M.S. 4503, conveyed by U.S. Patent No. 1220768 dated June 23, 1961, and recorded in the records of Maricopa County, Arizona, at Docket 3753, Page 360, containing 35.47 acres of land.

Parcel No. 8

A parcel of land situated in the northeast ¼ of section 12, being more particularly described as follows:

BEGINNING at the north ¼ section corner of said Section 12, which bears North 89°57'16" West, a distance of 2655.53 feet from the northeast section corner of said Section 12, being the point of beginning;

THENCE South 89°57'16" East, along the north section line of the northeast ¼ of said section 12, a distance of 1615.53 feet;

THENCE South 00°02'17" East, leaving said north section line, a distance of 1522.73 feet;

THENCE North 88°27'04" West, a distance of 513.91 feet to a point on the east line of Parcel No. 7, hereinbefore described;

THENCE North 00°02'17" West, a distance of 330.13 feet to the northeast corner of said Parcel No. 7;

THENCE North 88°27'04" West, a distance of 1101.27 feet to a point on the north and south center line of said Section 12;

THENCE North 00°05'11" West, along said north and south center line of said Section 12, a distance of 1150.23 feet to the point of beginning, containing 47.32 acres of land.

Parcel No. 9

A parcel of land situated in the northeast ¼ of section 12, being more particularly described as follows:

COMMENCING at the north ¼ section corner of said Section 12, which bears North 89°57'16" West, a distance of 2655.53 feet from the northeast section corner of said section 12;

THENCE South 89°57'16" East, along the north section line of said northeast ¼, a distance of 1615.53 feet to the point of beginning;

THENCE South 89°57'16" East, continuing along said north section line, a distance of 1040.00 feet to the northeast section corner of said Section 12;

THENCE South 00°02'17" East, along the east section line of said section 12, a distance of 1550.02 feet;

THENCE North 88°27'04" West, leaving said east section line, a distance of 1040.40 feet;

THENCE North 00°02'17" West, a distance of 1522.73 feet to the point of beginning, containing 36.68 acres of land.

Parcel Nos. 10 and 11

Sec. 1, NE¼SE¼ and SE¼SE¼, containing 80.00 acres of land (government record area).

Parcel No. 12

A parcel of land situated in the southeast ¼ of section 11, being more particularly described as follows:

BEGINNING at the southeast section corner of section 11, which bears North 89°14'17" West, a distance of 2644.37 feet from the south ¼ section corner of Section 12, being the point of beginning;

THENCE South 89°59'10" West, along the south section line of the southeast ¼ of said section 11, a distance of 620.83 feet;

THENCE North 00°11'08" West, leaving said south section line, a distance of 314.67 feet;

THENCE North 90°00'00" East, a distance of 620.58 feet, to the east section line of said section 11;

THENCE South 00°13'36" East, along the east section line of said section 11, a distance of 315.48 feet to the point of beginning, containing 4.48 acres of land.

Parcel No. 13

A parcel of land situated in the southeast ¼ of section 11, being more particularly described as follows:

COMMENCING at the southeast section corner of said section 11, which bears North 89°14'17" West, a distance of 2644.37 feet from the south ¼ section corner of Section 12;

THENCE South 89°59'10" West, along the south section line of the southeast ¼ of said section 11, a distance of 1310.93 feet;

THENCE North 00°11'13" West, a distance of 315.69 feet to the point of beginning;

THENCE North 00°11'13" West, a distance of 502.94 feet;

THENCE North 89°44'33" East, a distance of 454.34 feet;

THENCE South 00°11'13" East, a distance of 504.98 feet, to a point on the north line of Parcel No. 15, hereinafter described;

THENCE North 90°00'00" West, a distance of 454.34 feet to the point of beginning, containing 5.53 acres of land.

Parcel No. 14

A parcel of land situated in the southeast ¼ of section 11, being more particularly described as follows:

COMMENCING at the southeast section corner of said section 11, which bears North 89°14'17" West, a distance of 2644.37 feet from the south ¼ section corner of Section 12;

THENCE South 89°59'10" West, along the south section line of the southeast ¼ of said section 11, a distance of 1310.93 feet;

THENCE North 00°11'13" West, a distance of 315.69 feet;

THENCE South 90°00'00" East, a distance of 454.34 feet to the point of beginning;

THENCE North 00°11'13" West, a distance of 504.98 feet;

THENCE North 89°44'33" East, a distance of 345.66 feet;

THENCE North 00°11'08" West, a distance of 549.02 feet;

THENCE North 89°48'47" East, a distance of 9.99 feet;

THENCE 182.67 feet along an arc of a curve to the right having a radius distance of 135.00 feet, having a central angle of 77°31'39" and the long chord of which measures South 51°25'14" East, a distance of 169.05 feet;

THENCE South 12°39'24" East, a distance of 164.66 feet;

THENCE North 89°44'33" East, a distance of 332.78 feet, to the east section line of section 11;

THENCE South 00°13'44" East, along the east section line of said section 11, a distance of 262.91 feet;

THENCE South 00°13'36" East, a distance of 527.01 feet;

THENCE North 90°00'00" West, a distance of 620.56 feet, to the northeast corner of Parcel No. 15, hereinafter described;

THENCE North 00°11'08" West, a distance of 0.85 feet, to the northwest corner of Parcel No. 12, hereinbefore described;

THENCE North 90°00'00" West, a distance of 235.76 feet to the point of beginning;

EXCEPT that portion located within the NE¼SE¼ of said Section 11, containing 13.53 acres of land.

Parcel No. 15

A parcel of land situated in the southeast ¼ of section 11, being more particularly described as follows:

COMMENCING at the southeast section corner of said Section 11, which bears North 89°14'17" West, a distance of 2644.37 feet from the south ¼ section corner of Section 12;

THENCE South 89°59'10" West, along the south section line of the southeast ¼ of said section 11, a distance of 620.83 feet to the point of beginning;

THENCE South 89°59'10" West, along the south section line of the southeast ¼ of said section 11, a distance of 690.10 feet;

THENCE North 00°11'13" West, a distance of 315.69 feet;

THENCE North 90°00'00" East, a distance of 690.10 feet;

THENCE South 00°11'08" East, a distance of 315.52 feet to the point of beginning, containing 5.00 acres of land.

Parcel No. 16

A parcel of land situated in the southwest ¼ of section 12, being more particularly described as follows:

BEGINNING at the southwest section corner of said section 12, which bears North 89°14'17" West, a distance of 2644.37 feet from the south ¼ section corner of said Section 12, being the point of beginning;

THENCE South 89°14'17" East, along the south line of the southwest ¼ of Section 12, a distance of 330.55 feet;

THENCE North 00°13'36" West, leaving said south line, a distance of 838.92 feet;

THENCE North 88°27'04" West, a distance of 330.91 feet, to the west section line of said section 12;

THENCE South 00°13'36" East, along the west section line of said Section 12, a distance of 842.49 feet to the point of beginning, containing 6.38 acres of land.

The areas described for Parcels Nos. 1 through 16 aggregate 435.21 acres.

AZA-036488

Parcel No. 1

Gila and Salt River Meridian, Maricopa County, Arizona

T. 6 N., R. 4 E.,

Sec. 1, east 1210.00 feet of the NE¼SW¼, east 1210.00 feet of the SE¼NW¼, and the east 1210.00 feet of Lot 3.

EXCEPT those portions lying within the following described lands:

EXCEPTION PARCEL NO. 1

BEGINNING at the north ¼ section corner of said section 1, which bears South 89°38'30" West, a distance of 2652.21 feet from the northwest ¼ section corner of said Section 1, being the point of beginning;

THENCE South 00°10'19" West, a distance of 1980.03 feet;

THENCE North 89°38'30" West, a distance of 400.00 feet;

THENCE North 00°10'19" East, a distance of 1360.76 feet;

THENCE North 89°38'30" West, a distance of 810.00 feet;

THENCE North 00°10'19" East, a distance of 619.28 feet to a point on the north line of the northwest ¼ of said section 1;

THENCE South 89°38'29" East, along said north line, a distance of 1210.00 feet to the point of beginning;

EXCEPTION PARCEL NO. 2

COMMENCING at the north ¼ section corner of said section 1, from which the northwest section corner of said section 1 bears North 89°42'22" West, a distance of 2652.21 feet;

THENCE North 89°42'22" West, a distance of 1210.00 feet to the point of intersection with the west line of the east 1210.00 feet of the west ½ of Section 1;

THENCE South 00°06'00" West along said west line, a distance of 2502.98 feet to the point of beginning;

THENCE South 89°07'50" East, a distance of 805.67 feet;

THENCE South 15°34'27" West, a distance of 1473.72 feet to the point of intersection with the east and west center line of the southwest ¼ of said Section 1;

THENCE North 88°24'21" West, along said east and west center line, a distance of 415.55 feet to the point of intersection with the aforementioned west line of the east 1210.00 feet of the west ½ of Section 1;

THENCE North 00°06'00" East along said west line, a distance of 1420.32 feet to the point of beginning.

Containing 59.80 acres of land.

Parcel No. 2

Sec. 1, lots 1 and 2, S½NE¼, NE¼NW¼SE¼, S½NW¼SE¼, N½SW¼SE¼, SW¼SW¼SE¼, and N½SE¼SW¼SE¼.

Containing 224.56 acres of land.

Parcel No. 3

Sec. 12, E½SE¼.

Containing 80.00 acres of land.

The areas described for Parcels Nos. 1 through 3 aggregate 364.36 acres.

Section 209(b) of the FLPMA authorizes the conveyance of the federally owned mineral interests in land to the surface owner when the surface interest is not federally owned, upon payment of administrative costs. The objective is to allow consolidation of the surface and mineral interests when either one of the following conditions exist: (1) There are no known mineral values in the land; or (2) Where continued Federal ownership of the mineral interests interferes with or precludes appropriate non-mineral development and such development is a more beneficial use of the land than mineral development.

The applicant has deposited, a sum of funding sufficient to cover administrative costs, but not limited to, the cost for the mineral potential report.

Subject to valid existing rights, on January 19, 2017 the federally owned mineral interests in the land described above are hereby segregated from all forms of appropriation under the public lands laws, including the mining laws, while the application is being processed to determine if either one of the two specified conditions exists and, if so, to otherwise comply with the procedural requirements of 43 CFR part 2720. The segregative effect shall terminate upon: (1) Issuance of a patent or other document of conveyance as to such mineral interests; (2) Final rejection of the application; or (3) January 22, 2019, whichever occurs first.

Please submit all comments in writing to Benedict Parsons at the address listed

above. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made available to the public at any time. While you can ask in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 CFR 2720.1–1.

Leon Thomas,

Phoenix District Manager.

[FR Doc. 2017–01203 Filed 1–18–17; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MNES–058247]

Notice of Application for Withdrawal and Notification of Public Meeting; Minnesota

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The United States Forest Service (USFS) has filed an application with the Bureau of Land Management (BLM) requesting that the Secretary of the Interior withdraw, for a 20-year term, approximately 234,328 acres of National Forest System lands within the Rainy River Watershed on the Superior National Forest from disposition under the United States mineral and geothermal leasing laws, subject to valid existing rights. Publication of this notice temporarily segregates the lands for up to 2 years from the United States mineral and geothermal leasing laws while the withdrawal application is being processed.

DATES: Comments regarding this withdrawal proposal must be received by April 19, 2017. The BLM and the USFS will hold a public meeting in connection with the proposed withdrawal on March 16, 2017, from 5 p.m. to 7:30 p.m. Central Time (CT) at the Duluth Entertainment and Convention Center, 350 Harbor Drive, Duluth, MN 55802. During this 90-day comment period, the BLM and USFS will hold additional meetings in other areas of the State, notices of which will be provided in local newspapers or on agency Web sites. The USFS' 90-day scoping period associated with preparing an environmental impact statement (EIS) was announced on January 13, 2017 in the **Federal**

Register. The EIS will analyze the impacts of the proposed withdrawal and an amendment to the Superior National Forest Land and Resource Management Plan. Additional opportunities for public comment will be provided during the preparation of that EIS.

ADDRESSES: Comments regarding this withdrawal proposal should be sent to the Deputy State Director of Geospatial Services, Bureau of Land Management, Eastern States Office, 20 M Street SE., Suite 950, Washington, DC 20003; or by facsimile at 202–912–7710. Comments sent by email will not be accepted. The March 16, 2017, BLM and USFS public meeting location is the Duluth Entertainment and Convention Center, 350 Harbor Drive, Duluth, MN 55802.

FOR FURTHER INFORMATION CONTACT:

Dominica VanKoten, BLM Eastern States Office, 202–912–7756 during regular business hours, 8 a.m. to 4:30 p.m. Monday through Friday, except holidays. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 1–800–877–8339 to contact the above individual. The Service is available 24 hours a day, 7 days a week, to leave a message or question. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The applicant is the USFS. The application requests the Secretary of the Interior to withdraw National Forest System lands in the Superior National Forest from disposition under the United States mineral and geothermal leasing laws for a period of 20 years to protect and preserve the natural resources and waters located within the Rainy River Watershed that flow into the Boundary Waters Canoe Area Wilderness (BWCAW) and the Boundary Waters Canoe Area Wilderness Mining Protection Area (MPA) in northeastern Minnesota. The lands will remain open to other forms of use and disposition as may be allowed by law on National Forest System lands, including the disposition of mineral materials.

All the National Forest System Lands identified in the townships below and any lands acquired by the Federal government within the exterior boundaries described below are included in the withdrawal application. This area excludes the BWCAW and the Boundary Waters Canoe Area Wilderness MPA, as depicted on the map entitled Appendix B: Superior National Forest, dated December 5, 2016. This map is available from the BLM Eastern States Office at the address listed above, and from the USFS Superior National Forest office, 8901

Grand Ave. Pl, Duluth, Minnesota, 55808.

National Forest System Lands

Superior National Forest

4th Principal Meridian, Minnesota

Tps. 61 and 62 N., Rs. 5 W.

Tps. 60 to 62 N., Rs. 6 W.

Tps. 59 and 61 N., Rs. 7 W.

Tps. 59 to 61 N., Rs. 8 W.

Tps. 58 to 61 N., Rs. 9 W.

Tps. 57 to 62 N., Rs. 10 W.

Tps. 57 to 63 N., Rs. 11 W.

Tp. 59 N., R. 12 W.

Tps. 61 to 63 N., Rs. 12 W.

Tps. 61 to 63 N., Rs. 13 W.

Tp. 63 N., R. 15 W.

Tp. 63 N., R. 16 W.

Tps. 65 to 67 N., Rs. 16 W.

Tp. 64 N., R. 17 W.

The areas described contain approximately 234,328 acres of National Forest System lands in Cook, Lake, and Saint Louis Counties, Minnesota, located adjacent to the BWCAW and the MPA.

Non-Federal lands within the area proposed for withdrawal total approximately 190,321 acres in Cook, Lake and Saint Louis Counties. As non-Federal lands, these parcels would not be affected by the temporary segregation or proposed withdrawal unless they are subsequently acquired by the Federal Government. The temporary segregation and proposed withdrawal are subject to valid existing rights, which would be unaffected by these actions.

As stated in the application, the purpose of the requested withdrawal is to protect and preserve the natural resources and waters within the Rainy River Watershed that flow into the BWCAW and the MPA from the effects of mining and mineral exploration. Congress designated the BWCAW and established the MPA to protect and preserve the ecological richness of the lakes, waterways, and forested wilderness along the Canadian border. The protection of the Rainy River Watershed would extend the preservation of the BWCAW and MPA as well as Voyageurs National Park and Canada's Quetico Provincial Park, which are all interconnected through the unique hydrology of this region.

The application further states that the use of a right-of-way, interagency agreement, or cooperative agreement would not adequately constrain mineral and geothermal leasing to provide adequate protection throughout this pristine natural area.

According to the application, no alternative sites are feasible because the lands subject to the withdrawal application are the lands for which protection is sought from the impacts of exploration and development under the United States mineral and geothermal

leasing laws. No water will be needed to fulfill the purpose of the requested withdrawal.

The USFS will serve as the lead agency for the EIS analyzing the impacts of the proposed withdrawal. The USFS will designate the BLM as a cooperating agency. The BLM will independently evaluate and review the draft and final EISs and any other documents needed for the Secretary of the Interior to make a decision on the proposed withdrawal.

Records related to the application may be examined by contacting the individual listed in the **FOR FURTHER INFORMATION CONTACT** section above.

For a period until April 19, 2017, all persons who wish to submit comments, suggestions, or objections in connection with the withdrawal application may present their views in writing to the BLM Deputy State Director of Geospatial Services at the BLM Eastern States Office address noted in the **ADDRESSES** section above. Comments, including the names and street addresses of respondents, will be available for public review at that address during regular business hours.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Notice is hereby given that a public meeting in connection with the application for withdrawal will be held at Duluth Entertainment and Convention Center, 350 Harbor Drive, Duluth, Minnesota 55802 on March 16, 2017, from 5 p.m. to 7:30 p.m. CT. The USFS will publish a notice of the time and place in a local newspaper at least 30 days before the scheduled date of the meeting. During this 90-day comment period, the BLM and USFS will hold additional meetings in other areas of the State, notices of which will be provided in local newspapers or on agency Web sites.

For a period until January 21, 2017, subject to valid existing rights, the National Forest System lands described in this notice will be temporarily segregated from the United States mineral and geothermal leasing laws, unless the application is denied or canceled or the withdrawal is approved prior to that date. All other activities currently consistent with the Superior National Forest Land and Resource Management Plan could continue, including public recreation, mineral

materials disposition and other activities compatible with preservation of the character of the area, subject to USFS discretionary approval, during the segregation period.

The application will be processed in accordance with the regulations set forth in 43 CFR 2300.

Karen E. Mouritsen,

State Director, Eastern States Office.

[FR Doc. 2017-01202 Filed 1-18-17; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNM004000 L91450000.EJ000
16X.LVDIG16ZGK00]

Notice of Application for a Recordable Disclaimer of Interest: Dimmit County, Texas

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) received an application for a Recordable Disclaimer of Interest (Disclaimer of Interest) from Gringita, Ltd. pursuant to the Federal Land Policy and Management Act of 1976 (FLPMA), as amended, and the regulations in 43 CFR subpart 1864, for certain mineral estate in Dimmit County, Texas. This notice is intended to inform the public of the pending application, give notice of BLM's intention to grant the requested Disclaimer of Interest, and provide a public comment period for the proposed Disclaimer of Interest.

DATES: Comments on this action should be received by April 19, 2017.

ADDRESSES: Written comments must be sent to the Deputy State Director, Lands and Resources, BLM, New Mexico State Office, P.O. Box 27115, Santa Fe, NM 87502-0115.

FOR FURTHER INFORMATION CONTACT: John Ledbetter, Realty Specialist, BLM Oklahoma Field Office, (405) 579-7172. Additional information pertaining to this application can be reviewed in case file TXNM114510 located in the Oklahoma Field Office, 201 Stephenson Parkway, Room 1200, Norman, Oklahoma 73072-2037. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1-800-877-8339 to contact the above individual during normal business hours. The Service is available 24 hours a day, 7 days a week, to leave a message or question with the

above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The purpose of this Disclaimer is to remove a cloud on the title of a mineral interest in Dimmit County, Texas.

In 1938, the Banking Commissioner of Texas, as receiver for the Commonwealth Bank and Trust Company (in liquidation), reported to have conveyed a one-half, non-participating royalty interest in the property described below to the Reconstruction Finance Corporation (RFC), an independent agency of the United States Government. However, the real property records of Dimmit County, and the records of the United States, do not indicate that the Commonwealth Bank and Trust Company ever obtained this one-half, non-participating royalty interest in the property prior to the 1938 Banking Commissioner's action. The BLM therefore believes that the United States does not own this interest in the property described below. However, the conveyance from the Banking Commissioner of Texas to the RFC creates a cloud on the title. Therefore, pursuant to Section 315 of FLPMA, the BLM proposes to disclaim any claim by the United States to this one-half, non-participating royalty interest in the property described below.

The lands are described as:

Dimmit County, Texas

Parcel One

393.5 acres, being 50.94 acres, H.R. Trammel Survey No. 487½, Abstract No. 1508 and 342.56 acres, James P. Trezevant Survey No. 487, Abstract No. 708.

Parcel Two

621.26 acres, M. Devereaux Survey No. 488, Abstract No. 52.

The area described contains 1,014.76 acres, more or less.

This proposed Disclaimer of Interest does not address any surface interest that may still be vested with the United States of America.

The public is hereby notified that comments may be submitted to the Deputy State Director, Lands and Resources at the address shown above within the comment period identified in the notice. Any adverse comments will be evaluated by the State Director who may modify or vacate this action and issue a final determination.

In the absence of any valid objection, this notice will become the final determination of the Department of the Interior and a Disclaimer of Interest may be issued 90 days from publication of this notice.

All persons who wish to present comments, suggestions, or objections in connection with the proposed Disclaimer of Interest may do so by writing to the Deputy State Director at the above address. Comments, including names and street addresses of commenters, will be available for public review at the BLM New Mexico State Office (see address above), during regular business hours, Monday through Friday, except Federal holidays. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 CFR 1864.2(a).

Melanie Barnes,

Acting Deputy State Director, Lands and Resources.

[FR Doc. 2017–01201 Filed 1–18–17; 8:45 am]

BILLING CODE 4310–FB–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NERO–22407;
PPNEHART00.PPMPSPD1Y.YM0000]

Harriet Tubman National Historical Park

AGENCY: National Park Service, Interior.

ACTION: Notice of establishment.

SUMMARY: As authorized by the National Defense Authorization Act for Fiscal Year 2015, the National Park Service announces that the Secretary of the Interior (Secretary) has established, in the State of New York, Harriet Tubman National Historical Park as a unit of the National Park System.

FOR FURTHER INFORMATION CONTACT: Rose Fennell, Deputy Regional Director, National Park Service, Northeast Regional Office at (617) 223–5137.

SUPPLEMENTARY INFORMATION: Section 3036 of the National Defense Authorization Act for Fiscal Year 2015, Public Law 113–291 includes a specific provision relating to establishment of this unit of the National Park System. To establish the national historical park, the Secretary must determine that a sufficient quantity of land, or interests in land, has been acquired to constitute a manageable park unit and must publish notice of the establishment of

the historical park in the **Federal Register** no later than 30 days after the Secretary makes a determination.

The National Park Service acquired by Bargain and Sale Deed the fee simple interests in the 0.5 acres at 47–49 Parker Street in Auburn, New York, on December 30, 2016. This property contains the historic Thompson Memorial AME Zion Church and the adjacent, two-story rectory.

On January 10, 2017, the Secretary of the Interior signed a Decision Memorandum determining that a sufficient quantity of land, or interests in land, had been acquired to constitute a manageable park unit. With the signing of this Decision Memorandum by the Secretary, the site to be known as the “Harriet Tubman National Historical Park” was established as a unit of the National Park System, effective January 10, 2017, and is subject to all laws, regulations, and policies pertaining to such units.

Dated: January 10, 2017.

Michael T. Reynolds,

Acting Director.

[FR Doc. 2017–01081 Filed 1–18–17; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NER–GETT–22575;
PPMPSPD1Z.YM0000, PPNEGETTS1]

Notice of the 2017 Meeting Schedule for Gettysburg National Military Park Advisory Commission

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: The National Park Service is hereby giving notice of the 2017 meeting schedule for the Gettysburg National Military Park Advisory Commission.

DATES: The Gettysburg National Military Park Advisory Commission will host two meetings, one on Thursday, April 13, 2017, and one on Thursday, September 14, 2017. Both scheduled meetings will begin at 7:00 p.m. and end at 9:00 p.m. (Eastern). Efforts have been made locally to ensure that the interested public is aware of the meeting dates.

ADDRESSES: Both meetings will be held at the Gettysburg National Military Park Museum and Visitor Center in the Ford Education Center, 1195 Baltimore Pike, Suite 100, Gettysburg, Pennsylvania 17325.

FOR FURTHER INFORMATION CONTACT: Ed Clark, Superintendent and Designated Federal Official, Gettysburg National

Military Park, 1195 Baltimore Pike, Suite 100, Gettysburg, Pennsylvania 17325, at (717) 334-1124 or via email ed_w_clark@nps.gov.

SUPPLEMENTARY INFORMATION: The Gettysburg National Military Park Advisory Commission was established by Public Law 101-377. The scheduled meetings will be open to the public. Each scheduled meeting will include presentations on the Gettysburg National Military Park Operational Update, and subcommittee reports. The April 13, 2017, meeting will also include the nomination of new officers. Any member of the public may file with the Commission a written statement with issues or concerns. The statement should be addressed to Gettysburg National Military Park Advisory Commission, 1195 Baltimore Pike, Gettysburg, Pennsylvania 17325 or email Supt_Gettysburg@nps.gov.

Before including your address, telephone number, email address, or other personal identifying information in your comments—you should be aware that your entire comment—including your personal identifying information may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public view, we cannot guarantee that we will be able to do so.

Alma Rippis,
Chief, Office of Policy.

[FR Doc. 2017-01122 Filed 1-18-17; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-AKRO-LACL-22690; PPAKAKROR4]
[PPMPRL1Y.LS0000]

Notice of an Open Public Meeting for the Lake Clark National Park Subsistence Resource Commission

AGENCY: National Park Service, Interior.
ACTION: Meeting notice.

SUMMARY: The National Park Service (NPS) is hereby giving notice that the Lake Clark National Park Subsistence Resource Commission (SRC) will hold a public meeting to develop and continue work on NPS subsistence program recommendations, and other related regulatory proposals and resource management issues.

DATES: The Lake Clark National Park SRC will meet from 1:00 p.m. to 4:00 p.m. or until business is completed on Wednesday, February 15, 2017, at the Pedro Bay Community Building, 2516

Mountain Circle, Pedro Bay, AK 99647. There will be a community luncheon prior to the meeting at 12:00 p.m. Teleconference participants must call the National Park Service office at (907) 644-3648, prior to the meeting to receive teleconference passcode information. For more detailed information regarding this meeting, or if you are interested in applying for SRC membership, contact Megan Richotte, Designated Federal Official and Acting Superintendent, at (907) 644-3639, or via email at megan_richotte@nps.gov, or Liza Rupp, Subsistence Manager, at (907) 644-3648, or via email at elizabeth_rupp@nps.gov or Clarence Summers, Subsistence Manager, at (907) 644-3603 or via email at clarence_summers@nps.gov.

ADDRESSES: The SRC will meet in the Pedro Bay Community Building, 2516 Mountain Circle, Pedro Bay, AK 99647.

SUPPLEMENTARY INFORMATION: The NPS is holding the meeting pursuant to the Federal Advisory Committee Act (5 U.S.C. Appendix 1-16). The NPS SRC program is authorized until Section 808 of the Alaska National Interest Lands Conservation Act, (16 U.S.C. 3118), title VII. SRC meetings are open to the public and will have time allocated for public testimony. The public is welcome to present written or oral comments to the SRC. SRC meetings will be recorded and meeting minutes will be available upon request from the Superintendent for public inspection approximately six weeks after the meeting. Before including your address, telephone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Proposed Meeting Agenda: The agenda may change to accommodate SRC business. The proposed meeting agenda for each meeting includes the following:

1. Call to Order—Confirm Quorum
2. Welcome and Introduction
3. Review and Adoption of Agenda
4. Approval of Minutes
5. Superintendent's Welcome and Review of the SRC Purpose
6. SRC Membership Status
7. SRC Chair and Members' Reports
8. Superintendent's Report
9. Old Business
10. New Business
11. Federal Subsistence Board Update

12. Alaska Boards of Fish and Game Update
13. National Park Service Reports
 - a. Ranger Update
 - b. Resource Manager's Report
 - c. Subsistence Manager's Report
14. Public and Other Agency Comments
15. Work Session
16. Set Tentative Date and Location for Next SRC Meeting
17. Adjourn Meeting

The SRC meeting location and date may change based on inclement weather or exceptional circumstances. If the meeting date and location are changed, the Superintendent will issue a press release and use local newspapers and radio stations to announce the rescheduled meeting.

Alma Rippis,
Chief, Office of Policy.

[FR Doc. 2017-01121 Filed 1-18-17; 8:45 am]

BILLING CODE 4312-52-P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS-NERO-CACO-22602; PPNECACOS0,
PPMPSD1Z.YM0000]

Notice of March 13, 2017, Meeting for Cape Cod National Seashore Advisory Commission

AGENCY: National Park Service, Interior.
ACTION: Meeting notice.

SUMMARY: The National Park Service is hereby giving notice of the 306th meeting of the Cape Cod National Seashore Advisory Commission.

DATES: The public meeting of the Cape Cod National Seashore Advisory Commission will be held on Monday, March 13, 2017, at 1:00 p.m. (EASTERN).

ADDRESSES: The Commission members will meet in the conference room at park headquarters, 99 Marconi Site Road, Wellfleet, Massachusetts 02667.

FOR FURTHER INFORMATION CONTACT: Further information concerning the meeting may be obtained from George E. Price, Jr., Superintendent, Cape Cod National Seashore, 99 Marconi Site, Wellfleet, Massachusetts 02667, at (508) 771-2144 or via email at george_price@nps.gov.

SUPPLEMENTARY INFORMATION: The 306th meeting of the Cape Cod National Seashore Advisory Commission will take place on Monday, March 13, 2017, at 1:00 p.m., in the conference room at Headquarters, 99 Marconi Station Road, in Wellfleet, Massachusetts to discuss the following:

1. Adoption of Agenda
2. Approval of Minutes of Previous Meeting
(December 12, 2016)
3. Reports of Officers
4. Reports of Subcommittees
 - Update of Pilgrim Nuclear Plant Emergency Planning Subcommittee Nickerson Fellowship
5. Superintendent's Report
 - Storm Damage/Erosion Update
 - Shorebird Management Plan/Environmental Assessment—Update
 - Kite surfing Update
 - Seashore Projects
 - Nauset Spit Update
 - Improved Properties/Town Bylaws
 - Herring River Wetland Restoration
 - Highlands Center Update
 - Ocean Stewardship Topics—Shoreline Change
 - Climate Friendly Parks
 - National Park Service Centennial
6. Old Business
 - Update on Horton's Campground
 - Private Commercial Properties Related to their Certificates of Suspension from Condemnation
 - Live Lightly Campaign progress report
7. New Business
8. Date and Agenda for Next Meeting
9. Public Comment
10. Adjournment

The Commission was reestablished pursuant to Public Law 87–126, as amended by Public Law 105–280. The purpose of the Commission is to consult with the Secretary of the Interior, or her designee, with respect to matters relating to the development of Cape Cod National Seashore, and with respect to carrying out the provisions of sections 4 and 5 of the Act establishing the Seashore.

The meeting is open to the public. It is expected that 15 persons will be able to attend the meeting in addition to Commission members. Interested persons may make oral/written presentations to the Commission during the business meeting or file written statements. Such requests should be made to the park superintendent prior to the meeting. Before including your address, telephone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we

cannot guarantee that we will be able to do so.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2017–01126 Filed 1–18–17; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NERO–CEBE–22683; PPNECEBE00, PPMPSAS1Z.Y00000]

Notice of the 2017 Meeting Schedule for Cedar Creek and Belle Grove National Historical Park Advisory Commission

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: The National Park Service (NPS) is hereby giving notice of the 2017 meeting schedule of the Cedar Creek and Belle Grove National Historical Park Advisory Commission.

DATES: March 16, 2017.

ADDRESSES: Strasburg Town Hall, 174 East King Street, Strasburg, VA 22657.

DATES: June 15, 2017.

ADDRESSES: Warren County Government Center, 220 North Commerce Avenue, Front Royal, VA 22630.

DATES: September 21, 2017.

ADDRESSES: Middletown Town Hall Council Chambers, 7875 Church Street, Middletown, VA 22645.

DATES: December 21, 2017.

ADDRESSES: Strasburg Town Hall Council Chambers, 174 East King Street, Strasburg, VA 22657.

FOR FURTHER INFORMATION CONTACT:

Further information concerning the meetings may be obtained from Karen Beck-Herzog, Site Manager, Cedar Creek and Belle Grove National Historical Park, P.O. Box 700, Middletown, Virginia 22645, telephone (540) 868–9176, or visit the park Web site: <http://www.nps.gov/cebe/parkngmt/park-advisory-commission.htm>.

SUPPLEMENTARY INFORMATION: The NPS is holding the meetings pursuant to the Federal Advisory Committee Act (5 U.S.C. Appendix 1–16). The Commission was designated by Congress to provide advice to the Secretary of the Interior on the preparation and implementation of the park's general management plan and to advise on land protection (16 U.S.C. 410iii–7). Individuals who are interested in the park, the implementation of the plan, or the business of the Commission are

encouraged to attend the meetings. Interested members of the public may present, either orally or through written comments, information for the Commission to consider during the public meeting. Attendees and those wishing to provide comment are strongly encouraged to preregister through the contact information provided. Scheduling of public comments during the Commission meeting will be determined by the chairperson of the Commission.

Before including your address, telephone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public view, we cannot guarantee that we will be able to do so.

Agenda: All meetings are open to the public and begin at 9:00 a.m. (EASTERN). Topics to be discussed include: Visitor services and interpretation—including directional and interpretive signage and visitor facilities, land protection planning, historic preservation, and natural resource protection.

Commission meetings will consist of the following:

1. General Introductions
2. Review and Approval of Commission Meeting Notes
3. Reports and Discussions
4. Old Business
5. New Business
6. Closing Remarks

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2017–01123 Filed 1–18–17; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

Record of Decision for the 2017–2022 Outer Continental Shelf Oil and Gas Leasing Program Final Programmatic Environmental Impact Statement; MMAA104000

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Notice of availability.

SUMMARY: The Bureau of Ocean Energy Management (BOEM) announces the availability of the 2017–2022 Outer Continental Shelf (OCS) Oil and Gas Leasing Program Final Programmatic EIS (Final Programmatic EIS) Record of

Decision (ROD). The ROD is available at boemoceaninfo.com.

FOR FURTHER INFORMATION CONTACT: Jill Lewandowski, Ph.D., Bureau of Ocean Energy Management, 45600 Woodland Road VAM-OEP, Sterling, VA 20166. Dr. Lewandowski may also be reached by telephone at (703) 787-1703.

SUPPLEMENTARY INFORMATION: In accordance with 40 CFR 1505.2, the Bureau of Ocean Energy Management (BOEM) announces the availability of the 2017–2022 Outer Continental Shelf (OCS) Oil and Gas Leasing Program Final Programmatic EIS (Final Programmatic EIS) Record of Decision (ROD). The ROD is available at boemoceaninfo.com.

The Final Programmatic EIS was published on November 25, 2016 (81 FR 85221). BOEM considered comments submitted on the Final Programmatic EIS before a final decision was made.

Authority: This Notice of Availability of a ROD is issued in accordance with the National Environmental Policy Act of 1969, as amended (Pub. L. 91–190, 42 U.S.C. 4231 *et seq.*), and implementing regulations (See 40 CFR 1505.2).

Walter D. Cruickshank,

Acting Director, Bureau of Ocean Energy Management.

[FR Doc. 2017–00886 Filed 1–18–17; 8:45 am]

BILLING CODE 4310–MR–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–890 (Remand)]

Certain Sleep-Disordered Breathing Treatment Systems and Components Thereof; Commission Determination to Review In-Part a Final Initial Determination on Remand, and on Remand To Affirm With Modification; Vacatur of Suspended Remedial Orders; and Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in-part the presiding Administrative Law Judge’s (“ALJ”) final initial determination on remand (“RID”) for the limited purpose of modifying pages 20–21 and 24 of the RID. The Commission has also determined to vacate the issued remedial orders, which are currently suspended.

FOR FURTHER INFORMATION CONTACT: Panyin A. Hughes, Office of the General

Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–3042. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (<https://www.usitc.gov>). The public record for this investigation may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on August 23, 2013, based on a complaint filed by ResMed Corporation of San Diego, California; ResMed Incorporated of San Diego, California; and ResMed Limited of New South Wales, Australia (collectively, “ResMed”). 78 FR 52564 (Aug. 23, 2013). The complaint alleged violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain sleep-disordered breathing treatment systems and components thereof that infringe one or more of claims 32–37, 53, 79, 80, and 88 of U.S. Patent No. 7,997,267 (“the ‘267 patent’”); claims 1–7 of U.S. Patent No. 7,614,398 (“the ‘398 patent’”); claim 1 of U.S. Patent No. 7,938,116 (“the ‘116 patent’”); claims 30, 37, and 38 of U.S. Patent No. 7,341,060 (the ‘060 patent’); claims 1, 3, 5, 11, 28, 30, 31, and 56 of U.S. Patent No. 8,312,883 (“the ‘883 patent’”); claims 1, 3, 6, 7, 9, 29, 32, 35, 40, 42, 45, 50, 51, 56, 59, 89, 92, 94, and 96 of U.S. Patent No. 7,178,527 (the ‘527 patent’); claims 19–24, 26, 29–36, and 39–41 of U.S. Patent No. 7,950,392 (the ‘392 patent’); and claims 13, 15, 16, 26–28, 51, 52, and 55 of U.S. Patent No. 7,926,487 (“the ‘487 patent’”). The following patents are collectively referred to as the mask patents: the ‘527 patent; the ‘392 patent; the ‘267 patent; the ‘060 patent; and the ‘883 patent. The notice of investigation named the following respondents: BMC Medical Co., Ltd. of Beijing, China; 3B Medical, Inc. of Lake Wales, Florida; and 3B Products, L.L.C., of Lake Wales, Florida (collectively “BMC”). The Office of

Unfair Import Investigations (“OUII”) participated in the investigation.

On January 9, 2014, the ALJ issued an initial determination (“ID”) granting a motion by ResMed to amend the complaint and notice of investigation to substitute U.S. Patent No. RE 44,453 (“the ‘453 patent’”) for the ‘398 patent and to terminate the investigation as to the ‘398 patent. *See* Order No. 7 (Jan. 9, 2014). The Commission determined not to review the ID. *See* Commission Notice of Non-Review (Feb. 10, 2014); 79 FR 9000–01 (Feb. 14, 2014).

On February 24, 2014, the ALJ issued an ID granting a motion by ResMed to withdraw its allegations with respect to the ‘116 patent. *See* Order No. 11 (Feb. 24, 2014). The Commission determined not to review the ID. *See* Commission Notice of Non-Review (March 11, 2014). On March 18, 2014, the ALJ granted a motion by ResMed to terminate the investigation as to claims 26–28 of the ‘487 Patent. *See* Order No. 20 (Mar 18, 2012). The Commission determined not to review the ID. *See* Commission Notice of Non-Review (Apr. 29, 2014).

On August 21, 2014, the ALJ issued a final ID, finding a violation of section 337 by BMC with respect to certain asserted claims of the ‘392, ‘267, ‘060, ‘883, ‘527, and ‘453 patents. The ALJ found no violation of section 337 with respect to the asserted claims of the ‘487 patent.

On September 3, 2014, the parties filed petitions for review of the ID. On September 11, 2014, the parties filed responses to the petitions for review.

On October 16, 2014, the Commission determined to review the final ID in part. 79 FR 63163–65 (Oct. 22, 2014). On review, the Commission determined to affirm the ALJ’s finding of violation of section 337. The Commission, however, found the ‘453 patent invalid for anticipation. Having found a violation of section 337, the Commission determined that the appropriate form of relief was (1) a limited exclusion order prohibiting the unlicensed entry of sleep-disordered breathing treatment systems and components thereof that infringe one or more of claims 1, 9, 32, 89, and 92 of the ‘527 patent; claims 19, 21, 29, 32, and 36 of the ‘392 patent; claims 32, 33, 34, and 53 of the ‘267 patent; claims 30, 37, and 38 of the ‘060 patent; and claims 1, 3, 5, 11, 28, 30, 31, and 56 of the ‘883 patent that are manufactured by, or on behalf of, or are imported by or on behalf of BMC Medical Co., Ltd., 3B Medical, Inc., or 3B Products L.L.C. or any of their affiliated companies, parents, subsidiaries, agents, or other related business entities, or their successors or assigns, except for service

and replacement parts for customers that purchased their covered products prior to the date the exclusion order becomes final; and (2) cease and desist orders prohibiting domestic respondents BMC Medical Co., Ltd., 3B Medical, Inc. from conducting any of the following activities in the United States: Importing, selling, marketing, advertising, distributing, transferring (except for exportation), and soliciting U.S. agents or distributors for, sleep-disordered breathing treatment systems and components thereof covered by claims 1, 9, 32, 89, and 92 of the '527 patent; claims 19, 21, 29, 32, and 36 of the '392 patent; claims 32, 33, 34, and 53 of the '267 patent; claims 30, 37, and 38 of the '060 patent; and claims 1, 3, 5, 11, 28, 30, 31, and 56 of the '883 patent.

On February 18, 2015, ResMed filed a notice of appeal in the U.S. Court of Appeals for the Federal Circuit, seeking review of the Commission's determination as to the '453 patent (Appeal No. 2015-1360). On April 14, 2015, BMC filed a notice of appeal in the Federal Circuit, seeking review of the Commission's domestic industry determination as well as the Commission's finding that prior art does not render the asserted claims of the '267 patent invalid for obviousness (Appeal No. 2015-1576). The Court consolidated the two appeals on April 23, 2015.

On March 16, 2016, the parties jointly moved to dismiss ResMed's appeal as to the '453 patent. On March 17, 2016, the Commission moved to remand BMC's appeal in light of intervening domestic industry precedent in *Lelo Inc. v. International Trade Commission*, 789 F.3d 879 (Fed. Cir. 2015). On March 29, 2016, the Court granted the motion to dismiss ResMed's appeal. On April 22, 2016, the Court granted the Commission's remand motion.

On May 12, 2016, the Commission issued a notice suspending the remedial orders in place during the pendency of the remand proceedings. 81 FR 31254-55 (May 18, 2016). The Commission also issued an order asking the parties to comment on further proceedings. On June 8, 2016, the parties submitted initial comments. The parties filed responses on July 15, 2016. On August 16, 2016, the Commission issued an order remanding the investigation to the ALJ to: (1) Apply the Federal Circuit's intervening domestic industry precedent in *Lelo* to the existing record (as to the mask patents, the only patents remaining); and (2) issue an RID on remand as to violation.

On November 10, 2016, the ALJ issued the RID finding that ResMed

failed to establish the existence of a domestic industry that practices the mask patents. RID at 1. No petitions for review were received.

Having examined the record of this investigation, the Commission has determined to review in-part the RID for the limited purpose of modifying pages 20-21 and 24 of the RID. The Commission does not adopt the RID's statements that "the amount a complainant spends to purchase components manufactured in the United States is immaterial to the economic prong analysis" (RID at 20-21) or that evidence of payments to domestic suppliers is "*per se* insufficient to include in the quantitative analysis." RID at 24. The Commission has determined to otherwise not review the RID. The Commission has determined to vacate the suspended remedial orders. The investigation is terminated.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: January 12, 2017.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2017-01143 Filed 1-18-17; 8:45 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: Noramco, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.33(a) on or before March 20, 2017.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated her authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to

exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division ("Assistant Administrator") pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on July 12, 2016, Noramco, Inc., 500 Swedes Landing Road, Wilmington, Delaware 19801-4417 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

| Controlled substance | Drug code | Schedule |
|-------------------------|-----------|----------|
| Marihuana | 7360 | I |
| Codeine-N-oxide | 9053 | I |
| Dihydromorphine | 9145 | I |
| Hydromorphanol | 9301 | I |
| Morphine-N-oxide | 9307 | I |
| Amphetamine | 1100 | II |
| Methylphenidate | 1724 | II |
| Phenylacetone | 8501 | II |
| Codeine | 9050 | II |
| Dihydrocodeine | 9120 | II |
| Oxycodone | 9143 | II |
| Hydromorphone | 9150 | II |
| Hydrocodone | 9193 | II |
| Morphine | 9300 | II |
| Oripavine | 9330 | II |
| Thebaine | 9333 | II |
| Opium extracts | 9610 | II |
| Opium fluid extract ... | 9620 | II |
| Opium tincture | 9630 | II |
| Opium, powdered | 9639 | II |
| Opium, granulated | 9640 | II |
| Oxymorphone | 9652 | II |
| Noroxymorphone | 9668 | II |
| Tapentadol | 9780 | II |

The company plans to manufacture the above-listed controlled substances in bulk for distribution to its customers. In reference to drug code 7360, the company plans to manufacture a synthetic version of cannabidiol in bulk for sale to its customers, who are final dosage form manufacturers. No other activity for this drug code is authorized for this registration.

Dated: January 11, 2017.

Louis J. Milione,

Assistant Administrator.

[FR Doc. 2017-01103 Filed 1-18-17; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Notice of Lodging Proposed Consent Decree

In accordance with Departmental Policy, 28 CFR 50.7, notice is hereby given that a proposed Consent Decree in *United States, et al. v. Greer Industries, Inc., et al.*, Case No. 1:17-cv-00004-IMK, was lodged with the United States District Court for the Northern District of West Virginia on January 9, 2017.

This proposed Consent Decree concerns a complaint filed by the United States and the State of West Virginia against Greer Industries, Inc., Deckers Creek Limestone Company, and Pikewood, Inc., pursuant to 33 U.S.C. Sections 1319(b) and (d) of the Clean Water Act and W. Va. Code Section 22-11-22, to obtain injunctive relief from and impose civil penalties against the Defendants for violating the Clean Water Act by discharging pollutants without a permit into waters of the United States and waters of the State of West Virginia. The proposed Consent Decree resolves these allegations by requiring the Defendants to restore the impacted areas and/or perform mitigation and to pay a civil penalty.

The Department of Justice will accept written comments relating to this proposed Consent Decree for thirty (30) days from the date of publication of this Notice. Please address comments to Austin Saylor, Trial Attorney, United States Department of Justice, Environment and Natural Resources Division, Environmental Defense Section, Post Office Box 7611, Washington, DC 20044, and refer to *United States, et al. v. Greer Industries, Inc., et al.*, DJ # 90-5-1-19059.

The proposed Consent Decree may be examined at the Clerk's Office, United States District Court for the Northern District of West Virginia, 1125 Chapline Street, Suite 1000, Wheeling, West Virginia 26003. In addition, the proposed Consent Decree may be examined electronically at <http://www.justice.gov/enrd/consent-decrees>.

Cherie L. Rogers,

Assistant Section Chief, Environmental Defense Section, Environment and Natural Resources Division.

[FR Doc. 2017-01133 Filed 1-18-17; 8:45 am]

BILLING CODE 4410-15-P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-91,755]

Kraft Heinz Foods Company, a Subsidiary of the Kraft Heinz Company, Including On-Site Leased Workers From Kelly Services, U.S. Securities, West Side Hammer Electric, and Goodwill Keystone Area, Allentown, Pennsylvania; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on May 23, 2016, applicable to workers of Kraft Heinz Foods Company, a subsidiary of The Kraft Heinz Company, including on-site leased workers from Kelly Services, Allentown, Pennsylvania (TA-W-91,755). The Department's notice of determination was published in the **Federal Register** on June 28, 2016 (81 FR 41999).

At the request of the Pennsylvania Department's Workforce Partnership & Operations, the Department reviewed the certification for workers of the subject firm. The workers firm is engaged in activities related to the production of Tassimo Coffee Pods, K-cups, and condiments.

The company reports that workers leased from U.S. Securities, West Side Hammer Electric, and Goodwill Keystone Area were employed on-site at the Allentown, Pennsylvania location of Kraft Heinz Company. The Department has determined that these workers were sufficiently under the operational control of the subject firm to be considered leased workers.

The intent of the Department's certification is to include all workers of the subject firm who were adversely affected by a shift in production of Tassimo Coffee Pods, K-cups, and condiments to a foreign country.

Based on these findings, the Department is amending this certification to include workers leased from U.S. Securities, West Side Hammer Electric, and Goodwill Keystone Area working on-site at the Allentown, Pennsylvania location of the subject firm.

The amended notice applicable to TA-W-91,755 is hereby issued as follows:

All workers from Kraft Heinz Foods Company, a subsidiary of The Kraft Heinz

Company, including on-site leased workers from Kelly Services, U.S. Securities, West Side Hammer Electric, and Goodwill Keystone Area, Allentown, Pennsylvania who became totally or partially separated from employment on or after April 28, 2015 through May 23, 2018 and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 12th day of December, 2016.

Hope D. Kinglock,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2017-01216 Filed 1-18-17; 8:45 am]

BILLING CODE P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-92,084]

Northern Industrial Erectors, Inc., Grand Rapids, Minnesota; Notice of Affirmative Determination Regarding Application for Reconsideration

By application dated October 3, 2016, State Workforce Official requested administrative reconsideration of the negative determination regarding workers' eligibility to apply for worker adjustment assistance applicable to workers and former workers of Northern Industrial Erectors, Inc., Grand Rapids, Minnesota. The determination was issued on September 9, 2016.

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

The initial investigation resulted in a negative determination based on the findings that there was no increase in imports by the workers' firm or its customers, nor was there a foreign shift or acquisition by the workers' or its customers. In addition, neither the workers' firm nor its customers reported imports of steel erection services like or directly competitive with steel erection services provided by the workers' firm. Furthermore, the workers' firm was not

a Downstream Producer or a Supplier to a firm in which the workers' firm's services supplied was related to the article the basis of the certification.

The request for reconsideration asserts that the workers' firm should be considered a Downstream Producer.

The Department of Labor has carefully reviewed the request for reconsideration and the existing record, and has determined that the Department will conduct further investigation to determine if the workers meet the eligibility requirements of the Trade Act of 1974.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the U.S. Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 1st day of November 2016.

Hope D. Kinglock,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2017-01214 Filed 1-18-17; 8:45 am]

BILLING CODE P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA-W-91,121; TA-W-91,121A; TA-W-91,121B; TA-W-91,121C]

REC Silicon LLC, a Wholly Owned Subsidiary of Renewable Energy Corporation ASA, Including Workers Whose Wages Were Reported Under REC Solar Grade Silicon LLC, Including On-Site Leased Workers From Express Employment Professionals, Moses Lake, Washington; REC Silicon ASA, a Wholly Owned Subsidiary of REC Solar Grade Silicon LLC, Including Workers Whose Wages Were Reported Under REC Advanced Silicon Materials, Silver Bow, Montana; Nemo IT Solutions, Working On-Site at REC Silicon LLC, a Wholly Owned Subsidiary of Renewable Energy Corporation ASA, Moses Lake, Washington; Spherion Staffing LLC, Working On-Site at REC Silicon ASA, a Wholly Owned Subsidiary of REC Solar Grade Silicon LLC, Silver Bow, Montana; Notice of Revised Determination on Reconsideration

On May 16, 2016, the Department of Labor issued an Affirmative Determination Regarding Application for Reconsideration for the workers and former workers of REC Silicon LLC, a

wholly owned subsidiary of Renewable Energy Corporation ASA, Moses Lake, Washington (TA-W-91,121), and REC Silicon ASA, a wholly owned subsidiary of REC Solar Grade Silicon LLC, Silver Bow, Montana (TA-W-91,121A) (herein referred to as "REC Silicon"). The firm is engaged in activities related to the production of Silane Gas and Polysilicon. The worker group was previously certified eligible to apply for Trade Adjustment Assistance under petition number TA-W-82,458 and TA-W-82,458A which expired on March 22, 2015. The subject worker group includes on-site leased workers from Express Employment Professionals (TA-W-91,121), Nemo IT Solutions (TA-W-91,121B), and Spherion Staffing, LLC (TA-W-91,121C). Nemo IT Solutions and Spherion Staffing, LLC were not included in the certification for TA-W-82,458. The subject worker group also includes workers whose wages were reported under REC Solar Grade Silicon (TA-W-91,121) and REC Advanced Silicon Materials (TA-W-91,121A).

To support the request for reconsideration, the petitioner supplied additional information regarding the firms' previous certification to supplement that which was gathered during the initial investigation.

Based on the new information supplied by the firm and provided by the petitioner during the reconsideration investigation, the Department of Labor determines that a shift in production of silane gas and polysilicon has contributed importantly to the worker separations at the subject firm.

Conclusion

After careful review of the additional facts obtained on reconsideration, I determine that workers of REC Silicon LLC, a wholly owned subsidiary of Renewable Energy Corporation ASA, including workers whose wages were reported under REC Solar Grade Silicon LLC, including on-site leased workers from Express Employment Professionals, Moses Lake, Washington (TA-W-91,121), REC Silicon ASA, a wholly owned subsidiary of REC Solar Grade Silicon LLC, including workers whose wages were reported under REC Advanced Silicon Materials, Silver Bow, Montana (TA-W-91,121A), NEMO IT Solutions, working on-site at REC Silicon LLC, a wholly owned subsidiary of Renewable Energy Corporation ASA, Moses Lake, Washington (TA-W-91,121B), and Spherion Staffing LLC, working on-site at REC Silicon ASA, a wholly owned subsidiary of REC Solar Grade Silicon LLC, Silver Bow, Montana

(TA-W-91,121C) who were engaged in employment related to production of saline gas and polysilicon, meet the worker group certification criteria under Section 222(a) of the Act, 19 U.S.C. 2272(a). In accordance with Section 223 of the Act, 19 U.S.C. 2273, I make the following certification:

All workers of REC Silicon LLC, a wholly owned subsidiary of Renewable Energy Corporation ASA, including workers whose wages were reported under REC Solar Grade Silicon LLC, including on-site leased workers from Express Employment Professionals, Moses Lake, Washington (TA-W-91,121), REC Silicon ASA, a wholly owned subsidiary of REC Solar Grade Silicon LLC, including workers whose wages were reported under REC Advanced Silicon Materials, Silver Bow, Montana (TA-W-91,121A), who became totally or partially separated from employment on or after March 23, 2015, through two years from the date of this certification, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended; AND,

All workers of NEMO IT Solutions, working on-site at REC Silicon LLC, a wholly owned subsidiary of Renewable Energy Corporation ASA, Moses Lake, Washington (TA-W-91,121B) and Spherion Staffing LLC, working on-site at REC Silicon ASA, a wholly owned subsidiary of REC Solar Grade Silicon LLC, Silver Bow, Montana (TA-W-91,121C) who became totally or partially separated from employment on or after November 4, 2014, through two years from the date of this certification, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 18th day of October 2016.

Hope D. Kinglock,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2017-01212 Filed 1-18-17; 8:45 am]

BILLING CODE 4510-FN-P

DEPARTMENT OF LABOR**Employment and Training
Administration**

[TA-W-86,089; TA-W-86,089A]

Huntington Alloys Corporation, Special Metals Division, a Subsidiary of Special Metals Corporation, Including On-Site Leased Workers From Kelly Services, Huntington, West Virginia; Huntington Alloys Corporation, Special Metals Division, a Subsidiary of Special Metals Corporation, Burnaugh, Kentucky; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended ("Act"), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on January 19, 2016, applicable to workers of Huntington Alloys Corporation, Special Metals Division, a subsidiary of Special Metals Corporation, including on-site leased workers from Kelly Services, Huntington, West Virginia (TA-W-86,089). The Department's notice of determination was published in the **Federal Register** on February 25, 2016 (81 FR 9510).

At the request of a state workforce office, the Department reviewed the certification for workers of the subject firm. The workers are engaged in activities related to the production of nickel based alloys in a variety of forms including but not limited to ingot, billet, bar, wire rod, tube, plate, and sheet products.

The company reports that workers from Huntington Alloys Corporation, Special Metals Division, a subsidiary of Special Metals Corporation, Burnaugh, Kentucky are engaged in activities related to the production of nickel based alloys in a variety of forms including but not limited to ingot, billet, bar, wire rod, tube, plate, and sheet products.

The intent of the Department's certification is to include all workers of the subject firm who were adversely affected by increased imports of nickel based alloys in a variety of forms including but not limited to ingot, billet, bar, wire rod, tube, plate, and sheet products.

Based on these findings, the Department is amending this certification to include workers from Huntington Alloys Corporation, Special Metals Division, a subsidiary of Special Metals Corporation, Burnaugh, Kentucky.

The amended notice applicable to TA-W-86,089 and TA-W-86,089A is hereby issued as follows:

All workers of Huntington Alloys Corporation, Special Metals Division, a subsidiary of Special Metals Corporation, including on-site leased workers from Kelly Services, Huntington, West Virginia (TA-W-86,089) and Huntington Alloys Corporation, Special Metals Division, a subsidiary of Special Metals Corporation, Burnaugh, Kentucky (TA-W-86,089A) who became totally or partially separated from employment on or after June 10, 2014, through January 19, 2018, and all workers in the group threatened with total or partial separation from employment on date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Signed in Washington, DC, this 15th day of December, 2016.

Hope D. Kinglock,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2017-01211 Filed 1-18-17; 8:45 am]

BILLING CODE 4510-FN-P

DEPARTMENT OF LABOR**Employment and Training
Administration****Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance**

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers by (TA-W) number issued during the period of *December 19, 2016 through December 30, 2016*.

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Under Section 222(a)(2)(A), the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) the sales or production, or both, of such firm have decreased absolutely; and

(3) One of the following must be satisfied:

(A) Imports of articles or services like or directly competitive with articles produced or services supplied by such firm have increased;

(B) imports of articles like or directly competitive with articles into which one or more component parts produced by such firm are directly incorporated, have increased;

(C) imports of articles directly incorporating one or more component parts produced outside the United States that are like or directly competitive with imports of articles incorporating one or more component parts produced by such firm have increased;

(D) imports of articles like or directly competitive with articles which are produced directly using services supplied by such firm, have increased; and

(4) the increase in imports contributed importantly to such workers' separation or threat of separation and to the decline in the sales or production of such firm; or

II. Section 222(a)(2)(B) all of the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) One of the following must be satisfied:

(A) There has been a shift by the workers' firm to a foreign country in the production of articles or supply of services like or directly competitive with those produced/supplied by the workers' firm;

(B) there has been an acquisition from a foreign country by the workers' firm of articles/services that are like or directly competitive with those produced/supplied by the workers' firm; and

(3) the shift/acquisition contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected secondary workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) A significant number or proportion of the workers in the workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) the workers' firm is a Supplier or Downstream Producer to a firm that employed a group of workers who received a certification of eligibility under Section 222(a) of the Act, and such supply or production is related to the article or service that was the basis for such certification; and

(3) either—

(A) the workers' firm is a supplier and the component parts it supplied to the firm described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) a loss of business by the workers' firm with the firm described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in firms identified by the International Trade Commission and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(e) of the Act must be met.

(1) the workers' firm is publicly identified by name by the International Trade Commission as a member of a

domestic industry in an investigation resulting in—

(A) an affirmative determination of serious injury or threat thereof under section 202(b)(1);

(B) an affirmative determination of market disruption or threat thereof under section 421(b)(1); or

(C) an affirmative final determination of material injury or threat thereof under section 705(b)(1)(A) or 735(b)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)(1)(A) and 1673d(b)(1)(A));

(2) the petition is filed during the 1-year period beginning on the date on which—

(A) a summary of the report submitted to the President by the International Trade Commission under section 202(f)(1) with respect to the affirmative determination described in paragraph (1)(A) is published in the **Federal Register** under section 202(f)(3); or

(B) notice of an affirmative determination described in

subparagraph (1) is published in the **Federal Register**; and

(3) the workers have become totally or partially separated from the workers' firm within—

(A) the 1-year period described in paragraph (2); or

(B) notwithstanding section 223(b)(1), the 1-year period preceding the 1-year period described in paragraph (2).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

| TA-W No. | Subject firm | Location | Impact date |
|--------------|--|----------------------|-------------------|
| 92,086 | Wing Fai Label Inc | Bells, CA | August 2, 2015. |
| 92,153 | Duro Textiles, LLC, Abel Associates | Fall River, MA | August 29, 2015. |
| 92,357 | Samson Technologies Corporation, Sam Ash Music Corporation, Randstad US and Access Staffing. | Hauppauge, NY | October 24, 2015. |

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production or services) of the Trade Act have been met.

| TA-W No. | Subject firm | Location | Impact date |
|---------------|---|-------------------------|---------------------|
| 91,289 | CommScope Connectivity LLC, ADC Telecommunications, Inc., Sidney, CommScope Technologies, etc. | Sidney, NE | December 24, 2014. |
| 91,483 | Sprint, Hampton Call Center | Hampton, VA | February 19, 2015. |
| 91,515 | Sprint, Shared Services, Commissions Operations and Compensations and Incentives. | Overland Park, KS | February 24, 2015. |
| 91,802 | CooperSurgical Inc., The Cooper Companies, HART Employment Services. | Pasadena, CA | May 12, 2015. |
| 91,809 | Sprint, Overland Park Call Center | Overland Park, KS | May 12, 2015. |
| 91,824 | Paso Del Norte Publishing, Inc., El Diario De El Paso | El Paso, TX | May 18, 2015. |
| 92,183 | Applied Materials, Applied Materials Inc., Division of Common Solutions Mfg. Group, etc. | Austin, TX | August 8, 2016. |
| 92,198 | Ericsson, Inc., Insight Global, GlobalLogic, and Essential | Plano, TX | September 12, 2015. |
| 92,229 | BASF Corporation, BASF SE, Brown & Root Industrial Services and Insulation & Refractories. | West Memphis, AR | September 20, 2015. |
| 92,232 | Loud Technologies, EAW Division, Microtech Staffing | Whitinsville, MA | September 14, 2015. |
| 92,252 | LDLA Holdings LLC, Division of Garment Sample Coordinators | Los Angeles, CA | September 27, 2015. |
| 92,350 | Bosch Rexroth Corporation, Industrial and Mobile Applications Division, Robert Bosch LLC, etc. | Bethlehem, PA | October 20, 2015. |
| 92,352 | GE Fairchild, LLC, GE Transportation, Adecco | Glen Lyn, VA | October 20, 2015. |
| 92,364 | GE Dover Products Plant, GE Lighting, GE Lighting Inc | Dover, OH | October 25, 2015. |
| 92,364A | Tungsten Products Plant, GE Lighting, GE Lighting Inc | Euclid, OH | October 25, 2015. |
| 92,382 | Flowserve Corporation, Nesco Resources, Aerotek, and Affinity | Lawrence, MA | October 28, 2015. |
| 92,404 | Yodle Web.com, Inc., Client Services Division, Web.com Group, Inc | Austin, TX | November 8, 2015. |
| 92,409 | GE Packaged Power, Inc., General Electric Company, Kelly Services | Houston, TX | November 9, 2015. |
| 92,424 | WorleyParsons Group, Inc., Reading Office, WorleyParsons Ltd., Energy Resourcing Americas. | Reading, PA | November 16, 2015. |
| 92,467 | Lufkin-RMT, GE Oil and Gas | Wellsville, NY | December 6, 2015. |
| 92,492 | Getinge-La Calhene USA, Getinge-La Calhene SAS | Rush City, MN | December 15, 2015. |
| 92,493 | Pentair Technical Solutions, Panel Shop, Pentair plc, AmeriTech Staffing, Inc., CoWorx Staffing Services. | Houston, TX | December 15, 2015. |

The following certifications have been issued. The requirements of Section 222(b) (downstream producer for a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

| TA-W No. | Subject firm | Location | Impact date |
|--------------|---|-------------------|-------------------|
| 92,398 | Kahului Trucking and Storage, Inc., Bulk Sugar and Molasses Division, Alexander and Baldwin, Inc. | Kahului, HI | November 3, 2015. |

Negative Determinations for Worker Adjustment Assistance

In the following cases, the investigation revealed that the eligibility

criteria for worker adjustment assistance have not been met for the reasons specified.

The investigation revealed that the criterion under paragraph (a)(1), or

(b)(1) (employment decline or threat of separation) of section 222 has not been met.

| TA-W No. | Subject firm | Location | Impact date |
|--------------|--|---------------|-------------|
| 91,666 | Haymarket Media, Inc., Production Department | New York, NY. | |
| 92,250 | IBEX Global | Indiana, PA. | |

The investigation revealed that the criteria under paragraphs (a)(2)(A)(i)

(decline in sales or production, or both) and (a)(2)(B) (shift in production or

services to a foreign country) of section 222 have not been met.

| TA-W No. | Subject firm | Location | Impact date |
|--------------|---|-----------------|-------------|
| 92,335 | Titanium Wire Corporation, ATI Specialty Alloys and Components Division, Allegheny Technologies, etc. | Frackville, PA. | |

The investigation revealed that the criteria under paragraphs (a)(2)(A)

(increased imports) and (a)(2)(B) (shift in production or services to a foreign

country) of section 222 have not been met.

| TA-W No. | Subject firm | Location | Impact date |
|---------------|--|-----------------|-------------|
| 91,882 | SPX FLOW, Inc., SPX Flow Technology, Adecco, Manpower, SGF Global, Remedy Staffing, etc. | McKean, PA. | |
| 91,918 | Lufkin Industries LLC, Gear Repair Division, GE Oil & Gas, Malone's Cleaning Service, Inc. | Lufkin, TX. | |
| 91,924 | Mattel, Inc., Design and Development, Pro Unlimited | El Segundo, CA. | |
| 91,946 | York Metal Toll Processing | Syracuse, NY. | |
| 91,993 | TimkenSteel Corporation, Harrison Steel Plant | Canton, OH. | |
| 91,993A | TimkenSteel Corporation, Faircrest Steel Plant | Canton, OH. | |
| 91,993B | TimkenSteel Corporation, Faircrest Steel Plant | Canton, OH. | |
| 92,010 | Atos IT Solutions and Services, Inc., NSC Global | Redmond, WA. | |
| 92,286 | Salem Hospital, Salem Health, Division of Medical Transcriptionists | Salem, OR. | |

Determinations Terminating Investigations of Petitions for Worker Adjustment Assistance

After notice of the petitions was published in the **Federal Register** and

on the Department's Web site, as required by Section 221 of the Act (19 U.S.C. 2271), the Department initiated investigations of these petitions.

The following determinations terminating investigations were issued because the petitioner has requested that the petition be withdrawn.

| TA-W No. | Subject firm | Location | Impact date |
|--------------|--|---------------|-------------|
| 92,142 | Erickson Inc., Division of Accounting, Payroll, and Expense Reporting, NW Staffing, etc. | Portland, OR. | |

I hereby certify that the aforementioned determinations were issued during the period of December 19, 2016 through December 30, 2016. These determinations are available on the Department's Web site https://www.doleta.gov/tradeact/taa/taa_search_form.cfm under the searchable listing determinations or by calling the Office of Trade Adjustment Assistance toll free at 888-365-6822.

Signed at Washington, DC, this 3rd day of January 2017.

Hope D. Kinglock,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2017-01215 Filed 1-18-17; 8:45 am]

BILLING CODE 4510-FN-P

DEPARTMENT OF LABOR

Employment and Training Administration

DEPARTMENT OF EDUCATION

Office of Career, Technical, and Adult Education; Rehabilitation Services Administration; Agency Information Collection Activities; Comment Request; Workforce Innovation and Opportunity Act (WIOA) Common Performance Reporting

ACTION: Notice.

SUMMARY: The Department of Labor (DOL), Employment and Training Administration (ETA) and the Department of Education (ED) (jointly referred to as “the Departments”) are soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, “Workforce Innovation and Opportunity Act (WIOA) Common Performance Reporting.” This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.*

DATES: Consideration will be given to all written comments received by March 20, 2017.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting Docket ID number ETA-2017-0001 or via postal mail, commercial delivery, or hand delivery. A copy of the ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden

may be obtained free of charge from <http://www.regulations.gov> or by contacting Karen Staha by telephone at 202-693-2917 (this is not a toll-free number) or by email at Staha.Karen@dol.gov. Individuals with hearing or speech impairments may access the telephone number above via TTY by calling the toll-free Federal Information Relay Service at 1-877-889-5627 (TTY/TDD). Fax: 202-693-2766.

Mail and hand delivery/courier: Send written comments to Karen Staha, Office of Policy Development and Research, Room N5641, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. Due to security-related concerns, there may be a significant delay in the receipt of submissions by United States Mail. You must take this into consideration when preparing to meet the deadline for submitting comments.

Comments submitted in response to this comment request will become a matter of public record and will be summarized and included in the request for Office of Management and Budget (OMB) approval of the final ICR. In addition, comments regardless of the delivery method, will be posted without change on the <http://www.regulations.gov> Web site; consequently, the Departments recommend commenters not include personal information such as a Social Security Number, personal address, telephone number, email address, or confidential business information that they do not want made public. It is the responsibility of the commenter to determine what to include in the public record.

FOR FURTHER INFORMATION: Contact Karen Staha by telephone at 202-693-2917 (this is not a toll-free number) or by email at Staha.Karen@dol.gov.

Authority: 44 U.S.C. 3506(c)(2)(A).

SUPPLEMENTARY INFORMATION: The DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the OMB for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

The data collections in this ICR fulfill requirements in WIOA sec.116(d)(1) for

the development of report templates for the State Performance Report for WIOA core programs, the Local Area Performance Report, and the Eligible Training Provider (ETP) Report. The Departments propose to amend the information collection by adding new information collection requirements for WIOA Statewide performance reporting. In particular, the Departments propose to add: (1) Data elements related to training program information to the ETP Performance Report, and (2) a new information collection requirement, *i.e.*, an Annual Statewide Performance Report Narrative. This additional information would be helpful in the implementation and evaluation of the workforce development covered programs, and may include descriptions of such items as promising program practices, employer metrics, sector strategies, state evaluations, and rapid response activities. Also, a few adjustments made to the WIOA Annual Statewide Performance Report and Local Area Performance Report Template specifications that will align report specifications and the resulting values with the intent and requirements outlined in WIOA, and final rule. For example, the numerator specification of the Measurable Skill Gains Indicator was revised to ensure only a single gain per reporting period could be counted for each individual.

Section 116 of WIOA (29 U.S.C. 3141) requires States and Local Areas that operate the six core programs of the public workforce development system to comply with common performance accountability requirements for those programs, which are: The Adult, Dislocated Worker, and Youth programs (authorized under WIOA title I, administered by DOL); the Employment Service program authorized under the Wagner-Peyser Act, as amended by WIOA title III (administered by DOL); the Adult Education and Family Literacy Act (AEFLA) program (authorized under WIOA title II, administered by ED); and the Vocational Rehabilitation (VR) program authorized under title I of the Rehabilitation Act of 1973, as amended by WIOA title IV (administered by ED). As such, States and Local Areas that operate core programs must submit common performance data to demonstrate that specified performance levels are achieved. States and Local Areas report the common performance data through the “Workforce Innovation and Opportunity Act (WIOA) Common Performance Reporting” ICR (OMB Control No. 1205-0526).

In addition, and in accordance with WIOA sec. 122(b)(2), training providers

that are eligible to receive funds from Adult and Dislocated Worker programs authorized under title I of WIOA (also known as “eligible training providers” or ETPs) must report data on outcomes achieved under those programs to the State(s) in which they are listed on the State ETP list. States then report the information submitted by ETPs to DOL. The information collection requirements applicable to ETPs are also contained in the “Workforce Innovation and Opportunity Act (WIOA) Common Performance Reporting” ICR.

Section 116(d)(1) of WIOA mandates that the Secretaries of Labor and Education develop a template for performance reports to be used by States, Local Boards, and ETPs for reporting on outcomes achieved by participants in the six core programs. Corresponding regulations for these data collection requirements, including which primary performance indicators apply for each core program, have been issued jointly by the Departments. See 81 FR 55792 (Aug. 19, 2016). The WIOA regulations became effective on October 18, 2016. These joint performance regulations can be found at: (1) 20 CFR part 677 (which covers the Adult and Dislocated Worker programs (20 CFR part 680), the Youth program (20 CFR part 681), and the Wagner-Peyser Act Employment Service program (20 CFR part 652)); (2) 34 CFR part 463, subpart I (which covers the AEFLA program); and (3) 34 CFR part 361, subpart E (which covers the VR program).

The data collection instruments covered in this ICR are necessary to meet the requirements of sec. 116 of WIOA. These information collection instruments were developed jointly by the Departments, and include: (1) The Joint Participant Individual Record Layout (PIRL), which provides a standardized set of data elements, definitions, and reporting instructions for use by States and local entities administering WIOA core programs; (2) the Statewide Performance Report Template, to be used for the reporting of data by State entities that administer WIOA core programs; (3) the Local Area Performance Report Template, to be used for the reporting of data by local entities that administer WIOA core programs; (4) the ETP Performance Report specifications and definitions, to be used for the reporting of data by eligible providers of training services under WIOA title I Adult and Dislocated Worker programs; and (5) the Annual Statewide Performance Report Narrative, a new information collection requirement to be used for providing information on the status and progress

of workforce development program performance.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. In order to help ensure appropriate consideration, comments should mention Workforce Innovation and Opportunity Act (WIOA) Common Performance Reporting, OMB control number 1205–0526.

The DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–ETA.

Type of Review: Revision.

Title of Collection: Workforce Innovation and Opportunity Act (WIOA) Common Performance Reporting.

Forms: WIOA Statewide and Local Performance Report Template, ETA 9169; WIOA PIRL, ETA 9170; ETP Definitions, ETA 9171.

OMB Control Number: 1205–0526.

Affected Public: State, Local, and Tribal Governments; Private Sector—businesses or other for-profits and not-for-profit institutions.

Estimated Number of Respondents: 19,113,825.

Frequency: Annual for each form.

Total Estimated Annual Responses: 38,216,056.

Estimated Average Time per Response: Varies.

Estimated Total Annual Burden Hours: 9,863,065 hours.

Total Estimated Annual Other Cost Burden: \$30,957,760.

Portia Wu,

Assistant Secretary for Employment and Training, Department of Labor.

Johan Uvin,

Acting Assistant Secretary for the Office of Career, Technical, and Adult Education, Department of Education.

Sue Swenson,

Deputy Assistant Secretary for Special Education and Rehabilitative Services, delegated the authority to perform the functions and duties of the Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2017–01069 Filed 1–18–17; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221 (a) of the Trade Act of 1974 (“the Act”) and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221 (a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, no later than January 30, 2017.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than January 30, 2017.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of

Labor, Room N-5428, 200 Constitution Avenue NW., Washington, DC 20210.

Signed at Washington, DC, this 3rd day of January 2017.

Hope D. Kinglock,

Certifying Officer, Office of Trade Adjustment Assistance.

Appendix

17 TAA PETITIONS INSTITUTED BETWEEN 12/19/16 AND 12/30/16

| TA-W | Subject firm (petitioners) | Location | Date of institution | Date of petition |
|-------------|--|----------------------------|---------------------|------------------|
| 92497 | Marge Carson (State/One-Stop) | Pomona, CA | 12/19/16 | 12/16/16 |
| 92498 | IPS Penn Coil (Union) | Glassport, PA | 12/19/16 | 12/18/16 |
| 92499 | HealthSmart Benefit Solutions Inc (Workers) | Charleston, WV | 12/20/16 | 12/20/16 |
| 92500 | Projectplace a Planview Company (State/One-Stop) | Austin, TX | 12/21/16 | 12/20/16 |
| 92501 | Paoli Inc (Workers) | Orleans, IN | 12/22/16 | 12/19/16 |
| 92502 | Interlectric Corporation (Workers) | Warren, PA | 12/22/16 | 12/21/16 |
| 92503 | Asurion Services LLC (State/One-Stop) | Nashville, TN | 12/22/16 | 12/22/16 |
| 92504 | Optum (Company) | Colorado Springs, CO | 12/27/16 | 12/23/16 |
| 92505 | Batesville Casket Company (Company) | Batesville, MS | 12/27/16 | 12/23/16 |
| 92506 | Weyerhaeuser (State/One-Stop) | Kalispell, MT | 12/27/16 | 12/22/16 |
| 92507 | Halliburton (State/One-Stop) | Tulsa, OK | 12/27/16 | 12/22/16 |
| 92508 | Thermo Fisher Scientific (State/One-Stop) | Pittsburgh, PA | 12/28/16 | 12/27/16 |
| 92509 | Omak Forest Products, LLC (State/One-Stop) | Omak, WA | 12/28/16 | 12/23/16 |
| 92510 | Magnetic Metals Corporation (State/One-Stop) | Camden, NJ | 12/29/16 | 12/28/16 |
| 92511 | Source One Technologies (State/One-Stop) | San Jose, CA | 12/29/16 | 12/28/16 |
| 92512 | Uroboros Glass (State/One-Stop) | Portland, OR | 12/29/16 | 12/28/16 |
| 92513 | Trinity Industries (Workers) | Cartersville, GA | 12/30/16 | 12/28/16 |

[FR Doc. 2017-01210 Filed 1-18-17; 8:45 am]

BILLING CODE 4510-FN-P

DEPARTMENT OF LABOR

[Secretary's Order 1-2017]

Order of Succession to the Secretary of Labor in Periods of Vacancy, Continuity of Executive Direction, Repositioning and Devolution of Departmental Governance, and Emergency Planning Under Circumstances of Extreme Disruption

1. *Purpose.* To provide for succession to act as, or on behalf of, the Secretary of Labor in case of death or resignation of the Secretary, or if the Secretary is otherwise unable to perform the functions and duties of the office, including in case of absence or sickness; to provide lines of succession for executive continuity within the Department and its Agencies during vacancies arising in a period of national emergency or in the course of business; to provide for the repositioning and devolution of Departmental governance under circumstances of extreme disruption; and to identify the first assistant to those officers of the Department whose appointment to office is required to be made by the President, including those whose appointment is subject to the advice and consent of the Senate.

2. *Authority and Directives.*

A. This Order is issued pursuant to Executive Order 13755 (replacing Executive Order (E.O.) 13245, December 18, 2001); the Federal Vacancies Reform Act of 1998 (the FVRA) (codified generally at 5 U.S.C. 3345, et seq.); 29 U.S.C. 551 et seq.; Reorganization Plan No. 6 of 1950; Reorganization Plan No. 1 of 1958; Reorganization Plan No. 1 of 1973; Federal Civil Defense Act of 1950 as amended; Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 et seq., as amended; 5 USC 301; 31 U.S.C. 1531 and 1533; Executive Order 12656, as amended; and Executive Order 12148, as amended.

National Security Presidential Directive 51/Homeland Security Presidential Directive 20 (NSPD-51/HSPD-20) *National Continuity Policy* (May 2007); National Continuity Policy Implementation Plan (NCPIP) (Aug 2007); Federal Continuity Directive 1 (FCD-1) *Federal Executive Branch National Continuity Program and Requirements* (October 2012); Office of Personnel Management, *Handbook on Pay and Leave Benefits for Federal Employees Affected by Severe Weather Conditions or Other Emergency Situations* (June 2008).

B. Secretary's Order 4-2008 (August 4, 2008) is hereby superseded and canceled, and all agency delegations in conflict with this Order and/or its Attachment are hereby superseded.

3. *Background.* Pursuant to the 1998 Federal Vacancies Reform Act, the most

recent order of succession of officers to act as Secretary of Labor in periods of vacancy was set forth in Secretary's Order 4-2008 (August 4, 2008), which was issued under the authority of E. O. 13245 (December 18, 2001). On December 23, 2016, E.O. 13755 revoked E.O. 13245 and provided a new order of succession to the position of Secretary of Labor.

The Department's plan for continuity of operations in the event of a need for relocation involves movement of Emergency Response Group to a Continuity Site. The Department's plan for devolution was established by Secretarial Memorandum dated December 20, 2006, wherein the Secretary selected Dallas, Texas as the National Office, Department of Labor devolution site (the "Devolution Site").

4. *Order of Governance.* In accordance with E.O. 13755 and the FVRA, in case of absence due to death, resignation, or if the official is otherwise unable to perform the functions and duties of the office, the functions and duties of the officers of the Department of Labor and their respective responsibilities for operational management will be performed in an acting capacity or on behalf thereof by the incumbents of the positions designated in the following orders:

A. Succession to the Secretary of Labor

Sequence for identifying the Acting Secretary of Labor, who shall have all of

the authorities and responsibilities of the Secretary:

- (1) Deputy Secretary of Labor;
- (2) Solicitor of Labor;
- (3) Assistant Secretary for Administration and Management [Not subject to Senate Confirmation, Pub. L. 112–166];
- (4) Assistant Secretary for Policy;
- (5) Assistant Secretary for Congressional and Intergovernmental Affairs;
- (6) Assistant Secretary for Employment and Training;
- (7) Assistant Secretary for Employee Benefits Security;
- (8) Assistant Secretary for Occupational Safety and Health;
- (9) Assistant Secretary for Mine Safety and Health;
- (10) Assistant Secretary for Public Affairs [Not subject to Senate confirmation, Pub. L. 112–166];
- (11) Chief Financial Officer
- (12) Administrator, Wage and Hour Division
- (13) Assistant Secretary for Veterans' Employment and Training;
- (14) Assistant Secretary for Disability Employment Policy;
- (15) First assistants, as defined in the FVRA, to the officials in the order listed in (2), and (4)–(9);
- (16) Regional Solicitor—Dallas; and
- (17) Regional Administrator for the Office of the Assistant Secretary for Administration and Management—Region VI/Dallas—who, upon becoming Delegated Secretarial Designee (DSD) by order of operation of this Succession Order, the Secretary hereby authorizes and pre-approves for an immediate, noncompetitive appointment to the Senior Executive Service (SES) under a limited-term appointment using a DOL SES allocation).

Provided that, no individual who is serving in an acting capacity in any of the above positions shall serve as Acting Secretary pursuant to this Order.

B. Identifying the Delegated Secretarial Designee on Behalf of the Secretary of Labor

In the event and for such time(s) that none of the incumbents in the succession sequence set forth in Paragraph 4.A., above, are available to serve as Acting Secretary, the Delegated Secretarial Designee (DSD) shall fulfill, on an interim basis, the operational management of the Department except the Secretary's "functions and duties." The "functions and duties" of the Secretary are those non-delegable responsibilities (a) established by law (statute or regulation); and (b) required to be performed by, and only by, the

Secretary. Except as determined otherwise by the President, whoever from time to time is highest in the following sequence and is available to serve shall be the Delegated Secretarial Designee:

- (1) The following:
 - (a) Director, Office of Federal Contract Compliance Programs;
 - (b) Director of the Women's Bureau; and
 - (c) Director, Office of Labor Management Standards;
- (2) Specified DOL officials as follows:
 - (a) Regional Administrator for ETA located in Dallas;
 - (b) OSHA Regional Administrator—Dallas.

Provided that, no individual who is serving in an acting capacity in any of the above positions shall serve as the Delegated Secretarial Designee pursuant to this Order.

C. To All Other PAS Positions and Heads of Other Principal Organizational Units

(1) There are offices and agencies within the Department of Labor headed by officers whose appointment to office is required to be made by the President, by and with the advice and consent of the Senate (PAS). In the event of a vacancy in any of these PAS positions, the FVRA provides that, except in certain narrow circumstances, the "first assistant [to the PAS position] shall perform the functions and duties of the [PAS position] temporarily in an acting capacity" (subject to certain time limitations), unless and until the President makes an alternative designation under the FVRA. The functions and duties of the PAS officers of the Department and the operational management of the respective agency will be performed by the incumbent first assistant to the PAS position, as designated in the Secretarial Memorandum to Department of Labor Executive Staff (see, "Memorandum," attached to this Order).

(2) In the event that (a) there is a vacancy in the position of the first assistant, or (b) the first assistant position is occupied by a person who is statutorily barred from serving as an acting officer, the operational management of the agency headed by the PAS shall be performed by the person whose designation closest follows that of the first assistant, unless and until the President makes an alternative designation under the FVRA. However, the "functions and duties" of the PAS may not be performed by any person other than the person serving in an acting capacity (or, in the absence of an acting officer, by the Secretary

pursuant to the FVRA). The "functions and duties" are those non-delegable responsibilities (a) established by law (statute or regulation); and (b) required to be performed by, and only by, the PAS.

(3) The Memorandum described in Paragraph 4.C. (1) above shall include succession to the heads of other Departmental organizational units that report to the Secretary.

(4) Nothing in this Order or the Memorandum shall: (1) Be construed to override the provisions in the FVRA with respect to the Inspector General or the Chief Financial Officer (5 U.S.C. 3348(e)); or (2) limit the Secretary's authority to reassign functions or duties of officers unless otherwise precluded by law or regulation.

(5) The Memorandum shall be published in the **Federal Register** and codified in the Department of Labor Manual Series. It is also subject to periodic revision by the Secretary, as necessary, and is effective upon signature unless otherwise specified.

5. Emergency Governance of the Department of Labor and Devolution of Authorities and Responsibilities

A. Secretary (or Acting Secretary) of Labor. Unless otherwise directed by the President (or designee), upon the occurrence of a national emergency entailing a wholesale disruption of the operations, structure, and leadership of the Department of Labor, the Secretary or Acting Secretary (as designated by the President or as provided in the order of succession set forth in Paragraph 4.A. above) shall activate the governing Continuity Plans and determine whether the National Office of the Department of Labor will remain in the then existing location, be repositioned organizationally to the Continuity Site, or be repositioned at the Devolution Site.

B. Except as otherwise directed by the President (or designee), if (1) a catastrophic event occurs in the Washington, DC metropolitan area; (2) the incumbents identified in Paragraph 4.A. are unavailable or unlikely to be available promptly for succession; and (3) the incumbent(s) higher-situated to fill the role of Delegated Secretarial Designee (DSD) as provided in Paragraph 4.B. are unavailable or unlikely to be available promptly to assume the position of DSD, then consistent with the guidelines and operational plans of the Department and upon a review of the circumstances and Executive branch guidance, the incumbent in the next highest DSD-eligible position shall activate the governing Continuity Plans described in Paragraph 5.A. and, based upon those

plans, determine whether the National Office of the Department of Labor will remain in the then existing location, be repositioned organizationally to the Continuity Site, or be repositioned in Dallas, Texas. If emergency circumstances exist that make identification of the DSD untenable, then the Regional Solicitor located in Dallas shall assume the duties and responsibilities described above in this Paragraph 5.B. unless and until the Secretary, Acting Secretary or a higher-situated official listed in Paragraph 4.B. above is identified and is available to serve.

6. General and Specific Delegations of Authority and Assignment of Responsibilities

A. Acting Secretary: Upon designation in accordance with the conditions and sequence set forth in Section 4.A. of this Order, the Acting Secretary shall have all of the authorities of the Secretary of Labor, whether statutorily-conferred or delegated by the President. The Acting Secretary shall provide for the full operational management of the Department of Labor, including, for example, the activation or modification of pre-existing Continuity Plans for the repositioning and reconstitution of the Department of Labor in the event of a national emergency.

B. Delegated Secretarial Designee: Upon designation in accordance with the conditions and sequence set forth above and subject to direction by the President or designee, the Secretary, or the Acting Secretary, the DSD shall fulfill interim operational management functions for the Department of Labor, performing all of the duties and responsibilities of the Secretary of Labor (except the "functions and duties" as defined in Paragraph 4.B. above) including, for example, the activation or modification of pre-existing Continuity Plans for the repositioning and reconstitution of the Department of Labor in the event of a national emergency.

C. Assistant Secretary for Administration and Management: Upon conditions requiring implementation of this plan and any subsequent vacancies, ASAM shall be in charge of ensuring compliance with the FVRA. Further, as the DOL Continuity Coordinator, ASAM shall develop and provide on at least an annual basis a "duties and responsibilities" briefing to the designated Secretarial successors and DSDs and other key positions on their respective responsibilities, and on applicable relocation and reconstitution provisions, and shall establish (within 180 days from the date of this Order) and regularly thereafter update, in

consultation with DOL Agency Heads, governing Continuity Plans for the repositioning and reconstitution of the Department of Labor upon the occurrence of national emergency scenarios entailing a wholesale disruption of the operations, structure, and leadership of the Department of Labor. The governing Continuity Plans for the Department as approved by the ASAM shall reflect:

(1) The standards under a variety of scenarios for activation of the Continuity Plans;

(2) the determination of each agency head that the succession plans, delegations of authority and assignments of responsibility, emergency agency directives, standard operating procedures, and position descriptions needed to fulfill its mission, if devolved to or reconstituted in Dallas, are established, approved by the ASAM, and presented to the Dallas Regional Administrator (OASAM) for contingency activation by Secretary, Acting Secretary, or the Delegated Secretarial Designee; and

(3) plans prepared by the DOL component Agencies, to include OASAM, Dallas Regional Administrator (OASAM) for devolving essential operations for the component Agency and for reconstituting the Department or component Agency in the event of activation of the DOL Continuity Plans.

D. The Chief Human Capital Officer shall develop and approve (within 180 days from the date of this Order) and regularly thereafter update, a plan, consistent with applicable law, for managing, positioning and compensating DOL human resources in the event of a continuity of operations event, and shall assist with, and review the adequacy of, preparations by Agency Heads for repositioning and reconstituting the operations of their respective agencies. The Chief Human Capital Officer shall also assure that the position descriptions of all DSD-eligible incumbents reflect their potential DSD service.

E. The Chief Acquisition Officer shall develop and approve (within 180 days from the date of this Order) and regularly thereafter update, appropriate plans for assuring that all stages of the Department's central contracting needs can be met with regional resources and that emergency powers, to the extent permitted by law, are ready for activation upon the occurrence of a national emergency or major disruption, and shall assist with and review the adequacy of preparations by Agency Heads for repositioning and reconstituting the operations of their respective agencies.

F. The Chief Information Officer shall develop and approve (within 180 days from the date of this Order) and regularly thereafter update, appropriate plans for assuring that all of the Department's information technology systems have sufficient redundancies to support the timely relocation of the Department's Essential Functions and the reconstitution of the all the Department's organizations and functions, and shall assist with and review the adequacy of preparations by Agency Heads for repositioning and reconstituting the operations of their respective agencies.

G. The Assistant Secretary for Administration and Management shall develop and approve (within 180 days from the date of this Order) and regularly thereafter update, plans, consistent with applicable law, for the establishment of budget formulation for a relocated or reconstituted Department and for securing apportionment flexibilities that will permit functions to be transferred and redistributed among DOL agencies and their respective appropriation accounts, and shall assist with and review the adequacy of preparations by Agency Heads for repositioning and reconstituting the operations of their respective agencies.

H. The Chief Financial Officer shall develop and approve (within 180 days from the date of this Order) and regularly thereafter update, plans consistent with applicable law, for the establishment of budget execution capabilities for a relocated or reconstituted Department and shall assist with and review the adequacy of preparations by Agency Heads for repositioning and reconstituting the operations of their respective agencies.

I. The Chief Property Officer shall assist with and review the adequacy of preparations by Agency Heads for repositioning and reconstituting the operations of their respective agencies.

J. The Solicitor of Labor is delegated authority and assigned responsibility for providing legal advice and assistance to all officers of the Department relating to the administration and implementation of this Order and, if such an event arises, for a relocated or reconstituted Department. The bringing of legal proceedings, the representation of the Secretary and other officials of the Department, and the determination of whether such proceedings or representations are appropriate in a given case, are delegated exclusively.

In addition, the Solicitor of Labor shall assume responsibilities from the Assistant Secretary for Policy for performing the role of Departmental liaison with the Office of the Federal

Register in the event of devolution of departmental operations to Dallas.

K. *Agency Heads* shall assure completion (within 180 days from the date of this Order, and on a regular basis thereafter) of the planning, support, and consultation required by authorized officers in connection with all aspects of the administration of this Order, including:

(1) Establishing appropriate succession plans, delegations of authority and assignments of responsibility, emergency agency directives, vital record identification and protection, standard operating procedures, and position descriptions to assure for the continuity of agency operations relocated to the Continuity Site or the Devolution Site, as appropriate;

(2) Engaging in specific transitional planning with the ASAM, including provisions for appropriate transfer of staff and programs as appropriate, in order to create devolution plans for DOL Agencies whose Offices do not currently have staff and space available at the Devolution Site; and

(3) In consultation with the Office of the Solicitor, identifying, compiling, and reporting to the ASAM regarding those emergency authorities and responsibilities that may not be suspended, or are activated, during national emergencies of any type.

L. All employees, including contractors, of the Department shall be responsible for knowing their individual responsibilities in any continuity situation, for contacting DOL as soon as possible after a major incident consistent with applicable guidance and for being available to work during emergencies to the extent deemed necessary and appropriate and consistent with OPM guidance. All employees shall also comply with such further directions as may be published from time to time in the Department's internal regulations or otherwise distributed relating to their duties and responsibilities during emergency circumstances.

7. *Reservations of Authority*

A. Except to the extent stated in this Order, this Secretary's Order does not affect the authorities and responsibilities of the Inspector General under the Inspector General Act of 1978, as amended, or Secretary's Order 04–2006 (February 21, 2006).

B. This Order does not affect any authorities and responsibilities of the Chief Financial Officer under the Chief Financial Officers Act of 1990, any other Federal law or regulation, or any Office of Management and Budget, Government Accountability Office, or

U.S. Department of the Treasury policies and publications governing the fiscal responsibilities of Federal departments and agencies.

8. *Effective Date.* This Order is effective immediately.

Thomas E. Perez,
Secretary of Labor.

Attachment

MEMORANDUM FOR DEPARTMENT OF LABOR EXECUTIVE STAFF

FROM: THOMAS E. PEREZ

SUBJECT: To Provide for the Order of Succession for Executive Continuity

This memorandum is issued pursuant to Secretary's Order 1–2017 and the authorities cited therein, in order to provide lines of succession in periods of vacancy in case of absence, sickness, resignation, or death of agency heads and during periods of national emergency declared by the President and to provide for ongoing operational management of agency programs and personnel. This memorandum addresses succession in the Department for (1) appointments made by the President, by and with the advice and consent of the Senate (PAS), (2) appointments made by the President not subject to the Senate's advice and consent role (PA), and (3) appointments made by the Secretary.

Succession for PAS Agency Head Appointments

Functions and duties and ongoing operational management responsibilities of the officers of the Department whose appointment to office is required to be made by the President, by and with the advice and consent of the Senate (PAS), will be performed in an acting capacity by the below designated "first assistants," unless and until the President makes an alternative designation under the Federal Vacancies Reform Act of 1998 (FVRA). Functions and duties are those non-delegable responsibilities established by law (statute or regulation) and required to be performed by, and only by, the PAS.

In the event that the first assistant does not serve or is barred from serving, unless and until the President makes an alternative designation under the FVRA, the person whose designation closest follows that of the first assistant shall perform the operational management of the agency. However, the functions and duties of the PAS may not be performed by any person other than the person serving in an acting capacity, in accord with FVRA (or, in the absence of an acting officer, by the Secretary pursuant to the FVRA).

Succession for Other Agency Head Appointments

In addition, certain DOL offices are not covered by the FVRA because they are not subject to Senate confirmation. Nevertheless, they are included in this Memorandum in order to consolidate the presentation of the Department's program for establishing orderly internal succession in the event of vacancies. These agencies are: Office of the Assistant Secretary for Administration and Management, Office of the Assistant Secretary for Public Affairs, Office of Federal Contract Compliance Programs, Women's Bureau, Office of Labor-Management Standards, Office of Workers' Compensation Programs, Bureau of International Labor Affairs.

This memorandum supersedes all prior inconsistent agency delegations. Agency Heads shall assure that agency delegations, position descriptions, and other pertinent documents are maintained consistently with the designations provided below. Any modifications to the Order of Succession specified in this memorandum are solely reserved to the Secretary. This memorandum shall be published in the **Federal Register** and codified in the Department of Labor Manual Series. This memorandum is subject to periodic revision by the Secretary, as necessary, and is effective on the date indicated above.

DESIGNATION OF DOL AGENCY FIRST ASSISTANT¹ AND ORDER OF SUCCESSION

A. Presidential Appointments: Positions Under the Secretary of Labor

Deputy Secretary of Labor:

Designation to be made by Presidential direction, as provided in 5 U.S.C. 3345.

Solicitor of Labor:

Deputy Solicitor
Deputy Solicitor (Regional Enforcement)
Deputy Solicitor (National Operations)

Assistant Secretary for Administration and Management [not subject² to FVRA³]

¹ The first assistants or equivalent position are designated in *italic font* in the list that follows as the position designated immediately below the agency head position title. Unless otherwise indicated, the listed first assistants are those individuals holding non-career appointments. From time-to-time, DOL may create a "Principal Deputy" position and designate someone to fill that role. If any such position is filled and approved by OPM, that position would go immediately below the Agency Head position.

² P.L. 112–166, Presidential Appointment and Streamlining Act of 2011.

³ Federal Vacancies Reform Act of 1998, 5 U.S.C. 3345–3349d.

Deputy Assistant Secretary for Policy
Deputy Assistant Secretary for
Operations

Assistant Secretary for Policy:

Deputy Assistant Secretary for Policy
Deputy Assistant Secretary for Policy
(Operations and Analysis)

**Assistant Secretary for Congressional
and Intergovernmental Affairs:**

*Deputy Assistant Secretary for
Congressional Affairs*

Deputy Assistant Secretary for
Congressional Affairs

**Assistant Secretary for Employment
and Training:**

*Deputy Assistant Secretary Deputy
Assistant Secretary*

Deputy Assistant Secretary for
Operations and Management

**Assistant Secretary for Employee
Benefits Security:**

Deputy Assistant Secretary for Policy
Deputy Assistant Secretary for
Program Operations

**Assistant Secretary for Occupational
Safety and Health:**

Deputy Assistant Secretary
Deputy Assistant Secretary

**Assistant Secretary for Mine Safety and
Health:**

*Deputy Assistant Secretary for Mine
Safety and Health*

Deputy Assistant Secretary for Mine
Safety and Health (Operations)

**Assistant Secretary for Public Affairs
[not subject ⁴ to FVRA]:**

Deputy Assistant Secretary
Senior Managing Director

Chief Financial Officer:

Deputy Chief Financial Officer
Administrator, Wage and Hour

Division:

Deputy Wage and Hour Administrator
Deputy Wage and Hour Administrator
(Operations)

**Assistant Secretary for Veterans'
Employment and Training:**

*Deputy Assistant Secretary for
Veterans' Employment and
Training Service (Policy)*

Deputy Assistant Secretary for
Operations and Management

**Assistant Secretary for Disability
Employment Policy:**

Deputy Assistant Secretary

**Director of the Women's Bureau [not
subject ⁵ to FVRA]:**

Deputy Director⁶

Deputy Director

Commissioner of Labor Statistics:

Deputy Commissioner

Inspector General:

Deputy Inspector General

**B. Non-Career SES Agency Head
Positions**

**Director, Office of Federal Contract
Compliance Programs:**

Deputy Director

Director, Division of Program
Operations

**Director, Office of Labor-Management
Standards:**

Deputy Director

**Director, Office of Workers'
Compensation Programs:**

Deputy Director

Director, Division of Federal
Employee Compensation

**Deputy Under Secretary for
International Affairs of the Bureau
of International Labor Affairs:**

*Associate Deputy Under Secretary for
International Affairs*

Associate Deputy Under Secretary for
International Affairs

[FR Doc. 2017-01289 Filed 1-18-17; 8:45 am]

BILLING CODE 4510-XX-P

**OCCUPATIONAL SAFETY AND
HEALTH REVIEW COMMISSION**

**Senior Executive Service Performance
Review Board Membership**

AGENCY: Occupational Safety and Health
Review Commission.

ACTION: Annual Notice.

SUMMARY: Notice is given of the
appointment of members to the
Performance Review Board (PRB) of the
Occupational Safety and Health Review
Commission.

DATE: Membership is effective on
January 19, 2017.

FOR FURTHER INFORMATION CONTACT:

Linda M. Beard, Human Resources
Specialist, U.S. Occupational Safety and
Health Review Commission, 1120 20th
Street NW., Washington, DC 20036,
(202) 606-5393.

SUPPLEMENTARY INFORMATION: The
Review Commission, as required by 5
U.S.C. 4314(c)(1) through (5), has
established a Senior Executive Service
PRB. The PRB reviews and evaluates the
initial appraisal of a senior executive's
performance by the supervisor, and makes
recommendations to the Chairman of the
Review Commission regarding performance
ratings, performance awards, and pay-for-
performance adjustments. Members of the
PRB serve for a period of 24 months. In
the case of an appraisal of a career
appointee, more than half of the members
shall consist of career appointees, pursuant
to 5 U.S.C. 4314(c)(5). The names and titles
of the PRB members are as follows:

• Nancy P. Bray, Director, Spaceport
Integration and Services, National
Aeronautics and Space Administration;

• Christine M. Condon, Principal
Director, Deputy Chief Information
Officer for Resources and Analysis,
Office of the Secretary of Defense, DOD;

• Monica R. Shephard, Vice Director,
Joint Force Development, DOD; and

• Rebecca A. Fenneman, Director,
Office of Consumer Affairs and Dispute
Resolution Services, Federal Maritime
Commission.

Dated: January 11, 2017.

Cynthia L. Attwood,

Chairman.

[FR Doc. 2017-01124 Filed 1-18-17; 8:45 am]

BILLING CODE 7600-01-P

**NATIONAL AERONAUTICS AND
SPACE ADMINISTRATION**

[(Notice (17-001))]

**Notice of Intent To Grant a Partially
Exclusive License**

AGENCY: National Aeronautics and
Space Administration.

ACTION: Notice of intent To grant
partially exclusive license.

SUMMARY: NASA hereby gives notice of
its intent to grant a partially exclusive
patent license in the United States to
practice the inventions described and
claimed in U.S. Patent Number
7,075,295 B2 titled "Magnetic Field
Response Sensor for Conductive
Media," NASA Case Number LAR-
16571-1; U.S. Patent Number 7,589,525
B2 titled "Magnetic Field Response
Sensor for Conductive Media," NASA
Case Number LAR-16571-2; U.S. Patent
No. 7,759,932 B2 titled "Magnetic Field
Response for Conductive Media," NASA
Case Number LAR-16571-3; U.S. Patent
No. 7,086,593 B2 titled "Magnetic Field
Response Measurement Acquisition
System," NASA Case Number LAR-
16908-1; U.S. Patent No. 7,047,807 B2
titled "Flexible Framework for
Capacitive Sensing," NASA Case No.
LAR-16974-1; U.S. Patent No.
7,506,541 B2 titled "System and Method
for Wirelessly Determining Fluid
Volume," NASA Case No. LAR-17116-
1; U.S. Patent No. 7,255,004 B2 titled
"Wireless Fluid Level Measuring
System," NASA Case Number LAR-
17155-1; U.S. Patent No. 7,159,774 B2
titled "Magnetic Field Response
Measurement Acquisition System,"
NASA Case No. LAR-17280-1; U.S.
Patent No. 8,430,327 B2 titled "Wireless
Sensing System Using Open-Circuit,
Electrically-Conductive Spiral-Trace
Sensor," NASA Case No. LAR-17294-1;

⁴ See footnote 2.

⁵ See footnote 2.

⁶ 29 U.S.C. 14 creates first assistant to the Director
of the Women's Bureau.

U.S. Patent No. 7,711,509 B2 titled "Method of Calibrating a Fluid-Level Measurement System," NASA Case No. LAR-17480-1; and U.S. Patent Application No. 14/520,863 titled "Antenna for Far Field Transceiving," NASA Case No. LAR-18400-1, to Smart BioHealth, LLC, having its principal place of business in Minnesota City, MN. The fields of use may be limited to portable devices (excluding devices composed of threads, fabrics, textiles, and/or paper) for Human Performance (HP) measurement of body density (limited to body fat, muscle density, and bone density); body mechanics (limited to motion analysis, posture, and balance); physiological responses to physical activity, and energy usage (limited to lactic acid, blood glucose, blood oxygen, hydration, and electrolyte balance).

DATES: The prospective partially exclusive license may be granted unless, within fifteen (15) days from the date of this published notice, NASA receives written objections including evidence and argument that establish that the grant of the license would not be consistent with the requirements regarding the licensing of federally owned inventions as set forth in the Bayh-Dole Act and implementing regulations. Competing applications completed and received by NASA within fifteen (15) days of the date of this published notice will also be treated as objections to the grant of the contemplated partially exclusive license. Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act.

ADDRESSES: Objections relating to the prospective license may be submitted to Patent Counsel, Office of Chief Counsel, NASA Langley Research Center, MS 30, Hampton, Virginia 23681. Phone (757) 864-3221. Facsimile (757) 864-9190.

FOR FURTHER INFORMATION CONTACT: Robin W. Edwards, Patent Counsel, Office of Chief Counsel, NASA Langley Research Center, MS 30, Hampton, Virginia 23681. Phone (757) 864-3221. Facsimile (757) 864-9190.

SUPPLEMENTARY INFORMATION: This notice is issued in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(i). This notice of intent to grant a partially exclusive patent license is issued in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i). The patent rights in these inventions have been assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space

Administration. The prospective exclusive license will comply with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Information about other NASA inventions available for licensing can be found online at <http://technology.nasa.gov>.

Mark P. Dvorscak,
Agency Counsel for Intellectual Property.
[FR Doc. 2017-01179 Filed 1-18-17; 8:45 am]
BILLING CODE 7510-13-P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA-2017-024]

Advisory Committee on the Presidential Library-Foundation Partnerships

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of Federal Advisory Committee Meeting Change.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), the National Archives and Records Administration announces an upcoming Advisory Committee on Presidential Library-Foundation Partnerships meeting.

DATES: The meeting will be Thursday, February 23, 2017, from 9:00 a.m. to 12:00 noon.

Location: National Archives and Records Administration (NARA); 700 Pennsylvania Avenue NW., Room 105; Washington, DC 20408.

FOR FURTHER INFORMATION CONTACT: Denise LeBeck, by telephone at 301-837-3250, or by email at denise.lebeck@nara.gov.

SUPPLEMENTARY INFORMATION: The original notice about this meeting stated it was scheduled for February 29, 2017, at 10:00 a.m. (see 81 FR 94426, December 23, 2016). However, that was an incorrect date. This notice changes the meeting date to February 23, 2017, to reflect the actual meeting date.

The meeting's purpose is to discuss the Presidential Library program and topics related to public-private partnerships between Presidential Libraries and Presidential Foundations. The meeting is open to the public. Meeting attendees may enter from the Pennsylvania Avenue entrance, and must show photo identification to enter. No visitor parking is available at the Archives building; however, there are

commercial parking lots and metered curb parking nearby.

Patrice Little Murray,
Committee Management Officer.

[FR Doc. 2017-01129 Filed 1-18-17; 8:45 am]

BILLING CODE 7515-01-P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA-2017-023]

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments

SUMMARY: The National Archives and Records Administration (NARA) publishes notice at least once monthly of certain Federal agency requests for records disposition authority (records schedules). Once approved by NARA, records schedules provide mandatory instructions on what happens to records when agencies no longer need them for current Government business. The records schedules authorize agencies to preserve records of continuing value in the National Archives of the United States and to destroy, after a specified period, records lacking administrative, legal, research, or other value. NARA publishes notice in the **Federal Register** for records schedules in which agencies propose to destroy records not previously authorized for disposal or reduce the retention period of records already authorized for disposal. NARA invites public comments on such records schedules, as required by 44 U.S.C. 3303a(a).

DATES: NARA must receive requests for copies in writing by February 21, 2017. Once NARA finishes appraising the records, we will send you a copy of the schedule you requested. We usually prepare appraisal memoranda that contain additional information concerning the records covered by a proposed schedule. You may also request these. If you do, we will also provide them once we have completed the appraisal. You have 30 days after we send to you these requested documents in which to submit comments.

ADDRESSES: You may request a copy of any records schedule identified in this notice by contacting Records Appraisal and Agency Assistance (ACRA) using one of the following means:

Mail: NARA (ACRA); 8601 Adelphi Road; College Park, MD 20740-6001.
Email: request.schedule@nara.gov.

FAX: 301-837-3698.

You must cite the control number, which appears in parentheses after the name of the agency that submitted the schedule, and a mailing address. If you would like an appraisal report, please include that in your request.

FOR FURTHER INFORMATION CONTACT:

Margaret Hawkins, Director, by mail at Records Appraisal and Agency Assistance (ACRA); National Archives and Records Administration; 8601 Adelphi Road; College Park, MD 20740-6001, by phone at 301-837-1799, or by email at request.schedule@nara.gov.

SUPPLEMENTARY INFORMATION: Each year, Federal agencies create billions of records on paper, film, magnetic tape, and other media. To control this accumulation, agency records managers prepare schedules proposing records retention periods and submit these schedules for NARA's approval. These schedules provide for timely transfer into the National Archives of historically valuable records and authorize the agency to dispose of all other records after the agency no longer needs them to conduct its business. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

The schedules listed in this notice are media neutral unless otherwise specified. An item in a schedule is media neutral when an agency may apply the disposition instructions to records regardless of the medium in which it creates or maintains the records. Items included in schedules submitted to NARA on or after December 17, 2007, are media neutral unless the item is expressly limited to a specific medium. (See 36 CFR 1225.12(e).)

Agencies may not destroy Federal records without Archivist of the United States' approval. The Archivist approves destruction only after thoroughly considering the records' administrative use by the agency of origin, the rights of the Government and of private people directly affected by the Government's activities, and whether or not the records have historical or other value.

In addition to identifying the Federal agencies and any subdivisions requesting disposition authority, this notice lists the organizational unit(s) accumulating the records (or notes that the schedule has agency-wide applicability when schedules cover

records that may be accumulated throughout an agency); provides the control number assigned to each schedule, the total number of schedule items, and the number of temporary items (the records proposed for destruction); and includes a brief description of the temporary records. The records schedule itself contains a full description of the records at the file unit level as well as their disposition. If NARA staff has prepared an appraisal memorandum for the schedule, it also includes information about the records. You may request additional information about the disposition process at the addresses above.

Schedules Pending

1. Department of the Army, Agency-wide (DAA-AU-2016-0045, 1 item, 1 temporary item). Master files of an electronic information system used to track parts and asset shortages in support of depot-level maintenance operations.

2. Department of Defense, Defense Logistics Agency (DAA-0361-2017-0001, 1 item, 1 temporary item). Records relating to personally owned property abandoned at Department of Defense activities.

3. Department of Defense, Defense Logistics Agency (DAA-0361-2017-0002, 1 item, 1 temporary item). Master files of an electronic information system used to report food inspections at installations.

4. Department of Energy, Naval Nuclear Propulsion Program (DAA-0434-2015-0008, 11 items, 10 temporary items). Records relating to finance and procurement including accounting, purchasing, contract administration, asset valuation, and preparation and maintenance of the budget and payroll and related material. Proposed for permanent retention are records relating to first prime contracts.

5. Department of Health and Human Services, National Institutes of Health (DAA-0443-2016-0002, 4 items, 4 temporary items). Administrative technology transfer records including agreements, application files, letters, and progress and sales reports.

6. Department of Justice, Agency-wide (DAA-0060-2016-0006, 4 items, 4 temporary items). Records related to the coordination of agency rulemaking actions.

7. Department of Justice, Agency-wide (DAA-0060-2017-0004, 1 item, 1 temporary item). Records documenting office and program level annual work plans.

8. Department of the Navy, Agency-wide (DAA-NU-2015-0006, 36 items, 33 temporary items). Records relating to

medicine and dentistry including routine correspondence, tissue exam results, diving and hyperbaric medical treatment, dental reports, training, obesity case files and associated records. Proposed for permanent retention are records relating to policy and planning, individual health care files, and reports of medical research.

9. Department of the Navy, Agency-wide (DAA-NU-2015-0008, 35 items, 28 temporary items). Records relating to ordnance management including routine correspondence, deperming and degaussing, ordnance equipment, device calibration, occupational vision tests, and related matters. Proposed for permanent retention are records relating to policy and planning, ordnance technical instructions, logistics programs, ordnance design, technical reports and manuals, harbor defense, and special weapons records.

10. Commodity Futures Trading Commission, Agency-wide (DAA-0180-2017-0001, 1 item, 1 temporary item). Registered entity applications, and related amendments and supplements.

11. Peace Corps, Office of Global Operations (DAA-0490-2016-0004, 1 item, 1 temporary item). Records of the Office of Staging and Pre-Departure, related to facilitating the orientation and departure of volunteers to overseas posts.

Laurence Brewer,

Chief Records Officer for the U.S. Government.

[FR Doc. 2017-01130 Filed 1-18-17; 8:45 am]

BILLING CODE 7515-01-P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA-2017-024]

Advisory Committee on the Presidential Library-Foundation Partnerships

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of Federal Advisory Committee meeting change.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), the National Archives and Records Administration announces an upcoming Advisory Committee on Presidential Library-Foundation Partnerships meeting.

DATES: The meeting will be Thursday, February 23, 2017, from 9:00 a.m. to 12:00 noon.

Location: National Archives and Records Administration (NARA); 700

Pennsylvania Avenue NW., Room 105; Washington, DC 20408.

FOR FURTHER INFORMATION CONTACT:

Denise LeBeck, by telephone at 301-837-3250, or by email at denise.lebeck@nara.gov.

SUPPLEMENTARY INFORMATION: The original notice about this meeting stated it was scheduled for February 29, 2017, at 10:00 a.m. (see 81 FR 94426, December 23, 2016). However, that was an incorrect date. This notice changes the meeting date to February 23, 2017, to reflect the actual meeting date.

The meeting's purpose is to discuss the Presidential Library program and topics related to public-private partnerships between Presidential Libraries and Presidential Foundations. The meeting is open to the public. Meeting attendees may enter from the Pennsylvania Avenue entrance, and must show photo identification to enter. No visitor parking is available at the Archives building; however, there are commercial parking lots and metered curb parking nearby.

Patrice Little Murray,
Committee Management Officer.

[FR Doc. 2017-01155 Filed 1-18-17; 8:45 am]

BILLING CODE 7515-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-59; NRC-2017-0007]

Texas A&M University

AGENCY: Nuclear Regulatory Commission.

ACTION: Environmental assessment and finding of no significant impact; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering the issuance of a license amendment to Facility Operating License No. R-23, held by the Texas A&M University (TAMU or the licensee) for the Aerojet General Nucleonics Model 201-Modified (AGN-201M) reactor facility located in the Zachry Engineering Center on the TAMU College Station Campus, Brazos County, Texas. The amendment would delete from the technical specifications (TSs) the Zachry Engineering Center location that constituted the reactor facility for the AGN-201M reactor and associated components. The reactor, associated components, and its special nuclear material (SNM) have been removed from the Zachry Engineering Center and temporarily stored at the Texas Engineering Experiment Station, in

Brazos County, Texas, where TAMU operates another reactor. The license amendment would also delete the license conditions requiring a physical security plan (PSP) and TSs requiring procedures that implement the security plan and audits of the PSP and its implementing procedures as the SNM possession limit in the license is below the quantity of material that requires a security plan.

If approved, removal of the Zachry Engineering Center from the TSs would allow the unrestricted use of the rooms where the AGN-201M reactor, its associated components and its byproduct and SNM were formerly located. The NRC is issuing an environmental assessment (EA) and finding of no significant impact (FONSI) associated with the proposed license amendment.

DATES: The EA and FONSI are available as of January 19, 2017.

ADDRESSES: Please refer to Docket ID NRC-2017-0007 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2017-0007. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; email: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to pdr.resource@nrc.gov.

- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Patrick G. Boyle, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Rockville, MD 20852; telephone: 301-415-3936; email: Patrick.Boyle@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is considering the issuance of a license amendment to Facility Operating License No. R-23, held by TAMU, which would delete (1) part of TS 5.3, removing the Reactor Room, Control Room and Accelerator Room in the Zachry Engineering Center as a storage location for the AGN-201M reactor and associated components and allowing the unrestricted use of the Zachry Engineering Center that was the former location of the AGN-201M reactor; (2) license conditions 2.C.(3) and 2.D, removing the requirement that the licensee maintain a PSP; and (3) TS 6.4.3.c and parts of TS 6.6.f, removing requirements for procedures that implement the PSP and audits of the PSP and implementing procedures. The facility is located in the Zachry Engineering Center on the TAMU campus, Brazos County, Texas.

The licensee submitted its license amendment request by letter dated November 21, 2016 (ADAMS Accession No. ML16326A447), as supplemented by letters dated December 16 and 20, 2016 (ADAMS Accession Nos. ML16352A000, ML16351A502, and ML17011A079); and January 9 and 11, 2017 (ADAMS Accession Nos. ML17010A057 and ML17012A069). The NRC staff prepared an EA to document its environmental findings related to the proposed license amendment in accordance with section 51.21 of title 10 of the *Code of Federal Regulations* (10 CFR). Based on the results of the environmental review conducted for this EA, the NRC staff did not identify any significant environmental impacts associated with the proposed action and is, therefore, issuing a FONSI in accordance with 10 CFR 51.32.

II. Environmental Assessment

Facility Locations and Previous Actions

The Zachry Engineering Center, located on the TAMU College Station Campus, in Brazos County, Texas housed the AGN-201M reactor as well as offices and laboratories in which radiological materials were used in support of reactor operations. The AGN-201M has a power rating of 5 watts, thermal and uses a polyethylene and uranium dioxide plate type fuel with a uranium-235 enrichment of less than 20%. The reactor core is cooled by natural convection and therefore, the reactor does not have an external cooling loop. Texas A&M University purchased the AGN reactor in 1957 and moved it to the Zachry Engineering Center in 1972. The AGN-201M reactor was located on the ground floor in the

southwest portion of the building and has not been operated since 2014.

TAMU operates a second reactor at the Nuclear Science Center, within the Texas Engineering Experiment Station, also located on the TAMU College Station Campus, in Brazos County, Texas.

The NRC staff approved the SNM transfer and relocation of the AGN-201M reactor and associated components in license amendments dated August 31, 2016 (ADAMS Accession No. ML16109A153), and November 11, 2015 (ADAMS Accession No. ML15315A027), respectively. TAMU completed the transfer of SNM in the form of AGN-201M reactor fuel, control rods, and a plutonium beryllium start up source to the TAMU System, Nuclear Science Center Reactor Facility License No. R-83 and the remaining AGN-201M reactor components containing byproduct material and trace quantities of SNM were relocated to the Texas Engineering Experiment Station on October 15, 2016.

TAMU requested that the NRC amend the AGN-201M license to allow the unrestricted use of the Zachry Engineering Center, proposed changes to conditions and TSs in the license, and provided radiation survey results to support its amendment application.

Description of the Proposed Action

The proposed action would delete the Reactor Room, Control Room and Accelerator Room in the Zachry Engineering Center as a location for the storage of the AGN-201 reactor and associated components, allowing the unrestricted use of the Zachry Engineering Center that was the former location of the AGN-201M reactor. The proposed action would also delete license conditions that require a PSP, and delete TS 6.6.f. and 6.4.3.c, which require PSP implementing procedures and audits of the PSP and its implementing procedures because SNM for the AGN-201M has been transferred to another NRC license and, hence, the license no longer authorizes possession of a quantity of SNM that requires a PSP under the regulations in 10 CFR 73.67. In order to remove the Zachry Engineering Center rooms constituting the reactor facility from the TSs and allow unrestricted use of those locations in accordance with 10 CFR 20.1402, residual radioactivity that is distinguishable from background radiation at the reactor facility may not exceed 25 mrem (0.25 mSv) per year total effective dose equivalent (TEDE) to a member of the public and the residual radioactivity must be reduced to levels

that are as low as reasonably achievable (ALARA).

The Need for the Proposed Action

The proposed action is needed (1) to remove from Facility Operating License No. R-23 and release the rooms that constitute the AGN-201M reactor facility at the Zachry Engineering Center, which would enable the rooms to be used for other purposes without radiological restrictions, and (2) to delete license conditions requiring the licensee to maintain a PSP and delete associated PSP procedural and audit requirements in the TSs.

Environmental Impacts of the Proposed Action

The NRC staff has completed its environmental review of the proposed action and concludes that the proposed action will not present any undue risk to public health and safety. After removal of the AGN-201M reactor, associated components, and SNM, and their relocation to the Texas Engineering Experiment Station, TAMU conducted clean-up activities at the Zachry Engineering Center. TAMU developed a final status survey plan (ADAMS Accession No. ML16316A002), completed the final status survey of the Zachry Engineering Center rooms where the AGN-201M reactor, associated components, and SNM were previously located (ADAMS Accession No. ML17010A057) and found that the facility met the requirements for unrestricted use in 10 CFR part 20, subpart E. An NRC staff confirmatory survey was conducted during the week of November 14, 2016 (ADAMS Accession No. ML16355A083).

The NRC staff is preparing a safety evaluation in connection with its review of the proposed action. Based on the clean-up activities carried out by the licensee, the NRC staff's review of TAMU's final status survey report and the results of the NRC staff confirmatory survey, the NRC staff has concluded, pursuant to 10 CFR 20.1402, that residual radioactivity at the site does not exceed 25 mrem (0.25 mSv) TEDE. In addition, since no residual radioactivity distinguishable from background was found at the site, ALARA has been met. Therefore, the Zachry Engineering Center rooms which constituted the reactor facility (as designated in TS 5.3) are suitable to be released for unrestricted use and can be removed from the TSs. TAMU also requests that the NRC delete license conditions requiring a PSP and associated PSP TSs because physical possession of the SNM for the AGN-201M reactor has been transferred to,

and is being stored under, another NRC license and therefore a PSP is not required for the AGN-201M under 10 CFR 73.67. Further details of the NRC's safety review will be provided in the safety evaluation related to the license amendment that, if issued by the NRC, would authorize the proposed action.

The proposed action does not authorize any effluent or material releases, does not change any release criteria set forth in the present regulations, and the results of the NRC confirmatory survey confirmed that any residual radioactivity at the Zachry Engineering Center facility comply with criteria for unrestricted release of a site set forth in 10 CFR 20.1402. No changes would occur in the types of any effluents that may be released offsite, and there would be no significant increase in the amount of any effluent released offsite. Thus there would be no significant increase in occupational or public radiation exposure. In addition, because all of the SNM has been removed from the Zachry Engineering Center, deletion of license conditions requiring a PSP and deletion of associated TSs is appropriate. Therefore, the proposed action would result in no significant radiological environmental impacts.

With regard to potential non-radiological impacts, the proposed action does not authorize or involve any reactor facility construction activities and would not result in visual resource impacts, increases in noise or air emissions, or have any foreseeable impacts to historic properties, water resources, and aquatic or terrestrial resources. Similarly, the proposed action would result in no socioeconomic or environmental justice impacts. Therefore, there would be no significant non-radiological environmental impacts associated with the proposed action.

Accordingly, the NRC staff concludes that there would be no significant environmental impacts associated with the proposed action.

Environmental Impacts of the Alternatives to the Proposed Action

As an alternative to the proposed action, the NRC staff considered the denial of the proposed action (*i.e.*, the "no-action" alternative). Denial of the license amendment request would result in no change in current environmental impacts. The environmental impacts of the proposed action and the "no action" alternative would be similar.

Alternative Use of Resources

The proposed action would not involve the use of any different

resources than those previously considered in the document "Texas A&M University—Facility Operating License No. R-23," dated August 26, 1957 (ADAMS Accession No. ML16085A206).

Agencies and Persons Consulted

The NRC staff did not enter into consultation with any other Federal agency or with the State of Texas regarding the environmental impact of the proposed action. However, on December 22, 2016, the NRC notified the Texas State official, Mrs. DeAnn Walker, Director, Office of the Governor Office of Budget and Policy, of the proposed action. The State official had no comments.

III. Finding of No Significant Impact

The NRC is considering the issuance of a license amendment to Facility Operating License No. R-23, held by TAMU, which would delete (1) part of TS 5.3, removing the Reactor Room, Control Room and Accelerator Room in the Zachry Engineering Center as a storage location for the AGN-201M reactor and associated components and allowing the unrestricted use of the Zachry Engineering Center that was the former location of the AGN-201M reactor; (2) license conditions 2.C.(3) and 2.D, removing the requirement that the licensee maintain a PSP; and (3) TS 6.4.3.c and parts of TS 6.6.f, removing requirements for procedures that implement the PSP and audits of the PSP and implementing procedures. The facility is located in the Zachry Engineering Center on the TAMU campus, Brazos County, Texas.

On the basis of the EA included in Section II of this notice and incorporated by reference, the NRC staff finds that the proposed action will not have a significant effect on the quality of the human environment. The NRC staff's evaluation considered information provided in the licensee's application, as supplemented, and the NRC staff's review of related environmental documents. Section II above identifies the documents related to the proposed action and includes information on the availability of these documents. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

Dated at Rockville, Maryland, this 13th day of January 2017.

For the Nuclear Regulatory Commission.

Mirela Gavrilas,

Deputy Director, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation.

[FR Doc. 2017-01233 Filed 1-18-17; 8:45 am]

BILLING CODE 7590-01-P

Postal Regulatory Commission

[Docket No. T2017-1; Order No. 3751]

Income Tax Review

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the calculation of the assumed Federal income tax on competitive products income for Fiscal Year 2016. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* February 3, 2017.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202-789-6820.

SUPPLEMENTARY INFORMATION:

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- I. Introduction
- II. Notice of Commission Action
- II. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3634 and 39 CFR 3060.40 *et seq.*, the Postal Service filed its calculation of the assumed Federal income tax on competitive products income for fiscal year (FY) 2016.¹ The calculation details the FY 2016 competitive product revenue and expenses, the net competitive products income before tax, and the assumed Federal income tax on that income.

II. Notice of Commission Action

In accordance with 39 CFR 3060.42, the Commission establishes Docket No. T2017-1 to review the calculation of the

¹ Notice of the United States Postal Service of Submission of the Calculation of the FY 2016 Assumed Federal Income Tax on Competitive Products, January 12, 2017.

assumed Federal income tax and supporting documentation.

The Commission invites comments on whether the Postal Service's filing in this docket is consistent with the policies of 39 U.S.C. 3634 and 39 CFR 3060.40 *et seq.* Comments are due no later than February 3, 2017. The Postal Service's filing can be accessed via the Commission's Web site (<http://www.prc.gov>).

The Commission appoints Jennaca D. Upperman to serve as Public Representative in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. T2017-1 to consider the calculation of the assumed Federal income tax on competitive products for FY 2016.

2. Pursuant to 39 U.S.C. 505, Jennaca D. Upperman is appointed to serve as an officer of the Commission to represent the interests of the general public in this proceeding (Public Representative).

3. Comments are due no later than February 3, 2017.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,
Secretary.

[FR Doc. 2017-01196 Filed 1-18-17; 8:45 am]

BILLING CODE 7710-FW-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-79778; File No. SR-PEARL-2016-01]

Self-Regulatory Organizations; MIAx PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 510 To Extend the Penny Pilot Program

January 12, 2017.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² notice is hereby given that, on December 30, 2016, MIAx PEARL, LLC ("MIAx PEARL" or "Exchange") filed with the Securities and Exchange Commission ("Commission") a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend Rule 510, Interpretations and Policies .01 to extend the pilot program for the quoting and trading of certain options in pennies (the "Penny Pilot Program").

The text of the proposed rule change is available on the Exchange's Web site at <http://www.miaxoptions.com/content/miax-pearl>, at MIAX PEARL's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

MIAX PEARL plans to commence operations as a national securities exchange registered under Section 6 of the Act³ on February 6, 2017.⁴ The Exchange will be a participant in an industry-wide pilot program that provides for the quoting and trading of certain option classes in penny increments (the "Penny Pilot Program" or "Program"). The Penny Pilot Program allows the quoting and trading of certain option classes in minimum increments of \$0.01 for all series in such option classes with a price of less than \$3.00; and in minimum increments of \$0.05 for all series in such option classes with a price of \$3.00 or higher. Options overlying the PowerShares QQQTM ("QQQ"), SPDR® S&P 500® ETF ("SPY"), and iShares® Russell 2000 ETF ("IWM"), however, are quoted and

traded in minimum increments of \$0.01 for all series regardless of the price. The Penny Pilot Program was initiated at the then existing option exchanges in January 2007⁵ and currently includes more than 300 of the most active option classes. The Penny Pilot Program is set to expire on December 31, 2016.⁶ The purpose of the proposed rule change is to implement the Penny Pilot Program in its current format through June 30, 2017, to match the most recent extension date of all the other option exchanges.⁷

In addition to the extension of the Penny Pilot Program through June 30, 2017, the Exchange proposes to extend one other date in the Rule. Currently, Interpretations and Policies .01 states that the Exchange will replace any Penny Pilot issues that have been delisted with the next most actively traded multiply listed option classes that are not yet included in the Penny Pilot Program, and that the replacement issues will be selected based on trading activity in the previous six months. Such option classes will be added to the Penny Pilot Program on the second trading day following December 31, 2016.⁸ The Exchange intends to continue this practice for the duration of the Penny Pilot Program and is proposing to amend the Rule to reflect that such option classes will be added to the Penny Pilot Program on the second trading day following January 1, 2017.⁹

⁵ See Securities Exchange Act Release Nos. 55154 (January 23, 2007), 72 FR 4743 (February 1, 2007) (SR-CBOE-2006-92); 55161 (January 24, 2007), 72 FR 4754 (February 1, 2007) (SR-ISE-2006-62); 54886 (December 6, 2006), 71 FR 74979 (December 13, 2006) (SR-Phlx-2006-74); 54590 (October 12, 2006), 71 FR 61525 (October 18, 2006) (SR-NYSEArca-2006-73); and 54741 (November 9, 2006), 71 FR 67176 (November 20, 2006) (SR-Amex-2006-106).

⁶ See Exchange Rule 510, Interpretations and Policies .01.

⁷ See Securities Exchange Act Release Nos. 79425 (November 29, 2016), 81 FR 87633 (December 5, 2016) (SR-Phlx-2016-115); 79429 (November 30, 2016), 81 FR 87991 (December 6, 2016) (SR-BOX-2016-55); 79432 (November 30, 2016), 81 FR 87990 (December 6, 2016) (SR-MIAX-2016-45); 79523 (December 9, 2016), 81 FR 90895 (December 15, 2016) (SR-BatsBZX-2016-84); 79526 (December 12, 2016), 81 FR 91235 (December 16, 2016) (SR-BatsEDGX-2016-71); 79442 (December 1, 2016), 81 FR 88293 (December 7, 2016) (SR-CBOE-2016-083); 79441 (December 1, 2016), 81 FR 88282 (December 7, 2016) (SR-C2-2016-023); 79420 (November 29, 2016), 81 FR 87639 (December 5, 2016) (SR-BX-2016-062); and 79525 (December 12, 2016), 81 FR 91230 (December 16, 2016) (SR-NYSEMKT-2016-111).

⁸ The Exchange notes that the current rule text reflected December 31, 2016, whereas the date additional series would have been added during the prior pilot period was July 31, 2016.

⁹ The month immediately preceding a replacement class's addition to the Pilot Program (*i.e.*, December) is not used for purposes of the six-

The purpose of this provision is to reflect the new date on which replacement issues may be added to the Penny Pilot Program. The Exchange notes that this filing is based upon and, in all material respects, substantially similar to a recent filing of Miami International Securities Exchange, Inc. ("MIAX Options") regarding the extension of the Penny Pilot Program.¹⁰

2. Statutory Basis

MIAX PEARL believes that its proposed rule change is consistent with Section 6(b) of the Act¹¹ in general, and furthers the objectives of Section 6(b)(5) of the Act¹² in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

In particular, the proposed rule change, which extends the Penny Pilot Program for six months, allows the Exchange to participate in a program that has been viewed as beneficial to traders, investors and public customers and viewed as successful by the other options exchanges participating in it.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes that, by extending the expiration of the Pilot Program, the proposed rule change will enable the Exchange to participate in the Pilot Program and provide additional data for further analysis of the Penny Pilot Program and allow for a determination of how the Program should be structured in the future. In doing so, the proposed rule change will also serve to promote regulatory clarity and consistency, thereby reducing burdens on the marketplace, facilitating investor protection, and fostering a competitive environment.

month analysis. For example, a replacement added on the second trading day following January 1, 2017, will be identified based on trading activity from June 1, 2016, through November 30, 2016.

¹⁰ See Securities Exchange Act Release No. 79432 (November 30, 2016), 81 FR 87990 (December 6, 2016) (SR-MIAX-2016-45).

¹¹ 15 U.S.C. 78f(b).

¹² 15 U.S.C. 78f(b)(5).

³ 15 U.S.C. 78f.

⁴ See Securities Exchange Act Release No. 79543 (December 13, 2016), 81 FR 92901 (December 20, 2016) (File No. 10-227) (order approving application of MIAX PEARL, LLC for registration as a national securities exchange.)

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act¹³ and Rule 19b-4(f)(6)¹⁴ thereunder.

A proposed rule change filed under Rule 19b-4(f)(6)¹⁵ normally does not become operative prior to 30 days after the date of the filing.¹⁶ However, pursuant to Rule 19b-4(f)(6)(iii),¹⁷ the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because doing so will allow the Pilot Program to continue without interruption in a manner that is consistent with the Commission's prior approval of the extension and expansion of the Pilot Program and will allow the Exchange and the Commission additional time to analyze the impact of the Pilot Program. Accordingly, the Commission designates the proposed rule change as operative upon filing with the Commission.¹⁸

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may

temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) of the Act¹⁹ to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-PEARL-2016-01 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.
- All submissions should refer to File Number SR-PEARL-2016-01. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549-1090, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from

submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-PEARL-2016-01 and should be submitted on or before February 9, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2017-01150 Filed 1-18-17; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-79784; File No. SR-NASDAQ-2016-135]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 2, Relating to Continued Listing Requirements for Exchange-Traded Products

January 12, 2017.

I. Introduction

On September 30, 2016, The NASDAQ Stock Market LLC ("Exchange" or "Nasdaq") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change related to continued listing requirements and delisting procedures for exchange-traded products listed pursuant to the Nasdaq Rule 5700 Series. The proposed rule change was published for comment in the **Federal Register** on October 17, 2016.³ On November 25, 2016, the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change.⁴ On January 9, 2017, the Exchange filed Amendment No. 1 to the proposed rule change. On January 11, 2017, the Exchange filed Amendment No. 2 to the proposed rule change, which amended and replaced the original proposal as modified by

¹³ 15 U.S.C. 78s(b)(3)(A).

¹⁴ 17 CFR 240.19b-4(f)(6).

¹⁵ 17 CFR 240.19b-4(f)(6).

¹⁶ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹⁷ 17 CFR 240.19b-4(f)(6)(iii).

¹⁸ For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

¹⁹ 15 U.S.C. 78s(b)(2)(B).

²⁰ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 79081 (October 11, 2016), 81 FR 71548.

⁴ See Securities Exchange Act Release No. 79399, 81 FR 86759 (December 1, 2016).

Amendment No. 1.⁵ The Commission received no comment letters on the proposed rule change. The Commission is publishing this notice to solicit comments on Amendment No. 2 from interested persons, and is approving the proposed rule change, as modified by Amendment No. 2, on an accelerated basis.

II. Description of the Proposed Rule Change, as Modified by Amendment No. 2

The Exchange proposes to amend the Rule 5700 Series to specify continued listing requirements for products listed under those rules, which include products listed pursuant to Rule 19b-4(e) under the Act (“generically-listed products”) and products listed pursuant to proposed rule changes filed with the Commission (“non-generically-listed products”).⁶

The Exchange also proposes to amend the Rule 5700 Series to specify issuer notification requirements related to failures to comply with continued listing requirements. Specifically, the Exchange proposes to add Rule 5701(d) to require an issuer with securities listed under the Rule 5700 Series to promptly notify the Exchange of any non-compliance with the requirements of the Rule 5700 Series. In addition,

⁵ In Amendment No. 2, the Exchange: (i) Amended proposed Rule 5701(d) to require a Company with securities listed under the Rule 5700 Series to provide the Exchange with prompt notification if the Company (rather than an Executive Officer of the Company) becomes aware of its non-compliance with the requirements of the Rule 5700 Series; (ii) further amended rules within the Rule 5700 Series to reflect that certain listing requirements (including certain statements or representations in rule filings for the listing and trading of specific products) apply on an initial and ongoing basis; (iii) further amended rules within the Rule 5700 Series to consistently state that the Exchange will initiate delisting proceedings if continued listing requirements are not maintained; (iv) amended the Rule 5700 Series to provide that the Exchange would initiate delisting proceedings due to an interruption to the dissemination of index, reference asset, or intraday indicative values (as applicable to the product) only if the interruption persists past the trading day in which it occurred; (v) specified an implementation date for the proposed changes; and (vi) made non-substantive and conforming changes throughout the Rule 5700 Series in order to provide consistency throughout these rules, update rule numbering, and update cross-references. Amendment No. 2 is available at <https://www.sec.gov/comments/sr-nasdaq-2016-135/nasdaq2016135-1481751-130537.pdf>.

⁶ See *infra* notes 13–15 and accompanying text. The Exchange also proposes to amend certain listing requirements within the Rule 5700 Series. Specifically, the Exchange proposes to amend the requirement to delist a product if, following the initial 12-month period following commencement of trading on Nasdaq, there are fewer than 50 record or beneficial holders of the listed product for 30 or more consecutive trading days, by deleting the threshold of “30 or more consecutive trading days.” See, e.g., proposed changes to Rule 5705(a)(9)(B)(c).

with respect to non-generically-listed products, the Exchange proposes to require an issuer to notify the Exchange of its failure to comply with any continued listing requirements that were specified in the proposals to list those products. As proposed, the Exchange would initiate delisting proceedings for a product listed under the Rule 5700 Series if any of its continued listing requirements (including those set forth in a Nasdaq Rule and those set forth in an applicable proposed rule change) are not continuously maintained.⁷

The Exchange also proposes to amend Rule 5810 to specify the delisting procedures for products listed under the Rule 5700 Series. Under proposed Rule 5810(c)(2)(A), unless the issuer is currently under review by an Adjudicatory Body for a Staff Delisting Determination, the Listing Qualifications Department may accept and review a plan to regain compliance when an issuer fails to meet a continued listing requirement contained in the Rule 5700 Series. The issuer would be required to submit its compliance plan within 45 calendar days of the Exchange staff’s notification of deficiencies, and certain issuers would be required to pay a compliance plan review fee.

Finally, the Exchange proposes to make conforming and technical changes throughout the Rule 5700 Series to maintain consistency in its rules. For example, the Exchange proposes to consistently use the language “initiate delisting proceedings under the Rule 5800 Series” when describing the delisting process for a product that fails to meet continued listing requirements;⁸ consistently state in the Portfolio Depository Receipts and Index Fund Shares rules that, if the index that underlies a series of Portfolio Depository Receipts or Index Fund Shares is maintained by a broker-dealer or fund advisor, the index shall be calculated by a third party who is not a broker-dealer or fund advisor;⁹ and

⁷ Unlike failures to comply with other continued listing requirements, if there is an interruption to the dissemination of the reference asset, index, or intraday indicative values for a listed product, the Exchange would initiate delisting proceedings under the Rule 5800 Series only if the interruption persists past the trading day in which it occurred. See, e.g., proposed changes to Rules 5705(a)(9)(B)(i)(d)–(e) and 5705(b)(9)(B)(i)(d)–(e).

⁸ See, e.g., proposed changes to Rules 5705(a)(9)(B)(i) and 5705(b)(9)(B)(i).

⁹ See proposed changes to Rules 5705(a)(4)(B)(i), 5705(a)(5)(A)(i), 5705(b)(4)(B)(i), and 5705(b)(5)(A)(i); see also Rule 5705(a)(3)(B)(i) (currently stating that, for certain Portfolio Depository Receipts, “[i]f the index is maintained by a broker-dealer or fund advisor . . . the index shall be calculated by a third party who is not a broker-dealer or fund advisor”) and 5705(b)(3)(B)(i)

consistently reflect that delisting “following the initial 12-month period following commencement of trading on Nasdaq” only applies to the record/beneficial holder, number of shares issued and outstanding, and the market value of shares issued and outstanding requirements.¹⁰

The Exchange proposes to implement the rule changes by August 1, 2017.

III. Discussion and Commission Findings

The Commission finds that the proposed rule change, as modified by Amendment No. 2, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.¹¹ In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,¹² which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Commission does not believe that the proposal raises unique or novel regulatory issues. As the Commission previously stated, the development, implementation, and enforcement of standards governing the initial and continued listing of securities on an exchange are activities of critical importance to financial markets and the investing public. Once a security has been approved for initial listing, continued listing criteria allow an exchange to monitor the status and trading characteristics of that issue to ensure that it continues to meet the exchange’s standards for market depth and liquidity so that fair and orderly markets can be maintained.

Currently, certain rules within the Rule 5700 Series impose specific listing requirements on an initial basis, without

(currently stating that, for certain Index Fund Shares, “[i]f the index is maintained by a broker-dealer or fund advisor . . . the index shall be calculated by a third party who is not a broker-dealer or fund advisor”).

¹⁰ See, e.g., proposed changes to Rule 5711(d)(vi)(B); see also, e.g., Rule 5711(h)(iv)(B)(1) (currently applying the 12-month threshold only to the record/beneficial holder, number of units issued and outstanding, and market value of units issued and outstanding requirements for Partnership Units).

¹¹ In approving this proposed rule change, the Commission has considered the proposed rule’s impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

¹² 15 U.S.C. 78f(b)(5).

imposing ongoing listing requirements that are intended to achieve the same goals as these initial listing requirements.¹³ To fill this gap, the proposal would specify that certain listing requirements within the Rule 5700 Series apply both on an initial and ongoing basis, rather than only at a single point in time (*i.e.*, at the time of initial listing).¹⁴ Also, with respect to non-generically listed products, the Exchange proposes to amend the Rule 5700 Series to provide that any of the statements or representations in a proposed rule change regarding: (i) The description of the index, holdings, or reference asset (as applicable to a specific product); (ii) limitations on index composition, holdings, or reference assets (as applicable to a specific product); (iii) dissemination and availability of index, reference asset, or intraday indicative values (as applicable to a specific product); or (iv) the applicability of Exchange rules and surveillance procedures, constitute continued listing requirements.¹⁵

Because the proposal specifies continued listing requirements for products listed pursuant to the Rule 5700 Series, the Commission believes the proposal is designed to achieve on a continuing basis the goals of the

listing requirements, including ensuring that the Exchange lists products that are not susceptible to manipulation and maintaining fair and orderly markets for the listed products. In particular, the Commission believes that the proposal is designed to ensure that stocks with a substantial market capitalization and trading volume account for a substantial portion of the weight of an index or portfolio underlying a listed product;¹⁶ provide transparency regarding the components of an index or portfolio underlying a listed product;¹⁷ ensure that there is adequate liquidity in the listed product itself;¹⁸ and provide timely and fair disclosure of useful information that may be necessary to price the listed product.¹⁹ Moreover, the Commission believes that the proposal to require an issuer to notify the Exchange of its failures to comply with continued listing requirements would supplement the Exchange's own surveillance of the listed products.²⁰

¹⁶ For example, as proposed, the requirements under Rule 5705(a)(3)(A), including minimum market value and minimum monthly trading volume requirements for components of the index or portfolio underlying Portfolio Depository Receipts, would apply both on an initial and ongoing basis. Also, for non-generically listed products, the proposal would provide that statements or representations made in the proposed rule changes relating the description of the portfolio, among other things, constitute continued listing requirements. *See, e.g.*, proposed Rule 5705(a)(9)(B)(i)(b).

¹⁷ For example, as proposed, the requirements under Rule 5705(a)(3)(A), including the requirement that components of the index or portfolio underlying Portfolio Depository Receipts be exchange-listed and NMS stocks, would apply both on an initial and ongoing basis.

¹⁸ For example, the Exchange proposes to amend Rule 5715(b)(2) to explicitly state that listing requirements for Selected Equity-Linked Debt Securities ("SEEDS") apply both on an initial and ongoing basis, including, for example, the minimum public distribution and the minimum market value of an issue of SEEDS.

The Commission also believes that the proposal to delete the threshold of "30 or more consecutive trading days" in the requirements for the number of beneficial or record holders is consistent with the goal of ensuring that there is adequate liquidity in the listed product on an ongoing basis. As proposed, the Exchange would initiate delisting proceedings for a product if it fails to comply with the minimum number of beneficial holders requirement, even if the non-compliance does not continue for 30 consecutive trading days. *See supra* note 6.

¹⁹ For example, the proposed changes to Rule 5705(a)(3)(B)–(C) would make explicit that the requirements related to the dissemination of the value of the index underlying Portfolio Depository Receipts and the Intraday Indicative Value for Portfolio Depository Receipts apply on an initial and ongoing basis.

²⁰ The Commission notes that this concept of issuer notification is not novel. For example, in connection with its proposal to adopt generic listing standards for Managed Fund Shares, the Exchange stated that, prior to listing pursuant to the generic listing standards, an issuer would be required to represent to the Exchange that it will advise the

As noted above, the proposal specifies the delisting procedures for products listed pursuant to the Rule 5700 Series. The Commission believes that the proposed amendments to Rule 5810 provide transparency regarding the process that the Exchange will follow if a listed product fails to meet its continued listing requirements. The Commission also notes that the process surrounding compliance plans already exists in Rule 5810. As a result, the proposed delisting procedures are not novel.

Finally, the Commission believes that the conforming and technical proposed changes do not raise novel issues, are designed to further the goals of the listing standards, and provide clarity and consistency in the Exchange's rules.

For the reasons discussed above, the Commission finds that the proposed rule change, as modified by Amendment No. 2, is consistent with the Act.

IV. Accelerated Approval of Amendment No. 2

As noted above, in Amendment No. 2, the Exchange: (i) Amended proposed Rule 5701(d) to require a Company with securities listed under the Rule 5700 Series to provide the Exchange with prompt notification if the Company (rather than an Executive Officer of the Company) becomes aware of its non-compliance with the requirements of the Rule 5700 Series; (ii) further amended rules within the Rule 5700 Series to reflect that certain listing requirements (including certain statements or representations in rule filings for the listing and trading of specific products) apply on an initial and ongoing basis; (iii) further amended rules within the Rule 5700 Series to consistently state that the Exchange will initiate delisting proceedings if continued listing requirements are not maintained; (iv) amended rules within the Rule 5700 Series to provide that the Exchange will initiate delisting proceedings due to an interruption to the dissemination of index, reference asset, or intraday indicative values (as applicable to the product) only if the interruption persists past the trading day in which it occurred; (v) specified an implementation date for the proposed changes; and (vi) made conforming and non-substantive changes throughout the

Exchange of any failure by a series of Managed Fund Shares to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements. *See* Securities Exchange Act Release No. 78918 (September 23, 2016), 81 FR 67033, 67036 (September 29, 2016) (SR–NASDAQ–2016–104).

¹³ Moreover, certain of the listing requirements do not explicitly state that they apply on an ongoing, as well as initial, basis. In these cases, the proposal would make explicit that the requirements apply both on an initial and ongoing basis. *See, e.g.*, proposed changes to Rule 5705(a)(3)(B)–(C) (making explicit that, for Portfolio Depository Receipts, requirements related to index methodology and index value dissemination, as well as intraday indicative value dissemination, apply on an initial and ongoing basis); proposed changes to Rule 5710(e) (making explicit that, for Linked Securities, requirements related to tangible net worth and earnings apply on an initial and ongoing basis); proposed changes to Rule 5711(c), Commentary .03 (making explicit that, for Trust Certificates, requirements related to the qualifications of a trustee and changes to a trustee apply on an initial and ongoing basis).

¹⁴ For example, current Rule 5705(a)(3)(A)(i) sets forth requirements for component stocks of an index or portfolio underlying a series of generically-listed Portfolio Depository Receipts, which apply upon initial listing. These requirements include, for example, minimum market value, minimum monthly trading volume, and concentration limits for the component stocks. The proposal would specify that these requirements apply both on an initial and continued basis.

¹⁵ *See, e.g.*, proposed Rule 5705(a)(9)(B)(i)(b). The Commission notes that it has approved proposed rule changes for the listing and trading of exchange-traded products that included similar representations. *See, e.g.*, Securities Exchange Act Release No. 77548 (April 6, 2016), 81 FR 21626 (April 12, 2016) (SR–NASDAQ–2015–161). The Commission also notes that similar types of requirements exist in the Rule 5700 Series. *See, e.g.*, Rule 5705(a)(3) (setting forth, among other things, index composition requirements and intraday indicative value dissemination requirements for certain generically-listed Portfolio Depository Receipts).

Rule 5700 Series. The Commission believes that Amendment No. 2 furthers the goals of the proposed rule change and does not raise novel regulatory issues. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,²¹ to approve the proposed rule change, as modified by Amendment No. 2, on an accelerated basis.

V. Solicitation of Comments on Amendment No. 2

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 2 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NASDAQ-2016-135 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090. All submissions should refer to File Number SR-NASDAQ-2016-135. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal

identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NASDAQ-2016-135 and should be submitted on or before February 9, 2017.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,²² that the proposed rule change (SR-NASDAQ-2016-135), as modified by Amendment No. 2, be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²³

Brent J. Fields,
Secretary.

[FR Doc. 2017-01141 Filed 1-18-17; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-79782; File No. SR-Phlx-2017-01]

Self-Regulatory Organizations; NASDAQ PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Cabinet Trading Pilot Program

January 12, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on January 4, 2017, NASDAQ PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the pilot program in Phlx Rule 1059, Accommodation Transactions, to allow cabinet trading to take place below \$1 per option contract under specified circumstances (the "pilot program").

The text of the proposed rule change is set forth below. Proposed new

language is underlined; proposed deletions are in brackets.

* * * * *

NASDAQ PHLX Rules

* * * * *

Options Rules

* * * * *

Rule 1059. Accommodation Transactions

(a)-(b) No change.

• • • Commentary:

.01 No change.

.02 Limit Orders Priced Below \$1: Limit orders with a price of at least \$0 but less than \$1 per option contract may trade under the terms and conditions in Rule 1059 above in each series of option contracts open for trading on the Exchange, except that:

(a)-(c) No change.

(d) Unless otherwise extended, the effectiveness of the Commentary .02 terminates January 5, [2017] 2018, or, upon permanent approval of these procedures by the Securities and Exchange Commission, whichever occurs first.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to extend the pilot program in Commentary .02 of Exchange Rule 1059, Accommodation Transactions, which sets forth specific procedures for engaging in cabinet trades, to allow the Commission adequate time to consider permanently allowing transactions to take place on the Exchange in open outcry at a price of at least \$0 but less than \$1 per option

²² 15 U.S.C. 78s(b)(2).

²³ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

²¹ 15 U.S.C. 78s(b)(2).

contract.³ Prior to the pilot program, Rule 1059 required that all orders placed in the cabinet were assigned priority based upon the sequence in which such orders were received by the specialist. All closing bids and offers would be submitted to the specialist in writing, and the specialist effected all closing cabinet transactions by matching such orders placed with him. Bids or offers on orders to open for the accounts of customer, firm, specialists and Registered Options Traders (“ROTs”) could be made at \$1 per option contract, but such orders could not be placed in and must yield to all orders in the cabinet. Specialists effected all cabinet transactions by matching closing purchase or sale orders which were placed in the cabinet or, provided there was no matching closing purchase or sale order in the cabinet, by matching a closing purchase or sale order in the cabinet with an opening purchase or sale order.⁴ All cabinet transactions were reported to the Exchange following the close of each business day.⁵ Any (i) member, (ii) member organization, or (iii) other person who was a non-member broker or dealer and who directly or indirectly controlled, was controlled by, or was under common control with, a member or member organization (any such other person being referred to as an affiliated person) could effect any transaction as principal in the over-the-counter market in any class of option contracts listed on the Exchange for a premium not in excess of \$1.00 per contract.

On December 30, 2010, the Exchange filed an immediately effective proposal that established the pilot program being extended by this filing. The pilot program allowed transactions to take place in open outcry at a price of at least \$0 but less than \$1 per option contract until June 1, 2011.⁶ These lower priced transactions are traded pursuant to the same procedures applicable to \$1 cabinet trades, except that pursuant to the pilot program (i) bids and offers for opening transactions are only permitted to accommodate closing transactions in

order to limit use of the procedure to liquidations of existing positions, and (ii) the procedures are also made available for trading in options participating in the Penny Pilot Program.⁷ On May 20, 2011, the Exchange filed an immediately effective proposal that extended the pilot program until December 1, 2011 to consider whether to seek permanent approval of the temporary procedure.⁸ On November 16, 2011, the Exchange filed an immediately effective proposal that extended the pilot program until June 1, 2012.⁹ On May 29, 2012, the Exchange filed an immediately effective proposal that extended the pilot program until December 1, 2012.¹⁰ On November 1, 2012, the Exchange filed an immediately effective proposal that extended the pilot program until June 1, 2013.¹¹ On May 8, 2013, the Exchange filed an immediately effective proposal that extended the pilot program until January 5, 2014.¹² On December 4, 2013, the Exchange filed an immediately effective proposal that extended the pilot program until January 5, 2015.¹³ On January 2, 2015, the Exchange filed an immediately effective proposal that extended the pilot program until January 5, 2016.¹⁴ On December 9, 2015, the Exchange filed an immediately effective proposal that extended the pilot program until January 5, 2017.¹⁵ The Exchange now proposes an extension of the pilot program to allow additional time to consider its effects

⁷ Prior to the pilot, the \$1 cabinet trading procedures were limited to options classes traded in \$0.05 or \$0.10 standard increments. The \$1 cabinet trading procedures were not available in Penny Pilot Program classes because in those classes, an option series could trade in a standard increment as low as \$0.01 per share (or \$1.00 per option contract with a 100 share multiplier). The pilot allows trading below \$0.01 per share (or \$1.00 per option contract with a 100 share multiplier) in all classes, including those classes participating in the Penny Pilot Program.

⁸ See Securities Exchange Act Release No. 64571 (May 31, 2011), 76 FR 32385 (June 6, 2011) (SR-Phlx-2011-72).

⁹ See Securities Exchange Act Release No. 65852 (November 30, 2011), 76 FR 76212 (December 6, 2011) (SR-Phlx-2011-156).

¹⁰ See Securities Exchange Act Release No. 67106 (June 4, 2012), 77 FR 34108 (June 8, 2012) (SR-Phlx-2012-74).

¹¹ See Securities Exchange Act Release No. 68201 (November 9, 2012), 77 FR 68871 (November 16, 2012) (SR-Phlx-2012-131).

¹² See Securities Exchange Act Release No. 69583 (May 15, 2013), 78 FR 30380 (May 22, 2013) (SR-Phlx-2013-53).

¹³ See Securities Exchange Act Release No. 71096 (December 17, 2013), 78 FR 77538 (December 23, 2013) (SR-Phlx-2013-120).

¹⁴ See Securities Exchange Act Release No. 74012 (January 7, 2015), 80 FR 1688 (January 13, 2015) (SR-Phlx-2015-03).

¹⁵ See Securities Exchange Act Release No. 76671 (December 16, 2015), 80 FR 79642 (December 22, 2015) (SR-Phlx-2015-103).

while the pilot program continues uninterrupted.

The Exchange believes that allowing a price of at least \$0 but less than \$1 will continue to better accommodate the closing of options positions in series that are worthless or not actively traded, particularly due to recent market conditions which have resulted in a significant number of series being out-of-the-money. For example, a market participant might have a long position in a call series with a strike price of \$100 and the underlying stock might now be trading at \$30. In such an instance, there might not otherwise be a market for that person to close-out its position even at the \$1 cabinet price (e.g., the series might be quoted no bid).

The Exchange hereby seeks to extend the pilot period for such \$1 cabinet trading until January 5, 2018. The Exchange seeks this extension to allow the procedures to continue without interruption.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,¹⁶ in general, and with Section 6(b)(5) of the Act,¹⁷ in particular, in that the proposal is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Specifically, the Exchange believes that allowing for liquidations at a price less than \$1 per option contract pursuant to the pilot program will better facilitate the closing of options positions that are worthless or not actively trading, especially in Penny Pilot issues where cabinet trades are not otherwise permitted. The Exchange believes the extension is of sufficient length to allow the Commission to assess the impact of the Exchange's authority to allow transactions to take place in open outcry at a price of at least \$0 but less than \$1 per option in accordance with its attendant obligations and conditions.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in

¹⁶ 15 U.S.C. 78f.

¹⁷ 15 U.S.C. 78f(b)(5).

³ Cabinet or accommodation trading of option contracts is intended to accommodate persons wishing to effect closing transactions in those series of options dealt in on the Exchange for which there is no auction market.

⁴ Specialists and ROTs are not subject to the requirements of Rule 1014 in respect of orders placed pursuant to this Rule. Also, the provisions of Rule 1033(b) and (c), Rule 1034 and Rule 1038 do not apply to orders placed in the cabinet. Cabinet transactions are not reported on the ticker.

⁵ See Exchange Rule 1059.

⁶ Phlx Rule 1059, Commentary .02; See Securities Exchange Act Release No. 63626 (December 30, 2010), 76 FR 812 (January 6, 2011) (SR-Phlx-2010-185).

any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. The proposal does not raise any issues of intra-market competition because it applies to all options participants in the same manner.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁸ and subparagraph (f)(6) of Rule 19b-4 thereunder.¹⁹

A proposed rule change filed under Rule 19b-4(f)(6)²⁰ normally does not become operative for 30 days after the date of filing. However, Rule 19b-4(f)(6)(iii)²¹ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested a waiver of the 30-day operative delay so that the pilot program may continue without interruption. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because it will allow the pilot to continue uninterrupted, thereby avoiding any potential investor confusion that could result from a temporary interruption in the pilot and allowing members to continue to benefit from the program. Therefore, the Commission waives the 30-day operative delay and designates the proposed rule change operative upon filing.²²

¹⁸ 15 U.S.C. 78s(b)(3)(A)(iii).

¹⁹ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

²⁰ 17 CFR 240.19b-4(f)(6).

²¹ 17 CFR 240.19b-4(f)(6)(iii).

²² For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-Phlx-2017-01 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-Phlx-2017-01. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments

efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-Phlx-2017-01 and should be submitted on or before February 9, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²³

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2017-01153 Filed 1-18-17; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-79781; File No. SR-CHX-2016-20]

Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change in Connection With the Proposed Transaction Involving CHX Holdings, Inc. and North America Casin Holdings, Inc.

January 12, 2017.

I. Introduction

On December 2, 2016, the Chicago Stock Exchange, Inc. ("CHX" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change in connection with the proposed transaction ("Transaction") involving CHX Holdings, Inc. ("CHX Holdings") and North America Casin Holdings, Inc. ("N.A. Casin Holdings"). The proposed rule change was published for comment in the **Federal Register** on December 12, 2016.³ The Commission received five comment letters on the proposed rule change⁴ and two letters from the

²³ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 79474 (December 12, 2016), 81 FR 89543 ("Notice").

⁴ See letters from: Representative Robert Pittenger, Representative Earl L. "Buddy" Carter, Representative Peter DeFazio, Representative Collin Peterson, and Representative David Joyce, dated December 22, 2016 ("Pittenger Letter"); James N. Hill, dated December 23, 2016 ("Hill Letter"); John Ciccarella, dated January 2, 2017 ("Ciccarella Letter"); Anonymous, dated January 3, 2017 ("Anonymous Letter"); and David E. Kaplan, Executive Director, Global Investigative Journalism Network, dated January 4, 2017 ("GIJN Letter"). All

Continued

Exchange in response to certain comments.⁵ This order institutes proceedings under Section 19(b)(2)(B) of the Exchange Act⁶ to determine whether to approve or disapprove the proposed rule change.

II. Summary of the Proposal

The Exchange is a wholly-owned subsidiary of CHX Holdings. According to the Exchange, CHX Holdings is currently beneficially owned by 193 firms or individuals, including Exchange Participants or affiliates of Exchange Participants.⁷ Under the terms of the Transaction, CHX Holdings would become a wholly-owned subsidiary of N.A. Casin Holdings. According to the Exchange, current CHX Holdings stockholders would receive the right to receive cash in exchange for their shares under the terms of the Transaction.⁸ The Exchange states that consummation of the Transaction is subject to the satisfaction of certain conditions precedent, which include approval of the proposed rule change by the Commission.⁹

Upon the closing of the Transaction, the Exchange represents that all of the outstanding and issued shares of N.A. Casin Holdings would be held by the following firms and individuals (the “upstream owners”) in the following percentages:

- *Non-U.S. Upstream Owners:*
 - N.A. Casin Group, Inc. (“N.A. Casin Group”), a corporation incorporated under the laws of the State of Delaware and wholly-owned by Chongqing Casin Enterprise Group (“Chongqing Casin”)—20%
 - Chongqing Jintian Industrial Co., Ltd., a corporation incorporated under the laws of the People’s Republic of China—15%
 - Chongqing Longshang Decoration Co., Ltd., a corporation incorporated under the laws of the People’s Republic of China—14.5%
- *U.S. Upstream Owners:*
 - Castle YAC Enterprises, LLC (“Castle YAC”), a limited liability company

organized under the laws of the State of New York, the sole member of which is Jay Lu,¹⁰ a U.S. citizen and Vice President of N.A. Casin Group—19%

- Raptor Holdco LLC (“Raptor”), a limited liability company organized under the laws of the State of Delaware—11.75%
- Saliba Ventures Holdings, LLC (“Saliba”), a limited liability company organized under the laws of the State of Illinois—11.75%
- Xian Tong Enterprises, Inc., a corporation incorporated under the laws of the State of New York—6.94%
- Equity incentive shares to five members of the CHX Holdings management team, all U.S. citizens—0.88%
- Cheevers & Co., Inc., a corporation incorporated under the laws of the State of Illinois—0.18%¹¹

Following the closing of the Transaction, CHX would remain registered as a national securities exchange under Section 6 of the Act¹² and a self-regulatory organization (“SRO”) as defined in Section 3(a)(26) of the Act.¹³ According to the Exchange, CHX rules would remain in full force and effect as of the date of the proposed rule filing, would continue to govern the activities of CHX up to and after the closing of the Transaction, and CHX would continue to discharge its SRO responsibilities pursuant to CHX’s registration under Section 6 of the Act.¹⁴ In addition, the Exchange states that following the closing, CHX’s affiliated routing broker, CHXBD, would remain a Delaware limited liability corporation of which CHX Holdings would remain the sole member.

In order to facilitate the Transaction, the Exchange is proposing to amend its certificate of incorporation and bylaws,¹⁵ the certificate of incorporation and bylaws of CHX Holdings,¹⁶ and its rules.¹⁷ CHX has also filed the following documents in connection with the Transaction: (i) The certificate of incorporation and bylaws of N.A. Casin Holdings;¹⁸ (ii) text of a proposed resolution of the CHX Holdings Board of Directors to waive certain ownership

and voting limitations to permit the Transaction;¹⁹ (iii) the proposed N.A. Casin Holdings Stockholders Agreement,²⁰ which includes transfer-of-share provisions for the upstream owners that provide a right of first offer, a right to acquire interest upon change of control, and a right to purchase new securities; (iv) proposed put agreements between Saliba, N.A. Casin Group, and N.A. Casin Holdings,²¹ and Raptor, N.A. Casin Group, and N.A. Casin Holdings,²² respectively, which would grant Saliba and Raptor the right to compel N.A. Casin Holdings to purchase or arrange for an unspecified third-party to purchase a specified amount of Saliba’s or Raptors’s equity interest in N.A. Casin Holdings, respectively.

The Exchange proposes several substantive and technical amendments to its corporate governance documents, rules, and the governing documents of CHX Holdings. The amendments include revised provisions addressing, among other items, board and committee composition and procedures, procedures regarding stockholder meetings, consent to U.S. and Commission jurisdiction, and Commission access to corporate books and records.

The proposed amendments also would revise provisions in the certificate of incorporation of CHX Holdings relating to ownership and voting limitations. Additionally, the proposed certificate of incorporation of N.A. Casin Holdings would contain identical ownership concentration and voting limitations and other provisions substantially similar to those contained in the CHX Holdings documents, which would apply directly to the upstream owners.²³ These provisions specify that no person, either alone or with its Related Persons,²⁴ shall be permitted at

of the comments are available at <https://www.sec.gov/comments/sr-chx-2016-20/chx201620.shtml>.

⁵ See letters from John K. Kerin, President and Chief Executive Officer, CHX, dated January 5, 2016 (“CHX Response Letter 1”) and Albert J. Kim, Vice President and Associate General Counsel, CHX, dated January 6, 2016 (“CHX Response Letter 2”) (responding specifically to the Ciccarelli Letter). Both of these letters are available at <https://www.sec.gov/comments/sr-chx-2016-20/chx201620.shtml>.

⁶ 15 U.S.C. 78s(b)(2)(B).

⁷ See Notice, *supra* note 3 at 89544. See also CHX Article 1, Rule 1(s) defining “Participant.”

⁸ See Notice, *supra* note 3 at 89544.

⁹ See *id.*

¹⁰ According to the Exchange, Jay Lu, the sole member of Castle YAC, is associated with an affiliate of Chongqing Casin and is also the son of Shengju Lu, the Chairman of Chongqing Casin. See Notice, *supra* note 3 at 89545 n.18.

¹¹ See *id.* at 89544–55.

¹² 15 U.S.C. 78f.

¹³ 15 U.S.C. 78c(a)(26).

¹⁴ See Notice, *supra* note 3 at 89545–46.

¹⁵ See Exhibits 5C and 5D.

¹⁶ See Exhibits 5A and 5B.

¹⁷ See Exhibit 5E.

¹⁸ See Exhibits 5F and 5G.

¹⁹ See Exhibit 5H. See *infra* note 23.

²⁰ See Exhibit 5I.

²¹ See Exhibit 5J.

²² See Exhibit 5K.

²³ The current CHX Holdings Certificate contains ownership concentration and voting concentration limitations that are similar to those being proposed by the Exchange. In order to effect the Transaction, the CHX Holdings Board of Directors has waived the applicability of those limitations so that CHX Holdings can become a wholly owned subsidiary of N.A. Casin Holdings. See Exhibit 5H.

²⁴ As set forth in the proposed certificates of incorporation of N.A. Casin Holdings and CHX Holdings, the term “Related Persons” shall mean: “(1) with respect to any Person, any executive officer (as such term is defined in Rule 3b–7 under the Securities Exchange Act of 1934 (“Exchange Act”)) director, general partner, manager or managing member, as applicable, and all “affiliates” and “associates” of such Person (as those terms are defined in Rule 12b–2 under the Exchange Act), and other Person(s) whose beneficial ownership of shares of stock of the Corporation with the power to vote on any matter

any time to own beneficially shares of stock of CHX Holdings or N.A. Casin Holdings representing in the aggregate more than 40% of the then outstanding votes entitled to be cast on any matter unless specific procedures are followed prior to acquiring shares in excess of the ownership limitation.²⁵ Furthermore, as proposed, no Exchange Participant, either alone or with its Related Persons, shall be permitted at any time to own beneficially shares of stock of CHX Holdings or N.A. Casin Holdings representing in the aggregate more than 20% of the then outstanding votes entitled to be cast on any matter.²⁶ In addition, no person that is subject to any statutory disqualification as defined in Section 3(a)(39) of the Exchange Act shall be permitted at any time to own beneficially, either alone or with its Related Persons, shares of stock of CHX Holdings or N.A. Casin Holdings representing in the aggregate more than 20% of the then outstanding votes entitled to be cast on any matter.²⁷ CHX also proposes cure provisions that would require CHX Holdings or N.A. Casin Holdings, as applicable, to call shares held in excess of these ownership limitations and to not register any shares transferred in violation of these ownership limitations.²⁸

Additionally, both the certificates of incorporation of CHX Holdings and N.A. Casin Holdings would preclude any stockholder, either alone or with its Related Persons, from voting more than 20% of the then outstanding shares entitled to be cast on any matter unless specific procedures are followed prior to voting in excess of the limitation.²⁹ Similarly, no person, either alone or with its Related Persons, would be permitted to enter into an agreement,

would be aggregated with such first Person's beneficial ownership of such stock or deemed to be beneficially owned by such first Person pursuant to Rules 13d-3 and 13d-5 under the Exchange Act; and (2) in the case of any Person constituting a member (as that term is defined in Section 3(a)(3)(A) of the Exchange Act) of CHX (defined in the Rules of the Chicago Stock Exchange, Inc. ("CHX Rules"), as such rules may be amended from time to time, as a "Participant") for so long as CHX remains a registered national securities exchange, such Person and any broker or dealer with which such Person is associated; and (3) any other Person(s) with which such Person has any agreement, an arrangement or understanding (whether or not in writing) to act together for the purpose of acquiring, voting, holding or disposing of shares of the stock of the Corporation; and (4) in the case of a Person that is a natural person, any relative or spouse of such Person, or any relative of such spouse, who has the same home as such Person or who is a director or officer of the Corporation or any of its parents or subsidiaries."

²⁵ See Notice, *supra* note 3, at 89552.

²⁶ See *id.* at 89552-53.

²⁷ See *id.* at 89553.

²⁸ See *id.*

²⁹ See *id.*

plan, or other arrangement that would result in an aggregate of more than 20% of the then outstanding votes entitled to be cast on a matter to not be voted unless specific procedures are followed prior to entering into such an agreement, plan, or arrangement in violation.³⁰ The certificates of incorporation would require that CHX Holdings or N.A. Casin Holdings, as applicable, disregard any votes cast in excess of the voting limitations.³¹

III. Summary of the Comments

The Commission received four comments regarding the proposed rule change.³² The Commission also received one comment letter stating that, contrary to what the Ciccarelli Letter stated, the Ciccarelli Letter was not submitted by or on behalf of the Global Investigative Journalism Network.³³ The Exchange submitted a letter responding to the comments generally and a letter responding to the Ciccarelli Letter.³⁴

In general, three of the commenters express concern over the proposed upstream ownership of CHX.³⁵ One commenter questions whether the Chinese government may influence Chongqing Casin, stating that Chongqing Casin is involved in a number of Chinese market sectors that require close ties to the state, particularly in state-sensitive environmental protection areas, that its financial assets were originally state-controlled, and that its chairman sits on an industry council overseen directly by the mayor of the Chongqing Municipality.³⁶ The commenter states that, in particular, Chinese ownership or involvement presents risks as Chinese government-sponsored cyber-attacks have been conducted to devalue foreign businesses and steal intellectual property and proprietary data.³⁷ This commenter asserts that the United States government has been unable to adequately address transparency concerns with regard to the operations of Chinese businesses.³⁸ In its first response to comments, CHX affirms that no prospective investor controls, or is controlled by, or is under common control with, a governmental entity or

any political subdivision thereof, including the Chinese government.³⁹

Another commenter argues that due to jurisdiction limitations and transparency concerns, the Commission cannot exercise proper regulatory oversight under the current proposal.⁴⁰ In response, CHX states that it believes that its rules are consistent with the requirements of the Exchange Act, and that the CHX rules and Exchange Act contain various provisions that would facilitate the ability of U.S. regulators, including the Commission, to monitor, compel and enforce compliance by each of the upstream owners, particularly in that upstream owners would be required to adhere to the ownership and voting limitations; submit to U.S. regulatory jurisdiction and maintain agents in the U.S. for the service of process; maintain open books and records related to their ownership of CHX and keep such books and records in the U.S.; and refrain from interfering with, and give due consideration to, the SRO function of CHX.⁴¹ CHX also asserts that, pursuant to the Exchange Act, the Exchange is subject to direct and rigorous oversight by the Commission, which includes, among other things, frequent examinations of various aspects of CHX operations by Commission staff, including security and trading protocols, as well as Commission approval of certain regulatory, operational, and strategic initiatives prior to implementation by CHX.⁴²

This commenter also questions the identity of the proposed upstream owners and the validity of CHX's representation that there are no Related Persons among the proposed upstream owners other than Castle YAC and N.A. Casin Group.⁴³ The commenter asserts that contrary to CHX's representations in the Notice, several of the proposed upstream owners may be affiliated.⁴⁴ In addition, the commenter argues that Chongqing Casin has virtual control over Raptor and Saliba due to the put agreements.⁴⁵ The commenter therefore concludes that after the proposed transaction, approximately 99% of the voting stock in CHX would be controlled by Chinese entities or affiliated shell nominees.⁴⁶ In response, CHX asserts that 50.5% of CHX will be indirectly owned by U.S. citizens, and

³⁰ See *id.*

³¹ See *id.*

³² See *supra* note 4.

³³ See GIJN Letter, *supra* note 4; see also CHX Response Letter 2, *supra* note 5.

³⁴ See *supra* note 5.

³⁵ See generally Pittinger Letter, *supra* note 4; Ciccarelli Letter, *supra* note 4; Anonymous Letter, *supra* note 4.

³⁶ See Pittinger Letter, *supra* note 4, at 1.

³⁷ See *id.*

³⁸ See *id.* at 2.

³⁹ See CHX Response Letter 1, *supra* note 5, at 2.

⁴⁰ See Ciccarelli Letter, *supra* note 4, at 1-2.

⁴¹ See CHX Response Letter 1, *supra* note 5, at 4; CHX Response Letter 2, *supra* note 5, at 3.

⁴² See CHX Response Letter 2, *supra* note 5, at 3-4.

⁴³ See generally Ciccarelli Letter, *supra* note 4.

⁴⁴ See *id.* at 2-3.

⁴⁵ See *id.* at 3.

⁴⁶ See *id.* at 2.

that it has not misrepresented any facts regarding the Transaction.⁴⁷ CHX reaffirms the representations that it made in the Notice that the only Related Persons among the prospective owners are Castle YAC and N.A. Casin Group, there are no other Related Persons among the prospective owners, and that none of the prospective owners directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, a governmental entity or subdivision thereof.⁴⁸ CHX notes that each of these representations is supported by an opinion of counsel provided to the Commission by outside counsel for CHX.⁴⁹ CHX asserts that, as described in the Notice, Xian Tong Enterprises, Inc. and Castle YAC are controlled by U.S. citizens, *Quiling Luo and Jay Lu, respectively*.⁵⁰ CHX also states that under the terms of the Saliba and Raptor put agreements, N.A. Casin Holdings could not compel Saliba or Raptor to exercise their put options, and that in the event that either the Saliba or Raptor put agreement is exercised, the CHX rules would require the resulting ownership structure to comport with the ownership and voting limitations.⁵¹ In addition, CHX states that it “provided [the Committee for Foreign Investment in the United States (“CFIUS”)] with detailed information regarding the [p]rospective [o]wners, which recently concluded its investigation into the [p]roposed Transaction and found no unresolved national security concerns.”⁵²

This commenter also asserts that there are few or no controls in place at the upstream corporate ownership level that would prevent the upstream owners from transferring their voting power in CHX to what the commenter opines could be more opaque owners, including those that involve the Chinese government.⁵³ In response, CHX represents that no prospective owner and its Related Persons would maintain an equity interest in N.A. Casin Holdings in excess of the 40% ownership limitation, and that no prospective owner and its Related Persons would be permitted to exercise voting power in excess of the 20% voting limitation.⁵⁴ CHX also responds that the proposed governance documents for N.A. Casin Holdings and

CHX Holdings provide robust enforcement mechanisms for the ownership and voting limitations, and that the CHX board’s composition would be required to meet certain independence requirements.⁵⁵ As described above, CHX notes that the CHX rules and Exchange Act contain various provisions that would facilitate the ability of U.S. regulators, including the Commission, to monitor, compel and enforce compliance by each of the upstream owners.⁵⁶ CHX states that in the event that a prospective owner does not comply with the ownership or voting limitations, the proposed governance documents enable the relevant holding companies to cure non-compliance.⁵⁷

Two commenters assert that the proposed acquisition may present financial security risks to investors and the U.S. marketplace.⁵⁸ One of these commenters raises concerns that a bad actor with access to a national stock exchange’s data could use information available through brokerage records and the Consolidated Audit Trail to engage in spear phishing, blackmail attempts, and other similar attacks.⁵⁹ In its response, CHX states that CFIUS investigated the Transaction and “CFIUS determined that there were no unresolved national security concerns with respect to the [p]roposed Transaction. . . .”⁶⁰

Finally, three commenters express concern regarding the length of the comment period and the timing of the filing over the holiday season.⁶¹ Two of the commenters request that the Commission extend the comment period.⁶² In response, CHX states that it has been in regular contact with the Commission’s staff since the merger agreement was executed, and that the timing of the filing was not intended to circumvent thorough Commission review of the proposed rule change.⁶³

IV. Proceedings To Determine Whether To Approve or Disapprove SR-CHX-2016-20 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Exchange Act⁶⁴ to determine whether the proposed rule change should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as stated below, the Commission seeks and encourages interested persons to provide comments on the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Exchange Act,⁶⁵ the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change’s consistency with Section 6(b)(1) of the Exchange Act, which requires that a national securities exchange is so organized and has the capacity to be able to carry out the purposes of the Exchange Act and to comply, and to enforce compliance by its members and persons associated with its members, with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of the exchange. In addition, the Commission is instituting proceedings to allow for additional analysis of the proposed rule change’s consistency with Section 6(b)(5) of the Exchange Act, which requires, among other things, that the rules of a national securities exchange are designed to protect investors and the public interest.

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposal is consistent with Sections 6(b)(1), 6(b)(5), or any other provision of the Exchange Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of

⁵⁵ See CHX Response Letter 1, *supra* note 5, at 3; CHX Response Letter 2, *supra* note 5, at 3.

⁵⁶ See *supra* note 41 and accompanying text.

⁵⁷ See CHX Response Letter 2, *supra* note 5, at 3.

⁵⁸ See Pittinger Letter, *supra* note 4, at 1; Anonymous Letter, *supra* note 4.

⁵⁹ See Anonymous Letter, *supra* note 4.

⁶⁰ See CHX Response Letter 1, *supra* note 5, at 5.

⁶¹ See Pittinger Letter, *supra* note 4, at 1; Hill Letter, *supra* note 4; Ciccarelli Letter, *supra* note 4, at 4.

⁶² See Pittinger Letter, *supra* note 4, at 1; Hill Letter, *supra* note 4.

⁶³ See CHX Response Letter 1, *supra* note 5, at 4–5.

⁶⁴ 15 U.S.C. 78s(b)(2)(B).

⁶⁵ *Id.*

⁴⁷ See CHX Response Letter 2, *supra* note 5, at 2.

⁴⁸ See *id.* at 5.

⁴⁹ See *id.*

⁵⁰ See *id.* at 5–6.

⁵¹ See *id.* at 6.

⁵² See *id.* at 5.

⁵³ See Ciccarelli Letter, *supra* note 4, at 2.

⁵⁴ See CHX Response Letter 1, *supra* note 5, at 3; CHX Response Letter 2, *supra* note 5, at 2.

views, data, and arguments, the Commission will consider, pursuant to Rule 19b-4, any request for an opportunity to make an oral presentation.⁶⁶

Interested persons are invited to submit written data, views, and arguments regarding whether the proposal should be approved or disapproved by February 21, 2017. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by March 6, 2017. The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, in addition to any other comments they may wish to submit about the proposed rule change.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-CHX-2016-20 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090. All submissions should refer to File Numbers SR-CHX-2016-20. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE.,

Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of these filings also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-CHX-2016-20 and should be submitted on or before February 21, 2017. Rebuttal comments should be submitted by March 6, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶⁷

Eduardo A. Aleman,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-79783; File No. SR-CBOE-2016-080]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change, as Modified by Amendment No. 1, To Amend CBOE Rule 6.53C

January 12, 2017.

On November 17, 2016, Chicago Board Options Exchange, Incorporated ("CBOE" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to amend CBOE Rule 6.53C to allow complex orders in Hybrid 3.0 classes consisting of series in the group authorized for trading on the Hybrid 3.0 Platform and series in the group authorized for trading on the Hybrid Trading System to be executed electronically. The proposed rule change was published for comment in the **Federal Register** on December 2, 2016.³ On December 30, 2016, CBOE filed Amendment No. 1 to the proposal. The Commission has received no

comments regarding the proposed rule change.

Section 19(b)(2) of the Act⁴ provides that, within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is January 16, 2017.

The Commission is extending the 45-day time period for Commission action on the proposed rule change. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider and take action on the proposed rule change, as modified by Amendment No. 1. Accordingly, pursuant to Section 19(b)(2)(A)(ii)(I) of the Act,⁵ the Commission designates March 2, 2017, as the date by which the Commission should either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File Number SR-CBOE-2016-080), as modified by Amendment No. 1.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁶

Eduardo A. Aleman,

Assistant Secretary.

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⁶⁶ Section 19(b)(2) of the Exchange Act, as amended by the Securities Act Amendments of 1975, Public Law 94-29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. See Securities Act Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

⁶⁷ 17 CFR 200.30-3(a)(57).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 79406 (November 28, 2016), 81 FR 87102.

⁴ 15 U.S.C. 78s(b)(2).

⁵ 15 U.S.C. 78s(b)(2)(A)(ii)(I).

⁶ 17 CFR 200.30-3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-79779; File No. 4-678]

Program for Allocation of Regulatory Responsibilities Pursuant to Rule 17d-2; Notice of Filing of Proposed Amended Plan for the Allocation of Regulatory Responsibilities Among the Financial Industry Regulatory Authority, Inc., Miami International Securities Exchange, LLC, and MIA X PEARL, LLC

January 12, 2017.

Pursuant to Section 17(d) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 17d-2 thereunder,² notice is hereby given that on January 12, 2017, Miami International Securities Exchange, LLC (“MIA X”), MIA X PEARL, LLC (“MIA X PEARL”), and the Financial Industry Regulatory Authority, Inc. (“FINRA”) (together, the “Parties”) filed with the Securities and Exchange Commission (“Commission” or “SEC”) an amended plan for the allocation of regulatory responsibilities, dated January 11, 2017 (“17d-2 Plan” or the “Plan”). The Commission is publishing this notice to solicit comments on the 17d-2 Plan from interested persons.

I. Introduction

Section 19(g)(1) of the Act,³ among other things, requires every self-regulatory organization (“SRO”) registered as either a national securities exchange or national securities association to examine for, and enforce compliance by, its members and persons associated with its members with the Act, the rules and regulations thereunder, and the SRO’s own rules, unless the SRO is relieved of this responsibility pursuant to Section 17(d) or Section 19(g)(2) of the Act.⁴ Without this relief, the statutory obligation of each individual SRO could result in a pattern of multiple examinations of broker-dealers that maintain memberships in more than one SRO (“common members”). Such regulatory duplication would add unnecessary expenses for common members and their SROs.

Section 17(d)(1) of the Act⁵ was intended, in part, to eliminate unnecessary multiple examinations and regulatory duplication.⁶ With respect to

a common member, Section 17(d)(1) authorizes the Commission, by rule or order, to relieve an SRO of the responsibility to receive regulatory reports, to examine for and enforce compliance with applicable statutes, rules, and regulations, or to perform other specified regulatory functions.

To implement Section 17(d)(1), the Commission adopted two rules: Rule 17d-1 and Rule 17d-2 under the Act.⁷ Rule 17d-1 authorizes the Commission to name a single SRO as the designated examining authority (“DEA”) to examine common members for compliance with the financial responsibility requirements imposed by the Act, or by Commission or SRO rules.⁸ When an SRO has been named as a common member’s DEA, all other SROs to which the common member belongs are relieved of the responsibility to examine the firm for compliance with the applicable financial responsibility rules. On its face, Rule 17d-1 deals only with an SRO’s obligations to enforce member compliance with financial responsibility requirements. Rule 17d-1 does not relieve an SRO from its obligation to examine a common member for compliance with its own rules and provisions of the federal securities laws governing matters other than financial responsibility, including sales practices and trading activities and practices.

To address regulatory duplication in these and other areas, the Commission adopted Rule 17d-2 under the Act.⁹ Rule 17d-2 permits SROs to propose joint plans for the allocation of regulatory responsibilities with respect to their common members. Under paragraph (c) of Rule 17d-2, the Commission may declare such a plan effective if, after providing for appropriate notice and comment, it determines that the plan is necessary or appropriate in the public interest and for the protection of investors; to foster cooperation and coordination among the SROs; to remove impediments to, and foster the development of, a national market system and a national clearance and settlement system; and is in conformity with the factors set forth in Section 17(d) of the Act. Commission approval of a plan filed pursuant to Rule 17d-2 relieves an SRO of those

regulatory responsibilities allocated by the plan to another SRO.

II. The Plan

On November 19, 2014, the Commission declared effective the Plan entered into between FINRA and MIA X for allocating regulatory responsibility pursuant to Rule 17d-2.¹⁰ The Plan is intended to reduce regulatory duplication for firms that are common members of both MIA X and FINRA. The plan reduces regulatory duplication for firms that are members of MIA X and FINRA by allocating regulatory responsibility with respect to certain applicable laws, rules, and regulations. Included in the Plan is an exhibit that lists every MIA X rule for which FINRA bears responsibility under the Plan for overseeing and enforcing with respect to MIA X members that are also members of FINRA and the associated persons therewith.

III. Proposed Amendment to Plan

On January 12, 2017, the parties submitted a proposed amendment to the Plan. The primary purpose of the amendment is to add MIA X PEARL as a Participant to the Plan. The text of the proposed amended 17d-2 plan is as follows (additions are *italicized*; deletions are [bracketed]):

Agreement [Between] Among Financial Industry Regulatory Authority, Inc., [and] Miami International Securities Exchange, LLC and MIA X PEARL, LLC Pursuant to Rule 17d-2 Under the Securities Exchange Act of 1934

This Agreement, by and [between] among the Financial Industry Regulatory Authority, Inc. (“FINRA”), [and] Miami International Securities Exchange, LLC (“MIA X”) and MIA X PEARL, LLC (“MIA X PEARL”), is made this [13th] 11th day of [October] January, 201[4] 7 (the “Agreement”), pursuant to Section 17(d) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 17d-2 thereunder, which permits agreements between self-regulatory organizations to allocate regulatory responsibility to eliminate regulatory duplication. FINRA, [and] MIA X and MIA X PEARL may be referred to individually as a “party” and together as the “parties.”

This Agreement amends and restates the agreement entered into between FINRA and MIA X on October 13, 2014, entitled “Agreement between Financial Industry Regulatory Authority, Inc. and Miami International Securities

¹ 15 U.S.C. 78q(d).

² 17 CFR 240.17d-2.

³ 15 U.S.C. 78s(g)(1).

⁴ 15 U.S.C. 78q(d) and 15 U.S.C. 78s(g)(2), respectively.

⁵ 15 U.S.C. 78q(d)(1).

⁶ See Securities Act Amendments of 1975, Report of the Senate Committee on Banking, Housing, and

Urban Affairs to Accompany S. 249, S. Rep. No. 94-75, 94th Cong., 1st Session 32 (1975).

⁷ 17 CFR 240.17d-1 and 17 CFR 240.17d-2, respectively.

⁸ See Securities Exchange Act Release No. 12352 (April 20, 1976), 41 FR 18808 (May 7, 1976).

⁹ See Securities Exchange Act Release No. 12935 (October 28, 1976), 41 FR 49091 (November 8, 1976).

¹⁰ See Securities Exchange Act Release No. 73641 (November 19, 2014), 79 FR 70230 (November 25, 2014).

Exchange, LLC Pursuant to Rule 17d-2 under the Securities Exchange Act of 1934,” and any subsequent amendments thereafter.

Whereas, [FINRA and MIAx] the parties desire to reduce duplication in the examination of their [Dual] Common Members (as defined herein) and in the filing and processing of certain registration and membership records; and

Whereas, [FINRA and MIAx] the parties desire to execute an agreement covering such subjects pursuant to the provisions of Rule 17d-2 under the Exchange Act and to file such agreement with the Securities and Exchange Commission (the “SEC” or “Commission”) for its approval.

Now, therefore, in consideration of the mutual covenants contained hereinafter, [FINRA and MIAx] the parties hereby agree as follows:

1. *Definitions.* Unless otherwise defined in this Agreement or the context otherwise requires, the terms used in this Agreement shall have the same meaning as they have under the Exchange Act and the rules and regulations thereunder. As used in this Agreement, the following terms shall have the following meanings:

(a) “*MIAx Rules*,” “*MIAx PEARL Rules*” or “*FINRA Rules*” shall mean: (i) The rules of MIAx or MIAx PEARL, respectively, or (ii) the rules of FINRA, respectively, as the rules of an exchange or association are defined in Exchange Act Section 3(a)(27).

(b) “*Common Rules*” shall mean MIAx Rules and MIAx PEARL Rules that are substantially similar to the applicable FINRA Rules and certain provisions of the Exchange Act and SEC rules set forth on *Exhibit 1* in that examination for compliance with such provisions and rules would not require FINRA to develop one or more new examination standards, modules, procedures, or criteria in order to analyze the application of the provision or rule, or a [Dual] Common Member’s activity, conduct, or output in relation to such provision or rule. *Common Rules shall not include any provisions regarding (i) notice, reporting or any other filings made directly to or from MIAx or MIAx PEARL, (ii) compliance with other referenced MIAx or MIAx PEARL Rules that are not Common Rules, (iii) exercise of discretion including, but not limited to exercise of exemptive authority, by MIAx or MIAx PEARL, (iv) prior written approval of MIAx or MIAx PEARL and (v) payment of fees or fines to MIAx or MIAx PEARL.*

(c) “[Dual] Common Members” shall mean [those MIAx] members [that are

also members of FINRA and the associated persons therewith] of *FINRA and at least one of MIAx or MIAx PEARL.*

(d) “*Effective Date*” shall be the date this Agreement is approved by the Commission.

(e) “*Enforcement Responsibilities*” shall mean the conduct of appropriate proceedings, in accordance with FINRA’s Code of Procedure (the Rule 9000 Series) and other applicable FINRA procedural rules, to determine whether violations of Common Rules have occurred, and if such violations are deemed to have occurred, the imposition of appropriate sanctions as specified under FINRA’s Code of Procedure and sanctions guidelines.

(f) “*Regulatory Responsibilities*” shall mean the examination responsibilities and Enforcement Responsibilities relating to compliance by the [Dual] Common Members with the Common Rules and the provisions of the Exchange Act and the rules and regulations thereunder, and other applicable laws, rules and regulations, each as set forth on *Exhibit 1* attached hereto.

2. *Regulatory and Enforcement Responsibilities.* FINRA shall assume Regulatory Responsibilities and Enforcement Responsibilities for [Dual] Common Members. Attached as *Exhibit 1* to this Agreement and made part hereof, MIAx and MIAx PEARL furnished FINRA with a current list of Common Rules and certified to FINRA that such rules that are MIAx Rules and MIAx PEARL Rules are substantially similar to the corresponding FINRA Rules (the “*Certification*”). FINRA hereby agrees that the rules listed in the Certification are Common Rules as defined in this Agreement. Each year following the Effective Date of this Agreement, or more frequently if required by changes in [either the rules of MIAx or FINRA] the rules of the parties, MIAx and MIAx PEARL shall submit an updated list of Common Rules to FINRA for review which shall add MIAx Rules or MIAx PEARL Rules not included in the current list of Common Rules that qualify as Common Rules as defined in this Agreement; delete MIAx Rules or MIAx PEARL Rules included in the current list of Common Rules that no longer qualify as Common Rules as defined in this Agreement; and confirm that the remaining rules on the current list of Common Rules continue to be MIAx Rules or MIAx PEARL Rules that qualify as Common Rules as defined in this Agreement. Within 30 days of receipt of such updated list, FINRA shall confirm in writing whether the rules listed in

any updated list are Common Rules as defined in this Agreement. Notwithstanding anything herein to the contrary, it is explicitly understood that the term “*Regulatory Responsibilities*” does not include, and MIAx and MIAx PEARL shall retain full responsibility for (unless otherwise addressed by separate agreement or rule) (collectively, the “*Retained Responsibilities*”) the following:

(a) Surveillance, examination, investigation and enforcement with respect to trading activities or practices involving MIAx’s and MIAx PEARL’s own marketplace;

(b) registration pursuant to [its] their applicable rules of associated persons (i.e., registration rules that are not Common Rules);

(c) discharge of [its] their duties and obligations as a Designated Examining Authority pursuant to Rule 17d-1 under the Exchange Act; and

(d) any MIAx Rules and MIAx PEARL Rules that are not Common Rules as provided in paragraph 6.

3. *[Dual] Common Members.* Prior to the Effective Date, MIAx and MIAx PEARL shall furnish FINRA with a current list of [Dual] Common Members, which shall be updated no less frequently than once each quarter.

4. *No Charge.* There shall be no charge to MIAx and MIAx PEARL by FINRA for performing the Regulatory Responsibilities and Enforcement Responsibilities under this Agreement except as hereinafter provided. FINRA shall provide MIAx and MIAx PEARL with ninety (90) days advance written notice in the event FINRA decides to impose any charges to MIAx and MIAx PEARL for performing the Regulatory Responsibilities under this Agreement. If FINRA determines to impose a charge, MIAx and MIAx PEARL shall have the right at the time of the imposition of such charge to terminate this Agreement; provided, however, that FINRA’s Regulatory Responsibilities under this Agreement shall continue until the Commission approves the termination of this Agreement.

5. *Applicability of Certain Laws, Rules, Regulations or Orders.* Notwithstanding any provision hereof, this Agreement shall be subject to any statute, or any rule or order of the SEC. To the extent such statute, rule or order is inconsistent with one or more provisions of this Agreement, the statute, rule or order shall supersede the provision(s) hereof to the extent necessary to be properly effectuated and the provision(s) hereof in that respect shall be null and void.

6. *Notification of Violations.* In the event that FINRA becomes aware of

apparent violations of any MIAx Rules or MIAx PEARL Rules, which are not listed as Common Rules, discovered pursuant to the performance of the Regulatory Responsibilities assumed hereunder, FINRA shall notify MIAx and MIAx PEARL of those apparent violations for such response as MIAx and MIAx PEARL deem[s] appropriate. In the event that MIAx or MIAx PEARL becomes aware of apparent violations of any Common Rules, discovered pursuant to the performance of the Retained Responsibilities, MIAx and MIAx PEARL shall notify FINRA of those apparent violations and such matters shall be handled by FINRA as provided in this Agreement. Apparent violations of Common Rules shall be processed by, and enforcement proceedings in respect thereto shall be conducted by FINRA as provided hereinbefore; provided, however, that in the event a [Dual] Common Member is the subject of an investigation relating to a transaction on MIAx or MIAx PEARL, MIAx and MIAx PEARL may in [its] their discretion assume concurrent jurisdiction and responsibility. Each party agrees to make available promptly all files, records and witnesses necessary to assist the other in its investigation or proceedings.

7. Continued Assistance.

(a) FINRA shall make available to MIAx and MIAx PEARL all information obtained by FINRA in the performance by it of the Regulatory Responsibilities hereunder with respect to the [Dual] Common Members subject to this Agreement. In particular, and not in limitation of the foregoing, FINRA shall furnish MIAx and MIAx PEARL any information it obtains about [Dual] Common Members which reflects adversely on their financial condition. MIAx and MIAx PEARL shall make available to FINRA any information coming to its attention that reflects adversely on the financial condition of [Dual] Common Members or indicates possible violations of applicable laws, rules or regulations by such firms.

(b) The parties agree that documents or information shared shall be held in confidence, and used only for the purposes of carrying out their respective regulatory obligations. [Neither] No party shall assert regulatory or other privileges as against [the] any other with respect to documents or information that is required to be shared pursuant to this Agreement.

(c) The sharing of documents or information [between] among the parties pursuant to this Agreement shall not be deemed a waiver as against third parties of regulatory or other privileges

relating to the discovery of documents or information.

8. *Statutory Disqualifications.* When FINRA becomes aware of a statutory disqualification as defined in the Exchange Act with respect to a [Dual] Common Member, FINRA shall determine pursuant to Sections 15A(g) and/or Section 6(c) of the Exchange Act the acceptability or continued applicability of the person to whom such disqualification applies and keep MIAx and MIAx PEARL advised of its actions in this regard for such subsequent proceedings as MIAx and MIAx PEARL may initiate.

9. *Customer Complaints.* MIAx and MIAx PEARL shall forward to FINRA copies of all customer complaints involving [Dual] Common Members received by MIAx and MIAx PEARL relating to FINRA's Regulatory Responsibilities under this Agreement. It shall be FINRA's responsibility to review and take appropriate action in respect to such complaints.

10. *Advertising.* FINRA shall assume responsibility to review the advertising of [Dual] Common Members subject to the Agreement, provided that such material is filed with FINRA in accordance with FINRA's filing procedures and is accompanied with any applicable filing fees set forth in FINRA Rules.

11. *No Restrictions on Regulatory Action.* Nothing contained in this Agreement shall restrict or in any way encumber the right of [either] any party to conduct its own independent or concurrent investigation, examination or enforcement proceeding of or against [Dual] Common Members, as [either] any party, in its sole discretion, shall deem appropriate or necessary.

12. *Termination.* This Agreement may be terminated by [MIAx or FINRA] any party at any time upon the approval of the Commission after one (1) year's written notice to the other [party] parties (or such shorter time as agreed by the parties), except as provided in paragraph 4.

13. *Arbitration.* In the event of a dispute [between] among the parties as to the operation of this Agreement, [MIAx and FINRA] the parties hereby agree that any such dispute shall be settled by arbitration in Washington, DC in accordance with the rules of the American Arbitration Association then in effect, or such other procedures as the parties may mutually agree upon. Judgment on the award rendered by the arbitrator(s) may be entered in any court having jurisdiction. Each party acknowledges that the timely and complete performance of its obligations pursuant to this Agreement is critical to

the business and operations of the other [party] parties. In the event of a dispute [between] among the parties, the parties shall continue to perform their respective obligations under this Agreement in good faith during the resolution of such dispute unless and until this Agreement is terminated in accordance with its provisions. Nothing in this Section 13 shall interfere with a party's right to terminate this Agreement as set forth herein.

14. *Separate Agreement.* This Agreement is wholly separate from the following agreement: (1) The multiparty Agreement made pursuant to Rule 17d-2 of the Exchange Act among BATS Exchange, Inc., BOX Options Exchange, LLC, Chicago Board Options Exchange, Incorporated, C2 Options Exchange, Incorporated, the International Securities Exchange, LLC, FINRA, MIAx, [the New York Stock Exchange LLC,] NYSE MKT LLC, the NYSE Arca, Inc., The NASDAQ Stock Market LLC, NASDAQ OMX BX, Inc., NASDAQ OMX PHLX LLC, ISE Gemini, LLC, EDGX Exchange, Inc. and [Topaz Exchange, LLC] ISE Mercury, LLC involving the allocation of regulatory responsibilities with respect to common members for compliance with common rules relating to the conduct by broker-dealers of accounts for listed options or index warrants entered as approved by the SEC on [July 26, 2013] February 16, 2016, and as may be amended from time to time; and (2) the multiparty Agreement made pursuant to Rule 17d-2 of the Exchange Act among NYSE MKT LLC, BATS Exchange, Inc., EDGX Exchange, Inc., BOX Options Exchange LLC, NASDAQ OMX BX, Inc., C2 Options Exchange, Incorporated, Chicago Board Options Exchange, Incorporated, International Securities Exchange LLC, ISE Gemini, LLC, ISE Mercury, LLC, FINRA, NYSE Arca, Inc., The NASDAQ Stock Market LLC, NASDAQ OMX PHLX, Inc., and MIAx[, and Topaz Exchange, LLC] involving the allocation of regulatory responsibilities with respect to SRO market surveillance of common members activities with regard to certain common rules relating to listed options approved by the SEC on [July 26, 2013] February 16, 2016, and as may be amended from time to time.

15. *Notification of Members.* [MIAx and FINRA] The parties shall notify [Dual] Common Members of this Agreement after the Effective Date by means of a uniform joint notice.

16. *Amendment.* This Agreement may be amended in writing provided that the changes are approved by [both parties] each party. All such amendments must be filed with and approved by the

Commission before they become effective.

17. *Limitation of Liability.* [Neither FINRA nor MIA] *None of the parties* nor any of their respective directors, governors, officers or employees shall be liable to [the] *any* other party to this Agreement for any liability, loss or damage resulting from or claimed to have resulted from any delays, inaccuracies, errors or omissions with respect to the provision of Regulatory Responsibilities as provided hereby or for the failure to provide any such responsibility, except with respect to such liability, loss or damages as shall have been suffered by [one or the other of FINRA or MIA] *any party* and caused by the willful misconduct of [the other] *another* party or their respective directors, governors, officers or employees. No warranties, express or implied, are made by [FINRA or MIA] *any party hereto* with respect to any of the responsibilities to be performed by [each of] them hereunder.

18. *Relief from Responsibility.* Pursuant to Sections 17(d)(1)(A) and 19(g) of the Exchange Act and Rule 17d-2 thereunder, FINRA, [and] MIA and MIA PEARL join in requesting the

Commission, upon its approval of this Agreement or any part thereof, to relieve MIA and MIA PEARL of any and all responsibilities with respect to matters allocated to FINRA pursuant to this Agreement; provided, however, that this Agreement shall not be effective until the Effective Date.

19. *Severability.* Any term or provision of this Agreement that is invalid or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such invalidity or unenforceability without rendering invalid or unenforceable the remaining terms and provisions of this Agreement or affecting the validity or enforceability of any of the terms or provisions of this Agreement in any other jurisdiction.

20. *Counterparts.* This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and such counterparts together shall constitute one and the same instrument. *In witness whereof*, each party has executed or caused this Agreement to be executed on its behalf by a duly authorized officer as of the date first written above.

MIAMI INTERNATIONAL SECURITIES EXCHANGE, LLC.

By: _____

Name: _____

Title: _____

MIAX PEARL, LLC.

By: _____

Name: _____

Title: _____

FINANCIAL INDUSTRY REGULATORY AUTHORITY, INC.

By: _____

Name: _____

Title: _____

Exhibit 1

Miami International Securities Exchange, LLC and MIA PEARL, LLC Rules Certification for 17d-2 Agreement With FINRA

Miami International Securities Exchange, LLC ("MIA") and MIA PEARL, LLC ("MIA PEARL") hereby [certifies] *certify* that the requirements contained in the rules listed below are identical to, or substantially similar to, the comparable FINRA (NASD) Rule, Exchange Act provision or SEC rule identified ("Common Rules").

| MIAX rules | MIAX pearl rules | FINRA (NASD) rules, exchange act provision or SEC rule |
|--|--|--|
| Rule 301 Just and Equitable Principles of Trade ¹ . | Rule 301 Just and Equitable Principles of Trade ¹ . | FINRA Rule 2010 Standards of Commercial Honor and Principles of Trade*. |
| Rule 303 Prevention of the Misuse of Material Nonpublic Information ¹ [2]. | Rule 303 Prevention of the Misuse of Material Nonpublic Information ¹ #. | Section 15(g) of the Exchange Act and FINRA Rule 3110(b)(1) Supervision. |
| Rule 315 Anti-Money Laundering Compliance Program [2] #. | Rule 315 Anti-Money Laundering Compliance Program #. | FINRA Rule 3310 Anti-Money Laundering Compliance Program. |
| Rule 318(a) Manipulation | Rule 318(a) Manipulation | FINRA Rule 2020 Use of Manipulative, Deceptive or other Fraudulent Devices*. |
| Rule 318(b) Manipulation | Rule 318(b) Manipulation | FINRA Rule 6140 Other Trading Practices. |
| Rule 319 Forwarding of Proxy and Other Issuer-Related Materials [3] ² . | Rule 319 Forwarding of Proxy and Other Issuer-Related Materials ² . | FINRA Rule 2251 Processing and Forwarding of Proxy and Other Issuer-Related Materials. |
| Rule 320 Trading Ahead of Research Reports | Rule 320 Trading Ahead of Research Reports. | FINRA Rule 5280 Trading Ahead of Research Reports. |
| Rule 800(a), (b) and (d) Maintenance, Retention and Furnishing of Books, Records and Other Information ¹ [4] #. | Rule 800(a), (b) and (d) Maintenance, Retention and Furnishing of Books, Records and Other Information ¹ #. | FINRA Rule 4511 General Requirements* and Section 17 of the Exchange Act and the rules thereunder #. |
| Rule 1304 Continuing Education for Registered Persons [4] #. | Rule 1304 Continuing Education for Registered Persons #. | FINRA Rule 1250(a)(1)-(4), (6) and (b) Continuing Education Requirements #. |
| Rule 1321 Transfer of Accounts | Rule 1321 Transfer of Accounts | FINRA Rule 11870 Customer Account Transfer Contracts. |
| Rule 1325 Telemarketing | Rule 1325 Telemarketing | FINRA Rule 3230 Telemarketing. |

In addition, the following provisions shall be part of this 17d-2 Agreement:

SEA Rule 200 of Regulation SHO—Definition of "Short Sale" and Marking Requirements and SEA Rule 203 of Regulation SHO—Borrowing and Delivery Requirements

* FINRA shall not have Regulatory Responsibilities for these rules as they pertain to violations of insider trading activities, which is covered by a separate 17d-2 Agreement by and among BATS Exchange, Inc., BATS Y-Exchange, Inc., Chicago Board Options Exchange, Inc., Chicago Stock Exchange, Inc., EDGA Exchange, Inc., EDGX Exchange, Inc., Financial Industry Regulatory Authority, Inc., NASDAQ OMX BX, Inc., NASDAQ OMX PHLX LLC, the NASDAQ Stock Market LLC, National Stock Exchange, Inc., New York Stock Exchange LLC, NYSE Amex LLC, and NYSE Arca Inc., effective December 16, 2011, as may be amended from time to time.

FINRA shall not have Regulatory Responsibilities regarding (i) notice, reporting or any other filings made directly to or from MIA or MIA PEARL, (ii) compliance with other referenced MIA or MIA PEARL Rules that are not Common Rules, (iii) exercise of discretion including, but not limited to exercise of exemptive authority, by MIA or MIA PEARL, (iv) prior written approval of MIA or MIA PEARL and (v) payment of fees or fines to MIA or MIA PEARL.

¹ FINRA shall only have Regulatory Responsibilities regarding the rule and not the interpretations and policies.

[2] FINRA shall not have Regulatory Responsibilities regarding the rule to the extent it requires notification to MIA.]

[3] FINRA shall not have Regulatory Responsibilities regarding subsection (c) of Rule 319.

[4] FINRA shall not have Regulatory Responsibilities for exercise of exemptive or other discretionary authority by MIA to the extent it makes the rule inconsistent with the FINRA rule. In addition, FINRA shall only have Regulatory Responsibilities to the extent the category of persons subject to MIA registration is the same as FINRA.]

III. Date of Effectiveness of the Proposed Plan and Timing for Commission Action

Pursuant to Section 17(d)(1) of the Act¹¹ and Rule 17d-2 thereunder,¹² February 3, 2017 declare the plan submitted by MIAx, MIAx PEARL, and FINRA, File No. 4-678, to be effective if the Commission finds that the plan is necessary or appropriate in the public interest and for the protection of investors, to foster cooperation and coordination among self-regulatory organizations, or to remove impediments to and foster the development of the national market system and a national system for the clearance and settlement of securities transactions and in conformity with the factors set forth in Section 17(d) of the Act.

IV. Solicitation of Comments

In order to assist the Commission in determining whether to approve the proposed 17d-2 Plan and to relieve MIAx and MIAx PEARL of the responsibilities which would be assigned to FINRA, interested persons are invited to submit written data, views, and arguments concerning the foregoing. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/other.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number 4-678 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, Station Place, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number 4-678. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/other.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the

public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the plan also will be available for inspection and copying at the principal offices of MIAx, MIAx PEARL, and FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number 4-678 and should be submitted on or before February 3, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017-01151 Filed 1-18-17; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-79775; File No. SR-BatsBZX-2017-01]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Related to Fees for Use of the Exchange's Equity Options Platform

January 12, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on January 3, 2017, Bats BZX Exchange, Inc. (the "Exchange" or "BZX") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act³ and Rule 19b-4(f)(2) thereunder,⁴ which renders the proposed rule change effective upon filing with the Commission. The Commission is

publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the fee schedule applicable to Members⁵ and non-members of the Exchange pursuant to BZX Rules 15.1(a) and (c).

The text of the proposed rule change is available at the Exchange's Web site at www.batstrading.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its fee schedule for its equity options platform ("BZX Options") to: (i) Add definitions of terms "OCC Customer Volume" or "OCV" and "Options Step-Up Add TCv" to the Definitions section; and (ii) modify the criteria for tiers under footnotes 1 through 13 to reflect the new definition of OCV. The Exchange also proposes to (i) increase the rebate provided in the Customer⁶ Cross-Asset Add Tier under footnote 1; (ii) add a new Step-Up Tier under footnote 1; (iii) eliminate and replace the existing Step-Up Tier under footnote 3 with a new Step-Up Tier; (iv) add Tier 3 under footnote 7; (v) add Tier 2 and a Step-Up Tier under footnote 12; and (v) add a new footnote 14 entitled,

⁵ The term "Member" is defined as "any registered broker or dealer that has been admitted to membership in the Exchange." See Exchange Rule 1.5(n).

⁶ As defined in the Exchange's fee schedule available at http://www.bats.com/us/options/membership/fee_schedule/bzx/.

¹¹ 15 U.S.C. 78q(d)(1).

¹² 17 CFR 240.17d-2.

¹³ 17 CFR 200.30-3(a)(34).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A)(ii).

⁴ 17 CFR 240.19b-4(f)(2).

“Customer Penny Pilot Take Volume Tier.”

New Defined Terms

OCC Customer Volume or OCV. The Exchange proposes to add the definition of “OCC Customer Volume” or “OCV” to the definition section of its fee schedule. OCC Customer Volume or OCV will be defined as the total equity and Exchange Traded Fund (“ETF”) options volume that clears in the Customer range at the Options Clearing Corporation (“OCC”) for the month for which the fees apply, excluding volume on any day that the Exchange experiences an Exchange System Disruption⁷ and on any day with a scheduled early market close.

Options Step-Up Add OCV. The Exchange proposes to replace the definition of “Options Step-Up Add TCV”⁸ with the definition of “Options Step-Up Add OCV” to reflect the new tier qualifications resulting from the change in calculation from Total Consolidated Volume (“TCV”)⁹ to OCV. Similar to the definition of Options Step-Up Add TCV, Options Step-Up Add OCV will be defined as, “ADAV¹⁰ as a percentage of OCV in the relevant baseline month subtracted from current ADAV as a percentage of OCV”. The only difference between the two definitions is replacing the term TCV with OCV.

Tier Qualifications Change

The Exchange proposes to replace current tier qualifications which refer to TCV with a reference to OCV in the tiers under footnotes 1 through 13. Because OCV generally makes up a smaller range than the prior TCV, the Exchange also proposes to amend the percentage of OCV necessary to achieve the tier so that it is substantially identical to the previously required percentage of TCV. Doing so will keep each tier’s criteria relatively unchanged from its current requirements. The rates for each tier are unchanged. Changes to each tier are described below.

Customer Penny Pilot Add Tiers under footnote 1. Customer orders that yield fee code PY¹¹ are given a standard rebate of \$0.25 per contract. Footnote 1 of the fee schedule sets forth eight tiers,

each providing enhanced rebates, ranging from \$0.40 to \$0.53 per contract, to a Member’s order that yields fee code PY upon satisfying monthly volume criteria.

- Tier 1 currently requires that a Member has an ADV¹² equal to or greater than 0.05% of average TCV. As amended, a Member must have an ADV equal to or greater than 0.05% of average OCV.¹³

- Tier 2 currently requires that a Member has an ADV equal to or greater than 0.30% of average TCV. As amended, a Member must have an ADV equal to or greater than 0.40% of average OCV.

- Tier 3 currently requires that a Member has an ADV equal to or greater than 1.00% of average TCV. As amended, a Member must have an ADV equal to or greater than 1.30% of average OCV.

- Tier 4 currently requires that a Member has an ADAV in Customer orders equal to or greater than 1.00% of average TCV. As amended, a Member must have an ADAV in Customer orders equal to or greater than 1.30% of average OCV.

- Tier 5 currently requires that a Member has an: (i) ADAV in Customer orders equal to or greater than 0.60% of average TCV; (ii) ADAV in Market Maker¹⁴ orders equal to or greater than 0.25% of average TCV; and (iii) ADAV in orders on the Exchange equities platform (“BZX Equities”) equal to or greater than 0.30% of average TCV. As amended, a Member must have an: (i) ADAV in Customer orders equal to or greater than 0.80% of average OCV; (ii) ADAV in Market Maker orders equal to or greater than 0.35% of average OCV; and (iii) ADAV in orders on BZX Equities equal to or greater than 0.30% of average TCV.

- Tier 6 currently requires that a Member has an ADAV in Customer orders equal to or greater than 1.30% of average TCV. As amended, a Member must have an ADAV in Customer orders equal to or greater than 1.70% of average OCV.

- The Customer Step-Up Volume Tier currently requires that a Member has an Options Step-Up Add TCV in Customer orders from September 2015 baseline equal to or greater than 0.40%. As amended, a Member must have an Options Step-Up Add OCV in Customer orders from September 2015 baseline equal to or greater than 0.45%.

- The Customer Cross-Asset Add Tier currently requires that a Member has an: (i) ADV equal to or greater than 0.80% of average TCV; and (ii) ADAV on BZX Equities equal to or greater than 0.50% of average TCV. As amended, a Member must have an: (i) ADAV in Customer orders equal to or greater than 0.50% of average OCV; and (ii) ADAV on BZX Equities greater than or equal to 0.50% of average TCV. As a result of the change from requiring a Member to meet a certain threshold of ADV to a certain threshold of ADAV, the Exchange proposes to increase the rebate provided by this tier from \$0.50 to \$0.52 per contract. The Exchange believes an increased rebate more appropriately corresponds with the tier’s more stringent criteria.

Firm,¹⁵ Broker Dealer,¹⁶ and Joint Back Office¹⁷ Penny Pilot Add Volume Tiers under footnote 2. Firm, Broker Dealer and Joint Back Office orders that yield fee code PF¹⁸ are given a standard rebate of \$0.36 per contract. Footnote 2 of the fee schedule sets forth two tiers, each providing enhanced rebates of \$0.43 and \$0.46 per contract to a Member’s order that yields fee codes PF upon satisfying monthly volume criteria.

- Tier 1 currently requires that a Member has an: (i) ADAV in Away Market Maker,¹⁹ Firm, Broker Dealer and Joint Back Office orders greater than or equal to 0.80% of average TCV; and (ii) ADV greater than or equal to 1.50% of average TCV. As amended, a Member must have an: (i) ADAV in Away Market Maker, Firm, Broker Dealer and Joint Back Office orders greater than or equal to 1.05% of average OCV; and (ii) ADV greater than or equal to 1.95% of average OCV.

- Tier 2 currently requires that a Member has an: (i) ADV greater than or equal to 0.40% of average TCV; and (ii) ADAV in Away Market Maker, Firm, Broker Dealer and Joint Back Office greater than or equal to 0.30% of average TCV. As amended, a Member must have an: (i) ADV greater than or equal to 0.50% of average OCV; and (ii) ADAV in Away Market Maker, Firm, Broker Dealer and Joint Back Office greater than or equal to 0.40% of average OCV.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ Fee code PF is appended to a Member’s Firm, Broker Deal and Joint Back Office orders which add liquidity in Penny Pilot options. As defined in the Exchange’s fee schedule available at http://www.bats.com/us/options/membership/fee_schedule/bzx/.

¹⁹ *Id.*

⁷ An “Exchange System Disruption” means “any day that the Exchange’s system experiences a disruption that lasts for more than 60 minutes during Regular Trading Hours.” *Id.*

⁸ *Id.*

⁹ As defined in the Exchange’s fee schedule available at http://www.bats.com/us/options/membership/fee_schedule/bzx/.

¹⁰ *Id.*

¹¹ Fee code PY is appended to a Member’s Customer orders which add liquidity in Penny Pilot options. *Id.*

¹² *Id.*

¹³ The Exchange proposes to retain the 0.05% requirement as adjusting that number to reflect replacing TCV with OCV will result in a de minimis change in the percentage.

¹⁴ *Id.*

Non-Customer Penny Pilot Take Volume Tiers under footnote 3. Non-Customer orders that yield fee code PP²⁰ are charged a standard fee of \$0.50 per contract. Footnote 3 of the fee schedule sets forth three tiers, each providing reduced fees ranging from \$0.44 to \$0.47 per contract to a Member's order that yields fee codes PP upon satisfying monthly volume criteria.²¹

- Tier 1 currently requires that a Member has an: (i) ADAV in Customer orders greater than or equal to 0.60% of average TCV; (ii) ADAV in Market Maker orders greater than or equal to 0.25% of average TCV and (iii) ADAV on BZX Equities greater than or equal to 0.30% of average TCV. As amended, a Member must have an: (i) ADAV in Customer orders greater than or equal to 0.80% of average OCV; (ii) ADAV in Market Maker orders greater than or equal to 0.35% of average OCV; and (iii) ADAV on BZX Equities greater than or equal to 0.30% of average TCV.

- Tier 2 currently requires that a Member has an ADAV in Customer orders greater than or equal to 1.00% of average TCV. As amended, a Member must have an ADAV in Customer orders greater than or equal to 1.30% of average OCV.

- Tier 3 currently requires that a Member has an ADAV in Customer orders greater than or equal to 1.30% of average TCV. As amended, a Member must have an ADAV in Customer orders greater than or equal to 1.70% of average OCV.

National Best Bid or Best Offer ("NBBO") Setter Tiers under footnote 4. Footnote 4 of the fee schedule sets forth five tiers, each providing enhanced rebates, ranging from \$0.02 to \$0.05 per contract, to a Member's orders that establish a new NBBO and yield fee codes PF, PM²² or PN²³ upon satisfying monthly volume criteria.

- Tier 1 currently requires that a Member has an ADV greater than or equal to 0.30% of average TCV. As

amended, a Member must have an ADV greater than or equal to 0.40% of average OCV.

- Tier 2 currently requires that a Member has an ADV greater than or equal to 1.00% of average TCV. As amended, a Member must have an ADV greater than or equal to 1.30% of average OCV.

- Tier 3 currently requires that a Member has an: (i) ADV greater than or equal to 0.40% of average TCV; and (ii) ADAV in Away Market Maker, Firm, Broker Dealer and Joint Back Office orders greater than or equal to 0.30% of average TCV. As amended, a Member must have an: (i) ADV greater than or equal to 0.50% of average OCV; and (ii) ADAV in Away Market Maker, Firm, Broker Dealer and Joint Back Office orders greater than or equal to 0.40% of average OCV.

- Tier 4 currently requires that a Member has an ADAV in Market Maker²⁴ orders greater than or equal to 0.40% of average TCV. As amended a Member must have an ADAV in Market Maker orders greater than or equal to 0.50% of average OCV.

- Tier 5 currently requires that a Member has an ADAV in Non-Customer orders greater than or equal to 2.30% of average TCV. As amended a Member must have an ADAV in Non-Customer orders greater than or equal to 3.00% of average OCV.

Quoting Incentive Program ("QIP") Tiers under footnote 5. Footnote 5 sets forth four tiers each providing additional rebates ranging from \$0.02 to \$0.05 per contract for an order appended with fee code PM or NM²⁵ that adds liquidity to the BZX Options order book in options classes in which a Member is a Market Maker registered on BZX Options pursuant to Exchange Rule 22.2. A Market Maker must be registered with BZX Options in an average of 20% or more of the associated options series in a class in order to qualify for QIP rebates for that class.

- Tier 1 currently requires that a Member has an ADV greater than or equal to 0.30% of average TCV. As amended, a Member must have an ADV greater than or equal to 0.40% of average OCV.

- Tier 2 currently requires that a Member has an ADV greater than or equal to 1.00% of average TCV. As amended, a Member must have an ADV

greater than or equal to 1.30% of average OCV.

- Tier 3 currently requires that a Member has an ADV greater than or equal to 2.50% of average TCV. As amended, a Member must have an ADV greater than or equal to 3.25% of average OCV.

- Tier 4 currently requires that a Member has an ADV [sic] in Market Maker orders greater than or equal to 0.40% of average TCV. As amended, a Member must have an ADV [sic] in Market Maker orders greater than or equal to 0.50% of average OCV.

Market Maker Penny Pilot Add Volume Tiers under footnote 6. Footnote 6 of the fee schedule sets forth two tiers, each providing enhanced rebates of \$0.40 and \$0.42 per contract to a Member's order that yields fee code PM upon satisfying monthly volume criteria.

- Tier 1 currently requires that a Member has an ADV greater than or equal to 0.30% of average TCV. As amended, a Member must have an ADV greater than or equal to 0.40% of average OCV.

- Tier 2 currently requires that a Member has an: (i) ADAV in Market Maker and/or Away Market Maker orders greater than or equal to 1.00% of average TCV; and (ii) ADV greater than or equal to 2.00% of average TCV. As amended, a Member must have an: (i) ADAV in Market Maker and/or Away Market Maker orders greater than or equal to 1.30% of average OCV; and (ii) ADV greater than or equal to 2.60% of average OCV.

Market Maker Non-Penny Pilot Add Volume Tiers under footnote 7. Footnote 7 of the fee schedule sets forth two tiers, each providing enhanced rebates of \$0.45 and \$0.52 per contract to a Member's order that yields fee code NM upon satisfying monthly volume criteria.²⁶

- Tier 1 currently requires that a Member has an ADV greater than or equal to 0.30% of average TCV. As amended, a Member must have an ADV greater than or equal to 0.40% of average OCV.

- Tier 2 currently requires that a Member has an ADV greater than or equal to 1.00% of average TCV. As amended, a Member must have an ADV greater than or equal to 1.30% of average OCV.

Firm, Broker Dealer, and Joint Back Office Non-Penny Pilot Add Volume Tiers under footnote 8. Firm, Broker Dealer and Joint Back Office orders that

²⁰ Fee code PP is appended to a Member's Non-Customer orders which remove liquidity in Penny Pilot options. *Id.*

²¹ Footnote 3 also includes an additional Step-Up Tier under which Members orders that yield fee code PP receive an additional \$0.01 discount upon satisfying certain criteria. As described in more detail below, the Exchange proposes to delete this tier with a new Step-Up Tier as part of this filing.

²² Fee code PM is appended to a Member's Market Maker orders which add liquidity in Penny Pilot options and provides a standard rebate of \$0.35 per contract. *Id.*

²³ Fee code PN is appended to a Member's Away Market Maker orders which add liquidity in Penny Pilot options and provides a standard rebate of \$0.30 per contract. As defined in the Exchange's fee schedule available at http://www.bats.com/us/options/membership/fee_schedule/bzx/.

²⁴ *Id.*

²⁵ Fee code NM is appended to a Member's Market Maker orders which add liquidity in Non-Penny Pilot options. As defined in the Exchange's fee schedule available at http://www.bats.com/us/options/membership/fee_schedule/bzx/.

²⁶ As described in more detail below, the Exchange also proposes to adopt a third tier under footnote 7 as part of this filing.

yield fee code NF²⁷ are given a standard rebate of \$0.30 per contract. Footnote 8 of the fee schedule sets forth three tiers, each providing enhanced rebates ranging from \$0.45 to \$0.69 per contract to a Member's order that yields fee codes NF upon satisfying monthly volume criteria.

- Tier 1 currently requires that a Member has an ADV greater than or equal to 0.15% of average TCV. As amended, a Member must have an ADV greater than or equal to 0.20% of average OCV.

- Tier 2 currently requires that a Member has an ADV greater than or equal to 0.25% of average TCV. As amended, a Member must have an ADV greater than or equal to 0.35% of average OCV.

- Tier 3 currently requires that a Member has an: (i) ADV greater than or equal to 1.75% of average TCV; and (ii) ADAV in Away Market Maker, Firm, Broker Dealer, and Joint Back Office orders greater than or equal to 1.25% of average TCV. As amended, a Member must have an: (i) ADV greater than or equal to 2.30% of average OCV; and (ii) ADAV in Away Market Maker, Firm, Broker Dealer, and Joint Back Office orders greater than or equal to 1.65% of average OCV.

Professional Penny Pilot Add Volume Tiers under footnote 9. Professional orders that yield fee code PA²⁸ are given a standard rebate of \$0.25 per contract. Footnote 9 of the fee schedule sets forth four tiers, each providing enhanced rebates ranging from \$0.42 to \$0.48 per contract to a Member's order that yields fee codes PA upon satisfying monthly volume criteria.

- Tier 1 currently requires that a Member has an ADAV in Customer and Professional orders greater than or equal to 0.10% of average TCV. As amended, a Member must have an ADAV in Customer and Professional orders greater than or equal to 0.15% of average OCV.

- Tier 2 currently requires that a Member has an ADAV in Customer and Professional orders greater than or equal to 0.20% of average TCV. As amended, a Member must have an ADAV in Customer and Professional orders greater than or equal to 0.25% of average OCV.

- Tier 3 currently requires that a Member has an ADAV in Customer and Professional orders greater than or equal to 0.30% of average TCV. As amended,

a Member must have an ADAV in Customer and Professional orders greater than or equal to 0.40% of average OCV.

- Tier 4 currently requires that a Member has an ADAV in Customer and Professional orders greater than or equal to 0.50% of average TCV. As amended a Member must have an ADAV in Customer and Professional orders greater than or equal to 0.65% of average OCV.

Away Market Maker Penny Pilot Add Volume Tiers under footnote 10. Away Market Maker orders that yield fee code PN are given a standard rebate of \$0.30 per contract. Footnote 10 of the fee schedule sets forth three tiers, each providing enhanced rebates ranging from \$0.40 to \$0.46 per contract to a Member's order that yields fee code PN upon satisfying monthly volume criteria.

- Tier 1 currently requires that a Member has an ADV greater than or equal to 0.30% of average TCV. As amended, a Member must have an ADV greater than or equal to 0.40% of average OCV.

- Tier 2 currently requires that a Member has an: (i) ADAV in Away Market Maker, Firm, Broker Dealer and Joint Back Office orders greater than or equal to 0.80% of average TCV; and (ii) ADV greater than or equal to 1.50% of average TCV. As amended, a Member must have an: (i) ADAV in Away Market Maker, Firm, Broker Dealer and Joint Back Office orders greater than or equal to 1.05% of average OCV; and (ii) ADV greater than or equal to 1.95% of average OCV.

- Tier 3 currently requires that a Member has an: (i) ADV greater than or equal to 0.40% of average TCV; and (ii) ADAV in Away Market Maker, Firm, Broker Dealer and Joint Back Office orders greater than or equal to 0.30% of average TCV. As amended, a Member must have an: (i) ADV greater than or equal to 0.50% of average OCV; and (ii) ADAV in Away Market Maker, Firm, Broker Dealer and Joint Back Office orders greater than or equal to 0.40% of average OCV.

Away Market Maker Non-Penny Pilot Add Volume Tiers under footnote 11. Away Market Maker orders that yield fee code NN²⁹ are given a standard rebate of \$0.30 per contract. Footnote 11 of the fee schedule sets forth two tiers, each providing enhanced rebates of \$0.40 and \$0.52 per contract to a Member's order that yields fee code NN

upon satisfying monthly volume criteria.

- Tier 1 currently requires that a Member has an ADV greater than or equal to 0.30% of average TCV. As amended, a Member must have an ADV greater than or equal to 0.40% of average OCV.

- Tier 2 currently requires that a Member has an ADV greater than or equal to 1.00% of average TCV. As amended, a Member must have an ADV greater than or equal to 1.30% of average OCV.

Customer Non-Penny Pilot Add Volume Tier under footnote 12. Customer orders that yield fee code NY³⁰ are given a standard rebate of \$0.85 per contract. Footnote 12 of the fee schedule sets forth one tier, providing an enhanced rebate of \$1.00 per contract to a Member's order that yields fee code NY upon satisfying monthly volume criteria.³¹

- Tier 1 currently requires that a Member has an ADAV in Customer orders greater than or equal to 0.70% of average TCV. As amended a Member must have an ADAV in Customer orders greater than or equal to 0.90% of average OCV.

Non-Customer Non-Penny Pilot Take Volume Tiers, under footnote 13. Non-Customer orders that yield fee code NP³² are charged a standard fee of \$1.07 per contract. Footnote 13 of the fee schedule sets forth three tiers, each providing reduced fees ranging from \$1.01 to \$1.02 per contract to a Member's order that yields fee code NP upon satisfying monthly volume criteria.

- Tier 1 currently requires that a Member has an: (i) ADAV in Customer orders greater than or equal to 0.60% of average TCV; (ii) ADAV in Market Maker orders greater than or equal to 0.25% of average TCV; and (iii) ADAV on BZX Equities greater than or equal to 0.30% of average TCV. As amended, a Member must have an: (i) ADAV in Customer orders greater than or equal to 0.80% of average OCV; (ii) ADAV in Market Maker orders greater than or equal to 0.35% of average OCV; and (iii) ADAV on BZX Equities greater than or equal to 0.30% of average TCV.

- Tier 2 currently requires that a Member has an ADAV in Customer

³⁰ Fee code NY is appended to a Member's Customer orders which add liquidity in Non-Penny Pilot options. As defined in the Exchange's fee schedule available at http://www.bats.com/us/options/membership/fee_schedule/bzx/.

³¹ As described in more detail below, the Exchange proposes to implement a second and third tier under footnote 12 as part of this filing.

³² Fee code NP is appended to a Member's Non-Customer orders which remove liquidity in Non-Penny Pilot options. *Id.*

²⁷ Fee code NF is appended to a Member's Firm, Broker Dealer and Joint Back Office orders which add liquidity in Non-Penny Pilot options. *Id.*

²⁸ Fee code PA is appended to a Member's Professional orders which add liquidity in Penny Pilot options. *Id.*

²⁹ Fee code NN is appended to a Member's Away Market Maker orders which add liquidity in Non-Penny Pilot options. *Id.*

orders greater than or equal to 1.00% of average TCV. As amended a Member must have an ADAV in Customer orders greater than or equal to 1.30% of average OCV.

- Tier 3 currently requires that a Member has an ADAV in Customer orders greater than or equal to 1.30% of average TCV. As amended, a Member must have an ADAV in Customer orders greater than or equal to 1.70% of average OCV.

Addition of the Step-Up Tier, Under Footnote 1

As described above, the Exchange currently offers eight Customer Penny Pilot Add Volume Tiers under footnote 1 which provide enhanced rebates ranging from \$0.40 to \$0.53 per contract for orders which yield fee code PY and meet the required criteria. The Exchange now proposes to add a Step-Up Tier which would provide an additional rebate of \$0.02 to orders appended with fee code PY, including those orders that satisfy the required criteria under the tiers listed under footnote 1. To qualify for the additional rebate, a Member must have an Options Step-Up Add OCV in Customer orders from October 2016 baseline equal to or greater than 0.45%.

Elimination and Replacement of the Step-Up Tier Under Footnote 3

As described above, the Exchange currently offers three Non-Customer Penny Pilot Take Volume Tiers under footnote 3 which provide reduced fees of \$0.44 and \$0.47 per contract for orders which yield fee code PP and meet the required criteria. Additionally, footnote 3 provides a Step-Up Tier under which Members may receive an additional discount of \$0.01 per contract for orders appended with fee code PP, including those orders that satisfy the required criteria under the tiers listed under footnote 3. To receive the additional \$0.01 per contract discount, the Member must have an Options Step-Up Add TCV in Customer orders from September 2016 baseline greater than or equal to 0.30%. The Exchange now proposes to delete and replace this Step-Up Tier under footnote 3 with a new Step-Up Tier which would provide a reduced fee of \$0.47 per contract for orders which yield fee code PP and where the Member has an Options Step-Up Add OCV in Customer orders from October 2016 baseline greater than or equal to 0.45%.

Addition of Tier 3 Under Footnote 7

As described above, the Exchange currently offers two Market Maker Non-Penny Pilot Add Volume Tiers under

footnote 7 which provide enhanced rebates of \$0.45 and \$0.52 per contract for orders which yield fee code NM and meet the required criteria. The Exchange now proposes to add Tier 3 under which a Member would receive an enhanced rebate of \$0.65 per contract where that Member has an: (i) ADAV in Market Maker orders in Non-Penny Pilot Securities greater than or equal to 0.20% of average OCV; and (ii) ADAV in Non-Customer orders greater than or equal to 3.00% of average OCV. The Exchange also notes that changes are required to the Standard Rates table of the fee schedule applicable to fee code NM in connection with this change.

Addition of Tier 2 and the Customer Step-Up Tier Under Footnote 12

As described above, the Exchange currently offers one Customer Non-Penny Pilot Add Volume Tier under footnote 12 which provides an enhanced rebate of \$1.00 per contract for orders which yield fee code NY and meet the required criteria. The Exchange now proposes to add two new tiers under footnote 12. First, proposed Tier 2 would provide an enhanced rebate of \$1.05 per contract where that Member has an ADAV in Customer orders greater than or equal to 2.10% of average OCV. Second, the proposed Step-Up Tier will provide an enhanced rebate of \$1.00 per contract where that Member has an Options Step-Up Add OCV in Customer orders from October 2016 baseline greater than or equal to 0.45%. The Exchange also notes that changes are required to the Standard Rates table of the fee schedule applicable to fee code NY in connection with these changes.

Addition of Footnote 14, the Customer Penny Pilot Take Volume Tier

The Exchange proposes to add new footnote 14 entitled, "Customer Penny Pilot Take Volume Tier". Under the proposed Cross-Asset Tier, a Member's orders that yield fee code PC³³ would be charged a reduced fee of \$0.48 per contract where that Member has an: (i) ADAV in Customer orders greater than or equal to 0.50% of average OCV; and (ii) ADAV on BZX Equities greater than or equal to 0.50% of average TCV. The Exchange also notes that changes are required to the Standard Rates table of the fee schedule applicable to fee code PC in connection with this change. In addition, the Exchange proposes to append footnote 14 to fee code PC

within in the Fee Codes and Associated Fees table.

Implementation Date

The Exchange proposes to implement this amendment to its fee schedule on January 3, 2017.³⁴

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,³⁵ in general, and furthers the objectives of Section 6(b)(4),³⁶ in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. The Exchange also notes that it operates in a highly-competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive. The Exchange believes that the proposed fee changes are equitable and non-discriminatory in that they apply uniformly to all Members. The Exchange believes the rates remain competitive with those charged by other venues and, therefore, are reasonable and equitably allocated to Members.

New Defined Terms

The Exchange believes adopting a definition of OCV, utilizing OCV in lieu of TCV, and changing the definition of Options Step-Up Add TCV to Options Step-Up Add OCV are reasonable, fair and equitable, and non-discriminatory because the Exchange also proposed to modify the tier's related criteria in order to maintain substantially identical requirements to qualify for the tier without changing the rate provided for by the tiers. In addition, the amount of OCV historically tends to remain reasonably consistent from month to month, as opposed to TCV which is less consistent. OCV is also more consistent than options volume that clears in the Market Maker or Firm range at the OCC, as Market Maker and Firm volume may vary drastically from month to month based on market events, as opposed to Customer options volume which remains relatively consistent. Therefore, the Exchange believes utilizing OCV would result in consistent tier criteria as OCV is a relatively static monthly number which would enable market participants to better predict whether they may achieve a tier criteria each month and qualify for that tier's preferred pricing.

³⁴ The Exchange notes that the date of the fee schedule was updated to January 3, 2017 in SR-BatsBZX-2016-90 (filed on December 27, 2016).

³⁵ 15 U.S.C. 78f.

³⁶ 15 U.S.C. 78f(b)(4).

³³ Fee code PC is appended to a Member's Customer orders which remove liquidity in Penny Pilot options and is charged a standard fee of \$0.49 per contract. *Id.*

The Exchange also believes that the use of OCV provides a calculation that is identical to that which was implemented in December 2016 on the EDGX Options fee schedule.³⁷ Additionally, the OCV calculation is reasonably identical to and is not a significant departure from tier qualifications conventions offered by other exchanges.³⁸ The Exchange believes that the proposed definition of OCV and the proposed revision of the definition of Options Step-Up Add TCV to Options Step-Up Add OCV are reasonable, fair and equitable, and non-discriminatory, and will provide additional transparency and simplicity to Members regarding the calculations used to determine volume levels for purposes of the proposed tiered pricing model.

Volume-Based Tier Modifications

The Exchange believes that the proposed modifications to the tiered pricing structure are reasonable, fair and equitable, and non-discriminatory. The Exchange operates in a highly competitive market in which market participants may readily send order flow to many competing venues if they deem fees at the Exchange to be excessive. The proposed fee structure remains intended to attract order flow to the Exchange by offering market participants a competitive pricing structure. The Exchange believes it is reasonable to offer and incrementally modify incentives intended to help to contribute to the growth of the Exchange.

Volume-based rebates such as that proposed herein have been widely adopted by exchanges, including the Exchange, and are equitable because they are open to all Members on an equal basis and provide additional benefits or discounts that are reasonably related to: (i) The value to an exchange's market quality; (ii) associated higher levels of market activity, such as higher levels of liquidity provisions and/or growth patterns; and (iii) introduction of higher volumes of orders into the price and volume discovery processes.

The proposed modifications and additions proposed herein are also intended to incentivize additional Members to send orders to the Exchange in an effort to qualify for the enhanced rebate made available by the tiers. The Exchange believes the proposed change to each tier's criteria is consistent with the Act.

Proposed Revisions and New Tiers under Footnotes 1, 3, 7, and 12. The Exchange believes the proposed tiers under footnotes 1, 3, 7, and 12 are reasonable, fair and equitable, and non-discriminatory. The proposed tiers are intended to attract order flow to the Exchange by offering market participants a competitive pricing structure. The Exchange believes it is reasonable to offer incrementally modified incentives intended to help to contribute to the growth of the Exchange. First, the Exchange believes the revisions to the Customer Cross-Asset Add Tier under footnote 1 are equitable and reasonable because further incentivize Members to reach certain thresholds on both BZX Options and BZX Equities. Such pricing programs thereby reward a Member's growth pattern on the Exchange and such increased volume increases potential revenue to the Exchange, and will allow the Exchange to continue to provide and potentially expand the incentive programs operated by the Exchange. To the extent a Member participates on the BZX Options but not on BZX Equities, the Exchange does believe that the proposal is still reasonable, equitably allocated and non-discriminatory with respect to such Member based on the overall benefit to the Exchange resulting from the success of BZX Equities.

Additionally, the Exchange believes the elimination and replacement of the Step-Up tier under footnote 3 is reasonable, fair, and equitable because the current tier was not providing the desired result of incentivizing Members to increase their participation over time. Therefore, eliminating the current Step-Up Tier under footnote 3 will have a negligible effect on order flow and

market behavior. The Exchange believes the proposed new Step-Up Tier under footnote 3 should incentivize Members to increase their participation in Customer and Non-Customer orders. Likewise, the proposed tiers under footnotes 1, 7 and 12 are also designed to incentivize Members to increase their participation on the Exchange. The Exchange believes it is reasonable to continue to modify the volume based incentives to help to contribute to the growth of the Exchange. The Exchange also believes the proposed change is not unfairly discriminatory because it will apply equally to all participants.

Addition of Footnote 14, Customer Penny Pilot Take Volume Tier. The Exchange believes that the proposal to add a Cross-Asset Tier is a reasonable, fair and equitable, and not unfairly discriminatory allocation of fees and rebates for similar reasons stated above with regard to the revisions of the Customer Cross-Asset Add Tier under footnote 1. Specifically, the Exchange believes the proposed tier will provide Members with an additional incentive to reach certain thresholds on both BZX Equities and BZX Options. The increased liquidity from this proposal also benefits all investors by deepening the BZX Equities and BZX Options liquidity pools, offering additional flexibility for all investors to enjoy cost savings, supporting the quality of price discovery, promoting market transparency and improving investor protection. Such pricing programs thereby reward a Member's growth pattern on the Exchange and such increased volume increases potential revenue to the Exchange, and will allow the Exchange to continue to provide and potentially expand the incentive programs operated by the Exchange. To the extent a Member participates on the Exchange but not on BZX Equities, the Exchange does believe that the proposal is still reasonable, equitably allocated and non-discriminatory with respect to such Member based on the overall benefit to the Exchange resulting from the success of BZX Options. As noted above, such success allows the Exchange to continue to provide and potentially expand its existing incentive programs to the benefit of all participants on the Exchange, whether they participate on BZX Options or not. The proposed pricing program is also fair and equitable in that membership in BZX Options is available to all market participants which would provide them with access to the benefits on BZX Options provided by the proposed changes, as described above, even where a member of BZX Options is not

³⁷ See Securities Exchange Act Release No. 239239 [sic] (December 7, 2016), 81 FR 90009 (December 13, 2016) (SR-BatsEDGX-2016-68).

³⁸ See the NYSE MKT LLC ("NYSE MKT") fee schedule available at https://www.nyse.com/publicdocs/nyse/markets/amex-options/NYSE_Amex_Options_Fee_Schedule.pdf (setting forth tiers that provide preferred pricing to options market makers who meet certain criteria, including achieving a specific "Monthly Volume as a % of Industry Customer Equity and Exchange Traded Fund ("ETF") Option Volume"); NYSE Arca, Inc. ("NYSE ARCA") options fee schedule available at https://www.nyse.com/publicdocs/nyse/markets/arca-options/NYSE_Arca_Options_Fee_Schedule.pdf (setting forth a Market Maker Incentive tier that provides preferred pricing to market makers who meet certain criteria, including achieving a specific percentage of "Total Industry Customer equity and ETF option ADV"); Nasdaq Stock Market LLC ("Nasdaq") options fee schedule available at <http://www.nasdaqtrader.com/Micro.aspx?id=optionsPricing> (setting forth tiers that provide preferred pricing to market makers who meet certain criteria, including achieving a specific percentage of "total industry customer equity and ETF option ADV contracts per month"); and Nasdaq BX LLC ("BX") options fee schedule available at <http://www.nasdaqtrader.com/Micro.aspx?id=BXOptionsPricing> (setting forth tiers that provide preferred pricing to market makers who meet certain criteria, including achieving a specific percentage of "total industry customer equity and ETF option ADV contracts per month").

necessarily eligible for the proposed increased rebates on the Exchange. Further, the proposed changes will result in Members receiving either the same or an increased rebate than they would currently receive. The Exchange also believes that the proposed tiered pricing structure is consistent with pricing previously offered by the Exchange as well as other options exchanges and does not represent a significant departure from such pricing structures.³⁹

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe its proposed amendment to its fee schedule would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed changes represents a significant departure from previous pricing offered by the Exchange or pricing offered by the Exchange's competitors. The Exchange believes that its proposal to amend the qualification criteria and to incorporate OCV as proposed would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because the Exchange also proposed to modify the tier's related criteria in order to maintain substantially identical requirements to qualify for each tier. Additionally, Members may opt to disfavor the Exchange's pricing if they believe that alternatives offer them better value. Accordingly, the Exchange does not believe that the proposed changes to the volume discount and rebate structure will impair the ability of Members or competing venues to maintain their competitive standing in the financial markets. The Exchange believes that its proposal would not burden intramarket competition because the proposed rate changes would continue to apply uniformly to all Members. As stated above, the Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee structures to be unreasonable or excessive. The Exchange does not believe the proposed tiers would burden intramarket competition as they would apply to all Members uniformly.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from Members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act⁴⁰ and paragraph (f) of Rule 19b-4 thereunder.⁴¹ At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-BatsBZX-2017-01 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090. All submissions should refer to File Number SR-BatsBZX-2017-01. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the

Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-BatsBZX-2017-01 and should be submitted on or before February 9, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴²

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017-01149 Filed 1-18-17; 8:45 am]

BILLING CODE 8011-01-P

DEPARTMENT OF STATE

[Public Notice: 9825]

60-Day Notice of Proposed Information Collection: Passport Demand Forecasting Survey

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to March 20, 2017.

ADDRESSES: You may submit comments by any of the following methods:

- **Web:** Persons with access to the Internet may comment on this notice by going to www.Regulations.gov. You can search for the document by entering "Docket Number: DOS-2016-0079" in the Search field. Then click the "Comment Now" button and complete the comment form.

³⁹ See, e.g., BZX Exchange Options Fee Schedule, Footnote 1, Customer Add Tier, which provides an enhanced rebate to Customer orders on BZX Options based on both Customer volume and Market Maker volume. The BZX Options Fee Schedule is available at: http://www.batsoptions.com/support/fee_schedule/bzx/.

⁴⁰ 15 U.S.C. 78s(b)(3)(A).

⁴¹ 17 CFR 240.19b-4(f).

⁴² 17 CFR 200.30-3(a)(12).

- *Email: PassportStudy@state.gov.*
- *Regular Mail:* Send written comments to: Bureau of Consular Affairs, Passport Services Directorate, Attention: Strategic Planning Division CA/PPT/S/PPS/SP Office of Planning and Program Support, 600 19th Street NW., Washington, DC 20520-0001.

- *Fax:* (202) 485-6496 Attn: Desk Officer for Department of State.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT:

Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to the Office of Passport Services, who may be reached at *passportstudy@state.gov*.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Passport Demand Forecasting Survey.
- *OMB Control Number:* 1405-0177.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* Bureau of Consular Affairs, Office of Passport Services.
- *Form Number:* SV2012-0006.
- *Respondents:* A national representative sample of U.S. citizens, nationals, and any other categories of individuals that are entitled to a U.S. passport product.
- *Estimated Number of Respondents:* 48,000 survey respondents annually.
- *Estimated Number of Responses:* 48,000 survey respondents annually.
- *Average Time Per Response:* 10 minutes.
- *Total Estimated Burden Time:* 8,000 hours.
- *Frequency:* Monthly.
- *Obligation to Respond:* Voluntary.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public

record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The Secretary of State is authorized to issue U.S. passports under 22 U.S.C. 211a. The Department of State, Passport Services administers the U.S. passport issuance program and operates passport agencies and application adjudication centers throughout the United States. As part of the Intelligence Reform and Terrorism Prevention Act of 2004, the Western Hemisphere Travel Initiative required the Secretary of Homeland Security and the Secretary of State to implement a plan to require all U.S. citizen and non-citizen nationals to present a passport and/or other sufficient documentation when entering the U.S. from abroad. This resulted in an increase in demand for U.S. passports.

The Passport Demand Forecasting Survey requests information from the general public about the demand for U.S. passports, anticipated travel, and the demographic profile of the respondent. This voluntary survey is conducted on a monthly basis using responses from a randomly selected but nationally representative sample of U.S. nationals ages 18 and older. The information obtained from the survey is used to monitor and project the demand for U.S. passport books and U.S. passport cards. The Passport Demand Forecasting Survey aids the Department of State, Passport Services in making decisions about staffing, resource allocation, and budget planning.

Methodology

The Passport Demand Forecasting Study uses monthly surveys that will gather data from a national representative sample of U.S. nationals. Survey delivery methodologies can include mail, internet/web, telephone, and mix-mode surveys to ensure the CA/PPT reaches the appropriate audience and leverages the best research method to obtain valid responses. The survey data will cover an estimated 48,000 respondents annually.

Brenda S. Sprague,

Deputy Assistant Secretary, for Passport Services, Department of State.

[FR Doc. 2017-01087 Filed 1-18-17; 8:45 am]

BILLING CODE 4710-06-P

DEPARTMENT OF STATE

[Public Notice: 9823]

60-Day Notice of Proposed Information Collection: Evacuee Manifest and Promissory Note

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to *March 20, 2017*.

ADDRESSES: You may submit comments by any of the following methods:

- *Web:* Persons with access to the Internet may comment on this notice by going to *www.Regulations.gov*. You can search for the document by entering "Docket Number: DOS-2016-0078" in the Search field. Then click the "Comment Now" button and complete the comment form.

- *Email:* *RiversDA@state.gov*.

- *Regular Mail:* Send written comments to: U.S. Department of State, CA/OCS/PMO, SA-17, 10th Floor, Washington, DC 20522-1707.

- *Fax:* 202-736-9111.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT:

Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Derek A. Rivers, Bureau of Consular Affairs, Overseas Citizens Services (CA/OCS/PMO), U.S. Department of State, SA-17, 10th Floor, Washington, DC 20522-1707, who may be reached at *mailto:RiversDA@state.gov*.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Evacuee Manifest and Promissory Note.
- *OMB Control Number:* 1405-0211.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* Bureau of Consular Affairs, Overseas Citizens Services (CA/OCS).
- *Form Number:* DS-5528.

- *Respondents*: U.S. citizens, U.S. non-citizen nationals, lawful permanent residents, and third country nationals applying for emergency loan assistance during an evacuation.

- *Estimated Number of Respondents*: 525.

- *Estimated Number of Responses*: 525.

- *Average Time per Response*: 20 minutes.

- *Total Estimated Burden Time*: 175 annual hours.

- *Frequency*: On Occasion.

- *Obligation to Respond*: Required to Obtain Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.

- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.

- Enhance the quality, utility, and clarity of the information to be collected.

- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The purpose of the DS-5528 is to document the evacuation of persons from abroad when their lives are endangered by war, civil unrest, or natural disaster; document issuance of a crisis evacuation loan; obtain a Privacy Act Waiver to share information about the welfare of a U.S. citizen or U.S. lawful permanent resident consistent with the Privacy Act of 1974; and, to facilitate debt collection.

Methodology

An electronic version of the Evacuee Manifest and Promissory Note was created, allowing applicants to type their information into the form, print it, and present it to a consular officer at the evacuation point. Continued software development will provide the capability to electronically submit signed loan applications for adjudication. The final stage of software development will not only allow the applicant to enter his/her information and submit the form, but will also make the information available

for all stages of financial processing including the Department of State's debt collection process. Due to the potential for serious conditions during crisis events that often affect electronic and internet infrastructure systems, the electronic form will not replace the paper form. Rather, the paper form will still be maintained and used in the event that applicants are unable to submit forms electronically.

Michelle Bernier-Toth,

Managing Director, Bureau of Consular Affairs, Overseas Citizens Services, Department of State.

[FR Doc. 2017-01079 Filed 1-18-17; 8:45 am]

BILLING CODE 4710-06-P

DEPARTMENT OF STATE

[Public Notice 9858]

Additional Designation of Syrian Entity Pursuant to E.O. 13382

ACTION: Designation of the Organization for Technological Industries (OTI) Pursuant to E.O. 13382.

SUMMARY: Pursuant to the authority in section 1(ii) of E.O. 13382, "Blocking Property of Weapons of Mass Destruction Proliferators and Their Supporters", the Under Secretary of State for Arms Control and International Security, in consultation with the Secretary of the Treasury and the Attorney General, has determined that the Syrian entity Organization for Technological Industries (OTI) has engaged, or attempted to engage, in activities or transactions that have materially contributed to, or pose a risk of materially contributing to, the proliferation of weapons of mass destruction or their means of delivery (including missiles capable of delivering such weapons), including any efforts to manufacture, acquire, possess, develop, transport, transfer or use such items, by any person or foreign country of proliferation concern.

DATES: *Effective Dates:* The designation of and additional identifying information for the entity identified in this notice pursuant to E.O. 13382 is effective upon publication of this notice.

FOR FURTHER INFORMATION CONTACT: Director, Office of Counterproliferation Initiatives, Bureau of International Security and Nonproliferation, Department of State, Washington, DC 20520, tel.: 202-647-5193.

Background

On June 28, 2005, the President, invoking the authority, *inter alia*, of the International Emergency Economic

Powers Act (50 U.S.C. 1701-1706) ("IEEPA"), issued E.O. 13382 (70 FR 38567, July 1, 2005) (the "Order"), effective at 12:01 a.m. eastern daylight time on June 30, 2005. In the Order the President took additional steps with respect to the national emergency described and declared in E.O. 12938 of November 14, 1994, regarding the proliferation of weapons of mass destruction and the means of delivering them.

Section 1 of the Order blocks, with certain exceptions, all property and interests in property that are in the United States, or that hereafter come within the United States or that are or hereafter come within the possession or control of United States persons, of: (1) The persons listed in the Annex to the Order; (2) any foreign person determined by the Secretary of State, in consultation with the Secretary of the Treasury, the Attorney General, and other relevant agencies, to have engaged, or attempted to engage, in activities or transactions that have materially contributed to, or pose a risk of materially contributing to, the proliferation of weapons of mass destruction or their means of delivery (including missiles capable of delivering such weapons), including any efforts to manufacture, acquire, possess, develop, transport, transfer or use such items, by any person or foreign country of proliferation concern; (3) any person determined by the Secretary of the Treasury, in consultation with the Secretary of State, the Attorney General, and other relevant agencies, to have provided, or attempted to provide, financial, material, technological or other support for, or goods or services in support of, any activity or transaction described in clause (2) above or any person whose property and interests in property are blocked pursuant to the Order; and (4) any person determined by the Secretary of the Treasury, in consultation with the Secretary of State, the Attorney General, and other relevant agencies, to be owned or controlled by, or acting or purporting to act for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to the Order.

Information on the additional designee is as follows:

(U) Organization for Technological Industries

(U) Name: Organization for Technological Industries

(U) AKA: The Organization for Technical Industries

(U) Address: Sham Algadida OTip Box Damascus-11037, Syrian Arab Republic

Dated: January 12, 2017.

Thomas M. Countryman,

Acting Under Secretary for Arms Control and International Security, Department of State.

[FR Doc. 2017-01223 Filed 1-18-17; 8:45 am]

BILLING CODE 4710-27-P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 290 (Sub-No. 387X)]

Chesapeake Western Railway— Discontinuance of Service Exemption—in Rockingham and Shenandoah Counties, VA.

AGENCY: Surface Transportation Board.

ACTION: Correction to notice of exemption.

On June 27, 2016, Chesapeake Western Railway (CW) filed a verified notice of exemption under 49 CFR 1152 subpart F—*Exempt Abandonments and Discontinuances of Service* to discontinue service over an approximately 15.1-mile rail line between milepost CW 84.4 at Mt. Jackson, Va., and milepost CW 99.5 at Broadway, Va., in Rockingham and Shenandoah Counties, Va. (the Line). On July 15, 2016, notice of the exemption was served and published in the **Federal Register** (81 FR 46,152).

On September 23, 2016, CW filed a letter stating that the starting point of the Line at milepost CW 84.4 was inadvertently incorrect and should have been CW 84.0. As a result, CW states that the total length of the Line is approximately 15.5 miles as opposed to 15.1 miles. This notice corrects the description of the milepost and total length of the Line. All other information in the July 15, 2016 notice is correct.

Board decisions and notices are available on our Web site at “WWW.STB.GOV.”

Decided: January 12, 2017.

By the Board, Rachel D. Campbell,
Director, Office of Proceedings.

Rena Laws-Byrum,
Clearance Clerk.

[FR Doc. 2017-01165 Filed 1-18-17; 8:45 am]

BILLING CODE 4915-01-P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36088]

SMS Rail Lines of New York, LLC— Acquisition and Operation Exemption—Rail Line of WCC, LLC, in Hudson Falls, NY

SMS Rail Lines of New York, LLC (SMS), a Class III rail carrier, has filed a verified notice of exemption under 49

CFR 1150.41 to acquire by lease from WCC, LLC, and operate approximately 3.5 miles of rail line in Hudson Falls, Washington County, NY (the Line). According to SMS, there are no milepost designations on the Line.

SMS certifies that its projected annual revenues as a result of this transaction will not result in the creation of a Class II or Class I rail carrier and will not exceed \$5 million.

SMS further certifies that the transaction does not include a provision or agreement that may limit future interchange commitments.

The transaction may be consummated on February 4, 2017, the effective date of the exemption (30 days after the exemption was filed).

If the notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction. Petitions for stay must be filed no later than January 27, 2017 (at least 7 days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. FD 36088, must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423-0001. In addition, one copy of each pleading must be served on Robert A. Klein, 629 B Swedesford Rd., Malvern, PA 19355.

According to SMS, this action is categorically excluded from environmental review under 49 CFR 1105.6(c).

Board decisions and notices are available on our Web site at WWW.STB.GOV.

Decided: January 12, 2017.

By the Board, Rachel D. Campbell,
Director, Office of Proceedings.

Rena Laws-Byrum,
Clearance Clerk.

[FR Doc. 2017-01195 Filed 1-18-17; 8:45 am]

BILLING CODE 4915-01-P

SUSQUEHANNA RIVER BASIN COMMISSION

Projects Approved for Consumptive Uses of Water

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists the projects approved by rule by the Susquehanna River Basin Commission during the period set forth in **DATES**.

DATES: December 1–30, 2016.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110-1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel, telephone: (717) 238-0423, ext. 1312; fax: (717) 238-2436; email: joyler@srbc.net. Regular mail inquiries may be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists the projects, described below, receiving approval for the consumptive use of water pursuant to the Commission's approval by rule process set forth in 18 CFR 806.22(f) for the time period specified above:

Approvals By Rule Issued Under 18 CFR 806.22(f)

1. Chesapeake Appalachia, LLC, Pad ID: WGC, ABR-201205014.R1, Albany Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: December 2, 2016.

2. Chesapeake Appalachia, LLC, Pad ID: Iceman, ABR-201205016.R1, Wilmot Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: December 2, 2016.

3. SWEPI LP, Pad ID: Cotton Hanlon 595, ABR-201612001, Sullivan Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: December 2, 2016.

4. Anadarko E&P Onshore, LLC, Pad ID: COP Tract 356 Pad E, ABR-201112029.R1, Cummings Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: December 5, 2016.

5. Anadarko E&P Onshore, LLC, Pad ID: Larrys Creek F&G Pad E, ABR-201112030.R1, Cummings Township, Lycoming County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: December 5, 2016.

6. SWN Production Company, LLC, Pad ID: TONYA WEST, ABR-201201026.R1, New Milford Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: December 5, 2016.

7. SWN Production Company, LLC, Pad ID: WATTS, ABR-201202028.R1, New Milford Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: December 6, 2016.

8. Cabot Oil & Gas Corporation, Pad ID: Kielard P1, ABR-201112002.R1, Lathrop Township, Susquehanna County, Pa.; Consumptive Use of Up to 3.5750 mgd; Approval Date: December 12, 2016.

9. Cabot Oil & Gas Corporation, Pad ID: CareyR P1, ABR-201112023.R1, Harford Township, Susquehanna

County, Pa.; Consumptive Use of Up to 3.5750 mgd; Approval Date: December 12, 2016.

10. Chesapeake Appalachia, LLC, Pad ID: Maris, ABR–201205010.R1, Auburn Township, Susquehanna County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: December 12, 2016.

11. Carrizo (Marcellus), LLC, Pad ID: Trecoske North Pad, ABR–201201023.R1, Silver Lake Township, Susquehanna County, Pa.; Consumptive Use of Up to 2.1000 mgd; Approval Date: December 16, 2016.

12. Carrizo (Marcellus), LLC, Pad ID: Trecoske South Pad, ABR–201201024.R1, Silver Lake Township, Susquehanna County, Pa.; Consumptive Use of Up to 2.1000 mgd; Approval Date: December 16, 2016.

13. Talisman Energy USA Inc., Pad ID: Hemlock Valley, ABR–201201035.R1, Pike Township, Bradford County, Pa.; Consumptive Use of Up to 7.5000 mgd; Approval Date: December 16, 2016.

Authority: Pub. L. 91–575, 84 Stat. 1509 *et seq.*, 18 CFR parts 806, 807, and 808.

Dated: January 13, 2017.

Stephanie L. Richardson,
Secretary to the Commission.

[FR Doc. 2017–01184 Filed 1–18–17; 8:45 am]

BILLING CODE 7040–01–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2017–0002]

Controlled Substances and Alcohol Use and Testing: J.B. Hunt Transport, Inc., Schneider National Carriers, Inc., Werner Enterprises, Inc., Knight Transportation, Inc., Dupre Logistics, Inc. and Maveric Transportation, LLC Application for Exemption

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for exemption; request for comments.

SUMMARY: FMCSA announces that it has received an application from J.B. Hunt Transport, Inc. (J.B. Hunt), Schneider National Carriers, Inc. (Schneider), Werner Enterprises, Inc. (Werner), Knight Transportation, Inc. (Knight), Dupre Logistics, Inc. (Dupree), and Maveric Transportation, LLC (Maverick) (the Applicants) to allow hair analysis in lieu of urine testing for pre-employment controlled substances testing of commercial driver's license (CDL) holders. The Applicants currently conduct pre-employment urine testing

that satisfies the Department of Transportation's (the Department) requirements under 49 CFR part 40 and hair analysis, separate from the Department's controlled substances and alcohol testing program. The Applicants' believe their data “. . . demonstrates that hair analysis is a more reliable and comprehensive basis for ensuring detection of controlled substance use” and the exemption would enable these fleets to discontinue pre-employment urine testing. FMCSA requests public comment on the exemption application.

DATES: Comments must be received on or before February 21, 2017.

ADDRESSES: You may submit comments identified by Federal Docket Management System Number FMCSA–2017–0002 by any of the following methods:

- **Federal eRulemaking Portal:** www.regulations.gov. See the *Public Participation and Request for Comments* section below for further information.
- **Mail:** Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.
- **Hand Delivery or Courier:** West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays.
- **Fax:** 1–202–493–2251.

Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received, without change, to www.regulations.gov, including any personal information included in a comment. Please see the *Privacy Act* heading below.

Docket: For access to the docket to read background documents or comments, go to www.regulations.gov at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. The on-line FDMS is available 24 hours each day, 365 days each year.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at www.dot.gov/privacy.

FOR FURTHER INFORMATION CONTACT: For information concerning this notice, contact Mr. Thomas Yager, Chief,

FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; Telephone: (614) 942–6477. Email: MCPDSD@dot.gov. If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2017–0002), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to www.regulations.gov and put the docket number, “FMCSA–2017–0002” in the “Keyword” box, and click “Search.” When the new screen appears, click on “Comment Now!” button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party, and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period and may grant or not grant this application based on your comments.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also

provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

III. Request for Exemption

Background—Regulatory Requirements

Currently, 49 CFR 382.105, concerning FMCSA's controlled substances and alcohol testing regulations, requires that each employer ensure all alcohol or controlled substances testing conducted on CDL holders complies with the procedures under 49 CFR part 40. All parties who conduct controlled substances and alcohol tests required by the Department must follow the Part 40 requirements on how to conduct the test and what procedures to use. Currently, Part 40 only allows urine testing for controlled substances. Congress, through the Omnibus Transportation Employee Testing Act (OTETA) of 1991 (Pub. L. 102-143, Title V, 105 Stat. 952). OTETA requires the Department to follow the HHS Mandatory Guidelines for scientific testing issues. While DOT has discretion concerning many aspects of the regulations governing testing in the transportation industries' regulated programs, we must follow the HHS Mandatory Guidelines for the laboratory standards and procedures the Department will use for regulated testing.

Section 382.301 provides requirements concerning pre-employment testing of commercial driver's license (CDL) holders for controlled substances, while 49 CFR part 383 prescribes requirements for individuals who must obtain a CDL. With limited exceptions, an employer must conduct pre-employment testing for controlled substances prior to the first time a driver performs "safety-sensitive functions," as defined in 49 CFR 382.107. Employers must not allow a driver whom the employer intends to

hire or use to perform safety-sensitive functions unless the employer has received a controlled substances test result from the medical review officer (MRO) or consortium/third-party administrator (C/TPA), as those terms are defined in 49 CFR 40.3, indicating a verified negative test result for that driver.

Application for Exemption

The Applicants have requested an exemption from 49 CFR 382.105 and 382.301 with specific authorization for release of and obtaining hair test results to comply with 49 CFR 391.23, *Investigations and inquiries*. Under the exemption, the carriers would conduct pre-employment tests using hair analysis only, rather than hair analysis in addition to urine testing, and individuals with negative test results would be permitted to perform safety-sensitive functions for the employer. Individuals testing positive would not be allowed to perform safety-sensitive functions until the driver completes the return-to-duty process under Subpart O of 49 CFR part 40. In addition, the Applicants would share the positive hair testing results with prospective employers in response to safety-performance inquiries required by 49 CFR 391.23.

The carriers that would be covered by the exemption already use hair analysis as a method for pre-employment controlled substances testing of drivers on a voluntary basis. However, they also conduct urine testing for drugs because it is the only screening method accepted under the Department's regulations. The Applicant's view their use of multiple screening methods as an unnecessary and redundant financial burden. Also, the Applicants consider urine testing to be less effective in pre-employment screening for drugs than hair analysis.

A copy of the exemption application and all supporting documents submitted by the Applicant is available for review in the docket referenced at the beginning of this notice.

Request for Comments

In accordance with 49 U.S.C. 31315(b)(4) and 31136(e), FMCSA requests public comment on the application for an exemption from 49 CFR 382.105 and 382.301.

The Agency will consider all comments received by close of business on February 21, 2017. Comments will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. The Agency will consider to the extent practicable comments received in the

public docket after the closing date of the comment period.

Issued on: January 13, 2017.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2017-01278 Filed 1-18-17; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2016-0450]

Parts and Accessories Necessary for Safe Operation; Application for an Exemption From Hino Motors Manufacturing U.S.A., Inc.

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for exemption; request for comments.

SUMMARY: The Federal Motor Carrier Safety Administration (FMCSA) requests public comment on an application for exemption from Hino Motors Manufacturing U.S.A., Inc. (Hino) to allow an Automated Emergency Braking (AEB) system and a Lane Departure Warning (LDW) system camera to be mounted lower in the windshield than is currently permitted. Mounting the camera in this location does not meet the prohibition on obstructions to the driver's field of view requirements for windshields in the Federal Motor Carrier Safety Regulations (FMCSR) which requires devices meeting the definition of "vehicle safety technology" to be mounted not more than 4 inches below the upper edge of the area swept by the windshield wipers, or not more than 7 inches above the lower edge of the area swept by the windshield wipers, and outside the driver's sight lines to the road and highway signs and signals. Because the camera will be mounted outside of the driver's normal sight lines to all mirrors, Hino believes that they will maintain a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption.

DATES: Comments must be received on or before February 21, 2017.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA-2016-0450 using any of the following methods:

- *Web site:* <http://www.regulations.gov>. Follow the instructions for submitting comments on the Federal electronic docket site.

- *Fax:* 1-202-493-2251.

• *Mail:* Docket Management Facility, U.S. Department of Transportation, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001.

• *Hand Delivery:* Ground Floor, Room W12-140, DOT Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m. e.t., Monday-Friday, except Federal holidays.

Instructions: All submissions must include the Agency name and docket number for this notice. For detailed instructions on submitting comments and additional information on the exemption process, see the "Public Participation" heading below. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. Please see the "Privacy Act" heading for further information.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> or to Room W12-140, DOT Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

Public participation: The <http://www.regulations.gov> Web site is generally available 24 hours each day, 365 days each year. You may find electronic submission and retrieval help and guidelines under the "help" section of the <http://www.regulations.gov> Web site as well as the DOT's <http://docketsinfo.dot.gov> Web site. If you would like notification that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgment page that appears after submitting comments online.

FOR FURTHER INFORMATION CONTACT: Mrs. Amina Fisher, Vehicle and Roadside Operations Division, Office of Carrier, Driver, and Vehicle Safety, MC-PSV, (202) 366-2782, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590-0001.

SUPPLEMENTARY INFORMATION:

Background

Section 4007 of the Transportation Equity Act for the 21st Century (TEA-21) [Pub. L. 105-178, June 9, 1998, 112 Stat. 401] amended 49 U.S.C. 31315 and 31136(e) to provide authority to grant exemptions from the Federal Motor Carrier Safety Regulations (FMCSRs). On August 20, 2004, FMCSA published a final rule (69 FR 51589) implementing section 4007. Under this rule, FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public with an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews the safety analyses and the public comments and determines whether granting the exemption would likely achieve a level of safety equivalent to or greater than the level that would be achieved by the current regulation (49 CFR 381.305).

The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)). If the Agency denies the request, it must state the reason for doing so. If the decision is to grant the exemption, the notice must specify the person or class of persons receiving the exemption and the regulatory provision or provisions from which an exemption is granted. The notice must specify the effective period of the exemption (up to 5 years) and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.315(c) and 49 CFR 381.300(b)).

Hino's Application for Exemption

Hino has applied for an exemption from 49 CFR 393.60(e) to allow an Automated Emergency Braking (AEB) system and a Lane Departure Warning (LDW) system camera to be mounted lower in the windshield than is currently permitted. A copy of the application is included in the docket referenced at the beginning of this notice.

Section 393.60(e)(1)(i) of the FMCSRs prohibits the obstruction of the driver's field of view by devices mounted at the top of the windshield. Antennas and similar devices must not be mounted more than 152 mm (6 inches) below the upper edge of the windshield, and outside the driver's sight lines to the road and highway signs and signals. Section 393.60(e)(1)(i) does not apply to vehicle safety technologies, as defined in § 390.5 as including "a fleet-related incident management system,

performance or behavior management system, speed management system, lane departure warning system, forward collision warning or mitigation system, active cruise control system, and transponder." Section 393.60(e)(1)(ii) requires devices with vehicle safety technologies to be mounted (1) not more than 100 mm (4 inches) below the upper edge of the area swept by the windshield wipers, or (2) not more than 175 mm (7 inches) above the lower edge of the area swept by the windshield wipers, and outside the driver's sight lines to the road and highway signs and signals.

In its application, Hino states:

Hino is making this request so that it becomes possible to introduce an Automated Emergency Braking (AEB) system and a Lane Departure Warning (LDW) system as optional equipment on some Hino commercial motor vehicles. This system, like many other similar systems which FMCSA has granted exemptions for, requires that a camera be mounted to the upper center area of the windshield in an area where the windshield is swept by the windshield wipers to provide a clear view to the lane markings on the road.

In the Hino installation, the camera housing supplied by Meritor Wabco is approximately 4.67 inches wide by 4.30 inches tall. We propose to mount the camera such that is in the approximate center of the windshield and such that the bottom edge of the camera is approximately 7 inches below the upper edge of the windshield, outside of the driver's and passenger's normal sight lines to all mirrors, highway signs, signals and view of the road ahead. This location will allow for the optimal functionality of the advanced safety systems supported by the camera.

Hino has created a CAD layout of a typical Hino conventional type truck to verify that we do not significantly obstruct the FMVSS 104 specified zones A, B or C for passenger cars of 1730 or more mm overall width [Figure 1 of application]. In fact, we obstruct 0.0% of zone C, 0.1% of zone B and 1.4% of zone A.

Hino has installed one prototype camera housing in a Hino conventional type model 258LP (low profile) test vehicle with the lowest cab height we offer to assess, through a jury evaluation, the impact of the camera on driver and passenger visibility [Figure 2 of application].

All drivers and passengers agreed that there was no noticeable obstruction to the normal sight lines to the road ahead, highway signs, signals or any mirrors. Also, one driver noted that the camera did not interfere with the normal range of motion of the sun visor and that the sun visor lower edge extended lower than the camera housing [Figure 3 of application].

The exemption would apply to all CMV operators driving Hino vehicles with the AEB/LDW system camera installed. Hino believes that mounting the system as described will maintain a

level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption.

Request for Comments

In accordance with 49 U.S.C. 31315 and 31136(e), FMCSA requests public comment from all interested persons on Hino's application for an exemption from 49 CFR 393.60. All comments received before the close of business on the comment closing date indicated at the beginning of this notice will be considered and will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable. In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should continue to examine the public docket for new material.

Issued on: January 13, 2017.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2017-01265 Filed 1-18-17; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[Docket FTA-2017-0001]

Notice of Establishment of Emergency Relief Docket for Calendar Year 2017

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice.

SUMMARY: By this notice, the Federal Transit Administration (FTA) is establishing an Emergency Relief Docket for calendar year 2017 so grantees and subgrantees affected by national or regional emergencies may request temporary relief from FTA administrative and statutory requirements.

FOR FURTHER INFORMATION CONTACT:

Bonnie L. Graves, Attorney-Advisor, Office of Chief Counsel, Federal Transit Administration, 90 Seventh Street, Ste. 15-300, San Francisco, CA 94103; phone: (202) 366-0944, fax: (415) 734-9489, or email, *Bonnie.Graves@dot.gov*.

SUPPLEMENTARY INFORMATION: Pursuant to title 49 CFR part 601, subpart D, FTA is establishing the Emergency Relief Docket for calendar year 2017. Subsequent to an emergency or major disaster, the docket may be opened at

the request of a grantee or subgrantee, or on the FTA Administrator's own initiative.

In the event a grantee or subgrantee believes the Emergency Relief Docket should be opened and it has not been opened, that grantee or subgrantee may submit a petition to www.regulations.gov for posting in the docket (FTA-2017-0001). Alternatively, a grantee or subgrantee may submit a petition in duplicate to the FTA Administrator, via U.S. mail or hand delivery, to: Federal Transit Administration, 1200 New Jersey Ave. SE., Washington, DC 20590; via telephone, at: (202) 366-4011; via fax, at: (202) 366-3472; via email, to *Bonnie.Graves@dot.gov*; or via U.S. mail or hand delivery to the DOT Docket Management Facility, 1200 New Jersey Ave. SE., Room W12-140, Washington, DC 20590, requesting opening of the Docket for that emergency and including the information set forth below.

All petitions for relief from a provision of chapter 53 of title 49, U.S.C. or FTA administrative requirements must be posted in the docket in order to receive consideration by FTA. The docket is publicly available and can be accessed 24 hours a day, seven days a week, via the Internet at www.regulations.gov. Any grantee or subgrantee submitting petitions for relief or comments to the docket must include the agency name (Federal Transit Administration) and docket number FTA-2017-0001. Grantees and subgrantees making submissions to FTA or to the docket by mail or hand delivery should submit two copies. Grantees and subgrantees are strongly encouraged to contact their FTA regional office and notify FTA of the intent to submit a petition to the docket.

In the event a grantee or subgrantee needs to request immediate relief and does not have access to electronic means to request that relief, the grantee or subgrantee may contact any FTA regional office or FTA headquarters and request that FTA staff submit the petition on its behalf.

Federal public transportation law at 49 U.S.C. 5324(d) provides that a grant awarded under Section 5324 or under 49 U.S.C. 5307 or 49 U.S.C. 5311 that is made to address an emergency shall be subject to the terms and conditions the Secretary determines are necessary. This language allows FTA to waive statutory, as well as administrative, requirements. Therefore, grantees affected by an emergency or major disaster may request waivers of provisions of chapter 53 of title 49, U.S.C. when a grantee or subgrantee demonstrates the

requirement(s) will limit a grantee's or subgrantee's ability to respond to an emergency. Grantees must follow the procedures set forth below when requesting a waiver of statutory or administrative requirements.

A petition for relief shall:

(a) Identify the grantee or subgrantee and its geographic location;

(b) Identify the section of chapter 53 of title 49, U.S.C., or the FTA policy statement, circular, guidance document and/or rule from which the grantee or subgrantee seeks relief;

(c) Specifically address how a requirement in chapter 53 of title 49 U.S.C., or an FTA requirement in a policy statement, circular, agency guidance or rule will limit a grantee's or subgrantee's ability to respond to an emergency or disaster; and

(d) Specify if the petition for relief is one-time or ongoing, and if ongoing identify the time period for which the relief is requested. The time period may not exceed three months; however, additional time may be requested through a second petition for relief.

A petition for relief from administrative requirements will be conditionally granted for a period of three (3) business days from the date it is submitted to the Emergency Relief Docket. FTA will review the petition after the expiration of the three business days and review any comments submitted thereto. FTA may contact the grantee or subgrantee that submitted the request for relief, or any party that submits comments to the docket, to obtain more information prior to making a decision. FTA shall then post a decision to the Emergency Relief Docket. FTA's decision will be based on whether the petition meets the criteria for use of these emergency procedures, the substance of the request, and the comments submitted regarding the petition. If FTA does not respond to the request for relief to the docket within three business days, the grantee or subgrantee may assume its petition is granted for a period not to exceed three months until and unless FTA states otherwise.

A petition for relief from statutory requirements will not be conditionally granted and requires a written decision from the FTA Administrator.

Pursuant to 49 CFR 604.2(f) of FTA's Charter Rule, grantees and subgrantees may assist with evacuations or other movement of people that might otherwise be considered charter transportation when that transportation is in response to an emergency declared by the President, governor, or mayor, or in an emergency requiring immediate action prior to a formal declaration,

even if a formal declaration of an emergency is not eventually made by the President, governor or mayor. Therefore, a request for relief is not necessary in order to provide this service. However, if the emergency lasts more than 45 calendar days, the grantee or subgrantee shall follow the procedures set out in this notice.

FTA reserves the right to reopen any docket and reconsider any decision made pursuant to these emergency procedures based upon its own initiative, based upon information or comments received subsequent to the three business day comment period, or at the request of a grantee or subgrantee upon denial of a request for relief. FTA shall notify the grantee or subgrantee if it plans to reconsider a decision. FTA decision letters, either granting or denying a petition, shall be posted in the Emergency Relief Docket and shall reference the document number of the petition to which it relates.

Carolyn Flowers,
Acting Administrator.

[FR Doc. 2017-01172 Filed 1-18-17; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

FTA Fiscal Year 2017 Apportionments, Allocations, Program Information and Interim Guidance

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice.

SUMMARY: This notice provides interim guidance for programs in FY 2017, announces the apportionments and allocations for programs authorized and funded by the Further Continuing and Security Assistance Appropriations Act, 2017 (Pub. L. 114–254) and provides contract authority, and describes future plans for several competitive programs. The notice also includes locations of FY 2017 apportionment tables and unobligated (or carryover) funds allocated under the competitive programs from prior years.

FOR FURTHER INFORMATION CONTACT: For general information about this notice contact Kimberly Sledge, Director, Office of Transit Programs, at (202) 366–2053. Please contact the appropriate FTA Regional Office for any specific requests for information or technical assistance. FTA Regional Office contact information is available on FTA's Web site: www.transit.dot.gov.

An FTA headquarters contact for each major program area is included in the

discussion of that program in the text of this notice. FTA recommends that stakeholders subscribe on FTA's Web site www.transit.dot.gov to receive email notifications when new information is available.

SUPPLEMENTARY INFORMATION:

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I. Overview

This document contains important information and interim guidance about

existing FTA program statutes (49 U.S.C. 5301, *et. seq.*) and changes resulting from the Fixing America's Surface Transportation (FAST) Act (Pub. L. 114–94), signed by President Obama on December 4, 2015 and effective on October 1, 2015.

In addition, this document provides notice of funding availability through April 28, 2017 by the Further Continuing and Security Assistance Appropriations Act, 2017 (Pub. L. 114–254) contract authority for FTA formula and competitive programs pursuant to the Further Continuing and Security Assistance Appropriations Act, 2017 (Pub. L. 114–254) (“Continuing Appropriations Act”).

For each FTA program, FTA has provided information on the FY 2017 authorized funding levels, the basis for apportionment or allocation of funds, requirements specific to the program, the period of availability of funds, and other program information. A separate section provides information on pre-award authority as well as other requirements and guidance applicable to FTA programs and grant administration. Finally, the notice includes referred to tables on FTA's Web site that show \$5,323,087,320 in new contract authority apportioned through April 28, 2017 and approximately \$1.04 billion in unobligated or carryover contract authority that is available in FY 2017 from prior years.

Information in this document includes references to the existing FTA program guidance and circulars. Some information may have been superseded by new provisions in the FAST Act, but these guidance documents and circulars remain a resource for program management in most areas. FTA intends to revise the guidance and circulars, as appropriate, with an opportunity for public comment where necessary.

II. FY 2017 Funding for FTA Programs

A. Funding Based on the Further Continuing and Security Assistance Appropriations Act, 2017

The Further Continuing and Security Assistance Appropriations Act, 2017 (Pub. L. 114–254) makes new funding available for FY 2017 available through April 28, 2017. At approximately seven twelfths of the FY 2016 level.

Current funding availability for each program is identified in section IV of this notice and in Table 1 located on FTA's FY 2017 Apportionment Web page: www.transit.dot.gov/funding/apportionments.

B. Oversight Takedown

The FAST Act modified section 5338(f) to provide for the following oversight takedowns of FTA programs: 0.5 percent of Metropolitan and Statewide Planning funds, 0.75 percent of Urbanized Area Formula funds, 1 percent of Fixed Guideway Capital Investment funds, 0.5 percent of Formula Grants for the Enhanced Mobility of Seniors and Individuals with Disabilities, 0.5 percent of Formula Grants for Rural Areas, 1 percent of State of Good Repair Formula funds, 0.75 percent for Grants for Buses and Bus Facilities, and 1 percent of Capital and Preventive Maintenance Projects for Washington Metropolitan Area Transit Authority funds. The funds are used to provide necessary oversight activities, such as oversight of the construction of any major capital project receiving Federal transit assistance; to conduct State Safety Oversight, drug and alcohol, civil rights, procurement systems, management, planning certification, and financial reviews and audits, as well as evaluations and analyses of grantee-specific problems and issues; and to generally provide technical assistance and correct deficiencies identified in compliance reviews and audits.

C. FY 2017 Formula Apportionments: Data and Methodology

1. Apportionment Tables

FTA is publishing apportionment tables on its Web site for each program that reflects the funding level in the continuing resolution appropriations less oversight take-downs, as applicable. Tables displaying the funds available to eligible states, tribes, and urbanized areas have been posted to <http://www.transit.dot.gov/funding/apportionments>. This Web site contains a page listing the apportionment and allocation tables for FY 2017 as well as links to prior year formula apportionment notices and tables and the National Transit Database (NTD) and Census data used to calculate the FY 2017 apportionments.

2. National Transit Database and Census Data Used in the FY 2017 Apportionments

Consistent with past practices, the calculations for sections 5307, 5311, including 5311(j) (Tribal Transit), 5329, 5337, and 5339 programs rely on the most-recent transit service data reported to the (NTD), which for FY 2017 is the 2015 report year. In some cases where an apportionment is based on the age of the system, the age is calculated as of September 30, 2016, the last day before

FY 2017 began. Any recipient or beneficiary of either section 5307 or Rural Areas Formula Program program funds is required to report to the NTD. Additionally, a number of transit operators report to the FTA's NTD on a voluntary basis. For the 2015 report year, the NTD includes data from 866 reporters in urbanized areas, 836 of which reported operating transit service. The NTD also includes data from 1,551 providers of rural transit service, which includes 134 Indian Tribes providing transit service.

The 2010 Census data is used to determine population and population density for sections 5303, 5305, 5307 and 5339 as well as rural population and rural land area for Rural Areas Formula Program. The formulas for sections 5307, 5311, and 5311(j) include tiers where funding is allocated on the basis of the number of persons living in poverty, and the section 5310 formula program allocates funding on the basis of the population of older adults and people with disabilities. The Census Bureau no longer publishes decennial census data on persons living in poverty and persons with disabilities. As a result, since FY 2013, FTA used the data for these populations available via the Census' American Community Survey (ACS). The NTD and census data that FTA used to calculate the apportionments associated with this notice can be found on FTA's Web site: www.transit.dot.gov/funding/apportionments.

The FY 2017 apportionments use data on low-income persons, persons with disabilities, and older adults from the 2010–2014 ACS five-year data set, which was published in December 2015. This data represent the most recent five-year ACS estimates that are available as of October 1st for the year being apportioned. As was the case in prior years, data on low-income persons comes from ACS Table B17024, "Age by Ratio of Income to Poverty in the Last Twelve Months," and data on people with disabilities under 65 years old comes from ACS Table S1810, "Disability Characteristics." Data on older adults (over 65 years old) comes from ACS Table B01001, "Sex by Age."

III. FY 2017 Program Highlights and Changes

A. Focus Areas

1. Tribal Transportation Self-Governance Program (Title 23 Federal-Aid Highways Program)

Section 207 of title 23, United States Code establishes a Tribal Transportation Self-Governance Program (Self-Governance Program). The Self-

Governance Program establishes specific criteria for determining eligibility for a tribe to participate in the program. DOT will implement this program in consultation with tribal representatives and other interested stakeholders. A Negotiated Proposed Rulemaking to implement this program is under development.

2. Public Transportation Innovation

FTA's research mission is to advance public transportation innovation by leading multi-dimensional research, development, demonstration, deployment, and technical assistance projects for the transit industry that improves riders' experiences and enhances public transit's effectiveness, efficiency, quality, and safety. FTA's Office of Research, Demonstration, and Innovation sought industry input on a five year research strategic plan. The result was an affirmation of FTA's research strategic goals to improve safety, enhance mobility, promote asset management, and expand asset innovation. These goals directly address and support the six primary purposes of U.S. DOT's transportation research and development program as defined in Section 6503 of the FAST Act as follows:

- Improving mobility of people and goods;
- Reducing congestion;
- Promoting safety;
- Improving the durability and extending the life of transportation infrastructure;
- Preserving the environment; and
- Preserving the existing transportation system.

Going forward, FTA will continue to prioritize research investments based upon these goals. FTA expects to publish its Research Strategic Plan in FY 2017.

3. Shared Mobility

Shared Mobility continues to remain a key focus area within FTA's Public Transportation Innovation program. The definition of personal mobility is changing due to social and cultural trends combined with the powerful tools in handheld smartphones and related transportation technology innovations. New mobility concepts and solutions like bike-sharing, car-sharing, car-hailing, and innovative demand-response bus services are now possible and more convenient because of these developments. This gives travelers new, flexible and personally tailored transportation options. Many of these services are emerging in proximity to high-capacity transit corridors with land uses and activities that create the market

for new services. Supported by smart policies, the interaction between public transportation and these emerging services can create improved travel choices.

To support personal mobility innovation, (FTA) recently allocated \$8 million for 11 projects through the innovative Mobility on Demand (MOD) Sandbox Demonstration program using FTA research funds (Public Transportation Innovation/Public Transportation Innovation). The projects carried out by transit agencies will test new ideas in personal mobility and integrated multimodal transportation networks. From that MOD program solicitation process, and from dialogue with other stakeholders, FTA has identified questions about funding eligibility under Federal public transportation law for FTA grant programs, like the Urbanized Area and Rural formula programs, as well as compliance with federal requirements, such as the Americans with Disabilities Act (ADA), related to mobility on demand generally and, particularly, to electronic hailing of vehicles such as taxis or other transportation network company (TNC) vehicles.

FTA has prepared answers to Frequently Asked Questions (FAQs) to

address the eligibility and Federal requirement questions. This information is posted on the FTA Web site at <https://www.transit.dot.gov/shared-mobility>. FTA will use information from the MOD Sandbox projects and related efforts, such as the recently launched online dialogue, to continue the discussion with agency stakeholders and to address questions regarding innovative practices and shared-ride, on-demand mobility services as they emerge. FTA encourages your participation in this online discussion. Stakeholders can also send comments and questions to TransitInnovations@dot.gov.

4. Bus Testing Facility (49 U.S.C. 5318)

On August 1, 2016, FTA issued its final rule to implement minimum performance standards, a scoring system, and a pass/fail threshold for new model transit buses procured with FTA financial assistance authorized under 49 U.S.C. Chapter 53. Consistent with 49 U.S.C. 5318(e), FTA recipients are prohibited from using FTA financial assistance to procure new bus models, that were not previously tested, that have not met the minimum performance standards established by this rule. The standards and scoring system address the following categories: Structural

integrity, safety, maintainability, reliability, fuel economy, emissions, noise, and performance. Buses must meet a minimum performance standard in each of these categories in order to receive an overall passing score and be eligible for purchase using FTA financial assistance. Buses can achieve higher scores with higher performance in each category, and the final rule establishes a numerical scoring system based on a 100-point scale so that buyers can more effectively compare vehicles.

The final rule was effective on October 31, 2016. FTA's Web site has additional information, resources, and a link to sign up for email notices about the Bus Testing Program at: www.transit.dot.gov/research-innovation/bus-testing.

5. FY 2017 Competitive Programs Funding and Schedule

FTA will issue Notices of Funding Opportunities (NOFO) in FY 2017 for the programs listed in the following chart. Additional information about each competitive program is in section III of this notice.

| FY 2017 competitive programs | Statute 49 U.S.C. | 2017 Authorized funding level (in millions) | Timeline for notification of awards |
|--|----------------------------|---|-------------------------------------|
| Passenger Ferry Grant Program | 5307 | \$30.0 | Summer 2017. |
| Rides to Wellness Demonstration and Innovative Coordinated Access and Mobility Grants. | FAST Section 3006(b) | 3.0 | Summer 2017. |
| Tribal Transit | 5311(c)(1)(A) | 5.0 | Spring 2017. |
| Grants for Buses and Bus Facilities Competitive Program | 5339 | 228.0 | Summer 2017. |
| Low or No Emission Grants Competitive Program | 5339 | 55.0 | Spring 2017. |
| Pilot Program to D Planning | MAP-21 Section 2005(b) ... | 10.0 | Fall 2017. |

IV. FY 2017 Program-Specific Information

A. Metropolitan Planning Program (49 U.S.C. 5303 and 5305(d))

Section 5305(d) authorizes Federal funding to support a cooperative, continuous, and comprehensive planning program for transportation investment decision-making at the metropolitan area level. The specific requirements of metropolitan transportation planning are set forth in 49 U.S.C. 5303 and further explained in 23 CFR part 450, as incorporated by reference in 49 CFR part 613, Planning Assistance and Standards. State Departments of Transportation (DOTs) are direct recipients of funds allocated by FTA, which are then sub-allocated to Metropolitan Planning Organizations (MPOs), for planning activities that

support the economic vitality of the metropolitan area.

The MPO process must establish a performance-based approach in which the MPO will develop specific performance targets that address transportation system performance measures (to be issued by U.S. DOT), where applicable, to use in tracking progress towards attaining critical outcomes. These performance targets will be established by MPOs in coordination with States and transit providers. MPOs will provide a system performance report that evaluates the progress of the MPO in meeting the performance targets in comparison with the system performance identified in prior reports. This funding must support work elements and activities resulting in balanced and comprehensive intermodal transportation planning for the movement of people and goods in

the metropolitan area. Comprehensive transportation planning is not limited to transit planning or surface transportation planning, but also encompasses the relationships among land use and all transportation modes, without regard to the programmatic source of Federal assistance. Eligible work elements or activities include, but are not limited to studies relating to management, mobility management, planning, operations, capital requirements, economic feasibility, performance-based planning; evaluation of previously funded projects; peer reviews and exchanges of technical data, information, assistance, and related activities in support of planning and environmental analysis among MPOs and other transportation planners; work elements and related activities preliminary to and in

preparation for constructing, acquiring, or improving the operation of facilities and equipment; development of coordinated public transit human services transportation plans. An exhaustive list of eligible work activities is provided in FTA Circular 8100.1C, Program Guidance for Metropolitan Planning and State Planning and Research Program Grants, dated September 1, 2008.

For more information or questions on the Metropolitan Planning program, please contact Victor Austin at (202) 366-2996 or victor.austin@dot.gov.

1. Authorized Amounts

Federal transit law authorizes \$110,347,597 in FY 2017 to provide financial assistance for metropolitan planning needs under section 5305. Under the Further Continuing Appropriations Act, \$62,042,888 is available through April 28, 2017.

2. FY 2017 Funding Availability

In FY 2017, \$62,042,888 is available for the period October 1, 2016 through April 28, 2017 to the Metropolitan Planning Program (section 5305(d)) to support metropolitan transportation planning activities set forth in section 5303. The total amount apportioned for the Metropolitan Planning Program to States for use by MPOs in urbanized areas (UZAs) is \$61,732,673 as shown in the table below, after the deduction for oversight (authorized by section 5338).

METROPOLITAN PLANNING PROGRAM— FY 2017

| | |
|--|--------------|
| Total Appropriation available through April 28, 2017 | \$62,042,888 |
| Oversight Deductions | (310,214) |
| Total Apportioned | 61,732,673 |

3. Basis for Formula Apportionment

Of the amounts authorized in section 5305, 82.72 percent is made available to the Metropolitan Planning Program. Eighty percent of the funds are apportioned on a statutory basis to the States based on the most recent decennial Census for each State's UZA population. The remaining 20 percent is provided to the States based on an FTA administrative formula to address planning needs in larger, more complex UZAs. The amount published for each State includes the supplemental allocation.

4. Requirements

The State allocates Metropolitan Planning funds to MPOs in UZAs or portions thereof to provide funds for planning projects included in a one or

two-year program of planning work activities (the Unified Planning Work Program, or UPWP) that includes multimodal systems planning activities spanning both highway and transit planning topics. Each State has either reaffirmed or developed, in consultation with its MPOs, an allocation formula among MPOs within the State, based on the 2010 Census. The allocation formula among MPOs in each State may be changed annually, but any change requires approval by the FTA Regional Office before grant approval. Program guidance for the Metropolitan Planning Program is found in FTA Circular 8100.1C, *Program Guidance for Metropolitan Planning and State Planning and Research Program Grants*, dated September 1, 2008.

5. Period of Availability

The Metropolitan Planning program funds apportioned in this notice are available for obligation during FY 2017 plus three additional fiscal years. Accordingly, funds apportioned in FY 2017 must be obligated in grants by September 30, 2020. Any FY 2017 apportioned funds that remain unobligated at the close of business on September 30, 2020, will revert to FTA for reapportionment under the Metropolitan Planning Program.

6. Other Program Information

The planning programs provide funding and procedural requirements to metropolitan areas and States for multimodal transportation planning that is cooperative, continuous, and comprehensive, resulting in long-range plans and short-range programs of projects that reflect transportation investment priorities. The planning programs are jointly administered by FTA and the Federal Highway Administration (FHWA), which provides additional funding. The FAST Act sections 5303 and 5304 as noted below:

- New emphasis is placed on intercity transportation, including intercity buses and intermodal facilities that support intercity transportation, and commuter vanpool providers.
- The selection and role of the transit representation on MPO policy boards in large urbanized areas is clarified. MPOs in urbanized areas designated as transportation management areas must include officials of agencies that administer or operate major modes of transportation, as well as representatives of public transit operators, on MPO policy boards. The representative of public transit shall be selected according to the bylaws or enabling legislation of the MPO, and the

representative of public transit may also serve as a representative of a local municipality on the MPO board. For additional information please reference the Final Rule on Statewide and Nonmetropolitan Transportation Planning and Metropolitan Transportation Planning (81 FR, 3404, May 27, 2016).

- The scope of the planning process adds two new planning factors, in addition to the eight pre-existing factors established under prior law. The two new factors are: (1) Improve the resiliency and reliability of the transportation system, and reduce the vulnerability of the existing transportation infrastructure to natural disasters, and (2) enhance travel and tourism.

- MPOs and State DOTs should provide public ports, intercity bus operators and employer-based commuting programs with a reasonable opportunity to comment on transportation plans.

- Plans must place greater emphasis on the congestion management process. MPOs that serve transportation management areas must develop a congestion management plan with input from employers, private and public transit providers, transportation management associations, and organizations that provide low-income individuals transportation access to jobs and job related services.

- The long-range statewide transportation plan and metropolitan transportation plan must include a description of the performance measures and performance targets. State DOTs and MPOs are also required to provide a system performance report evaluating the condition and performance of the transportation system.

In the Final Rule on Statewide and Nonmetropolitan Transportation Planning and Metropolitan Transportation Planning, FHWA and FTA make the statewide, metropolitan, and nonmetropolitan transportation planning regulations consistent with current statutory requirements. The final rule establishes the following: (1) A new mandate for States and MPOs to take a performance-based approach to planning and programming; (2) a new emphasis on the nonmetropolitan transportation planning process, by requiring States to have a higher level of involvement with nonmetropolitan local officials and providing a process for the creation of RTPOs; (3) implementation of the afore mentioned statutory requirement for a structural change to the membership of the larger MPOs; (4) a new framework for voluntary scenario

planning; (5) a new authority for the integration of the planning and environmental review processes; and (6) a process for programmatic mitigation plans.

Among the most significant changes is the new mandate for a performance-based planning process: MPOs and State DOTs must establish performance targets that address forthcoming U.S. DOT-issued national performance measures that are based on the goals outlined in the legislation—safety, infrastructure condition, congestion reduction, system reliability, economic vitality, environmental sustainability, reduced project delivery delays, transit safety, and transit asset management. MPOs also must coordinate their performance targets, to the maximum extent practicable, with performance targets set by FTA grantees under the new performance measure requirements for safety and state of good repair. Transportation Improvement Programs (TIPs) must include a description of the anticipated progress toward achieving the performance targets resulting from implementation of the TIP. By October 1, 2017, DOT will provide Congress with a report evaluating the effectiveness of performance-based planning and assessing the technical capacity of MPOs in smaller areas to undertake performance-based planning. After May 27, 2018, a State's and MPO's long-range plans, STIPs, and TIPs must reflect performance targets and plans according to the provisions of the final rule.

B. State Planning and Research Program (49 U.S.C. 5304 and 5305(e))

This program provides financial assistance to States for statewide transportation planning and other technical assistance activities, including supplementing the technical assistance program provided through the Metropolitan Planning program. The specific requirements of Statewide transportation planning are set forth in 49 U.S.C. 5304 and further explained in 23 CFR part 450 as referenced in 49 CFR part 613, Planning Assistance and Standards. State DOTs are required to reference performance measures and performance targets within the Statewide Planning process. This funding must support work elements and activities resulting in balanced and comprehensive intermodal transportation planning for the movement of people and goods. Comprehensive transportation planning is not limited to transit planning or surface transportation planning, but also encompasses the relationships among land use and all transportation modes,

without regard to the programmatic source of Federal assistance.

For more information or questions on the State Planning and Research program, please contact Victor Austin at (202) 366-2996 or victor.austin@dot.gov.

1. Authorized Amounts

Federal transit law authorizes \$23,051,336 in FY 2017, to provide financial assistance for statewide planning and other technical assistance activities under section 5305. Under the Continuing Appropriations Act of 2017, \$12,960,603 is available through April 28, 2017. As specified in law, this represents the 17.28 percent of the amounts available for section 5305 that are allocated to the Statewide Planning and Research program.

2. FY 2017 Funding Availability

In FY 2017, \$12,960,603 is available for the period October 1, 2016 through April 28, 2017 to the State Planning and Research Program (section 5305(e)). The total amount apportioned for the State Planning and Research Program (SPRP) is \$12,895,800 as shown in the table below, after the deduction for oversight (authorized by section 5338).

STATEWIDE PLANNING PROGRAM—FY 2017

| | |
|--|--------------|
| Total Appropriation Available through April 28, 2017 | \$12,960,603 |
| Oversight Deductions | (64,803) |
| Total Apportioned | 12,895,800 |

States' apportionments for this program are displayed in Table 2.

3. Basis for Formula Apportionment

Of the amount authorized for section 5305, 17.28 percent is allocated to the State Planning and Research program. FTA apportions funds to States by a statutory formula that is based on the most recent decennial Census data available, and the State's UZA population as compared to the UZA population of all States.

4. Requirements

Funds are provided to States for Statewide transportation planning programs. These funds may be used for a variety of purposes such as planning, technical studies and assistance, performance-based planning, demonstrations, and management training. In addition, a State may authorize a portion of these funds to be used to supplement Metropolitan Planning funds allocated by the State to its UZAs, as the State deems appropriate. Program guidance for the

State Planning and Research program is found in FTA Circular 8100.1C, *Program Guidance for Metropolitan Planning and State Planning and Research Program Grants*, dated September 1, 2008.

5. Period of Availability

The State Planning and Research program funds apportioned in this notice are available for obligation during FY 2017 plus three additional fiscal years. Accordingly, funds apportioned in FY 2017 must be obligated in grants by September 30, 2020. Any FY 2017 apportioned funds that remain unobligated at the close of business on September 30, 2020 will revert to FTA for reappportionment under the State Planning and Research program.

C. Urbanized Area Formula Program (49 U.S.C. 5307)

The Urbanized Area Formula Program provides financial assistance to designated recipients in urbanized areas (UZAs) for capital investments in public transportation systems, planning, job access and reverse commute projects, and, in some cases, operating assistance. FTA apportions funds for this program through a statutory formula. Of the amount authorized for Section 5307 each year, \$30 million is set aside for the competitive Passenger Ferry Grant Program (Ferry program), as authorized under 49 U.S.C., 5307(h). The Ferry program offers financial assistance to public ferry systems in urbanized areas for capital projects. Projects are selected annually through a funding competition. Additionally 0.5 percent will be apportioned to eligible States for State Safety Oversight (SSO) Program grants, and 0.75 percent will be set aside for program oversight. Further information on the 0.5 percent apportionment to States for the State Safety Oversight Program is provided in section IV.M. of this notice.

For more information or questions on the *Urbanized Area Formula Program*, contact Tara Clark at (202) 366-2623 or tara.clark@dot.gov. For more information on the *Ferry Program*, contact Vanessa Williams at (202) 366-4818 or vanessa.williams@dot.gov.

1. Authorized Amounts

Federal transit law authorizes \$4,629,683,814 in FY 2017 to provide financial assistance for urbanized areas under section 5307. Under the Continuing Appropriations Act of 2017, \$2,604,058,475 is available through April 28, 2017.

2. FY 2017 Funding Availability

Under the Further Continuing and Security Assistance Appropriations Act, 2017, only \$2,604,058,475 is available for the Urbanized Area Formula program for the period of October 1, 2016 through April 28, 2017. The total amount apportioned to urbanized areas is \$2,817,580,866, which includes the addition of amounts apportioned to UZAs pursuant to the Section 5340 Growing States and High Density States Formula factors. This amount excludes the set-aside for the Ferry program, apportionments under the State Safety Oversight Program, and oversight (authorized by section 5338), as shown in the table below:

**URBANIZED AREA FORMULA
PROGRAM—FY 2017**

| | |
|---|------------------------------|
| Total Appropriation available thru April 28, 2017 | |
| Oversight Deduction | ^a \$2,604,058,475 |
| Ferry Competitive Program | (19,530,439) |
| State Safety Oversight Program | (17,211,583) |
| Section 5340 High Density States | (13,020,292) |
| Section 5340 Growing States | 151,441,543 |
| Total Apportioned | 111,800,668 |
| | 2,817,538,371 |

^aIncludes 1.5 percent set-aside for Small Transit Intensive Cities Formula.

Table 3 displays the amounts apportioned under the Urbanized Area Formula Program.

3. Basis for Formula Apportionment

FTA apportions Urbanized Area Formula Program funds based on statutory formulas. Congress established four separate formulas to apportion portions of the available funding: The Section 5307 Urbanized Area Formula Program formula, the Small Transit Intensive Cities (STIC) formula, the Growing States and High Density States formula, and a formula based on low-income population.

Consistent with prior apportionment notices, Table 3 shows a total section 5307 apportionment for each UZA, which includes amounts apportioned under each of these formulas. Detailed information about the formulas is provided in Table 4. For technical assistance purposes, the UZAs that receive STIC funds are listed in Table 6. FTA will provide breakouts of the funding allocated to each UZA under these formulas upon request to the FTA Regional Office.

FTA has calculated dollar unit values for the formula factors used in the Urbanized Area Formula Program apportionment calculations. These values represent the amount of money

each unit of a factor is worth in this year's apportionment. The unit values change each year, based on all of the data used to calculate the apportionments, as well as the amount appropriated by Congress for the apportionment. The dollar unit values for FY 2017 are displayed in Table 5. To replicate the basic formula component of a UZA's apportionment, multiply the dollar unit value by the appropriate formula factor (*i.e.*, the population, population x population density), and when applicable, data from the NTD (*i.e.*, route miles, vehicle revenue miles, passenger miles, and operating cost).

a. Section 5307—Urbanized Area Formula

For UZAs between 50,000 and 199,999 in population, the Urbanized Area Formula is based on population and population density. For UZAs with populations of 200,000 or more, the formula is based on a combination of bus revenue vehicle miles, bus passenger miles, bus operating costs, fixed guideway vehicle revenue miles, and fixed guideway route miles, as well as population and population density. The Urbanized Area Formula is defined in 49 U.S.C. 5336. Consistent with section 5336(b), FTA has included 27 percent of the fixed guideway directional route miles and vehicle revenue miles from eligible urbanized area transit systems, but which were attributable to rural areas outside of the urbanized areas from which the system receives funds.

b. Small Transit Intensive Cities Formula

Under the STIC formula, FTA apportions 1.5% of the funds made available for section 5307 to UZAs that are under 200,000 in population and have public transportation service that operates at a level equal to or above the industry average for UZAs with a population of at least 200,000, but not more than 999,999. STIC funds are apportioned on the basis of six performance categories: Passenger miles traveled per vehicle revenue mile, passenger miles traveled per vehicle revenue hour, vehicle revenue miles per capita, vehicle revenue hours per capita, passenger miles traveled per capita, and passengers per capita. In FY 2019, the STIC set aside will increase from 1.5% to 2%.

The data used to determine a UZA's eligibility under the STIC formula and to calculate the STIC apportionments was obtained from the NTD for the 2015 reporting year. Because performance data change with each year's NTD reports, the UZAs eligible for STIC

funds and the amount each receives may vary each year. UZAs that received funding through the STIC formula for FY 2017 are listed in Table 6.

c. Section 5340—Growing States and High Density States Formula

FTA also apportions funds to qualifying UZAs and States according to the section 5340 Growing States and High Density States formula, as shown in Table 3. More information on this program and its formula is found in section IV.P. of this notice.

d. Low-Income Population

Of the amount authorized and appropriated for the Urbanized Area Formula Program in each year, 3.07 percent is apportioned on the basis of low income population. As specified in statute, FTA apportions 75 percent of the available funds to UZAs with a population of 200,000 or more. Funds are apportioned based on the ratio of the number of low income individuals in each UZA to the total number of low income individuals in all urbanized areas of that size. FTA apportions the remainder of the funds (25 percent) to UZAs with populations of less than 200,000, according to an equivalent formula. The low income populations used for this calculation were based on the American Community Survey (ACS) data set for 2010–2014. This information is updated by the Census Bureau annually.

4. Requirements

The maximum Federal share for the Urbanized Area Formula Program, including the Ferry Program, is 80 percent, or 85 percent for the net project cost of acquiring vehicles (including clean-fuel or alternative fuel) for the purpose of complying with or maintaining compliance with the Clean Air Act (CAA) or the Americans with Disabilities Act (ADA) of 1990. The maximum Federal share is 90 percent of the net project cost for acquiring vehicle-related equipment or facilities (including clean-fuel or alternative-fuel vehicle-related equipment or facilities) for the purpose of complying with or maintaining compliance with the CAA or ADA.

Program guidance for the Urbanized Area Formula Program is found in FTA Circular 9030.1E, Urbanized Area Formula Program: Program Guidance and Application Instructions, dated January 16, 2014, and is supplemented by additional information and changes provided in this notice and that may be posted to the Urbanized Area Formula Grants program Web page. FTA is in the process of updating the program circular

to incorporate changes resulting from FAST Act amendments to 49 U.S.C. 5307.

5. Period of Availability

Funds made available under the Urbanized Area Formula Program are available for obligation during the year of apportionment plus five additional years. Accordingly, funds apportioned in FY 2017 must be obligated by September 30, 2022. Any FY 2017 apportioned funds that remain unobligated at the close of business on September 30, 2022 will revert to FTA for reapportionment under the Urbanized Area Formula Program.

Funds allocated under the Ferry program follow the same period of availability as section 5307. Accordingly, funds allocated in FY 2017 must be obligated by September 30, 2022. Any of the funds allocated in FY 2017 that remain unobligated at the close of business on September 30, 2022 will revert to FTA for reallocation under the Ferry program.

6. Other Program Information

a. Special Rule for Operating Assistance in Large Urbanized Areas

The special rule at 49 U.S.C. 5307(a)(2) makes recipients in urbanized areas with populations of 200,000 or above that operate 100 or fewer buses in fixed route service or general public demand response service during peak hours, excluding ADA complementary paratransit service, eligible for operating assistance subject to a maximum amount per system as explained below:

i. Public transportation systems that operate a minimum of 76 buses and a maximum of 100 buses in fixed route service or general public demand response, excluding ADA complementary paratransit service, during peak service hours may receive operating assistance in an amount not to exceed 50 percent of the share of the apportionment that is attributable to such systems within the urbanized area, as measured by vehicle revenue hours.

ii. Public transportation systems that operate 75 or fewer buses in fixed route service or demand response, excluding ADA complementary paratransit service, during peak service hours may receive operating assistance in an amount not to exceed 75 percent of the share of the apportionment that is attributable to such systems within the urbanized area, as measured by vehicle revenue hours.

iii. A list of eligible recipients and their maximum operating assistance amounts for FY 2017 is shown in Table

3–A. FTA identified the systems eligible to use this provision and their maximum amounts for FY 2017 using data from the NTD for reporting year 2015. Operating assistance requires a 50 percent local match.

In accordance with section 5307(a)(2), FTA has calculated a fixed annual cap on operating assistance for each eligible agency that provides service in a large UZA. The cap is determined by dividing the UZA's apportionment by the total number of vehicle revenue hours reported from all public transportation operators and from all transit modes in the UZA, and then by multiplying this quotient by the number of bus vehicle revenue hours operated in the UZA by the eligible system. The result is the proportional share of the apportionment that is attributable to the qualifying system, as measured by vehicle revenue hours. This cap is calculated based on the FY 2017 apportionment for an eligible provider's UZA. Eligible systems operating in more than one UZA over 200,000 in population will receive separate operating caps from each UZA in which the system operates. The FY 2017 Apportionment Table 3A includes all eligible general public demand response operators. Systems that operate more than 100 buses in general public demand response service, and which do not operate any fixed-route service are not eligible for operating assistance under this provision. Systems that only operate ADA complimentary paratransit are not eligible for operating assistance under this provision.

Systems that operate more than 100 buses in fixed route service are not eligible for operating assistance under this provision. Systems that operate 100 or fewer fixed route buses are eligible, regardless of the number of demand response vehicles they operate.

In determining the amount of operating assistance available for specific systems in urbanized areas under the Special Rule, public transportation systems may execute a written agreement with one or more other public transportation systems within the urbanized area to allocate funds by a method other than by measuring vehicle revenue hours. Systems within the urbanized area may combine their individual operating assistance caps and allocate the combined funds using a method that is agreed upon by all of the systems. The operating assistance cap for the urbanized area does not change as a result of any agreement between two or more systems. The method used to allocate the funds must be documented in a written agreement, signed by the

participating parties, and transmitted to FTA as part of the split letter.

b. Eligibility of Substitute Transit Service as a Capital Project

The cost of operating substitute service (*i.e.* a bus bridge) is an eligible capital project expense when incidental to a scheduled capital maintenance, rehabilitation, or construction project on an existing system. Eligible substitute service must be temporary, scheduled, and the costs defined in the grant agreement for the capital project. Substitute service costs are not an eligible capital project expense in conjunction with emergency maintenance, operating incidents, or other contingency operations, including emergency operations associated with an emergency or a disaster.

c. Prohibition on Funding for Art and Non-Functional Landscaping

While formerly eligible for Urbanized Area Formula Program funds as a "Transit Enhancement" (the precursor to Associated Transit Improvement), at 49 U.S.C. 5323 (h) now prohibits the use of FTA funds for the "incremental costs of incorporating art or non-functional landscaping into facilities, including the costs of an artist on the design team." This prohibition applies to the creation, production, or installation of artworks, defined as objects intended for a primarily aesthetic purpose, or the involvement of artists in the development of a capital project. However, FTA does not interpret the law to exclude or generally prohibit the functional and aesthetic design of transit stations or related facilities, including designs intended to minimize adverse visual effects on the surrounding community. Transit facilities and surrounding landscape designs should incorporate aesthetic considerations, including but not limited to decisions regarding the use of light, shape, color, materials, the use of space, and the historic setting to achieve a functional and welcoming public transit facility.

FTA will not require grantees to assess the often indeterminate incremental costs associated with functional design elements, including, but not limited to, the use of different types or colors of paint or tile, wayfinding elements intended to direct passengers or staff, or different or alternate construction materials in the design of a transit facility.

Recipients may continue to use local funds for art in association with transit capital projects, but such expenditures may not be counted towards the local

share of a project cost, and should not be included in the grant award.

With regard to landscaping, FTA recognizes that landscaping is a functional element of many transit facilities. For example, landscaping can be used to aid in the absorption or drainage of rainwater, prevention of erosion, support of structures on a steep grade, minimization of noise impacts, protection of habitat, provision of shade in hot climates, channeling of pedestrian or vehicle traffic, definition of useable or unsafe spaces, and many other purposes. In interpreting the term "functional landscaping" under this provision of law, FTA draws a similar distinction, as with art, between functionally appropriate landscape design and landscape elements installed primarily for visual or aesthetic appeal.

For additional information see the Art and Non-Functional Landscaping frequently asked questions posted on the Urbanized Area Formula Grants Web page.

d. Employee Training Expenses

Costs associated with employee training may be eligible for Urbanized Area Formula Program funding as operating expenses, as preventive maintenance expenses, or as provided for under the following provisions. A recipient may fund training expenses as an operating expense under Section 5307, where allowed, at a 50 percent Federal share.

i. Under Section 5314(b), up to 0.5 percent of the program a recipient's section 5307, 5337, and 5339 funds may be used for human resources and workforce development activities at an 80 percent Federal cost share, including the cost of administering a training program. Eligible activities include:

- Various public transportation training programs;
- Outreach programs for targeted groups to increase public transportation employment for veterans, women, individuals with disabilities, and minorities;
- Development of training partnerships with key stakeholders including community colleges, workforce development boards, and other industry groups;
- Development of apprenticeships, on-the-job-training, and instructional training for public transportation; maintenance and operations occupations;
- Improve safety, security, and emergency preparedness in local public transportation system through improved safety culture and workforce communication with first responders and the riding public. And other

activities approved by FTA that address human resource needs as they apply to public transportation activities.

ii. Under Section 5314(c), up to 0.5 percent of Section 5307, 5337, and 5339 funds are available to a state or public transportation authority recipient in a fiscal year to use for tuition and direct educational expenses at the National Transit Institute for education and training of state and local transportation employees, at a federal share not to exceed 80 percent. States may also use these funds for training State and local transportation agency employees through grants and contracts with public and private agencies, and other institutions and individuals with prior FTA approval.

D. Fixed Guideway Capital Investment Grant Program (49 U.S.C. 5309)

The Capital Investment Grant (CIG) Program includes four types of eligible projects—New Starts projects, Small Starts projects, Core Capacity Improvement projects, and Programs of Inter-related Projects. Funding is provided for construction of: (1) New fixed guideway systems or extensions to existing fixed guideway systems such as rapid rail (heavy rail), commuter rail, light rail, trolleybus (using overhead catenary), cable car, passenger ferries, and bus rapid transit operating on an exclusive transit lane for the majority of the corridor length that also includes features that emulate the services provided by rail fixed guideway including defined stations, traffic signal priority for public transit vehicles, and short headway bi-directional service for a substantial part of weekdays and weekends; (2) corridor-based bus rapid transit service that does not operate on an exclusive transit lane but includes features that emulate the services provided by rail fixed guideway including defined stations, traffic signal priority for public transit vehicles, and short headway bi-directional services for a substantial part of weekdays; (3) projects that expand the capacity by at least 10 percent in an existing fixed guideway corridor that is at capacity today or will be in five years; and (4) programs of two or more interrelated projects as described above that have logical connectivity with one another and will all begin construction in a reasonable timeframe.

For more information about the Capital Investment Grant program contact Elizabeth Day, Office of Capital Project Development, at (202) 366-5159 or elizabeth.day@dot.gov. For information about published allocations contact Eric Hu, Office of Transit

Programs, at (202) 366-0870 or eric.hu@dot.gov.

1. Authorized Amounts

Federal transit law authorizes \$2,301,785,760 in FY 2017, to provide financial assistance under section 5309. Under the Continuing Appropriations Act of 2017, \$1,241,314,889 is available through April 28, 2017.

2. FY 2017 Funding Availability

In FY 2017, \$1,241,314,889 is available for the period October 1, 2016 through April 28, 2017 to the Fixed Guideway Capital Investment Grant Program. The total amount available for projects is \$1,228,901,740 as shown in the table below, after the deduction for oversight (authorized by section 5338).

CAPITAL INVESTMENT GRANTS (NEW STARTS)—FY 2017

| | |
|--|-----------------|
| Total Appropriation Available through April 28, 2017 | \$1,241,314,889 |
| Oversight Deduction | (12,413,149) |
| Total Apportioned | 1,228,901,740 |

3. Basis for Allocation

Funds are allocated on a competitive basis and subject to program evaluation.

4. Requirements

Projects become candidates for funding under the Capital Investment Grant Program by successfully completing steps in the process defined in section 5309 and obtaining a satisfactory rating under the statutorily-defined criteria. For New Starts and Core Capacity Improvement projects, the steps in the process include project development, engineering, and construction. For Small Starts projects, the steps in the process include project development and construction. For programs of interrelated projects, the steps in the process depend on the combination of project types included. New Starts and Core Capacity Improvement projects receive construction funds from the program through a full funding grant agreement (FFGA) that defines the scope of the project and specifies the total multi-year Federal commitment to the project. Small Starts projects receive construction funds through a single year grant or a Small Starts grant agreement (SSGA) that defines the scope of the project and specifies the Federal commitment to the project.

5. Period of Availability

Funds for the Fixed Guideway Capital Investment Grant Program remain

available for obligation for four years, which includes the fiscal year in which the funds are allocated to projects plus three additional years.

E. Enhanced Mobility of Seniors and Individuals With Disabilities Program (49 U.S.C. 5310)

The Section 5310 Enhanced Mobility of Seniors and Individuals with Disabilities Program provides formula funding to states for the purpose of meeting the transportation needs of older adults and people with disabilities when the transportation service provided is unavailable, insufficient, or inappropriate to meet these needs. The program aims to improve mobility for seniors and individuals with disabilities by removing barriers to transportation service and expanding transportation mobility options.

The Pilot Program for Innovative Coordinated Access and Mobility Program (Pilot Program) open to Section 5310 recipients—was established by Section 3006(b) of the *FAST Act*. The purpose of the program is to assist in financing innovative projects for the transportation disadvantaged that improve the coordination of transportation services and non-emergency medical transportation (NEMT) services, including, for example, the deployment of coordination technology, and projects that create or increase access to community One-Call/One-Click Centers.

For more information or questions on the Enhanced Mobility of Seniors and Individuals with Disabilities program, please contact Kelly Tyler at (202) 366-3120 or Kelly.Tyler@dot.gov.

1. Authorized Amounts

Federal transit law authorizes \$268,208,388 in FY 2017 to provide formula funding to states for the purpose of meeting the transportation needs of older adults and people with disabilities. The law also authorizes \$3 million for the competitive Pilot Program. Under the Further Continuing and Security Assistance Appropriations Act, 2017, \$150,859,185 is available through April 28, 2017 for the formula program.

2. FY 2017 Funding Availability

The total available funding for projects under the Section 5310 formula program for FY 2017 is \$150,104,889 after the oversight deduction as shown in the table below.

SECTION 5310 FORMULA PROGRAM— FY 2017

| | |
|---|---------------|
| Total Appropriation Available through April 28, 2017) | \$150,859,185 |
| Oversight Deductions (oversight 0.5%) | (754,296) |
| Total Apportioned | 150,104,889 |
| Competitive Pilot Program | 1,147,439 |

3. Basis for Formula Apportionment

Sixty percent of the funds are apportioned among designated recipients for urbanized areas with a population of 200,000 or more individuals. Twenty percent of the funds are apportioned among the States for urbanized areas with a population of at least 50,000 but less than 200,000. Twenty percent of the funds are apportioned among the States for rural areas, defined as areas with a population less than 50,000. Census Data on Older Adults and People with Disabilities is used for the Section 5310 Enhanced Mobility of Older Adults and People with Disabilities Apportionments. FY 2017

Apportionments Table 8 displays the amounts apportioned under the Enhanced Mobility of Seniors and Individuals with Disabilities Program.

Under the section 5310 formula, funds are allocated using Census data on older adults (*i.e.*, persons 65 and older) and people with disabilities. However, beginning in 2010, the Census Bureau stopped collecting this demographic information as part of its decennial census. Data on seniors and people with disabilities is now only available from the American Community Survey (ACS), which is conducted and published on a rolling basis. FTA's FY 2017 section 5310 apportionments incorporate ACS data published in December, 2015. Data on seniors comes from the ACS 2010–2014 five-year data set, Table B01001, “Sex by Age. Data on persons with disabilities comes from the ACS 2010–2014 five-year data set, Table S.1810, “Disability Characteristics.”

4. Requirements

At least 55 percent of program funds must be used on capital projects such as buses and vans; wheelchair lifts, ramps, and securement devices or transit-related information technology systems including scheduling/routing/one-call systems. Mobility management programs are also defined as capital projects for purposes of this provision. The acquisition of transportation services under a contract, lease, or other arrangement is also eligible; both the capital and operating costs associated

with contracted service are eligible capital expenses for purposes of this provision. The capital eligibility of acquisition of services is limited to the section 5310 program. The remaining 45 percent of a recipient's 5310 funds can be used for capital or operating.

a. Eligible Recipients

Eligible recipients include States for rural and small urban areas and designated recipients chosen by the Governor of the State for large urban areas; or a State or local governmental entity that operates a public transportation service. For urbanized areas less than 200,000 in population and in the rural areas, the State is the designated recipient for section 5310. Current section 5310 designations remain in effect until changed by the Governor of a State by officially notifying the appropriate FTA Regional Administrator of re-designation. A State or local governmental entity that operates a public transportation service may be a direct recipient for Section 5310 funds.

In urbanized areas over 200,000 in population, the recipient charged with administering the section 5310 Program must be officially designated in accordance with the planning process, by the Governor of a State, responsible local officials, and publicly owned operators of public transportation prior to grant award (See the definition of designated recipient, 49 U.S.C. 5302(4)). Designated recipients are responsible for administering the program. Eligible subrecipients include private nonprofit agencies, public bodies approved by the state to coordinate services for seniors and people with disabilities, or public bodies which certify to the Governor that no nonprofit organizations or associations are readily available in an area to provide the service.

b. Local Match

Capital assistance is provided at 80 percent Federal share; 20 percent local share. Operating assistance requires a 50 percent local match. Funds provided under other Federal programs (other than those of the DOT, with the exception of the Federal Lands Transportation Program may be used for local match for funds provided under section 5310, and revenue from service contracts may be used as local match.

c. Planning and Consultation

The coordinated planning provision requires that all projects be included in the local coordinated human service-public transportation plan. The plan must be developed and adopted with representation from seniors, individuals

with disabilities, representatives of public, private, nonprofit transportation and human services providers, and other members of the public.

d. State and Project Management Plans

States, designated recipients, and State or local governmental entities that operate a public transportation service that are responsible for implementing the section 5310 program are required to document their approach to managing the program. The Management Plans serve as the basis for FTA management reviews of the program, and provide public information on the administration of the programs.

e. Program of Projects (POP)

Designated recipients are required to develop a Program of Projects (POP) with the grant application and submit it to the FTA Regional Office. The POP should be developed with respect to the coordinated plan, long range plan, and the transportation improvement plan. For additional guidance in developing the required POP, see Chapter IV of the FTA Circular 9070.1G, *Enhanced Mobility of Seniors and Individuals with Disabilities Program Guidance and Application Instructions*, dated July 7, 2014.

5. Period of Availability

For Enhanced Mobility of Seniors and Individuals with Disabilities Program funds apportioned under this notice, the period of availability is three years, which includes the year of apportionment plus two additional years. Accordingly, funds apportioned in FY 2017 must be obligated in grants by September 30, 2019. Any FY 2017 apportioned funds that remain unobligated at the close of business on September 30, 2019 will revert to FTA for reapportionment among the States and urbanized areas.

6. Other Program Information

A State may transfer apportioned funds between small urbanized areas and rural areas if it can certify that the needs are being met in the area to which the funds were originally apportioned. The State can transfer the funds (rural and small urbanized area) to any area within the state if a statewide program for section 5310 is established. Section 5310 funds may not be transferred to other FTA programs. Section 5310 funds apportioned to large urbanized areas may not be transferred to other areas. Section 5310 program recipients may partner with meal delivery programs such as the OAA-funded meal programs (to find local programs, visit: www.Eldercare.gov) and the USDA

Summer Food Service Program <http://www.fns.usda.gov/sfsp/summer-food-service-program-sfsp>. Transit service providers receiving 5310 funds may coordinate and assist in providing meal delivery services on a regular basis as long as this does not conflict with the provision of transit services.

Program Guidance is found in FTA Circular 9070.1G, *Enhanced Mobility of Seniors and Individuals with Disabilities Program Guidance and Application Instructions*, dated July 7, 2014. Section 3006(b) of the FAST Act creates a new competitive pilot program for innovative coordinated access and mobility that is discussed in section III of this notice. The Federal share is 80% for capital projects. Local Match can come from other Federal (non-DOT) funds.

F. Formula Grants for Rural Areas Program (49 U.S.C. 5311)

The Rural Areas program provides formula funding to States and Indian tribes for the purpose of supporting public transportation in areas with a population of less than 50,000. Funding may be used for capital, operating, planning, job access and reverse commute projects, and State administration expenses. Eligible sub-recipients include State and local governmental authorities, Indian Tribes, private non-profit organizations, and private operators of public transportation services, including intercity bus companies. Indian Tribes are also eligible direct recipients under Rural Areas Formula Program, both for funds apportioned to the States and for projects apportioned or selected to be funded with funds set aside for a separate Tribal Transit Program. *For more information about the Formula Grants for Rural Areas program, please contact Élan Flippin at (202) 366-3800 or Elan.flippin@dot.gov.*

1. Authorized Amounts

Federal transit law authorizes \$632,355,120 in FY 2017 to provide financial assistance for rural areas under Rural Areas Formula Program.

2. FY 2017 Funding Availability

Under the Further Continuing Security Assistance Appropriations Act, 2017, \$317,012,628 is available through April 28, 2017 to the Rural Area Programs which includes \$44,378,969 for Growing States. The total amount apportioned to the program is \$359,613,193 as shown in the table below, after the deduction for oversight (authorized by section 5338).

FORMULA GRANTS FOR RURAL AREAS PROGRAM—FY 2017

| | |
|--|---------------|
| Total Appropriation Available Through April 28, 2017 | \$317,012,628 |
| Oversight Deductions | (1,778,404) |
| Section 5340 Growing States | 44,421,465 |
| Total Apportioned | 359,655,689 |

3. Basis for Formula Apportionment

FTA apportions Rural Areas Formula Program funds to the states by a statutory formula using the latest available U.S. decennial census data. The majority of Rural Formula Program funds (83.15 percent) are apportioned based on land area and population factors. In this first tier, no state may receive more than 5 percent of the amount apportioned on the basis of land area. The remaining Rural Formula Program funds (16.85 percent) are apportioned based on land area, vehicle revenue miles, and low-income individual factors. In this second tier, no state may receive more than 5 percent of the amount apportioned on the basis of land area, or more than 5 percent of the amounts apportioned for vehicle revenue miles. In addition to funds made available under section 5311, FTA adds amounts apportioned based on rural population according to the growing states formula factors of 49 U.S.C. 5340 to the amounts apportioned to the states under the section 5311 formula. Before FTA apportions section 5311 funds to the states, FTA subtracts funding from the total available amounts for the Appalachian Development Transportation Assistance Program, the Tribal Transit Program, the Rural Transportation Assistance Program (RTAP), and FTA oversight activities.

Data from the National Transit Database (NTD) 2015 Report Year was used for this apportionment, including data from directly-reporting Indian tribes. Data from public transportation systems that reported as urbanized area systems, but that was not attributable to an urbanized area, was also included. The Rural Areas Formula Program program includes three takedowns: The Appalachian Development Public Transportation Assistance Program; the Rural Transit Assistance Program (RTAP); and the Tribal Transit Program. These separate programs are described in the sections that follow.

4. Requirements

The Rural Areas Formula Program provides funding for capital, operating, planning, job access and reverse commute projects, and administration expenses for public transit service in

rural areas under 50,000 in population. The planning activities undertaken with Rural Areas Formula Program funds are in addition to those awarded to the State under section 5305 and must be used specifically for the needs of rural areas.

a. Intercity Bus Transportation

Each State must spend no less than 15 percent of its annual Rural Areas Formula Program apportionment for the development and support of intercity bus transportation, unless it can certify, after consultation with affected intercity bus service providers, that the intercity bus service needs of the State are adequately met. FTA encourages consultation with other stakeholders, such as communities affected by loss of intercity service. The cost of an unsubsidized portion of privately provided intercity bus service that connects feeder service, including all operating and capital costs of such service whether or not offset by revenue from such service may be used as in-kind local match for the intercity bus projects. FTA is updating the Rural Areas Formula Program program circular to include this change.

b. State Administration

States may elect to use up to 10 percent of their apportionment at 100 percent Federal share to administer the Rural Areas Formula Program program and provide technical assistance to subrecipients. Technical assistance includes project planning, program and management development, public transportation coordination activities, and research the State considers appropriate to promote effective delivery of public transportation to rural areas.

c. Other Requirements

The Federal share for capital assistance is 80 percent and for operating assistance is 50 percent, except that States eligible for the sliding scale match under FHWA programs may use that match ratio for Rural Areas Formula Program capital projects and 62.5 percent of the sliding scale capital match ratio for operating projects. No longer exists

Each State prepares an annual program of projects, which must provide for fair and equitable distribution of funds within the States, including Indian reservations, and must provide for maximum feasible coordination with transportation services assisted by other Federal sources.

Additional program guidance for the Rural Areas Formula Program is found in FTA Circular 9040.1G, *Formula*

Grants for Rural Areas: Program Guidance and Application Instructions, dated November 24, 2014, and is supplemented by additional information that may be posted to FTA's Web page.

5. Period of Availability

Rural Areas Formula Program funds remain available to states for obligation for three Federal fiscal years, beginning with the year of apportionment plus two additional years. The Rural Areas Formula Program funds apportioned in this notice are available for obligation during FY 2017 plus two additional years. Any FY 2017 apportioned funds that remain unobligated at the close of business on September 30, 2019 will revert to FTA for reapportionment under the Rural Areas program.

6. Other Program Information

Revenue from the sale of advertising and concessions may be used as local match.

G. Rural Transportation Assistance Program (49 U.S.C. 5311(b)(3))

This program provides funding to assist in the design and implementation of training and technical assistance projects, research, and other support services tailored to meet the needs of transit operators in rural areas. *For more information about Rural Transportation Assistance Program (RTAP), please contact Elan Flippin at (202) 366-3800 or Elan.flippin@dot.gov.*

1. Authorized Amounts

There is a two percent takedown from the funds made available for RTAP. Of the remaining amount, 15 percent is reserved for the National RTAP program. The remainder is available for allocation to the States.

Federal Transit Law authorizes \$12,647,102 in FY 2017 to provide technical assistance.

2. FY 2017 Funding Availability

Under the Further Continuing and Security Assistance Appropriations Act, 2017 \$7,113,616 is available through April 28, 2017 to the RTAP Program. The total amount apportioned for RTAP is \$6,046,574 as shown in the table below, after the deduction for National RTAP.

RURAL TRANSPORTATION ASSISTANCE PROGRAM—FY 2017

| | |
|--|-------------|
| Total Appropriation Available through April 28, 2017 | \$7,113,616 |
| National RTAP (15%) | (1,067,042) |
| Total Apportioned | 6,046,574 |

3. Basis for Formula Apportionment

FTA allocates funds to the States by an administrative formula. First, FTA allocates \$65,000 to each State (\$10,000 to territories), and then allocates the balance based on rural population in the 2010 census.

4. Requirements

Eligible expenses include the design and implementation of training and technical assistance projects, research, and other support services tailored to meet the needs of transit operators in rural areas.

States may use the funds to undertake research, training, technical assistance, and other support services to meet the needs of transit operators in rural areas. These funds are to be used in conjunction with a State's administration of the Rural Areas Formula Program, but also may support the rural components of the section 5310 program.

5. Period of Availability

The RTAP funds apportioned in this notice are available for obligation in FY 2017 plus two additional years, consistent with that established for the Rural Areas Formula Program Rural Program.

6. Other Program Information

The National RTAP project is administered by cooperative agreement and re-competed at five-year intervals. In July of 2014, FTA awarded a cooperative agreement to the Neponset Valley Transportation Management Association to administer the National RTAP Program. The National RTAP projects are guided by a project review board that consists of managers of rural transit systems and State DOT RTAP programs. National RTAP resources also support the biennial Transportation Research Board National Conference on Rural Public and Intercity Bus Transportation and other research and technical assistance projects of a national scope.

H. Appalachian Development Public Transportation Assistance Program (49 U.S.C. 5311(c)(2))

This program is a take-down under the Rural Areas Formula Program to provide additional funding to support public transportation in the Appalachian region. There are sixteen eligible States that receive an allocation under this provision. The State allocations are shown in the Rural Areas Formula program table posted on FTA's Web site on the FY 2017 Apportionments page. For more information about the Appalachian

Development Public Transportation Assistance Program, please contact *Élan Flippin* at (202) 366–3800 or *Elan.flippin@dot.gov*.

1. Authorized Amounts

Federal transit law authorizes \$20 million in each of FY 2016 through FY 2020 as a take-down under the Rural Areas Formula Program to support public transportation in the Appalachian region.

2. FY 2017 Funding Availability

Under the Further Continuing and Security Assistance Appropriations Act, 2017 \$11,474,389 is available through April 28, 2017.

APPALACHIAN DEVELOPMENT PUBLIC TRANSPORTATION ASSISTANCE PROGRAM FUNDS FY 2017

| | |
|--|--------------|
| Total Appropriation Available through April 28, 2017 | \$11,474,389 |
| Total Apportioned | 11,474,389 |

3. Basis for Formula Apportionment

FTA apportions the funds using percentages established under section 9.5(b) of the Appalachian Regional Commission Code (subtitle IV of title 40). Allocations are based in general on each State's remaining estimated need to complete eligible sections of the Appalachian Development Highway System as determined from the latest percentages of available cost estimates for completion of the System. Such cost estimates are produced at approximate five year intervals. Allocations contain upper and lower limits in amounts determined by the Commission and are made in accordance with legislative instructions.

4. Requirements

Funds apportioned under this program can be used for purposes consistent with the Rural Areas Formula Program to support public transportation in the Appalachian region. Funds can be applied for in the State's annual Rural Areas Formula Program grant.

Appalachian program funds that cannot be used for operating may be used for a highway project under certain circumstances. States should contact their regional office if they intend to request a transfer. Additional information about the requirements for this section can be found in Chapter VII of FTA Circular 9040.1G, *Formula Grants for Rural Areas: Program Guidance and Application Instructions*, dated November 24, 2014.

5. Period of Availability

Appalachian Program funds are available for three years, which includes the year of apportionment plus two additional years, consistent with that established for the Rural Areas Formula Program.

I. Formula Grants for Public Transportation on Indian Reservations Program (49 U.S.C. 5311(j))

The Public Transportation on Indian Reservations Program, or Tribal Transit Program (TTP), totals \$35 million, of which \$30 million is for a formula program and \$5 million is for a competitive grant program. It is funded as a takedown from funds made available for the section Rural Areas Formula Program. Formula factors include vehicle revenue miles and the number of low-income individuals residing on tribal lands (defined as American Indian Areas, Alaska Native Areas, and Hawaiian Home Lands). Eligible direct recipients are Federally recognized Indian tribes and Alaskan Native Villages providing public transportation in rural areas. The TTP funds are allocated for grants to eligible recipients for any purpose eligible under Rural Areas Formula Program, which includes capital, operating, planning, and job access and reverse commute projects. *For more information about the Tribal Transit Program contact Elan Flippin, Office of Transit Programs at (202) 366–3800 or elan.flippin@dot.gov.*

1. Authorized Amounts

Federal transit law authorizes \$35 million in FY 2017 (\$30 million for formula and \$5 million for the competitive program).

2. FY 2017 Funding Availability

Under the Further Continuing and Security Assistance Appropriations Act, 2017 \$15,080,181 is available for the formula program and \$5 million for the competitive program through April 28, 2017 as shown below.

FORMULA GRANTS FOR PUBLIC TRANSPORTATION ON INDIAN RESERVATIONS PROGRAM FY 2017

| | |
|---------------------------------------|--------------|
| Total Appropriation (formula) | \$15,080,181 |
| Total Apportioned (competitive) | 5,000,000 |
| Total Apportioned | 20,080,181 |

3. Basis for Formula Apportionment

Funding is allocated by formula and distributed to eligible Indian tribes providing public transportation on tribal

lands. The formula apportionment shown in Table 10 is based on a statutory formula which includes three tiers. Tiers 1 and 2 are based on data reported to NTD by Indian tribes; Tier 3 is based on 2010–2014 American Community Survey data. The three tiers for the formula are: Tier 1—50 percent based on vehicle revenue miles reported to the NTD; Tier 2—25 percent provided in equal shares to Indian tribes reporting at least 200,000 vehicle revenue miles to the NTD; Tier 3—25 percent based on Indian tribes providing public transportation on tribal lands (American Indian Areas, Alaska Native Areas, and Hawaiian Home Lands) on which more than 1,000 low income individuals reside. If more than one eligible tribe provides public transportation services on tribal lands in a single Tribal Statistical Area, and the tribes cannot determine how to allocate Tier 3 funds, FTA will allocate the funds based on the relative portion of transit (as defined by unlinked passenger trips) operated by each tribe, as reported to the National Transit Database.

4. Requirements

Formula funds apportioned under this program can be used for purposes consistent with Rural Areas Formula Program to support public transportation on Indian Reservations in rural areas. Funds allocated under the competitive program must be used consistent with the tribe's proposal and the allocation notice published in the **Federal Register**, which is used to announce the selected projects. Eligible recipients under both the competitive and formula program include federally-recognized Indian tribes or Alaska native villages, groups, or communities as identified by the U.S. Department of the Interior Bureau of Indian Affairs (BIA). A tribe must have the legal, financial and technical capabilities to receive and administer Federal funds.

Section 5335 requires NTD reporting for all recipients or beneficiaries all section 5311 funds. This reporting requirement continues to apply to the Tribal Transit Program. Tribes that provide public transportation in rural areas are reminded to report annually so they are included in the TTP formula apportionments. To be considered in the FY 2017 formula apportionments, tribes should have submitted their reports to the NTD no later than April 30, 2016; voluntary reporting to the NTD is also encouraged. Additionally, to be considered for the FY 2018 formula apportionment funds, tribes need to submit their reports to the NTD no later than April 30, 2017. Tribes needing assistance with reporting to the NTD

should contact the NTD Helpline at 1-888-252-0936 or NTDHelp@dot.gov.

5. Period of Availability

Funding for the TTP is available for three years, which includes the year of apportionment plus two additional years, consistent with that established for the Rural Areas Formula Program. Any FY 2017 formula funds that remain unobligated at the close of business on September 30, 2019 will revert to FTA for reapportionment under the TTP.

6. Other Program Information

Section 207 of title 23, United States Code establishes a Tribal Transportation Self-Governance Program (Self Governance Program). The Self Governance Program will establish specific criteria for determining eligibility for a tribe to participate in the program. A Negotiated Rulemaking to implement this program in consultation with tribal representatives and other interested stakeholders is under development.

The funds set aside for the TTP are not meant to replace or reduce funds that Indian tribes receive from States through the Rural Areas Formula Program but are to be used to enhance public transportation on Indian reservations and transit serving tribal communities. Funds allocated to Indian tribes by the States may be included in the State's Rural Areas Formula Program application or maybe awarded by FTA in a grant directly to the Indian tribe. FTA encourages Indian tribes intending to apply to FTA as direct recipients to contact the appropriate FTA Regional Office at the earliest opportunity.

TTP grantees must comply with all applicable Federal statutes, regulations, executive orders, FTA circulars, and other Federal requirements in carrying out the project supported by the FTA grant. To assist tribes with understanding these requirements, FTA regularly conducts Tribal Transit Technical Assistance Workshops. FTA has also expanded its technical assistance to tribes receiving funds under this program. In FY 2015, FTA implemented the Tribal Transit Technical Assistance Assessments initiative. Through these assessments, FTA collaborates with tribal transit leaders to review processes and identify areas in need of improvement and then assist with solutions to address these needs—all in a supportive and mutually beneficial manner. These assessments include discussions of compliance areas pursuant to the Master Agreement, a site visit, promising practices reviews, and technical assistance from FTA and its contractors. FTA will post information

about upcoming workshops to its Web site and will disseminate information about the reviews through its Regional offices. FTA has regional tribal transit liaisons in each of the FTA Regional Offices that are available to assist tribes with applying for and managing FTA grants. Tribes are encouraged to work directly with their regional tribal transit liaison.

J. Public Transportation Innovation (49 U.S.C. 5312)

Public Transportation Innovation is FTA's research program. Within this section, are several different activities that comprise three distinct programs: (a) A Research, Development, Demonstration, Deployment, & Evaluation program (49 U.S.C. 5312(b-e)); (b) a Low or No Emission Vehicle Component Assessment Program (LoNo-CAP) (49 U.S.C. 5312(h)); and (c) a Transit Cooperative Research Program (49 U.S.C. 5312(i)). *For more information about the Public Transportation Innovation program, contact Edwin Rodriguez, Office of Research, Demonstration and Innovation at (202) 366-0671 or edwin.rodriguez@dot.gov.*

1. Authorized Amounts

Federal transit law authorizes \$48 million for FY 2017 for the Public Transportation Innovation program.

2. FY 2017 Funding Availability

Under the Further Continuing and Security Assistance Appropriations Act, 2017 \$16,064,145 is available through April 28, 2017 shown in the table below.

PUBLIC TRANSPORTATION INNOVATION APPORTIONED THRU APRIL 28, 2017

| | |
|--|-------------------|
| Research, Development, Demonstration, Deployment, & Evaluation | \$11,474,389 |
| Low or No Emission Vehicle Component Testing | 1,721,158 |
| Transit Cooperative Research Program (TCRP) ... | 2,868,597 |
| Total Apportioned | 16,064,145 |

3. Basis for Formula Apportionment

Public Transportation Innovation funds are allocated according to the authorized purposes and amounts described above, and then remaining amounts are subject to competitive allocations where not specifically authorized. For FY 2017, FTA intends to fund projects and activities consistent with its Research Strategic Plan and in support of three major areas: Asset Innovation and Management, Mobility,

and Safety. Projects may be selected through Notices of Funding Opportunity (NOFO) or Requests for Proposals (RFPs), or sole-sourced. Potential recipients can register to receive notification of funding availability under this program on Grants.gov.

FTA awards an annual cooperative agreement to the National Academies of Science to administer the TCRP. For the LoNo-CAP, proposals were due November 28, 2016 and FTA expects to announce the selected testing facility or facilities in January 2017.

4. Requirements

Eligible expenses include activities involving (a) Research, Innovation, Development, Demonstration, Deployment, Evaluation; (b) Low or No Emission Vehicle Component Testing; and (c) Transit Cooperative Research.

The Government share of the cost of a project carried out under FTA's Research, Development, Deployment, and Demonstration program shall not exceed 80 percent; the remaining 20 percent of the costs can be met with in-kind resources. In some cases, FTA may require a higher non-Federal share if FTA determines a recipient would obtain a clear and direct financial benefit from the project, or if the non-Federal share is an evaluation factor under a competitive selection process.

However, for the LoNo-CAP, the Government share is 50 percent; the remaining 50 percent of the costs will be paid by amounts recovered through the fees established by the testing facilities. There is no match requirement for the TCRP.

Application instructions and program management guidelines are set forth in FTA Circular C 6100.1E, Technology Development and Deployment, "Research, Technical Assistance and Training Program: Application Instructions and Program Management Guidelines" dated May 11, 2015.

All research recipients are required to work with FTA to develop approved Statements of Work. FTA will be updating the Circular for the Research Program during FY 2017.

5. Period of Availability

FTA establishes the period in which the funds must be obligated to the project. If the funds are not obligated within that period of time, they revert to FTA for reallocation under the program.

6. Other Program Information

FTA publishes an annual Research Report on projects, evaluations, and benefits of its research portfolio. The FY2015 Report is posted on FTA's Web

site, with the FY2016 report expected in February 2017. Section 6019(b) of the FAST Act establishes new requirements for annual modal research plans in 49 U.S.C. 6501. The FY 2016 plans are posted on DOT's Web site.

For the new LoNo-CAP (5312(h)), FTA solicited proposals for the LoNo-CAP in the Fall of 2016, with selection(s) expected in January 2017. Per the statute, FTA only considered proposals from "institutions of higher education" as defined in section 1002 of title 20, U.S.C., the Higher Education Act of 1965. Eligible institution(s) of higher education must have capacity to carry out transportation-related advanced component testing and evaluation, with laboratories capable of testing and evaluation, and direct access to or a partnership with a testing facility capable of emulating real-world circumstances in order to test low or no emission components.

LoNo-CAP differs from the Bus Testing Program (Section 5318) in that LoNo-CAP testing is voluntary; it will only test components, and it will not assign passing or failing scores. The LoNo component testing performed under LoNo-CAP complements the Section 5318 Bus Testing Program, under which FTA will continue to test complete buses as a condition of eligibility for FTA grant funding. Eligible activities under LoNo-CAP include testing and assessing voluntarily submitted Lo-No components for transit buses, publishing the results of these LoNo component assessments, and preparing an annual report to Congress summarizing the results of the component assessments. *For more information on the LoNo-CAP, please contact Marcel Belanger at marcel.belanger@dot.gov or visit: <https://www.transit.dot.gov/research-innovation/lonocap>.*

TCRP is a cooperative effort of three organizations: FTA; the National Academies, acting through the Transportation Research Board (TRB); and the Transit Development Corporation, Inc. (TDC), a nonprofit educational and research organization established by the American Public Transportation Association (APTA). FTA funds the TCRP through a cooperative agreement and it is governed by an independent board—the TCRP Oversight and Project Selection (TOPS) Committee. The TOPS Committee sets priorities to decide what research studies will be undertaken and annually selects projects. The FY 2017 selected projects can be found at <http://www.trb.org/TCRP>. *For more*

information about TCRP, please contact Faith Hall at faith.hall@dot.gov.

Pursuant to the Small Business Innovation Development Act, a portion of the 5312 funds must be set aside for the Department's SBIR program to address high priority research that will demonstrate innovative, economic, accurate, and durable technologies, devices, applications, or solutions to significantly improve current transit-related service including transit vehicle operation, safety, infrastructure and environmental sustainability, mobility, rider experience, or broadband communication. Information on current and past SBIR projects can be found on the DOT SBIR Web site.

K. Technical Assistance and Workforce Development (49 U.S.C. 5314)

The Technical Assistance and Workforce Development program, 49 U.S.C. 5314, provides assistance to: (1) Carry out technical assistance activities that enable more effective and efficient delivery of transportation services, foster compliance with Federal laws, and improve public transportation service; (2) develop standards and best practices for the transit industry; and (3) address public transportation workforce needs through research, outreach, training and the implementation of a frontline workforce grant program, and conduct training and educational programs in support of the public transportation industry.

For more information or questions about the Technical Assistance and Workforce Development programs, please contact Edwin Rodriguez, Office of Research, Demonstration, and Innovation at (202) 366-0671 or Edwin.rodriguez@dot.gov.

1. Authorized Amounts

The Technical Assistance and Workforce Development Program is at \$14 million in FY 2017. Under the Further Continuing and Security Assistance Appropriations Act, 2017 \$5,163,475 is authorized through April 28, 2017 as shown in the table below.

2. FY 2017 Funding Availability

TECHNICAL ASSISTANCE AND WORKFORCE DEVELOPMENT FUNDS AVAILABLE THRU APRIL 28, 2017

| | |
|--|--------------------------|
| Technical Assistance, Standards Development & Human Resource Training National Transit Institute | \$2,294,878 2,868,597 |
| Total Appropriated | 5,163,475 |

3. Basis for Formula Apportionment

Under the Technical Assistance and Workforce Development Program, \$2,868,597 is available for the NTI. The remaining \$2,294,878 will be allocated in support of FTA and USDOT strategic goals for technical assistance, standards development, and workforce development. Projects may be selected through sole source, Notices of Funding Opportunity (NOFO) or Requests for Proposals (RFPs). Potential recipients can register to receive notification of funding availability under this program on Grants.gov. Once selected, FTA enters into cooperative agreements, grants, contracts, or other agreements to award funds and manage the projects carried out under this section.

4. Requirements

Eligible expenses include activities involving: (a) Technical assistance; (b) standards development; and (c) human resources and training, including workforce development programs and activities. Eligible technical assistance activities may include activities to support: (a) Compliance with the ADA; (b) compliance with coordinating planning and human services transportation; (c) meeting the transportation needs of elderly individuals; (d) increasing transit ridership in coordination with MPOs and other entities, particularly around transit-oriented development; (e) addressing transportation equity with regard to the effect that transportation planning, investment, and operations have for low-income and minority individuals; (f) facilitating best practices to promote bus driver safety; (g) compliance with Buy America requirements and pre- and post-award audits; (h) assisting with the development and deployment of low and no emission vehicles or components for vehicles; (i) and other technical assistance activities that are necessary to advance the interests of public transportation.

Eligible standards development activities include the development of voluntary and consensus-based standards and best practices by the industry including those needed for safety, fare collection, intelligent transportation systems, accessibility, procurement, security, asset management, operations, maintenance, vehicle propulsion, communications, and vehicle electronics.

Eligible human resources and training activities include (a) employment training programs; (b) outreach programs to increase employment for veterans, females, individuals with

disabilities, and minorities in public transportation; (c) research on public transportation personnel and training needs; (d) training and assistance for veteran and minority business opportunities; and (e) consensus-based national training standards and certifications in partnership with industry stakeholders. FTA funding directly allocated for these eligible purposes must be done through a competitive frontline workforce development program as required by section 5314. Should FTA allocate funds for these purposes, it will advertise the available funding in a Notice of Funding Opportunity (NOFO) on *Grants.gov* and on its Web site. In the meantime, recipients of funds under sections 5307, 5337, and 5339 may use 0.5 percent of their available funds to pay for workforce development activities (up to an 80 percent Federal share). There is a separate eligibility to use 0.5 percent of available funds under the sections above for training at the National Transit Institute.

The Government's share of the cost of a project carried out using a grant under this section shall not exceed 80 percent. However, for the human resources and training, including the Innovative Public Transportation Frontline Workforce Development Program, the Government's share cannot exceed 50 percent. The Federal share for other types of awards will be stated in the agreement. In some cases, FTA may require a higher non-Federal share if FTA determines a recipient would obtain a clear and direct financial benefit from the project, or if the non-Federal share is an evaluation factor under a competitive selection process.

The non-Government share of the cost of a project carried out under these sections (Technical Assistance and Standards and Technical Assistance and Training) may be derived from in-kind contributions as defined in the most current version of FTA Circular 5010, "Award Management Guidelines" found on FTA's Circular Web page at <http://www.fta.dot.gov/circulars>). Application instructions and program management guidelines are set forth in FTA Circular 6100.1E, "Research, Technical Assistance and Training Programs: Application Instructions and Program Management Guidelines" dated May 11, 2015.

All research recipients are required to work with FTA to develop approved statements of work. There is no match requirement for the National Transit Institute.

5. Period of Availability

FTA establishes the period in which the funds must be obligated to the project. If the funds are not obligated within that period of time, they revert to FTA for reallocation under the program.

6. Other Program Information

FTA publishes an annual report to Congress on the technical assistance and standards activities that receive assistance under this section. Additionally, FTA must report annually on the Frontline Workforce Development Program. These reports can be found on FTA's Web site.

L. Public Transportation Emergency Relief Program (49 U.S.C. 5324)

FTA's Emergency Relief (ER) Program is authorized to provide funding for public transportation expenses incurred as a result of an emergency or major disaster. No funding was provided in the Further Continuing and Security Assistance Appropriations Act, 2017 for this program.

In the event funds are appropriated to this program to assist in responding to a publicly declared emergency or disaster, eligible expenses will include emergency operating expenses, such as evacuations, rescue operations, and expenses incurred to protect assets in advance of a disaster, as well as capital projects to protect, repair, reconstruct, or replace equipment and facilities of a public transportation system that the Secretary determines is in danger of suffering serious damage or has suffered serious damage as a result of an emergency. Additionally, transit agencies in the affected areas may request relief from certain FTA administrative and regulatory requirements for costs incurred in support of evacuations, rescue efforts, and the efficient shut down and resumption of transit services during and after the storm. Requests for relief from these requirements may be submitted to FTA's Emergency Relief Docket at <https://www.regulations.gov/>. The docket number for calendar year 2017 is FTA-2017-0001.

FTA also encourages transit agencies in affected areas to become familiar with FTA's Emergency Relief Program Manual, available at transit.dot.gov/emergencyrelief. Should funding be made available by Congress through FTA's Emergency Relief Program, or at FEMA's direction, FTA will work with agencies to assess the impacts of the storm, including emergency operations and any potential damages to transit rolling stock or facilities.

While Congress has not provided funding for this program in FY 2017, so far recipients of FTA funding affected by a declared emergency or disaster are authorized to use funds apportioned under sections 5307 and 5311 for emergency purposes under the provisions of FTA's Emergency Relief Program. Recipients are advised that formula funds disbursed to a grantee for emergency purposes will not be replaced or restored in the event that funding is subsequently made available through FTA under the ER Program or by the Federal Emergency Management Agency (FEMA).

In the event of a disaster affecting a public transportation system, the affected recipient should contact its FTA Regional Office as soon as practicable to determine whether Emergency Relief Program funds are available, and to notify FTA that it plans to seek reimbursement for emergency operations and/or repairs that have already taken place or are in process. If Emergency Relief funds are unavailable the recipient may seek reimbursement from FEMA. Properly documented costs for which the grantee has not received reimbursement from FEMA may later be reimbursed by grants made either from Emergency Relief Program funding (if appropriated) or from sections 5307 and 5311 program funding, once the eligible recipient formally applies to FTA for reimbursement and FTA determines that the expenses are eligible for emergency relief.

More information on the Emergency Relief Program and FTA's response to Hurricane Sandy is available on the FTA Web site at <https://www.transit.dot.gov/funding/grant-programs/emergency-relief-program/emergency-relief-program>.

For more information or questions on this program, please contact Adam Schildge at 202-366-0778 or www.adam.schildge@dot.gov.

M. Public Transportation Safety Program (49 U.S.C. 5329)

The State Safety Oversight Formula Program provides funding to support States with rail fixed guideway public transportation systems (rail transit systems) to develop and carry out State Safety Oversight (SSO) Programs consistent with the requirements of 49 U.S.C. 5329.

For more information or questions on the Public Transportation Safety program, please contact Maria Wright at (202) 366-5922 or maria1.wright@dot.gov.

1. Authorized Amounts

Federal transit law authorizes \$23,148,419 in FY 2017 to provide funding to support States in developing and carrying out the SSO Program.

2. FY 2017 Funding Availability

Under the Further Continuing and Security Assistance Appropriations Act, 2017 \$13,020,292 is available through April 28, 2017 for the period October 1, 2016 through April 28, 2017 for the State Safety Oversight (SSO) program as shown in the table below.

**PUBLIC TRANSPORTATION SAFETY
PROGRAM FUNDS APPORTIONED
THRU APRIL 28, 2017**

| | |
|---------------------------|--------------|
| Total Appropriation | \$13,020,292 |
| Total Apportioned | 13,020,292 |

3. Basis for Formula Apportionment

FTA will continue to allocate funds to the States by an administrative formula, which is detailed in the **Federal Register** notice apportioning SSO Formula Grant Program FY 2013 and FY 2014 funds (Mar. 10, 2014). Grant funds for the SSO program are apportioned to eligible States using a three-tier formula based on statutory requirements, which apportion sixty percent (60%) of available funds based rail transit system passenger miles (PMT), vehicle revenue miles (VRM), and directional route miles (DRM), twenty percent (20%) of available funds equally to each eligible State, and twenty percent (20%) based on the number of rail transit systems in each state.

4. Requirements

FTA requires each applicant to demonstrate in its grant application that its proposed grant activities will develop, lead to, or carry out a State Safety Oversight program that meets the requirements under 49 U.S.C. 5329(e). Grant funds may be used for program operational and administrative expenses, including employee training activities. Please see the **Federal Register** notice which apportioned SSO Formula Grant Program FY 2013 and FY 2014 funds (79 FR 13380, Mar. 10, 2014) for more information.

5. Period of Availability

SSO Formula Grant Program funds are available for the year of apportionment plus two additional years. Any FY 2017 funds that remain unobligated at the close of business on September 30, 2019 will revert to FTA for reapportionment under the SSO Formula Grant Program.

6. Other Program Information

Section 5329 authorizes FTA to temporarily assume oversight of a rail transit safety system, under certain circumstances. FTA also has the authority to issue restrictions and prohibitions to address unsafe conditions or practices. On August 11, 2016, FTA published a final rule to set procedures for FTA's administration of the Public Transportation Safety Program. The final rule provides procedures whereby FTA may: (1) Require a recipient to use Chapter 53 funds to correct safety violations identified by the Administrator or a State Safety Oversight Agency before such funds are used for any other purpose, or (2) withhold up to than 25 percent of funds apportioned under 49 U.S.C. 5307 from a recipient when the Administrator has evidence that the recipient has engaged in a pattern or practice of serious safety violations, or has otherwise refused to comply with the Public Transportation Safety Program, or any regulation or directive issued under those laws for which the Administrator exercises enforcement authority for safety.

N. State of Good Repair Program (49 U.S.C. 5337)

The State of Good Repair Program provides financial assistance to designated recipients in Urbanized Areas (UZAs) with fixed guideway and high intensity motorbus systems for capital investments that maintain, rehabilitate, and replace aging transit assets and bring fixed guideway and high intensity motorbus systems into a state of good repair. FTA apportions funds for this program through a statutory formula using data reported to the National Transit Database (NTD).

For more information or questions on the State of Good Repair program, please contact Eric Hu at (202) 366-0870 or erichu@dot.gov.

1. Authorized Amounts

Federal transit law authorizes \$2,549,670,000 in FY 2017 for the State of Good Repair Program.

2. FY 2017 Funding Availability

Under the Further Continuing and Security Assistance Appropriations Act, 2017 \$1,438,314,657 is available through April 28, 2017. The total amount apportioned is \$1,423,931,511 after the deduction for oversight as shown in the table below, after the deduction for oversight (authorized by section 5338).

**STATE OF GOOD REPAIR PROGRAM
FUNDS APPORTIONED FY 2017**

| | |
|--|-----------------|
| Total Appropriation Available through April 28, 2017 | \$1,438,314,657 |
| Oversight Deductions | (14,383,147) |
| Total Apportioned | 1,423,931,511 |

3. Basis for Formula Apportionment

FTA apportions State of Good Repair Program funds according to a statutory formula. Funds are apportioned to urbanized areas with high intensity fixed guideway and high intensity motorbus systems that have been in operation for at least seven years. This means that only segments of high intensity fixed guideway and high intensity motorbus systems that entered into revenue service on or before September 30, 2009 are included in the formula, as identified in the NTD. Funds apportioned to urbanized areas with high intensity fixed guideway and motorbus systems are determined by two equal elements: (1) The proportion of the amount an urbanized area would have received in FY 2011 to the total amount apportioned to all urbanized areas in the FY 2011 Fixed Guideway Modernization program using the fixed guideway definition defined in prior law; and (2) the proportion of vehicle revenue miles of an urbanized area to the total vehicle revenue miles of all urbanized areas and the proportion of directional route miles of an urbanized area to the total directional miles of all urbanized areas. 97.15 percent of the total appropriation is apportioned to the fixed guideway tier, the remaining 2.85 percent is apportioned to the high-intensity motorbus tier.

4. Requirements

In addition to the program guidance found in the FTA Circular 5300.1, "State of Good Repair Grants Program: Guidance and application Instructions" all recipients will need to comply with the rule issued under section 5326 for the Transit Asset Management plan (TAM).

5. Period of Availability

The State of Good Repair Program funds apportioned in this notice are available for obligation during FY 2017 plus three additional years. Accordingly, funds apportioned in FY 2017 must be obligated in grants by September 30, 2020. Any FY 2017 apportioned funds that remain unobligated at the close of business on September 30, 2020 will revert to FTA for reappointment under the State of Good Repair Program.

6. Other Program Information

In July 2016, FTA published a Final Rule for Transit Asset Management (81 FR 48890, July 26, 2016). Grantees must have a TAM plan in place by October 1, 2018. Beginning in FY 2019 all projects funded under the State of Good Repair Program must appear in the investment prioritization of the grantees TAM plan.

O. Grants for Buses and Bus Facilities Program (49 U.S.C. 5339)

The Grants for Buses and Bus Facilities Program provides financial assistance to states and designated recipients for capital investments in public transportation systems to replace, rehabilitate and purchase buses and related equipment and to construct bus-related facilities, including technological changes or innovations to modify low or no emission vehicles or facilities. Funding is provided through formula allocations and competitive grants. A sub-program, the Low- or No-Emission Vehicle Program, provides competitive grants for bus and bus facility projects that support low and zero-emission vehicles.

For more information or questions on the Grants for Buses and Bus Facilities Program, please contact Vanessa Williams at (202) 366-4818 or vanessa.williams@dot.gov. For information or questions regarding the competitive Low or No Emissions Grant Program, contact Tara Clark at (202) 366-2623 or tara.clark@dot.gov.

1. Authorized Amounts

Federal transit law authorizes \$719,960,000 in FY 2017, to provide financial assistance for the Grants for Buses and Bus Facilities Program.

2. Funding Availability

Under the Continuing Appropriations Act of 2017, \$399,193,992 is available through April 28, 2017. After the 0.75 percent take-down for oversight, \$396,200,037 is available after the deduction for oversight, as shown in the table below.

GRANTS FOR BUSES AND BUS FACILITIES—FY 2017

| | |
|--|------------------------------|
| Total Appropriation (Formula) Oversight Deduction | \$245,437,180 (1,840,779) |
| Total Apportioned (Formula) | 243,596,401 |
| Total Appropriation (Low No Competition) Oversight Deduction | 31,554,570 (236,659) |
| Total to be Allocated (Competition) | 31,317,910 |

GRANTS FOR BUSES AND BUS FACILITIES—FY 2017—Continued

| | |
|---|-------------|
| Total Appropriation (Bus Competition) | 122,202,243 |
| Oversight Deduction | (916,517) |
| Total to be Allocated (Competition) | 121,285,726 |

3. Basis for Formula Apportionment

Buses and Bus Facilities Program formula funds are apportioned to States, territories, and designated recipients based on a statutory formula. Under the National Distribution, each State is allocated \$1.0 million and each territory is allocated \$286,860 for use anywhere in the State or territory for each of fiscal years 2016 through 2020. The remainder of the available funding is then apportioned to UZAs based on population, vehicle revenue miles, and passenger miles using the same apportionment formula and allocation process as the Urbanized Area Formula Program. Funds for UZAs under 200,000 in population are apportioned to the State for allocation to eligible recipients within such areas of the State at the Governor's discretion. Funds for UZAs with populations of 200,000 or more are apportioned directly to one or more designated recipient(s) within each UZA for allocation to eligible projects and recipients within the UZA.

FTA allocates funds under the competitive section 5339(b) and 5339(c) programs on an annual basis based on a notice of funding opportunity, which contains detailed guidance on applicant eligibility, project eligibility, evaluation criteria, and application requirements.

4. Requirements

Eligible recipients for section 5339(a) formula grants include: (1) Designated recipients that allocate funds to fixed route bus operators, and (2) States local governmental entities that operate fixed route bus service. Eligible subrecipients to include public agencies or private nonprofit organizations engaged in public transportation, including those providing services open to a segment of the general public, as defined by age, disability, or low income. The definition of eligible recipients applies to funding apportioned in previous fiscal years that remain available for obligation. The requirements of the Urbanized Area Formula Program apply to recipients of section 5339 funds within an urbanized area. The requirements of Rural Areas Formula Program apply to recipients of section 5339 funds within rural areas.

Under prior law, only designated recipients were eligible direct recipients of section 5339(a) funds. Given that

State and local government entities that operate fixed route service are now eligible direct recipients of section 5339(a) funds. FTA does not require designated recipients to maintain program management plans (PMPs) if they do not manage any sub-awards of section 5339 funds.

For additional program requirements, refer to FTA Circular 5100, "Bus and Bus Facilities Formula Program: Guidance and Application Instructions."

5. Period of Availability

The Bus and Bus Facilities Program formula funds apportioned in this notice are available for obligation during FY 2017 plus three additional years. Accordingly, funds apportioned in FY 2017 must be obligated in grants by September 30, 2020. Any FY 2017 apportioned funds that remain unobligated at the close of business on September 30, 2020 will revert to FTA for reapportionment under the Bus and Bus Facilities Formula Program. Competitive program funds authorized under sections 5339(b) and 5339(c) follow the same period of availability.

6. Other Program Information

Although it does not provide additional funding, as authorized under section 5339(a)(9), FTA has established a pilot program to allow designated recipients in urbanized areas between 200,000 and 1 million in population to elect to pool their Bus and Bus Facilities Program formula allocations with other designated recipients within their respective states. The purpose of this provision is to allow for the transfer of formula funding within a State in a manner that supports the transit asset management plans of the participating designated recipients. A State that intends to participate in this pilot program beginning in FY 2018 must submit a request to establish a State Pool to its FTA Regional Office by August 31, 2017. The request must identify the urbanized areas that will participate in the pool for FY 2018, and must include a letter from each participating designated recipient, and from any affected eligible recipients of section 5339(a) funds within the urbanized area, indicating their intention to participate in this pooling provision for FY 2017. An urbanized area that participates in a State Pool must contribute its entire section 5339(a) apportionment for the fiscal years in which it participates in the pool. A designated recipient for a multistate area may participate in only one State Pool. A State that does not establish a State Pool in FY 2018 may

choose to begin participating in this provision in a future fiscal year, but should be aware that the benefits of pooling program funds will be diminished over a shorter duration. For FY 2018, the request must specify the proposed distribution of the pooled funding and must provide a detailed explanation of how this distribution will support the transit asset management plans of each participating designated recipient, including any eligible recipients to which the designated recipient will allocate funding. Upon approval, FTA will make the requested amounts of program funding available to the urbanized areas as directed in the request. A State that elects to participate in this pilot program will be required to develop an allocation plan for the period of fiscal years 2018 through 2020 that ensures that a designated recipient participating in the State's pool receives under the program an amount of funds that equals the amount of funds that would have otherwise been available to the designated recipient for that period pursuant to the formulas provided. The amounts in the State Pool will be apportioned separately from funds apportioned to the State under the Governor's Apportionment for urbanized areas under 200,000 in population, and will be made available directly by FTA to the participating urbanized areas, as directed in the approved allocation plan. An allocation plan may be revised for future fiscal years, provided that it remains compliant with the requirement to ensure equity over the period the pool is in effect. Approved requests to establish a State Pool for the specified UZAs will remain in effect until cancelled at the request of the State or one or more designated recipients. If a State or designated recipient elects to end its participation in this pooling provision in any future fiscal year, FTA will adjust the formula allocations so that the total amount that each affected urbanized area has received over the fiscal years in which it participated, plus the following apportionment, equals the amount it would have received over this period had it not participated in the State pool. Adjustments will be made using the formula apportionment factors used for each of the affected fiscal years. After the pools are determined, FTA will publish a supplementary table showing the participating UZAs, the State total, and the amounts for each UZA for FY 2017. In future years, the States must provide the amounts determined by August 31 (in an updated allocation

plan), so that FTA can publish the breakdowns and make the funds available in the Apportionment Notice.

P. Growing States and High Density States Formula Factors (49 U.S.C. 5340)

Federal transit law authorizes the use of formula factors to distribute additional funds to the section 5307 and Rural Areas Formula Program programs for growing states and high density states. FTA will continue to publish single urbanized and rural apportionments that show the total amount for section 5307 and 5311 programs that includes section 5340 apportionments for these programs.

For more information or questions on this program, please contact Tara Clark at (202) 366-2623 or tara.clark@dot.gov.

1. Authorized Amounts

Federal transit law authorizes \$544,433,788 for apportionment in FY 2017 for the Growing States and High Density States Formula factors.

2. FY 2017 Funding Availability

Under the Further Continuing and Security Assistance Appropriations Act, 2017 \$307,663,675 is available through April 28, 2017.

| Growing states and high density states formula factors available thru April 28, 2017 | 2017 |
|--|---------------|
| Growing States | \$156,222,132 |
| High Density States | 151,441,543 |
| Total Apportioned | 307,663,675 |

3. Basis for Formula Apportionment

Under the Growing States portion of the section 5340 formula, FTA projects each State's 2025 population by comparing each State's apportionment year population (as determined by the Census Bureau) to the State's 2010 Census population and extrapolating to 2025 based on each State's rate of population growth between 2010 and the apportionment year. Each State receives a share of Growing States funds on the basis of its projected 2025 population relative to the nationwide projected 2025 population.

Once each State's share is calculated, funds attributable to that State are divided into an urbanized area allocation and a non-urbanized area allocation on the basis of the percentage of each State's 2010 Census population that resides in urbanized and non-urbanized areas. Urbanized Areas receive portions of their State's urbanized area allocation on the basis of the 2010 Census population in that urbanized area relative to the total 2010 Census population in all urbanized

areas in the State. These amounts are added to the Urbanized Area's section 5307 apportionment.

The States' rural area allocation is added to the allocation that each State receives under the Rural Areas Formula Program Formula Grants for Rural Areas program.

The High Density States portion of the section 5340 formula are allocated to urbanized areas in States with a population density equal to or greater than 370 persons per square mile. Based on this threshold and 2010 Census data, the States that qualify are Maryland, Delaware, Massachusetts, Connecticut, Rhode Island, New York and New Jersey. The amount of funds provided to each of these seven States is allocated on the basis of the population density of the individual State relative to the population density of all seven States. Once funds are allocated to each State, funds are then allocated to urbanized areas within the States on the basis of an individual urbanized area's population relative to the population of all urbanized areas in that State.

Q. Washington Metropolitan Area Transit Authority Grants

Section 601 of the Passenger Rail Investment and Improvement Act of 2008 (PRIIA) authorized an aggregate amount of \$150,000,000 to be available in increments over 10 fiscal years beginning in fiscal year 2009 to assist Washington Metropolitan Transit Authority (WMATA) in implementing Capital Improvement Program and preventive maintenance projects.

For more information or questions on the Washington Metropolitan Area Transit Authority Grants program, please contact Eric Hu at (202) 366-0870 or eric.hu@dot.gov or Corey Walker at (202) 219-3562 or corey.walker@dot.gov.

1. Authorized Amounts

Section 601 of PRIIA authorizes \$150,000,000 in FY 2017.

2. FY 2017 Funding Availability

Under the Continuing Appropriations Act of 2017, \$86,057,917 is available through April 28, 2017. The total amount available is \$85,197,338 after the deduction for oversight as shown in the table below.

**WASHINGTON METROPOLITAN AREA
TRANSIT AUTHORITY GRANTS
FUNDS—FY 2017**

| | |
|--|--------------|
| Total Appropriation Available through April 28, 2017 | \$86,057,917 |
| Oversight Deduction | (860,579) |

WASHINGTON METROPOLITAN AREA
TRANSIT AUTHORITY GRANTS
FUNDS—FY 2017—Continued

| | |
|-------------------------|------------|
| Total Apportioned | 85,197,338 |
|-------------------------|------------|

3. Basis for Formula Apportionment

The funding is authorized under Section 601, Authorization for Capital and Preventive Maintenance Projects for Washington Metropolitan Area Transit Authority, of the Passenger Rail Investment and Improvement Act of 2008, (Pub. L. 110–432) Division B, Title VI.

4. Requirements

Grants may be provided for capital and preventive maintenance expenditures for WMATA after it has been determined that WMATA has placed the highest priority on investments that will improve the safety of the system, including but not limited to fixing the track signal system, replacing 1000 series railcars, installing guarded turnouts, buying equipment for wayside worker protection, and installing rollback protection on cars that are not equipped with the safety feature. FTA will communicate further program requirements directly to WMATA. The maximum Federal share for each project shall be for 50 percent of the net project cost of the project, and matching funds shall be provided in cash from sources other than Federal funds or revenues from the operation of public transportation systems.

5. Period of Availability

Funds appropriated for WMATA under Section 601 PRIIA shall remain available until expended.

R. Paul S. Sarbanes Transit in Parks Program

The Paul S. Sarbanes Transit in Parks Program (Transit in Parks) at former 49 U.S.C. 5320, has provided grants for alternative transportation in and around America's national parks and Federal lands since 2006. FTA is establishing a deadline of September 30, 2017 to obligate funds allocated to recipients under the Transit in Parks program. Any competitive allocations that remain unobligated after September 30, 2017 will revert back to FTA.

Alternative transportation projects formerly eligible under Transit in Parks are now eligible under the Federal Highway Administration's Federal Lands Transportation Program and the Federal Lands Access Program.

V. FTA Policy and Procedures for FY 2017 Grants

A. Automatic Pre-Award Authority To Incur Project Costs

1. Caution to New Grantees

While FTA provides pre-award authority to incur expenses before grant award for formula programs, it recommends that first-time grant recipients NOT utilize this automatic pre-award authority without verifying with the appropriate FTA Regional Office that all pre-requisite requirements have been met. As a new grantee, it is easy to misunderstand pre-award authority conditions and be unaware of all of the applicable FTA requirements that must be met in order to be reimbursed for project expenditures incurred in advance of grant award. FTA programs have specific statutory requirements that are often different from those for other Federal grant programs with which new grantees may be familiar. If funds are expended for an ineligible project or activity, or for an eligible activity but at an inappropriate time (*e.g.*, prior to NEPA completion), FTA will be unable to reimburse the project sponsor and, in certain cases, the entire project may be rendered ineligible for FTA assistance.

2. Policy

FTA provides pre-award authority to incur expenses before grant award for certain program areas described below. This pre-award authority allows grantees to incur certain project costs before grant approval and retain the eligibility of those costs for subsequent reimbursement after grant approval. The grantee assumes all risk and is responsible for ensuring that all conditions are met to retain eligibility. This pre-award spending authority permits an eligible grantee to incur costs on an eligible transit capital, operating, planning, or administrative project without prejudice to possible future Federal participation in the cost of the project. In this notice, FTA provides pre-award authority through the authorization period of the FAST Act (October 1, 2015 through September 30, 2020) for capital assistance under all formula programs, so long as the conditions described below are met. FTA provides pre-award authority for planning and operating assistance under the formula programs without regard to the period of the authorization. All pre-award authority is subject to conditions and triggers stated below:

a. Operating, Planning, or Administrative Assistance

FTA does not impose additional conditions on pre-award authority for operating, planning, or administrative assistance under the formula grant programs. Grantees may be reimbursed for expenses incurred before grant award so long as funds have been expended in accordance with all Federal requirements, would have been allowable if incurred after the date of award, and the grantee is otherwise eligible to receive the funding. In addition to cross-cutting Federal grant requirements, program specific requirements must be met. For example, a planning project must have been included in a Unified Planning Work Program (UPWP); a section 5310 project must have been included in a coordinated public transit-human services transportation plan (coordinated plan) and selected by the designated recipient before incurring expenses; expenditures on State Administration expenses under State Administered programs must be consistent with the State Management Plan (as defined in FTA Circular 9040.1G, Chapter 6). Designated recipients for section 5310 have pre-award authority for the ten percent of the apportionment they may use for program administration.

b. Transit Capital Projects

For transit capital projects, the date that costs may be incurred varies depending on the type of activity and its potential to have a significant impact on the human and natural environment as described under conditions in section 3 below. Before an applicant may incur costs when pre-award authority has not been granted, it must first obtain a written Letter of No Prejudice (LONP) from FTA. To obtain an LONP, a grantee must submit a written request accompanied by adequate information and justification to the appropriate FTA regional office, as described in section 4 below.

c. Public Transportation Innovation, Technical Assistance and Workforce Development

Unless provided for in an announcement of project selections, pre-award authority does not apply to Public Transportation Innovation Public Transportation Innovation projects or section 5314 Technical Assistance and Workforce Development. Before an applicant may incur costs for activities under these programs, it must first obtain a written Letter of No Prejudice (LONP) from FTA. To obtain an LONP,

a grantee must submit a written request accompanied by adequate information and justification to the appropriate FTA headquarters office. Information about LONP procedures may be obtained from the appropriate headquarters office.

3. Conditions

The conditions under which pre-award authority may be utilized are specified below:

a. Pre-award authority is not a legal or implied commitment that the subject project will be approved for FTA assistance or that FTA will obligate Federal funds. Furthermore, it is not a legal or implied commitment that all items undertaken by the applicant will be eligible for inclusion in the project.

b. All FTA statutory, procedural, and contractual requirements must be met.

c. No action will be taken by the grantee that prejudices the legal and administrative findings that the Federal Transit Administration must make in order to approve a project.

d. Local funds expended by the grantee after the date of the pre-award authority will be eligible for credit toward local match or reimbursement if FTA later makes a grant or grant amendment for the project. Local funds expended by the grantee before the date of the pre-award authority will not be eligible for credit toward local match or reimbursement. Furthermore, the expenditure of local funds or the undertaking of certain activities that would compromise FTA's ability to comply with Federal environmental laws (e.g., project implementation activities such as land acquisition, demolition, or construction before the date of pre-award authority) may render the project ineligible for FTA funding.

e. The Federal amount of any future FTA assistance awarded to the grantee for the project will be determined on the basis of the overall scope of activities and the prevailing statutory provisions with respect to the Federal/local match ratio at the time the funds are obligated.

f. For funds to which the pre-award authority applies, the authority expires with the lapsing of the fiscal year funds.

g. When a grant for the project is subsequently awarded, the grant and the Federal Financial Report in TrAMS must indicate the use of pre-award authority.

h. Environmental Requirements.

All Federal environmental grant requirements must be met at the appropriate time for the project to remain eligible for Federal funding. Designated recipients may incur costs for design and environmental review activities for all projects from the date of the authorization of formula funds or

the date of the announcement of the competitive allocations of funds for the project. For projects that qualify for a categorical exclusion pursuant to 23 CFR 771.118(c), designated recipients may start activities and incur costs for property acquisition, demolition, construction, and acquisition of vehicles, equipment, or construction materials from the date of the authorization of formula funds or the date of the announcement of the competitive allocation of funds for the project. FTA recommends that a grant applicant considering a categorical exclusion pursuant to 23 CFR 771.118(c) contact FTA's Regional Office for assistance in determining the appropriate environmental review process and level of documentation necessary before incurring costs for property acquisition, demolition, construction, and acquisition of vehicles, equipment, or construction materials. If FTA subsequently finds that a project does not to qualify for this CE, it will be ineligible for FTA assistance. In particular, FTA encourages grant applicants to contact FTA's Regional Office before exercising pre-award authority for projects to which it believes a CE at 23 CFR 771.118(c)(8), (9), (10), (12), or (13) applies.

For all other projects that do not qualify for a categorical exclusion under 23 CFR 771.118(c), grant applicants may take action and incur costs for property acquisition, demolition, construction, and acquisition of vehicles, equipment, or construction materials from the date that FTA completes the environmental review process required by NEPA and its implementing regulations, 23 U.S.C. 139, and other environmental laws by its issuance of a section 771.118(d) categorical exclusion determination, a Finding of No Significant Impact (FONSI), or a Record of Decision (ROD).

i. Planning and other requirements.

Formula funds must be authorized or appropriated and earmarked project allocations published or announced before pre-award authority can be considered.

The requirement that a project be included in a locally-adopted Metropolitan Transportation Plan, the metropolitan transportation improvement program and federally-approved statewide transportation improvement program (23 CFR part 450) must be satisfied before the grantee may advance the project beyond planning and preliminary design with non-federal funds under pre-award authority. If the project is located within an EPA-designated non-attainment or maintenance area for air quality, the

conformity requirements of the Clean Air Act, 40 CFR part 93, must also be met before the project may be advanced into implementation-related activities under pre-award authority triggered by the completion of the NEPA process.

For a planning project to have pre-award authority, the planning project must be included in a MPO-approved Unified Planning Work Program (UPWP) that has been coordinated with the State.

j. Federal procurement procedures, as well as the whole range of applicable Federal requirements (e.g., Buy America, Davis-Bacon Act, and Disadvantaged Business Enterprise) must be followed for projects in which Federal funding will be sought in the future. Failure to follow any such requirements could make the project ineligible for Federal funding. In short, this increased administrative flexibility requires a grantee to make certain that no Federal requirements are circumvented through the use of pre-award authority.

k. All program specific requirements must be met. For example, projects under section 5310 must comply with specific program requirements, including coordinated planning. Before incurring costs, grantees are strongly encouraged to consult with the appropriate FTA Regional office regarding the eligibility of the project for future FTA funds and for questions on environmental requirements, or any other Federal requirements that must be met.

4. Pre-Award Authority for the Fixed Guideway Capital Investment Grant Program (New and Small Starts Projects and Core Capacity Projects)

Projects proposed for section 5309 Capital Investment Grant (CIG) program funds are required to follow a multi-step, multi-year process defined in law. For New Starts and Core Capacity projects, this process includes three phases: Project development (PD), engineering, and construction. For Small Starts projects, this process includes two phases: PD and construction. After receiving a letter from the project sponsor requesting entry into the PD phase, FTA must respond in writing within 45 days whether the information was sufficient for entry. If FTA's correspondence indicates the information was sufficient and the New Starts, Small Starts or Core Capacity project enters PD, FTA extends pre-award authority to the project sponsor to incur costs for PD activities. PD activities include the work necessary to complete the environmental review process and as much engineering and

design activities as the project sponsor believes are necessary to support the environmental review process. Upon completion of the environmental review process with a ROD, FONSI, or CE determination by FTA for a New Starts, Small Starts, or Core Capacity Improvement project, FTA extends pre-award authority to project sponsors to incur costs for as much engineering and design as needed to develop a reasonable cost estimate and financial plan for the project, utility relocation, and real property acquisition and associated relocations for any property acquisitions not already accomplished as a separate project for hardship or protective purposes or right-of-way under 49 U.S.C. 5323(q).

For Small Starts projects, upon completion of the environmental review process and confirmation from FTA that the overall project rating is at least a Medium, FTA extends pre-award authority for vehicle purchases. Upon receipt of a letter notifying a New Starts or Core Capacity project sponsor of the project's approval into the engineering phase, FTA extends pre-award authority for vehicle purchases as well as any remaining engineering and design, demolition, and procurement of long lead items for which market conditions play a significant role in the acquisition price. The long lead items include, but are not limited to, procurement of rails, ties, and other specialized equipment, and commodities.

Please contact the FTA Regional Office for a determination of activities not listed here, but which meet the intent described above. FTA provides this pre-award authority in recognition of the long-lead time and complexity involved with purchasing vehicles as well as their relationship to the "critical path" project schedule. FTA cautions grantees that do not currently operate the type of vehicle proposed in the project about exercising this pre-award authority. FTA encourages these sponsors to wait until later in the process when project plans are more fully developed. FTA reminds project sponsors that the procurement of vehicles must comply with all Federal requirements including, but not limited to, competitive procurement practices, the Americans with Disabilities Act, Disadvantaged Business Enterprise program requirements and Buy America. FTA encourages project sponsors to discuss the procurement of vehicles with FTA in regards to Federal requirements before exercising pre-award authority. Because there is not a formal engineering phase for Small Starts projects, FTA does not extend pre-award authority for demolition and

procurement of long lead items. Instead, this work must await receipt of a construction grant award or an expedited grant agreement.

a. Real Property Acquisition

As noticed above, FTA extends pre-award authority for the acquisition of real property and real property rights for fixed Guideway Capital Investment Grant projects (New or Small Starts or Core Capacity) upon completion of the environmental review process for that project. The environmental review process is completed when FTA signs an environmental Record of Decision (ROD) or Finding of No Significant Impact (FONSI), or makes a Categorical Exclusion (CE) determination. With the limitations and caveats described below, real estate acquisition may commence, at the project sponsor's risk. For FTA-assisted projects, any acquisition of real property or real property rights must be conducted in accordance with the requirements of the Uniform Relocation Assistance and Real Property Acquisition Policies Act (URA) and its implementing regulations, 49 CFR part 24. This pre-award authority is strictly limited to costs incurred: (i) To acquire real property and real property rights in accordance with the URA regulation; and (ii) to provide relocation assistance in accordance with the URA regulation. This pre-award authority is limited to the acquisition of real property and real property rights that are explicitly identified in the final environmental impact statement (FEIS), environmental assessment (EA), or CE document, as needed for the selected alternative that is the subject of the FTA-signed ROD or FONSI, or CE determination. This pre-award authority regarding property acquisition that is granted at the completion of the environmental review process does not cover site preparation, demolition, or any other activity that is not strictly necessary to comply with the URA, with one exception—namely when a building that has been acquired, has been emptied of its occupants, and awaits demolition poses a potential fire safety hazard or other hazard to the community in which it is located, or is susceptible to reoccupation by vagrants. Demolition of the building is also covered by this pre-award authority upon FTA's written agreement that the adverse condition exists. Pre-award authority for property acquisition is also provided when FTA makes a CE determination for a protective buy or hardship acquisition in accordance with 23 CFR 771.117(d)(12). Pre-award authority for property acquisition is also provided when FTA completes the environmental review process for the

acquisition of right-of-way as a separate project in accordance with 49 U.S.C. 5323(q). When a tiered environmental review in accordance with 23 CFR 771.111(g) is used, pre-award authority is NOT provided upon completion of the first tier environmental document except when the Tier-1 ROD or FONSI signed by FTA explicitly provides such pre-award authority for a particular identified acquisition. Project sponsors should use pre-award authority for real property acquisition relocation assistance with a clear understanding that it does not constitute a funding commitment by FTA. FTA provides pre-award authority upon completion of the environmental review process for real property acquisition and relocation assistance to maximize the time available to project sponsors to move people out of their homes and places of business, in accordance with the requirements of the URA, but also with maximum sensitivity to the circumstances of the people so affected.

b. Reimbursement of Costs Incurred Under Pre-Award Authority

Although FTA provides pre-award authority for property acquisition, long lead items, and vehicle purchases upon completion of the environmental review process, FTA will not make a grant to reimburse the sponsor for real estate activities, vehicle purchases or purchases of long lead items conducted under pre-award authority until the project receives its construction grant. This is to ensure that Federal funds are not risked on a project whose advancement into construction is not yet assured.

c. National Environmental Policy Act (NEPA) Activities

NEPA requires that major projects proposed for FTA funding assistance be subjected to a public and interagency review of the need for the project, its environmental and community impacts, and alternatives to avoid and reduce adverse impacts. Projects of more limited scope also need a level of environmental review, either to support an FTA finding of no significant impact (FONSI) or to demonstrate that the action is categorically excluded (*i.e.*, CE) from the more rigorous level of NEPA review. FTA's regulation titled "Environmental Impact and Related Procedures," at 23 CFR part 771 states that the costs incurred by a grant applicant for the preparation of environmental documents requested by FTA are eligible for FTA financial assistance (23 CFR 771.105(e)). Accordingly, FTA extends pre-award authority for costs incurred to comply

with NEPA regulations and to conduct NEPA-related activities, effective as of the earlier of the following two dates: (1) The date of the Federal approval of the relevant STIP or STIP amendment that includes the project or any phase of the project, or that includes a project grouping under 23 CFR 450.216(j) that includes the project; or (2) the date that FTA approves the project into the project development phase of the CIG program. The grant applicant must notify the FTA Regional Office to initiate the Federal environmental review process in accordance with the "Dear Colleague" letter from the FTA Administrator dated February 24, 2011. NEPA-related activities include, but are not limited to, public involvement activities, historic preservation reviews, section 4(f) evaluations, wetlands evaluations, endangered species consultations, and biological assessments. This pre-award authority is strictly limited to costs incurred to conduct the NEPA process and associated engineering, and to prepare environmental, historic preservation and related documents. When a New Starts, Small Starts, or Core Capacity project is granted pre-award authority for the environmental review process, the reimbursement for NEPA activities conducted under pre-award authority may be sought at any time through section 5307 (Urbanized Area Formula Program) or the flexible highway programs (STP and CMAQ). Reimbursement from the section 5309 CIG program for NEPA activities conducted under pre-award authority is provided only for expenses incurred after entry into the project development phase and only once a construction grant agreement is signed. As with any pre-award authority, FTA reimbursement for costs incurred is not guaranteed.

d. Other New and Small Starts and Core Capacity Project Activities Requiring Letter of No Prejudice (LONP)

Except as discussed in paragraphs i through iii above, a CIG project sponsor must obtain a written LONP from FTA before incurring costs for any activity not covered by pre-award authority. To obtain an LONP, an applicant must submit a written request accompanied by adequate information and justification to the appropriate FTA Regional Office, as described in B below.

B. Letter of No Prejudice (LONP) Policy

1. Policy

LONP authority allows an applicant to incur costs on a project utilizing non-

Federal resources, with the understanding that the costs incurred subsequent to the issuance of the LONP may be reimbursable as eligible expenses or eligible for credit toward the local match should FTA approve the project at a later date. LONPs are applicable to projects and project activities not covered by automatic pre-award authority. The majority of LONPs will be for section 5309 Capital Investment Grant program projects (New or Small Starts or Core Capacity) undertaking activities not covered under automatic pre-award authority. LONPs may be issued for formula and competitive funds beyond the life of the current authorization or FTA's extension of automatic pre-award authority; however, the LONP is limited to a five-year period, unless otherwise authorized in the LONP. Receipt of Federal funding under any program is not implied or guaranteed by an LONP.

2. Conditions and Federal Requirements

The conditions and requirements for pre-award authority specified in section V.4.ii and V.4.iii above apply to all LONPs. Because project implementation activities may not be initiated before completion of the environmental review process, FTA will not issue an LONP for such activities until the environmental review process has been completed with a ROD, FONSI, or CE determination.

3. Request for LONP

Before incurring costs for project activities not covered by automatic pre-award authority, the project sponsor must first submit a written request for an LONP, accompanied by adequate information and justification, to the appropriate regional office and obtain written approval from FTA. FTA approval of an LONP is determined on a case-by-case basis. Federal funding under the Fixed Guideway Capital Investment Grant program for a New Starts, Small Starts, or Core Capacity project is not implied or guaranteed by an LONP. Specifically, when requesting an LONP, the applicant shall provide the following items:

- a. Description of the activities to be covered by the LONP.
- b. Justification for advancing the identified activities. The justification should include an accurate assessment of the consequences to the project scope, schedule, and budget should the LONP not be approved.
- c. Allocated level of risk and contingency for the activity requested.

C. FY 2017 Annual List of Certifications and Assurances

The FY 2017 Certifications and Assurances and Master Agreement are currently available in TrAMS and must be used for all grants and cooperative agreements awarded in FY 2017. All recipients with active projects are required to sign the FY 2017 Certifications and Assurances within 90 days of publication. The FY 2017 Certifications and Assurances publication date of December 20, 2016.

D. Civil Rights Requirements

1. Equal Employment Opportunity (EEO)

The FTA Office of Civil Rights released an updated EEO Circular, FTA Circular 4704.1A, effective October 31, 2016. The Circular provides guidance to FTA grant recipients to carry out EEO requirements and prepare EEO Program Plans. The updated FTA EEO Circular is posted at <https://www.transit.dot.gov/regulations-and-guidance/civil-rights-ada/eo-circular>. Based on feedback received since publication of the Circular, FTA would like to provide clarification regarding the Circular.

First, State DOTs are subject to the same threshold requirements for FTA EEO Program submissions, located in Circular Section 1.4, Applicability, as other recipients. A State DOT must only submit a transit-related EEO Program if: (1) It employs 100 or more transit-related employees; and (2) requests or receives capital or operating assistance in excess of \$1 million in the previous Federal fiscal year, or requests or receives planning assistance in excess of \$250,000 in the previous Federal fiscal year. In accordance with a One DOT approach and pursuant to the forthcoming Memorandum of Understanding (MOU) with the Federal Highway Administration (FHWA), State DOTs must submit a single EEO Program to FHWA and FTA which will be jointly reviewed, monitored, and approved in accordance with FHWA and FTA regulations every four years. As part of the implementation of the MOU, FTA will be collecting all State DOT EEO Programs every four years via TrAMS. Therefore, a State DOT that does not meet the threshold requirements outlined in Circular Section 1.4 must still submit the FHWA-required EEO Program every four years to FTA, but will not be required to submit a transit-related EEO Program.

Second, we wish to clarify the threshold requirements for preparing and maintaining an abbreviated EEO Program, which is discussed in Circular Section 1.4. In the paragraph discussing

the requirements for agencies employing between 50–99 transit-related employees, FTA inadvertently did not include the monetary threshold that has been in place since at least 1988. Thus, an agency is required to prepare and maintain an abbreviated EEO Program only if: (1) It has between 50–99 transit-related employees; and (2) it requests or receives capital or operating assistance in excess of \$1 million in the previous Federal fiscal year, or requests or receives planning assistance in excess of \$250,000 in the previous Federal fiscal year. The inadvertent absence of the monetary threshold would require more agencies to prepare and maintain EEO Programs. Thus, reinstating the threshold reduces the burden on transit agencies and maintains the status quo.

Third, only direct recipients who cross the EEO Program threshold requirements in Circular Section 1.4, and State DOTs are required to prepare and/or submit an EEO Program to FTA. All subrecipients and contractors who cross the EEO Program threshold must submit EEO Programs to the entity from which they receive funds, generally the transit agency or the State DOT, as appropriate. This will allow State DOTs and transit agencies to determine and document that subrecipients and contractors comply with EEO statutes and regulations, in accordance with their monitoring responsibilities. FTA applicants, recipients, subrecipients, and contractors that do not meet the EEO Program threshold are not required to submit an EEO Program to FTA or to the entity from which they receive funds.

FTA will amend the pages of the Circular affected by the above clarifications and will post the updated Circular on FTA's Web site.

2. Title VI of the Civil Rights Act of 1964

The U.S. DOT's Title VI implementing regulations are found in 49 CFR part 21. FTA's Title VI Circular (4702.1B) provides guidance for carrying out the regulatory requirements. Recipients in urbanized areas of 200,000 or more in population and with 50 or more fixed-route vehicles in peak service must conduct a service or fare equity analysis for all service changes that meet the recipient's definition of "major service change" prior to implementing the service change. A service equity analysis is also required for all New Start, Small Start, or other new fixed guideway capital projects, and must be completed six months prior to implementing revenue service. Recipients also must conduct a fare equity analysis for all fare increases or

decreases prior to implementing a fare change. Recipients that do not meet the abovementioned threshold of 200,000 or more in population and 50 fixed route vehicles in peak service (*i.e.*, small transit providers) are not required to conduct a service or fare equity analysis but should review their policies and practices to ensure their service and fare changes do not result in disparate impacts on the basis of race, color, or national origin.

FTA would also like to stress the importance of public participation. Recipients must facilitate effective public engagement throughout all stages of the consultation, planning, and the decision-making process. Particular emphasis should be given to affected, and potentially affected, communities. FTA recommends that recipients anticipating service and fare changes review FTA Circular 4703.1, Environmental Justice Policy Guidance, Chapter III, Achieving Meaningful Public Engagement with Environmental Justice Populations, available at <https://www.transit.dot.gov/regulations-and-guidance/fta-circulars/environmental-justice-policy-guidance-federal-transit> for ideas on how to engage affected populations. Should you have any questions, please contact your Regional Civil Rights Officer.

E. Consolidated Planning Grants

FTA and FHWA planning funds under both the Metropolitan Planning and State Planning and Research Programs can be consolidated into a single consolidated planning grant, awarded by either FTA or FHWA. The CPG eliminates the need to monitor individual fund sources, if several have been used, and ensures that the oldest funds will always be used first.

Under the CPG, States can report metropolitan planning program expenditures (to comply with the Single Audit Act) for both FTA and FHWA under the Catalogue of Federal Domestic Assistance number for FTA's Metropolitan Planning Program (20.505). Additionally, for States with an FHWA Metropolitan Planning (PL) fund-matching ratio greater than 80 percent, the State can waive the 20 percent local share requirement, with FTA's concurrence, to allow FTA funds used for metropolitan planning in a CPG to be granted at the higher FHWA rate. For some States, this Federal match rate can exceed 90 percent.

States interested in transferring planning funds between FTA and FHWA should contact the FTA Regional Office or FHWA Division Office for more detailed procedures. Current guidelines are included in Federal

Highway Administration Memorandum dated July 12, 2007, "Information: Final Transfers to Other Agencies that Administer Title 23 Programs." For further information on CPGs, contact Ann Souvandra, Office of Budget and Policy, FTA, at (202)366-0649.

F. Grant Application Procedures

All applications for FTA funds should be submitted to the appropriate FTA Regional Office. All applications are filed electronically. FTA continues to award and manage grants and cooperative agreements using the Transit Award Management System (TrAMS) which re-opened for financial activity on November 1, 2016. Information on accessing and using TrAMS, including a list of FTA points of contact for the system, can be found on FTA's Web site at <http://www.transit.dot.gov/TrAMS>.

FTA regional staff is responsible for working with grantees to review and process grant applications. In order for an application to be considered complete and for FTA to assign a Federal Award Identification Number (FAIN), enabling submission in TrAMS, and submission to the Department of Labor (when applicable), the following requirements must be met:

1. Recipient has registered in the System for Award Management (SAM) and its registration is current. If your agency is not registered or needs to ensure it is current, visit the SAM Web site at (<https://www.sam.gov>).

2. Recipient's contact information, including Dun and Bradstreet Data Universal Numbering System (DUNS), is correct and up-to-date. If requested by phone (1-866-705-5711), DUNS is provided immediately. If your organization does not have a DUNS, you will need to go to the Dun & Bradstreet Web site at <http://fedgov.dnb.com/webform> to obtain the number.

3. Recipient has properly submitted its annual certifications and assurances.

4. Recipient's Civil Rights submissions are current.

5. Documentation is on file to support recipient's status as either a designated recipient (for the program and area) or a direct recipient.

6. Funding is available, including any flexible funds included in the budget, and split letters or suballocation letters on file (where applicable) to support amount being applied for in grant application.

7. The project is listed in a currently approved Transportation Improvement Program (TIP); Statewide Transportation Improvement Program (STIP), or Unified Planning Work Program (UPWP).

8. All eligibility issues are resolved.
9. Required environmental findings are made.

10. The application contains a well-defined scope of work including at least one project with accompanying project narratives, budget scope and activity line item information, Federal and non-Federal funding amounts, and milestones.

11. Major Capital Projects as defined by 49 CFR part 633 "Project Management Oversight" must document FTA has reviewed the project management plan and provided approval.

12. Milestone information is complete, or FTA determines that milestone information can be finalized before the grant is ready for award. FTA will also review status of other open grants' reports to confirm financial and milestone information is current on other open grants and projects.

Before FTA can award grants for competitive projects and activities, notification must be provided to the House and Senate authorizing and appropriations committees.

Other important issues that impact FTA grant processing activities are discussed below.

a. System for Award Management (SAM) Registration and Dun and Bradstreet Universal Numbering System (DUNS) Number

Each applicant or recipient of Federal Funds is required to: (1) Be registered in SAM before submitting its application; (2) provide a valid DUNS number in its application; and (3) continue to maintain an active SAM registration with current information at all times during which it has an active award or an application or plan under consideration by the Federal Transit Administration (FTA). FTA will not make an award to an applicant until the applicant has complied with all applicable DUNS and SAM requirements and, if an applicant has not fully complied with the requirements by the time the FTA is ready to make a Federal award, FTA may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

The System for Award Management (SAM) <https://www.sam.gov/portal/SAM/> is the Official U.S. Government system that consolidated the capabilities of many systems. There is no fee to register or use this site. Entities may register and update their information at no cost directly from the above site. SAM registration (formerly CCR

registration) needs to be renewed at least annually.

b. Award Budgets—Scope Codes and Activity Line Items (ALI) Codes; Financial Purpose Codes

FTA uses the Scope and Activity Line Item (ALI) Codes in the award budgets to track disbursements, monitor program trends, report to Congress, and to respond to requests from the Inspector General and the Government Accountability Office (GAO), as well as to manage grants. The accuracy of the data is dependent on the careful and correct use of codes.

c. Designated and Direct Recipients Documentation

For its formula programs, FTA primarily apportions funds to the designated recipient in the large UZAs (areas over 200,000), or for areas under 200,000 (small UZAs and rural areas), it apportions the funds to the Governor, or its designee (e.g., State DOT). Depending on the program and as described in the individual program sections found in Section IV of this notice, further suballocation of funds may be permitted to eligible recipients who can then apply directly to FTA for the funding (direct recipients), so long as the required documentation is on file.

For the programs in which FTA can make grants to eligible direct recipients, other than the designated recipient(s), recipients are reminded that documentation must be on file to support the: (1) Status of the recipient either as a designated recipient or direct recipient; and (2) the allocation of funds to the direct recipient.

Documentation to support existing designated recipients for the UZA must also be on file at the time of the first application in FY 2017. Further, split letters and/or suballocation letters (Governor's Apportionment letters), must also be on file to support grant applications from direct recipients. Once suballocation letters for FY 2017 funding are finalized they should also be uploaded into TrAMS.

The Direct Recipient is required to upload to TrAMS a copy of the Designated Recipient letter indicating their allocation of funding [for the appropriate fund program] when the applicant transmits their application for initial review. The letter must be signed by the Designated Recipient, or as applicable in accordance with their planning requirements. If there are two Designated Recipients, both entities must sign the Letter. The Letter must: (1) Indicate the allocations to the respective Direct Recipients listed in the letter; (2) incorporate language above

the signatories to reflect this agreement; and (3) make clear that the Direct Recipient will assume any/all responsibility associated with the award for the funds. When drafting the letter, Designated Recipients may use the template language below:

"As identified in this Letter, the Designated Recipient(s) authorize the reassignment/reallocation of [enter fund source; e.g. Section 5307 funds] to the Direct Recipient(s) named herein. The undersigned agree to the amounts allocated/reassigned to each direct Recipient. Each Direct Recipient is responsible for its application to the Federal Transit Administration to receive such funds and assumes the responsibilities associated with any award for these funds."

2. Payments

Once a grant has been awarded and executed, requests for payment can be processed. To process payments, FTA uses ECHO-Web, an Internet accessible system that provides grantees the capability to submit payment requests on-line, as well as receive user-IDs and passwords via email. New applicants should contact the appropriate FTA Regional Office to obtain and submit the registration package necessary for set-up under ECHO-Web.

3. Oversight

FTA is responsible for conducting oversight activities to help ensure that grants recipients use FTA Federal financial assistance in a manner consistent with their intended purpose and in compliance with regulatory and statutory requirements. FTA conducts periodic oversight reviews to assess grantee compliance with applicable Federal requirements. Each Urbanized Area Formula Program recipient is reviewed every three years, (also known as FTA's Triennial Review); and States and state-wide public transportation agencies are reviewed periodically to assess the management practices and program implementation of FTA state-wide programs (e.g., Planning, Rural Areas, Enhanced Mobility of Seniors and Individuals with Disabilities Programs). Other more detailed reviews are scheduled based on an annual grantee oversight assessment. Important objectives of FTA's oversight program include, but are not limited to: Determining grantee compliance with Federal requirements; identifying technical assistance needs, and delivering technical assistance to meet those needs; spotting emerging issues with grantees in a forward-looking fashion; recognizing when there is a need for more in-depth reviews in the

areas of procurement, financial management, and civil rights; and identifying grantees with recurring or systemic issues.

4. Technical Assistance

As noted throughout the notice, FTA continues to rely on several of the existing program circulars for general program guidance. FTA is continuing to update the program circulars, with an opportunity for notice and comment (where warranted), to reflect amendments to chapter 53 of title 49, U.S.C. made by the FAST Act. In the meantime, if you have any questions, please do not hesitate to contact FTA. FTA headquarters and regional staff will be pleased to answer your questions and provide any technical assistance you may need to apply for FTA program funds and manage the grants you receive. At its discretion, FTA may also use program oversight consultants to provide technical assistance to grantees on a case by case basis. This notice and the program guidance circulars previously identified in this document may be accessed via the FTA Web site at www.fta.dot.gov

G. Grant Management

1. Grant Reporting

Recipients of FTA funds are reminded that all FTA grantees are required to report on their grants and it is critical to ensure reports demonstrate that reasonable progress is being made on the project. At a minimum, all awards require a Federal Financial Report (FFR) and a Milestone Progress Report (MPR) on an annual basis, with some reports required quarterly depending on the recipient and the type of projects funded under the grant. The requirements for these reports and other reporting requirements can be found in the latest version of FTA Circular 5010. FTA staff, auditors, and contractors rely on the information provided in the FFR and MPR to review and report on the status of both financial and project-level activities contained in the grant. It is critical that recipients provide accurate and complete information in these reports and submit them by the required due date. Failure to report and/or demonstrate reasonable progress on projects can result in suspension or premature close-out of a grant.

2. Inactive Grants and Grant Closeout

In FY 2017, FTA will continue to focus on identifying and working with recipients to close inactive grants. If appropriate, FTA will take action to close out and deobligate funds from these grants if reasonable progress is not

made. The efficient use of funds will further FTA's fulfillment of its mission to provide efficient and effective public transportation systems for the nation. As inactive grants continue to be an audit finding within the DOT, FTA must take action to ensure its grants do not impact the DOT from receiving a "clean audit" opinion on its annual financial statements.

In October 2016, FTA identified a list of grants that were awarded on or prior to September 30, 2013 and have had no funds disbursed since September 30, 2015 or have never had a disbursement. FTA Regional Offices will be contacting grant recipients with grants that meet this criteria to notify them that FTA intends to close the grant and deobligate any remaining funds unless the grantee can provide information that demonstrates that the projects funded by the grant remain active and the grantee has a realistic schedule to expedite completion of the projects funded in the grant.

Matthew Welbes,
Executive Director.

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BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

FY 2017 Competitive Funding Opportunity: Public Transportation on Indian Reservations Program; Tribal Transit Program

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice of Funding Opportunity (NOFO).

SUMMARY: The Federal Transit Administration (FTA) announces the availability of approximately \$5 million in funding provided by the Public Transportation on Indian Reservations Program (Tribal Transit Program), as authorized by Federal Transit law 49 U.S.C. 5311(c)(1)(A), as amended by the Fixing America's Surface Transportation (FAST) Act, Public Law 114-94 (December 4, 2015), contingent on full appropriations. This notice is a national solicitation for project proposals and includes the selection criteria and program eligibility information for FY 2017 projects. FTA may fund the program for more or less than the full year appropriation when made available, and may include other funding toward project proposals received in response to this Notice of Funding Opportunity (NOFO).

This announcement is available on the FTA Web site at:

www.transit.dot.gov/funding/grants/grant-programs/public-transportation-indian-reservations-program-tribal-transit-fy-2017. Additionally, a synopsis of the funding opportunity, FTA-2017-002-TPM, will be posted in the FIND module of the government-wide electronic grants Web site at <http://www.grants.gov>. The program can be located in the Catalog of Federal Domestic Assistance (CFDA) under 20.509.

DATES: Complete proposals for the Tribal Transit Program announced in this Notice must be submitted by 11:59 p.m. EDT on March 20, 2017. All proposals must be submitted electronically through the **GRANTS.GOV APPLY** function. Any applicant intending to apply should initiate the process of registering on the **GRANTS.GOV** site immediately to ensure completion of registration before the submission deadline. Instructions for applying can be found on FTA's Web site at www.transit.dot.gov/funding/grants/notices and in the "FIND" module of **GRANTS.GOV**. Mail and fax submissions will not be accepted.

FOR FURTHER INFORMATION CONTACT:

Contact the appropriate FTA Regional Office at www.transit.dot.gov/about/regional-offices/regional-offices for proposal-specific information and issues. For general program information, contact Élan Flippin, Office of Program Management, (202) 366-3800, email: elan.flippin@dot.gov. A TDD is available at 1-800-877-8339 (TDD/FIRS).

SUPPLEMENTARY INFORMATION:

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B. Federal Award Information
C. Eligibility Information
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Appendix A: Registering in SAM and Grants.gov

A. Program Description

The Tribal Transit Program (TTP) was established by the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU) as a competitive program from FY 2006 & FY 2012. The Moving Ahead for Progress in the 21st Century (MAP-21) Act modified the program to include a \$25 million formula component and a \$5 million competitive program, totaling \$30 million. The FAST Act increased the Tribal Transit Formula Program to \$30 million and continued the \$5 million competitive program found at

49 U.S.C. 5311(c)(1). The program authorizes grants “under such terms and conditions as may be established by the Secretary” to Indian tribes for any purpose eligible under FTA’s Formula Grants for Rural Areas Program, 49 U.S.C. 5311. Tribes may apply for this funding directly.

The primary purpose of these competitively selected grants is to support planning, capital, and, in limited circumstances, operating assistance for tribal public transit services. Funds distributed to Indian tribes under the TTP should NOT replace or reduce funds that Indian tribes receive from States through FTA’s Formula Grants for Rural Areas Program. Specific project eligibility under this competitive allocation is described in Section C below.

B. Federal Award Information

Five million dollars is authorized for the Tribal Transit competitive allocation in FY 2017 subject to enactment of funds to projects selected pursuant to the process described in the following sections. Federal awards under this competitive program will be in the form of grants. Additionally, there is a cap on planning grant awards at \$25,000, and FTA has the discretion to cap capital and operating awards as well.

C. Eligibility Information

1. Eligible Applicants

Eligible applicants include federally recognized Indian tribes or Alaska Native villages, groups, or communities as identified by the U.S. Department of Interior (DOI) Bureau of Indian Affairs (BIA). As evidence of Federal recognition, an Indian tribe may submit a copy of the most up-to-date **Federal Register** Notice published by BIA: Entities Recognized and Eligible to Receive Service from the United States Bureau of Indian Affairs (81 FR 5019, January 29, 2016). To be an eligible recipient, an Indian tribe must have the requisite legal, financial and technical capabilities to receive and administer Federal funds under this program. Additionally, applicants must be located and provide service in a rural area with a population of 50,000 or less. A service area can include some portions of urban areas, as long as the tribal transit service begins in and serves rural areas. Any applicant must be registered in the System for Award Management (SAM) database and maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by FTA.

2. Cost Sharing or Matching

There is a 90 percent federal share for projects selected under the TTP competitive program, unless the Indian tribe can demonstrate a financial hardship in its application. FTA is interested in the Indian tribe’s financial commitment to the proposed project, thus the proposal should include a description of the Indian tribe’s financial commitment. Tribes may use any eligible local match under Chapter 53.

3. Eligible Projects

Eligible projects include public transportation planning and capital expenses. Operating projects are eligible in limited circumstances as, in FY 2017, FTA will only consider operating assistance requests from tribes without existing transit service, or those tribes who received a TTP formula allocation of less than \$20,000.

Public transportation includes regular, continuing shared-ride surface transportation services open to the public or open to a segment of the public defined by age, disability, or low income. Projects exclusive to an urbanized area, as defined by the Census Bureau, are not eligible. FTA will award grants to eligible Indian tribes located in rural areas. Applicants may submit one proposal for each project or one proposal containing multiple projects. Specific types of projects include: Capital projects for start-ups, replacement or expansion needs; operating assistance for start-ups; and planning projects up to \$25,000. Indian tribes applying for capital replacement or expansion needs must demonstrate a sustainable source of operating funds for existing or expanded services.

D. Application and Submission Information

1. Address To Request Application Package

A complete proposal submission will consist of at least two files: (1) The SF 424 Mandatory form (downloaded from [GRANTS.GOV](http://www.GRANTS.GOV)); and (2) the Tribal Transit supplemental form found on the FTA Web site at www.transit.dot.gov/funding/grants/tribal-transit-2017-supplemental-form. The Tribal Transit supplemental form provides guidance and a consistent format for applicants to respond to the criteria outlined in this NOFO.

2. Content and Form of Application Submission

(i) Proposal Submission

A complete proposal submission will consist of at least two files: (1) The SF 424 Mandatory form (downloaded from [GRANTS.GOV](http://www.GRANTS.GOV)); and (2) the Tribal Transit supplemental form found on the FTA Web site at www.transit.dot.gov/funding/grants/tribal-transit-2017-supplemental-form. The applicant must place the supplemental form in the attachments section of the SF-424 Mandatory form. Applicants must use the supplemental form designated for TTP and attach the form to their submission in [GRANTS.GOV](http://www.GRANTS.GOV) to complete the application process. A proposal submission may contain additional supporting documentation as attachments. Within 24 to 48 hours after submitting an electronic application, the applicant should receive three email messages from [GRANTS.GOV](http://www.GRANTS.GOV): (1) Confirmation of successful transmission to [GRANTS.GOV](http://www.GRANTS.GOV); (2) confirmation of successful validation by [GRANTS.GOV](http://www.GRANTS.GOV); and (3) confirmation of successful validation by FTA. If the applicant does not receive confirmations of successful validation or instead receives a notice of failed validation or incomplete materials, the applicant must address the reason for the failed validation or incomplete materials, as described in the notice, and resubmit the proposal before the submission deadline. If making a resubmission for any reason, the applicant must include all original attachments regardless of which attachments were updated and check the box on the supplemental form indicating this is a resubmission. Complete instructions on the application process can be found at <https://www.transit.dot.gov/funding/grants/notices>.

Important: FTA urges applicants to submit their project proposals at least 72 hours prior to the due date to allow time to receive the validation message and to correct any problems that may have caused a rejection notification. FTA will not accept submissions after the stated submission deadline. [GRANTS.GOV](http://www.GRANTS.GOV) scheduled maintenance and outage times are announced on the [GRANTS.GOV](http://www.GRANTS.GOV) Web site <http://www.GRANTS.GOV>. The deadline will not be extended due to scheduled maintenance or outages.

Applicants are encouraged to begin the process of registration on the [GRANTS.GOV](http://www.GRANTS.GOV) site well in advance of the submission deadline. Registration is a multi-step process which may take several weeks to complete before an application can be submitted. Registered

proposers may still be required to take steps to keep their registration up to date before submissions can be made successfully: (1) Registration in the SAM is renewed annually; and (2) persons making submissions on behalf of the Authorized Organization Representative (AOR) must be authorized in *GRANTS.GOV* by the AOR to make submissions. Instructions on the *GRANTS.GOV* registration process are provided in the Appendix.

Applicants may submit one proposal for each project or one proposal containing multiple projects. Applicants submitting multiple projects in one proposal must be sure to clearly define each project by completing a supplemental form for each project. Additional supplemental forms must be added within the proposal by clicking the "add project" button in Section II of the supplemental form.

Information such as applicant name, Federal amount requested, description of areas served, and other information may be requested in varying degrees of detail on both the SF 424 form and supplemental form. Applicants must fill in all fields unless stated otherwise on the forms. Applicants should use both the "Check Package for Errors" and the "Validate Form" validation buttons on both forms to check all required fields on the forms, and ensure that the Federal and local amounts specified are consistent.

(ii) Application Content

The SF424 Mandatory Form and the Supplemental Form will prompt applicants for the required information, including:

- a. Name of federally recognized tribe and, if appropriate, the specific tribal agency submitting the application.
- b. Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number if available. (Note: If selected, applicant will be required to provide DUNS number prior to grant award).
- c. Contact information including: Contact name, title, address, fax and phone number, email address if available.
- d. Description of existing public transportation services including areas currently served by the tribe, if any.
- e. Name of person(s) authorized to apply on applicant's behalf must accompany the proposal (attach a signed transmittal letter).

f. Complete Project Description: Indicate the category for which funding is requested (*i.e.*, project type: Capital, operating or planning), and then indicate the project purpose (*i.e.*, start-up, expansion or replacement). Describe the proposed project and what

it will accomplish (*e.g.*, number and type of vehicles, routes, service area, schedules, type of services, fixed route or demand responsive, safety aspects), route miles (if fixed route), ridership numbers expected (actual if an existing system, estimated if a new system), major origins and destinations, population served, and whether the tribe provides the service directly, contracts for services, and note vehicle maintenance plans.

g. Project Timeline:

Include significant milestones such as date of contract for purchase of vehicle(s), actual or expected delivery date of vehicles; facility project phases (*e.g.* NEPA compliance, design, construction); or dates for completion of planning studies. If applying for operational funding for new services, indicate the period of time funds are used to operate the system (*e.g.* one year). This section should also include any needed timelines for tribal council project approvals, if applicable.

h. Budget:

Provide a detailed budget for each proposed purpose noting the Federal amount requested and any additional funds that will be used. An Indian tribe may use up to fifteen percent of a grant award for capital projects for specific project-related planning and administration, and the indirect costs rate may not exceed ten percent (if necessary add as an attachment) of the total amount requested/awarded. Indian tribes must also provide their annual operating budget as an attachment or under the *Financial Commitment and Operating Capacity* of the supplemental form.

i. Technical, Legal, Financial Capacity: Applicants must be able to demonstrate adequate technical, legal and financial capacity to be considered for funding. Every proposal MUST describe this capacity to implement the proposed project.

1. Technical Capacity: Provide examples of management of other Federal projects, including previously funded FTA projects and/or similar types of projects for which funding is being requested. Describe the resources available to implement the proposed transit project.

2. Legal Capacity: Provide documentation or other evidence to demonstrate status as a federally recognized Indian tribe. Further, demonstrate evidence of an authorized representative with authority bind the applicant and execute legal agreements with FTA. If applying for capital or operating funds, identify whether appropriate Federal or State operating authority exists.

3. Financial Capacity: Provide documentation or other evidence demonstrating current adequate financial systems to receive and manage a Federal grant. Fully describe: (1) All financial systems and controls; (2) other sources of funds currently managed; and (3) the long-term financial capacity to maintain the proposed or existing transit services.

3. Unique Entity Identifier and System for Award Management (SAM)

Each applicant is required to: (1) Be registered in SAM before submitting an application; (2) provide a valid unique entity identifier in its application; and (3) continue to maintain an active SAM registration with current information at all times during which the applicant has an active Federal award or an application or plan under consideration by FTA. These requirements do not apply if the applicant: (1) Is an individual; (2) is excepted from the requirements under 2 CFR 25.110(b) or (c); or (3) has an exception approved by FTA under 2 CFR 25.110(d). FTA may not make an Award until the applicant has complied with all applicable unique entity identifier and SAM requirements. If an applicant has not fully complied with the requirements by the time FTA is ready to make an Award, FTA may determine that the applicant is not qualified to receive an Award and use that determination as a basis for making a Federal award to another applicant. SAM registration takes approximately three to five business days, but FTA recommends allowing ample time, up to several weeks, for completion of all steps.

Step 1: Obtain DUNS Number

Same day. If requested by phone (1-866-705-5711) DUNS is provided immediately. If your organization does not have one, you will need to go to the Dun & Bradstreet Web site at <http://fedgov.dnb.com/webform> to obtain the number.

Step 2: Register With SAM

Three to five business days or up to two weeks. If you already have a Taxpayer Identification Number (TIN), your SAM registration will take three to five business days to process. If you are applying for an Employer Identification Number (EIN) please allow up to two weeks. Ensure that your organization is registered with the System for Award Management (SAM) at <https://www.sam.gov>. If your organization is not, an authorizing official of your organization must register.

Step 3: Establish an Account in *Grants.gov*—Username & Password

Same day. Complete your Authorized Organization Representative (AOR) profile on *Grants.gov* and create your username and password. You will need to use your organization's DUNS Number to complete this step. <https://apply07.grants.gov/apply/OrcRegister>.

Step 4: *Grants.gov*—AOR Authorization

* Same day. The E-Business Point of Contact (E-Biz POC) at your organization must login to *Grants.gov* to confirm an Authorized Organization Representative (AOR). Please note that there can be more than one AOR for your organization. In some cases the E-Biz POC is also the AOR for an organization. *Time depends on responsiveness of your E-Biz POC.

Step 5: Track AOR Status

At any time, you can track your AOR status by logging in with your username and password. Login as an Applicant (enter your username & password you obtained in Step 3) using the following link: [applicant_profile.jsp](#).

4. Submission Dates and Times

Project proposals must be submitted electronically through *GRANTS.GOV* by March 20, 2017. Mail and fax submissions will not be accepted. Proposals submitted after the deadline will not be considered under any circumstance. Applications are time and date stamped by the Discretionary Grants System (DGS) upon successful submission.

5. Funding Restrictions

Funds must be used only for the specific purposes requested in the application. Funds under this NOFO cannot be used to reimburse projects for otherwise eligible expenses incurred prior to FTA award.

6. Other Submission Requirements

FTA requires that all project proposals be submitted electronically through <http://www.GRANTS.GOV> by 11:59 p.m. EDT on March 20, 2017. Mail and fax submissions will not be accepted.

E. Application Review

1. Selection Criteria

FTA will use the following primary selection criteria when evaluating competing capital and operating assistance projects eligible under this program. Applications will be evaluated based on the quality and extent to which the following evaluation criteria are addressed.

i. Planning and Local/Regional Prioritization

Applications will be evaluated based on the degree to which the applicant: (1) Describes how the proposed project was developed; (2) demonstrates that a sound basis for the project exists; and (3) demonstrates that the applicant is ready to implement the project if funded. Information may vary depending upon how the planning process for the project was conducted and what is being requested. Planning and local/regional prioritization should:

a. Describe the planning document and/or the planning process conducted to identify the proposed project;

b. Provide a detailed project description including the proposed service, vehicle and facility needs, and other pertinent characteristics of the proposed or existing service implementation;

c. Identify existing transportation services in and near the proposed service area, and document in detail whether the proposed project will provide opportunities to coordinate service with existing transit services, including human service agencies, intercity bus services, or other public transit providers;

d. Discuss the level of support by the community and/or tribal government for the proposed project;

e. Describe how the mobility and client-access needs of tribal human service agencies were considered in the planning process;

f. Describe what opportunities for public participation were provided in the planning process and how the proposed transit service or existing service has been coordinated with transportation provided for the clients of human service agencies, with intercity bus transportation in the area, or with any other rural public transit providers;

g. Describe how the proposed service complements rather than duplicates any currently available services;

h. Describe the implementation schedule for the proposed project, including time period, staffing, and procurement; and

i. Describe any other planning or coordination efforts not mentioned above.

ii. Project Readiness: Applications will be evaluated on the degree to which the applicant describes readiness to implement the project. The project readiness factor involves assessing whether:

a. Project is a Categorical Exclusion (CE) or the required environmental work has been initiated or completed for

construction projects requiring an Environmental Assessment (EA) or Environmental Impact Statement (EIS) under, among others, the National Environmental Policy Act of 1969, as Amended;

b. Project implementation plans are complete, including initial design of facilities Projects;

c. Project funds can be obligated and the project can be implemented quickly, if selected; and

d. Applicant demonstrates the ability to carry out the proposed project successfully.

iii. Demonstration of Need

Applications will be evaluated based on the degree to which the applicant identifies the need for transit for resources. In addition to project-specific criteria, FTA will consider the project's impact on service delivery and whether the project represents a one-time or periodic need that cannot reasonably be funded from the FTA program formula allocations or State and/or local resources. FTA will evaluate how the proposal demonstrates the transit needs of the Indian tribe as well as how the proposed transit improvements or the new service will address identified transit needs. Proposals should include information such as destinations and services not currently accessible by transit, needs for access to jobs or health care, safety enhancements or special needs of elders, individuals with disabilities, behavioral health care needs of youth, income-based community needs, or other mobility needs. If an applicant received a planning grant in previous fiscal years, it should indicate the status of the planning study and how the proposed project relates to that study.

Applicants applying for capital expansion or replacement projects should also address the following factors in their proposal. If the proposal is for capital funding associated with an expansion or expanded service, the applicant should describe how current or growing demand for the service necessitates the expansion (and therefore, more capital) and/or the degree to how the project is addressing a current capacity constraint. Capital replacement projects should include information about the age, condition, and performance of the asset to be replaced by the proposed project and/or how the replacement may be necessary to maintain the transit system in a state of good repair.

iv. Demonstration of Benefits

Applications will be evaluated based on the degree to which the applicant

identifies expected or, in the case of existing service, achieved/project benefits. FTA is particularly interested in how these investments will improve the quality of life for the tribe and surrounding communities in which it is located. Applicants should describe how the transportation service or capital investment will provide greater access to employment opportunities, educational centers, healthcare, or other needs that profoundly impact the quality of life for the community, as described in the program purpose above. Possible examples include increased or sustained ridership and daily trips, improved service, elimination of gaps in service, improved operations and coordination, increased reliability, health care, education, and economic benefits to the community. Benefits can be demonstrated by identifying the population of tribal members and non-tribal members in the proposed project service area and estimating the number of daily one-way trips the proposed transit service will provide or the actual number of individual riders served. Applicants are encouraged to consider qualitative and quantitative benefits to the Indian tribe and to the surrounding communities that are meaningful to them.

Based on the information provided under the demonstration of benefits, FTA will rate proposals based on the quality and extent to which they discuss the following four factors:

- a. The project's ability to improve transit efficiency or increase ridership;
- b. Whether the project will improve or maintain mobility, or eliminate gaps in service for the Indian tribe;
- c. Whether the project will improve or maintain access to important destinations and services;
- d. Any other qualitative benefits, such as greater access to jobs, education and health care.

v. Financial Commitment and Operating Capacity

Applications must identify the source of local match (ten percent is required for all operating and capital projects), and any other funding sources used by the Indian tribe to support proposed transit services, including human service transportation funding, FHWA's Tribal Transportation Program funding, or other FTA programs. If requesting that FTA waive the local match based on financial hardship, the applicant must submit budgets and sources of other revenue to demonstrate hardship. FTA will review this information and notify tribes at the time of award if the waiver is approved. If applicable, the applicant also should describe how

prior year TTP funds were spent to date to support the service. Additionally, Indian tribes applying for operating of new services should provide a sustainable funding plan that demonstrates how it intends to maintain operations.

In evaluating proposals, FTA will consider any other resources the Indian tribe will contribute to the project, including in-kind contributions, commitments of support from local businesses, donations of land or equipment, and human resources. The proposal should describe to what extent the new project or funding for existing service leverages other funding. Based upon the information provided, the proposals will be rated on the extent to which the proposal demonstrates that:

- a. TTP Funding does not replace existing funding;
- b. The Indian tribe will provide non-financial support to the project;
- c. The Indian tribe is able to demonstrate a sustainable funding plan; and
- d. Project funds are used in coordination with other services for efficient utilization of funds.

vi. Evaluation Criteria for Planning Proposals

For planning grants, the proposal must describe the need for and a general scope of the proposed study. Applications will be evaluated based on the degree to which the applicant addresses the following:

1. The tribes' long-term commitment to transit; and
2. The method used to implement the proposed study and/or further tribal transit.

2. Review and Selection Process

A technical evaluation committee will review proposals under the project evaluation criteria. Members of the technical evaluation committee and other involved FTA staff reserve the right to screen, rate the applications, and seek clarification about any statement in an application. After consideration of the findings of the technical evaluation committee, the FTA Administrator will determine the final selection and amount of funding for each project. Geographic diversity and the applicant's receipt and management of other Federal transit funds may be considered in FTA's award decisions. FTA expects to announce the selected projects and notify successful applicants in the spring of 2017.

F. Federal Award Administration

1. Federal Award Notice

Subsequent to an announcement by the FTA Administrator of the final project selections posted on the FTA Web site, FTA will publish a list of the selected projects, including Federal dollar amounts and recipients in the **Federal Register**. Project recipients should contact their FTA Regional Offices and tribal liaison for information about setting up grants in FTA's Transit Award Management System (TrAMS).

2. Award Administration

Successful proposals will be awarded through TrAMS as Grant Agreements. The appropriate FTA Regional Office and tribal liaison will manage project agreements.

3. Administrative and National Policy Requirements

Except as otherwise provided in this NOFO, TTP grants are subject to the requirements of 49 U.S.C. 5311(c)(1) as described in the latest FTA Circular 9040.1G for the Formula Grants for Rural Areas Program.

4. Reporting

The post award reporting requirements include submission of the Federal Financial Report (FFR) and Milestone Progress Report in TrAMS, and National Transit Database (NTD) reporting as appropriate (see FTA Circular 9040.1G). Reports to TrAMS and NTD are due annually.

G. Federal Awarding Agency Contacts

For further information concerning this notice, please contact Élan Flippin, Office of Program Management, (202) 366-3800, email: elan.flippin@dot.gov. A TDD is available at 1-800-877-8339 (TDD/FIRS).

H. Other Information

This program is not subject to Executive Order 12372, "Intergovernmental Review of Federal Programs." FTA will consider applications for funding only from eligible recipients for eligible projects listed in Section C-2. Due to funding limitations, applicants that are selected for funding may receive less than the amount requested.

Additionally, to assist tribes with understanding requirements under the TTP, FTA has conducted Tribal Transit Technical Assistance Workshops, and will continue those efforts in FY2017. FTA also has expanded its technical assistance to tribes receiving funds under this program. Additionally, through the Tribal Transit Technical

Assistance Assessments Initiative, FTA collaborates with Tribal Transit Leaders to review processes and identify areas in need of improvement and then assists to offer solutions to address these needs—all in a supportive and mutually beneficial manner that results in technical assistance. FTA has completed thirty assessments to date, and expects to do fifteen assessments in FY17. These assessments include discussions of compliance areas pursuant to the Master Agreement, a site visit, promising practices reviews, and technical assistance from FTA and its contractors. These workshops and assessments have received exemplary feedback from Tribal Transit Leaders and provided FTA with invaluable opportunities to learn more about Tribal Transit Leaders' perspectives so to better honor the sovereignty of tribal nations.

FTA will post information about upcoming workshops to its Web site and will disseminate information about the assessments through its regional offices. Contact information for FTA's regional offices can be found on FTA's Web site at www.transit.dot.gov/about/regional-offices. Applicants may also receive technical assistance by contacting their FTA regional Tribal Liaison. A list of Tribal Liaisons is available on FTA's Web site at www.transit.dot.gov/funding/grants/grant-programs/public-transportation-indian-reservations-program-tribal-transit.

Carolyn Flowers,
Acting Administrator.

Appendix A

Registering in SAM and Grants.Gov

Registration in Brief

Registration takes approximately three to five business days, please allow four weeks for completion of all steps.

In order to apply for a grant, you and/or your organization must first complete the registration process in *Grants.gov*. The registration process for an Organization or an Individual can take between three to five business days or as long as four weeks if all steps are not completed in a timely manner. So please register in *Grants.gov* early.

The *Grants.gov* registration process ensures that applicants for Federal Funds have the basic prerequisites to apply for and to receive federal funds. Applicants for FTA competitive funds must:

- Have a valid DUNS number
- Have a current registration in SAM (formerly CCR)
- Register and apply in *Grants.gov*

The required registration steps are described in greater detail on *Grants.gov* Web site. The following is a link to a helpful checklist and explanations published by *Grants.gov* to assist applicants: Organization Registration Checklist. If you have not recently applied for federal funds, we

recommend that you initiate your search, registration, and application process with *Grants.gov*. Visiting the *Grants.gov* site will inform you of how to apply for grant opportunities, as well as assist you in linking to the other required registrations, *i.e.*, Dun & Bradstreet to obtain a DUNS Number, and System for Award Management (SAM).

Summary of steps (these steps are available in *Grants.gov* during registration):

Step 1: Obtain DUNS Number

Same day. If requested by phone (1-866-705-5711) DUNS is provided immediately. If your organization does not have one, you will need to go to the Dun & Bradstreet Web site at <http://fedgov.dnb.com/webform> to obtain the number.

Step 2: Register With SAM

Three to five business days or up to two weeks. If you already have a Taxpayer Identification Number (TIN), your SAM registration will take three to five business days to process. If you are applying for an Employer Identification Number (EIN) please allow up to two weeks. Ensure that your organization is registered with the System for Award Management (SAM) at <https://www.sam.gov>. If your organization is not, an authorizing official of your organization must register.

Step 3: Establish an Account in *Grants.gov*—Username & Password

Same day. Complete your Authorized Organization Representative (AOR) profile on *Grants.gov* and create your username and password. You will need to use your organization's DUNS Number to complete this step. <https://apply07.grants.gov/apply/OrcRegister>.

Step 4: *Grants.gov*—AOR Authorization

* Same day. The E-Business Point of Contact (E-Biz POC) at your organization must login to *Grants.gov* to confirm you as an Authorized Organization Representative (AOR). Please note that there can be more than one AOR for your organization. In some cases the E-Biz POC is also the AOR for an organization. *Time depends on responsiveness of your E-Biz POC.

* Please Note: *Grants.gov* gives you the option of registering as an "individual" or as an "organization." If you register in *Grants.gov* as an as an "Individual," your "Organization" will not be allowed to use the *Grants.gov* username and password. To apply for grants as an Organization you must register as an Organization and use that specific username and password issued during the "organization" registration process.

[FR Doc. 2017-01171 Filed 1-18-17; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2017-0004]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel MIRA MAR; Invitation for Public Comments

AGENCY: Maritime Administration

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before February 21, 2017.

ADDRESSES: Comments should refer to docket number MARAD-2017-0004. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-9309, Email Bianca.carr@dot.gov.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel MIRA MAR is:

—Intended Commercial Use of Vessel:

Vessel will be used for captained charters and sailing instruction with a heavy emphasis on recreational boating safety knowledge and skills, and for the promotion of the National ON-Water Standards (NOWS) program and the American National Standards (ANS) adoption by individuals and organizations.

—*Geographic Region:* "Delaware, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia"

The complete application is given in DOT docket MARAD-2017- 0004 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

By Order of the Maritime Administrator.

Dated: January 10, 2017.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2017-01085 Filed 1-18-17; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2017-0003]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel SHAUN T; Invitation for Public Comments

AGENCY: Maritime Administration.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the

Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before February 21, 2017.

ADDRESSES: Comments should refer to docket number MARAD-2017-0003. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-9309, Email Bianca.carr@dot.gov.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel SHAUN T is:

—*Intended Commercial Use Of Vessel:*

“The intended use is an un-inspected 6-passenger commercial tour/cruising vessel”

—*Geographic Region:* Hawaii

The complete application is given in DOT docket MARAD-2017-0003 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

By Order of the Maritime Administrator.

Dated: January 10, 2017.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2017-01088 Filed 1-18-17; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2017-0008]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel MAJESTIK; Invitation for Public Comments

AGENCY: Maritime Administration.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before February 21, 2017.

ADDRESSES: Comments should refer to docket number MARAD-2017-0008. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this docket and will be available for

inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-9309, Email Bianca.carr@dot.gov.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel MAJESTIK is:

- Intended Commercial Use of Vessel:* “Limited private small charter”
- Geographic Region:* “Washington State, Oregon, California”

The complete application is given in DOT docket MARAD-2017-0008 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD’s regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter’s interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD’s regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

By Order of the Maritime Administrator.

Dated: January 10, 2017.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2017-01089 Filed 1-18-17; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. DOT MARAD 2017-0010]

Agency Requests for Renewal of a Previously Approved Information Collection(s): Application for Conveyance of Port Facility Property

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice and request for comments.

SUMMARY: The Department of Transportation (DOT) invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The information collection is necessary for MARAD to determine whether the applicant is committed to the redevelopment plan; the plan is in the best interests of the public, and the property will be used in accordance with the terms of the conveyance and applicable statutes and regulations. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Written comments should be submitted by March 20, 2017.

ADDRESSES: You may submit comments [identified by Docket No. DOT-MARAD-2017-0010 through one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Fax:* 1-202-493-2251.

- *Mail or Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building, Room W12-140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Linden Houston, Office of Deepwater Ports and Offshore Activities, Maritime Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; Telephone: (202) 366-4839 or Email: Linden.Houston@dot.gov. Copies of this collection can also be obtained from that office.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2133-0524.

Title: Application for Conveyance of Port Facility Property.

Form Numbers: MA-1047.

Type of Review: Renewal of a currently approved information collection.

Background: Public Law 103-160, which is included in 40 U.S.C. 554 authorizes the Department of Transportation to convey to public entities surplus Federal property needed for the development or operation of a port facility. The information collection will allow MARAD to approve the conveyance of property and administer the port facility conveyance program.

Respondents: Eligible state and local public entities.

Number of Respondents: 13.

Frequency: Annually.

Total Annual Burden: 572.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) whether the proposed collection of information is necessary for the Department’s performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB’s clearance of this information collection.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT’s complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477-78) or you may visit <http://www.regulations.gov>.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.93

Dated: January 10, 2017.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2017-01084 Filed 1-18-17; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION**Maritime Administration****[Docket No. MARAD-2017-0009]****Requested Administrative Waiver of the Coastwise Trade Laws: Vessel GRAVITY; Invitation for Public Comments****AGENCY:** Maritime Administration, Department of Transportation.**ACTION:** Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before February 21, 2017.

ADDRESSES: Comments should refer to docket number MARAD-2017-0009. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-9309, Email Bianca.carr@dot.gov.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel GRAVITY is:

—*Intended Commercial Use of Vessel:* “Private Vessel Charters”

—*Geographic Region:* “Maine, New Hampshire, Massachusetts, Rhode Island, Connecticut, New York, New Jersey, Pennsylvania, Delaware, Maryland, Virginia, North Carolina, South Carolina, Georgia, Florida, California, Oregon, Washington, and Alaska (excluding waters in Southeastern Alaska and waters north of a line between Gore Point to Cape Suckling [including the North Gulf Coast and Prince William Sound])”

The complete application is given in DOT docket MARAD-2017-0009 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD’s regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter’s interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD’s regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

By Order of the Maritime Administrator.

Dated: January 10, 2017.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2017-01092 Filed 1-18-17; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION**Maritime Administration****[Docket No. MARAD-2017-0006]****Requested Administrative Waiver of the Coastwise Trade Laws: Vessel SERENITY; Invitation for Public Comments****AGENCY:** Maritime Administration**ACTION:** Notice.

SUMMARY: The Secretary of Transportation, as represented by the

Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before February 21, 2017.

ADDRESSES: Comments should refer to docket number MARAD-2017-0006. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-9309, Email Bianca.carr@dot.gov.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel SERENITY is:

—*Intended Commercial Use of Vessel:*

Day charters, sunset cruises, captained charters and bareboat charters for hire

—*Geographic Region:* “Maryland, Virginia, North Carolina, South Carolina, Georgia, Florida”

The complete application is given in DOT docket MARAD-2017-0006 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD’s regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter’s interest in the waiver application, and address the waiver

criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

By Order of the Maritime Administrator.

Dated: January 10, 2017.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2017-01086 Filed 1-18-17; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD 2017-0002]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel SAIL BE HAPPY; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before February 17, 2017.

ADDRESSES: Comments should refer to docket number MARAD-2017-0002. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the

Internet at <http://www.regulations.gov>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-9309, Email Bianca.carr@dot.gov.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel SAIL BE HAPPY is:

—*Intended Commercial Use of Vessel:*

“Will provide sailing and also overnight stay opportunities”

—*Geographic Region:* “Washington State, Oregon, California, Florida, Texas”

The complete application is given in DOT docket MARAD-2017-0002 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or

confidential information, please contact the agency for alternate submission instructions.

By Order of the Maritime Administrator.

Dated: January 10, 2017.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2017-01093 Filed 1-18-17; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2017-0007]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel HAVORN; Invitation for Public Comments

AGENCY: Maritime Administration.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before February 21, 2017.

ADDRESSES: Comments should refer to docket number MARAD-2017-0007. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at <http://www.regulations.gov>. All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23-453, Washington, DC 20590. Telephone 202-366-9309, Email Bianca.carr@dot.gov.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel HAVORN is:

—*Intended Commercial Use of Vessel:*
“Carrying Passengers”

—*Geographic Region*: “Alaska (excluding waters in Southeastern Alaska and waters north of a line between Gore Point to Cape Suckling [including the North Gulf Coast and Prince William Sound]), Washington, Oregon, California, Hawaii”

The complete application is given in DOT docket MARAD-2017-0007 at <http://www.regulations.gov>. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD’s regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter’s interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD’s regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

By Order of the Maritime Administrator.

Dated: January 10, 2017.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2017-01091 Filed 1-18-17; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Revenue Procedure 98-32

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Revenue Procedure 98-32, Electronic Federal Tax Payment System (EFTPS) Programs for Reporting Agents.

DATES: Written comments should be received on or before March 20, 2017 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to LaNita Van Dyke at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at Lanita.VanDyke@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Electronic Federal Tax Payment System (EFTPS) Programs for Reporting Agents.

OMB Number: 1545-1601.

Revenue Procedure Number: Revenue Procedure 98-32.

Abstract: This revenue procedure provides information about the Electronic Federal Tax Payment System (EFTPS) programs for Batch Filers and Bulk Filers (Filers). EFTPS is an electronic remittance processing system for making federal tax deposits (FTDs) and federal tax payments (FTP). The Batch Filer and Bulk Filer programs are used by Filers for electronically submitting enrollments, FTDs, and FTPs on behalf of multiple taxpayers.

Current Actions: There are no changes being made to this revenue procedure at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 229,237.

Estimated Average Time per Respondent: 1 hr, 5 min.

Estimated Total Annual Burden Hours: 246,877.

The following paragraph applies to all the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 10, 2017.

Tuawana Pinkston,

IRS Reports Clearance Officer.

[FR Doc. 2017-01160 Filed 1-18-17; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8874-A

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this

opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13(44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8874–A, Notice of Qualified Equity Investment for New Markets Credit.

DATES: Written comments should be received on or before March 20, 2017 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to LaNita Van Dyke at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at LaNita.VanDyke@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Notice of Qualified Equity Investment for New Markets Credit.

OMB Number: 1545–2065.

Form Number: 8874–A

Abstract: New modernized e-file return for partnerships. Internal Revenue Code Sections 6109 and 6103.w code section 45N. 45N was added by section 405 of the Tax Relief and Health Care Act of 2006. The new form provides a means for the qualified mining company to compute and claim the credit.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individual or households, Business or other for-profit.

Estimated Number of Respondents: 500.

Estimated Time per Respondent: 5 hours and 26 minutes.

Estimated Total Annual Burden Hours: 2,715.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the

request for OMB approval. All comments will become a matter of public record. Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 10, 2017.

Tuawana Pinkston,

IRS Tax Clearance Officer.

[FR Doc. 2017–01162 Filed 1–18–17; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning, (TD 7533, Disc Rules on Procedure and Administration; Rules on Export Trade Corporations), and (TD 7896, Income From Trade Shows).

DATES: Written comments should be received on or before March 20, 2017 to be assured of consideration.

ADDRESSES: Direct all written comments to Tuawana Pinkston, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to LaNita Van Dyke, at Internal Revenue Service, Room 6526, 1111

Constitution Avenue NW., Washington, DC 20224, or through the internet at LaNita.VanDyke@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Disc Rules on Procedure and Administration; Rules on Export Trade Corporations; and, Income From Trade Shows.

OMB Number: 1545–0807.

Regulation Project Numbers: TD 7533 and TD 7896. Abstract: Regulation section 1.6071–1(b) requires that when a taxpayer files a late return for a short period, proof of unusual circumstances for late filing must be given to the District Director. Sections 6072(b), (c), (d), and (e) of the Internal Revenue Code deal with the filing dates of certain corporate returns. Regulation section 1.6072–2 provides additional information concerning these filing dates.

Current Actions: There is no change to these existing regulations.

Type of Review: Extension of a currently approved collection.

Affected Public: Individual or households, business or other for-profit organizations, not-for-profit institutions, farms, and state, local or tribal governments.

Estimated Number of Respondents: 12,417.

Estimated Time Per Respondent: 15 minutes.

Estimated Total Annual Burden Hours: 3,104.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to

minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 10, 2017.

Tuawana Pinkston,

IRS Reports Clearance Officer.

[FR Doc. 2017-01158 Filed 1-18-17; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0567]

Information Collection Activity: (Presidential Memorial Certificate Form)

AGENCY: National Cemetery Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The National Cemetery Administration (NCA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each revised collection allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before March 20, 2017.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at www.Regulations.gov or to Willie Lewis, National Cemetery Administration (43D), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420; or email: willie.lewis@va.gov. Please refer to "OMB Control No. 2900-0567" in any correspondence. During the comment period, comments may be viewed online through the FDMS.

FOR FURTHER INFORMATION CONTACT: Willie Lewis at (202) 461-4242 or FAX (202) 501-2240.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104-13; 44 U.S.C. 3501-21), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor.

This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, NCA invites comments on:

(1) Whether the proposed collection of information is necessary for the proper performance of NCA's functions, including whether the information will have practical utility; (2) the accuracy of NCA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Presidential Memorial Certificate Form VA form 40-0247.

OMB Control Number: 2900-0567.

Type of Review: Revision of a currently approved collection.

Abstract: The National Cemetery Administration (NCA) made updates to its current VA Form 40-0247. The original VA Form 40-0247 is for requests for initial copies of a Presidential Memorial Certificates (PMC's). The updates to the form would include the following changes with no additional respondent burden:

- Format changes
- SSN or Military Service Number from Discharge Documents
- Mailing address, email address, telephone and fax number updates
- Wording changed to allow the public to also use the form for first time requests

Upon appropriate approval, the NCA Web site will display the updated version of the VA Form 40-0247 for public use.

Affected Public: Individuals or Households.

Estimated Annual Burden: 7,200 hours.

Estimated Average Burden per Respondent: 3 minutes each.

Frequency of Response: One-time.

Estimated Number of Respondents: 125,000.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Department Clearance Officer, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2017-01144 Filed 1-18-17; 8:45 am]

BILLING CODE 8320-01-P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0613]

Agency Information Collection Activity: (Record Keeping at Flight Schools)

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to determine a claimant's entitlement to education benefits.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before March 20, 2017.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at www.Regulations.gov or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420 or email to nancy.kessinger@va.gov. Please refer to "OMB Control No. 2900-0613" in any correspondence. During the comment period, comments may be viewed online through the FDMS.

FOR FURTHER INFORMATION CONTACT: Nancy J. Kessinger at (202) 632-8924 or FAX (202) 632-8925.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104-13; 44 U.S.C. 3501-21), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of

information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Record Keeping at Flight Schools.

OMB Control Number: 2900–0613.

Type of Review: Extension of a currently approved collection.

Abstract: 2900–0613 is for information reports provided by educational institutions. VA will use data collected to determine if courses offered by flight schools should be approved and to verify the accuracy of VA educational payments made to students training at flight schools.

Affected Public: Businesses or other for-profits, not-for-profit institutions.

Estimated Annual Burden: 572 hours.

Estimated Average Burden per Respondent: 20 minutes.

Frequency of Response: Annual.

Estimated Number of Respondents: 1717.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Agency Clearance Officer, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2017–01146 Filed 1–18–17; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0065]

Agency Information Collection Activity: (Employment Information in Connection With Claim for Disability Benefits (VA Form 21–4192))

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice.

VA Form 21–4192 is used to gather necessary employment information from

veterans' employers so VA can determine eligibility to increased disability benefits based on unemployability.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before March 20, 2017.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at www.Regulations.gov or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420 or email to nancy.kessinger@va.gov. Please refer to “OMB Control No. 2900–0065” in any correspondence. During the comment period, comments may be viewed online through the FDMS.

FOR FURTHER INFORMATION CONTACT:

Nancy J. Kessinger at (202) 632–8924 or FAX (202) 632–8925.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–21), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Request for Employment Information in Connection with Claim for Disability Benefits (VA Form 21–4192).

OMB Control Number: 2900–0065.

Type of Review: Revision of an approved collection.

Abstract: VA Form 21–4192 is used to gather necessary employment information from veterans' employers so VA can determine eligibility to increased disability benefits based on unemployability.

Affected Public: Individuals or households.

Estimated Annual Burden: 15,000 hours.

Estimated Average Burden per Respondent: 15 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 60,000.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Agency Clearance Officer, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2017–01145 Filed 1–18–17; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–NEW]

Proposed Information Collection

Activity: (Authorization To Disclose Personal Information to a Third Party (VA Form 29–0975))

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to enable a third party to act on behalf of the insured Veteran/beneficiary.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before March 20, 2017.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at www.Regulations.gov or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420 or email to nancy.kessinger@va.gov. Please refer to “OMB Control No. 2900–NEW” in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT:

Nancy J. Kessinger at (202) 632–8924 or FAX (202) 632–8925.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C.

3501–21), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Title: Authorization to Disclose Personal Information to a Third Party (VA Form 29–0975).

OMB Control Number: 2900–NEW.

Type of Review: New Collection.

Abstract: This form will be used by the Department of Veterans Affairs Insurance Center (VAIC) to enable a third party to act on behalf of the insured Veteran/beneficiary. Many of our customers are of advanced age or suffer from limiting disabilities and need assistance from a third party to conduct their affairs. The information

collected provides an optional service and is not required to receive insurance benefits.

Affected Public: Individuals or households.

Estimated Annual Burden: 100 hours.

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 1200.

By direction of the Secretary.

Cynthia Harvey-Pryor,

Program Specialist, Office of Privacy and Records Management, Department of Veterans Affairs.

[FR Doc. 2017–01147 Filed 1–18–17; 8:45 am]

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Part II

Department of Agriculture

Food Safety and Inspection Service

9 CFR Parts 301, 304, 316, et al.

Revision of the Nutrition Facts Labels for Meat and Poultry Products and
Updating Certain Reference Amounts Customarily Consumed; Proposed
Rule

DEPARTMENT OF AGRICULTURE**Food Safety and Inspection Service****9 CFR Parts 301, 304, 316, 317, 318, 319, 320, 327, 362, 381, 412 and 413****[Docket No. FSIS–2014–0024]****RIN 0583–AD56****Revision of the Nutrition Facts Labels for Meat and Poultry Products and Updating Certain Reference Amounts Customarily Consumed****AGENCY:** Food Safety and Inspection Service, USDA.**ACTION:** Proposed rule.

SUMMARY: Consistent with the recent changes that the Food and Drug Administration (FDA) finalized, the Food Safety and Inspection Service (FSIS) is proposing to amend the nutrition labeling requirements for meat (including fish of the order Siluriformes) and poultry products to better reflect the most recent scientific research and dietary recommendations and to improve the presentation of nutrition information to assist consumers in maintaining healthy dietary practices. FSIS is proposing to update the list of nutrients that are required or permitted to be declared; provide updated Daily Reference Values (DRVs) and Reference Daily Intake (RDI) values that are based on current dietary recommendations from consensus reports; and amend the labeling requirements for foods represented or purported to be specifically for children under the age of 4 years and pregnant women and lactating women and establish nutrient reference values specifically for these population subgroups. FSIS is also proposing to revise the format and appearance of the Nutrition Facts label; amend the definition of a single-serving container; require dual-column labeling for certain containers; and update and modify several reference amounts customarily consumed (RACCs or reference amounts). Finally, FSIS is proposing to consolidate the nutrition labeling regulations for meat and poultry products into a new Code of Federal Regulations (CFR) part.

DATES: Comments must be received by March 20, 2017.**ADDRESSES:** FSIS invites interested persons to submit comments on this proposed rule. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This Web site provides the ability to type short comments directly into the

comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- *Mail, including CD-ROMs, etc.:*

Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8–163B, Washington, DC 20250–3700.

- *Hand- or Courier-Delivered*

Submittals: Deliver to Patriots Plaza 3, 355 E Street SW., Room 8–163B, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2014–0024. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW., Room 8–164, Washington, DC 20250–3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Jeff Canavan, Deputy Director, Labeling and Program Delivery Staff, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Stop Code 3784, Patriots Plaza 3, 8–161A, 1400 Independence Avenue SW., Washington, DC 20250–3700; Telephone (301) 504–0879; Fax (202) 245–4792.

SUPPLEMENTARY INFORMATION:**Executive Summary**

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) direct the Secretary of Agriculture to maintain meat and poultry product inspection programs designed to assure consumers that meat and poultry products distributed to them (including imports) are safe, wholesome, not adulterated, and properly marked, labeled, and packaged. The FMIA and PPIA (“the Acts”) also provide that the labels of meat and poultry products must be approved by the Secretary of Agriculture, who has delegated this authority to FSIS, before these products can enter commerce. The Acts prohibit the sale or offer for sale by any person, firm, or corporation of any article in commerce under any name or other marking or labeling that is false or misleading or in any container of a

misleading form or size (21 U.S.C. 607(d); 21 U.S.C. 457(c)). The Acts also prohibit the distribution in-commerce of meat or poultry products that are adulterated or misbranded. The FMIA and PPIA give FSIS broad authority to promulgate such rules and regulations as are necessary to carry out the provisions of the Acts (21 U.S.C. 621 and 463(b)).

To prevent meat and poultry products from being misbranded, the meat and poultry product inspection regulations require that the labels of meat and poultry products include specific information, and that such information be displayed as prescribed in the regulations (9 CFR part 317 and part 381). The nutrition labeling requirements for meat and meat food products are in 9 CFR 317.300–317.400, and the nutrition labeling requirements for poultry products are in 9 CFR 381.400–381.500. The nutrition labeling regulations for meat and poultry products include requirements regarding: Location of nutrition information; labeling with number of servings; nutrition label content; reference amounts customarily consumed per eating occasion; and nutrient content claims.

On March 3, 2014, the Food and Drug Administration (FDA) published two proposed rules, “Food Labeling: Revision of the Nutrition and Supplement Facts Labels” (the “FDA Nutrition Labeling Proposed Rule”)(79 FR 11880) and “Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments” (the “FDA Serving Size Proposed Rule”)(79 FR 11989). FDA proposed these rules to update the Nutrition Facts label to reflect newer nutrition and public health research and recent dietary recommendations from expert groups and to improve the presentation of nutrition information to help consumers make more informed choices and maintain healthy dietary practices. On July 27, 2015, FDA published a supplemental notice of proposed rulemaking “Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Supplemental Notice of Proposed Rulemaking” (the “FDA Nutrition Labeling Supplemental Proposed Rule”)(80 FR 44303) to revise certain provisions of the FDA Nutrition Labeling Proposed Rule. On May 27, 2016, FDA published two final rules, “Food Labeling: Revision of the Nutrition and Supplement Facts Labels”

(the “FDA Nutrition Labeling Final Rule”)(81 FR 33742) and “Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One-Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments” (the “FDA Serving Size Final Rule”)(81 FR 34000).

FSIS has reviewed FDA’s analysis, and to ensure that there is consistency in how nutrition information is presented across the food supply, FSIS is proposing to amend the nutrition labeling regulations for meat and poultry products to parallel, to the extent possible, FDA’s final regulations. This approach will clarify information for consumers and improve efficiency in the marketplace.

FSIS is proposing to consolidate the nutrition labeling regulations that

currently are presented separately for meat and for poultry products (in 9 CFR 317.300–317.400 and 381.400–381.500, respectively) into a single part, 9 CFR part 413. Consistent with FDA’s final regulations, FSIS is also proposing to update the list of nutrients that are required or permitted to be declared and to provide updated DRVs and RDIs that are based on current dietary recommendations from consensus reports. For example, FSIS is proposing to remove the requirement to declare “Calories from Fat;” require the declaration of “Added Sugars,” vitamin D, and potassium; permit the voluntary declaration of vitamins A and C; and update the reference value for the declaration of percent Daily Value (DV) for sodium from the current value of 2,400 mg (milligrams) to 2,300 mg. FSIS is also proposing to amend the requirements for foods represented or

purported to be specifically for children under the age of 4 years and pregnant women and lactating women and establish nutrient reference values specifically for these population subgroups.

FSIS is also proposing to revise the format and appearance of the Nutrition Facts label. Some of the proposed changes include increasing the type size for “Calories,” “servings per container,” and the “Serving size” declarations, and bolding the number of calories and the “Serving size” declaration to highlight this information.

FSIS is also proposing to amend the definition of a single-serving container; require dual-column labeling for certain containers; and update and modify several RACCs. These proposed changes will provide consumers information to assist them in maintaining healthy dietary practices.

Current Label

| Nutrition Facts | | | |
|--|----------------------|----------------|---------|
| Serving Size 2/3 cup (55g) | | | |
| Servings Per Container About 8 | | | |
| Amount per serving | | | |
| Calories 230 | Calories from Fat 40 | | |
| | | % Daily Value* | |
| Total Fat 8g | | | 12% |
| Saturated Fat 1g | | | 5% |
| Cholesterol 0mg | | | 0% |
| Sodium 160mg | | | 7% |
| Total Carbohydrate 37g | | | 12% |
| Dietary Fiber 4g | | | 16% |
| Sugars 1g | | | |
| Protein 3g | | | |
| Vitamin A | | | 10% |
| Vitamin C | | | 8% |
| Calcium | | | 20% |
| Iron | | | 45% |
| * Percent Daily Values are based on a diet of other people's secretaries. Your daily value may be higher or lower depending on your calorie needs. | | | |
| | Calories: | 2,000 | 2,500 |
| Total Fat | Less than | 65g | 80g |
| Sat Fat | Less than | 20g | 25g |
| Cholesterol | Less than | 300mg | 300mg |
| Sodium | Less than | 2,400mg | 2,400mg |
| Total Carbohydrate | | 300g | 375g |
| Dietary Fiber | | 25g | 30g |

Proposed Label

| Nutrition Facts | |
|--|----------------------|
| 8 servings per container | |
| Serving size | 2/3 cup (55g) |
| Amount per serving | |
| Calories | 230 |
| % Daily Value* | |
| Total Fat 8g | 10% |
| Saturated Fat 1g | 5% |
| Trans Fat 0g | |
| Cholesterol 0mg | 0% |
| Sodium 160mg | 7% |
| Total Carbohydrate 37g | 13% |
| Dietary Fiber 4g | 14% |
| Total Sugars 12g | |
| Includes 10g Added Sugars | 20% |
| Protein 3g | |
| Vitamin D 2mcg | 10% |
| Calcium 260mg | 20% |
| Iron 8mg | 45% |
| Potassium 235mg | 6% |
| * The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. A diet of other people's secretaries is used as the basis for comparison. | |

Summary of Costs and Benefits

Quantitative costs for the proposed rule include relabeling, recordkeeping, and reformulation. Quantitative benefits

are a measure of expected health improvements experienced from increased label-use by overweight and hypertensive adults. The summary of cost and benefits in Table 1 are

annualized at a 3 percent discount rate over 20 years with a compliance period of 24 months for large manufacturers and 36 months for small.

TABLE 1—SUMMARY OF COSTS AND BENEFITS

| | Costs | Benefits | Net benefits |
|---|--------------|--------------|--------------|
| Annualized (3% Discount Rate, 20 Years) | \$10,802,809 | \$36,894,007 | \$26,091,198 |
| Annualized (7% Discount Rate, 20 Years) | 14,603,562 | 22,541,264 | 7,937,702 |

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I. Background

The Nutrition Labeling and Education Act (NLEA) of 1990 required the nutrition labeling of most foods regulated by the FDA. Because FSIS is committed to providing consumers with the most informative labeling system possible, FSIS published regulations establishing comparable nutrition labeling requirements for meat and poultry products on January 6, 1993 (58 FR 632). These regulations required nutrition labels on the packages of all multi-ingredient and heat-processed meat and poultry products, unless an exemption applied. The required nutrition labeling provisions were referred to as “the mandatory nutrition labeling program.” The Agency’s 1993 regulations also established guidelines for voluntary nutrition labeling of single-ingredient, raw meat and poultry products, including single-ingredient, raw ground or chopped products.

FSIS published technical amendments to the 1993 final rule (August 18, 1993, 58 FR 43787; September 10, 1993, 58 FR 47624; and March 16, 1994, 59 FR 12157), a final rule on the placement of nutrition labeling on meat and poultry products (August 8, 1994), a final rule with additional technical amendments to the nutrition labeling regulations (September 1, 1994; 59 FR 45189), and a final rule to provide codified language for provisions that previously cross-referenced FDA’s nutrition labeling regulations on January 3, 1995 (60 FR 174). FSIS also published a final rule to require nutrition labeling of the major cuts of single-ingredient raw meat and poultry products and ground or chopped meat and poultry products on December 29, 2010 (75 FR 82164).

Currently, FSIS requires nutrition labels on the packages of all multi-ingredient and heat-processed meat and poultry products, and all ground or chopped products, unless an exemption applies (9 CFR 317.300; 317.301; 381.400; 381.401). FSIS also requires that nutrition information be provided on the label or at the point-of-purchase for the major cuts of single-ingredient, raw meat and poultry products identified in 9 CFR 317.344 and 381.444 that are not ground or chopped, except for certain exemptions. The following exemptions in 9 CFR 317.400 and 381.500 from the nutrition labeling requirements apply to the major cuts of

single-ingredient, raw meat and poultry products and ground or chopped meat and poultry products:

- Products intended for further processing, provided that the labels for these products bear no nutrition claims or nutrition information;
- Products that are not for sale to consumers, provided that the labels for these products bear no nutrition claims or nutrition information;
- Products in small packages that are individually wrapped packages of less than ½ ounce net weight, provided that the labels for these products bear no nutrition claims or nutrition information;
- Products that are custom slaughtered or prepared; and
- Products intended for export.

FSIS also provides the following additional exemptions in 9 CFR 317.400 and 381.500 for ground or chopped products:

- Ground or chopped products that qualify for the small business exemption in 9 CFR 317.400(a)(1) or 381.500(a)(1);
- Products that are ground or chopped at an individual customer’s request and that are prepared and served at retail, provided that the labels or labeling of these products bears no nutrition claims or nutrition information;
- Ground or chopped products in packages that have a total surface area for labeling of less than 12 square inches, provided that the product’s labeling includes no nutrition claims or nutrition information and provided that an address or telephone number that a consumer can use to obtain the required information is included on the label; and
- Ground products produced by small businesses that use statements of percent fat and percent lean on the label or in labeling of ground products, provided they include no other nutrition claims or nutrition information on the product labels or labeling.

Generally, ready-to-eat products that are packaged and portioned at a retail store or similar retail-type establishment and multi-ingredient products (e.g., sausage) processed at a retail store or similar retail-type establishment are exempt from nutrition labeling, provided that this exemption does not apply to ready-to-eat or multi-ingredient ground or chopped products described in 9 CFR 317.301 or 381.401. Restaurant menus also do not generally fall within the scope of FSIS’s current nutrition labeling regulations (9 CFR 317.400 and 381.500). However, FDA requires that restaurants and similar retail food establishments that are part of a chain

with 20 or more locations doing business under the same name and offering for sale substantially the same menu items disclose certain nutrition information for standard menu items (see “Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments”; December 1, 2014; 79 FR 71155). FDA also requires that operators who own or operate 20 or more vending machines disclose calorie information for food sold from vending machines, subject to certain exemptions (see “Food Labeling; Calorie Labeling of Articles of Food in Vending Machines”; December 1, 2014; 79 FR 71259).

FSIS does not require nutrition information for single-ingredient, raw meat and poultry products that are not major cuts and that are not ground or chopped. But, if nutrition information is provided for these products, it must be provided in accordance with the nutrition labeling requirements for the major cuts (9 CFR 317.300 and 381.400).

II. The Proposed Rule

Nutrition labeling continues to be an integral part of USDA’s efforts to educate consumers about nutrition and diet. Since 1980, USDA and the Department of Health and Human Services (HHS) have jointly published the Dietary Guidelines for Americans (DGA) every five years. The 2015–2020 DGA provides advice on food choices that promote overall health, reduce the risk of chronic disease, and help individuals attain and maintain a healthy weight.¹ The nutrition labeling information that FSIS is proposing to require in this rule would assist consumers in maintaining healthy dietary practices. The information should also help consumers follow the advice in the 2015–2020 DGA.

For example, the 2015–2020 DGA concluded that some Americans do not consume enough vitamin D or potassium, and inadequate intake of these nutrients presents public health concerns (pages 60). Vitamin D is important for bone health, and potassium helps to reduce the effects of excess sodium on blood pressure. This proposed rule would require vitamin D and potassium to be declared on nutrition labels, to assist consumers in maintaining healthy dietary practices. Moreover, consistent with the 2015–2020 DGA, the information should help consumers follow the 2015–2020 DGA’s

¹ U.S. Department of Agriculture and U.S. Department of Health and Human Services, 2015–2020 Dietary Guidelines for Americans, 8th edition, Washington, DC: U.S. Government Printing Office, December 2015. Available at <http://www.health.gov/dietaryguidelines/2015.asp>.

advice to select foods that provide more of these nutrients (page 60). Additionally, the 2015–2020 DGA does not consider low intake of vitamins A and C to be a major public health concern (page 60). Currently, vitamins A and C must be declared on the Nutrition Facts label, but this proposed rule would make their declaration voluntary.

This proposed rule also proposes changes to the Daily Values for certain nutrients, consistent with the more recent scientific evidence from the 2015–2020 DGA. For example, FSIS is proposing to amend the current DV for sodium of 2,400 to 2,300 mg, which is consistent with the scientific evidence reflected in the 2015–2020 DGA's recommendation to limit intake of sodium to less than 2,300 mg per day and is the upper limit for individuals ages 14 years and older set by the Institute of Medicine. (page 15). Revising DVs to reflect the most current science on nutrient requirements will help consumers choose a better overall diet.

The 2015–2020 DGA also supports listing added sugars on nutrition labels. It affirms that poor diet and physical inactivity are primary factors contributing to overweight, obesity, and chronic illness (pages 2–3). Calories from added sugars, solid fats (including saturated and *trans* fats), and refined grains replace nutrient-dense foods and make it difficult to consume sufficient nutrients while controlling caloric intake (page 14). FSIS is proposing to require that added sugars be listed on nutrition labels to assist consumers in selecting a more nutrient-dense diet while controlling the total number of calories consumed (see section II.E.3 for discussion of the rationale for the proposed changes).

Section 403(q)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(q)(1)(A)) defines serving size as an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food. FSIS, consistent with FDA, is proposing to update, modify, and establish certain RACCs and require that packages which contain more than 150 percent and less than 200 percent of a given RACC be labeled as containing one serving, regardless of the RACC of the product. Certain packages that contain at least 200 percent and up to and including 300 percent of a given RACC would be required to include dual column labels that provide nutrition information per serving or per package, as applicable. These changes will ensure that serving sizes are based on current consumption data and will provide consumers with information on

the Nutrition Facts label related to the serving size that will assist them in maintaining healthy dietary practices.

Finally, FSIS is proposing several updates to the design of the current Nutrition Facts labels, including making the caloric content and serving size declarations more prominent. These and other changes aim to address current public health problems such as obesity, chronic disease, and nutrient deficiency by emphasizing important nutritional information and providing additional information to consumers.

A. Consolidating the Nutrition Labeling Requirements Into 9 CFR Part 413

Currently, the nutrition labeling regulations for meat and poultry products are presented separately (in 9 CFR 317.300–317.400 and 381.400–381.500, respectively). FSIS believes that the public would be better served by consolidating these regulations in one part of title 9. Rather than searching through two separate parts of title 9—CFR parts 317 and 381—to find the nutrition labeling regulations, interested parties would only have to read part 413. Therefore, FSIS is proposing to consolidate the nutrition labeling regulations for meat and poultry products into a single part, 9 CFR part 413.

B. Calories

FSIS requires the total number of calories per serving of a meat or poultry product to be declared on the Nutrition Facts label (9 CFR 317.309(c)(1); 9 CFR 381.409(c)(1); and proposed 9 CFR 413.309(c)(1)). FSIS is not proposing to change this requirement but is proposing changes to the requirements related to “Calories from fat” and “Calories for saturated fat.”

1. Calories from Fat

FSIS currently requires that “Calories from Fat” be declared on Nutrition Facts labels (9 CFR 317.309(c)(1)(ii); 9 CFR 381.409(c)(1)(ii)). FSIS is proposing to no longer require, and to not allow voluntarily, the declaration of “Calories from fat” on the Nutrition Facts label.

Section 403(q)(2)(B) of the FD&C Act (21 U.S.C. 343(q)(2)(B)) grants the Secretary of HHS (and by delegation, FDA) discretion to remove information relating to a nutrient required to be declared on food labels by regulation if the Secretary determines that it is not necessary to assist consumers in maintaining healthy dietary practices. FDA considered a number of factors related to the declaration of “Calories from Fat,” including dietary recommendations and consensus reports that emphasize intake of total

calories and the type of fat consumed, as well as comments from their 2005 and 2007 Advanced Notices of Proposed Rulemaking (ANPRMS) (April 4, 2005, 70 FR 17008; November 2, 2007, 72 FR 62149) that supported eliminating the declaration of “Calories from fat” in order to place greater emphasis on total calories. FDA determined that the declaration of “Calories from fat” is not necessary to assist consumers in maintaining healthy dietary practices (81 FR 33780). Under FDA's Nutrition Labeling Final Rule, FDA no longer requires, and does not allow voluntarily, the declaration of “Calories from fat” on the Nutrition Facts label (81 FR 33780). FSIS has reviewed FDA's analysis and has tentatively concluded that the declaration of “Calories from fat” is not necessary to assist consumers in maintaining healthy dietary practices. FSIS agrees with FDA that “the amount of fat being consumed can still be obtained from the total fat declaration elsewhere on the Nutrition Facts label, and consumers can still use the percent DV for total fat to put fat content in the context of a total daily diet, compare products, and plan diets” (79 FR 11891; 81 FR 33780).

2. Calories From Saturated Fat

Under current FSIS regulations, the declaration of “Calories from saturated fat” on the Nutrition Facts label is voluntary (9 CFR 317.309(c)(1)(iii); 9 CFR 381.409(c)(1)(iii)); will be consolidated in proposed 9 CFR 413.309(c)(1)(ii)). FSIS continues to believe that “Calories from saturated fat” can be declared voluntarily. The amount of saturated fat can be obtained from the total saturated fat declaration on the Nutrition Facts label, and consumers can use the percent DV for saturated fat to put saturated fat content in the context of a total daily diet, compare products, and plan diets (79 FR 11892; 81 FR 33781). Therefore, FSIS does not believe it is necessary to require the mandatory declaration of “Calories from saturated fat” on the Nutrition Facts label. But with the revisions to the Nutrition Facts label, FSIS is proposing to require that “Calories from saturated fat” be indented when declared under the statement of calories (proposed 9 CFR 413.309(c)(1)(ii)).

3. Two Thousand Calories as the Reference Caloric Intake Level

FSIS regulations (9 CFR 317.309(c)(9) and 381.409(c)(9)) set a percent DRV for fat, saturated fatty acids, cholesterol, total carbohydrate, fiber, sodium, potassium, and protein, based on a reference caloric intake of 2,000

calories. Just as FDA did not make any changes to the reference calorie intake, FSIS is not proposing any changes to the reference caloric intake currently used to set the DRVs under 9 CFR

317.309(c)(9) and 381.409(c)(9) (which will both be consolidated in proposed 9 CFR 413.309(c)(9)).

FDA considered a number of factors related to the reference calorie intake of 2,000 calories, including the relevant recommendations from the IOM macronutrient report² that provided estimated energy requirements, the IOM Labeling Report,³ and the comments regarding the 2,000 calorie reference intake level received in response to FDA's 2007 ANPRM (79 FR 11892). FDA decided not to propose changes to the reference calorie intake level (81 FR 33782). "The IOM Labeling Committee concluded that retaining the current 2,000 reference calorie intake level would be the best approach as it would provide continuity and would not encourage higher calorie intake and overconsumption of energy" (79 FR 11892). FSIS agrees with FDA and the recommendation of the IOM Labeling Committee.

4. Percent Daily Value (DV) Declaration for Calories

FSIS's current regulations do not establish a DRV for calories and do not require a percent DV declaration for calories. FDA reviewed recommendations in current consensus reports, including the IOM macronutrient report,⁴ and comments received in response to their 2005 and 2007 ANPRMs (79 FR 11892, 11893). FDA decided not to require a percent DV for total calories because of a lack of an appropriate quantitative intake recommendation or other data or information on which FDA could rely to establish a DRV for calories (81 FR 33782). FSIS agrees with FDA's conclusion.

² Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Chapter 5: Energy", Washington, DC: National Academies Press; 2002.

³ The amount of vitamin D may, but is not required to, be expressed in international units (IU), in addition to the mandatory declaration in mcg. Any declaration of the amount of vitamin D in IU must appear in parentheses after the declaration of the amount of vitamin D in mcg.

⁴ 1 mg α -tocopherol (label claim) = 1 mg α -tocopherol = 1 mg RRR- α -tocopherol = 2 mg *all rac*- α -tocopherol.

C. Fat

1. Total Fat

a. Definition and Mandatory Declaration

FSIS is not proposing any changes to its definition of "total fat" under 9 CFR 317.309(c)(2) and 381.409(c)(2) (which will both be consolidated in proposed 9 CFR 413.309(c)(2)). FSIS is proposing to define "fatty acids" in 9 CFR 413.309(c)(2) as aliphatic carboxylic acids consisting of a chain of alkyl groups and characterized by a terminal carboxyl group to harmonize with FDA's Nutrition Labeling Final Rule and clarify what FSIS considers to be a fatty acid. FSIS is not proposing to change the requirement for mandatory declaration for total fat on the Nutrition Facts label.

b. DRV

FSIS's regulations 9 CFR 317.309(c)(9) and 381.409(c)(9), which would be consolidated in proposed 9 CFR 413.309(c)(9), set 65 grams as the DRV for total fat based on a reference calorie intake of 2,000 calories (*i.e.*, 30 percent of a 2,000 calorie diet). In FDA's Nutrition Labeling Final Rule, FDA increased the DRV for total fat to 78 grams, or 35 percent of a 2,000 calorie diet. The upper level of the IOM Acceptable Macronutrient Distribution Range (AMDR)⁵ for total fat for adults is 35 percent and serves as an appropriate basis on which to set the DRV for total fat (81 FR 33784). FDA reviewed new information and evidence that corroborated the position that the types of fats consumed are more important in influencing the risk of heart disease than is the total amount of fat (81 FR 33784). FDA stated that keeping the DRV for total fat at 30 percent of calories could be misinterpreted as advising consumers to limit their intake of total fat to 30 percent or less, and that it is conceivable that consumers could view foods that are good sources of mono and polyunsaturated fats negatively because their percent DV declaration for total fat is high (81 FR 33784). FSIS agrees with FDA's analysis, and is proposing to increase the DRV for total fat from 30 percent of calories to 35 percent of calories for a DRV of 78 grams.

2. Saturated Fat

a. Definition

FSIS regulations currently define "Saturated fat" as the sum of all fatty

⁵ "The AMDR for a macronutrient is based on the amount of the macronutrient that is associated with a reduced risk of chronic disease while providing adequate intakes of essential nutrients" (79 FR 11886).

acids, including stearic acid, containing no double bonds (*see* 9 CFR 317.309(c)(2)(i); 381.409(c)(2)(i); and 21 CFR 101.9(c)(2)(i)). However, in FSIS's 1993 Nutrition Labeling of Meat and Poultry Products final rule, based on requests from the red meat industry and the scientific knowledge in 1993 that stearic acid did not have the same serum cholesterol-raising effects of the other three saturated fatty acids, myristic, palmitic, and lauric acids, FSIS provided for the voluntary declaration of stearic acid as a subcomponent of saturated fat (58 FR 641). FDA had no similar request for the voluntary listing of stearic acid and did not provide for such listing.

In FDA's Nutrition Labeling Proposed Rule, FDA considered voluntary declaration of stearic acid on the Nutrition Facts label, as recommended by a few comments to their 2007 ANPRM (79 FR 11894). The effects of stearic acid on Low-density lipoprotein (LDL) cholesterol levels appear to vary depending on the macronutrient component that is replaced by stearic acid (79 FR 11894). FDA found that moderate evidence indicates that when stearic acid substitutes for other saturated fatty acids or *trans* fat, plasma LDL cholesterol levels decrease, whereas when it replaces monounsaturated or polyunsaturated fatty acids, LDL cholesterol levels increase (79 FR 11894). Considering such scientific data, the *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans*, 2010 (2010 DGAC),⁶ concluded that the potential effects of changes in dietary intake of stearic acid on the risk of CVD remain unclear (79 FR 11894). In FDA's Nutrition Labeling Proposed Rule, FDA tentatively concluded that the individual declaration of stearic acid is not necessary to assist consumers in maintaining healthy dietary practices, and proposed to not permit the declaration on the Nutrition Facts label (79 FR 11894). FDA addressed the evidence for a role of stearic acid in human health (*e.g.*, changes in plasma LDL cholesterol levels), which is not well-established, and the fact that there is no quantitative intake recommendation available for stearic acid (*Id.*) In FDA's final rule, FDA did not exclude stearic acid from the calculation of the percent DV for

⁶ U.S. Department of Agriculture and U.S. Department of Health and Human Services. (2010) "Report of the Dietary Guidelines Advisory Committee on the *Dietary Guidelines for Americans*, 2010", Washington, DC: U.S. Government Printing Office. Retrieved from <http://www.cnpp.usda.gov/dietary-guidelines-2010>.

saturated fat because the scientific evidence supporting the current dietary recommendations for saturated fat does not differentiate among the individual saturated fatty acids (81 FR 33786).

Based on this updated scientific information and the fact that few if any companies have included stearic acid as a voluntary nutrient in the current Nutrition Facts label, FSIS is proposing to remove the voluntary declaration of stearic acid below saturated fat.

Also, consistent with FDA's final rule, FSIS is not proposing to exclude acetic, propionic, and butyric acids from the definition of saturated fat.

b. Mandatory Declaration

FSIS requires the mandatory declaration of the number of grams of saturated fat per serving (9 CFR 317.309(c)(2)(i) and 381.409(c)(2)(i) will be consolidated in proposed 9 CFR 413.309(c)(2)(i)). FSIS is not proposing to change this requirement because FSIS is unaware of any evidence that supports that this information is no longer needed to assist consumers in maintaining healthy dietary practices.

c. Dietary Reference Value (DRV)

FSIS's regulations 9 CFR 317.309(c)(9) and 381.409(c)(9), which will be consolidated in proposed 9 CFR 413.309(c)(9), set 20 grams as the DRV for saturated fat based on a reference calorie intake of 2,000 calories. FSIS is not proposing to change the DRV for saturated fat.

FDA reviewed the IOM Labeling Committee recommendation,⁷ the comments in response to their 2007 ANPRM, and current consensus reports relating to the DRV for saturated fat, and stated that "the existing scientific evidence does not support a change to the current 20 g DRV" for saturated fat (79 FR 11895–11896). FDA determined "the existing DRV of 20 grams is consistent with the scientific evidence supporting a maximum intake level that covers the general U.S. population." (81 FR 33786). FSIS has reviewed FDA's analysis and has tentatively concluded not to change the DRV for saturated fat.

3. Trans Fat

On July 11, 2003, FDA published a final rule requiring manufacturers to declare *trans* fatty acids, or *trans* fat, on the Nutrition Facts label of conventional foods and some dietary supplements (68 FR 41461). At that time, FSIS published information on its Web site stating that FSIS was planning rulemaking on *trans*

fat label declarations to consider provisions in the meat and poultry regulations that are consistent with FDA's rules.⁸ In the interim, FSIS has not objected to the voluntary declaration of *trans* fat in Nutrition Facts labels on food products under its jurisdiction if the declaration is made in accordance with FDA regulations published in the **Federal Register** on July 11, 2003, that amended 21 CFR part 101. There are no FDA or FSIS provisions for claims regarding *trans* fatty acids. Thus, any labeling that includes a statement regarding *trans* fatty acids that is outside of and in addition to the Nutrition Facts label declaration would need to be submitted to FSIS (the Labeling and Program Delivery Staff (LPDS)) for evaluation. To date, FSIS has not permitted any claims regarding *trans* fatty acids.

Based on FSIS's label review, FSIS believes that the majority of meat and poultry product Nutrition Facts labels voluntarily declare *trans* fat. However, because FSIS is now proposing major modifications to the Nutrition Facts label, FSIS believes it is time to address the need for *trans* fat labeling on meat and poultry products. According to FDA's Nutrition Labeling Proposed Rule, *trans* fat continues to be a nutrient with public health significance because of its role in chronic disease (79 FR 11896). FDA is unaware of evidence to support a determination that information relating to *trans* fat on the Nutrition Facts label is not necessary to assist consumers in maintaining healthy dietary practices (79 FR 11896). FDA tentatively concluded that information on the amount of *trans* fat in food products allows consumers to reduce their intake of *trans* fat and thus reduce the risk of coronary heart disease (CHD) (79 FR 11896). However, in 2013, FDA published a tentative determination that partially hydrogenated oils (PHOs), the source of industrially produced *trans* fat, may not be generally recognized as safe (GRAS) (78 FR 67169; November 8, 2013). FDA requested comment on whether mandatory labeling of *trans* fat would still be necessary if this determination is finalized (79 FR 11896). Per 21 CFR 101.9(c)(2)(ii), if a food contains less than 0.5 g of *trans* fat per serving, the content, when declared, is to be expressed as zero. On June 17, 2015, FDA published a final determination that there is no longer a consensus among qualified experts that PHOs, which are the primary dietary source of industrially-produced *trans*

fatty acid are GRAS for any use in human food and therefore are food additives subject to section 409 of the FD&C Act (80 FR 34650). FDA has set a compliance period of three years for companies to either reformulate products without PHOs or petition FDA to permit specific uses of PHOs. Following the compliance period, no PHOs can be added to human food unless they are otherwise approved by FDA. In FDA's Nutrition Labeling Final Rule, FDA did not make any changes to the requirement for mandatory declaration of *trans* fat on the Nutrition Facts label in 21 CFR 101.9(c)(2)(ii), stating "it is premature to consider removing *trans* fat from the Nutrition Facts label at this time." (81 FR 33786–88).

Although FDA's final determination that PHOs are not GRAS for use in any human food may eliminate the source of industrially produced *trans* fat, FSIS recognizes that there are *trans* fats caused by the way that some animals, such as cattle, sheep and goats, digest their food (the ruminating process). Consistent with FDA's Nutrition Labeling Final Rule (81 FR 33786–33787), FSIS is proposing to require the declaration of *trans* fat in the Nutrition Facts label (proposed 9 CFR 413.309(c)(2)(ii)). The mandatory declaration of *trans* fat will assist consumers in making informed choices and maintaining healthy dietary practices.

4. Polyunsaturated Fat

a. Voluntary Declaration

FSIS permits the voluntary declaration of the number of grams of polyunsaturated fat per serving (defined as *cis*, *cis*-methylene interrupted polyunsaturated fatty acids) on the Nutrition Facts label (9 CFR 317.309(c)(2)(ii) and 381.409(c)(2)(ii), which will be consolidated in proposed 9 CFR 413.309(c)(2)(iii)). FDA considered current consensus reports and comments received in response to their 2007 ANPRM when deciding to propose to continue to permit the voluntary declaration of polyunsaturated fat on the Nutrition Facts label (79 FR 11897; 81 FR 33788). FDA recognized that, although polyunsaturated fat is related to public health as a replacement for saturated fat, there is no dose-response relationship between polyunsaturated fat and risk of CHD, independent of saturated fat, and therefore continued to permit the voluntary declaration of polyunsaturated fat (81 FR 33788–89). FSIS has reviewed FDA's analysis and agrees with its conclusion and therefore,

⁷ Institute of Medicine (IOM) of the National Academies, "Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification", Washington, DC: National Academies Press; 2003.

⁸ <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-policies/trans-fat-declarations>.

is not proposing to make any changes to the voluntary declaration of polyunsaturated fat. Polyunsaturated fat has public health significance because replacing saturated fatty acids with polyunsaturated and monounsaturated fatty acids reduces blood LDL cholesterol levels and in turn the risk of cardiovascular disease (CVD).⁹ Polyunsaturated fat is a macronutrient, not an essential vitamin or mineral, does not have a quantitative intake recommendation, but does have public health significance. Therefore, FSIS believes it is appropriate to continue to permit the voluntary declaration of polyunsaturated fat consistent with FDA's final rule.

b. DRV

FSIS's regulations do not provide a DRV for polyunsaturated fat. FDA did not propose a DRV for polyunsaturated fat, tentatively concluding "that there is no appropriate quantitative intake recommendation to form a basis for setting a DRV for polyunsaturated fat" (79 FR 11898). FDA did not change its position in the final rule (81 FR 33789). Consistent with FDA's final rule, FSIS is not proposing to provide a DRV for polyunsaturated fat.

c. Declaration of Individual Polyunsaturated Fatty Acids

FSIS's regulations do not permit the declaration of individual polyunsaturated fatty acids on the Nutrition Facts label. Consistent with FDA's final rule, FSIS is not proposing to provide for the individual declaration of either *n*-3 or *n*-6 polyunsaturated fatty acids or the declaration of eicosapentaenoic acid (EPA) or docosahexaenoic acid (DHA) on the Nutrition Facts label (81 FR 33789).

5. Monounsaturated Fat

a. Voluntary Declaration

FSIS's regulations currently allow the voluntary declaration of monounsaturated fat (defined as *cis*-monounsaturated fatty acids (*e.g.*, oleic acid)) on the Nutrition Facts label (9 CFR 317.309(c)(2)(iii) and 381.409(c)(2)(iii), which would be consolidated in proposed 9 CFR 413.309(c)(2)(iv)). Consistent with FDA's final rule, FSIS is not proposing to change the voluntary declaration of monounsaturated fat (81 FR 33788).

b. DRV

FSIS's regulations do not provide a DRV for monounsaturated fat. FDA did not provide a DRV for monounsaturated fat for the same reasons it did not set a DRV for polyunsaturated fat (81 FR 33789). Consistent with FDA's final rule, FSIS is not proposing to set a DRV for monounsaturated fat.

D. Cholesterol

1. Mandatory Declaration

FSIS's regulations require the amount of cholesterol be declared on the Nutrition Facts label (9 CFR 317.309(c)(3) and 381.409(c)(3), which would be consolidated in proposed 9 CFR 413.309(c)(3)). Consistent with FDA's final rule, FSIS is not proposing changes to the requirement for mandatory declaration of cholesterol.

2. DRV

FSIS sets 300 mg as the DRV for cholesterol based on the reference calorie intake of 2,000 calories (9 CFR 317.309(c)(9) and 381.409(c)(9), which would be consolidated in proposed 9 CFR 413.309(c)(9)). FSIS is not proposing to change the DRV for cholesterol.

E. Carbohydrate

1. Total Carbohydrate

a. Calculation of Total Carbohydrate

FSIS requires the number of grams of total carbohydrate per serving be listed on the Nutrition Facts label (9 CFR 317.309(c)(6) and 381.409(c)(6), which would be consolidated in proposed 9 CFR 413.309(c)(6)). Total carbohydrate content must be calculated by subtracting the sum of the crude protein, total fat, moisture, and ash from the total weight of the product (9 CFR 317.309(c)(6) and 381.409(c)(6), which would be consolidated in proposed 9 CFR 413.309(c)(6)).

FDA considered a citizen petition requesting that dietary fiber be excluded from the calculation of total carbohydrate, comments received on its 2007 ANPRM, and scientific evidence and declined to change the current method for calculating total carbohydrate (79 FR 11899–11900; 81 FR 33794–33795). Just as FDA is not making any change, FSIS has reviewed FDA's analysis and has decided not to propose to change the current method for calculating total carbohydrate.

b. Classification of Carbohydrates Based on a Chemical Definition or Physiological Effect

FSIS is not proposing to change its requirements for the classification or

declaration of carbohydrates (9 CFR 317.309(c)(6) and 381.409(c)(6), which would be consolidated in proposed 9 CFR 413.309(c)(6)). FSIS agrees with FDA that a chemical definition for total carbohydrate is still consistent with the classification and declaration of fat on the Nutrition Facts label (79 FR 11901; 81 FR 33795). It would be difficult to apply a definition for total carbohydrates based on physiological effects because the different components of carbohydrates have different physiological effects.

c. Separate Declaration of Additional Individual Types of Carbohydrates

FSIS is not proposing to require the separate declaration of additional types of individual carbohydrates (*e.g.*, starch) because, as FDA also concluded, the comments to the 2007 ANPRM did not support the declaration of additional types of carbohydrates, such as starch (81 FR 33795).

d. Mandatory Declaration

FSIS requires the number of grams of total carbohydrate per serving be listed on the Nutrition Facts label (9 CFR 317.309(c)(6) and 381.409(c)(6), which would be consolidated in proposed 9 CFR 413.309(c)(6)), and has tentatively concluded, that the mandatory declaration of total carbohydrates continues to be necessary to assist consumers in making informed choices. Therefore, consistent with FDA's Nutrition Labeling Final Rule, FSIS is not proposing to change the requirement for mandatory declaration of total carbohydrate.

e. DRV

FSIS sets 300 grams as the DRV for total carbohydrate based on 60 percent of a 2,000 calorie diet ((0.60 × 2,000 calories)/4 calories per gram of carbohydrate = 300 grams) (9 CFR 317.309(c)(9) and 381.409(c)(9), which would be consolidated in proposed 9 CFR 413.309(c)(9)). The percentage of calories from total carbohydrate, total fat, and protein must add up to 100 percent on the Nutrition Facts label. Because, as discussed in part (II)(C)(1), FSIS is proposing to increase the DRV for total fat from 30 to 35 percent of calories consistent with FDA's final rule, either the DRV for total carbohydrate or protein must be decreased. As discussed in FDA's Nutrition Labeling Final Rule, decreasing the DRV for protein from 10 percent of calories to 5 percent of calories to account for the increase in the DRV for total fat would result in a DRV of 5 grams of protein, which falls below the RDA for protein for children

⁹ U.S. Department of Agriculture and U.S. Department of Health and Human Services. (2010) "Report of the Dietary Guidelines Advisory Committee on the *Dietary Guidelines for Americans, 2010*", 4. Washington, DC: U.S. Government Printing Office. Retrieved from <http://www.cnpp.usda.gov/dietary-guidelines-2010>.

and adults 9 years and older (81 FR 33784). Therefore, consistent with FDA's final rule, FSIS is proposing to decrease the DRV for total carbohydrate from 60 percent of calories to 55 percent of calories for a DRV of 275 grams to account for the increase in the DRV for total fat.

f. Calculation of Calories From Carbohydrate

FSIS requires that calories from total carbohydrate be calculated using the general factor of 4 calories per gram total carbohydrate less the amount of insoluble dietary fiber (9 CFR 317.309(c)(1)(i)(C) and 381.409(c)(1)(i)(C)). Consistent with FDA's final rule, FSIS is proposing a new definition for dietary fiber (see section II.E.5) that only allows for the declaration of dietary fibers that FDA has determined to have a physiological effect that is beneficial to human health. The new definition of dietary fiber includes: (1) Non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin that are intrinsic and intact in plants; and (2) isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health. For the purpose of calculating calories from carbohydrate, all soluble and insoluble non-digestible carbohydrates should be excluded from the calculation, not just those known to meet the definition of dietary fiber. Therefore, FSIS is proposing that all soluble and insoluble non-digestible carbohydrates be excluded from the calculation for calories from total carbohydrate (proposed 9 CFR 413.309(c)(1)(i)(C)).

2. Sugars

a. Mandatory Declaration

FSIS requires a statement of the number of grams of sugars per serving on the Nutrition Facts label, except for products that contain less than 1 gram of sugars per serving if no claims are made about sweeteners, sugars, or sugar alcohol content (9 CFR 317.309(c)(6)(ii) and 381.409(c)(6)(ii)); would be consolidated in proposed 9 CFR 413.309(c)(6)(ii). FSIS defines sugars as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose) (9 CFR 317.309(c)(6)(ii) and 381.409(c)(6)(ii)). Consistent with FDA's final rule, FSIS has tentatively concluded that the mandatory declaration of sugars continues to be necessary to assist consumers in making informed choices and maintaining healthy dietary

practices. But, FSIS is proposing to replace the declaration of "Sugars" with the term "Total Sugars," which is also consistent with FDA's final rule. The rationale for this proposed change is discussed in part K(5).

b. DRV

FSIS's regulations do not provide a DRV for sugars. FDA did not propose a DRV for sugars because there are no upper limits or set dietary reference values on which a DRV for sugars could be based (79 FR 11902). Consistent with FDA's final rule, FSIS is not proposing to set a DRV for sugars.

3. Added Sugars

a. Declaration

FSIS's regulations do not define "added sugars" nor permit its declaration on the Nutrition Facts label. FDA is requiring the declaration of added sugars on the Nutrition Facts label and considered, in its review, new data and information from U.S. consensus reports and scientific evidence supporting recommendations related to the consumption of added sugars, a citizen petition, and public comments (79 FR 11902–11906; 81 FR 33799–33851) and FDA's consumer study on added sugars¹⁰ (80 FR 44306). FSIS has reviewed FDA's analysis and is also proposing to require the declaration of added sugars on the Nutrition Facts label to provide consumers with the information they need to make more informed choices and meet the dietary recommendation to reduce caloric intake from added sugars. FSIS is proposing changes consistent with FDA's final rule. FSIS is proposing to require the mandatory declaration of added sugars as an indented line item underneath the declaration of "Total Sugars" on the Nutrition Facts label. FSIS is also proposing that the phrase "Not a significant source of added sugars" be placed at the bottom of the table of nutrient values if a statement of the added sugars content is not required and, as a result, is not provided. FSIS is also proposing that a statement of added sugars content would not be required for products that contain less than 1 gram of added sugars in a serving if no claims are made about sweeteners, sugars, or sugar alcohol content (proposed 9 CFR 413.309(c)(6)(iii)). FSIS is also proposing to permit alternative statements for added sugars similar to the current alternative statements for

total carbohydrate, dietary fiber, soluble fiber, insoluble fiber, sugars, and sugar alcohol, when a serving contains less than 1 gram of the nutrient. Proposed 9 CFR 413.309(c)(6)(iii) would provide for the alternative statements "Contains less than 1 gram" or "less than 1 gram," or, if the serving contains less than 0.5 g of added sugars, the content can be expressed as zero.

b. Proposed Definition

FSIS regulations do not currently define the term "added sugars." Because FSIS is proposing to require the mandatory declaration of added sugars on the Nutrition Facts label, FSIS is also proposing to define the term "added sugars." Proposed 9 CFR 413.309(c)(6)(iii) defines "added sugars" as sugars that are either added during the processing of foods or are packaged as such and include sugars (free, mono- and disaccharides), sugars from syrups, honey, and fruit juice concentrates (see proposed 9 CFR 413.309(c)(6)(iii) for specific requirements for fruit juice concentrates) (see proposed 9 CFR 413.309(c)(6)(iii) for the complete "added sugars" definition). Examples of "added sugars" added to meat and poultry products include: Table sugar, brown sugar, corn sweetener, corn syrup, dextrose, fructose, apple juice concentrate glucose, Glucono-Delta-Lactone (GDL), high-fructose corn syrup, invert sugar, lactose, maltose, malt sugar, maple syrup, molasses, raw sugar, turbinado, sugar, trehalose, and sucrose. Sugar alcohols would not be considered added sugars.

c. Daily Value

FDA established a DRV for added sugars of 10 percent of total energy intake based on new information in the "Scientific Report of the 2015 Dietary Guidelines Advisory Committee" (the "2015 DGAC report"¹¹) regarding added sugars (80 FR 44308; 81 FR 33842). Consistent with FDA's final rule, FSIS is proposing a DRV for added sugars of 50 g for children and adults 4 years of age and older, including pregnant women and lactating women, and that the percent DV for added sugars be declared on the Nutrition Facts label. As discussed in FDA's supplemental proposed rule, the 2015 DGAC report recommended reducing the intake of added sugars, including an added sugars declaration and a percent DV for added sugars declaration in the Nutrition Facts label, and recommended that Americans keep added sugars intake below 10 percent of total energy intake (80 FR

¹⁰ U.S. Food and Drug Administration. Memorandum to the File—"Experimental study on consumer responses to Nutrition Facts labels with declaration of amount of added sugars (OMB No. 0910-0764)," 2015.

¹¹ <http://www.health.gov/dietaryguidelines/2015-scientific-report/>.

44308). FSIS's proposed DRV of 50 g for added sugars was determined by taking 10 percent of the 2,000 reference calorie intake for adults and children 4 years of age and older ($10 \times 2,000 = 200$ calories) and then dividing by 4 calories/gram, which provides a 50 g reference amount for added sugars as the DRV.

d. Compliance

FSIS is not aware of an analytical method that is capable of distinguishing between added and intrinsically occurring sugars in a food product, nor did FDA identify such a method (9 FR 11906). Therefore, to verify compliance with the proposed mandatory declaration of added sugars, FSIS is proposing in 9 CFR 413.309(h)(8)(iv) that establishments make and keep certain records to verify the amount of added sugars in the product (see compliance section II.N. below for more details about this requirement). For example, FSIS is proposing that a manufacturer must make and keep written records of the amount of sugars added to the product during the processing of the product and, if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient).

FSIS is aware that sugars in some foods may undergo chemical changes as a result of non-enzymatic browning (*i.e.*, Maillard reactions and caramelization) or fermentation during food processing. Some sugars are metabolized or otherwise transformed and converted into compounds that are no longer recognizable or detectable as sugars through conventional analytical methods.¹² As FDA concluded, FSIS expects that the amount of added sugars transformed during non-enzymatic browning reactions in most products is insignificant relative to the initial levels of sugars (81 FR 33830–33831). Unlike browning reactions, fermentation is a process that typically involves the action of desirable microorganisms (*e.g.*, yeasts and lactic acid bacteria) and enzymes that convert organic compounds, especially sugars and other carbohydrates, into simpler compounds such as carbon dioxide, lactic acid, and ethyl alcohol.^{13 14} Fermented sausages

are one example of a fermented meat product and include certain types of pepperoni, salami, Lebanon bologna, mettwurst, and certain types of chorizo. Fermentation can affect the flavor, color, and microbiological safety of meat products. Both natural and controlled meat fermentation involve lactic acid bacteria. This type of bacteria converts naturally occurring glycogen and added sugars into lactic acid. This conversion reduces the amount of sugar in a meat product.¹⁵ However, FSIS expects that the majority of manufacturers would be able to use the amount of sugars added as an ingredient as a reasonable approximation of the amount of added sugars in a serving of their product. When the amount of added sugars is reduced through non-enzymatic browning or fermentation, FSIS is proposing in 9 CFR 413.309(h)(8)(v) to require: (1) Records of scientific data and information that demonstrate the amount of added sugars in the food after non-enzymatic browning or fermentation and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food, provided the data and information used is specific to the type of food manufactured; or (2) records of the amount of sugars added to the food before and during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient) and in no event shall the amount of added sugars declared exceed the amount of total sugars on the label.

In some food products, non-enzymatic browning or fermentation could result in a significant reduction in the amount of added sugars, leaving manufacturers with no way to reasonably approximate the amount of added sugars in a serving of the finished food. Similar to FDA, FSIS is proposing that manufacturers may submit a request to FSIS's LPDS to use an alternative means of compliance. The request must provide scientific data or other information for why the amount of added sugars in a serving of the product is likely to have a significant reduction in added sugars compared to the amount added prior to non-enzymatic browning or fermentation.

4. Sugar Alcohols

For nutrition labeling purposes, consistent with FDA, FSIS defines sugar alcohols "as the sum of saccharide derivatives in which a hydroxyl group

replaces a ketone or aldehyde group and whose use in the food is listed by FDA (*e.g.*, mannitol or xylitol) or is generally recognized as safe (*e.g.*, sorbitol)" (9 CFR 317.309(c)(6)(iii) and 381.409(c)(6)(iii), which would be consolidated in proposed 9 CFR 413.309(c)(6)(iv)). Consistent with FDA, FSIS permits the voluntary declaration of sugar alcohols on the Nutrition Facts label (9 CFR 317.309(c)(6)(iii) and 381.409(c)(6)(iii)). FSIS is not proposing to change the voluntary declaration of sugar alcohols on the Nutrition Facts label, just as FDA did not.

a. DRV

Consistent with FDA, FSIS does not provide a DRV for sugar alcohols and is not proposing a DRV for sugar alcohols because there is no quantitative reference intake recommendation for sugar alcohols from current consensus reports on which to base a DRV.

b. Caloric Value

Caloric content for total carbohydrate less the amount of insoluble dietary fiber is calculated using a factor of 4 calories per gram (9 CFR 317.309(c)(1)(i)(C) and 381.409(c)(1)(i)(C)). FSIS has reviewed the Life Sciences Research Office reports^{16 17} that recommended the following caloric values for sugar alcohols: isomalt (2.0 kcal/g); lactitol (2.0 kcal/g), xylitol (2.4 kcal/g); maltitol (2.1 kcal/g); sorbitol (2.6 kcal/g); hydrogenated starch hydrolysates (3.0 kcal/g); and mannitol (1.6 kcal/g). FSIS has tentatively concluded that the values recommended by the Life Sciences Research Office are closer to the energy contribution of sugar alcohols than the current factors. FSIS also reviewed FDA's analysis for determining a caloric value for erythritol and agrees with the analysis (81 FR 33852). Therefore, consistent with FDA's final rule (81 FR 33852), FSIS is proposing to amend its regulations to establish the following general factors for caloric values for sugar alcohols: isomalt (2.0 kcal/g); lactitol (2.0 kcal/g), xylitol (2.4 kcal/g); maltitol (2.1 kcal/g); sorbitol (2.6 kcal/g); hydrogenated starch hydrolysates (3.0 kcal/g); mannitol (1.6 kcal/g); and erythritol (0 kcal/g). Proposed 9 CFR 413.309(c)(1)(i)(F) will establish these values, and proposed 9 CFR 413.309(c)(1)(i)(C) will clarify that the

¹² Skibsted, L.H., Risbo, J., Andersen, M.L. "Chemical Deterioration and Physical Instability of Food and Beverages". Woodhead Publishing; 2010; pp. 70–94.

¹³ Lewis, R.J., Sr., editor. Hawley's Condensed Chemical Dictionary. 15th Ed. John Wiley & Sons, 2007; pp. 549–550.

¹⁴ Murano, P.S. "Understanding Food Science and Technology". Belmont, California: Wadsworth/Thomas Learning; 2003; pp. 123–125.

¹⁵ Toldrá, et al., "Handbook of Fermented Meat and Poultry," Wiley Blackwell; 2015; Chapters 1–2.

¹⁶ Life Sciences Research Office. "The Evaluation of the Energy of Certain Sugar Alcohols Used as Food Ingredients", Bethesda, MD: Life Sciences Research Office; 1994.

¹⁷ Life Sciences Research Office. "Evaluation of the Net Energy Value of Maltitol", Bethesda, MD: Life Sciences Research Office; 1999.

factor of 4 kcal/g does not apply to sugar alcohols.

5. Fiber

a. Dietary Fiber

i. Definition

FSIS's regulations do not define "dietary fiber." After considering IOM recommendations, comments received on FDA's 2007 ANPRM, and international guidelines (*e.g.*, The Codex Alimentarius Commission's definition of dietary fiber), FDA adopted a definition of dietary fiber that is equivalent to the IOM's definition of "total fiber" and emphasizes the beneficial physiological effects in humans (81 FR 33853). FSIS has reviewed FDA's analysis and is proposing to include a definition for dietary fiber in 9 CFR 413.309(c)(6)(i) that is consistent with FDA's definition. FSIS is proposing the following definition for dietary fiber: (1) Non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin that are intrinsic and intact in plants; and (2) isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health.

FSIS is proposing to include isolated or synthetic non-digestible carbohydrates that have been determined by FDA to have a physiological effect that is beneficial to human health in the proposed definition of dietary fiber in 9 CFR 413.309(c)(6)(i). For example, β -glucan soluble fiber and psyllium husk that are added to foods meet the proposed definition of dietary fiber and would be listed in 9 CFR 413.309(c)(6)(i). FSIS would consider amending 9 CFR 413.309(c)(6)(i) to list any additional isolated or synthetic non-digestible carbohydrates that FDA determines have a physiological effect that is beneficial to human health.

ii. Mandatory Declaration

FSIS requires that a statement of the number of grams of total dietary fiber per serving be declared on the Nutrition Facts label, except when a serving contains less than 1 gram of total dietary fiber (9 CFR 317.309(c)(6)(i) and 381.409(c)(6)(i), which would be consolidated in proposed 9 CFR 413.309(c)(6)(i)). FSIS is not proposing to change the requirement for mandatory declaration of dietary fiber, just as FDA did not.

iii. Analytical Methods

The amount of dietary fiber may be calculated by subtracting the amount of non-digestible carbohydrates added during processing that do not meet the proposed definition of dietary fiber from the value obtained using AOAC 2009.01, AOAC 2011.25, or an equivalent AOAC method of analysis as given in the "Official Methods of Analysis of the AOAC International" 19th Edition. Because an AOAC method would not accurately quantify the dietary fiber that meets the proposed definition if the product contains both non-digestible carbohydrates that meet the definition and those that do not, consistent with FDA's final rule, FSIS is proposing to require that manufacturers maintain written records to verify the amount of added non-digestible carbohydrates that do not meet the proposed definition of dietary fiber. (See Compliance section II.N. below.)

iv. DRV

Currently, 25 g is the DRV for total dietary fiber based on the reference calorie intake of 2,000 calories (9 CFR 317.309(c)(9) and 381.409(c)(9)). FSIS is proposing to amend its regulations to establish 28 g as the DRV for total dietary fiber (proposed 9 CFR 413.309(c)(9)). FSIS is proposing to use 28 g as the DRV for total dietary fiber because: (1) the IOM set an adequate intake level (AI) of 14 g/1,000 kcal for total fiber primarily based on the intake level that was associated with the greatest reduction in the risk of CHD;¹⁸ and (2) FDA now uses 14 g/1,000 kcal as the basis for a DRV for dietary fiber and setting a DRV of 28 g for dietary fiber using a reference calorie intake of 2,000 calories (81 FR 33865–33866).

b. Soluble and Insoluble Fiber

Soluble fibers (*e.g.*, pectin) dissolve in water and are digested by the bacteria in the large intestine. Insoluble fibers (*e.g.*, cellulose) do not dissolve in water and are not digested by the bacteria in the large intestine. FSIS regulations do not define the terms soluble and insoluble fiber, but provide for the voluntary declaration of soluble and insoluble fiber (9 CFR 317.309(c)(6)(i) and 381.409(c)(6)(i)), which would be consolidated in proposed 9 CFR 413.309(c)(6)(i)). Consistent with FDA, FSIS is proposing that when soluble fiber or insoluble fiber is declared, the soluble fiber and insoluble fiber must

meet the definition of "dietary fiber" in proposed 9 CFR 413.309(c)(6)(i) because they are components of dietary fiber.

i. Analytical Methods

AOAC 2011.25 or an equivalent AOAC method may be used to calculate soluble and insoluble fiber that meet the proposed definition of dietary fiber and can be declared on the Nutrition Facts label. AOAC 2011.25 can measure low molecular weight non-digestible carbohydrates, as well as separately measure soluble and insoluble non-digestible carbohydrates.¹⁹ Consistent with FDA, if a product contains a mixture of non-digestible carbohydrates that do not meet the proposed dietary fiber definition, and the label of the product declares soluble or insoluble fiber content, FSIS is proposing to require establishments to make and keep records to verify the amount of non-digestible carbohydrate(s) that does not meet the proposed definition of dietary fiber present in the food. (See discussion in compliance section II.N. below.)

ii. DRV

FDA did not find a basis on which to derive DRVs for soluble or insoluble fiber. Consistent with FDA's final rule, FSIS is not proposing DRVs for soluble fiber or insoluble fiber.

iii. Caloric value

FSIS regulations provide that the caloric content of a product may be calculated by, among other methods, using general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate less the amount of insoluble dietary fiber, and total fat, respectively (9 CFR 317.309(c)(1)(i)(C) and 381.409(c)(1)(i)(C)). Soluble fiber, which is included in total carbohydrate, is assigned a general factor of 4 kcal/g. FDA established a general factor of 2 kcal/g as the caloric value of soluble non-digestible carbohydrates (81 FR 33867). Insoluble non-digestible carbohydrates are not included in the caloric calculation (81 FR 33867). FDA required that calories from carbohydrate be calculated using a general factor of 4 kcal/g of total carbohydrate less the amount of non-digestible carbohydrates, which includes soluble (2 kcal/g) and insoluble non-digestible carbohydrates (0 kcal/g) that do and do not meet the definition of dietary fiber (81 FR 33867). The calorie contribution of soluble non-digestible carbohydrate would be added

¹⁸ Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Chapter 7: Dietary, Functional, and Total Fiber", Washington, DC: National Academies Press; 2002.

¹⁹ McCleary, B.V., DeVries, J.W., Rader, J.L., et al. "Determination of Total Dietary Fiber (CODEX definition) by Enzymatic-Gravimetric Method and Liquid Chromatography: Collaborative Study". *Journal of AOAC International*. 2010;93:221–233.

to that sum to determine the total carbohydrate calorie contribution (Id.). Therefore, in order to harmonize with FDA's regulations, FSIS is proposing the same changes to the caloric value for soluble non-digestible carbohydrates and the calculation of calories from carbohydrate.

6. Other Carbohydrate

FSIS's regulations define "Other carbohydrate" as the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, except that if sugar alcohol is not declared (even if present), "Other carbohydrate" is defined as the difference between total carbohydrate and the sum of dietary fiber and sugars (9 CFR 317.309(c)(6)(iv) and 381.409(c)(6)(iv)). A statement of the number of grams of "Other carbohydrate" per serving may be voluntarily declared on the Nutrition Facts label (9 CFR 317.309(c)(6)(iv) and 381.409(c)(6)(iv)).

FDA concluded that "Other carbohydrate" should no longer be permitted on the Nutrition Facts label because of its lack of public health significance and a quantitative intake recommendation for "Other carbohydrate" is not available from relevant consensus reports (81 FR 33867–33868). FDA removed the provision that allows for its voluntary declaration in the regulations (81 FR 33867–33868). FSIS has reviewed FDA's analysis and is proposing to no longer permit the voluntary declaration of "Other carbohydrate" on the Nutrition Facts label for the reasons above.

F. Protein

FSIS's regulations require that a statement of the number of grams of protein per serving be declared on the Nutrition Facts label (9 CFR 317.309(c)(7) and 381.409(c)(7)), which would be consolidated in proposed 9 CFR 413.309(c)(7)). The DRV for protein is 50 g and represents 10 percent of the 2,000 reference calories intake level. Consistent with FDA, FSIS is not proposing to change the mandatory declaration of protein or the DRV for protein.

1. Analytical Methods

Under FSIS's regulations (9 CFR 317.309(c)(7) and 381.409(c)(7)), protein may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food as determined by appropriate methods of analysis in accordance with 9 CFR 317.309(h) or 9 CFR 381.409(h), except when the procedure for a specific food requires another factor. According to 9 CFR

317.309(h)(2) and 381.409(h)(2), FSIS determines compliance by appropriate methods and procedures used by the Department for each nutrient in accordance with the *Chemistry Laboratory Guidebook*, or, if no USDA method is available and appropriate for the nutrient, by appropriate methods for the nutrient in accordance with the 1990 edition of the *Official Methods of Analysis of the AOAC International*, formerly Association of Official Analytical Chemists, 15th ed., to determine compliance with the nutrition labeling regulations. FSIS is proposing to update the version of the *Official Methods of Analysis of the AOAC International* referenced in the regulations because more analytical methods for nutrients have been published in later versions. The 20th edition is the most recent edition of the published AOAC methods, so FSIS is proposing in 9 CFR 413.309(h) that the 20th edition be used if no USDA method is available. If a newer version of the *Official Methods of Analysis of the AOAC International* is published before a final rule is published for this rulemaking, FSIS will consider using the most recent version of the official AOAC methods in the final rule.

G. Sodium

FSIS's regulations require the declaration of the number of milligrams of sodium per serving on the Nutrition Facts label (9 CFR 317.309(c)(4) and 381.409(c)(4)), which would be consolidated in proposed 9 CFR 413.309(c)(4)). Consistent with FDA, FSIS is not proposing to change the requirement that sodium be declared.

FSIS's regulations set a DRV of 2,400 mg of sodium based on a reference caloric intake of 2,000 calories (9 CFR 317.309(c)(9) and 381.409(c)(9)). FDA considered the following options for updating the DRV for sodium: "(1) A DRV of 2,300 mg which reflects the Upper Intake Level (UL)²⁰ for individuals aged 14 years and older; (2) An RDI of 1,500 mg which reflects the AI for individuals 9 to 50 years of age; and (3) Alternative approaches such as retaining a DRV of 2,400 mg, using a tiered approach or setting a DRV of 1,900 mg based on the UL for children 4 to 9 years of age" (79 FR 11915). In FDA's Nutrition Labeling Proposed Rule, FDA tentatively concluded that

²⁰ "The UL is the highest average daily intake level likely to pose no risk of adverse health effects for nearly all people in a particular group. The UL is not intended to be a recommended level of intake. The UL is used to assess the risk of adverse health effects from excessive nutrient intake. As intake above the UL increases, so does the potential for risk of adverse health effects" (79 FR 11885).

2,300 mg is the most appropriate DV for sodium to "assist consumers in maintaining healthy dietary practices and in understanding the relative significance of the sodium content within the context of a total daily diet" (79 FR 11917). FDA did not change its view in the final rule that 2,300 mg/day is an appropriate DRV for sodium (81 FR 33874–33880). FSIS has reviewed FDA's analysis, and consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to set a DRV of 2,300 mg for sodium (proposed 9 CFR 413.309(c)(9)).

H. Fluoride

FSIS's regulations do not permit the declaration of fluoride on the Nutrition Facts label. FDA amended its regulations to provide for the voluntary declaration of fluoride because fluoride's positive health effects are well established (e.g., reduces the risk of dental caries), but an appropriate quantitative intake recommendation is not available for setting a DRV (81 FR 33880–33884) (proposed 9 CFR 413.309(c)(5)). FSIS has reviewed FDA's analysis and consistent with FDA, FSIS is proposing to (i) permit the voluntary declaration of fluoride on the Nutrition Facts label; (ii) require the mandatory declaration of fluoride when a claim about fluoride is made on the label or in labeling of the product; and (iii) require that when fluoride content is declared, it must be expressed as zero when a serving contains less than 0.1 mg of fluoride, to the nearest 0.1 mg increment when a serving contains less than or equal to 0.8 mg of fluoride, and the nearest 0.2 mg when a serving contains more than 0.8 mg of fluoride, consistent with how FSIS and FDA have approached incremental values for other nutrients that are present in products in small amounts. FSIS is not proposing a DRV for fluoride because an appropriate quantitative intake recommendation is not available for setting a DRV.

I. Essential Vitamins and Minerals

1. Updates to Declaration of Vitamins and Minerals and Reference Daily Intakes

FSIS currently requires the declaration of vitamin A, vitamin C, calcium, and iron on the Nutrition Facts label (9 CFR 317.309(c)(8)(ii) and 381.409(c)(8)(ii)). Vitamin D, vitamin E, vitamin B₆, vitamin B₁₂, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, copper, and potassium may all be declared voluntarily on the Nutrition Facts label (9 CFR 317.309(c)(8)(iv)),

381.409(c)(8)(iv), 317.309(c)(9), and 381.409(c)(9)). FSIS has also permitted the voluntary declaration of nutrients for which FSIS has not codified RDIs, but that are codified in Title 21 of FDA's regulations.²¹ These nutrients are vitamin K, selenium, manganese, chromium, molybdenum, and chloride.

FDA amended its regulations to: (i) Require the declaration of vitamin D, calcium, iron, and potassium on the Nutrition Facts label; (ii) allow the voluntary declaration of vitamin A and C; (iii) retain the voluntary declaration of vitamin E, vitamin K, vitamin B₆, vitamin B₁₂, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, and chloride; and (iv) allow the voluntary declaration of choline (81 FR 33884–33897). FDA made these changes based on its

analysis of data and consideration of such factors as public health significance, quantitative intake recommendations, and the role of a nutrient in chronic disease risk (81 FR 33884–33897). Consistent with FDA and proposed 9 CFR 413.309(c)(8)(ii), the vitamins and minerals would be updated in proposed 9 CFR 413.363(b)(4) to replace “vitamin A, vitamin C, calcium, and iron” with “vitamin D, calcium, iron, and potassium.”

FDA also revised the existing RDIs for vitamins and minerals after considering the Dietary Reference Intakes (DRIs)²² set by the IOM that reflect current nutrient requirements (81 FR 33897–33901). Percent DVs for vitamins and minerals that are required or permitted on the Nutrition Facts label are based on RDIs (9 CFR 317.309(c)(8)(iv) and 381.409(c)(8)(iv)).

FSIS is proposing to adopt FDA's list of nutrients as mandatory or voluntary components of nutrition labeling, the definition of those nutrients, and the increments for declaring nutrients, in the interest of harmonizing with FDA (proposed 9 CFR 413.309(c)(8)(iv)). Consistent with FDA's final rule, FSIS is also proposing to update the RDIs for calcium, copper, folate, iodine, iron, magnesium, niacin, phosphorus, riboflavin, thiamin, zinc, and vitamins A, B₆, B₁₂, C, D, and E and to establish RDIs for vitamin K, selenium, manganese, chromium, molybdenum, chloride, and choline (proposed 9 CFR 413.309(c)(8)(iv)) (see Table 2). A more extensive discussion of FDA's list of nutrients and RDIs can be found in the preamble of FDA's Nutrition Labeling Proposed and Final Rules (79 FR 11918–11931; 81 FR 33897–33901).

TABLE 2—CURRENT AND PROPOSED RDIs FOR NUTRITION LABELING

[Based on a 2,000 calorie intake for adults and children 4 or more years of age]

| Nutrient | Current RDIs | Proposed RDIs |
|-------------------------------|---------------------------------|----------------------------------|
| Vitamins: | | |
| Biotin | .3 milligram | 30 micrograms. |
| Choline | N/A | 550 milligrams. |
| Folate ⁶ | .4 milligram | 400 micrograms DFE. ¹ |
| Niacin | 20 milligrams | 16 milligrams NE. ² |
| Pantothenic acid | 10 milligrams | 5 milligrams. |
| Riboflavin | 1.7 milligrams | 1.3 milligrams. |
| Thiamin | 1.5 milligrams | 1.2 milligrams. |
| Vitamin A | 5,000 International Units | 900 micrograms RAE. ³ |
| Vitamin B ₆ | 2.0 milligrams | 1.7 milligrams. |
| Vitamin B ₁₂ | 6 micrograms | 2.4 micrograms. |
| Vitamin C | 60 milligrams | 90 milligrams. |
| Vitamin D | 400 International Units | 20 micrograms. ⁴ |
| Vitamin E | 30 International Units | 15 milligrams. ⁵ |
| Vitamin K | N/A | 120 micrograms. |
| Minerals: | | |
| Calcium | 1.0 gram | 1,300 milligrams. |
| Chloride | N/A | 2,300 milligrams. |
| Chromium | N/A | 35 micrograms. |
| Copper | 2.0 milligrams | 0.9 milligrams. |
| Iodine | 150 micrograms | 150 micrograms. |
| Iron | 18 milligrams | 18 milligrams. |
| Magnesium | 400 milligrams | 420 milligrams. |
| Manganese | N/A | 2.3 milligrams. |
| Molybdenum | N/A | 45 micrograms. |
| Phosphorus | 1.0 gram | 1,250 milligrams. |
| Potassium ⁷ | 3,500 milligrams | 4,700 milligrams. |
| Selenium | N/A | 55 micrograms. |
| Zinc | 15 milligrams | 11 milligrams. |

¹ DFE = Dietary Folate Equivalents; 1 DFE = 1 mcg naturally-occurring folate = 0.6 mcg of folic acid.

² NE = Niacin equivalents, 1 mg NE = 1 mg niacin = 60 mg of tryptophan.

³ RAE = Retinol activity equivalents; 1 microgram RAE = 1 microgram retinol, 2 micrograms supplemental β-carotene, 12 micrograms β-carotene, or 24 micrograms α-carotene, or 24 micrograms β-cryptoxanthin.

⁴ The amount of vitamin D may, but is not required to, be expressed in international units (IU), in addition to the mandatory declaration in mcg. Any declaration of the amount of vitamin D in IU must appear in parentheses after the declaration of the amount of vitamin D in mcg.

⁵ 1 mg α-tocopherol (label claim) = 1 mg α-tocopherol = 1 mg RRR-α-tocopherol = 2 mg all rac-α-tocopherol.

⁶ “Folate” and “Folic Acid” must be used for purposes of declaration in the labeling of conventional foods and dietary supplements. The declaration for folate must be in mcg DFE (when expressed as a quantitative amount by weight in a conventional food or a dietary supplement), and percent DV based on folate in mcg DFE. Folate may be expressed as a percent DV in conventional foods. When folic acid is added or when a claim is made about the nutrient, folic acid must be declared in parentheses, as mcg of folic acid.

⁷ These minerals currently have a DRV and we are proposing to establish an RDI.

²¹ <http://www.fsis.usda.gov/wps/portal/ffsis/topics/regulatory-compliance/labeling/labeling-policies/trans-fat-declarations/trans-fat-declaration>.

²² A set of reference values that include the Estimated Average Requirement, RDA, Adequate

Intake, and Tolerable Upper Intake Level. See 79 FR 11885–6 for more background on DRIs.

2. Terms for Vitamins and Minerals

FSIS currently allows the term “Folacin” to be added in parenthesis immediately following the term “Folate” on the Nutrition Facts label (9 CFR 317.309(c)(8)(v) and 381.409(c)(8)(v)). FSIS is proposing to remove the synonym “folacin” from 9 CFR 317.309(c)(8)(v) and 381.409(c)(8)(v) and require that the term “folate” be used on meat and poultry products that contain folate, folic acid, or a mixture of folate and folic acid (proposed 9 CFR 413.309(c)(8)(vii)). The declaration must be folate in mcg DFE (when expressed as a quantitative amount by weight) and the percent Daily Value based on folate in mcg DFE, or may be expressed as folate and the percent DV based on folate in mcg DFE. Because of the proposed changes to the units of measure for folate that take into account the differences between folate and folic acid, FSIS is proposing that when folic acid is added or when a claim is made about the nutrient, folic acid must be declared in parentheses as mcg of folic acid after the folate declaration. FSIS’s proposed changes are consistent with FDA’s Nutrition Labeling Final Rule (81 FR 33909–33912).

J. Labeling of Foods for Infants, Young Children, and Pregnant or Lactating Women

The general labeling requirements for foods in 9 CFR 317.309(c) and 381.409(c) apply to foods for infants, young children, and pregnant women and lactating women with certain exceptions. For example, meat and poultry products represented or purported to be specifically for infants and children less than 4 years of age are not permitted to include declarations of percent DV for the following nutrients: Total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber (9 CFR 317.400(c)(2)(i) and 381.500(c)(2)(i)). There are additional exceptions to labeling for meat and poultry products represented or purported to be specifically for infants and children less than 2 years of age. For example, these foods are also not permitted to declare calories from fat, calories from saturated fat, saturated fat, stearic acid, polyunsaturated fat, monounsaturated fat and cholesterol on the Nutrition Facts label (9 CFR 317.400(c)(1) and 381.500(c)(1)).

FSIS regulations do not include DRVs or RDIs for nutrients, generally, for infants, children under 4 years of age, or pregnant women and lactating women. However, there are requirements for a DRV for protein for children 4 or more

years of age, and an RDI for protein for each of the following subpopulations: (1) Children less than 4 years of age; (2) infants; (3) pregnant women; and (4) lactating women (9 CFR 317.309(c)(7)(iii) and 381.409(c)(7)(iii)).

FDA changed its requirements for the labeling of foods, other than infant formula, represented or purported to be specifically for infants, children under 4 years of age, and pregnant women and lactating women after considering current consensus reports, changes to the Nutrition Facts label, and comments to its 2007 ANPRM (81 FR 33916–33932). FSIS has reviewed FDA’s analysis and is proposing to make consistent changes to its requirements for the labeling of meat and poultry products represented or purported to be specifically for infants, children under 4 years of age, and pregnant women and lactating women (proposed 9 CFR 413.309(c)).

1. Age Range for Infants and Young Children

FSIS regulations currently use the age ranges “less than 2 years of age” and “less than 4 years of age” to establish labeling requirements for meat and poultry products represented or purported to be specifically for infants and young children (9 CFR 317.400(c) and 381.500(c)). FDA amended its regulations so that the age categories were changed to infants through 12 months and young children 1 through 3 years (13 through 48 months) which would be consistent with the age ranges used in the IOM’s DRIs for infants and children (81 FR 33916–33917). FDA’s new DVs are also based on these age-specific DRIs (81 FR 33916–33917).

Consistent with FDA’s final rule, FSIS is proposing to replace the current category of infants and children less than 4 years in 9 CFR 317.400(c)(1); 381.500(c)(1); 317.309(c)(7)–(8); 381.409(c)(7)–(8); 317.309(d)(1); 381.409(d)(1); 317.313(b)(3); 381.413(b)(3); 317.313(q)(3); and 381.413(q)(3) with infants through 12 months and children 1 through 3 years of age (proposed 9 CFR 413.400(c)(1); 413.309(c)(7)–(9); 413.309(d)(1); 413.313(b)(3); and 413.313(q)(3)).

2. Mandatory Declaration of Calories and Other Nutrients

Currently, meat and poultry products represented or purported to be specifically for infants and children less than 4 years must declare certain nutrients, including calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, sugars, dietary fiber, and protein (9 CFR 317.400(c)(2) and 381.500(c)(2)). For

meat and poultry products represented or purported to be for infants and children less than 2 years, the declaration of certain nutrients, which include calories from fat, saturated fat, and cholesterol, is not required or permitted (9 CFR 317.400(c)(1) and 381.500(c)(1)).

a. Declaration of Saturated Fat and Cholesterol

Because FSIS is proposing new categories of infants through 12 months and children 1 through 3 years of age, FSIS is considering whether there is a need to require or permit the declaration of calories from fat, saturated fat, and cholesterol in the labeling for foods represented or purported to be specifically for these subpopulations. As discussed in section II.B.1. above, FSIS is proposing to no longer require and not permit the declaration of calories from fat on the Nutrition Facts label (proposed 9 CFR 413.309(c)(1)(ii)). Therefore, if these proposed changes are finalized, the exception in 9 CFR 317.400(c)(1) and 381.500(c)(1) for calories from fat will no longer be needed, and the reference to calories from fat will be removed. FSIS’s regulations currently do not require or permit the labeling of any fat, with the exception of total fat, or fatty acids on meat and poultry products represented or purported to be specifically for children less than 2 years of age.

FDA considered a recent consensus report suggesting that: Fat intake in infants less than 12 months of age should not be restricted. Fat is still an important source of calories for infants and young children. Evidence suggests a diet with saturated fat of less than 10 percent of calories and cholesterol intake less than 300 mg/d can safely and effectively reduce the levels of total and LDL cholesterol in healthy children, and that the 2010 DGA recommended that Americans 2 years of age and older consume less saturated fatty acids and less than 300 mg/d of cholesterol (79 FR 11934). FDA requires, except for the declaration of calories from fat, the mandatory declaration of statutorily required nutrients under section 403(q) of the FD&C Act that include saturated fat and cholesterol on the label of foods represented or purported to be specifically for infants through 12 months and children 1 through 3 years of age (81 FR 33917–33918). Therefore, consistent with FDA’s final rule, FSIS is proposing to require the declaration of saturated fat and cholesterol on the label of meat and poultry products purported to be for infants through 12 months and children 1 through 3 years of age (proposed 9 CFR 413.400(c)(1)).

Currently, meat and poultry products consumed by pregnant women and lactating women must declare certain nutrients, including calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, sugars, dietary fiber, and protein. As discussed in FDA's Nutrition Labeling Proposed Rule, women of reproductive age consume the same foods as the general population and, in general, continue consuming similar foods during pregnancy and lactation (79 FR 11934). FDA requires, except for the declaration of calories from fat, the mandatory declaration of statutorily required nutrients under section 403(q) of the FD&C Act (81 FR 33917–33918).

Accordingly, FSIS is proposing to require the mandatory declaration of calories and the amount of total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, and protein on foods represented or purported to be specifically for infants through 12 months of age, children 1 through 3 years of age, and pregnant women and lactating women and to permit the declaration of calories from saturated fat such that these nutrients would be subject to the same requirements applicable to meat and poultry products for the general population (proposed 9 CFR 413.309(c)).

b. Percent DV Declaration

Currently, the percent DV declaration is not permitted on the Nutrition Facts label for meat and poultry products represented or purported to be specifically for infants and children less than 4 years of age (which includes infants and children less than 2 years of age) for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber (9 CFR 317.400(c)(2)(i) and 381.500(c)(2)(i)). Percent DV is required for protein and vitamins and other minerals and, as discussed in sections II.F and II.I, provides information in a manner that enables consumers to understand the relative significance of nutrition information in the context of a total daily diet. FDA concluded that it is appropriate to require declarations of percent DV for those nutrients for which FDA is establishing a DRV or RDI for infants through 12 months, for children 1 through 3 years of age, and for pregnant women and lactating women (81 FR 33918–33919). Accordingly, FSIS is proposing in 9 CFR 413.400(c)(2)(i) to require declarations of percent DV for those nutrients for which FSIS is establishing a DRV or RDI for infants through 12 months, for children 1 through 3 years of age, and for pregnant women and lactating women consistent

with FDA's Nutrition Labeling Final Rule.

c. Mandatory Declaration of Added Sugars

As discussed in section II.E.3, FSIS is proposing to require the mandatory declaration of added sugars on the Nutrition Facts label. The 2010 DGA provides recommendations for consumption of added sugars for the U.S. population 2 years of age and older but not for infants and children under age 2. It is expected, however, that the role of added sugars are not markedly different between children 1 and 2 years of age (79 FR 11936). Similarly, the IOM has established DRI ranges for 1-through-3-year-olds because growth velocity is most similar during this age range (79 FR 11936; 81 FR 33916). FDA has concluded that mandatory declaration of added sugars is needed for foods for infants through 12 months, just as it is for the general population, to provide consumers with information to construct a healthy dietary pattern that meets the dietary recommendations for added sugars (81 FR 33921).

Consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing the mandatory declaration of added sugars on the Nutrition Facts label of meat and poultry products represented or purported to be specifically for infants through 12 months, children 1 through 3 years of age, and pregnant women and lactating women.

d. Mandatory Declaration of Trans Fat

As discussed in section II.C.3, FSIS is proposing to require the mandatory declaration of *trans* fat on the Nutrition Facts label. The mandatory declaration of *trans* fat is needed for foods for infants through 12 months, children 1 through 3 years of age, and pregnant women and lactating women, just as it is needed for the general population to assist in maintaining healthy dietary practices. For example, the relationship between the consumption of *trans* fat and risk of CHD is well established^{23 24} and cardiovascular disease is also known to begin in childhood.^{25 26}

²³ U.S. Department of Agriculture and U.S. Department of Health and Human Services. (2010) "Dietary Guidelines for Americans, 2010", 7th Ed., Washington DC: U.S. Government Printing Office. Retrieved from <http://www.cnpp.usda.gov/DGAs2010-PolicyDocument.htm>.

²⁴ Institute of Medicine (IOM) of the National Academies. "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients), Chapter 8: Dietary Fats: Total Fat and Fatty Acids", Washington, DC: National Academies Press; 2002.

²⁵ U.S. Department of Health and Human Services, National Institutes of Health, and National, Heart Lung and Blood Institute. (October, 2012) "Integrated Guidelines for Cardiovascular

Consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to require the declaration of trans fat on the Nutrition Facts label of meat and poultry products represented or purported to be specifically for infants through 12 months, children 1 through 3 years of age, and pregnant women and lactating women.

3. Voluntary Declaration of Nutrients Other Than Essential Vitamins and Minerals

Currently, meat and poultry products represented or purported to be specifically for infants and children less than 2 years of age are not permitted to declare calories from fat, calories from saturated fat, and the amount of polyunsaturated fat and monounsaturated fat (9 CFR 317.400(c)(1) and 381.500(c)(1)), whereas soluble fiber, insoluble fiber, and sugar alcohols can be voluntarily declared. Polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, and sugar alcohols can be voluntarily declared on the label of meat and poultry products represented or purported to be specifically for children 2 through 4 years of age and pregnant women and lactating women (9 CFR 317.400(c)(2) and 381.500(c)(2)). FSIS is proposing the following changes to voluntary declaration of certain nutrients.

a. Voluntary Declaration of Calories From Saturated Fat, and the Amount of Polyunsaturated and Monounsaturated Fat

For infants through 12 months, there are no specific recommendations provided about calories from saturated, polyunsaturated, or monounsaturated fat. However, as discussed in FDA's Nutrition Labeling Proposed Rule, there is some evidence to suggest that reduction of total and LDL cholesterol levels can occur with reducing saturated fat intake to less than 10 percent of calories, beginning in infancy and sustained throughout childhood into adolescence (79 FR 11935). Because consensus reports provide no discussion or recommendation about providing nutrient guidelines for fatty acids to children under the age of 2 years, and there is no evidence to suggest that infants through 12 months of age would

Health and Risk Reduction In Children and Adolescents: The Report of the Expert Panel"; NIH Publication No. 12–7486A. Retrieved from http://www.nhlbi.nih.gov/guidelines/cvd_ped/index.htm.

²⁶ American Academy of Pediatrics. "Chapter 32: Hyperlipidemia and Prevention of Cardiovascular Disease". In: *Pediatric Nutrition Handbook* 6th Ed. Kleinman, R.E., ed. American Academy of Pediatrics; 2009; p.723.

be different than children 1 through 3 years of age, FDA explained that there is no basis to continue to prohibit the declaration of calories from saturated fat or polyunsaturated and monounsaturated fats on foods represented or purported to be specifically for infants and children less than 2 years of age (81 FR 33919–33920).

Also, as discussed in FDA's Nutrition Labeling Proposed Rule, quantitative intake recommendations are not available from relevant U.S. consensus reports for monounsaturated and polyunsaturated fats for children 1 through 3 years of age or pregnant women and lactating women. There is well-established evidence to indicate that replacing saturated fatty acids with polyunsaturated and monounsaturated fatty acids reduces blood LDL cholesterol levels and, therefore, the risk of CVD; and that monounsaturated and polyunsaturated fats have public health significance when they replace saturated fat (79 FR 11936). FDA finalized its proposed requirements and permits the declaration of calories from saturated fat, polyunsaturated and monounsaturated fat on foods represented or purported to be specifically for infants through 12 months and children 1 through 3 years of age (81 FR 33919–33920).

Consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to revise 9 CFR 317.400(c)(1) and 381.500(c)(1) (which would be consolidated in proposed 9 CFR 413.400(c)(1)) to remove the exceptions for the declaration of calories from saturated fat and the amount of polyunsaturated fat and monounsaturated fat on meat and poultry products represented or purported to be specifically for infants through 12 months, children 1 through 3 years of age, or pregnant or lactating women. If finalized, these declarations for the new age categories, infants through 12 months and children 1 through 3 years of age, would be the same as the proposed voluntary declarations for foods for the general population.

b. Voluntary Declaration of Soluble Fiber, Insoluble Fiber, and Sugar Alcohols

As discussed in section II.E, FSIS is proposing to allow the declaration of soluble fiber and insoluble fiber that meet the definition of "dietary fiber" on the Nutrition Facts label for the general population. FDA has concluded that there is no evidence to suggest that the role of these nutrients would be different among infants through 12

months, children 1 through 3 years of age, or pregnant women and lactating women compared to the general population (81 FR 33920).

FSIS has reviewed FDA's analysis and is not proposing any changes to the provisions for the voluntary declaration of soluble fiber, insoluble fiber, and sugar alcohols on the label of meat and poultry products represented or purported to be specifically for infants through 12 months, children 1 through 3 years of age, or pregnant women and lactating women, consistent with FDA's Nutrition Labeling Final Rule (81 FR 33920).

c. Voluntary Declaration of Fluoride

FSIS regulations currently do not provide for the declaration of fluoride on the Nutrition Facts label of any meat or poultry product. For the reasons discussed in section II.H, FSIS is proposing to permit voluntary declaration of fluoride on the labeling of meat and poultry products for the general population. As discussed in FDA's Nutrition Labeling Proposed Rule and Final Rule (in which FDA did not change its tentative conclusions from the proposed rule), because fluoride provides protection against dental caries by strengthening the tooth enamel before and after teeth appear, and because excessive fluoride intake can cause dental fluorosis in young children, the declaration of fluoride on foods represented or purported to be specifically for children 1 through 3 years of age and for pregnant women and lactating women can assist in maintaining healthy dietary practices (79 FR 11936; 81 FR 33921). Further, while evidence on dental caries is lacking for infants through 12 months of age, there is no reason to expect the role of fluoride in the protection against dental caries to be different from other age groups (*Id.*). Therefore, consistent with FDA's Nutrition Labeling Final Rule on the voluntary declaration of fluoride for these subpopulations, FSIS is proposing to permit the voluntary declaration of fluoride on meat and poultry products represented or purported to be specifically for infants through 12 months of age, children 1 through 3 years of age, and pregnant women and lactating women (proposed 9 CFR 413.309(c)(5)).

4. Declaration of Essential Vitamins and Minerals

FSIS requires the declarations of vitamin A, vitamin C, calcium, and iron on the Nutrition Facts label, and there are no specific exceptions to this requirement for meat and poultry products represented or purported to be

specifically for infants and children less than 2 years and children less than 4 years of age, and pregnant women and lactating women (9 CFR 317.309(c)(8) and 381.409(c)(8)). FSIS is proposing to replace the current categories "infants and children less than 2 years of age and children less than 4 years of age" with "infants through 12 months and children 1 through 3 years of age."

Since the needs of essential vitamin and minerals are increased for both pregnant women and lactating women, FDA applied its conclusions about nutrient inadequacy during pregnancy to lactating women and made the requirements related to essential vitamins and minerals in labeling of foods for pregnant women and lactating women the same (81 FR 33921–33922). Consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to remove the current provision in 9 CFR 317.309(c)(8)(i) and 381.409(c)(8)(i) that requires separate declaration of percent DVs based on both RDI values for pregnant women and for lactating women in the labeling of foods represented or purported to be for use by both pregnant women and lactating women (proposed 9 CFR 413.309(c)(8)(i)).

a. Mandatory Declaration of Calcium and Iron

FSIS is not proposing any changes to the mandatory declaration of calcium on foods for the general population (see section II.I.1.). As discussed in FDA's Nutrition Labeling Proposed Rule, the AI for calcium for infants through 12 months of age is based on average calcium consumption of this nutrient rather than on chronic disease risk, health related-condition, or physiological endpoints (79 FR 11937). For children 1 through 3 years of age and pregnant women and lactating women, the Recommended Dietary Allowances (RDAs)²⁷ for calcium are based, in part, on bone health (79 FR 11937).

FDA's analysis of the Centers for Disease Control and Prevention (CDC) National Health and Nutrition Examination Survey (NHANES) 2003–2006 data estimated that infants ages 7 to 12 months have usual calcium intakes above the AI and estimated that about 12 percent of children 1 through 3 years of age had usual intakes of calcium below the Estimated Average

²⁷ "The RDA is an estimate of the average intake level that meets the nutrient requirements of nearly all (97 to 98 percent) healthy individuals in a particular life stage and gender group" (79 FR 11885).

Requirement (EAR),²⁸ based on intakes from conventional foods only (79 FR 11937). FDA has found that promoting the development of eating patterns that are associated with adequate calcium intake later in life is important given that calcium intakes are inadequate for the majority of the population. Intakes of calcium, which is necessary for growth and bone development, are inadequate among children. Also, similar to the general population, approximately 20 percent of pregnant women consumed less than the EAR for calcium from conventional foods as well as from conventional foods and supplements (79 FR 11937).

FDA concluded that calcium is a nutrient of public health significance for children 1 through 3 years of age and pregnant women and lactating women and infants through 12 months and requires the mandatory declaration of calcium on foods purported to be specifically for infants through 12 months, children 1 through 3 years of age, or pregnant and lactating women (81 FR 33922). Consistent with FDA's Nutrition Labeling Final Rule, FSIS is not proposing to change the mandatory declaration of calcium for meat and poultry products purported to be specifically for infants through 12 months, children 1 through 3 years of age, or pregnant or lactating women.

FSIS is not proposing any changes to the mandatory declaration of iron on foods for the general population (see section II.I.1.). As discussed in FDA's Nutrition Labeling Proposed Rule, although the EAR and RDA are based on daily iron requirements and not directly on chronic disease risk, iron deficiency is associated with delayed normal infant motor function (*i.e.*, normal activity and movement) and mental function (*i.e.*, normal thinking and processing skills) (79 FR 11937). FDA's analysis of NHANES 2003–2006 data estimated that about 18 percent of infants ages 7 to 12 months have usual iron intakes below the EAR, based on intakes from conventional foods only and 4 percent of infants ages 7 to 12 months have usual iron intakes below the EAR based on intakes from conventional foods and supplements (79 FR 11937; 81 FR 33922).

As discussed in FDA's Nutrition Labeling Proposed Rule, about 1 percent of children 1 through 3 years of age have usual iron intakes below the EAR, based on intakes from conventional foods

only, and 0.4 percent of children have usual iron intakes below the EAR based on intakes from conventional foods and supplements (79 FR 11937). The IOM set the EAR by modeling components of iron requirements. The prevalence of iron deficiency in children ages 1 to 2 years has been reported to be 14.4 percent, and the prevalence of iron deficiency anemia in children younger than 5 years has been reported to be 14.9 percent. FDA requires the mandatory declaration of iron in the labeling of foods for infants through 12 months and children 1 through 3 years of age (81 FR 33922).

As discussed in FDA's Nutrition Labeling Proposed Rule, inadequate iron intakes during pregnancy are of public health significance because of the adverse effects for both the mother and the fetus (such as maternal anemia, premature delivery, low birth weight, and increased perinatal infant mortality) (79 FR 11938). FDA analyzed NHANES 2003–2006 data and estimated that 5 percent of pregnant women 14 to 50 years of age had usual iron intakes below the EAR based on intakes from conventional foods and supplements. The EAR for iron for pregnant women was based on estimates of iron stores needed during the first trimester (79 FR 11938). FDA's analysis of NHANES 2003–2006 data also indicated that, among pregnant women aged 12 to 49 years, 25 percent were iron deficient, and 13 percent had iron deficiency anemia (79 FR 11938). FDA considered iron deficiency based on two out of three cutoffs of iron deficiency variables (transferrin saturation, serum ferritin, and erythrocyte protoporphyrin) (79 FR 11938).

FDA found that calcium and iron have quantitative intake recommendations and have public health significance for infants through 12 months, children 1 through 3 years of age, and pregnant women and lactating women. FDA did not receive comments to its proposed rule to change its tentative conclusion that the declaration of calcium and iron is necessary to assist consumers in maintaining healthy dietary practices (81 FR 33922). FSIS has reviewed FDA's analysis and is proposing to require the mandatory declaration of calcium and iron on foods represented or purported to be specifically for infants through 12 months, children 1 through 3 years of age, or pregnant women and lactating women without providing any exceptions for these subpopulations

from the requirement for declaration of calcium and iron applicable to foods for the general population (proposed 9 CFR 413.309(c)(8)(ii)).

b. Mandatory Declaration of Vitamin D and Potassium

FSIS is proposing to require the declaration of vitamin D on meat and poultry products for the general population (see section II.I.1.). FDA identified vitamin D as a nutrient of public health significance in children 1 through 3 years of age and pregnant women based on the high prevalence of inadequate intakes of vitamin D and its important role in bone development and health (81 FR 33922–33923). FDA also identified vitamin D as a nutrient of public health significance for infants through 12 months of age based on its importance for growth and development during infancy (81 FR 33922–33923).

FSIS is proposing to require the declaration of potassium on foods for the general population (see proposed 9 CFR 413.309(c)(8)(ii) and section II.I.1.). As discussed in FDA's Nutrition Labeling Proposed Rule, the AI for infants is based on average potassium intake from breast milk and complementary foods (79 FR 11938). The AI for the other life-stage and gender groups is set at a level to maintain blood pressure, reduce the adverse effects of sodium chloride intake on blood pressure, and reduce the risk of recurrent kidney stones (79 FR 11938).

FSIS has reviewed FDA's analysis of potassium intake from NHANES 2003–2006 for infants 7 to 12 months of age; potassium intake for children 1 through 3 years of age; and the importance of potassium in the risk reduction of chronic diseases for children 2 years of age and older (79 FR 11938). Because of the benefits of adequate potassium intake in lowering blood pressure and data indicating low likelihood of potassium adequacy, FSIS agrees with FDA that it is important to establish healthy dietary practices for later life (79 FR 11938). FDA tentatively concluded in the Nutrition Labeling Proposed Rule that there is no basis to conclude that the public health significance of potassium among infants through 12 months of age would be different than the science-based evidence for children 1 through 3 years of age, and that potassium is of public health significance to infants through 12 months, children 1 through 3 years of age and pregnant women and lactating women (79 FR 11938). FDA did not change its tentative conclusion in the final rule (81 FR 33922–33923).

²⁸ “The EAR is the average daily nutrient intake level that is estimated to meet the requirements of half of the healthy individuals in a particular life stage and gender group. EARs are used for assessing the statistical probability of adequacy of nutrient intakes of groups of people” (79 FR 11885).

Consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to require the labeling of vitamin D and potassium on foods represented or purported to be specifically for infants through 12 months of age, children 1 through 3 years of age, and pregnant women and lactating women based on the quantitative intake recommendations for vitamin D and potassium and the public health significance of these nutrients. Consequently, FSIS is not providing for any exceptions for these subpopulations from the general requirement in proposed 9 CFR 413.309(c)(8)(ii) to declare vitamin D and potassium.

c. Voluntary Declaration of Vitamin A and Vitamin C

FSIS is proposing to no longer require the declaration of vitamin A and vitamin C on foods for the general population (see section II.I.1.). As discussed in FDA's Nutrition Labeling Proposed Rule, none of the DRIs (AIs or RDAs) for vitamin A were based on chronic disease risk, a health related-condition, or health-related physiological endpoints (79 FR 11939).

FDA looked at vitamin A intake from NHANES 2003–2006 for children and pregnant women and found a very low prevalence of inadequate intakes of vitamins A and C or inadequate status among children 1 through 3 years of age or pregnant women and also the lack of evidence to indicate that this would be different for infants or lactating women (79 FR 11939). FDA concluded that vitamin A and vitamin C are not of public health significance among infants through 12 months of age, children 1 through 3 years of age, and pregnant women and lactating women and that this supports the voluntary declaration of vitamins A and C in the labeling of foods for young children (81 FR 33923–33924). Consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to permit, but not to require, that the declaration of vitamin A and vitamin C on foods represented and purported to be specifically for infants through 12 months, children 1 through 3 years of age, or pregnant women and lactating women. Similar to other voluntary nutrients, the declaration of vitamins A and C would be required when claims are made about them on the label or labeling (proposed 9 CFR 413.309(c)(8)(ii)).

d. Voluntary Declaration of Other Vitamins and Minerals

As discussed in section II.I.3., for the general population, FSIS is proposing to permit the voluntary declaration of vitamin E, vitamin K, vitamin B₆,

vitamin B₁₂, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and choline (proposed 9 CFR 413.309(c)(8)(ii)). As discussed in FDA's Nutrition Labeling Proposed Rule, vitamins and minerals other than iron, calcium, vitamin D, and potassium for infants either have DRIs that are not based on chronic disease risk, health-related conditions, or health-related physiological endpoints or are not shown to have public health significance because of the prevalence of a clinically relevant nutrient deficiency (79 FR 11939). FDA determined, in the final rule that, for infants through 12 months, children 1 through 3 years of age, and pregnant women and lactating women, the essential vitamins and minerals, other than iron, calcium, vitamin D and potassium, do not have public health significance, and there is no basis for the declaration of these nutrients to be different from that proposed for the general population (81 FR 33924). Consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to allow the voluntary declaration of vitamin E, vitamin K, vitamin B₆, vitamin B₁₂, thiamin, riboflavin, niacin, folate, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and choline on foods represented or purported to be specifically for infants through 12 months, children 1 through 3 years of age, or pregnant women and lactating women, unless the labeling makes a claim about them, in which case the nutrients would have to be declared (proposed 9 CFR 413.309(c)(8)(ii)).

5. DRVs and Reference Daily Intakes (RDIs) for Infants Through 12 Months of Age

FSIS regulations do not include DRVs or RDIs for nutrients for infants through 12 months of age, except an RDI for protein of 14 g for infants. Consistent with FDA, FSIS is considering establishing DRVs and RDIs for nutrients for infants through 12 months of age and revisions to the current RDI for protein.

a. Calories

FSIS's regulations do not provide, and FDA has not established, a reference calorie intake level for infants and children less than 2 years of age. As discussed in FDA's Nutrition Labeling Proposed Rule, there is no quantitative intake recommendation for calories for

infants, and FDA is not aware of other scientific data and information on which it could rely to establish that level (79 FR 11939). FDA did not establish a reference calorie intake for infants through 12 months of age in the final rule (81 FR 33925). Therefore, consistent with FDA's Nutrition Labeling Final Rule, FSIS is not proposing to establish a reference calorie intake level for infants through 12 months (81 FR 33925).

b. Total Fat

As discussed in FDA's Nutrition Labeling Proposed Rule, the IOM set an AI of 30 g/d for fat for infants through 12 months of age based on the average intake of human milk and complementary foods. There was no AI available in 1993, and the current AI provides a basis to determine an appropriate DRV for total fat for this subpopulation that can assist consumers in maintaining healthy dietary practices among this subpopulation (79 FR 11939). FDA established a DRV of 30 g for fat for infants through 12 months in its final rule (81 FR 33925). Therefore, consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to include a DRV of 30 g for fat for infants through 12 months of age (proposed 9 CFR 413.309(c)(9)).

c. Saturated Fat, Trans Fat, Cholesterol, Dietary Fiber, and Sugars

As discussed in FDA's Nutrition Labeling Proposed Rule, there are no quantitative intake recommendations from U.S. consensus reports available for saturated fat, *trans* fat, cholesterol, dietary fiber, and sugars for infants (79 FR 11939). FDA was not aware of other reliable scientific data and information on which to establish DRVs for these nutrients for infants through 12 months of age (79 FR 11939). FDA did not establish DRVs for infants through 12 months of age for these nutrients in its final rule (81 FR 33925). Accordingly, FSIS is not proposing to establish DRVs for these nutrients for infants through 12 months of age, consistent with FDA's Nutrition Labeling Final Rule because appropriate scientific data is not available.

d. Polyunsaturated Fat, Monounsaturated Fat, Insoluble Fiber, Soluble Fiber, Added Sugars, and Sugar Alcohols

As discussed in FDA's Nutrition Labeling Proposed Rule, quantitative intake recommendations from U.S. consensus reports are not available for polyunsaturated fat, monounsaturated fat, insoluble fiber, soluble fiber, added sugars, or sugar alcohols for infants (79

FR 11940). FDA was not aware of other reliable scientific data and information on which to establish DRV for these nutrients for this subpopulation (79 FR 11940). FDA did not establish DRV for infants through 12 months of age for these nutrients in its final rule (81 FR 33925). Accordingly, consistent with FDA's Nutrition Labeling Final Rule, FSIS is not proposing to establish DRV for these nutrients for infants through 12 months of age because appropriate scientific data are not available.

e. Total Carbohydrate

As discussed in FDA's Nutrition Labeling Proposed Rule, the IOM set an AI of 95 g/d for carbohydrate for infants through 12 months of age based on the average intake of human milk and complementary foods. There was no AI available in 1993, and the current AI provides a basis on which FDA could determine an appropriate DRV for total carbohydrate for this subpopulation that can assist consumers in maintaining healthy dietary practices among this subpopulation (79 FR 11940). FDA established a DRV of 95 g for total carbohydrate for infants through 12 months of age in its final rule (81 FR 33925). Therefore, consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to establish a DRV of 95 g for total carbohydrate for infants through 12 months of age (proposed 9 CFR 413.309(c)(9)).

f. Protein

As discussed in FDA's Nutrition Labeling Proposed Rule, the DV for protein for infants is an RDI, rather than a DRV. Before 1993, FDA established the RDIs for protein for all age groups based on the 1989 RDA. In 1993, FDA changed the RDI for protein for the general population to a DRV (58 FR 2206 at 2216). FDA retained the RDI for infants based on the highest 1968 RDA value (14 g/d for infants) to be consistent with a population-coverage approach, but it found no reason to change the approach of using the RDI for infants through 12 months. FDA determined that it would be appropriate to revise the RDI to rely on current quantitative intake recommendations. In 2002, the IOM established an RDA for infants through 12 months of 1.2 g/kg/d based on nitrogen balance studies and using a reference body weight of 9 kg consistent with current growth charts for infants. Protein intakes are well above the current and proposed RDI, and mean protein intake for infants 6 to 11 months of age was well above the RDA of 11 g/d (79 FR 11940). FDA established an RDI of 11 grams for protein for infants through 12 months of

age in its final rule (81 FR 33925). Accordingly, consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to establish an RDI of 11 g for protein for infants through 12 months of age (proposed 9 CFR 413.309(c)(8)(iv)).

g. Sodium

FSIS is proposing to establish a DRV for sodium based on the IOM's UL for the general population (section II.G.). However, as discussed in FDA's Nutrition Labeling Proposed Rule, the IOM did not set a UL for sodium for infants through 12 months of age because there was insufficient data on adverse effects of chronic overconsumption in this age group (79 FR 11940). In addition, FDA was not aware of other reliable scientific data and information on which to establish a DRV for sodium for this subpopulation (79 FR 11940). FDA did not establish a DRV for sodium for infants through 12 months of age in its final rule (81 FR 33926). Therefore, consistent with FDA's Nutrition Labeling Final Rule, FSIS is not proposing a DRV for sodium for infants through 12 months of age because of the lack of appropriate scientific data.

h. Fluoride

As discussed in section II.H, although the IOM set an AI for fluoride, the AIs for infants through 12 months and children 1 through 3 years are close to the Environmental Protection Agency benchmarks for total fluoride intake. FDA did not propose a DRV for fluoride for use in the labeling of foods for the general population because of a concern about excess intakes associated with dental fluorosis (79 FR 11918). FDA did not establish a DRV for fluoride for infants through 12 months in its final rule (81 FR 33926). The use of such a DRV to calculate percent DV may have the unintended effect of consumers selecting foods with higher fluoride amounts, which are not necessary or advised (79 FR 11940). Accordingly, consistent with FDA's Nutrition Labeling Final Rule, FSIS is not proposing to establish a DRV for fluoride for infants through 12 months of age.

i. Vitamins and Minerals

FSIS regulations do not include DRV for nutrients, generally, for infants, children under 4 years of age, or pregnant women and lactating women. However, there are requirements for a DRV for protein for children 4 or more years of age and an RDI for protein for (1) children less than 4 years of age; (2) infants; (3) pregnant women; and (4)

lactating women (9 CFR 317.309(c)(7)(iii) and 381.409(c)(7)(iii)).

FDA reviewed current quantitative intake recommendations for vitamins and minerals for infants and considered comments received in response to its 2007 ANPRM to determine appropriate RDIs for vitamins and minerals for infants through 12 months of age (79 FR 11940). FSIS agrees with FDA that it is important to establish RDIs for infants through 12 months of age because infants in this age range transition from a diet of mostly breast milk and infant formula to infant cereal and baby foods; that labeling foods for this subpopulation with percent DV declarations can assist parents in making nutritious food choices; that the DRIs (AIs and RDAs) provide a basis on which to determine RDIs for vitamins and minerals for this subpopulation; that it is appropriate to use RDAs and, in the absence of RDAs, AIs to determine appropriate micronutrient RDIs for infants; that both RDAs and AIs are sufficient for setting RDIs because they both represent intake levels that are expected to meet or exceed the nutrient needs of the majority of infants; that the IOM established DRIs based on scientific knowledge that update and supersede previous RDA recommendations; and that DRIs are available for infants through 12 months of age (79 FR 11940).

FDA established RDIs for vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, vitamin B₁₂, folate, choline, riboflavin, niacin, vitamin B₆, calcium, iron, thiamin, biotin, pantothenic acid, phosphorous, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and potassium for infants through 12 months of age in its final rule (81 FR 33926–33927). Accordingly, consistent with FDA's Nutrition Labeling Final Rule (81 FR 33926–33927), FSIS is proposing to include a listing of RDIs for these same nutrients for infants through 12 months of age (proposed 9 CFR 413.309(c)(8)(iv)).

6. DRV and RDI for Children 1 Through 3 Years of Age

FSIS regulations do not include DRV or RDI for nutrients for children 1 through 3 years of age, except an RDI for protein of 16 g for children less than 4 years of age. As discussed in FDA's Nutrition Labeling Proposed Rule, FDA reviewed scientific evidence and current recommendations, as well as comments in response to FDA's 2007 ANPRM, to consider establishing DRV and RDI for nutrients for this subpopulation and to consider revisions

to the current RDI for protein (79 FR 11940).

a. Calories

FSIS regulations currently do not provide a reference calorie intake level for nutrition labeling for children ages 1 through 3 years. FDA established a reference calorie intake level for children 1 through 3 years of age and set DRV's using quantitative intake recommendations that are based on calories (e.g., total fat, saturated fat, and dietary fiber). Current recommendations from the IOM, American Heart Association (AHA), American Academy of Pediatrics (AAP), and the 2015–2020 DGA for caloric intake range from 800 to 900 calories/d for children 1 year old, approximately 1,000 calories/d for children 2 years of age, and from 1,000 to 1,200 calories/d for children 3 years of age. FDA considered that an average of the range of these caloric intake recommendations (800 to 1,200 calories/d), i.e., 1,000 calories/d, provides a reasonable reference calorie intake level (79 FR 11941). FDA established a reference calorie intake of 1,000 calories/day for children aged 1 through 3 years in its final rule (81 FR 33927). FSIS has reviewed FDA's analysis and is proposing to provide a reference calorie intake level of 1,000 calories/day for children 1 through 3 years of age (proposed 9 CFR 413.309(c)(9)) consistent with FDA's Nutrition Labeling Final Rule.

b. Total Fat

Currently, FSIS regulations do not provide a DRV for total fat for children ages 1 through 3 years. As discussed in FDA's Nutrition Labeling Proposed Rule, FDA agreed with a comment to its 2007 ANPRM that 35 percent of calories from fat for children 1 through 3 years of age, the midpoint of the IOM AMDR of 30 to 40 percent, serves as an appropriate basis on which to set the DRV for total fat. The approach to calculating the DRV for total fat is consistent with FDA's approach to setting the DRV for total fat for the general population. Thirty-five percent is consistent with AHA and AAP recommendations that 30 to 40 percent of calories consumed by children 12 through 24 months of age, and 30 to 35 percent of calories consumed by children 24 through 48 months of age, should come from fat (79 FR 11941). In FDA's Nutrition Labeling Proposed Rule, FDA tentatively concluded that 35 percent of total calories from fat (i.e., 39 g using the finalized reference calorie intake level of 1,000 calories/d) is an appropriate DRV for total fat for children 1 through 3 years of age (*Id.*).

FDA established a DRV of 39 grams for total fat in its final rule (81 FR 33927–33928). FSIS has reviewed FDA's analysis and is proposing to establish a DRV of 39 g for fat for children 1 through 3 years of age (proposed 9 CFR 413.309(c)(9)) consistent with FDA's Nutrition Labeling Final Rule.

c. Saturated Fat, Trans Fat, and Cholesterol

FSIS has not established DRV's for saturated fat, *trans* fat, or cholesterol for children 1 through 3 years of age. As discussed in FDA's Nutrition Labeling Proposed Rule, FDA considered a comment to its 2007 ANPRM that suggested using the midpoint of 10 to 15 percent of calories for saturated fat, 2 percent of calories for *trans* fat based on estimates of mean *trans* fat intake for the U.S. population 3 years of age and older, and less than or equal to 300 mg/d for cholesterol based on the 2005 DGA recommendation. CVD is known to begin in childhood, and the 2010 DGA recommended that Americans 2 years of age and older consume less than 10 percent of calories from saturated fat and less than 300 mg/d of cholesterol (79 FR 11941). FDA tentatively concluded that it is appropriate to set a DRV of 10 g for saturated fat, based on 10 percent of total calories from saturated fat and using the proposed reference calorie intake level of 1,000 calories/d which equals 11 g, rounded down to 10 g, and a DRV of 300 mg for cholesterol for children 1 through 3 years of age (79 FR 11941). FDA established a DRV of 10 g for saturated fat and a DRV of 300 mg for cholesterol for children 1 through 3 years of age in its final rule (81 FR 33928). Consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to establish a DRV of 10 g for saturated fat and a DRV of 300 mg for cholesterol for children 1 through 3 years of age (proposed 9 CFR 413.309(c)(9)).

FSIS is not proposing to establish a DRV for *trans* fat because the IOM and 2015–2020 DGA do not provide any specific appropriate levels of intake and FDA did not establish a DRV for *trans* fat (81 FR 33928).

d. Polyunsaturated Fat, Monounsaturated Fat, Sugars, Added Sugars, Insoluble Fiber, Soluble Fiber, and Sugar Alcohols

FSIS has not established DRV's for polyunsaturated fat, monounsaturated fat, sugars, added sugars, insoluble fiber, soluble fiber, or sugar alcohol for children 1 through 3 years of age. As discussed in FDA's Nutrition Labeling Proposed Rule, FDA stated that there was no reliable data or information

available to establish DRV's for polyunsaturated fat, monounsaturated fat, sugars, insoluble fiber, soluble fiber, and sugar alcohols, and tentatively concluded that there was no basis for setting DRV's for these nutrients (79 FR 11941). FDA established a DRV reference point for the added sugars declaration at 10 percent of calories in its final rule, after considering the scientific evidence in the 2015 DGAC report (81 FR 33842). FDA set a DRV for children 1 through 3 years of age of 25 g of added sugars (1,000 calorie reference amount $\times .10 = 100$ calories and 100 calories $\div 4$ calories/gram = 25 grams) (81 FR 33928–33929). FSIS has reviewed FDA's analysis and is proposing a DRV for added sugars of 25 g for children 1 through 3 years of age and that the percent DV for added sugars be declared on the Nutrition Facts label consistent with FDA's final rule. FSIS is not proposing DRV's for polyunsaturated fat, including *n-3* or *n-6* polyunsaturated fatty acids, monounsaturated fat, sugars, soluble fiber, insoluble fiber, or sugar alcohols for children 1 through 3 years of age consistent with the FDA Nutrition Labeling Final Rule.

e. Total Carbohydrate

FSIS has not established a DRV for total carbohydrate for children 1 through 3 years of age. As discussed in section II.E.1, consistent with FDA, FSIS is proposing a DRV for total carbohydrate for the general population based on the percentage of calories in a 2,000 calorie diet remaining after the sum of the DRV for fat (30 percent) plus the DRV for protein (10 percent) have been subtracted consistent with FDA's Nutrition Labeling Final Rule. As discussed in FDA's proposed rule, FDA considered this method to be appropriate for setting a DRV for total carbohydrate for children 1 through 3 years of age because it falls within the IOM AMDR recommendation of 45 to 65 percent of calories from carbohydrates for children 1 through 3 years of age (79 FR 11941). FDA tentatively concluded that an appropriate DRV for total carbohydrate is 60 percent of calories (i.e., 150 g using the proposed reference calorie intake level of 1,000 calories/d) (*Id.*) FDA did not receive comments on its tentative conclusion and finalized this requirement as proposed (81 FR 33929). Consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to set a DRV of 150 g for total carbohydrate for children 1 through 3 years of age (proposed 9 CFR 413.309(c)(9)).

f. Dietary Fiber

FSIS has not established a DRV for dietary fiber for children 1 through 3 years of age. As discussed in FDA's Nutrition Labeling Proposed Rule, FDA tentatively concluded that the AI of 14 g/1,000 calories for dietary fiber for children 1 through 3 years of age should be used to set a DRV for dietary fiber to be consistent with how other proposed DRVs are being set; for example, proposing a reference calorie intake level of 1,000 calories/d for this subpopulation (79 FR 11941–11942). FDA established a DRV of 14 g for dietary fiber in its final rule (81 FR 33929). Consistent with FDA's Nutrition Labeling Final Rule, FSIS is proposing to establish a DRV of 14 g for dietary fiber for children 1 through 3 years of age (9 CFR 413.309(c)(9)).

g. Protein

The current RDI for protein for children less than 4 years of age was based on the 1989 RDA for protein of 16 g/d (9 CFR 317.309(c)(7)(iii) and 381.409(c)(7)(iii)).

As discussed in FDA's Nutrition Labeling Proposed Rule, FDA considered current recommendations and acknowledged that protein intakes are well above the current RDI; the mean protein intake for children 12 to 23 months of age was 44 g/d; the protein AMDR for children 1 through 3 years of age is 5 to 20 percent of calories; and the proposed reference calorie intake level and the approaches used for the proposed DRVs for fat and carbohydrate are based on percent of calories (79 FR 11942). FDA tentatively concluded that the DV for protein for children 1 through 3 years of age should be a DRV, rather than an RDI (using the RDA), and that a DRV for protein should be based on 5 percent of 1,000 calories or 50 calories, which equals 12.5 g or, when rounded up, is 13 g (*Id.*) FDA established a DRV for protein of 13 g for children 1 through 3 years of age in its final rule (81 FR 33929). FSIS agrees with FDA's conclusion and is proposing to establish a DRV for protein of 13 g for children 1 through 3 years of age (proposed 9 CFR 413.309(c)(9)) consistent with FDA's Nutrition Labeling Final Rule.

h. Sodium

For the general population, FSIS is proposing to establish a DRV based on the UL for sodium (section II.G.). There is no current DRV for sodium for children 1 through 3 years of age.

As discussed in FDA's Nutrition Labeling Proposed Rule, FDA agreed with comments to its 2007 ANPRM that

1,500 mg is an appropriate DRV for sodium for children 1 through 3 years of age (79 FR 11942). FDA did not receive comments on this proposed requirement and finalized this requirement (81 FR 33929). Consistent with FSIS's proposed approach for the general population and FDA's Nutrition Labeling Final Rule, FSIS is proposing to establish a DRV of 1,500 mg for sodium for children 1 through 3 years of age (proposed 9 CFR 413.309(c)(9)).

i. Fluoride

FSIS has not established a DV for fluoride for children 1 through 3 years of age. As discussed in section II.H, FSIS is not establishing a DRV for fluoride for the general population. FSIS agrees with FDA that a DRV for fluoride is not warranted for children 1 through 3 years of age and is not proposing to establish a DRV for fluoride for children 1 through 3 years of age (79 FR 11942; 81 FR 33929).

j. Vitamins and Minerals

FSIS regulations do not currently include a table listing the RDIs for children less than 4 years of age. The preamble to FDA's 1993 DRV/RDI final rule provides a table listing RDIs for children less than 4 years of age (58 FR 2206 at 2213), which is also provided in FDA's Food Labeling Guide. FDA reviewed current quantitative intake recommendations for vitamins and minerals for infants and considered comments received in response to their 2007 ANPRM to determine appropriate RDIs for vitamins and minerals for children 1 through 3 years of age.

As discussed in FDA's Nutrition Labeling Proposed Rule, the IOM's quantitative intake recommendations (AIs and RDAs) provide a basis on which to determine RDIs for vitamins and minerals for this subpopulation. The IOM determined that available evidence was sufficient to establish appropriate RDAs and AIs for vitamins and minerals for this subpopulation; that it is appropriate to use RDAs and, in the absence of RDAs, AIs to determine appropriate micronutrient RDIs for children 1 through 3 years of age; that the RDA, when available, is the best estimate of an intake level that will meet the nutrient goals of practically all consumers who would use the Nutrition Facts label; that AIs have less certainty than RDAs, but they represent goals for nutrient intake for individuals and provide the best estimate based on current science for use in setting RDIs for such nutrients; that promoting the development of eating patterns associated with adequate potassium intake later in life is important because

chronic conditions such as elevated blood pressure, bone demineralization, and kidney stones likely result from inadequate potassium intakes over an extended period of time, including childhood; and that the AI for potassium is 3,000 mg/d and is considered an appropriate basis for establishing a RDI for potassium for children 1 through 3 years of age (79 FR 11942). FDA established RDIs for vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, vitamin B₁₂, folate, choline, riboflavin, niacin, vitamin B₆, calcium, iron, thiamin, biotin, pantothenic acid, phosphorous, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, and potassium for children 1 through 3 years of age in its final rule (81 FR 33929–33930).

Therefore, consistent with FDA's Nutrition Labeling Final Rule (81 FR 33927), using the RDAs and AIs, FSIS is proposing to establish RDIs as set forth in proposed 9 CFR 413.309(c)(8)(iv) for these same nutrients for children 1 through 3 years of age.

7. DRVs and RDIs for Pregnant Women and Lactating Women

a. Calories

The reference calorie intake of 2,000 used for the general population applies to pregnant women and lactating women (9 CFR 317.309(c)(9) and 381.409(c)(9)). As discussed in FDA's Nutrition Labeling Proposed Rule, the calorie needs for pregnant women and lactating women are similar to the general population, and few products are purported for pregnant women and lactating women (79 FR 11943). FDA explained that the calorie needs for pregnant and lactating women are similar to the general population (*Id.*) FDA established a 2,000 reference calorie intake level for the DRV for pregnant women and lactating women in its final rule (81 FR 33931). Consistent with FDA's final rule, FSIS is proposing to use the 2,000 reference calorie intake level for setting DRVs for pregnant women and lactating women (proposed 9 CFR 413.309(c)(9)).

b. Total Fat, Saturated Fat, Cholesterol, Total Carbohydrate, Sodium, Added Sugars, and Dietary Fiber

FSIS regulations do not provide DRVs for total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber for pregnant women and lactating women. As discussed in FDA's Nutrition Labeling Proposed Rule, quantitative intake recommendations for total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber

for pregnant women and lactating women are generally similar to the general population (79 FR 11943). FDA tentatively concluded that the DRV for total fat, saturated fat, cholesterol, total carbohydrate, sodium, and dietary fiber for pregnant women and lactating women should remain the same as for the general population (*Id.*). FDA established DRVs for pregnant women and lactating women using the same DRVs for these nutrients as used for the general population (81 FR 33931). FDA also requires a DRV of 50 g of added sugars for adults and children 4 years of age and older, including pregnant women and lactating women (81 FR 33931). Consistent with FDA's final rule, FSIS is proposing to establish DRVs for pregnant women and lactating women using the proposed DRVs for the general population for total fat, saturated fat, cholesterol, total carbohydrate, sodium, added sugars and dietary fiber (proposed 9 CFR 413.309(c)(9)).

c. Trans Fat, Polyunsaturated Fat, Monounsaturated Fat, Soluble Fiber, Insoluble Fiber, Sugars, and Sugar Alcohols

There are no DRVs for *trans* fat, polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, sugars, or sugar alcohol for pregnant women and lactating women. As discussed in sections II.C. and II.E., FSIS is not proposing DRVs for these nutrients for the general population because of a lack of quantitative intake recommendations. Similarly, quantitative intake recommendations are lacking for these nutrients for pregnant women and lactating women. Therefore, FSIS is not proposing to establish DRVs for *trans* fat, polyunsaturated and monounsaturated fat, soluble fiber, insoluble fiber, sugars, or sugar alcohols for pregnant women and lactating women consistent with FDA's Nutrition Labeling Final Rule (81 FR 33931).

d. Protein

FSIS has established RDIs of 60 g protein for pregnant women and 65 g protein for lactating women (9 CFR 317.309(c)(7)(iii) and 381.409(c)(7)(iii)). As discussed in FDA's Nutrition Labeling Proposed Rule, the IOM established 71 g/d protein as the RDA for pregnant women and lactating women based on the needs for maternal and fetal development and human milk production (79 FR 11943). FDA tentatively concluded that the DV for protein for pregnant women and lactating women should remain an RDI (using the RDA) instead of a DRV because the DRV approach used to

calculate protein for the general population based on 10 percent of 2,000 calories, which equals 50 g of protein/d, falls short of the recommended protein needs of pregnant women and lactating women of 71 g/d (*Id.*). FDA did not receive comments on its tentative conclusion and established an RDI of 71 g for protein for pregnant women and lactating women in its final rule (81 FR 33931). Consistent with FDA's final rule, FSIS is proposing to establish an RDI of 71 g for protein for pregnant women and lactating women (proposed 413.309(c)(7)(iii)).

e. Fluoride

There is no DRV for fluoride for the general population or for pregnant women and lactating women. While an AI has been established for fluoride, FSIS is not proposing to establish a DRV for fluoride for the general population for the reasons discussed in section II.H. Similarly, because the AI for fluoride for pregnant women and lactating women is not different from the general population, as discussed in FDA's Nutrition Labeling Proposed Rule (79 FR 11943), FSIS is not proposing a DRV for fluoride for pregnant women and lactating women.

f. Vitamins and Minerals

While not included in FSIS regulations, the preamble to the FDA 1993 DRV/RDI final rule provides a table listing RDIs for pregnant women and lactating women (58 FR 2206 at 2213), which is also provided in FDA's Food Labeling Guide (79 FR 11943). As discussed in FDA's Nutrition Labeling Proposed Rule, FDA reviewed current quantitative intake recommendations for vitamins and minerals for pregnant women and lactating women and concluded that it is appropriate to establish RDIs for pregnant women and lactating women for vitamins and minerals that have DRIs, using population-coverage RDAs and AIs, instead of population-weighted EARs (79 FR 11943). In addition, FDA established a single set of RDIs intended for both pregnant women and lactating women because nutrient needs during pregnancy and lactation are similar and because using one set of RDIs would address practical concerns related to limited space on food labels (81 FR 33932).

Therefore, FSIS is proposing to establish RDIs as set forth in proposed 9 CFR 413.309(c)(8)(iv) for vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, vitamin B₁₂, folate, choline, riboflavin, niacin, vitamin B₆, calcium, iron, thiamin, biotin, pantothenic acid, phosphorous, iodine, magnesium, zinc,

selenium, copper, manganese, chromium, molybdenum, chloride, and potassium for pregnant women and lactating women consistent with FDA's Nutrition Labeling Final Rule.

K. Format

FSIS requires that nutrition information for meat and poultry products be presented in a specific format on the labels of those products (see 9 CFR 317.309(d)(1)–(f) and 381.409(d)(1)–(f)). Since 1995 when FSIS last published a final rule effecting the nutrition labeling format regulations (60 FR 174; January 3, 1995), more research has been done on trends in health conditions and how best to present information to consumers. FDA, in its changes to the Nutrition Facts label format, took into consideration “graphic design principles such as alignment, consistency, repetition, and contrast,” emphasizing “key nutrients and key information” through highlighting and “removing or modifying parts of the label to assist consumers in maintaining healthy dietary practices” (79 FR 11948; 81 FR 33936). FSIS has reviewed FDA's rationale for the changes to the Nutrition Facts label format (see 79 FR 11948–11955; 81 FR 33936–33959) and agrees with its approach. FSIS believes it is necessary to propose changes to the Nutrition Facts label format for meat and poultry products that will parallel, to the extent possible, FDA's new regulations. This approach will help prevent consumer confusion and non-uniformity in the marketplace. Therefore, FSIS is proposing the following changes to the Nutrition Facts label format.

1. Increasing the Prominence of Calories and Serving Size

Consistent with FDA's final rule (81 FR 33937–33940), FSIS is proposing (i) to increase the type size for “Calories” and the numeric value for “Calories,” and (ii) to require that the numeric value for calories be highlighted in bold or extra bold type (proposed 9 CFR 413.309(d)). These changes will emphasize the importance of calories on the label and draw more consumer attention to the calories declaration.

2. Changing the Order of the “Serving Size” and “Servings per Container” Declarations and Increasing the Prominence of “Servings per Container”

FSIS currently requires that information on serving size, which includes a statement of the serving size and the number of servings per container, follow the heading “Nutrition Facts” (9 CFR 317.309(d)(3) and

381.409(d)(3)). Consistent with FDA's Nutrition Labeling Final Rule (*see* 81 FR 33940–33943), FSIS is proposing to (i) reverse the order of the declarations of “Servings Per Container” and “Serving Size;” (ii) require that no capital letters are used for serving size information, except for the first letter in “Serving size;” (iii) require that “servings per container” (with the blank filled in with the actual number of servings) be in type size no smaller than 10 point (except for the tabular and linear displays for small packages) (proposed 9 CFR 413.309(d)(3)(i)); and (iv) require that the serving size information be highlighted in bold or extra bold type and be in a type size no smaller than 10 point (except for the linear display for small packages) (proposed 9 CFR 413.309(d)(3)(i)). FSIS has tentatively concluded that these proposed changes will help consumers better locate, identify, and understand the information in the Nutrition Facts label and assist consumers in making informed purchase decisions and maintaining health dietary practices.

3. Right-Justifying the Quantitative Amounts Declared in the “Serving size” Statement

Currently, the label statement for “Serving size” expressed in common household measures (*e.g.*, cup, tablespoon, piece or slice) and gram amounts is stated immediately adjacent to the “Serving Size” declaration as seen in 9 CFR 317.309(d)(12) and 381.409(d)(12). FSIS is proposing to require that the “Serving size” declaration be left-justified and the corresponding numerical value as determined in proposed 9 CFR 413.309(b)(9) be right-justified (proposed 9 CFR 413.309(d)(3)(i)). FSIS agrees with FDA that the proposed change will create more white space on the Nutrition Facts label that “would result in a less cluttered appearance, heightened focus and emphasis, and improved readability” and will improve ease of use for consumers (79 FR 11950).

4. Presentation of Percent DVs

FSIS currently requires that the column heading “% Daily Value” and a list of nutrient names and amounts as described in 9 CFR 317.309(d)(7) and 381.409(d)(7) be to the left of and below this column heading in the Nutrition Facts label (9 CFR 317.309(d)(6) and (7) and 381.409(d)(6) and (7)). On all dual column labels, including those (1) for two or more forms of the same food (proposed 9 CFR 413.309(e)(5)); (2) displaying nutrition information per container and per unit, in addition to nutrition information per serving

(proposed 9 CFR 413.309(e)(6)(i); (3) using the tabular display (proposed 9 CFR 413.309(e)(6)(ii)); and (4) that provide the aggregate display (proposed 9 CFR 413.309(d)(13)(ii)), FSIS is proposing to use thin vertical lines to separate the information in the “% Daily Value” column from the information in the column containing the quantitative weights. Further, FSIS is proposing to use the same style of thin vertical lines to separate each of the dual columns and aggregate display columns from each other. FSIS has tentatively concluded that the use of these vertical lines will help differentiate the columns and make the information easier to read for consumers. In addition, FSIS is proposing that protein would no longer be listed with the vitamins and minerals at the bottom of these labels as currently required.

5. Placement of “Added Sugars”

As discussed in section I.E.3 of this proposed rule, FSIS is proposing to require the declaration of added sugars as an indented line item underneath the declaration of “Total Sugars” on the Nutrition Facts label. “Added Sugars” would be the only mandatory nutrient required to be listed in a double indentation format on the Nutrition Facts label.

FDA conducted a consumer study that, among other things, looked at how consumers would use the new information regarding added sugars, but did not evaluate the impact of listing a percent DV for added sugars on the Nutrition Facts label (80 FR 44306). The study was a controlled, randomized, web-based experiment where participants viewed three different Nutrition Facts label formats and responded to questions regarding their ability to accurately recognize and compare nutrients on the Nutrition Facts label and their judgments about the foods’ overall healthfulness and relative nutrient levels (80 FR 44306). The study found that when both total and added sugars declarations appeared on the label, the majority of study participants correctly reported the added sugars amount and accurately identified which products had less added sugars (80 FR 44306). The study also found that where an added sugars declaration was indented below a “Total Sugars” declaration the study participants’ understanding that added sugars are part of the total amount of sugars in the product improved (80 FR 44306). Therefore, consistent with FDA’s final rule, FSIS is proposing to use the term “Total Sugars” instead of “Sugars” on the label. A summary of

FDA’s Added Sugars Experiment is available at 80 FR 44306 and a full description is available in the FDA Nutrition Labeling Supplemental Proposed Rule docket.²⁹

FDA’s Nutrition Labeling Final Rule also addressed commenters’ concerns regarding potential consumer confusion when including an “Added Sugars” declaration under “Total Sugars” on the Nutrition Facts label. Based on the recommendations of two independent FDA experts, as well as literature suggesting linking terms are useful for increasing comprehension, FDA added the word “Includes” in front of “Added Sugars” (81 FR 33827.) FDA also minimized the line between “Total Sugars” and “Added Sugars” to help denote that “Added Sugars” are a subcomponent of “Total Sugars.” Consistent with FDA, FSIS is proposing to add the word “Includes” in front of “Added Sugars” such that the added sugars declaration reads “Includes X g Added Sugars.” FSIS is also proposing to minimize the hairline between “Total Sugars” and “Added Sugars.”

6. Declaration of Absolute Amounts of Vitamins and Minerals

FSIS currently requires that the quantitative amount by weight of mandatory and voluntary nutrients be declared on the Nutrition Facts label, except for vitamins and minerals (other than sodium and potassium) which must be declared only as percent DVs (9 CFR 317.309(c)(8) and 381.309(c)(8)). Consistent with FDA’s Nutrition Labeling Final Rule (81 FR 33946–33949), FSIS is not proposing to require the declaration of the absolute amounts of all mandatory and voluntary vitamins and minerals as well as the percent DV declaration on the Nutrition Facts label. FSIS is, however, proposing to clarify in proposed 9 CFR 413.309(c)(8) that the declaration of voluntarily declared vitamins and minerals listed in proposed 9 CFR 413.309(c)(8)(iv) may include the quantitative amount by weight and percent of the RDI. FSIS is also proposing that if vitamins or minerals are added or there is a claim made about them, the manufacturer must include a declaration of the nutrient as a percent DV, or alternatively, as a quantitative amount by weight and percent DV (proposed 9 CFR 413.309(c)(8)(ii)).

²⁹ U.S. Food and Drug Administration. Memorandum to the File—“Experimental study on consumer responses to Nutrition Facts labels with declaration of amount of added sugars (OMB No. 0910–0764),” 2015.

7. The Footnote

FSIS currently requires that a footnote, preceded by an asterisk, be placed beneath the list of vitamins and minerals and be separated from that list by a hairline on the Nutrition Facts label (9 CFR 317.309(d)(9) and 381.409(d)(9)). The footnote must state “Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs” followed by a table that lists the DRVs for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber based on 2,000 and 2,500 calorie diets. (9 CFR 317.309(d)(9)(i) and 381.409(d)(9)(i)). Caloric conversion information on a per-gram basis for fat, carbohydrate, and protein may be presented beneath the information required in paragraph 9 CFR 317.309(d)(9) and 381.409(d)(9) separated by a hairline (9 CFR 317.309(d)(10) and 381.409(d)(10)).

Comments to FDA’s 2007 ANPRM cited to research that the comments said showed that consumers do not understand what information is being conveyed in the footnote (79 FR 11953). In 2014, FDA conducted a controlled, randomized, web-based experiment that compared consumer reactions to seven footnote formats, which included five modified footnotes, in addition to the current footnote and no footnote at all, for explaining percent DVs and how to use them (the “Footnote Experiment”).³⁰ In FDA’s Nutrition Labeling Final Rule, FDA finalized a revised footnote requirement (81 FR 33952). FDA removed the requirement for the footnote table listing the DRVs for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber for 2,000 and 2,500 calorie diets that is specified in 21 CFR 101.9(d)(9)(i) and added the following footnote text: “*The %Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.” *Id.* The footnote text is similar to one of the options tested in the Footnote Experiment, except that the sentences in the footnote are reversed (80 FR 44309). The study participants perceived the language in this footnote to be more useful than the current footnote; and FDA switched the order of the sentences in the footnote so the explanation of the %DV clearly follows

the asterisk that leads to the footnote in the %DV column (80 FR 44309).

FDA stated that the new footnote “which explains the term “% Daily Value” and provides a reference calorie level will assist consumers in better understanding the information of the Nutrition Facts label and in maintaining healthy dietary practices” (81 FR 33952). FDA did not change the caloric conversion information in the footnote specified in 21 CFR 101.9(d)(10). FDA stated, in its Nutrition Labeling Proposed Rule, that “increasing the type size, bolding key elements of the footnote (space permitting), and adding a bar clearly separating it from the micronutrient information directly above will assist consumers in using the information” (79 FR 11953). FDA did not finalize this proposed requirement.

Under the Nutrition Labeling Final Rule, FDA now allows the footnote to be omitted from products that qualify for a simplified format (21 CFR 101.9(f)), provided that the following abbreviated statement is used “%DV = %Daily Value” in a type size no smaller than 6 point on these package labels when Daily Value is not spelled out in the column heading (81 FR 33952). FDA is also not requiring the footnote on small or intermediate-sized packages (21 CFR 101.9(j)(13)(ii)(A)(1) and (2)), but manufacturers may voluntarily include the abbreviated footnote on these packages. The abbreviated statement would allow for more space on the label and informs consumers what %DV means. In addition, FDA is providing an exemption from the footnote requirement for foods that can use the terms “calorie free,” “free of calories,” “without calories,” “trivial source of calories,” “negligible source of calories,” or “dietarily insignificant source of calories” on the label or in the labeling of foods, as defined in 21 CFR 101.60(b) (81 FR 33952). FDA is also allowing the voluntary use of the first part of the footnote statement, “*The %Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet” on these products (81 FR 33952). FDA stated that such products would have little to no impact on the average daily 2,000 calorie intake, which the footnote addresses (80 FR 44309).

Consistent with FDA’s Nutrition Labeling Final Rule (81 FR 33949–33954), FSIS is proposing to remove the requirement for the footnote table listing the DRVs for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber for 2,000 and 2,500 calorie diets (proposed 9 CFR 413.309(d)(9)(i)). FSIS is also proposing the following footnote text: “The

%Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.” Consistent with FDA, FSIS is not proposing changes to the caloric conversion information in the footnote currently specified in 9 CFR 317.309(d)(10) and 381.409(d)(10) (which would be consolidated in proposed 9 CFR 413.309(d)(10)). FSIS is proposing that the footnote may be omitted from products that qualify for a simplified format (proposed 9 CFR 413.309(f)), provided that the following abbreviated statement is used “%DV = %Daily Value,” when the package labels do not spell out Daily Value in the column heading. FSIS is also proposing that the footnote may be omitted from small or intermediate-sized packages (proposed 9 CFR 413.309(g)). FSIS is also proposing an exemption from the footnote requirement for foods that can use the terms “calorie free,” “free of calories,” “no calories,” “zero calories,” “without calories,” “trivial source of calories,” “negligible source of calories,” or “dietarily insignificant source of calories” on the label or in the labeling of foods as defined in proposed 9 CFR 413.360(b). FSIS is also proposing to allow the voluntary use of the first part of the footnote statements, “*The %Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet,” on these products.

8. Addition of a Horizontal Line Beneath the Nutrition Facts Heading

FSIS requires that the “Nutrition Facts” heading on the Nutrition Facts label be set in a type size larger than all other print size in the nutrition label (9 CFR 317.309(d)(2) and 381.409(d)(2)). FDA amended its regulations to require a hairline rule be inserted directly beneath the “Nutrition Facts” heading on all label formats, except for the linear display for small packages, to direct the reader’s eye to the serving size information, place emphasis on the information about servings, and break the information into smaller chunks to make it easier to process (79 FR 11954; 81 FR 33954). Consistent with FDA’s final rule, FSIS is proposing to require that a hairline rule be inserted immediately below the “Nutrition Facts” heading on all nutrition label formats except for the linear display for small packages (proposed 9 CFR 413.309(d)(1)(iii)).

³⁰ U.S. Food and Drug Administration. Memorandum to the File—“Experimental study on consumer responses to Nutrition Facts labels with various footnote formats (OMB No. 0910–0764),” 2015.

L. Single-Serving Containers/Units and Dual-Column Labeling

1. Single-Serving Containers/Units

FSIS's current regulations require that a product that is packaged and sold individually and that contains less than 200 percent of the applicable RACC be considered a single-serving container, and that the entire content of the product be labeled as one serving, except that for products that have RACCs of 100g or 100mL or larger, manufacturers may decide whether a package containing more than 150 percent but less than 200 percent of the RACC be labeled as 1 or 2 servings (9 CFR 317.309(b)(8) and 381.409(b)(8)). FSIS's current regulations also require that for products that have RACCs of 100g or 100mL or larger and are individual units within a multi-serving package, manufacturers may decide whether an individual unit that contains more than 150 percent but less than 200 percent of the RACC be labeled as 1 or 2 servings (9 CFR 317.309(b)(4)(v) and 381.409(b)(4)(v)).

Based on a review of recent research, FDA has determined that many consumers do not correctly calculate nutrient amounts in food products by multiplying the nutrient amount by the number of servings per container (79 FR 11998–11999). FDA also found that the exemption from the requirement to label a product with a large RACC as a single-serving container is no longer warranted because “there is a low correlation between the RACCs (whether the reference amount is more than or less than 100 g or mL) and the consumption variation for all products containing less than 200 percent of the RACC, regardless of whether the RACC is ‘large’ (*i.e.*, greater than 100 g or 100 mL) or not” (79 FR 12001). Under pre-existing FDA regulations, if a package or discrete unit of food with a “large” RACC contained more than 150 percent but less than 200 percent of the RACC, the manufacturer was permitted to decide whether to declare the package or individual unit as 1 or 2 servings (81 FR 34004–34008). The FDA Serving Size Final Rule, however, removed this exemption and, for products subject to FDA requirements, requires that all packages of food containing less than 200 percent of the RACC be labeled as a single serving (see 21 CFR 101.9(b)(6)), and that discrete units containing at least 67 percent of the RACC but less than 200 percent of the RACC be labeled as a single serving (see 21 CFR 101.9(b)(2)(i)(C)). FDA also removed the provision that products packaged and sold individually and containing 200 percent or more of the applicable RACC

may be labeled as a single serving if the entire contents of the container can reasonably be consumed at a single eating occasion (81 FR 34004–34008).

FSIS has reviewed FDA's research and analysis and tentatively agrees with FDA's conclusions. Therefore, FSIS is proposing to revise the requirements for single-serving labeling so that a product packaged and sold individually that contains less than 200 percent of the applicable RACC must be considered a single serving, and that a discrete unit containing at least 150 percent but less than 200 percent of the RACC must be labeled as one serving regardless of whether the RACC exceeds 100 g or mL (proposed 9 CFR 413.309(b)(8)).

2. Dual-Column Labeling

FSIS currently permits manufacturers to voluntarily provide an additional column of nutrition information (*i.e.*, dual column labeling) in the following situations:

- Per 100 g, 100 mL, or 1 oz of the product as packaged or purchased (9 CFR 317.309(b)(13)(i) and 381.409(b)(13)(i));
- Per one unit if the serving size of a product in discrete units in a multi-serving container is more than one unit (9 CFR 317.309(b)(13)(ii) and 381.409(b)(13)(ii));
- For the product alone if the product is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided (*e.g.*, a cream soup mix may be labeled with one set of DVs for the dry mix (per serving), and another set for the serving of the final soup when prepared (*e.g.*, per serving of cream soup mix and 1 cup of vitamin D fortified whole milk) (9 CFR 317.309(b)(15) and 381.409(b)(15));
- For two or more forms of the same product (*e.g.*, both “raw” and “cooked”) as provided in 9 CFR 317.309(b)(3) and (e) and 381.409(b)(3) and (e); and
- For two or more groups for which RDIs are established (*e.g.*, both infants and children less than 4 years of age) as provided in 9 CFR 317.309(c)(8)(i) and (e) and 381.409(c)(8)(i) and (e).

Research has shown that package and portion sizes have a considerable impact on the amount of food consumed, and that the size of the package or unit of food can set a consumption norm for consumers; that consumers do not correctly calculate nutrient amounts in food products by multiplying the nutrient amount by the number of servings per container; and that dual-column labeling with the nutrition information given per serving and per package may help certain consumers

recognize nutrient amounts per package in certain types of packaged food (79 FR 11998–11999). Therefore, consistent with FDA's Serving Size Final Rule, FSIS is proposing mandatory dual-column labeling on certain packages of meat and poultry products.

FSIS is proposing that meat and poultry products in packages or units that contain at least 200 percent and up to and including 300 percent of the applicable RACC be required to have two columns in the Nutrition Facts label. One column would list the quantitative amounts and percent DVs for the entire package or unit, and the other column would list the quantitative amounts and percent DVs for a serving, based on the amount most closely approximating the RACC, that is less than the entire package or unit (proposed 9 CFR 413.309(b)(4)(iv) and 9 CFR 413.309(b)(16)). FSIS is proposing an upper limit of 300 percent for dual-column labeling based on FDA's analysis that showed that “providing an upper limit at 300 percent of the RACC would ensure that dual-column labeling captures 90 percent of the consumption habits for about 91 percent of food products and limit the possibility that dual-column labeling will be required for package sizes that are not likely to be consumed in a single eating occasion” (81 FR 34015–34016). Providing nutrition information for these products in dual columns will make it easier for consumers, regardless of whether they consume the entire container or unit in a single eating occasion, consume part of the entire container or unit in a single eating occasion, or share the container or unit, to identify the amount of nutrients consumed without having to perform mathematical calculations.

FSIS is proposing that meat and poultry products in packages that meet the requirements to use a tabular display for small packages or to use a linear format be exempt from the dual-column labeling requirements (proposed 9 CFR 413.309(b)(16)(i)(A)). FSIS is also proposing that products that require further preparation and provide two columns of nutrition information (*e.g.*, one column “as purchased” and one column “as prepared”) would be exempt from the dual-column labeling requirements in proposed 9 CFR 413.309(b)(16). If products that already provide two columns of nutrition information for “as purchased” and “as prepared” forms of the product were required to have dual-column labeling with nutrition information per serving size and per the entire container, the products would have at least three columns of nutrition information, or

manufacturers would decide to no longer provide the voluntary information for the prepared form of the product. FSIS is also proposing that products that are commonly consumed in combination with another food and provide an additional column of nutrition information under proposed 9 CFR 413.309(e) be exempt from the dual-column labeling requirements in proposed 9 CFR 413.309(b)(16). Similar to the products that require further preparation, nutrition information based on the entire container of an uncombined food (e.g., the dry mix alone for a cream soup mix) (for a food that is commonly combined with another food) may be less meaningful to consumers than information on a serving of the combined food (e.g., per serving of cream soup mix and 1 cup of vitamin D fortified whole milk) because these types of products are commonly consumed in combination with another food. FSIS is also proposing that products that provide an additional column of nutrition information for two or more groups for which RDIs are established (e.g., both infants through 12 months and children 1 through 3 years of age) and random weight products be exempt from the dual-column labeling requirements (proposed 9 CFR 413.309(b)(16)(i)(C)). Information provided for subpopulations will be more useful to distinct populations for certain products than information per container or unit.

FSIS is proposing that the Nutrition Facts label for a meat or poultry product that is packaged and sold individually that contains more than 150 percent and less than 200 percent of the applicable reference amount, may voluntarily provide, to the left of the column that provides nutrition information per container (*i.e.*, per serving), an additional column that lists the quantitative amounts and percent Daily Values per common household measure that most closely approximates the reference amount (proposed 9 CFR 317.309(b)(8)).

3. Use of Nutrient Content Claims and Health Claims on Products With Dual-Column Labeling per Serving and per Container

RACCs set forth in 9 CFR 317.312(b)–(e) and 381.412(b)–(e) are currently used to determine whether a product meets the criteria for a nutrient content claim (9 CFR 317.313(p) and 381.413(p)). Consistent with the FDA Serving Size Final Rule, if nutrition information is presented on a per serving basis and on a per container or unit basis (*i.e.*, the proposed dual-column labeling requirements or if a dual-column is

provided voluntarily) on the Nutrition Facts Label, FSIS is proposing to require that the nutrient content claim be followed by a statement that sets forth the basis on which the claim is made (proposed 9 CFR 413.309(b)(16)(ii)). The statement must express the amount of the nutrient in a serving (e.g., “good source of calcium” “a serving of oz of this product contains mg of calcium” or for a health claim “A serving of ounces of this product conforms to such a diet”). However, if the serving size declared on the product label differs from the RACC, and the amount of the nutrient contained in the labeled serving does not meet the maximum or minimum amount criterion in the definition for the descriptor for that nutrient, FSIS is proposing that the claim must be followed by the criteria for the claim as required by proposed 9 CFR 413.313(p). This criteria statement would help clarify that the nutrient content claim or health claim is based on the RACC and not the amount in the entire container. FSIS is also proposing that this criteria statement would not be required for products when the nutrient that is the subject of the claim meets the criteria based on the entire container amount or the unit amount, as applicable (proposed 9 CFR 413.309(b)(16)(ii)).

4. Additional Changes to Serving Size Regulations

FSIS currently allows by policy the use of an ounce unit in the serving size, e.g., 4oz (112g), instead of a household unit, e.g., 1 piece (112g), when the size of the product naturally varies in weight and is not uniform in size (e.g., poultry parts, such as chicken breasts and chicken wings, and non-formed meat cuts, such as pork chops). Consistent with 21 CFR 101.9(b)(2)(i)(G), proposed 9 CFR 413.309(b)(4)(vii) would permit the use of an ounce unit in the serving size for products that naturally vary in size (e.g., poultry parts or non-formed cuts of meat).

Current FSIS regulations require the serving size to declare the as-packaged amount in accordance with 9 CFR 317.309(b)(3) and 381.409(b)(3). Consistent with 21 CFR 101.9(b)(7)(v), proposed 9 CFR 413.309(b)(9)(5) would permit the serving size to include the finished product amount as part of the serving size when water or other ingredients with insignificant amounts of nutrients are instructed to be added during preparation. For example, when the consumer is directed to add a specific amount of water to prepare a condensed soup, the serving size may state “½ cup (120g) concentrated soup

(makes 1 cup prepared)” instead of “½ cup (120g).”

Currently, FSIS requires the serving size for a product marketed for two different purposes, e.g., gravy or a soup, to be based on the larger serving size, e.g., soup (1 cup RACC) instead of gravy (¼ cup RACC) (9 CFR 317.312 and 381.412). Consistent with 21 CFR 101.9(b)(11), proposed 9 CFR 413.309(b)(13)(iii) would require the Nutrition Facts label to include the nutrient information for both marketed serving sizes when the amount served for each differs in quantity by twofold or greater based on the RACC in accordance with proposed 9 CFR 413.313(b) (e.g., the Nutrition Facts label would provide nutrient data for both soup (1 cup) and gravy (¼ cup) because the soup serving size is greater than twofold over the serving size for gravy).

M. Reference Amounts Customarily Consumed

1. Factors Considered To Determine the Existing RACCs To Update

The current RACCs for meat and poultry products are listed in 9 CFR 317.312 and 381.412, respectively. The RACCs represent the amount of food customarily consumed per eating occasion and are listed by product categories. The RACCs and product categories are used as the basis for determining serving sizes for specific products. The current RACCs were primarily derived from the 1977–1978 (<http://www.ars.usda.gov/Services/docs.htm?docid=16184>) and the 1987–1988 (<http://www.ars.usda.gov/Services/docs.htm?docid=16185>) Nationwide Food Consumption Surveys conducted by USDA. Since the current RACCs were established, there is new consumption data that shows that the amount of foods Americans customarily consume has changed, and there are new food products in the marketplace. Therefore, FSIS analyzed more up-to-date consumption data to determine whether the RACCs and product categories for meat and poultry products needed to be updated or revised.

FSIS analyzed the recent consumption data from the NHANES 2003–2008 surveys using Statistical Analysis Systems (SAS)³¹ and Survey Data Analysis (SUDAAN)³² procedures to determine the amount of food being consumed by individuals. FSIS

³¹ SAS version 9.2 Cary, NC, 2011 <http://www.sas.com/technologies/analytics/statistics/stat/index.html>.

³² SUDAAN version 10.1 Research Triangle Park, NC, 2011 http://www.rti.org/page.cfm/Survey_Statistics.

considered the following factors in determining whether to revise the 1993 RACCs and product categories: (1) Whether there was an adequate sample size from the NHANES 2003–2008 consumption data for the product category; (2) whether the median intake estimate from the NHANES 2003–2008 consumption data for the product significantly differs (*i.e.*, at least a 25 percent difference) from the 1993 RACC; (3) whether the intake distribution was skewed (based on comparing the median intake estimate with the mean intake estimate from the NHANES 2003–2008 consumption data); (4) the “reasonable consumption amount” from the Food and Nutrient Database for Dietary Studies (FNDDS)³³; (5) the difference between the median intake estimates, converted to common household measures as applicable, and the 1993 RACC for the product; (6) the median intake estimates for comparable products; and (7) the RACCs for comparable FDA-regulated products. More detailed information about how the factors were applied to change or not change the RACCs for a specific food product are contained in a rationale chart available on the FSIS Web site.³⁴ FDA used similar methodology for updating the RACCs for foods regulated by FDA. The following sections describe the proposed changes to the RACC tables in FSIS’s regulations.

2. Changes to Table 1: Reference Amounts Customarily Consumed per Eating Occasion: Food Labeling for Infants and Children 1 Through 3 Years of Age

FSIS is proposing to combine the tables containing the RACCs for infant and toddler foods that exist in 9 CFR 317.312 for meat products and 9 CFR 381.412 for poultry products into a new table for meat and poultry products in proposed 9 CFR 413.312 for infants and children 1 through 3 years of age. FSIS is also proposing to add a third column titled “label statement” to the RACC table to provide examples of how the “label statement” may appear in the Nutrition Facts label as a formatted serving size and to parallel the FDA proposed RACC table 1 (21 CFR 101.12(b)). The titles of the combined

product categories would stay the same, except the combined product category for meat sticks and poultry sticks would be titled “Plain meats, plain poultry, meat sticks, poultry sticks, ready to serve.”

FSIS is also proposing to change the RACC from 60 g to 110 g for the product category “Dinners, ready-to-serve, strained type.” The 2003–2008 median intake estimates for dinner, ready-to-serve, strained type poultry was 101.8 g, and dinner, ready-to-serve, strained type, meat was 88.9 g. FDA, which regulates products containing less than 2% cooked meat or poultry, and less than 3% raw meat, increased the RACC for the comparable product category, “Dinner, desserts, fruits, vegetables, or soups, ready-to-serve, strained type” from 60 g to 110 g. The 2003–2008 median intake estimates for these two product categories was 104 g and 103 g, respectively. The products in these FDA regulated product categories are comparable to the FSIS regulated product category, “Dinner, ready-to-serve, strained type, poultry” and “Dinner, ready-to-serve, strained type meat”, because all of the products have similar type usage and product characteristics as strained baby foods. In addition, the current RACC for “Dinner, soups, ready-to-serve junior type” is 110 g, and the same RACC for both strained type and junior baby foods would help consumers compare nutrition information.

FSIS is also proposing to update the footnotes to proposed RACC Table 1 as follows: Footnote 1 would be updated to include new data sources, footnote 2 would be updated to include “brown and serve” as a type of “almost ready-to-serve” product and to include “(*e.g.*, ready to serve)” after “prepared for consumption,” and footnote 4 would be added to explain the purpose and use of the third column titled “label statement” in RACC Table 1.

3. Changes to Table 2: Reference Amounts Customarily Consumed per Eating Occasion: General Food Supply

FSIS is proposing to combine the tables containing the RACCs for the general food supply that currently exist in 9 CFR 317.312 for meat products and 9 CFR 381.412 for poultry products into a new table for meat and poultry products in proposed 9 CFR 413.312. FSIS is proposing to include a third column titled “label statement” in the new RACC table for meat and poultry products. The “label statement” column, which provides similar examples to what FDA provides in FDA RACC table 2 (21 CFR 101.12(b)), provides examples of how serving size

statements may appear in the Nutrition Facts label as a formatted serving size. For example, the RACC for a raw poultry cut is 114 grams but the formatted serving size in the Nutrition Facts label would be based on instructions in proposed 9 CFR 413.309(b), for example, 4oz (112g).

FSIS is also proposing to change some of the RACCs and product categories, establish new product categories for the general food supply, and update the footnotes to RACC table 2 as follows.

In the product category “Egg mixtures (western style omelet, soufflé, egg foo young),” FSIS is proposing to combine the meat and poultry categories for egg mixtures into one product category. The new name for the product category would be “Egg mixtures with meat or poultry; *e.g.*, western style omelet, soufflé, egg foo young.” Egg mixtures with meat and egg mixtures with poultry are comparable products with similar dietary usage and product characteristics. The same RACC will help consumers compare nutrition information between these products.

FSIS is proposing to combine the meat and poultry categories for luncheon meat into one product category as follows, “Luncheon products, luncheon meat, bologna, poultry bologna, Canadian style bacon, poultry Canadian style bacon, meat or poultry pattie crumbles, blood pudding, meat or poultry luncheon loaf, old fashioned loaf, berlinger, bangers, minced luncheon roll, thuringer, liver sausage, mortadella, uncured sausage (franks), ham and cheese loaf, P&P loaf, scrapple souse, head cheese, pizza loaf, olive loaf, pate, deviled ham, sandwich spread, teawurst, cervelat, Lebanon bologna, potted meat or poultry food product, taco fillings, pie fillings.” Luncheon meat and luncheon products made with poultry are comparable products with similar dietary usage and product characteristics. The same RACC will help consumers compare nutrition information between these products.

FSIS is proposing to combine the meat and poultry categories for entrees without sauce into one product category as follows, “Entrees without sauce; *e.g.*, cuts of meat or poultry including marinated, tenderized, injected cuts of meat or poultry, patties, corn dogs, croquettes, fritters, cured ham, dry cured ham, dry cured cappicola, cured poultry ham products, corned beef, pastrami, country ham, pork shoulder picnic, meatballs, pureed adult foods.” Entrees without sauce made with meat or poultry are comparable products with similar dietary usage and product characteristics. The same RACC will

³³ The reasonable consumption amount is a default consumption amount of food that researchers have defined and is used in NHANES when survey participants cannot recall the amount of food that was consumed at one eating occasion. Agricultural Research Service, Food Surveys Research Group, “U.S. Department of Agriculture, Food and Nutrient Database for Dietary Studies, 4.1” Beltsville, MD, 2010.

³⁴ <http://www.fsis.usda.gov/wps/portal/ffsis/topics/regulations/federal-register/proposed-rules>.

help consumers compare nutrition information between these products.

FSIS is proposing to combine the meat and poultry categories for mixed dishes not measurable with a cup into one product category as follows, “Mixed dishes NOT measurable with a cup; *e.g.*, burrito, egg roll, enchilada, pizza, pizza roll, quiche, all types of sandwiches with meat or poultry, cracker and meat/poultry lunch type packages, gyro, Stromboli, burger on a bun, poultry burger on a bun, frank on a bun, poultry frank on a bun, calzone, taco, stuffed pockets, foldovers, stuffed vegetables with meat or poultry, shish kabobs, empanada, chicken cordon bleu.” Mixed dishes not measurable with a cup made with meat or poultry are comparable products with similar dietary usage and product characteristics. The same RACC will help consumers compare nutrition information between these products.

FSIS is proposing to combine the meat and poultry categories for mixed dishes measurable with a cup into one product category as follows, “Mixed dishes measurable with a cup; *e.g.*, casserole, macaroni and cheese with meat or poultry, pot pie, spaghetti with sauce, poultry spaghetti with sauce, meat or poultry chili, meat or poultry chili with beans, hash, creamed chipped beef, creamed dried poultry, ravioli in sauce, stroganoff, Brunswick stew, goulash, poultry a la king, meat or poultry stew, ragout, meat or poultry lasagna, meat or poultry filled pasta.” Mixed dishes measurable with a cup made with meat or poultry are comparable products with similar dietary usage and product characteristics. The same RACC (1 cup) will help consumers compare nutrition information between these products.

FSIS is proposing to combine the meat and poultry categories for “Salads-all other” into one product category as follows, “Salads—all other meat salads, all other poultry salads; *e.g.*, chicken salad, ham salad, turkey salad.” Salads made with meat and salads made with poultry are comparable products with similar dietary usage and product characteristics. The same RACC (100g) will help consumers compare nutrition information between these products.

FSIS is proposing to combine the meat and poultry categories for “Soups-all varieties” into one category as follows, “Soups with meat or poultry-all varieties.” Soups made with meat and soups made with poultry are comparable products with similar dietary usage and product characteristics. The same RACC (245g) will help consumers compare nutrition information between these products.

FSIS is proposing to create a new product category “Appetizers, hors d’oeuvres, Mini mixed dishes with meat or poultry; *e.g.*, mini bagel pizzas, mini egg rolls, dumplings, mini pizza rolls, mini quesadilla, mini quiche” with a RACC of 85 g ready-to-serve (plus 35 g for products with sauce toppings). Recently, several mini or snack-size versions of several products in the “Mixed dishes, not measurable with a cup” product category have become available, such as mini pizza rolls, mini egg rolls, mini quiche, and mini sandwiches. Also, since 1993, other miniature products (smaller individual piece products) that are often used as appetizers and hors d’oeuvres have become available in the market place. To accommodate appetizer type products, the USDA’s Guide to Federal Food Labeling Requirements for Meat and Poultry Products (2007)³⁵ includes a RACC of 85 g for “Appetizers (*e.g.*, meat (or poultry), hors d’oeuvres, mini eggrolls, mini pizza rolls, bagel pizza).” Miniature products with or without meat have similar dietary usage and product characteristics and are often used interchangeably by consumers. If the product is marketed for use with a sauce, FSIS is proposing to use 35 g for the amount of the sauce. This amount is calculated proportionally based on adding 55 g of sauce or gravy for a RACC of 140 g for the product category, “Mixed dishes not measurable with cup,” under the general category “Mixed Dishes.”

FSIS is proposing to create a new category “Appetizers, hors d’oeuvres—Dips with meat or poultry; *e.g.*, chicken dip, chicken and cheese dip, meat dip” with a RACC of 2 tbsp. ready-to-serve. Recently, dip products with amenable amounts of meat or poultry, for example, cheesy chicken dip and chicken dip, meant to be served with chips such as corn chips, have been introduced into the market place. The “All dips (*e.g.*, bean dips, dairy-based dips, salsa)” product category in FDA’s regulations is comparable to the proposed FSIS “Dip with Meat or Poultry” product category, because dips with meat or poultry have similar dietary usage and product characteristics as dips regulated by FDA. Therefore, FSIS is proposing to establish a RACC of 2 tablespoons for the proposed “Dip with Meat or Poultry” product category. Establishing

³⁵ http://www.fsis.usda.gov/shared/PDF/Labeling_Requirements_Guide.pdf. 85 g for Appetizers is a suggested RACC provided in Guidance by USDA (see question 68 at <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-policies/fdq-generic-labeling>).

the same RACC for products with similar dietary usage, similar amounts customarily consumed, and product characteristics whether they are regulated by FDA or FSIS will help consumers compare nutrition information between these products.

FSIS is proposing to create a new product category “Candies with meat or poultry; *e.g.*, chocolate with bacon, chocolate dipped bacon, chocolate with salami” with a RACC of 30 g ready-to-serve. Recently, candies with amenable amounts of meat or poultry, for example, chocolate bars with bacon, chocolate dipped bacon, and chocolate bars with salami, have been introduced into the market place. Such products have been marketed as “Candies” based on information available from the Mintel Global New Products Database³⁶ for products that are currently available in the market, and they are comparable to products in the “All Other Candies” product category, which is regulated by FDA. FDA’s Serving Size Final Rule updated the RACC from 40 g to 30 g for the “All Other Candies” product category. Because the products in both FDA’s and FSIS’s candy product categories have similar usage and product characteristics, the same RACC (30g) for FDA’s “All Other Candies” product category and FSIS’s “Candies with meat or poultry; *e.g.*, chocolate with bacon, chocolate dipped bacon, chocolate with salami” product category will help consumers compare nutrition information between these products.

FSIS is proposing to combine the separate canned meat and poultry categories into one product category as follows, “Canned Meats (*e.g.*, canned beef, canned pork) and Canned Poultry (*e.g.*, canned chicken, canned turkey).” FSIS is also proposing to increase the RACC from 55 g to 85 g. There was an inadequate sample size for a reliable 2003–2008 intake estimate (82.1 g) for “Canned Meats,” and the 2003–2008 median intake estimate (89.5 g) for “Canned Poultry” did not show a significant change from the 1993 RACC. But, FDA updated the 1993 RACC for the “Fish, shellfish, and game meat, canned” product category from 55 g to 85 g. FDA’s “Fish, shellfish, and game meat, canned” product category is comparable to FSIS’s “Canned Meats (*e.g.*, canned beef, canned pork) and Canned Poultry” category. The same RACC for products with similar dietary usage and product characteristics whether regulated by FDA or FSIS will

³⁶ Mintel Global New Products Database (GNPD). Mintel Group Ltd. 333 West Wacker Drive, Suite 1100, Chicago, IL 60606. Internet: <http://www.gnps.com/sinatra/gnps/frontpage/> (accessed September 23, 2014).

help consumers compare nutrition information between these products. Therefore, FSIS is proposing that the RACC for “Canned Meats (*e.g.*, canned beef, canned pork) and Canned Poultry (*e.g.*, canned chicken, canned turkey)” be 85 g.

FSIS is proposing to include pork back fat into the category for “Bacon” with the category name of “Bacon; *e.g.*, bacon, beef breakfast strips, pork breakfast strips, pork rinds, pork back fat” because its use is most similar to that of bacon and pork rinds. FSIS is proposing the RACC for pork back fat to be 15 g ready-to-eat and 54 g ready-to-cook to reflect the previously established RACCs for bacon and pork rinds. The categories for bacon and poultry bacon products were not combined into one category because of their differing ready-to-cook RACCs. In addition, FSIS is proposing to modify the category name for poultry bacon to “poultry bacon, poultry breakfast strips” to clarify that these are different products as indicated by the differing ready-to-cook amounts from the 1993 regulation.

FSIS is proposing the following category names for the combined meat and poultry product categories that have the same RACC values and did not meet any of the factors for updating the RACCs: “Salad and potato toppers; *e.g.*, bacon bits, poultry bacon bits,” “Dried meat or poultry products; *e.g.*, jerky, dried beef or poultry, Parma ham, meat or poultry sausage products with a moisture/protein ratio of less than 2:1; *e.g.*, pepperoni,” “Snacks, *e.g.*, meat or poultry snack food sticks,” “Linked meat or poultry products, Vienna sausage, frankfurters, poultry franks, pork sausage, imitation frankfurters, bratwurst, kielbasa, Polish sausage, poultry Polish sausage, summer sausage, mettwurst, smoked country sausage, smoked sausage, poultry smoked sausage, smoked pickled meat or poultry meat, pickled pigs feet,” “Salads—pasta or potato, potato salad with bacon, potato salad with poultry, macaroni and meat or poultry salad,” “Major main entrée type sauce; *e.g.*, spaghetti sauce with meat or poultry, spaghetti sauce with meatballs, spaghetti sauce with poultry meatballs,” “Minor main entrée type sauce; *e.g.*, pizza sauce with meat or poultry, gravy,” and “Seasoning mixes dry, bases, extracts, dried broths and stock/juice, freeze dry trail mix products with meat or poultry: As reconstituted: Amount to make one Reference Amount of the final dish; *e.g.*, Gravy, Major main entrée type sauce, Soup, Entrée measurable with a cup.”

FSIS is proposing to update the footnotes to proposed 9 CFR 413.312 Table 2 as follows: Footnote 1 will be updated to include new data sources and to clarify that the RACC values presented in the table are for the “edible portion” of the food, and Footnote 6 will be added to explain the purpose and use of the “label statement” column.

N. Compliance

Currently, 9 CFR 317.309(h) and 381.409(h) provide information about how FSIS determines compliance with its nutrition labeling requirements, including the methods of analysis used, reasonable excesses and deficiencies of nutrients, acceptable levels of variance from declared values, and records requirements. FSIS is proposing to consolidate 9 CFR 317.309(h) and 381.409(h) into a single section (proposed 9 CFR 413.309(h)). The following discusses the additional revisions that FSIS will be proposing in 9 CFR 413.309(h), as compared to current 9 CFR 317.309(h) and 381.409(h).

1. Level of Variance Allowed for the Label Declaration of Specific Nutrients

Proposed 9 CFR 413.309(h)(5) establishes that a meat or poultry product with a label declaration of calories, sugars, added sugars (when the only source of sugars in the food is added sugars), total fat, saturated fat, cholesterol, or sodium shall be deemed to be misbranded under sections 1(n) of the FMIA (21 U.S.C. 601(n)(1)) or 4(h) of the PPIA (21 U.S.C. 453(h)) if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. However, no regulatory action will be based on such a determination if the excess is less than the inherent nutrient variation in a product or the variability generally recognized for the analytical method used in that product at the level involved. FSIS is not proposing to change the level of variance allowed for the label declaration of nutrients.

2. Methods Used To Determine Compliance

Under proposed 9 CFR 413.309(h)(2), a sample for nutrient analysis must consist of at least six consumer units, each from a production lot, or alternatively, chosen randomly to be representative of a production lot. In each case, the units may be individually analyzed, and the results averaged, or the units may be combined, and the composite analyzed. FSIS will consider the results—whether the average or the

single result from the composite—to be the nutrient content of the composite. All analyses must be performed, if possible, by the appropriate methods and procedures used by the U.S. Department of Agriculture (USDA) for each nutrient in accordance with the “Chemistry Laboratory Guidebook.” If no USDA method is available, the appropriate methods for the nutrient in accordance with the 2016 edition of the “Official Methods of Analysis” of the AOAC International, 20th ed., must be used, unless a particular method of analysis is specified in 9 CFR 413.309(c). If no USDA, AOAC, or specified method is available or appropriate, any other reliable and appropriate analytical procedures may be used, as determined by FSIS. The current edition (20th ed.) of the “Official Methods of Analysis” includes many updates to the 15th edition.

When FSIS issued 9 CFR 317.309(h) and 381.409(h) on compliance with nutrition labeling requirements, the most current version of the AOAC methods was its 15th edition, and, therefore, FSIS identified the 15th edition in its regulation. Newer and better methods of analysis have since been validated and recognized as “official” methods in the current 20th edition. Accordingly, FSIS is proposing, in 9 CFR 413.309(h)(2), to use the 20th edition and incorporate it by reference in 9 CFR (h)(9)(i). The “Official Methods of Analysis of AOAC International” is a comprehensive collection of chemical and microbiological methods of analysis. The Official Methods of Analysis have undergone rigorous scientific review and validation to determine the performance characteristics for the intended analytical application and fitness for purpose. Each method includes specific instructions for performing the chemical analysis of a substance in a particular matrix. If a newer edition of the Official Methods of Analysis is published before issuance of a final rule, FSIS intends to finalize this rule with the newer edition, as appropriate, provided there are no substantive changes in the newer edition requiring additional comment.

FSIS does not currently sample or conduct routine nutrient analyses of products for regulatory purposes because FSIS has not, in the past, found gross non-compliance with the nutrition labeling requirements (*i.e.*, large variations in the nutrient content of the samples compared to the declared nutrition information provided on product labels). FSIS, for a limited period of time, is conducting surveillance sampling for nutrient content of raw ground beef samples

collected for pathogen analysis, such as Shiga toxin-producing *Escherichia coli* (STEC) and *Salmonella*, to ascertain compliance with the recent nutrition labeling requirements for raw ground product packages. FSIS randomly analyzes samples of raw ground beef products in consumer-ready packaging bearing a Nutrition Facts label that have already been collected for pathogen analysis at Federally-inspected establishments. In addition, when Office of Investigation, Enforcement and Audit (OIEA) Investigators collect samples of raw ground beef in consumer-ready packaging bearing a Nutrition Facts label at retail for pathogen analysis, the FSIS laboratory also randomly selects some of these samples for nutrient content analysis. The nutrient content results are non-regulatory and are for surveillance purposes only at this time. If there is a discrepancy between the laboratory results and the Nutrition Facts label, LPDS directly contacts the establishment or the OIEA-Compliance and Investigation Division Regional Director with the results of the nutrient content testing.

FSIS will explore its regulatory options, including seeking criminal penalties or rescinding label approvals, if it discovers a violation of the nutrition labeling requirements. In addition, FSIS will consider when additional surveillance sampling for nutrient content should be conducted for various products, as well as when regulatory verification testing should occur.

3. Records Requirements

Currently, FSIS regulations require that establishment management maintain records to support the validity of nutrient declarations contained on meat and poultry product labels (9 CFR 317.309(h)(8) and 381.409(h)(8)). Such records are required to be made available to the inspector or any duly authorized representative of FSIS upon request (9 CFR 317.309(h)(8) and 381.409(h)(8)). These records are generally required to be retained for 2 years (9 CFR 320.3 and 381.177). FSIS is proposing to consolidate the requirements in 9 CFR 317.309(h)(8) and 381.409(h)(8) into proposed 9 CFR 413.309(h)(8).

As discussed in sections II.E.5.a. (dietary fiber), II.E.5.b. (soluble and insoluble fiber), II.E.3. (added sugars), II.J.2. (vitamin E), and II.J.3. (folate), there are no suitable analytical procedures for measuring the following nutrients under the circumstances described: (1) Dietary fiber (when non-digestible carbohydrates that do and do not meet the proposed definition of dietary fiber are both contained in a

food product); (2) soluble fiber (when a mixture of soluble fiber and non-digestible carbohydrates that do not meet the definition of dietary fiber is present in a food); (3) insoluble fiber (when a mixture of insoluble fiber and non-digestible carbohydrates that do not meet the definition of dietary fiber is present in a food); (4) added sugars (when a food product contains both naturally occurring sugars and added sugars); (5) vitamin E (when a food product contains both RRR- α -tocopherol and all rac- α -tocopherol); and (6) folate (when a food product contains both folate and folic acid).

Because there are no reliable or appropriate analytical procedures available for FSIS to ensure that the declared nutrient amount for certain nutrients is truthful, accurate, and in compliance with all applicable labeling requirements, FSIS is proposing to require specific recordkeeping for certain nutrients. FSIS is proposing to require that manufacturers make and keep written records to verify the declaration of: (1) The amount of added non-digestible carbohydrates that do not meet the proposed definition of dietary fiber when the dietary fiber present in a food is a mixture of dietary fiber and non-digestible carbohydrates that do not meet the definition of dietary fiber (proposed 9 CFR 413.309(h)(8)(i)); (2) the amount of added non-digestible carbohydrates that do not meet the proposed definition of dietary fiber when the food contains a mixture of soluble fiber and non-digestible carbohydrates that do not meet the definition of dietary fiber (proposed 9 CFR 413.309(h)(8)(ii)); (3) the amount of added insoluble non-digestible carbohydrates that do not meet the proposed definition of dietary fiber when the food contains a mixture of insoluble fiber and non-digestible carbohydrates that do not meet the definition of dietary fiber (proposed 9 CFR 413.309(h)(8)(iii)); (4) the amount of added sugars added to the food during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single-ingredient), when both naturally occurring and added sugars are present in a food (proposed 9 CFR 413.309(h)(8)(iv)); (5) (a) scientific data and information that demonstrate the amount of added sugars in the food after non-enzymatic browning or fermentation and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food, provided the data and information

used is specific to the type of food manufactured; or (b) records of the amount of sugars added to the food before and during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient) and in no event shall the amount of added sugars declared exceed the amount of total sugars on the label (proposed 9 CFR 413.309(h)(8)(v)); (6) the amount of all rac- α -tocopherol added to the food and RRR- α -tocopherol in the finished food when a mixture of both forms of vitamin E is present in a food (proposed 9 CFR 413.309(h)(8)(vi)); and (7) the amount of synthetic folate or folic acid added to the food and the amount of naturally-occurring folate in the finished food, when a mixture of folate and folic acid is present in a food (proposed 9 CFR 413.309(h)(8)(vii)).

Most manufacturers should already have the types of records needed to validate the declared amount of each nutrient. They are in the best position to know which records will contain the information necessary for FSIS to determine compliance. These records may include analyses of databases, recipes or formulations, or batch records. FSIS recognizes that the nutrient profile of processed foods that have dietary fiber, soluble fiber, insoluble fiber, added sugars, vitamin E, or folate/folic acid can vary depending on the recipe or formulation, the suppliers of ingredients, and other factors. Although the nutrient levels in foods may change if a manufacturer changes ingredient suppliers or recipes, manufacturers still need to ensure that the records they maintain substantiate the nutrient composition of the specific food. Therefore, manufacturers must be able to distinguish among the same or similar products they have in the marketplace that may contain differing amounts of a declared nutrient. The records required under proposed 9 CFR 413.309(h)(8) must be available for review and copying while the product is available for purchase in the marketplace. There is a wide range of shelf lives among food products. The current retention period for nutrition labeling records under 9 CFR 320.3 and 381.177—a period not to exceed two years after December 31 of the year in which the transaction to which the record relates has occurred—will be sufficient to enforce the nutrient declarations on the nutrition labels.

4. Inclusion of Potassium as a Mineral

Potassium is currently the only vitamin or mineral specified as a Class I and Class II nutrient in 9 CFR

317.309(h)(4)(i–ii) and 381.409(h)(4)(i–ii). Potassium is a mineral for which an RDI is being proposed (proposed 9 CFR 413.309(c)(8)(iv)), and the absolute amount would be required to be declared along with a percent DV on the Nutrition Facts label. FSIS has tentatively concluded that there is no need to separately list potassium under the description of Class I and Class II nutrients because it is encompassed within the minerals category. Therefore, FSIS is proposing to omit a specific reference to potassium in proposed 9 CFR 413.309(h)(4) and (h)(6). Any listing of potassium on the Nutrition Facts label will have to meet the specific compliance requirements for minerals under 9 CFR 413.309(h)(4) and (h)(6).

5. Requirements for Other Carbohydrate, Soluble and Insoluble Fiber, Added Sugars, and Sugar Alcohols

The labeling requirements for Class I and Class II nutrients are provided in proposed 9 CFR 413.309(h)(4). For the reasons discussed in section II.E.6., FSIS is proposing to omit the provision for voluntary declaration of “Other carbohydrate” in proposed 9 CFR 413.309(c)(6) that is in 9 CFR 317.309(c)(6)(iv) and 381.409(c)(6)(iv). Therefore, FSIS is proposing to omit the compliance requirements related to “Other carbohydrate” in proposed 9 CFR 413.309(h)(4) and (h)(6) that are in 9 CFR 317.309(h)(4) and (h)(6) and 381.409(h)(4) and (h)(6).

Dietary fiber is included as both a Class I and Class II nutrient because food products may contain only non-digestible carbohydrates that meet the definition of dietary fiber and that may be naturally occurring or that may be added to fortified or fabricated foods. The same is true for soluble and insoluble fiber, yet these nutrients are not currently listed as Class I or Class II nutrients (see 9 CFR 317.309(h)(4) and 381.409(h)(4)). Therefore, FSIS is proposing to include dietary fiber in 9 CFR 413.309(h)(4) as both a Class I and Class II nutrient.

Currently, 9 CFR 317.309(h)(5) and 381.409(h)(5) (consolidated in proposed 9 CFR 413.309(h)(5)) specify that a food with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium is deemed to be misbranded under section 1(n) of the FMIA (21 U.S.C. 601(n)(1)) or 4(h) of the PPIA (21 U.S.C. 453(h)) if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. The nutrients listed in this section can have a negative impact on health in the general U.S. population if consumed in excess, and there are current dietary

recommendations to reduce the consumption of these nutrients. Therefore, FSIS is ensuring in proposed 9 CFR 413.309(h)(5) that foods do not contain excessive amounts of these nutrients of which the consumer is unaware.

Current dietary recommendations acknowledge that Americans consume excess amounts of added sugars and encourage reducing intake of calories from added sugars. A FSIS has an interest in ensuring that foods do not contain excessive amounts of added sugars that are not declared on the label (see section II.E.3) and is proposing to include added sugars in 9 CFR 413.309(h)(5). In some food products, all of the sugars are added. In such cases, an analytical method could be used to determine the amount of added sugars, and the permitted analytical variability would be applicable. Accordingly, FSIS is proposing to include “added sugars (when the only source of sugars in the food is added sugars)” among the list of nutrients in proposed 9 CFR 413.309(h)(5).

Reasonable excesses or deficiencies in relation to certain declared nutrients are acceptable within current good manufacturing practice. FSIS is proposing to allow reasonable excesses over the labeled amount of soluble and insoluble fiber and sugar alcohols when they are acceptable within current good manufacturing practice, and reasonable deficiencies under labeled amounts of added sugars when they are acceptable within current good manufacturing practice (proposed 9 CFR 413.309(h)(6)). FSIS expects that when a food product only contains added sugars, when all of the dietary fiber (both soluble and insoluble) is added non-digestible carbohydrates that meet the definition of dietary fiber, when all of the vitamin E is all *rac*- α -tocopherol, and when only folic acid is present in a food, the declared amount must be at least equal to the amount of the nutrient added to the food.

In summary, FSIS is proposing the following changes related to compliance in 9 CFR 413.309(h) as compared to current 9 CFR 317.309(h) and 381.409(h): (1) Cite the 20th edition of the Official Methods of Analysis of the AOAC International and incorporate it as the reference for the appropriate methods used to determine compliance with amounts of nutrients declared on the Nutrition Facts label (proposed 9 CFR 413.309(h)(2) and (h)(9)(i)); (2) establish general recordkeeping requirements when records are necessary to verify information related to dietary fiber, soluble and insoluble fiber, added sugars, folate, and vitamin

E provided on the label (proposed 9 CFR 413.309(h)(8)); (3) omit a specific reference to potassium in proposed 9 CFR 413.309(h)(4)(i–ii) and (h)(6) such that any listing of potassium on the Nutrition Facts label would meet the specific compliance requirements for minerals under proposed 9 CFR 413.309(h)(4) and (h)(6); (4) include dietary fiber, under proposed 9 CFR 413.309(h)(4); (5) include added sugars within proposed 9 CFR 413.309(h)(5) such that the label declaration of added sugars will be deemed misbranded under sections 1(n) of the FMIA (21 U.S.C. 601(n)(1)) or 4(h) of the PPIA (21 U.S.C. 453(h)) if the nutrient content of the composite is greater than 20 percent in excess of the added sugars declared on the label, and within proposed 9 CFR 413.309(h)(6) such that reasonable deficiencies of added sugars would be permitted; (6) include soluble and insoluble fiber and sugar alcohols within proposed 9 CFR 413.309(h)(6) such that reasonable excesses of these nutrients would be permitted; and (7) consistent with the tentative conclusion in section II.E.6., omit references to “Other carbohydrate” in proposed 9 CFR 413.309(h).

O. Technical Amendments

FSIS is proposing to update the name of Food Labeling Division in proposed 9 CFR 413.312 and 413.369 to the Labeling and Program Delivery Staff, Office of Policy and Program Development. FSIS is also proposing to update the docket room address in proposed 9 CFR 413.309.

Proposed 9 CFR 413.400(a)(1)(ii) is updated to remove compliance criteria that expired in July 1997.

FSIS is proposing to update the cross-references to parts 317 and 381 in sections 301.2, 304.2, 316.8, 316.11, 316.13, 317.16, 318.10, 319.1, 319.10, 320.1, 327.15, 362.2, 381.172, 381.2, and 412.2.

III. Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated an “economically significant regulatory

action” under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

Need for the Rule

The USDA began requiring nutrition and serving size information on food labels in the early 1990’s (58 FR 632). The requirements were intended to provide producers with a credible way of communicating nutrient related information to consumers and ensure consumers had access to the necessary information for maintaining a healthy diet. Today, nearly 80 percent of U.S. adults report using nutrition labels at

least some of the time.³⁷ Table 1—Use of Nutritional Facts Label by Average Daily Caloric, Sodium and Sugar Intake from Food at Home. However, over the past 20 years American caloric and nutritional consumption and recommendations³⁸ for daily nutrition requirements have changed and no longer match the current nutrition labeling requirements. This gradual reversion to underlying information asymmetries raises concerns over the usefulness of the information provided on nutritional facts and serving size labels. In addition, consumer groups have raised concerns over the required formats. According to national

consumer surveys,³⁹ a sizeable number of consumers effectively lack access to the provided information because of their inability to simply read or quickly comprehend nutritional labels, leading to inadequate information distribution. The proposed rule seeks to correct the market failures caused by asymmetric and inadequate information by ensuring that nutritional and serving size requirements for FSIS products is consistent with FDA’s requirements and are based on current diets and nutritional needs as well as addressing those issues that inhibit consumers from using this information.

TABLE 1—USE OF NUTRITIONAL FACTS LABEL BY AVERAGE DAILY CALORIC, SODIUM AND SUGAR INTAKE FROM FOOD AT HOME

| Nutritional facts label use | Portion of the population ¹ | Caloric intake ² (kcal) | Sodium intake ² (mg) | Sugar intake ² (mg) |
|----------------------------------|--|------------------------------------|---------------------------------|--------------------------------|
| Always or Most of the Time | 102,281,465 (43%) | 1,439 | 2,327 | 85 |
| Sometimes | 83,877,978 (36%) | 1,462 | 2,325 | 89 |
| Rarely | 33,653,297 (14%) | 1,554 | 2,429 | 103 |
| Never | 15,807,324 (7%) | 1,741 | 2,517 | 122 |

¹ Population includes all individuals 16 years of age and older.

² Intake values are limited to food consumed at home.

Source: NHANES. 2013. “Questionnaires, Datasets, and Related Documentation” Centers for Disease Control and Prevention. Accessed on 5/6/2014. Table derived from data in the Consumer Behavior Phone Follow-up Module—Adult, Dietary Interview—Individual Foods, First Day, and Demographic Variables & Sample Weights. http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm.

Government labeling requirements provide producers with a credible way to communicate product attributes that are not obvious to consumers, *e.g.*, calorie count or amount of fiber per serving. In this manner, labeling requirements allow producers to compete based on nutritional quality. In turn, consumers use nutritional fact and serving size labels to select products with desired qualities and tie individual decisions to overall health impacts.⁴⁰ More than 185 million adults reported referencing the Nutrition Facts label at least some of the time.⁴¹ Further still, recent research conducted by the

Economic Research Service indicated that use of nutritional and health information is on the rise.⁴² The 2008 Health and Diet Survey conducted by the FDA provides further insight into food label use.⁴³ When consumers were asked “when you buy a product for the first time, how often do you read (ingredient and nutrition) information,” 54 percent reported often, and 23 percent reported sometimes. Ninety percent of label users reported using food labels to see how high or low the food is in calories and macro- and micro-nutrients like sodium, fat, or vitamins either often or sometimes (66

percent often, 24 percent sometimes). Lastly, 49 percent of survey respondents affirmed that during the previous two weeks, they had based a decision to buy or use a food product based on the nutrition label. Clearly, many consumers demand and use nutritional information on food labels. However, the changes in consumers’ diets and basing the nutrition facts and serving size labels on outdated recommendations does not clearly and conspicuously reveal the essential information to consumers.

³⁷ NHANES. 2013. “Questionnaires, Datasets, and Related Documentation” Centers for Disease Control and Prevention. Accessed on 5/6/2014. Data derived from the Consumer Behavior Phone Follow-up Module—Adult http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm.

³⁸ U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2015–2020 Dietary Guidelines for Americans. 8th Edition. December 2015. Available at <http://health.gov/dietaryguidelines/2015/guidelines/>.

³⁹ Health and Diet Survey. 2008. U.S. Food and Drug Administration. <http://www.fda.gov/Food/>

<http://www.fda.gov/FoodScienceResearch/ConsumerBehaviorResearch/ucm193895.htm> National Health and Nutrition Examination Survey Questionnaire, NHANES. 2009–2010. http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm.

⁴⁰ Caswell, J. and E.M. Mojduszka. 1996. Using information labeling to influence the market for quality in food products. *American Journal of Agricultural Economics*. 29: 47–54.

⁴¹ NHANES. 2013. “Questionnaires, Datasets, and Related Documentation” Centers for Disease Control and Prevention. Accessed on 5/6/2014.

http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm NHANES.

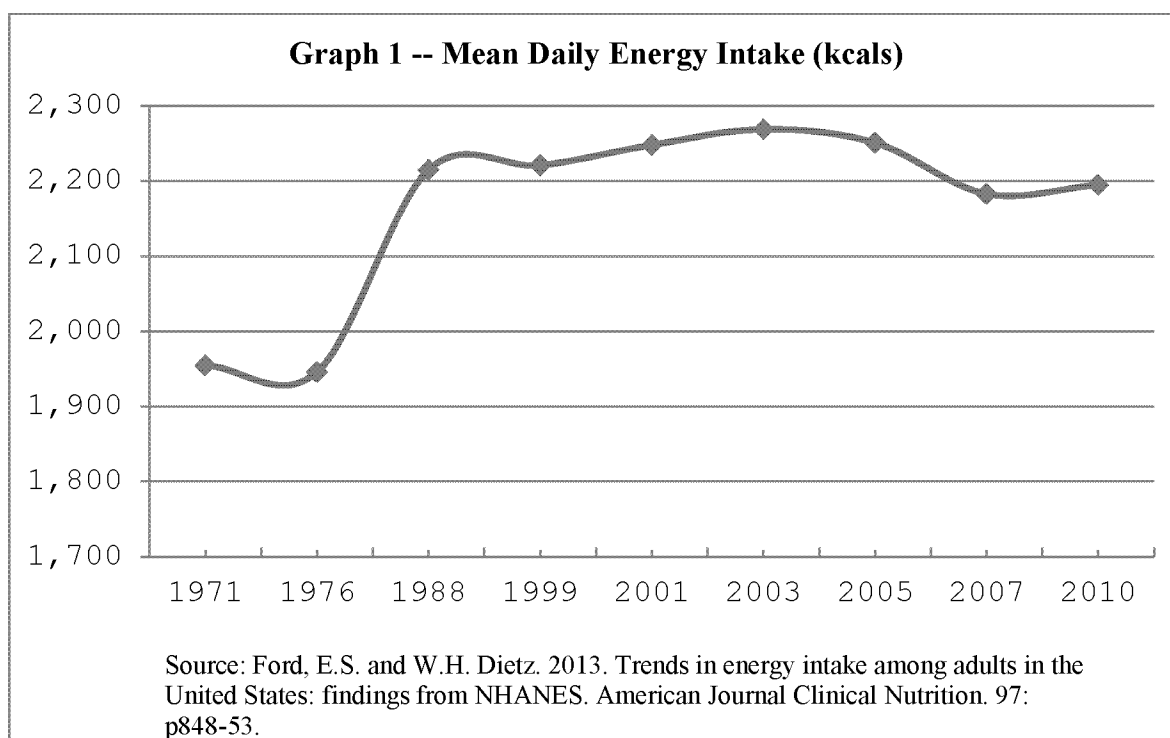
⁴² Todd, J. 2014. Changes in eating patterns and diet quality among working-age adults, 2005–2010. U.S. Department of Agriculture, Economic Research Service. ERR–161. Todd 2014.

⁴³ Choiniere, C.J. and A. Lando. 2008. “FDA 2008 Health and Diet Survey—Consumer Behavior Research” Accessed on 5/6/2014. < <http://www.fda.gov/Food/FoodScienceResearch/ConsumerBehaviorResearch/ucm193895.htm>.>

As is shown on Graph 1, from 1971–2010, mean energy intake increased by 240 kcal/day⁴⁴ although recent reports suggest overweight and obesity has leveled-off nationally and even declined in certain groups.⁴⁵ During this period, an emphasis on health aspects such as “low in sodium” or “low in fat” led consumers to disregard other pertinent health information, e.g., calorie count, sugars and serving size, leading to overconsumption.⁴⁶ Between 1970 and 2005, sugars and sweeteners available for consumption increased by 19 percent. This increase in supply enabled

an increase in consumption such that by 2004, the daily sugar intake for men and women averaged 25.4 tsp (406 kcal) and 18.3 tsp (292 kcal) respectively.⁴⁷ From 2007–2010, children and adults consumed more than double the amount of recommended added sugars, with lower income individuals consuming more added sugars than higher income individuals.⁴⁸ For perspective, the 2015–2020 Dietary Guidelines for Americans recommends less than 10 percent of calories per day from added sugars combined, yet added sugars alone contributed an average of 16

percent of the total calories in American diets. The increase in caloric density worsened the negative health impacts associated with overconsumption. Updating nutrition facts and serving size labels so as to take into consideration current consumption patterns, dietary recommendations, and scientific evidence will help producers credibly communicate hard to distinguish product attributes as well as aid current and future label-users overcome the issues presented above.



Of those U.S. adults who rarely or never use Nutrition Facts labels, over 31 million of them are overweight or obese; conditions linked to increased incidence of coronary heart disease, stroke, type 2 diabetes, cancer, and high blood pressure. For perspective, overweight and obese individuals spend

10 and 43 percent more money on health care as compared to normal weight individuals, respectively.⁴⁹ Overall annual medical expenditure caused by overweight or obesity has been estimated to account for between 5 and 7 percent of national medical expenditures⁵⁰ and is projected to

increase to 17 percent by 2030.⁵¹ With regard to health care providers, obesity accounts for 8.5 percent of Medicare spending, 12 percent of Medicaid spending, and 13 percent of private payer spending.⁵²

A daily energy surplus of 50–100 kcals will lead to overweight and

⁴⁴ Ford, E.S. and W. H. Dietz. 2013. Trends in energy intake among adults in the United States: finding from NHANES. *American Journal of Clinical Nutrition*. 97: 848–853. Ford and Dietz, 2013.

⁴⁵ Fryar, C. Carroll, M., Ogden, C. 2014. Prevalence of Overweight, Obesity, and Extreme Obesity Among Adults: United States, 1960–162 Through 2011–2012. CDC National Center for Health Statistics. http://www.cdc.gov/nchs/data/hestat/obesity_adult_11_12/obesity_adult_11_12.htm.

⁴⁶ Chandon, P. 2013. How package design and packaged-based marketing claims lead to overeating. *Applied Economic Perspectives and Policy*. 35: 7–31.

⁴⁷ Johnson, R.K., L.J. Appel, M. Brands, B.V. Howard, M. Lefevre, R.H. Lustig, F. Sacks, L.M. Steffen, and J. Wylie-Rosett. 2009. Dietary sugars intake and cardiovascular health: a scientific statement from the American Heart Association. *Circulation*. 1012–1020.

⁴⁸ Biing-Hwan Lin and Rosanna Mentzer Morrison. 2014. ERS's Food Consumption and Nutrient Intake Data-Tool for Assessing Americans' Diets. USDA Economic Research Service. <https://www.ers.usda.gov/amber-waves/2014/october/erss-food-consumption-and-nutrient-intake-data-tools-for-assessing-americans-diets/>.

⁴⁹ Tsai, A.G., D.F. Williamson, and H.A. Glick. 2010. Direct medical cost of overweight and obesity

in the USA: A quantitative systematic review. *Obesity Reviews*. 12: 50–61. Tsai et al. 2010.

⁵⁰ Tsai, A.G., D.F. Williamson, and H.A. Glick. 2010. Direct medical cost of overweight and obesity in the USA: A quantitative systematic review. *Obesity Reviews*. 12: 50–61. Tsai et al. 2010.

⁵¹ Wang, Y.C., K.M. T.M., S.L. Gortmaker, and M. Brown. 2011. Health and economic burden of the projected obesity trends in the USA and the UK. *The Lancet*. 378: 815–825 Wang 2011.

⁵² Finkelstein, E.A., J.G. Trogon, J.W. Cohen, and W.Dietz. 2009. Annual medical spending attributable to obesity: Payer and service-specific estimates. *Health Affairs Web Exclusive*. 33:11.

obesity.⁵³ Thus, the 92–279 kcal difference in kcals consumed at home between those who rarely or never read labels as compared to those who at least sometimes read labels is understood to be significant, Table 1—Use of Nutritional Facts Label by Average Daily Caloric, Sodium and Sugar Intake from Food at Home. When asked why they did not use nutritional labels, approximately 10 percent of overweight respondents exclusively had issues related to readability and comprehensibility: The print is too small, they would not know what to look for, or they do not have enough time. Addressing these design limitations would provide consumers with information that will convey relevant nutrition information.

These modest reductions are known to lead to significant benefits in the form of weight loss, health improvements, and reduced medical expenditures.⁵⁴ These issues can be addressed by altering the design and content of nutritional and serving size labels, *e.g.*, reducing the variance between food labels by more closely aligning FSIS's requirements with FDA's, providing a calorie count for the entire package and/or utilizing a dual column layout when appropriate, along with increasing and bolding the font size for the most salient information.

In total, the USDA and FDA regulate roughly 50,000⁵⁵ and 740,000⁵⁶ labels. The proposed rule reduces the amount of inconsistent information across FSIS and FDA products by more closely aligning nutrition labeling requirements with FDA's final changes, which ensures that food nutrition information is consistent across food products. This proposed rule allows nutrition labeling to more accurately reflect current

dietary guidelines and is more easily understood by consumers. As will be detailed in the following sections, the magnitude of the sum of public health benefits brought about by even a small change in consumer behavior because of the information provided by the label warrants the proposed rule.

Baseline

FSIS estimates that there are roughly 50,000 different retail nutrition labels for meat or poultry products, roughly 25 percent of which are private labels (store brand). The Agency estimates that FSIS products are produced by 3,307 establishments, of which, 3,125 are considered either small or very small establishments. The number of labels and establishments is based on Information Resources, Incorporated (IRI) scanner data⁵⁷ and the Small Business Administration's (SBA's) business size classifications.

There are almost 50 million adults who rarely or never use the Nutrition Facts label. Of this population, nearly 32 million are overweight, are obese, or have hypertension, Table 11 and 12. FSIS estimated this proposed rule would impact a portion of these consumers by increasing the usability of nutrition labeling which will, in turn, improve their health and welfare.

Expected Costs of the Proposed Rule

Quantitative costs for the proposed rule include relabeling, recordkeeping, and reformulation costs. FSIS anticipates allowing a 24-month compliance period with a 36-month compliance for small businesses,⁵⁸ consistent with FDA's final rules (81 FR 33742 and 81 FR 34000). On December 1, 2014, FSIS issued a final rule that established January 1, 2018, as the uniform compliance date for new meat

and poultry product labeling regulations that are issued between January 1, 2015 and December 31, 2016 (79 FR 71007). However, according to the uniform compliance date final rule, if any food labeling regulation involves special circumstances that justify a compliance date other than the uniform compliance date, FSIS will determine an appropriate compliance date and will publish that compliance date in the rulemaking (79 FR 71008). FSIS is proposing not to use the uniform compliance date for a final rule resulting from this proposed rule because, depending on when the final rule is published, the use of the uniform compliance date may result in a compliance period of less than 24 months.

The combined expected annualized costs equal \$10.8 million annualized at a 3 percent rate over 20 years. The one-time costs, staggered over the first three years, are \$165,540,072. In addition, consumers will incur costs associated with learning how to use new labels, which is a form of qualitative costs. What follows are details for each of the quantitative costs.

Relabeling Costs

To estimate the costs associated with relabeling products under USDA jurisdiction, this analysis utilized the 2014 FDA Labeling Cost Model⁵⁹ and Information Resources, Inc. (IRI) scanner data. The cost of relabeling depends on the number of labels required to change, whether or not the change can be coordinated with another label update, and the type of label change (extensive, major or minor). To determine the number of FSIS regulated labels in the retail market, we relied on IRI scanner data. Overall, there are 56,905 labels in the retail market under FSIS jurisdiction (14,056 private and 42,849 branded), though some are exempt from nutrition labeling per 9 CFR 317.400 and 381.500. To find the number of labels that are exempt, we utilized data from IRI and the National Meat Case Study. Data from IRI estimates 30.64 percent (3,619 private and 13,806 branded labels) of meat and poultry products are fresh in the retail market, thus possibly eligible for a labeling exemption. Of these products, approximately 39 percent do not have

⁵³ Finkelstein, E.A., C.J. Ruhm, and K.M. Kosal. 2005. Economic causes and consequences of obesity. *Annual Review of Public Health*. 26. 239–257. and Johnson, R. K., L.J. Appel, M. Brands, B.V. Howard, M. Lefevre, R.H. Lustig, F. Sacks, L.M. Steffen, and J. Wylie-Rosett. 2009. Dietary sugars intake and cardiovascular health a scientific statement from the American Heart Association. *Circulation*: 1012–1020.

⁵⁴ Dall, T.M., V.L. Fulgoni III, Y. Zhang, K.J. Reimers, P.T. Packard, and J.D. Astwood. 2009. Potential health benefits and medical cost savings from calorie, sodium, and saturated fat reductions in the American diet. *American Journal of Health Promotion*. 23. 412–422 and Sturm, R. 2002 The effects of obesity, smoking, and drinking on medical problems and costs. *Health Risks and Costs*. 21: 245–253.

⁵⁵ IRI (2012). InfoScan data. Information Resources, Inc. (IRI).

⁵⁶ Nutrition Facts/Serving Sizes Combined PRIA for Docket No. FDA–2012–N–1210 and Docket No. FDA–2004–N–0258. Available at: <http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocuments/RegulatoryInformation/LabelingNutrition/UCM385669.pdf>.

⁵⁷ Any opinions, findings, recommendations, or conclusions are those of the authors and do not necessarily reflect the views of the Economic Research Service, U.S. Department of Agriculture. The analysis, findings, and conclusions expressed in this paper also should not be attributed to either Nielsen or Information Resources, Inc. (IRI). This research was conducted in collaboration with USDA under a Third Party Agreement with IRI.

⁵⁸ Small Businesses are based on the Small Business Administration (SBA) size standards. The SBA defines a small business in NAICS code 311611—Animal (except Poultry) Slaughter and NAICS code 311612—Meat Processed from Carcasses as having less than 1,000 employees. A business in NAICS code 311615—Poultry Processing has a small business standard of less than 1,250 employees and NAICS code Seafood Product Preparation and Packaging has a less than 750-employee standard.

United States Small Business Administration (SBA), Table of Small Business Standards Matched to North American Industry Classification System Codes. Effective February 26, 2016. Available at https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.

⁵⁹ RTI International. “2014 FDA Labeling Cost Model.” Prepared by Mary K. Muth, Samantha Bradley, Jenna Brophy, Kristen Capogrossi, Michaela C. Coglaiti, and Shawn A. Karns. Contract No. HHSP–223–2011–10005B, Task Order 20, August 2015.

nutrition labeling.⁶⁰ Therefore, we estimate there are 50,110 FSIS labels

with nutrition labeling; 12,645 private (14,056 – (3,619 × 39%)) and 37,465

branded (42,849 – (13,806 × 39%)). See Table 2 below for details.

TABLE 2—TOTAL NUMBER OF FSIS UPCs WITH NUTRITION FACTS LABELS

| Type of label | Total FSIS labels | Number of UPCs exempt from NFL | Total FSIS UPCs with NFL |
|---------------|-------------------|--------------------------------|--------------------------|
| Branded | 42,849 | 5,384 | 37,465 |
| Private | 14,056 | 1,411 | 12,645 |
| Total | 56,905 | 6,795 | 50,110 |

Using SBA's small business definition of small business and IRI scanner data, FSIS estimates 53.6 percent of UPCs are from small businesses and 46.4 percent of UPCs are from large. The 26,859 UPCs (53.6 percent of 50,110) from small manufacturers have 36 months to comply with the proposed regulations and the 23,251 (46.4 percent of 50,110) from large manufacturers will have 24 months to comply. In total, there are 6,778 private labels (12,645 × 53.6%) and 20,081 branded labels (37,465 × 53.6%) for small businesses, and 5,867 private labels (12,645 × 46.4%) and 17,384 branded labels (37,465 × 46.4%) for large businesses. The Small Business Administration (SBA) defines a small business in NAICS code 311611—Animal (except Poultry) Slaughter and NAICS code 311612—Meat Processed from Carcasses as having less than 1,000 employees.⁶¹ A business in NAICS code 311615—Poultry Processing has a small business standard of less than 1,250 employees and NAICS code Seafood Product Preparation and Packaging has a less than 750-employee standard.⁶²

To adjust for inflation in the 2014 FDA Labeling Cost Model, we updated the wage rates using the most current (2015) wages and applied a benefits and overhead factor of two to estimate the total cost per type of label change. The cost estimates in 2015 U.S. Dollars (USD) are \$572 per label (with a range of \$141 to \$1,620) for minor coordinated changes and \$3,887 per label (with a

range of \$1,842 to \$7,741) for minor uncoordinated changes (FDA Labeling Cost Model, 2014). The cost estimates in 2015 USD are \$1,152 per label (with a range of \$296 and \$3,204) for major coordinated changes and \$9,401 per label (with a range of \$5,125 to \$17,400) for major uncoordinated changes. The cost estimate in 2015 USD is \$13,858 per label (with a range of \$7,038 and \$25,399) for both coordinated and uncoordinated extensive changes.

Based on FDA's Labeling Cost Model, the majority of the label changes required by the proposed rule are considered minor. Minor changes are categorized as alterations that do not require the entire label to be redesigned, e.g., changing a single color or updating the ingredient list. In contrast, a major change requires completely redesigning a label, e.g., changing multiple colors or modifying the front of the package. An extensive change is a major format change requiring a modification to the product packaging to accommodate labeling information. An example of an extensive change is increasing the package surface area.

Over 24 percent of the labels will undergo a major change; 22.8 percent (11,432/50,110) for the dual column and 1.6 percent (805/50,110) for removing a front of package (FOP) health or nutrient claim in response to changes in the DVs, RACCs, or the definition of dietary fiber, Table 3. The estimate of products requiring a dual column label was

determined using IRI scanner data and identifying packaged products containing between 200 to 300 percent of the RACC. From this group, packaged products that required further processing before consuming or that are traditionally eaten in combination with other products, such as raw meat, poultry, and condiments, were excluded as they are exempted from the dual column labeling requirements. Alterations of health and nutrient claims were dependent on updates in Daily Values, RACCs, or the definition of dietary fiber.

Extensive changes are changes for products that may increase their package size to continue to make a health or nutrient content claim in response to the change in definition of a single-serving container. The proposed rule requires products that have RACCs of 100 g or larger and are packaged such that they contain more than 150 percent but less than 200 percent of the RACC to be defined as a single-serving container. Using IRI scanner data, we identified the UPCs with RACCs over 100 g that contain more than 150 percent but less than 200 percent of the RACC and that make a health or nutrient content claim. Based on these criteria, we estimate 13 UPCs may have an extensive change due to increasing the package size to continue to make a health or nutrient content claim. See Table 3 below for details.

TABLE 3—NUMBER OF LABEL CHANGES BY TYPE OF LABEL CHANGES

| Type of change | Description of change | Number of UPCs |
|-----------------|--|----------------|
| Major | Dual Column Label | 11,432 |
| | FOP claim and RACC, Daily Value, or fiber change | 805 |
| Extensive | Over 100 g RACC and FOP claim | 13 |
| Minor | Total Minor Change | 37,860 |

⁶⁰ National Cattlemen's Beef Association, 2010. A Snapshot of Today's Retail Meat Case, 2010 National Meat Case Study Executive Summary. Available here: <http://www.beefretail.org/CMDocs/BeefRetail/research/2010NationalMeatCaseStudy.pdf>.

⁶¹ United States Small Business Administration (SBA), Table of Small Business Standards Matched to North American Industry Classification System Codes. Effective February 26, 2016. Available at https://www.sba.gov/sites/default/files/files/SizeStandards_Table.pdf.

⁶² United States Small Business Administration (SBA), Table of Small Business Standards Matched to North American Industry Classification System Codes. Effective February 26, 2016. Available at https://www.sba.gov/sites/default/files/files/SizeStandards_Table.pdf.

TABLE 3—NUMBER OF LABEL CHANGES BY TYPE OF LABEL CHANGES—Continued

| Type of change | Description of change | Number of UPCs |
|---|-----------------------|-------------------|
| Total Number of NFL under USDA Jurisdiction | | 50,110 |

As shown in Table 4—Label Changes That Can Be Coordinated with a Planned Change, private (store brand) labels change less frequently than branded labels. Allowing a producer to coordinate a required label change with a planned change saves costs associated with recordkeeping, labor, and materials. As such, under a 24 month compliance period for large businesses, changes to all branded labels will be

coordinated with another planned label change. However, for private (store brand) labels only 26 percent will be coordinated with another change, and 74 percent will be uncoordinated. Allowing small businesses 36 months to comply, all branded products can coordinate a change and 57 percent of private labels can coordinate the label changes, Table 4—Label Changes That Can Be Coordinated with a Planned

Change. As a result, the mid-point annualized cost at a 3 percent discount rate over 20 years for updating all of the labels under USDA jurisdiction is estimated to equal \$4,484,734, with an average per label one-time cost of \$1,371, Table 5. The total one-time cost, staggered over the total 36-month compliance period, is \$68,723,156 with a range of \$26,933,776 to \$159,581,369.

TABLE 4—LABEL CHANGES THAT CAN BE COORDINATED WITH A PLANNED CHANGE

| Compliance period (months) | Branded (percent) | Private label (percent) | Weighted average ¹ (percent) |
|-------------------------------|----------------------|----------------------------|---|
| 12 | 11 | 5 | 10 |
| 18 | 37 | 15 | 32 |
| 24 | 100 | 26 | 82 |
| 30 | 100 | 40 | 85 |
| 36 | 100 | 57 | 89 |
| 42 | 100 | 100 | 100 |

¹ Based on IRI data analysis, 25% of FSIS labels are private and 75% are branded.
Source: August 2015, "2014 FDA Labeling Cost Model".

TABLE 5—ALTERNATIVE 2—LABELING COSTS
[24 Month for large, 36 months for small]

| | Small | | Large | | Costs | | |
|--|---------|---------|---------|---------|-------------|--------------|--------------|
| | Private | Branded | Private | Branded | Lower | Mean | Upper |
| Total Number of Labels Coordinated Change: | 6,778 | 20,081 | 5,867 | 17,384 | | | |
| Major | 943 | 4,904 | 373 | 4,245 | \$3,097,640 | \$12,055,680 | \$33,529,860 |
| Minor | 2,919 | 15,172 | 1,153 | 13,134 | 4,565,298 | 18,520,216 | 52,452,360 |
| Uncoordinated Change: | | | | | | | |
| Extensive | 2 | 5 | 1 | 5 | 91,494 | 180,154 | 330,187 |
| Major | 712 | 0 | 1,060 | 0 | 9,081,500 | 16,658,572 | 30,832,800 |
| Minor | 2,202 | 0 | 3,280 | 0 | 10,097,844 | 21,308,534 | 42,436,162 |
| Total Cost | | | | | 26,933,776 | 68,723,156 | 159,581,369 |
| Annualized Cost (3% DR, 20 Year) | | | | | 1,757,644 | 4,484,734 | 10,413,956 |
| Annualized Cost (7% DR, 20 Year) | | | | | 2,376,035 | 6,062,598 | 14,077,899 |
| Average Per label one time cost | | | | | 537 | 1,371 | 3,184.62 |
| Per label Annualized Cost (3% DR, 20 Year) | | | | | 35 | 89 | 208 |
| Per label Annualized Cost (7% DR, 20 Year) | | | | | 47 | 121 | 281 |

Recordkeeping Cost

This proposed rule requires that under certain circumstances manufacturers must maintain additional records to verify the amount of added

sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, and folate/folic acid in products. Thus, if adopted, manufacturers will be required to maintain records sufficient to verify the label declaration for these nutrients.

Examples of appropriate retained records include nutrient database analyses, nutrient database calculation based on recipes or formulations, batch records, or any other information a

manufacturer retains which verify the nutrient content in the final product.

We assume that manufacturers currently have records for added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, and folate/folic acid. However, the proposed changes will require manufacturers to maintain these records and verify as needed. Thus, the recordkeeping cost is the initial time burden for meat and poultry product manufacturers to maintain these records to verify the amount of such nutrients in a food and to make such records available to appropriate regulatory officials upon request. From IRI scanner data, we estimate there are roughly

3,307 manufacturers making products regulated by FSIS. The declaration of Vitamin E and folate/folic acid is not mandatory unless accompanied with a nutrient claim. However, consistent with FDA's Final RIA, FSIS estimates each manufacturer would incur six hours of recordkeeping burden, one hour for each nutrient, resulting in 19,842 recordkeeping hours for the industry as a whole. This estimate is likely an overestimate as not all manufacturers will need to keep records for added sugars, dietary fiber, soluble fiber, vitamin E, and folate/folic acid. According to the Bureau of Labor

Statistics, Occupational Employment and Wages, the median hourly wage of an operations manager is \$46.99⁶³ with a range of \$31.13 to 73.21 at the 25th and 75th percentile. In addition to the base wage, FSIS increased this cost by 100 percent to account for benefits and overhead. Consequently, FSIS assumed a mid-point total hourly compensation rate of \$93.98 (\$46.99 × 2) with a range of \$62.26 (31.13 × 2) to \$146.42 (73.21 × 2). The total recordkeeping costs, discounted over 20 years using a 3 percent discount rate are an estimated \$121,690 with a range of \$80,617 to \$189,592.

TABLE 6—ESTIMATED RECORDKEEPING BURDEN

| Type of declaration | Total annual recordkeeping burden hours | Cost (in 2015 USD) | | |
|---|---|--------------------|-----------|-----------|
| | | Lower | Mid | Upper |
| Added Sugars | 3,307 | \$205,894 | \$310,792 | \$484,211 |
| Dietary Fiber | 3,307 | 205,894 | 310,792 | 484,211 |
| Soluble Fiber | 3,307 | 205,894 | 310,792 | 484,211 |
| Insoluble Fiber | 3,307 | 205,894 | 310,792 | 484,211 |
| Vitamin E | 3,307 | 205,894 | 310,792 | 484,211 |
| Folate/Folic Acid | 3,307 | 205,894 | 310,792 | 484,211 |
| Total | 19,842 | 1,235,363 | 1,864,751 | 2,905,266 |
| Annualized 3%, 20 years | | 80,617 | 121,690 | 189,592 |
| Annualized 7%, 20 years | | 108,981 | 164,504 | 256,296 |
| Median hourly wage for operations manager | | | | 93.98 |
| 25 percentile wage estimate | | | | 62.26 |
| 75 percentile wage estimate | | | | 146.42 |

Reformulation Costs

The proposed rule could motivate food manufacturers to reformulate their products. Food manufacturers may reformulate their products due to the increased visibility of added sugars or to maintain a health or nutrient content claim driven by a change in the Daily Values or RACC and changes in the definition of dietary fiber. We estimate reformulation costs associated with each group in the sections below. Note that we do not anticipate reformulation costs for mandating *trans* fat labeling because *trans* fat in meat and poultry products are usually naturally occurring.

Consistent with FDA, the Agency estimated costs using the 2014 FDA Reformulation Cost Model.⁶⁴ The model accounts for variations in food product complexity, company size, compliance period, reformulation types and activities. Consistent with FDA, the Agency estimated the cost of reformulation for a minor nonfunctional ingredient at all complexity levels, (low,

medium and high) at all company size levels, (small, medium and large). As defined by the reformulation model, small businesses have less than \$1 million in annual sales, medium businesses have between \$1–500 million in annual sales, and large businesses have over \$500 million in sales. The reformulation model estimates all private label brands are medium businesses and branded products are small, medium or large, depending on the type of product or brand.

The compliance period used in our estimate is 24 months for all businesses, as an estimate for a 36-month compliance period for a small business is not available in the model. The model only estimates the cost for small businesses at the 12 or 24-month compliance period and at the 12, 24 or 36 month for large businesses. Therefore, the reformulation cost estimates is an overestimate.

To adjust for inflation in the 2014 Reformulation model, we adjusted the wage rates using the most current (2015) Consumer Price Index for All Urban Consumers and applied a benefits and overhead factor of two to estimate the total cost per formula. The cost per formula ranges from \$4,723 to \$361,371 for a high complexity product, \$2,898 to \$361,371 for a medium complexity product, and \$2,264 to \$338,918 for a low complexity product. The cost varies by the size of company, with large and medium businesses having higher costs per formula than small businesses.

Number of Product Reformulations for Added Sugars Declaration

The proposed rule emphasizes the amount of sugar in a product by requiring a label to declare both the amount of “Total Sugar” and “Added Sugars” with a Daily Reference Value (DRV) for added sugars of 10 percent of calories.⁶⁵ Manufacturers may decide to reformulate products in light of these

⁶³ Bureau of Labor Statistics, Occupational Employment and Wages, May 2015. Mean hourly wage for 11–1021 General and Operations Managers. Accessed May 26, 2016. available at: [http://www.bls.gov/oes/current/oes111021.htm#\(1\)](http://www.bls.gov/oes/current/oes111021.htm#(1)).

⁶⁴ RTI International. “Reformulation Cost Model.” Prepared by Mary K. Muth, Samantha Bradley, Jenna Brophy, Kristen Capogrossi, Michaela Coglahti, Shawn Karns, and Catherine Viator.

Contract No. HHSF–223–2011–10005B, Task Order 20, August 2015.

⁶⁵ 50 grams for children and adults 4 years of age and older and 25 grams for children 1 through 3 years of age.

new requirements. This model uses IRI data to identify those USDA regulated products that exceed the proposed DRV for added sugars. Based on this proposed provision, FSIS regulates roughly 12,080 products where sugar contributes to more than 10 percent of the calories. Reformulation costs are based on the formula counts, not individual product labels. Many of these

products have the same formula. For example, while there is one original Slim Jim formula, there is a plethora of products, e.g., in different sizes. Therefore, the FDA's Reformulation Cost Model was used to determine the number of formulas from the number of products. We found 10,518 formulas associated with these 12,080 products with high sugar content.

FSIS does not estimate that manufacturers would reformulate all 10,518 products because reformulation is voluntary and can be quite expensive. We assume 7.5 to 9 percent (8.25%) of all formulas with high sugar content will reformulate, which is consistent with FDA's assumptions.⁶⁶ Table 7 below summarizes the total formulas that may reformulate for added sugars.

TABLE 7—TOTAL FORMULAS THAT MAY REFORMULATE FOR ADDED SUGARS DECLARATION

| Complexity formulas | Branded (small) | Branded (medium) | Branded (large) | Private (medium) | Total formulas |
|---------------------|-----------------|------------------|-----------------|------------------|----------------|
| High | 93 | 205 | 87 | 213 | 598 |
| Medium | 83 | 86 | 21 | 51 | 241 |
| Low | 7 | 8 | 2 | 12 | 29 |

Number of Product Reformulations to Maintain Health and Nutrient Content Claims

The proposed rule would disqualify some products from bearing a health or nutrient claim as a result of changes in the RACC categories, changes in Daily Values for certain vitamins and minerals, and modifications to the definition of fiber to exclude certain isolated and synthetic fibers from the definition. As a result, manufacturers of these products would either have to remove the claim from the product's label or reformulate in order to continue to make the claim.⁶⁷

To determine the reformulation cost related to RACC changes, the Agency

used IRI scanner data and identified 62 products with new or changing RACC categories with a health or nutrient claim (e.g., "good source of . . .," "low cholesterol," etc.). To determine the reformulation cost of Daily Value (DV) changes, we used IRI scanner data and identified 12 products with claims for the proposed vitamins and mineral DV changes (e.g., "good source of Vitamin C"). For the fiber claims, we refined the IRI scanner data and identified 731 products containing a synthetic or isolated fiber with a fiber claim. As noted above, reformulation costs are by formula counts, not by individual labels. We used FDA's Reformulation Cost Model to determine the number of formulas from the number of products.

This work identified 53 formulas for RACC changes, 11 formulas for DV changes, and 654 formulas for new fiber definition. FSIS assumed that manufacturers will elect to reformulate 50 percent of their products and to remove the claim from the other 50 percent. Therefore, 365 formulas will incur reformulation costs: 30 formulas for RACC, 6 formulas for Daily Value and 329 formulas for fiber. The estimates may vary due to rounding in the business size and complexity categories. See Table 8 below for summary of the formulas that may reformulate due to the new fiber definition, or for changes in the Daily Values or RACC.

TABLE 8—TOTAL FORMULAS THAT MAY REFORMULATE FOR NEW FIBER DEFINITION, DV, OR RACC

| Complexity formulas | Branded (small) | Branded (medium) | Branded (large) | Private (medium) | Total formulas |
|---------------------|-----------------|------------------|-----------------|------------------|----------------|
| High | 56 | 127 | 59 | 103 | 345 |
| Medium | 4 | 6 | 4 | 6 | 20 |

Total Reformulation Cost for Sugars Declaration and To Maintain Health and Nutrient Content Claims

The mean one-time cost for reformulation is \$77,294,020, with an

average per formula one-time cost of \$77,009. The annualized cost at a 3 percent discount rate over 20 years for reformulation is \$6,196,385, with a range of \$2,908,387 to \$10,019,460.

One-time reformulation costs are \$94,952,165 with a range of \$44,567,540 to \$153,536,199. See Table 9 below for a summary of the estimated reformulation cost in 2015 dollars.

TABLE 9—ALTERNATIVE 2—REFORMULATION COST

| | Lower | Mid | Upper |
|--------------------------------|--------------|--------------|---------------|
| High Complexity Formulas | \$36,295,355 | \$77,294,020 | \$124,785,011 |

⁶⁶ Regulatory Impact Analysis for Final Rules on "Food labeling: Revision of the Nutrition and Supplement Facts Labels". Docket No. FDA-2012-N-1210 and "Food Labeling: Serving Sizes of Foods that can Reasonably be consumed at One Eating Occasion: Dual-Column Labeling: Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments" Docket No. FDA-2004-N-0258., page 70, available at:

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM506797.pdf>.

⁶⁷ To illustrate, consider these examples:

1. Reformulate due to DV change—A Beef Tomato Sauce with 12 mgs of vitamin C makes a "High in Vitamin C" claim since it meets the claim requirement of 20 percent or more of the Vitamin C RDI per RACC. By increasing the Vitamin C RDI

from 60 mg to 90 mg, the product can no longer make the claim.

2. Reformulate due to New Fiber definition—A product with mostly synthetic fiber is making an "excellent source of fiber" fiber since certain synthetic and isolated fibers are included in the fiber definition. By removing some synthetic fibers from the fiber definition, the product can no longer make the claim.

TABLE 9—ALTERNATIVE 2—REFORMULATION COST—Continued

| | Lower | Mid | Upper |
|--|------------|------------|-------------|
| Med Complexity Formulas | 7,488,995 | 15,983,483 | 25,998,357 |
| Low Complexity Formulas | 783,190 | 1,674,662 | 2,752,831 |
| Total Cost | 44,567,540 | 94,952,165 | 153,536,199 |
| Annualized Cost (3% DR, 20 Year) | 2,908,387 | 6,196,385 | 10,019,460 |
| Annualized Cost (7% DR, 20 Year) | 3,931,645 | 8,376,460 | 13,544,608 |
| Average Per formula one time cost | 36,146 | 77,009 | 124,522 |
| Per formula Annualized Cost (3% DR, 20 Year) | 2,359 | 5,025 | 8,126 |
| Per formula Annualized Cost (7% DR, 20 Year) | 3,189 | 6,794 | 10,985 |

Quantitative Benefits of the Proposed Rule

By ensuring that recommendations are based on current dietary guidelines and making the most salient information prominent, the proposed rule will benefit the nearly 186 million Americans who frequently or sometimes use nutritional facts and serving size labels. However, this Preliminary Regulatory Impact Analysis (PRIA) limits the quantitative benefits to the medical costs savings for overweight or hypertensive adults who report not using or rarely using Nutrition Facts labels that are expected to experience health benefits with increased label use and modified diet. The annual present value of benefits at a 3 percent discount rate over 20 years is estimated at \$36,894,007. A detailed description of this analysis follows.

As noted in the Need for Rule section above, a significant portion of U.S. citizens are overweight, obese, or hypertensive. Such conditions afflict individuals and society with poorer health and higher medical expenditures. It is well established that improved nutrition reduces overweight, obesity, and hypertension rates, which in turn reduces medical expenses.⁶⁸ Based on the NHANES analysis, using and understanding the Nutrition Facts label is linked to healthier diets. If finalized, this proposed rule will improve nutritional labels by updating and simplifying the information found on them. The frequency of label usage will increase as improved, and simpler to understand information will be

available to the consumer, which will, in turn, promote consumption of healthier diets, e.g., lower caloric or sodium consumption.

In this analysis, quantified benefits are a measure of expected health improvements resulting from increased label-use, causing diet modification for some overweight and hypertensive adults. The benefits analysis can be broken down into a series of steps. The first step is determining the baseline caloric and sodium intake for consumers by label-use. The second step is estimating the number of consumers who could potentially change their behavior from increased label-use because of this rule. The third step is estimating the change in diet from increased label-use. The final step is measuring the medical cost savings benefit using the Dall et al. (2009), Nutrition Impact Model, which links the health benefits and medical cost savings from reductions in caloric and sodium intake. A description of each step in the benefits analysis is given in this section.

Benefits Analysis: Baseline Caloric and Sodium Intake for Consumers by Label-Use

The first step in this analysis is to determine the baseline relationship between caloric and sodium intake with label-use. To determine this relationship, FSIS used NHANES data to correlate use of nutritional and serving size labels with caloric and sodium intake. NHANES is a continuous CDC survey with data released in two-year segments. This analysis included data from the 2009–2010 survey. NHANES collects detailed information through questionnaires, dietary recall, and a physical exam. In the Flexible Consumer Behavior Survey (FCBS) section of NHANES, respondents provided information on how frequently they used nutritional and serving size information found on food labels. Also, respondents who reported rarely or never using labels provided reasons for not doing so.

In the dietary recall component, respondents report everything they ate or drank, and where the food was obtained, for two days (two 24 hour periods). Food obtained from a store or catalog was identified as food at home (FAH). This analysis excluded calories consumed away from home, as these foods typically do not include a Nutrition Facts label. Weights were applied to the dataset to account for the survey design (including oversampling of certain groups), survey non-response, and post stratification so that the population totals represent the U.S. Census civilian non-institutionalized adult population.

The baseline links degree of label use, ranging from always to never, with average caloric, sugar and sodium intake, Table 1—Use of Nutritional Facts Label by Average Daily Caloric, Sodium and Sugar Intake from Food at Home. While data limitations prevent establishing causation between label use and behavior, the two are inversely correlated. Revealed in Table 1—Use of Nutritional Facts Label by Average Daily Caloric, Sodium and Sugar Intake from Food at Home, Nutrition Facts label use has an inverse relationship with total caloric, sugar and sodium intake. Based on this information, this analysis assumes if an average consumer who “never” used the Nutrition Facts label began to rarely read labels, they would reduce their daily caloric intake by 187 kcals. For most overweight or obese individuals, a stable daily reduction of 187 kcals would lead to weight loss and corresponding reductions in medical expenditures.⁶⁹ Like caloric and sodium intake, sugar consumption is greater for

⁶⁸ Campos, A., J. Doxey, and D. Hammond. 2011. Nutrition labels on pre-packaged foods: a systematic review. *Public Health Nutrition*. 14: 1496–1506; Dall, T.M., V.L. Fulgoni III, Y. Zhang, K.J. Reimers, P.T. Packard, and J.D. Astwood. 2009. Potential health benefits and medical cost savings from calorie, sodium, and saturated fat reductions in the American diet. *American Journal of Health Promotion*. 23: 412–422; Mokdad, A.H., J.S. Marks, D.F. Stroup, and J.L. Gerberdin. 2004. Actual causes of death in the U.S., 2000. *American Medical Association*. 291: 1238–1245; and Young, L.R. and M. Nestle. 2002. The contribution of expanding portion sizes to the US obesity epidemic. *American Journal of Public Health*. 83: 717–724.

⁶⁹ Dall et al. 2009—“With the 100-kcal reduction, for example, the number of obese adults would decline by more than 34 million. Many obese adults would move into the overweight category, with a net decrease of overweight adults of close to 37 million . . . The prevalence of chronic conditions associated with excess weight would decline such that national medical expenditures would be approximately \$58 billion lower than current spending levels.”

individuals that use nutrition information less.

Further, we find as nutritional label usage increases, not only is the average caloric intake reduced, but also the portion of calories from sugar is reduced. For consumers that “never” use the Nutrition Facts label, calories from sugar account for 27 percent of their total at home consumption.⁷⁰ In contrast, for consumers that most frequently use the Nutrition Facts label, calories from sugar account for 23 percent of their total at home consumption.⁷¹ Overall, the less an individual uses nutritional information, the more sugar accounts for total caloric intake.

Benefits Analysis: Estimating the Number of Consumers Who Will Potentially Change Their Behavior

This study monetizes the health benefits derived from adults:

- Who report rarely or never reading Nutrition Facts labels;
- Who are overweight or hypertensive;
- Whose reasons for not reading labels will be addressed by the proposed rule;
- Who are expected to change their behavior.

For caloric reduction benefits, we only include overweight individuals who are maintaining or losing weight. This is because the Nutrition Impact Model assumed that all overweight adults are at weight equilibrium and not gaining weight. The overweight and gaining weight adults may not experience weight loss from a small reduction in caloric intake and therefore will not obtain the medical cost savings from weight loss as calculated in the Nutrition Impact Model. The caloric reduction benefits from the model is calculated by a constant reduction in caloric intake below the Estimated Energy Requirement⁷² (EER) (*i.e.* a level of caloric intake below that required to maintain current body weight) for a given weight, age, height and gender and physical activity level (PAL) for

overweight adults. It takes about four years until a new weight equilibrium is reached where the EER equals the new daily caloric intake. Utilizing NHANES dietary recall data, most adults (72.8 percent⁷³) are consuming at or below their EER. Although NHANES dietary recall data is self-reported and individuals, especially overweight or obese individuals, sometimes underreport caloric intake in these types of surveys^{74 75}, the dietary recall component of NHANES is used in reporting for the Dietary Guidelines for Americans and many other official government documents. Also, this finding is consistent with recent reports in which prevalence of obesity and overweight have stabilized and in some population groups have reduced in recent years.^{76 77} Therefore, this analysis measures the benefit of caloric reduction among overweight adult consumers maintaining or losing weight.

NHANES data identified the number of overweight adults who are maintaining or losing weight that never or rarely use labels, Table 8. An overweight adult maintaining or losing weight has a Body Mass Index (BMI) of 25 or over, aged 16 years or older and consumes calories equal to or less than their Estimated Energy Requirement, EER.⁷⁸ Based on NHANES data, 60 percent (9,501,972) of users who never read labels are either overweight or obese. Conversely, 64 percent (21,611,037) of label-users who rarely read labels are overweight or obese, Table 11. To find the number of overweight individuals maintaining or

losing weight, we relied on NHANES data and the Institute of Medicine (IOM) EER calculation. Below are the IOM calculations:

For adult males:

$$\text{EER} = 662 - (9.53 \times \text{age}) + \text{PAL} \times (15.91 \times \text{weight} + 539.6 \times \text{height})$$

For adult females:

$$\text{EER} = 354 - (6.91 \times \text{age}) + \text{PAL} \times (9.36 \times \text{weight} + 726 \times \text{height})$$

For a conservative estimate, the IOM PAL coefficient associated with sedentary activity estimated individuals EER (1.0 for men and women). All other components of the IOM EER calculation (gender, age, weight, height) were derived from NHANES 2009–2010 and calculated using SAS.⁷⁹ The overweight individuals with a kcal intake at or less than their EER are maintaining or losing weight. The analysis found approximately 57.5 percent of these overweight rarely label-users are maintaining or losing weight, while 55.7 percent of overweight never label-users are maintaining or losing weight. In total, there are 12,428,680 rarely label-users and 5,293,397 never label-users that are overweight and maintaining or losing weight, Table 11.

Although the same person can experience health costs savings from both caloric and sodium reduction, it may overestimate benefits if using both the caloric and sodium reduction models. Therefore, to avoid double counting for the sodium reduction benefits, the analysis excluded the population benefiting from caloric reduction, overweight rarely and never label-users maintaining or losing weight. The sodium reduction analysis only includes hypertensive individuals who are normal weight or overweight and gaining weight. An estimated 461,384 and 118,705 normal weight hypertensive adults rarely or never use labels, respectively. In addition, an estimated 563,394 rarely and 551,856 never adult label-users are overweight and gaining weight with hypertension. In total, there are 1,024,778 rarely and 670,561 never hypertensive label-users who are normal weight or overweight and gaining weight, Table 12.

While the proposed changes will help many normal weight, non-hypertensive consumers use labels to maintain healthy diets, this analysis does not quantify these benefits.

Identifying the reasons overweight or hypertensive consumers do not read nutritional and serving size information is another important factor in estimating

⁷⁰ Per Table 1—Use of Nutritional Facts Label by Average Daily Caloric, Sodium and Sugar Intake from Food at Home, consumers that “never” use the Nutrition Facts panel consume 1,741 kcal and 122 grams of sugar from foods at home each day. A gram of sugar = 3.87 calories. ((122mg*3.87)/1,741)

⁷¹ Per Table 1—Use of Nutritional Facts Label by Average Daily Caloric, Sodium and Sugar Intake from Food at Home, consumers that “Always or Most of the Time” use the Nutrition Facts panel consume 1,439 kcal and 85 grams of sugar from foods at home each day. A gram of sugar = 3.87 calories. ((85mg*3.87)/1,439)

⁷² For adult males: $\text{EER} = 662 - (9.53 \times \text{age}) + \text{PAL} \times (15.91 \times \text{weight} + 539.6 \times \text{height})$;

For adult females: $\text{EER} = 354 - (6.91 \times \text{age}) + \text{PAL} \times (9.36 \times \text{weight} + 726 \times \text{height})$.

⁷³ The IOM PAL (1.11 for men and 1.12 for women) associated with low physical activity was utilized in estimating individuals EER. All other components of the IOM EER calculation (gender, age, weight, height) were derived from NHANES 2009–2010.

⁷⁴ Archer E, Hand GA, Blair SN (2013) Correction: Validity of U.S. Nutritional Surveillance: National Health and Nutrition Examination Survey Caloric Energy Intake Data, 1971–2010. PLoS ONE 8(10): <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0076632>.

⁷⁵ Champagne C, et al, (2002) Energy Intake and Energy Expenditure: A controlled Study Comparing Dietitians and Non-dietitians, Journal of the American Dietetic Association, Available at: <http://www.sciencedirect.com/science/article/pii/S0002822302903160>.

⁷⁶ Ogden C.L., Carroll M.D., Kit B.K., Flegal K.M. Prevalence of obesity in the United States, 2009–2010. NCHS data brief, no 82. Hyattsville, MD: National Center for Health Statistics. 2012.

⁷⁷ Flegal K.M., Carroll M.D., Kit B.K., Ogden C.L. Prevalence of Obesity and Trends in the Distribution of Body Mass Index Among U.S. Adults, 1999–2010. JAMA. 2012;307(5):491–497. doi:10.1001/jama.2012.39.

⁷⁸ For adult males: $\text{EER} = 662 - (9.53 \times \text{age}) + \text{PAL} \times (15.91 \times \text{weight} + 539.6 \times \text{height})$;

For adult females: $\text{EER} = 354 - (6.91 \times \text{age}) + \text{PAL} \times (9.36 \times \text{weight} + 726 \times \text{height})$.

⁷⁹ SAS version 9.2 Cary, NC, 2011 <http://www.sas.com/technologies/analytics/statistics/stat/index.html>.

increased label use. NHANES respondents that rarely or never read nutrition information were able to select multiple reasons for not reading labels. Responses provided for not reading labels were mixed, Table 10. Many of the reasons for not reading labels are not addressed by this proposed rule and will not lead to increased label use: *i.e.* “I can’t read English well” or “I usually buy food that I’m used to, so I don’t feel the need to check labels.” The proposed rule is intended to make the most important information more prominent and the entire label quicker to read, reducing the time spent gathering information on the label. As such, only those overweight or hypertensive consumers who exclusively selected a combination of “the print is too small,” “I won’t know what to look for,” and “I don’t have time” reasons for not reading labels were considered in the mid-point

benefits estimate. That group constitutes approximately 10 percent. Of this group, approximately 1 percent exclusively replied “the print is too small,” approximately 2 percent exclusively replied “I won’t know what to look for,” approximately 3 percent exclusively replied “I don’t have time,” and approximately 4 percent gave a combination of these reasons for not using labels, Table 10. Excluded from the mid-point benefits estimate were consumers who reported not using labels because for a variety of reasons, they expressed little to no interest in the information, or because they could not read English. As such, this analysis assumes that only 10 percent of overweight/hypertensive rarely/never users will increase their label use as a mid-point estimate, Table 11 and 12.

For the lower bound estimate, only those overweight or hypertensive

consumers who exclusively gave “the print is too small for me to read” reason for not reading labels were considered (1 percent) as print size is directly changed by the regulation. The lower bound estimate excludes everyone who did not exclusively give “the print is too small for me to read” as a reason for not reading labels, 99 percent of consumers.

For the upper bound estimate, only those overweight or hypertensive consumers who selected one or more of the following reasons for not reading labels were considered: “the print is too small,” “I won’t know what to look for,” and “I don’t have time”. This group constitutes approximately 44 percent. The upper bound estimate includes consumers who gave the three above reasons and does not exclude anyone if they gave other reasons for not using labels.

TABLE 10—REASONS OVERWEIGHT RARELY AND NEVER USERS DO NOT USE LABELS

| Reasons for not reading labels | Total response with overlap ¹ (%) | Exclusive response ² (%) | Exclusive group, no overlap ³ (%) | Total responses from exclusive group w/overlap ⁴ (%) |
|---|--|-------------------------------------|--|---|
| Targeted Population | | | | |
| The print is too small for me to read | 16 | 1 | 10 | 44 |
| I won't know what to look for even if I read the labels | 20 | 2 | | |
| I don't have time | 24 | 3 | | |
| Other | | | | |
| I usually buy foods that I'm used to, so I don't feel that I need to check labels | 53 | 7 | | |
| I buy what I or my family like, I don't care about the labels | 51 | 5 | | |
| I have a good diet so there is no need to check | 12 | 1 | | |
| I'm satisfied with my health so there is no need for me to check | 25 | 2 | | |
| I don't think food labels are important to me | 15 | 2 | | |
| I can't read English well | 8 | 2 | | |
| Other/Refused/Don't know | 14 | 8 | | |

¹ Total Response with Overlap includes the percentage of NHANES respondents who gave this reason for rarely or never using food labels.

² Exclusive Response includes the percentage of respondents who only gave this reason for rarely or never using food labels. The lower-bound estimate is 1% for consumers who exclusively gave “the print is too small for me to read” reason.

³ Exclusive Group No Overlap includes the percentage of NHANES respondents who only gave some combination of 3 reasons that are addressed by the rule: “The Print is too small for me to read,” “I won’t know what to look for even if I read the labels” and or “I don’t have time”. This is the mid-point estimate.

⁴ Total Responses from Exclusive Group with Overlap includes the percentage of NHANES respondents who gave some combination of 3 reasons that are addressed by the rule: “The Print is too small for me to read,” “I won’t know what to look for” and “I don’t have time”. This is the upper-bound estimate.

Source: NHANES. 2013. “Questionnaires, Datasets, and Related Documentation” Centers for Disease Control and Prevention. Accessed on 1/23/2014. http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm.

Increasing label use does not necessarily lead to a change in behavior. Our analysis further refines the benefits analysis by estimating only a portion of the overweight or hypertensive rarely/never label-users increasing their label use will potentially change their diet. This estimate was derived from data in the FDA 2008 Health and Diet Survey. In 2008, FDA asked consumers “In the last two weeks, can you remember an

instance where your decision to buy or use a food product was changed because you read the nutrition label?” and 49 percent of respondents said yes.⁸⁰ As such, this analysis assumes only 49 percent of overweight/hypertensive

⁸⁰ Choiniere, C.J. and A. Lando. 2008. “FDA 2008 Health and Diet Survey—Consumer Behavior Research” Accessed on 5/6/2014. <<http://www.fda.gov/Food/FoodScienceResearch/ConsumerBehaviorResearch/ucm193895.htm>>.

consumers who increase label use will potentially change their behavior, Table 11 and 12. As a mid-point estimate, there are 868,382 overweight users maintaining or losing weight that could potentially increase label use and reduce their caloric intake (1,772,208 * 49%). This estimate ranges from 86,838 (177,221 * 49%) to 3,820,880 (7,797,714 * 49%) for the lower and upper bound, Table 11. As a mid-point estimate, there

are 83,072 hypertensive normal weight or overweight and gaining weight individuals that could potentially increase their label use and reduce their sodium intake (169,534 * 49%). This estimate ranges from 8,307 (16,953 * 49%) to 365,515 (745,949 * 49%) for the lower and upper bound, Table 12.

TABLE 11—CALCULATING THE TARGETED POPULATION FOR CALORIC REDUCTION BENEFITS

| | Rarely | Never | Totals |
|--|------------|------------|------------|
| Start with all users | 33,653,297 | 15,807,324 | 49,460,621 |
| Reduce to only: | | | |
| Overweight Users | 21,611,037 | 9,501,972 | 31,113,009 |
| Overweight users maintaining or losing weight | 12,428,680 | 5,293,397 | 17,722,077 |
| Lower bound population (1% of users) | 124,287 | 52,934 | 177,221 |
| Mid-point population (10% of users) | 1,242,868 | 529,340 | 1,772,208 |
| Upper bound population (44% of users) | 5,468,619 | 2,329,095 | 7,797,714 |
| Lower bound population expected to change behavior (49% of lower bound pop.) | 60,901 | 25,938 | 86,838 |
| Mid-point population expected to change behavior (49% of mid-point pop.) | 609,005 | 259,376 | 868,382 |
| Upper bound population expected to change behavior (49% of upper bound pop.) | 2,679,623 | 1,141,257 | 3,820,880 |

Source: NHANES. 2013. "Questionnaires, Datasets, and Related Documentation" Centers for Disease Control and Prevention. Accessed on 1/23/2014. http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm.

TABLE 12—CALCULATING THE TARGETED POPULATION FOR SODIUM REDUCTION BENEFITS

| | Rarely | Never | Totals |
|--|------------|------------|------------|
| Start with all users | 33,653,297 | 15,807,324 | 49,460,621 |
| Reduce to only hypertensive users: | | | |
| Normal weight | 461,384 | 118,705 | 580,089 |
| Overweight and gaining weight | 563,394 | 551,856 | 1,115,250 |
| Total hypertensive normal weight or overweight and gaining weight | 1,024,778 | 670,561 | 1,695,339 |
| Lower bound population (1% of users) | 10,248 | 6,706 | 16,953 |
| Target Population (10% of users) | 102,478 | 67,056 | 169,534 |
| Upper bound population (44% of users) | 450,902 | 295,047 | 745,949 |
| Lower bound population expected to change behavior (49% of lower bound pop.) | 5,022 | 3,286 | 8,307 |
| Mid-point population expected to change behavior (49% of mid-point pop.) | 50,214 | 32,857 | 83,072 |
| Upper bound population expected to change behavior (49% of upper bound pop.) | 220,942 | 144,573 | 365,515 |

Source: NHANES. 2013. "Questionnaires, Datasets, and Related Documentation" Centers for Disease Control and Prevention. Accessed on 1/23/2014. http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm.

Benefits Analysis: Estimating Changes in Diet

FSIS assumed that the population expected to change its behavior will do so by moderately increasing its label-use from either never to rarely or rarely to sometimes. The expected diet change is the difference in caloric and sodium intake between each user group. Accordingly, the mid-point estimate of 259,376 overweight consumers who never use the Nutrition Facts label could potentially begin to rarely use labels and reduce their daily caloric intake by 187 kcals (1,741 – 1,554). The mid-point estimate of 609,005 overweight consumers who rarely use the Nutrition Facts label could potentially begin to use labels sometimes and reduce their caloric intake by 92 kcal (1,554 – 1,462). The same formula is followed for the normal weight consumers with hypertension resulting in a 87 mg daily sodium reduction for the 32,857 former never label-users and 104 mg reduction for 50,214 former rarely label-users.

Benefits Analysis: Estimate the Economic Benefits of Caloric and Sodium Reduction

To quantify the medical cost savings from reductions in caloric and sodium intake, FSIS used the Nutrition Impact Model developed by Tim Dall et al. (2009). The Nutrition Impact Model estimates the potential health benefits of weight loss by reducing daily caloric intake for overweight adults.

The Nutrition Impact Model also estimates the benefits of sodium reduction in adults with hypertension. The model combines these benefits to estimate national medical costs savings from changes in dietary habits among the general adult population. The model concludes modest to aggressive changes in diet can improve health and reduce annual national medical expenditures by \$60 to \$120 billion.

The Nutrition Impact Model used scientific reports and peer-reviewed literature to quantify the relationships between dietary change, body mass index, and blood pressure (Systolic BP/Diastolic BP) and between these same factors and disease risk. By modeling the reduction in health conditions

associated with long-term improved nutritional intake, the model can measure the potential health conditions averted by reducing daily caloric and sodium intake in the American diet. For example, weight loss can improve or prevent many diseases risks such as cancer and diabetes, resulting in a medical savings. The benefits of caloric reductions in overweight adults is measured by the medical savings of reductions in the following health conditions; arthritis, asthma, cancer, cerebrovascular disease, congestive heart failure, coronary heart disease, diabetes, esophagus/stomach disease, gallbladder disease, gynecological conditions, kidney/urinary disease, other cardiovascular disease, and sleep apnea. The benefits of sodium reductions are measured by the medical savings of reductions in hypertension cases. Some health conditions are jointly attributed to multiple risk factors.

Caloric Reduction Benefits

For caloric reductions benefits, the Nutrition Impact Model begins to calculate the benefits starting in the fourth year of diet as weight loss is more

significant in the first few years then stabilizes in year four with little additional weight loss. As discussed in the Nutrition Impact Model, if the total overweight and obese population (139 million people in 2007) reduced their daily caloric intake by 100 kcal, many obese adults would move into the overweight category while many overweight adults would move into the normal weight category. In turn, the prevalence of chronic health conditions associated with excess weight would be reduced. There would be 1.7 million fewer cases of coronary heart disease and 1.5 million fewer cases of type 2 diabetes in a given year. Overall, a 100 kcal reduction in the diets of all U.S. overweight adults (139 million) will lead to \$58.4 billion in national medical costs savings annually, or \$420 (\$58.4B/139M) per overweight adult after a period of four years. Also, the Nutrition Impact Model concludes that if the overweight and obese population reduced its daily caloric intake by 500-kcal, almost the entire U.S. adult population would stabilize at normal weight levels with national medical savings at \$110.5 billion, or \$795 per overweight person.

As displayed in Table 13, our analysis expects potentially 259,376 overweight adults to reduce their total caloric intake by 187 kcal and 609,005 adults to reduce their total caloric intake by 92 kcal as the mid-point estimate. The Nutrition Impact Model estimates a 92 kcal reduction could potentially result in \$55 billion of annual medical savings after 4 years or \$395.68 (\$55B/139M) dollars per person. For a 187 kcal reduction, the potential annual medical savings is \$84 billion or \$575.54 (\$84B/139M) per person after four years. Table 13 provides details of the distribution of increased label users, associated reductions in calories, and potential savings.

Recognizing that individuals will benefit from both improved FDA and FSIS labels, this analysis took additional steps to distill out benefits specific to FSIS products with Nutrition Facts labeling. First, our analysis scaled down the estimate by only including the average caloric and sodium intake of FSIS products for adults. Using Table 1B—Mean Intake of Energy and Mean Contribution (KCAL) of Various Foods among U.S. Population by Age from the National Cancer Institute,⁸¹ we estimate about 397 of the 2,199 daily calorie

consumption (18.1 percent) from adults are derived from USDA products affected by this rulemaking.⁸² These products include all chicken and chicken mixed dishes, beef and beef mixed dishes, burgers, sausages, franks, bacon and ribs and some pizzas, pasta dishes, and eggs and egg mixed dishes.

In addition, although the analysis only incorporates sodium and caloric intake from food at home, some meat and poultry products are exempt from nutrition labeling, and therefore removed from the benefits analysis. As discussed in the cost section above, we estimate approximately 11.95 percent (30.64% * 39%) of food-at-home meat and poultry products are exempt from nutrition labeling. Therefore, our analysis further scales back the benefits estimate first by removing 81.9 percent for the kcal intake of FDA products and second by removing 11.95 percent for the FSIS products exempt from nutrition labeling. This results in the mid-point annual benefits of \$79,173,871 (496M * (100% – 81.9%) * (100% – 11.95%)) for caloric reduction. The lower bound estimate is \$7,917,474 and upper bound estimate is \$348,365,416, Table 13.

TABLE 13—ANNUAL MEDICAL SAVINGS FROM REDUCING CALORIC INTAKE ^

| User type | Lower bound number of users | Mid-point number of users | Upper bound number of users | Potential savings per person | Lower bound total potential savings | Mid-point total potential savings | Upper bound total potential savings |
|---|-----------------------------|---------------------------|-----------------------------|------------------------------|-------------------------------------|-----------------------------------|-------------------------------------|
| Sometimes | 60,901 | 609,005 | 2,679,623 | \$395.68 | \$24,097,308 | \$240,971,098 | \$1,060,273,229 |
| Rarely | 25,938 | 259,376 | 1,141,257 | 575.54 | 14,928,357 | 149,281,263 | 656,839,054 |
| Annual benefits after 4 years (\$ 2007) | | | | | 39,025,665 | 390,252,361 | 1,717,112,283 |
| Annual benefits after 4 years (\$ 2015) * | | | | | 49,679,672 | 496,791,256 | 2,185,883,936 |
| Benefits from USDA products (\$ 2015) | | | | | 7,917,474 | 79,173,871 | 348,365,416 |

^ It is expected to take 4 years for the medical benefits from a reduction in calories to be experienced.

* CPI-U for Medical Care of 1.273% was used to adjust for inflation (2007–2015).

Sodium Reduction Benefits

While the benefits of caloric reduction weight-loss are measured at year four in the Nutrition Impact Model, sodium reduction benefits are experienced right away. In most individuals, blood pressure is reduced within days to weeks of reducing sodium intake.⁸³ Therefore, the potential benefits are estimated in the first year for increased label use for adults with hypertension. The Nutrition Impact Model estimates 1.5 million fewer cases of hypertension with a potential annual savings of \$2.3

billion if adults with hypertension reduced their daily sodium intake by 400 mg.

As displayed in Table 14, our mid-point estimate expects 32,857 adults with hypertension to reduce their sodium intake by 87 mg for food at home, and 50,214 adults with hypertension to reduce their sodium intake by 104 mg for food at home. The Nutrition Impact Model estimates a 104 mg daily sodium reduction for all adults with hypertension results in \$1.17B dollars of annual medical savings, or

\$27.86 (\$1.17B/42M) dollars per person. For an 87 mg daily sodium reduction for all adults with hypertension, the potential annual medical savings are \$1.11B, or \$26.43 (\$1.11B/42M) per person.

As calculated with the caloric benefits, our analysis scaled down the estimate for sodium reduction benefits by only incorporating the average sodium intake of FSIS products with labeling for adults. Using Table 1B—Mean Intake of Sodium, Mean Intake of Energy, and Mean Sodium Contribution

⁸¹ Sources of Energy among the U.S. Population, 2005–06. Applied Research Program Web site. National Cancer Institute. <http://appliedresearch.cancer.gov/diet/foodsources/energy/>. Table 1B. Updated April 11, 2014. Accessed June 21, 2014.

⁸² FDA estimated 353 of 2,157 calories (16.4 percent) an average American consumes daily come

from USDA products in FDAs Nutrition Facts/ Serving Sizes Combined PRIA. This differs from our estimate by age, group and food product category. FDA used the average kcal intake for all age groups, including children (2,157) and our estimate used the average kcal for adults age 19 plus (2,199). Also, we assumed half of pizzas and pasta dishes were USDA products and FDA did not. FDA included

cold cuts, which was not included in the 30 most common food groups in adult diets.

⁸³ He F.J., Li J., and G.A. MacGregor. 2013. Effect of longer-term modest salt reduction on blood pressure. Cochrane Database of Systematic Reviews. Issue 4. Art. No.: CD004937. DOI: 10.1002/14651858.CD004937. pub2.

(mg) of Various Foods Among US Population, by Age, NHANES 2005–06,⁸⁴ we estimate about 965 of the 3,535 daily sodium consumption (27.3% percent) from adults are derived from USDA products. These products include all chicken and chicken mixed dishes, beef and beef mixed dishes, burgers, cold cuts, sausages, franks, bacon and

ribs and some pizzas, pasta dishes, and eggs and egg mixed dishes.

In addition, as discussed in the caloric reduction benefits section above, we scaled back the potential benefits by 11.95 percent for the food-at-home FSIS products that are exempt from nutrition labeling. Overall, our benefits estimate scales back the benefits by removing 72.7 percent for the sodium intake of

FDA products and removing 11.95 percent for the FSIS products exempt from nutrition labeling, resulting in the mid-point annual benefits estimate of \$693,815 ($\$2.9M \times (100\% - 72.7\%) \times (100\% - 11.95\%)$) for sodium reduction. The lower bound estimate is \$69,389 and upper bound estimate is \$3,052,804, Table 14.

TABLE 14—ANNUAL MEDICAL SAVINGS FROM REDUCING SODIUM INTAKE ^

| User type | Lower bound number of users | Mid-point number of users | Upper bound number of users | Potential savings per person | Lower bound total potential savings | Mid-point total potential savings | Upper bound total potential savings |
|---|-----------------------------|---------------------------|-----------------------------|------------------------------|-------------------------------------|-----------------------------------|-------------------------------------|
| Sometimes | 5,022 | 50,214 | 220,942 | \$27.86 | \$139,913 | \$1,398,962 | \$6,155,444 |
| Rarely | 3,286 | 32,857 | 144,573 | 26.43 | 86,849 | 868,411 | 3,821,064 |
| Annual benefits after 4 years (\$ 2007) | | | | | 226,762 | 2,267,373 | 9,976,508 |
| Annual benefits after 4 years (\$ 2015) * | | | | | 288,668 | 2,886,366 | 12,700,095 |
| Benefits from USDA products (\$ 2015) | | | | | 69,389 | 693,815 | 3,052,804 |

^ It is expected to take 4 years for the medical benefits from a reduction in calories to be experienced.

* CPI-U for Medical Care of 1.273% was used to adjust for inflation (2007–2015).

Summary of Potential Benefits Over 20 Years With a 24 Month Compliance Period for Large and 36 Month Compliance Period for Small Businesses

The welfare gains from caloric and sodium reduction estimated above reflect the full annual potential impact of the regulation without adjusting for the potential lag between reaching a particular weight and experiencing the associated health outcomes and medical cost savings. However, industry would need time to modify labels under the new regulations. Table 15 uses the FDA Cost Label model⁸⁵ to estimate the frequency of label changes in twelve-month increments. As shown in Table 4—Label Changes That Can Be Coordinated with a Planned Change, only 10 percent of all labels will be updated by the end of the first year and 82 percent by the end of the second year. After 24 months, all large manufacturers are in compliance and 82 percent of small businesses are in compliance. Based on IRI scanner data and SBA small business standards, 53.6 percent of FSIS labels are from small businesses and 46.4 percent are from Large. Therefore, after 24 months, 90.35 percent of FSIS's Nutrition Facts labels are updated ($(100\% \text{ of Large} \times 46.4\% \text{ of labels}) + (82\% \text{ of Small} \times 53.6\% \text{ of Labels})$). After 36 months, 100 percent of FSIS's nutrition facts labels are updated.

To arrive at the present value estimate of potential benefits, FSIS multiplied the percentage of label changes in each 12 month period by the annual potential benefits estimate. The percentage of label changes estimates the percentage of updated labels at a given time: 10 percent after 12 months, 90.35 percent after 24 months, and 100 percent after 36 or more months. Again, the Nutrition Impact Model estimates benefits immediately for reductions in sodium intake and at year four for reductions in caloric intake. Therefore, benefits for caloric reduction start four years after the labels update while benefits for sodium reduction are realized as the labels are updated. For example, as is shown in Table 4—Label Changes That Can Be Coordinated with a Planned Change, 12 months after publication of the final rule, an estimated 10 percent of FSIS labels are changed, resulting in 10 percent of the annual sodium benefits and no quantified benefits for the caloric intake reductions. After 24 months, 90.35 percent of Nutrition Facts labels are updated, resulting in 90.35 percent of the annual sodium benefits and no quantified benefits for the caloric intake reductions. The benefits in year 6 are a product of 100 percent of the sodium reduction benefits and 10 percent of the caloric reduction benefits as four years have passed since 10 percent of the labels were updated. Not

until year seven are the full annual sodium and caloric reduction mid-point benefits without latency applied.

FSIS could not determine the weight-level-to-health outcome latency for each health condition included in the Nutrition Impact Model. But, to try and account for this latency, FSIS assumed a uniform health impacts time pattern between present age and age 80 and a uniform age distribution between age 18 and 79 to determine weighting factors that could be applied to the benefits estimates from the Nutrition Impact Model to calculate the present and annualized benefits. FSIS multiplied average weighting factors of 0.665 (3 percent discount rate) and 0.458 (7 percent discount rate) by the present value annual benefit from caloric and sodium reduction to estimate the total annual health impact for each year. FSIS is requesting comment on accounting for latency between weight change and health outcomes.

The mid-point present value, discounted at 3 percent rate is \$549 million and \$239 million with a 7 percent discount rate. The mid-point annual benefit is \$37 million at a 3 percent discount rate and \$23 million at 7 percent. The lower bound estimate is \$3,689,445 and upper bound estimate is \$162,333,818 at a 3 percent discount rate, Table 15.

⁸⁴ Sources of Energy among the U.S. Population, 2005–06. Applied Research Program Web site. National Cancer Institute. <http://appliedresearch.cancer.gov/diet/foodsources/>

energy/. Table 1B. Updated April 11, 2014. Accessed June 21, 2014.

⁸⁵ RTI International. "2014 FDA Labeling Cost Model." Prepared by Mary K. Muth, Samantha

Bradley, Jenna Brophy, Kristen Capogrossi, Michaela C. Coglaiti, and Shawn A. Karns. Contract No. HHSF-223-2011-10005B, Task Order 20, August 2015.

TABLE 15—PRESENT VALUE OF BENEFITS OVER 20 YEARS GIVEN A 24 MONTH COMPLIANCE PERIOD FOR LARGE AND 36 MONTH COMPLIANCE PERIOD FOR SMALL BUSINESSES

| Year | Lower bound benefits from caloric and sodium reduction | Mid-point benefits from caloric and sodium reductions | Upper bound benefits from caloric and sodium reduction |
|--------------------|--|---|--|
| NPV 3% | \$54,889,631 | \$548,889,659 | \$2,415,117,294 |
| NPV 7% | 23,880,540 | 238,802,476 | 1,050,732,115 |
| Annual PV 3% | 3,689,445 | 36,894,007 | 162,333,818 |
| Annual PV 7% | 2,254,154 | 22,541,264 | 99,181,679 |

Uncertainty in the Quantitative Benefits Analysis

The ramifications of the proposed rule are not expected to have a significant impact on the food market. As a mid-point estimate, we estimate potentially 609,005 adults would potentially reduce their caloric intake by 92 kcals, and 259,376 adults will potentially reduce their caloric intake by 187 kcals for FDA and FSIS regulated products. Additionally, as a mid-point estimate, we estimate potentially 50,214 adults would potentially reduce their sodium intake by 104 mg and 32,857 adults would potentially reduce sodium intake by 87 mg for FDA and FSIS regulated products. Only a small portion of the caloric and sodium intake are from meat or poultry products as only 18 percent of all caloric intake is from FSIS products. Further still, this small change in diet may lead to increased consumption of lower calorie or lower sodium products, including food products reformulated in response to the changes on the label. Therefore, we estimate the market impact will distribute across all food markets with minimal impact on meat and poultry markets. The benefits analysis for the proposed rule may underestimate the full consumer welfare gain for several reasons. This analysis only includes the potential medical savings for the overweight and hypertension population that sparsely uses labels. The analysis does not account for benefits in diet modifications for children under the age of 16 or most people of normal weight. Though, we can expect the diet behavior of adults to transfer to their children under the age of 16. Normal weight consumers and consumers currently using labels when buying food may modify their diet and benefit from the new content and design on the Nutrition Facts label. The analysis only includes benefits from caloric and sodium reductions leading to averted health conditions associated with hypertension, overweight and obesity. Many major health conditions are associated with obesity; therefore the medical savings benefit for calorie

reduction weight-loss is substantial in overweight and obese individuals. However, other modifications to the label, such as updates to RACCs and Daily Values for added sugars, nutrients and minerals, may help consumers adjust their diet and improve their personal welfare. Modifications such as the dual column labels will simplify the calculation for total nutrients in an entire package, which may contribute to a healthful diet. Additionally, health benefits from caloric reduction do occur before four years, and health benefits may continue to increase over time; however the Nutrition Impact Model begins to calculate the benefits from caloric reductions starting at year four. FSIS has no means to quantify these benefits. Further, there may be indirect benefits to reducing caloric and sodium intake through improved lifestyle, wages, or productivity that are not measured in this benefits estimate. Therefore, the resulting potential benefits estimate should be interpreted as an underestimate of overall benefits.

However, data supporting the benefits analysis is from national consumer surveys where results are on self-reported behavior changes, which could potentially overstate actual results. In addition, the consumers in our quantitative benefits estimate may lose utility associated with consuming products high in sugar, calories and sodium.⁸⁶ Furthermore, as noted earlier in the analysis, the available estimates of the relationship between label use and calorie and sodium intake generally establish only correlation, but the way they are used to develop benefits estimates reflects an assumption of causation. Therefore, in some instances, the analysis may overestimate the welfare gains.

⁸⁶ Ashley, Elizabeth M., Clark Nardinelli and Rosemarie A. Lavaty. "Estimating the Benefits of Public Health Policies that Reduce Harmful Consumption." *Health Economics* 24(5): 617–624. May 2015. <http://onlinelibrary.wiley.com/doi/10.1002/hec.3040/full>.

Qualitative Benefits

FSIS believes there are several additional benefits associated with the proposed changes which are hard to quantify. To start, the millions of normal weight not hypertensive users who currently use nutritional information will benefit from the clearer label format. Additionally, the proposed changes would harmonize the labels between FDA and USDA products, reducing producer administration costs. Further still, the proposed changes could potentially simplify the communication of hard to distinguish, but sought after, product attributes benefiting both producers and consumers.

The mandatory declaration of *trans* fat, added sugars, vitamin D and potassium and other changes on the Nutrition Facts label will assist consumers in making informed choices and maintaining healthy dietary practices. Consumers can better determine which products are suitable for their personal preference and dietary needs. The more up-to-date information included on the Nutrition Facts label better reflects the current recommendations for American diets, allowing consumers to make informed decisions leading to an increase in consumer welfare.

Small businesses will benefit from the additional 12-month compliance period. Allowing small businesses additional time to comply reduces costs of relabeling, reformulation and recordkeeping and allows additional time to understand and implement the proposed regulations.

Also, the Agency believes that the public would be better served by having the regulations governing nutrition labeling consolidated in one part of title 9. Rather than searching through two separate parts of title 9—317 and 381—to find the nutrition labeling regulations, interested parties would only have to survey one, 9 CFR part 413, to be able to apply nutrition panels to their meat and poultry products.

Alternative Regulatory Approaches

Four alternatives, Table 16, are considered for the proposed serving size and Nutrition Facts label proposed rule.

- Alternative 1: Take no regulatory action by continuing with the existing labeling requirements.

- Alternative 2: The proposed rule, giving large manufacturers a 24-month compliance period and small manufacturers 36-months.

- Alternative 3: The proposed rule, giving manufacturers a 42-month compliance period.

- Alternative 4: The proposed rule, giving all manufacturers 24-months to comply.

- Alternative 5: The proposed rule, giving large manufacturers a 12-month compliance period and small manufactures 24-months.

TABLE 16—COMPARISON OF THE CONSIDERED ALTERNATIVES

| Considered Alternative | Benefits ¹ | Costs ¹ | Net benefits ¹ |
|---|---|--|---|
| 1—Take No Action. | Zero | Zero | Zero. |
| 2—The Proposed Rule—24-month compliance large, 36-month compliance small. | About 1 million consumers would increase their label use, leading to roughly \$36.9 million in health benefits. Small businesses benefit from the additional compliance time. | Costs equal \$10.8 million. Relabeling FSIS products will be coordinated and uncoordinated and is estimated to cost industry \$4.5 million. Recordkeeping costs are estimated at \$121,690. Reformulation is expected to cost industry \$6.2 million. | In addition to the \$26.1 million in net benefits, the proposed rule would harmonize USDA and FDA labels and give small businesses additional compliance time. |
| 3—42-month Compliance Period. | The extended compliance period delays the speed at which an estimated 1 million consumers would increase their label use. This delay reduces health benefits to \$36.4 million. | Costs equal \$7.8 million. The extended compliance period reduces labeling costs to \$2.3 million by allowing all coordinated changes. Recordkeeping costs remain at \$121,690. Reformulation costs are expected to cost \$5.3 million. Consumers and producers would incur costs because FSIS and FDA labels would be inconsistent. | Net benefits are \$28.6 million. In comparison to alternative 2, benefits are reduced 1.4 percent, and costs are reduced 27.9 percent. However, alternative 3's compliance period is longer than alternative 2's, delaying benefits. |
| 4—24-month Compliance Period. | About 1 million consumers would increase their label use leading to roughly \$37.2 million in health benefits. | Costs equal to \$11.4 million. Small businesses do not have additional time to comply, increasing labeling costs to \$5.1 million for the additional uncoordinated changes. In addition, reformulation is expected to increase to \$6.2 million. Recordkeeping costs remain at \$121,690. Consumers and producers would incur costs because FSIS and FDA labels would be inconsistent. | Net benefits are \$25.8 million, 1 percent lower than alternative 2's. While benefits are \$288,829 higher than alternative 2's, costs are \$619,687 higher. The increase in benefits may be reduced due to confusion between inconsistent FSIS and FDA labels. |
| 5—12-month compliance large, 24-month compliance small. | Updates to the labels for FDA and FSIS products have the same compliance date. About 1 million consumers would increase their label use leading to roughly \$38.5 million in health benefits. | Costs equal to \$17.4 million, the highest of all alternatives. Labeling costs increase to \$8.5 million for the coordinated and uncoordinated changes. Recordkeeping costs remain at \$121,690. Reformulation costs are expected to cost \$8.8 million. In addition, both consumers and producers would incur costs because USDA and FDA labels would be inconsistent. | Net benefits are \$21.1 million, almost 20 percent lower than alternative 2's. While benefits are 4 percent higher than alternative 2's, costs are 61 percent higher. Qualitative benefits are consistency between FSIS and FDA labels. |

¹ All quantified benefits and costs are annualized at 3 percent over 20 years.

Alternative 1—Take No Regulatory Action by Continuing With the Existing Labeling

Both producers and consumers will be worse off absent the proposed action. While “no action” means the 3,307 manufacturers with roughly 50,000 products under USDA jurisdiction would continue to be regulated in the same manner as they currently are, the market will be impacted in several costly ways.

First, no action would create inconsistencies between USDA and FDA labels. As such, the manufacturers that produce products regulated by both USDA and FDA will have to operate

under two differentiated procedures, *e.g.*, maintaining multiple label formats, recording different product attributes, and utilizing differing RACCs for products with similar uses. This would increase administration costs for producers and make label use more difficult for consumers, decreasing their benefit.⁸⁷

Second, if the USDA were to take “no action,” the Agency would fail to

⁸⁷ Bialkova, S. and H. Trijp. 2010. What determines consumer attention to nutrition labels? Food Quality and Preference. 21 1042–1051 and Campos, A., J. Doxey, and D. Hammond. 2011. Nutrition labels on pre-packaged foods: a systematic review. Public Health Nutrition. 14: 1496–1506. Bialkova and Trijp, 2010 and Campos et al., 2011.

address the health problems related to diet by making it more difficult for consumers to heed dietary guidelines. Third, the “no action” would fail to make any improvements to address the problems that prohibit millions of consumers from using labels: The print being too small, not knowing what to look for, or not having enough time. The targeted population of nearly 32 million overweight or hypertensive adults, whom rarely or never use the Nutrition Facts label, would continue to not read the labels and continue with high sodium or calorie diets. In combination, these impacts would hinder producers vying to compete based on hard to

distinguish health and nutritional attributes, reducing market competition, and would do nothing to address the nation's overweight and obesity epidemic.

Alternative 2—The Proposed Rule, Giving Large Manufacturers a 24-Month Compliance Period and Small Manufacturers 36-Months

Alternative 2, the proposed rule, addresses many of the current nutritional and serving size labels' short comings by applying the changes proposed in the preamble with a 24-month compliance period for large and 36-month for small, consistent with FDA's compliance period. While industry will incur costs associated with relabeling, recordkeeping, and reformulation, consumers will benefit from an increase in information which may lead to improved health. The estimated net benefits are \$26.1 million. The proposed costs and benefits associated with this alternative are detailed in Expected Costs of the Proposed Rule and Quantitative Benefits of the Proposed Rule sections of this PRIA.

Alternative 3—The Proposed Rule, Giving Manufacturers a 42 Month Compliance Period

Alternative 3 would apply the changes detailed in the preamble but extends the compliance period to 42 months. Compared to alternative 2, this alternative reduces costs while holding benefits nearly constant. As shown in Table 4—Label Changes That Can Be Coordinated with a Planned Change, a 42-month compliance period would provide industry sufficient time to coordinate all required label changes, subsequently reducing annualized relabeling costs by about \$2.1 million, as compared to alternative 2. Recordkeeping costs would remain the same as alternative 2 and annualized reformulation costs would be reduced by about \$1 million.

Health benefits would be delayed by extending the compliance period. Annual benefits at a 3 percent discount rate under alternative 3 are estimated to be \$36.4 million, which is roughly \$500,000 less than alternative 2's estimated annual benefits. However, a 42-month compliance period would result in delayed label updates, and extend inconsistencies between USDA and FDA labels for an additional 18 months compared to alternative 2.

Also, extending the compliance period would require a further exception to current uniform compliance guidelines⁸⁸ set by the Agency. Consistent with FDA's uniform compliance dates for food labels, USDA sets uniform compliance dates in 2-year increments to enhance the industry's ability to make orderly adjustments to new labeling requirements without unduly exposing consumers to outdated labels. Further, cost estimates may be understated as producers who market FDA-regulated and FSIS related products may voluntarily adopt the FDA timetable and not use the additional compliance period allotted.

Relabeling Costs

Alternative 3 applies FDA's 2014 Labeling Cost Model to estimate the cost of relabeling roughly 50,000 food labels under a 42-month compliance period. In this scenario both branded and private (store brand) label changes can be coordinated, reducing the average one time per label cost from \$1,371 to \$717, Table 17. In sum, extending the compliance period reduces the average annualized relabeling costs to \$2.3 million, assuming a 3 percent discount rate over 20 years.

TABLE 17—ALTERNATIVE 3—LABELING COSTS
[42 Month]

| | Private | Branded | Costs | | |
|--|---------|---------|-------------|--------------|--------------|
| | | | Lower | Mid | Upper |
| Total Number of Labels | 12,645 | 37,465 | | | |
| Coordinated Change: | | | | | |
| Major | 3,088 | 9,149 | \$3,622,152 | \$14,097,024 | \$39,207,348 |
| Minor | 9,554 | 28,306 | 5,338,260 | 21,655,920 | 61,333,200 |
| Uncoordinated Change: | | | | | |
| Extensive | 3 | 10 | 91,494 | 180,154 | 330,187 |
| Total Cost | | | 9,051,906 | 35,933,098 | 100,870,735 |
| Annualized Cost (3% DR, 20 Year) | | | 590,709 | 2,344,921 | 6,582,619 |
| Annualized Cost (7% DR, 20 Year) | | | 798,538 | 3,169,935 | 8,898,583 |
| Average Per label one time cost | | | 181 | 717 | 2,013 |
| Per label Annualized Cost (3% DR, 20 Year) | | | 12 | 47 | 131 |
| Per label Annualized Cost (7% DR, 20 Year) | | | 16 | 63 | 178 |

Recordkeeping Costs

Alternative 3 does not alter the recordkeeping requirements as presented in the Expected Cost section above. As such, we assume the recordkeeping costs associated under

alternative 3 are equal to those under alternative 2.

Reformulation Costs

Extending the compliance period reduces the cost for product reformulation. However, the longest

compliance period covered in the 2014 Reformulation Cost Model is 36 months for large and 24 months for small businesses. As such, the reformulation costs associated with alternative 3 are based on a 24 month compliance period for small and 36 month compliance

⁸⁸ Uniform Compliance Date for Food Labeling Regulations, 79 FR 71007 (2014). Depending on the Alternative 2 final publication date, Alternative 2 may not deviate from the uniform compliance date,

except for small businesses as they have an additional 12 months to comply.

period for large. Therefore, the reformulation costs are under estimated for this alternative.

TABLE 18—ALTERNATIVE 3—REFORMULATION COST
[42 months]

| | Lower | Mid | Upper |
|--|--------------|--------------|---------------|
| High | \$30,918,175 | \$65,967,997 | \$107,198,289 |
| Med | 6,568,245 | 14,044,083 | 22,986,932 |
| Low | 714,402 | 1,529,728 | 2,526,885 |
| Total Cost | 38,200,822 | 81,541,808 | 132,712,106 |
| Annualized Cost (3% DR, 20 Year) | 2,492,908 | 5,321,253 | 8,660,522 |
| Annualized Cost (7% DR, 20 Year) | 3,369,988 | 7,193,430 | 11,707,555 |
| Average Per formula one time cost | 30,982 | 66,133 | 107,634 |
| Per formula Annualized Cost (3% DR, 10 Year) | 2,022 | 4,316 | 7,024 |
| Per formula Annualized Cost (7% DR, 10 Year) | 2,733 | 5,834 | 9,495 |

Quantitative Benefits

Again, the present value of health benefits was derived by multiplying the percentage of label changes in each 12 month period by annual health benefits. The prolonged compliance period

reduces the rate labels are updated, which in turn reduces the rate at which consumers are exposed to updated labels and overall benefits. As is shown on Table 19, the expected difference in annual health benefits between alternative 2 and alternative 3 is about

\$0.5 million. Alternative 3 has the benefit of saving roughly \$3 million annually from reductions in labeling and reformulation costs, \$2.1 million of which is derived from reductions in labeling costs.

TABLE 19—COMPARISON OF ALTERNATIVES 2 AND 3

| | Alternative 2 | | | Alternative 3 | | |
|---------------------|---------------|--------------------|--------------|---------------|--------------------|--------------|
| | Benefits | Costs ¹ | Net benefits | Benefits | Costs ¹ | Net benefits |
| Annual PV2 3% | \$36,894,007 | \$10,802,809 | \$26,091,198 | \$36,382,559 | \$7,787,864 | \$28,594,695 |
| Annual PV 7% | 22,541,264 | 14,603,562 | 7,937,702 | 22,154,586 | 10,527,869 | 11,626,717 |

¹ Costs include relabeling, recordkeeping, and reformulation costs.

² Present Value (PV) is the current worth of a future sum of money or stream of cash flows given a specified rate of return.

Qualitative Benefits

Alternative 3 is expected to have the same type of qualitative benefits as alternative 2, but their realization is delayed. Labels would not be harmonized as soon as alternative 2, resulting in confusion between USDA and FDA labels. Producers who market FDA-regulated products also may voluntarily adopt the FDA timetable and update their labels prior to the 42-month compliance period.

Alternative 4—The Proposed Rule, Giving All Manufacturers 24 Months To Comply

Under this alternative, all manufacturers are given a 24 month compliance period. This alternative does not give small businesses additional time to comply and is inconsistent with FDA's compliance period.

Relabeling Costs

Under alternative 4, small and large businesses are given 24 months to comply with the proposed changes. Under a 24-month compliance period, all branded labels and 26 percent of private labels will incur a coordinated label change while 74 percent of private labels will incur an uncoordinated label change, Table 20.

TABLE 20—ALTERNATIVE 4—LABELING COSTS
[24 Month compliance period]

| | Private | Branded | Costs | | |
|--|---------|---------|-------------|--------------|--------------|
| | | | Lower | Mean | Upper |
| Total Number of Labels | 12,645 | 37,465 | | | |
| Coordinated Change: | | | | | |
| Major | 803 | 9,149 | \$2,945,792 | \$11,464,704 | \$31,886,208 |
| Minor | 2,484 | 28,306 | 4,341,390 | 17,611,880 | 49,879,800 |
| Uncoordinated Change: | | | | | |
| Major | 2,285 | | 11,710,625 | 21,481,285 | 39,759,000 |
| Minor | 7,070 | | 13,022,940 | 27,481,090 | 54,728,870 |
| Extensive | 3 | 10 | 91,494 | 180,154 | 330,187 |
| Total Cost | | | 32,112,241 | 78,219,113 | 176,584,065 |
| Annualized Cost (3% DR, 20 Year) | | | 2,095,580 | 5,104,420 | 11,523,517 |
| Annualized Cost (7% DR, 20 Year) | | | 2,832,868 | 6,900,309 | 15,577,838 |

TABLE 20—ALTERNATIVE 4—LABELING COSTS—Continued
[24 Month compliance period]

| | Private | Branded | Costs | | |
|--|---------|---------|-------|-------|----------|
| | | | Lower | Mean | Upper |
| Average Per label one time cost | | | 641 | 1,561 | 3,524.00 |
| Per label Annualized Cost (3% DR, 20 Year) | | | 42 | 102 | 230 |
| Per label Annualized Cost (7% DR, 20 Year) | | | 57 | 138 | 311 |

Recordkeeping Costs

Compared to alternative 2, alternative 4 does not alter the recordkeeping requirements. As such, we assume the recordkeeping costs associated under alternative 4 are equal to those under alternative 2.

Reformulation Costs

Reducing the compliance period for small businesses increases the cost for product reformulation. However, the longest compliance period covered in the 2014 Reformulation Cost Model for small businesses is 24 months. Therefore, the reformulation cost for alternative 2 and alternative 3 are both

estimated on a 24 month compliance period for both large and small businesses. Alternative 2 overestimated reformulation cost since this alternative is based on a 24 month compliance period for large and 36 months for small businesses and alternative 4 reformulation cost is most accurate given the compliance period is 24 months for large and small businesses.

TABLE 9—ALTERNATIVE 2—REFORMULATION COST

| | Lower | Mid | Upper |
|--|--------------|--------------|---------------|
| High Complexity Formulas | \$36,295,355 | \$77,294,020 | \$124,785,011 |
| Med Complexity Formulas | 7,488,995 | 15,983,483 | 25,998,357 |
| Low Complexity Formulas | 783,190 | 1,674,662 | 2,752,831 |
| Total Cost | 4,567,540 | 94,952,165 | 153,536,199 |
| Annualized Cost (3% DR, 20 Year) | 2,908,387 | 6,196,385 | 10,019,460 |
| Annualized Cost (7% DR, 20 Year) | 3,931,645 | 8,376,460 | 13,544,608 |
| Average Per formula one time cost | 36,146 | 77,009 | 124,522 |
| Per formula Annualized Cost (3% DR, 20 Year) | 2,359 | 5,025 | 8,126 |
| Per formula Annualized Cost (7% DR, 20 Year) | 3,189 | 6,794 | 10,985 |

Quantitative Benefits

The reduced compliance period increases the rate labels are updated, which in turn increases the rate at which consumers are exposed to updated labels, resulting in earlier and

higher consumer welfare benefits. Again, the present value of health benefits was calculated by multiplying the percentage of label changes in each 12 month period by annual health benefits. As is shown in Table 22, the expected difference in annual health

benefits between alternative 2 and alternative 4 is about \$288,829. Alternative 4 increases the annual labeling cost by over \$0.6 million annually. Overall, the net benefit decreases by \$330,858 under alternative 4.

TABLE 22—COMPARISON OF ALTERNATIVES 2 AND 4

| | Alternative 2 | | | Alternative 4 | | |
|---------------------------------|---------------|--------------------|--------------|---------------|--------------------|--------------|
| | Benefits | Costs ¹ | Net Benefits | Benefits | Costs ¹ | Net Benefits |
| Annual PV ² 3% | \$36,894,007 | \$10,802,809 | \$26,091,198 | \$37,182,836 | \$11,422,496 | \$25,760,340 |
| Annual PV 7% | 22,541,264 | 14,603,562 | 7,937,702 | 22,763,888 | 15,441,274 | 7,322,614 |

¹ Costs include relabeling, recordkeeping, and reformulation costs.

² Present Value (PV) is the current worth of a future sum of money or stream of cash flows given a specified rate of return.

Qualitative Benefits

Alternative 4 may benefit consumers from the potential reformulation of products to reduce added sugars. Also, alternative 4 would still benefit the public by consolidating nutrition labeling regulations to one location; however, it would result in inconsistencies between products regulated by either the FDA or USDA. These inconsistencies would likely

increase confusion amongst both producers and consumers, reducing overall benefits.

Alternative 5—The Proposed Rule, Giving Large Manufacturers 12-Month Compliance Period and Small 24-Month Compliance

Alternative 5 more closely aligns the compliance date with FDA labels. Sharing the same compliance date with FDA products allows for harmonized

labels across agencies. However, FSIS labels will have a shorter time to comply than FDA by sharing the same compliance date. FDA is giving a 24-month compliance period for large businesses and 36 months for small businesses to comply, the same compliance period as alternative 2. Also, compared to alternative 2, this alternative greatly increases costs while holding benefits nearly constant. For

these reasons, this is not our preferred alternative. The sections below outline the costs and benefits for this alternative.

Relabeling Costs

Alternative 5 applies FDA's 2014 Labeling Cost Model to estimate the cost

of relabeling roughly 50,000 food labels under a 12-month compliance period for large manufacturers and 24 months for small. Reducing the compliance period increases the number of uncoordinated changes, resulting in higher labeling costs. For a 12-month compliance period, only 11 percent of branded and

5 percent of private labels will have a coordinated change. For a 24-month compliance period, only 26 percent of private brands will have a coordinated change. The average one-time per label cost increases from \$1,371 to \$2,591, Table 23.

TABLE 23—ALTERNATIVE 5—LABELING COSTS
[12 month for large, 24 months for small]

| | Small | Large | Costs | | |
|--|--------|--------|-------------|-------------|--------------|
| | | | Lower | Mean | Upper |
| Total Number of Labels | 26,859 | 23,251 | | | |
| Coordinated Change: | | | | | |
| Major | 5,334 | 1,828 | \$2,119,952 | \$8,250,624 | \$22,947,048 |
| Minor | 16,504 | 5,656 | 3,124,560 | 12,675,520 | 35,899,200 |
| Uncoordinated Change: | | | | | |
| Extensive | 7 | 6 | 91,494 | 180,154 | 330,187 |
| Major | 1,225 | 3,850 | 26,008,391 | 47,708,270 | 88,301,659 |
| Minor | 3,789 | 11,911 | 28,919,400 | 61,025,900 | 121,533,700 |
| Total Cost | | | 60,263,797 | 129,840,468 | 269,011,794 |
| Annualized Cost (3% DR, 20 Year) | | | 3,932,693 | 8,473,125 | 17,555,163 |
| Annualized Cost (7% DR, 20 Year) | | | 5,316,333 | 11,454,226 | 23,731,598 |
| Average Per label one time cost | | | 1,203 | 2,591 | 5,368.43 |
| Per label Annualized Cost (3% DR, 20 Year) | | | 78 | 169 | 350 |
| Per label Annualized Cost (7% DR, 20 Year) | | | 106 | 229 | 474 |

Recordkeeping Costs

Alternative 5 does not alter the recordkeeping requirements as presented in the Expected Cost section above. As such, we assume the recordkeeping costs associated under alternative 5 are equal to those under alternative 2.

Reformulation Costs

Reducing the compliance period increases the cost for product reformulation. However, the longest compliance period covered in the 2014 Reformulation Cost Model for a small business is 24 months. Therefore, the reformulation cost for small and medium businesses in alternative 2 is based on a 24 month compliance period,

resulting in an overestimate of cost in alternative 2. Even with the overestimation in alternative 2 reformulation cost, the one-time cost for reformulation increases by \$40.2 million with alternative 5, with an average per formula cost increasing from \$77,009 to \$109,638, Table 24. The increase is attributed to the 12-month compliance period for large manufacturers.

TABLE 24—ALTERNATIVE 5—REFORMULATION COST
[12 month large, 24 months small]

| | Lower | Mid | Upper |
|--|--------------|---------------|---------------|
| High Complexity Formulas | \$52,426,895 | \$111,272,089 | \$177,545,177 |
| Med Complexity Formulas | 10,251,245 | 21,801,633 | 35,032,632 |
| Low Complexity Formulas | 989,550 | 2,109,464 | 3,430,665 |
| Total Cost | 63,667,690 | 135,183,186 | 216,008,474 |
| Annualized Cost (3% DR, 20 Year) | 4,154,824 | 8,821,780 | 14,096,274 |
| Annualized Cost (7% DR, 20 Year) | 5,616,616 | 11,925,548 | 19,055,768 |
| Average Per formula one time cost | 51,636 | 109,638 | 175,189 |
| Per formula Annualized Cost (3% DR, 20 Year) | 3,370 | 7,155 | 11,433 |
| Per formula Annualized Cost (7% DR, 20 Year) | 4,555 | 9,672 | 15,455 |

Quantitative Benefits

By reducing the compliance period, labels are updated faster, resulting in earlier consumer welfare benefits. Again, the present value of health benefits was derived by multiplying the percentage of label changes in each 12-month period by annual health benefits. Alternative 5 proposed a 12-month compliance period for large and 24

month compliance period for small. Based on IRI scanner data and SBA small business standards, 53.6 percent of labels are from small businesses and 46.4 percent are from Large. Utilizing these proportions and Table 4—Label Changes That Can Be Coordinated with a Planned Change, we estimate that after 12 months, 50.76 percent of FSIS's Nutrition Facts labels are updated

((100% of Large * 46.4% of labels) + (10% of Small * 53.6% of Labels)). After 24 months, 100 percent of FSIS's nutrition facts labels are updated.

As shown in Table 25, the expected increase in annual health benefits between alternative 2 and alternative 5 is about \$1.6 million. However, alternative 5 increases cost by \$6.6

million annually, of which \$4 million is derived from increases in labeling costs.

TABLE 25—COMPARISON OF ALTERNATIVES 2 AND 5

| | Alternative 2 | | | Alternative 5 | | |
|--------------------|---------------|--------------------|--------------|---------------|--------------------|--------------|
| | Benefits | Costs ¹ | Net Benefits | Benefits | Costs ¹ | Net Benefits |
| Annual PV 3% | \$36,894,007 | \$10,802,809 | \$26,091,198 | \$38,470,229 | \$17,416,595 | \$21,053,634 |
| Annual PV 7% | 22,541,264 | 14,603,562 | 7,937,702 | 23,794,722 | 23,544,278 | 250,444 |

¹ Costs include relabeling, recordkeeping, and reformulation costs.

² Present Value (PV) is the current worth of a future sum of money or stream of cash flows given a specified rate of return.

Qualitative Benefits

Alternative 5 is expected to have similar qualitative benefits as alternative 2, with the additional benefit of harmonized labels between FSIS and FDA. Assuming FSIS has a one-year lag from FDA's final rule (81 FR 33742 and 81 FR 34000), under this alternative, USDA and FDA labels will have the same compliance date, resulting in less confusion over similar food products.

IV. Regulatory Flexibility Act

The FSIS Administrator made a preliminary determination that this proposed rule will not have a significant impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). This determination was made because small businesses only account for 50 percent of the Nutrition Facts Labels and are given an additional 12 months to comply, reducing the costs of the proposed regulations.

All manufacturers are required to update labels if this proposed rule is finalized. FSIS considered other alternatives and the preferred alternative gives small businesses an additional 12 months to comply with the regulations to reduce the impact on small businesses. The additional compliance time reduces the burden and cost for small business and is consistent with FDA's compliance period.

On the basis of IRI scanner data, FSIS estimates that 3,307 manufacturers produce roughly 50,000 different retail labels with nutrition labeling for meat or poultry products. Using SBA's small business definition⁸⁹ and IRI scanner data, FSIS estimates 3,125 small manufacturers would be affected by the proposed rule. The small FSIS manufacturers produce 26,859 labels (53.6 percent of 50,110) as shown in Table 5—Alternative 2—Labeling Costs

(24 Month for Large, 36 Months for Small). Note that the disproportionately large percentage of labels from the 182 large manufacturers is attributable to the fact that they typically produce more labeled products per manufacturer than small manufacturers.

The average one-time cost per label change is \$1,208 or \$79 annualized over 10 years at a 3-percent discount rate for small businesses. The annualized costs at a 3-percent discount rate for all labels changes from small retail manufacturers is \$2,116,554 with an average cost of \$677 (\$2.1M/3,125) per small business. Relabeling costs for small businesses are less than half (\$2.1M out of \$4.5M) of the total annualized cost at a 3-percent discount rate (Table 5—Alternative 2—Labeling Costs (24 Month for Large, 36 Months for Small)). These estimates in Table 5 include small business relabeling costs from minor, major, extensive coordinated and uncoordinated changes for a 36-month compliance period.

V. Paperwork Requirements

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection and recordkeeping requirements included in this proposed rule have been submitted for approval to OMB.

Title: Revision of the Nutrition Facts Labels for Meat and Poultry Products and Updating Certain Reference Amounts Customarily Consumed.

Type of Collection: New.

Abstract: The proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the PRA. The provisions include burden for recordkeeping, annual reporting, and third-party disclosure for the declaration of Added Sugars, Dietary Fiber, Soluble Fiber, Insoluble Fiber, Vitamin E, and Folate/Folic Acid. The

likely respondents to this information collection are manufacturers of FSIS retail food products containing Added Sugars, Dietary Fiber, Soluble Fiber, Insoluble Fiber, Vitamin E, and Folate/Folic Acid.

Proposed Recordkeeping and Annual Record Reporting Requirements

Under this proposed rule manufacturers must maintain additional records for Added Sugars, Dietary Fiber, Soluble Fiber, Insoluble Fiber, Dietary Fiber, Vitamin E, and Folate/Folic Acid. Manufacturers are also required to provide these records to the inspector or any duly authorized representative of the Agency upon request.⁹⁰

FSIS believes the new records required from this proposed rule are records that responsible manufacturers use and retain as a normal part of business. Thus, the recordkeeping burden consists of the time required to identify and assemble the records for copying and holding and the reporting burden consists of the time required to assemble and provide records to the appropriate FSIS officials. FSIS estimates one hour of recordkeeping and one hour of recordkeeping burden for each newly required nutrient per manufacturer. If the rule is finalized as proposed, the declaration for added sugars, dietary fiber, soluble fiber, and insoluble fiber would be mandatory and 3,307 manufacturers for FSIS products would incur this burden. The declaration of Vitamin E and folate/folic acid is not mandatory unless accompanied with a nutrient claim. However, we estimate that roughly all 3,307 FSIS manufacturers will incur a one hour recordkeeping burden for the mandatory components and one hour record burden for vitamin E and folic acid. As shown in Table 26, the initial recordkeeping and reporting burden for covered respondents is 39,684 hours.

⁹⁰ Proposed 9 CFR 413.309(h)(8).

TABLE 27—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

| Type of declaration | Number of respondents | Hours of recordkeeping burden per respondent | Hours of reporting burden per respondent | Total burden hours |
|---------------------------|-----------------------|--|--|--------------------|
| Added Sugars | 3,307 | 1 | 1 | 6,614 |
| Dietary Fiber | 3,307 | 1 | 1 | 6,614 |
| Soluble Fiber | 3,307 | 1 | 1 | 6,614 |
| Insoluble Fiber | 3,307 | 1 | 1 | 6,614 |
| Vitamin E | 3,307 | 1 | 1 | 6,614 |
| Folate/Folic Acid | 3,307 | 1 | 1 | 6,614 |
| Total initial hours | | | | 39,684 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² These estimates are likely to be large overestimates, as not all manufacturers will need to keep records for added sugars, dietary fiber, and soluble and insoluble fiber. Manufacturers will only need to keep records for products with both added and naturally occurring sugars and products with non-digestible carbohydrates (soluble or insoluble) that do and do not meet the definition of dietary fiber.

³ These estimates are likely to be large overestimates, as not all manufacturers will need to keep records for vitamin E and folate/folic acid. The declaration of vitamin E and folate/folic acid is not mandatory unless a health or nutrient content claim is being made or these nutrients are directly added to the food for enrichment purposes.

Third Party Disclosures Burden for Manufacturers

FSIS estimated that the burden associated with the proposed changes would be a one-time burden for the food manufacturers to revise the nutrition labels. We estimate the one-time third

party disclosure burden would be approximately two hours. Each label would require a respondent one hour of review to determine how to bring it into compliance with the proposed requirements. FSIS estimated each label redesign would require one additional hour per label, for a total of two hours

per unique label for each respondent. Based on estimates from IRI scanner data, there are 50,110 unique nutrition labels under FSIS jurisdiction. Therefore, the estimated burden for this collection of information is 200,440 hours for respondents as shown in Table 27.

TABLE 28—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE

| Action | Number of labels | Average time burden per disclosure | Total hours |
|------------------------|------------------|------------------------------------|-------------|
| Reviewing Labels | 50,110 | 2 | 100,220 |
| Label Redesign | 50,110 | 2 | 100,220 |
| Total hours | | | 200,440 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Summary of Burden for Paperwork Reduction Act Section

Estimate of Burden: FSIS estimates that it would take 2.00 hours per respondent for recordkeeping and record reporting. FSIS also estimates it will take a respondent 2 hours per label to review and redesign the label.

Respondents: Manufacturers of FSIS products at the retail level.

Estimated Number of respondents: 3,307.

Estimated Number of FSIS labels: 50,110.

Estimated Number of Responses per Respondent: about 73 hours.

Estimated Total Annual Burden on Respondents: 241,411 hours.

Copies of this information collection assessment can be obtained from Gina Kouba, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW., Room 6065, South Building, Washington, DC 20250.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to both Gina Kouba, Paperwork Reduction Act Coordinator, at the address provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington,

DC 20253. To be most effective, comments should be sent to OMB.

VI. E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to government information and services, and for other purposes.

VII. Executive Order 12988, Civil Justice Reform

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

VIII. Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments." E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

FSIS has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a Tribe requests consultation, the Food Safety and Inspection Service will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

IX. USDA Nondiscrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:
Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250-9410.
Fax: (202) 690-7442.

Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotope, etc.),

should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

X. Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

XI. Proposed Regulatory Amendments

List of Subjects

9 CFR Parts 301 and 304

Meat inspection.

9 CFR Part 316

Food labeling, Food packaging, Meat inspection.

9 CFR Part 317

Food labeling, Food packaging, Meat inspection, Nutrition, Reporting and recordkeeping.

9 CFR Part 318

Food additives, Food packaging, Laboratories, Meat inspection, Reporting and recordkeeping requirements, Signs and symbols.

9 CFR Part 319

Food grades and standards, Food labeling, Frozen foods, Meat inspection, Oils and fats.

9 CFR Part 320

Meat inspection, Reporting and recordkeeping.

9 CFR Part 327

Food labeling, Food packaging, Imports, Meat inspection.

9 CFR Part 362

Meat inspection, Poultry and poultry products, Reporting and recordkeeping.

9 CFR Part 381

Administrative practice and procedure, Animal diseases, Crime, Exports, Food grades and standards, Food labeling, Food packaging, Government employees, Grant programs—agriculture, Imports, Intergovernmental relations, Laboratories, Meat inspection, Nutrition, Polychlorinated biphenyls (PCB's), Poultry and poultry products, Reporting and recordkeeping requirements, Seizures and forfeitures, Signs and symbols, Technical assistance, Transportation.

9 CFR Parts 412 and 413

Food labeling, Food packaging, Meat inspection, Poultry and poultry products, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, FSIS is proposing to amend 9 CFR Chapter III as follows:

PART 301—TERMINOLOGY; ADULTERATION AND MISBRANDING STANDARDS

- 1. The authority citation for part 301 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 U.S.C. 138–138i, 450, 1901–1906; 7 CFR 2.7, 2.18, 2.53.

- 2. Amend § 301.2 by revising paragraph (10) under the definition of "Misbranded" to read as follows:

§ 301.2 Definitions.

* * * * *

(10) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as is required by the regulations in part 317 of this subchapter and part 413 of subchapter E.

* * * * *

PART 304—APPLICATION FOR INSPECTION; GRANT OF INSPECTION

- 3. The authority citation for part 304 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

- 4. Amend § 304.2 by revising paragraph (b) to read as follows:

§ 304.2 Information to be furnished; grant or refusal of inspection.

* * * * *

(b) The Administrator is authorized to grant inspection upon his or her

determination that the applicant and the establishment are eligible therefor and to refuse to grant inspection at any establishment if he or she determines that it does not meet the requirements of this part or the regulations in parts 305, 307, and part 416, §§ 416.1 through 416.6 of this chapter, or that the applicant has not received approval of labeling and containers to be used at the establishment as required by the regulations in parts 316 and 317 of this subchapter and part 412 of subchapter E. Any application for inspection may be refused in accordance with the rules of practice in part 500 of this chapter.

* * * * *

PART 316—MARKING PRODUCTS AND THEIR CONTAINERS

- 5. The authority citation for part 316 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

- 6. Amend paragraph (b) of § 316.8 by replacing the phrase “this part and part 317 of this subchapter” with “this part, part 317 of this subchapter, and part 413 of subchapter E.”

- 7. Amend paragraph (e) of § 316.11 by adding the phrase “and part 413 of subchapter E” after “in part 317 of this subchapter”.

- 8. Amend paragraph (b) of § 316.13 by adding the phrase “and part 413 of subchapter E” after “part 317 of this subchapter”.

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

- 9. The authority citation for part 317 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

- 10. Amend § 317.16 by replacing the phrase “this part 317” with “this part 317 or part 413 of subchapter E”.

Subpart B—[Removed and Reserved]

- 11. Remove and reserve subpart B, consisting of §§ 317.300 through 317.400.

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

- 12. The authority citation for part 318 continues to read as follows:

Authority: 7 U.S.C. 138f, 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

- 13. Amend paragraph (b) of § 318.10 by replacing the phrase “part 317 of the regulations in this subchapter” with “part 412 of subchapter E”.

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

- 14. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

- 15. Amend paragraph (a) of § 319.1 by adding the phrase “and part 413 of subchapter E” after “part 317 of this subchapter”.

- 16. Amend § 319.10 by revising paragraph (a) to read as follows:

§ 319.10 Requirements for substitute standardized meat food products named by use of an expressed nutrition content claim and a standardized term.

(a) *Description.* The meat food products prescribed by this general definition and standard of identity are those products that substitute, in accordance with § 413.313(d), for a standardized product defined in this part and use the name of that standardized product in their statements of identity, but that do not comply with the established standard because of a compositional deviation that results from reduction of a constituent that is described by an expressed nutrient content claim that has been defined by regulation in part 413 of subchapter E. The expressed nutrient content claim shall comply with the requirements of § 413.313 and with the requirements of part 413, which define the particular nutrient content claim that is used. The meat food product shall comply with the relevant standard in this part in all other respects, except as provided in paragraphs (b) and (c) of this section.

* * * * *

- 17. Amend paragraph (b) of § 319.10 by replacing the reference to “§ 317.313(d)(1) and (2)” with “§ 413.313(d)(1) and (2)”.

PART 320—RECORDS, REGISTRATION, AND REPORTS

- 18. The authority citation for part 320 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.7, 2.18, 2.53.

- 19. Amend § 320.1 by revising paragraph (b)(8) to read as follows:

§ 320.1 Records required to be kept.

* * * * *

- (b) * * *
- (8) Records of nutrition labeling as required by part 413 of subchapter E.

* * * * *

PART 327—IMPORTED PRODUCTS

- 20. The authority citation for part 327 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

- 21. Amend § 327.15 by revising paragraph (b) to read as follows:

§ 327.15 Outside containers of foreign products; marking and labeling; application of official inspection legend.

* * * * *

(b) All labeling used with an outside container of foreign product must be approved in accordance with part 317 of this subchapter and parts 412 and 413 of subchapter E.

* * * * *

PART 362—VOLUNTARY POULTRY INSPECTION REGULATIONS

- 22. The authority citation for part 362 continues to read as follows:

Authority: 7 U.S.C. 1622; 7 CFR 2.18(g) and (i) and 2.53.

- 23. Amend paragraph (a) of § 362.2 by replacing “Part 381” with “parts 381 and 413.”

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

- 24. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451–470; 7 CFR 2.7, 2.18, 2.53.

§ 381.172 [Amended]

- 25. Amend § 381.172 by revising paragraphs (a) and (b) to read as follows:

(a) *Description.* The poultry products prescribed by this general definition and standard of identity are those products that substitute, in accordance with § 413.313(d), for a standardized product defined in this subpart and use the name of that standardized product in their statements of identity, but that do not comply with the established standard because of a compositional deviation that results from reduction of a constituent that is described by an expressed nutrient content claim that has been defined by regulation in this subpart. The expressed nutrient content claim shall comply with the requirements of § 413.313 and with the requirements in part 413 which define the particular nutrient content claim that is used. The poultry product shall comply with the relevant standard in this part in all other respects, except as provided in paragraphs (b) and (c) of this section.

(b) *Performance characteristics.* The performance characteristics, such as physical properties, functional properties, and shelf-life, of the poultry product shall be similar to those of the standardized poultry product produced under subpart P of this part. If there is

a significant difference in a performance characteristic that materially limits the use of the product compared to the use of the standardized product defined in subpart P of this part, the label shall include a statement in accordance with § 413.313(d)(1) and (2) that informs the consumer of such differences (*e.g.*, if appropriate, “not recommended for frozen storage” or “not suitable for roller grilling”). Deviations from the ingredient provisions of the standard must be the minimum necessary to qualify for the nutrient content claim, while maintaining similar performance characteristics.

* * * * *

■ 26. Amend § 381.175 by revising paragraph (b)(5) to read as follows:

§ 381.175 Required records to be kept.

* * * * *

(b) * * *

(5) Records of nutrition labeling as required by part 413.

* * * * *

Subpart Y—[Removed and Reserved]

■ 27. Remove and reserve subpart Y, consisting of §§ 381.400 through 381.500.

PART 412—LABEL APPROVAL

■ 28. The authority citation for part 412 continues to read as follows:

Authority: 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

■ 29. Amend § 412.2 by revising paragraph (a)(1) to read as follows:

§ 412.2 Approval of generic labels.

(a)(1) An official establishment, or an establishment certified under a foreign inspection system in accordance with part 327, or part 381, subpart T of this chapter, is authorized to use generically approved labels, as defined in paragraph (b) of this section, and thus is free to use such labels without submitting them to the Food Safety and Inspection Service for approval, provided the label, in accordance with this section, displays all mandatory features in a prominent manner in compliance with parts 317, 381, and 413 and is not otherwise false or misleading in any particular.

* * * * *

■ 30. Add part 413 to subchapter E to read as follows:

PART 413—NUTRITION LABELING

Sec.

413.1–413.299 [Reserved]

413.300 Nutrition labeling of meat, meat food products, and poultry products.

413.301 Required nutrition labeling of ground or chopped products.

413.302 Location of nutrition information.

413.303–413.307 [Reserved]

413.308 Labeling of products with number of servings.

413.309 Nutrition label content.

413.310–413.311 [Reserved]

413.312 Reference amounts customarily consumed per eating occasion.

413.313 Nutrient content claims; general principles.

413.314–413.343 [Reserved]

413.344 Identification of major cuts of meat products and poultry products.

413.345 Nutrition labeling of single-ingredient, raw meat or poultry products that are not ground or chopped products described in § 413.301.

413.346–413.353 [Reserved]

413.354 Nutrient content claims for “good source,” “high,” and “more”.

413.355 [Reserved]

413.356 Nutrient content claims for “light” or “lite”.

413.357–413.359 [Reserved]

413.360 Nutrient content claims for calorie content.

413.361 Nutrient content claims for the sodium content.

413.362 Nutrient content claims for fat, fatty acids, and cholesterol content.

413.363 Nutrient content claims for “healthy”.

413.364–413.368 [Reserved]

413.369 Labeling applications for nutrient content claims.

413.370–413.379 [Reserved]

413.380 Label statements relating to usefulness in reducing or maintaining body weight.

413.381–413.399 [Reserved]

413.400 Exemptions from nutrition labeling.

Authority: 21 U.S.C. 451–470, 601–695; 7 CFR 2.7, 2.18, 2.53.

§ 413.300 Nutrition labeling of meat, meat food products, and poultry products.

(a) Nutrition labeling must be provided for all meat, meat food products, and poultry products intended for human consumption and offered for sale, except single-ingredient, raw meat or poultry products that are not ground or chopped meat or poultry products described in § 413.301 and are not major cuts of single-ingredient, raw meat or poultry products identified in § 413.344, unless the product is exempted under § 413.400. Nutrition labeling must be provided for the major cuts of single-ingredient, raw meat or poultry products identified in § 413.344, either in accordance with the provisions of § 413.309 for nutrition labels, or in accordance with the provisions of § 413.345 for point-of-purchase materials, except as exempted under § 413.400. For all other products for which nutrition labeling is required, including ground or chopped meat or poultry products described in § 413.301, nutrition labeling must be provided in

accordance with the provisions of § 413.309, except as exempted under § 413.400.

(b) Nutrition labeling may be provided for single-ingredient, raw meat or poultry products that are not ground or chopped meat or poultry products described in § 413.301 and that are not major cuts of single-ingredient, raw meat or poultry products identified in § 413.344, either in accordance with the provisions of § 413.309 for nutrition labels, or in accordance with the provisions of § 413.345 for point-of-purchase materials.

§ 413.301 Required nutrition labeling of ground or chopped products.

(a) Nutrition labels must be provided for all ground or chopped products (livestock species or kind) and hamburger with or without added seasonings (including, but not limited to, ground beef, ground beef patties, ground sirloin, ground pork, ground lamb, ground chicken, ground turkey, and (kind) burgers) that are intended for human consumption and offered for sale, in accordance with the provisions of § 413.309, except as exempted under § 413.400.

(b) [Reserved]

§ 413.302 Location of nutrition information.

(a) Nutrition information on a label of a packaged product shall appear on the label’s principal display panel or on the information panel, except as provided in paragraphs (b) and (c) of this section.

(b) Nutrition information for gift packs may be shown at a location other than on the product label, provided that the labels for these products bear no nutrition claim. In lieu of on the product label, nutrition information may be provided by alternate means such as product label inserts.

(c) Products in packages that have a total surface area available to bear labeling greater than 40 square inches but whose principal display panel and information panel do not provide sufficient space to accommodate all required information may use any alternate panel that can be readily seen by consumers for the nutrition information. In determining the sufficiency of available space for the nutrition information, the space needed for vignettes, designs, and other nonmandatory label information on the principal display panel may be considered.

§§ 413.303–413.307 [Reserved]**§ 413.308 Labeling of products with number of servings.**

The label of any package of a product that bears a representation as to the number of servings contained in such package shall meet the requirements of § 317.2(h)(10) or § 381.121(c)(7).

§ 413.309 Nutrition label content.

(a) All nutrient and food component quantities shall be declared in relation to a serving as defined in this section.

(b)(1) The term “serving” or “serving size” means an amount of food customarily consumed per eating occasion by persons 4 years of age or older, which is expressed in a common household measure that is appropriate to the product. When the product is specially formulated or processed for use by infants or by toddlers, a serving or serving size means an amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively.

(2) Except as provided in paragraphs (b)(8), (b)(12), and (b)(14) of this section and for products that are intended for weight control and are available only through a weight-control or weight-maintenance program, serving size declared on a product label shall be determined from the “Reference Amounts Customarily Consumed Per Eating Occasion—General Food Supply” (Reference Amounts) that appear in § 413.312(b) using the procedures described in this paragraph (b). For products that are both intended for weight control and available only through a weight-control program, a manufacturer may determine the serving size that is consistent with the meal plan of the program. Such products must bear a statement, “for sale only through the _____ program” (fill in the blank with the name of the appropriate weight-control program, e.g., Smith’s Weight Control), on the principal display panel. However, the Reference Amounts in § 413.312(b) shall be used for purposes of evaluating whether weight-control products that are available only through a weight-control program qualify for nutrition claims.

(3) The declaration of nutrient and food component content shall be on the basis of the product “as packaged” for all products, except that single-ingredient, raw products that are not ground or chopped products described in § 413.301 may be declared on the basis of the product “as consumed”. For single-ingredient, raw products that are not ground or chopped products described in § 413.301, if data are based

on the product ‘as consumed,’ the data must be presented in accordance with § 413.345(d). In addition to the required declaration on the basis of “as packaged” for products other than single-ingredient, raw products that are not ground or chopped products described in § 413.301, the declaration may also be made on the basis of “as consumed,” provided that preparation and cooking instructions are clearly stated.

(4) For products in discrete units (e.g., hot dogs, chicken wings, and individually packaged products within a multi-serving package), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is in discrete units (e.g., beef fritters and barbecue sauce, chicken wings and barbecue sauce), the serving size shall be declared as follows:

(i) If a unit weighs 50 percent or less of the Reference Amount, the serving size shall be the number of whole units that most closely approximates the Reference Amount for the product category.

(ii) If a unit weighs more than 50 percent but less than 67 percent of the Reference Amount, the manufacturer may declare one unit or two units as the serving size.

(iii) If a unit weighs 67 percent or more but less than 200 percent of the Reference Amount, the serving size shall be one unit.

(iv) If a unit weighs at least 200 percent and up to and including 300 percent of the applicable reference amount, the serving size shall be the amount that approximates the reference amount. In addition to providing a column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values per serving size, the manufacturer shall provide a column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values per individual unit. The first column would be based on the serving size for the product and the second column would be based on the individual unit. The exemptions in paragraphs (b)(16)(i)(A), (B), and (C) of this section apply to this provision.

(v) For products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is in discrete units (e.g., beef fritters and barbecue sauce, chicken wings and barbecue sauce), the serving size may be the number of discrete units represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount for the

combined product as determined in § 413.312(c).

(vi) For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in this section (i.e., are labeled appropriately for individual sale as single-serving containers), the serving size shall be 1 unit.

(vii) The serving size for products that naturally vary in size (e.g., chicken breast, poultry parts, pork chop) may be the amount in ounces that most closely approximates the reference amount for the product category. Manufacturers shall adhere to the requirements in paragraph (b)(7)(iii) of this section for expressing the serving size in ounces.

(5) For products in large discrete units that are usually divided for consumption (e.g., pizza, pan of poultry lasagna), for unprepared products where the entire contents of the package is used to prepare large discrete units that are usually divided for consumption (e.g. pizza kit), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is a large discrete unit usually divided for consumption, the serving size shall be the fractional slice of the ready-to-eat product (e.g., $\frac{1}{8}$ quiche, $\frac{1}{4}$ pizza) that most closely approximates the Reference Amount for the product category. The serving size may be the fraction of the package used to make the Reference Amount for the unprepared product determined in § 413.312(d) or the fraction of the large discrete unit represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount of the combined product determined in § 413.312(c). In expressing the fractional slice, manufacturers shall use $\frac{1}{2}$, $\frac{1}{3}$, $\frac{1}{4}$, $\frac{1}{5}$, $\frac{1}{6}$, or smaller fractions that can be generated by further division by 2 or 3.

(6) For nondiscrete bulk products (e.g., whole roast beef, marinated beef tenderloin, large can of chili, whole turkey, turkey breast, ground poultry), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is a bulk product (e.g., roast beef and gravy, turkey breast and gravy), the serving size shall be the amount in household measure that most closely approximates the Reference Amount for the product category and may be the amount of the bulk product represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount for the

combined product determined in § 413.312(c).

(7) For labeling purposes, the term “common household measure” or “common household unit” means cup, tablespoon, teaspoon, piece, slice, fraction (e.g., $\frac{1}{4}$ pizza), ounce (oz), or other common household equipment used to package food products (e.g., jar or tray). In expressing serving size in household measures, except as specified in paragraphs (b)(7)(iv), (v), and (vi) of this section, the following rules shall be used:

(i) Cups, tablespoons, or teaspoons shall be used wherever possible and appropriate. Cups shall be expressed in $\frac{1}{4}$ - or $\frac{1}{3}$ -cup increments, tablespoons in whole number of tablespoons for quantities less than $\frac{1}{4}$ cup but greater than or equal to 2 tablespoons (tbsp), 1, $1\frac{1}{3}$, $1\frac{1}{2}$, or $1\frac{1}{2}$ tbsp for quantities less than 2 tbsp but greater than or equal to 1 tbsp, and teaspoons in whole number of teaspoons for quantities less than 1 tbsp but greater than or equal to 1 teaspoon (tsp), and in $\frac{1}{4}$ -tsp increments for quantities less than 1 tsp.

(ii) If cups, tablespoons or teaspoons are not applicable, units such as piece, slice, tray, jar, and fraction shall be used.

(iii) If cups, tablespoons and teaspoons, or units such as piece, slice, tray, jar, or fraction are not applicable, ounces may be used. Ounce measurements shall be expressed in 0.5-ounce increments most closely approximating the Reference Amount with rounding indicated by the use of the term “about” (e.g., about 2.5 ounces).

(iv) A description of the individual container or package shall be used for single-serving containers and for individually packaged products within multi-serving containers (e.g., can, box, package, meal, or dinner). A description of the individual unit shall be used for other products in discrete units (e.g., chop, slice, link, or patty).

(v) For unprepared products where the entire contents of the package is used to prepare large discrete units that are usually divided for consumption (e.g., pizza kit), the fraction or portion of the package may be used.

(vi) For products that consist of two or more distinct ingredients or components packaged and presented to be consumed together (e.g., ham with a glaze packet, chicken wings with a glaze packet), the nutrition information may be declared for each component or as a composite. The serving size shall be provided in accordance with the provisions of paragraphs (b)(4), (b)(5), and (b)(6) of this section, whichever is applicable.

(vii) For nutrition labeling purposes, a teaspoon means 5 milliliters (mL), a tablespoon means 15 mL, a cup means 240 mL, and 1 oz in weight means 28 grams (g).

(viii) When a serving size, determined from the Reference Amount in § 413.312(b) and the procedures described in this section, falls exactly half way between two serving sizes (e.g., 2.5 tbsp), manufacturers shall round the serving size up to the next incremental size.

(8) A product that is packaged and sold individually that contains less than 200 percent of the applicable reference amount must be considered to be a single-serving container, and the entire content of the product must be labeled as one serving. In addition to providing a column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values per serving, for a product that is packaged and sold individually that contains more than 150 percent and less than 200 percent of the applicable reference amount, the Nutrition Facts label may voluntarily provide, to the left of the column that provides nutrition information per container (i.e., per serving), an additional column that lists the quantitative amounts and percent Daily Values per common household measure that most closely approximates the reference amount.

(9) A label statement regarding a serving shall be the serving size expressed in common household measures as set forth in paragraphs (b)(2) through (b)(8) of this section and shall be followed by the equivalent metric quantity in parenthesis (fluids in milliliters and all other foods in grams), except for single-serving containers.

(i) For a single-serving container, the parenthetical metric quantity, which will be presented as part of the net weight statement on the principal display panel, is not required except where nutrition information is required on a drained weight basis according to paragraph (b)(11) of this section.

However, if a manufacturer voluntarily provides the metric quantity on products that can be sold as single servings, then the numerical value provided as part of the serving size declaration must be identical to the metric quantity declaration provided as part of the net quantity of contents statement.

(ii) The gram or milliliter quantity equivalent to the household measure should be rounded to the nearest whole number except for quantities that are less than 5 g (mL). The gram (mL) quantity between 2 and 5 g (mL) should be rounded to the nearest 0.5 g (mL) and

the g (mL) quantity less than 2 g (mL) should be expressed in 0.1-g (mL) increments.

(iii) In addition, serving size may be declared in ounce, in parenthesis, following the metric measure separated by a slash where other common household measures are used as the primary unit for serving size, e.g., 1 slice (28 g/1 oz) for sliced bologna or for sliced chicken roll. The ounce quantity equivalent to the metric quantity should be expressed in 0.1-oz increments.

(iv) If a manufacturer elects to use abbreviations for units, the following abbreviations shall be used: tbsp for tablespoon, tsp for teaspoon, g for gram, mL for milliliter, and oz for ounce.

(v) For products that only require the addition of water or another ingredient that contains insignificant amounts of nutrients in the amount added and that are prepared in such a way that there are no significant changes to the nutrient profile, the amount of the finished product may be declared in parentheses at the end of the serving size declaration (e.g., $\frac{1}{2}$ cup (120g) concentrated soup (makes 1 cup prepared)).

(10) Determination of the number of servings per container shall be based on the serving size of the product determined by following the procedures described in this section.

(i) The number of servings must be rounded to the nearest whole number except for the number of servings between 2 and 5 servings and random weight products. The number of servings between 2 and 5 servings must be rounded to the nearest 0.5 serving. Rounding should be indicated by the use of the term “about” (e.g., about 2 servings; about 3.5 servings).

(ii) When the serving size is required to be expressed on a drained solids basis and the number of servings varies because of a natural variation in unit size (e.g., pickled pigs feet), the manufacturer may state the typical number of servings per container (e.g., usually 5 servings).

(iii) For random weight products, manufacturers may declare “varied” for the number of servings per container provided the nutrition information is based on the reference amount expressed in the appropriate household measure based on the hierarchy described in paragraph (b)(7) of this section. Random weight products are foods such as meat roasts or whole turkeys that are sold as random weights that vary in size, such that the net contents for different containers would vary. The manufacturer may provide the typical number of servings in parentheses following the “varied”

statement (*e.g.*, varied (approximately 8 servings per pound)).

(iv) For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in this section (*i.e.*, are labeled appropriately for individual sale as single-serving containers), the number of servings shall be the number of individual packages within the total package.

(v) For packages containing several individually packaged multi-serving units, the number of servings shall be determined by multiplying the number of individual multi-serving units in the total package by the number of servings in each individual unit. The declaration of the number of servings per container need not be included in nutrition labeling of single-ingredient, raw products that are not ground or chopped products described in § 413.301, including those that have been previously frozen.

(11) The declaration of nutrient and food component content shall be on the basis of product as packaged or purchased with the exception of single-ingredient, raw products that are not ground or chopped products described in § 413.301 and products that are packed or canned in water, brine, or oil but whose liquid packing medium is not customarily consumed. Declaration of the nutrient and food component content of products that are packed in liquid which is not customarily consumed shall be based on the drained solids.

(12) The serving size for meal-type products and main-dish products as defined in § 413.313(l) and § 413.313(m) in single-serving containers will be the entire edible content of the package. Serving size for meal-type products and main-dish products in multi-serve containers will be based on the reference amount applicable to the product in § 413.312(b) if the product is listed in § 413.312(b). Serving size for meal-type products and main-dish products in multi-serve containers that are not listed in § 413.312(b) will be based on the reference amount according to § 413.312(c), (d), and (e).

(13) Another column of figures may be used to declare the nutrient and food component information in the same format as required by § 413.309(e).

(i) Per 100 grams, 100 milliliters, or 1 ounce of the product as packaged or purchased.

(ii) Per one unit if the serving size of a product in discrete units is more than one unit.

(14) If a product consists of assortments of meat, meat food

products, or poultry products (*e.g.*, variety packs) in the same package, nutrient content shall be expressed on the entire package contents or on each individual product.

(15) If a product is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare nutrition information on the basis of the product as consumed in the format required in paragraph (e) of this section (*e.g.*, a cream soup mix may be labeled with the percent Daily Value and quantitative amounts for the dry mix alone (per serving), and the percent Daily Value and quantitative amounts for the serving of the final soup when prepared (*e.g.*, per serving of cream soup mix and 1 cup of vitamin D fortified whole milk)); *Provided*, that the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

(16)(i) Products that are packaged and sold individually and that contain at least 200 percent and up to and including 300 percent of the applicable reference amount must provide an additional column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values for the entire package, as well as a column listing the quantitative amounts and percent Daily Values for a serving that is less than the entire package (*i.e.*, the serving size derived from the reference amount). The first column would be based on the serving size for the product and the second column would be based on the entire contents of the package.

(A) This provision does not apply to products that meet the requirements to use the tabular display for small packages in paragraph (g)(1)(i)(A) of this section or to products that meet the requirements to use the linear format in paragraph (g)(1)(i)(B) of this section.

(B) This provision does not apply to products that require further preparation and provide an additional column of nutrition information under paragraph (e) of this section, to products that are commonly consumed in combination with another food and provide an additional column of nutrition information under paragraph (e) of this section, to products that provide an additional column of nutrition information for two or more groups for which RDIs are established (*e.g.*, both infants through 12 months and children 1 through 3 years of age), or to random-weight products covered

under paragraph (b)(10)(iii) of this section.

(ii) When a nutrient content claim or health claim is made on the label of a product that uses a dual column in accordance with paragraph (b) of this section, the claim must be followed by a statement that sets forth the basis on which the claim is made, except that the statement is not required for products when the nutrient that is the subject of the claim meets the criteria for the claim based on the reference amount for the product and the entire container or the unit amount. When a nutrient content claim is made, the statement must express that the claim refers to the amount of the nutrient per serving (*e.g.*, “good source of calcium per serving” or “per X [insert unit] serving” or per reference amount (*e.g.*, “good source of calcium per [insert reference amount (*e.g.*, per 8 ounces)]”), as required based on § 413.313(p). When a health claim is made, the statement shall be “A serving of ____ ounces of this product conforms to such a diet.”

(c) The declaration of nutrition information on the label and in labeling of a meat or meat food product or poultry product shall contain information about the level of the following nutrients, except for those nutrients whose inclusion, and the declaration of the amounts, is voluntary as set forth in this paragraph. No nutrients or food components other than those listed in this paragraph as either mandatory or voluntary may be included within the nutrition label. Except as provided for in paragraphs (f) or (g) of this section, nutrient information shall be presented using the nutrient names specified and in the following order in the formats specified in paragraphs (d) or (e) of this section.

(1) “Calories, total,” “Total calories,” or “Calories”: A statement of the caloric content per serving, expressed to the nearest 5-calorie increment up to and including 50 calories, and 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. Energy content per serving may also be expressed in kilojoule units, added in parenthesis immediately following the statement of the caloric content.

(i) Caloric content may be calculated by the following methods. Where either specific or general food factors are used, the factors shall be applied to the actual amount (*i.e.*, before rounding) of food components (*e.g.*, fat, carbohydrate, protein, or ingredients with specific food factors) present per serving.

(A) Using specific Atwater factors (*i.e.*, the Atwater method) given in Table

13, USDA Handbook No. 74 (slightly revised, 1973);

(B) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate, and total fat, respectively, as described in USDA Handbook No. 74 (slightly revised, 1973) pp. 9–11;

(C) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate (less the amount of non-digestible carbohydrates and sugar alcohols), and total fat, respectively, as described in USDA Handbook No. 74 (slightly revised, 1973) pp. 9–11. A general factor of 2 calories per gram for soluble non-digestible carbohydrates shall be used. The general factors for caloric value of sugar alcohols provided in paragraph (c)(1)(i)(F) of this section shall be used;

(D) Using data for specific food factors for particular foods or ingredients approved by the Food and Drug Administration (FDA) and provided in parts 172 or 184 of 21 CFR, or by other means, as appropriate;

(E) Using bomb calorimetry data subtracting 1.25 calories per gram protein to correct for incomplete digestibility, as described in USDA Handbook No. 74 (slightly revised, 1973) p. 10; or

(F) Using the following general factors for caloric value of sugar alcohols:

Isomalt—2.0 calories per gram, lactitol—2.0 calories per gram, xylitol—2.4 calories per gram, maltitol—2.1 calories per gram, sorbitol—2.6 calories per gram, hydrogenated starch hydrolysates—3.0 calories per gram, mannitol—1.6 calories per gram, and erythritol—0 calories per gram.

(ii) “Calories from saturated fat” or “Calories from saturated” (VOLUNTARY): A statement of the caloric content derived from saturated fat as defined in paragraph (c)(2)(i) of this section per serving may be declared voluntarily, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. This statement shall be indented under the statement of calories as provided in paragraph (d)(5) of this section.

(2) “Fat, total” or “Total fat”: A statement of the number of grams of total fat per serving defined as total lipid fatty acids and expressed as triglycerides where fatty acids are aliphatic carboxylic acids consisting of a chain of alkyl groups and characterized by a terminal carboxyl group. Amounts shall be expressed to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving

contains less than 0.5 gram, the content shall be expressed as zero.

(i) “Saturated fat” or “Saturated”: A statement of the number of grams of saturated fat per serving defined as the sum of all fatty acids containing no double bonds, except that label declaration of saturated fat content information is not required for products that contain less than 0.5 gram of total fat per serving if no claims are made about fat, fatty acid, or cholesterol content, and if “calories from saturated fat” is not declared. Saturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(A) [Reserved]

(B) [Reserved]

(ii) “Trans Fat” or “Trans”: A statement of the number of grams of trans fat in a serving, defined as the sum of all unsaturated fatty acids that contain one or more isolated (*i.e.*, nonconjugated) double bonds in a trans configuration. The word “trans” may be italicized to indicate its Latin origin.

Trans fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content, when declared, shall be expressed as zero.

(iii) “Polyunsaturated fat” or “Polyunsaturated” (VOLUNTARY): A statement of the number of grams of polyunsaturated fat per serving defined as cis, cis-methylene-interrupted polyunsaturated fatty acids may be declared voluntarily, except that when monounsaturated fat is declared, or when a claim about fatty acids or cholesterol is made on the label or in labeling of a product other than one that meets the criteria in § 413.362(b)(1) for a claim for “fat free,” label declaration of polyunsaturated fat is required. Polyunsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(iv) “Monounsaturated fat” or “Monounsaturated” (VOLUNTARY): A statement of the number of grams of monounsaturated fat per serving defined as cis-monounsaturated fatty acids may be declared voluntarily, except that when polyunsaturated fat is declared, or when a claim about fatty acids or cholesterol is made on the label or in

labeling of a product other than one that meets the criteria in § 413.362(b)(1) for a claim for “fat free,” label declaration of monounsaturated fat is required. Monounsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(3) “Cholesterol”: A statement of the cholesterol content per serving expressed in milligrams to the nearest 5-milligram increment, except that label declaration of cholesterol information is not required for products that contain less than 2 milligrams of cholesterol per serving and make no claim about fat, fatty acids, or cholesterol content, or such products may state the cholesterol content as zero. If the product contains 2 to 5 milligrams of cholesterol per serving, the content may be stated as “less than 5 milligrams.”

(4) “Sodium”: A statement of the number of milligrams of sodium per serving expressed as zero when the serving contains less than 5 milligrams of sodium, to the nearest 5-milligram increment when the serving contains 5 to 140 milligrams of sodium, and to the nearest 10-milligram increment when the serving contains greater than 140 milligrams.

(5) “Fluoride” (VOLUNTARY): A statement of the number of milligrams of fluoride in a specified serving of food may be declared voluntarily, except that when a claim is made about fluoride content, label declaration shall be required. Fluoride content shall be expressed as zero when the serving contains less than 0.1 milligrams of fluoride, to the nearest 0.1-milligram increment when the serving contains less than or equal to 0.8 milligrams of fluoride, and the nearest 0.2 milligram-increment when a serving contains more than 0.8 milligrams of fluoride.

(6) “Carbohydrate, total” or “Total carbohydrate”: A statement of the number of grams of total carbohydrate per serving expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement “Contains less than 1 gram” or “less than 1 gram” may be used as an alternative, or, if the serving contains less than 0.5 gram, the content may be expressed as zero. Total carbohydrate content shall be calculated by subtraction of the sum of the crude protein, total fat, moisture, and ash from the total weight of the product. This calculation method is described in USDA Handbook No. 74 (slightly revised, 1973), pp. 2–3.

(i) "Dietary fiber": A statement of the number of grams of total dietary fiber per serving, indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, declaration of dietary fiber is not required, or, alternatively, the statement "Contains less than 1 gram" or "less than 1 gram" may be used, and if the serving contains less than 0.5 gram, the content may be expressed as zero. Dietary fiber is defined as non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin that are intrinsic and intact in plants; isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health. Except as provided for in paragraph (f) of this section, if dietary fiber content is not required, and as a result not declared, the statement "Not a significant source of dietary fiber" shall be placed at the bottom of the table of nutrient values in the same type size. The following isolated or synthetic non-digestible carbohydrate(s) have been determined by FDA to have physiological effects that are beneficial to human health and, therefore, shall be included in the calculation of the amount of dietary fiber: [beta]-glucan soluble fiber (as described in 21 CFR 101.81(c)(2)(ii)(A)), psyllium husk (as described in 21 CFR 101.81(c)(2)(ii)(A)(6)), cellulose, guar gum, pectin, locust bean gum, and hydroxypropylmethylcellulose. The manufacturer must make and keep records in accordance with paragraphs (h) of this section to verify the declared amount of dietary fiber in the label and labeling of food when a mixture of dietary fiber, and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, is present in the food.

(A) "Soluble fiber" (VOLUNTARY): A statement of the number of grams of soluble dietary fiber per serving may be declared voluntarily except when a claim is made on the label or in labeling about soluble fiber, label declaration shall be required. Soluble fiber must meet the definition of dietary fiber in this paragraph (c)(6)(i). The manufacturer must maintain records in accordance with paragraph (h)(8) of this section to verify the declared amount of soluble fiber in the label and labeling of food when a mixture of soluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, is present in the food. Soluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except

that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(B) "Insoluble fiber" (VOLUNTARY): A statement of the number of grams of insoluble dietary fiber per serving may be declared voluntarily except when a claim is made on the label or in labeling about insoluble fiber, label declaration shall be required. Insoluble fiber must meet the definition of dietary fiber in this paragraph (c)(6)(i). The manufacturer must make and keep records in accordance with paragraph (h)(8) of this section to verify the declared amount of insoluble fiber in the label and labeling of food when a mixture of insoluble and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food. Insoluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(ii) "Total Sugars": A statement of the number of grams of sugars per serving, except that the label declaration of sugars content is not required for products that contain less than 1 gram of sugars per serving if no claims are made about sweeteners, sugars, or sugar alcohol content. Total sugars shall be defined as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose). Total sugars content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iii) "Added Sugars": A statement of the number of grams of added sugars in a serving, except that label declaration of added sugars content is not required for products that contain less than 1 gram of added sugars in a serving if no claims are made about sweeteners, sugars, added sugars, or sugar alcohol content. If a statement of the added sugars content is not required and, as a result, not declared, the statement "Not a significant source of added sugars" shall be placed at the bottom of the table of nutrient values in the same type size. Added sugars are either added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides), sugars from syrups

and honey, and sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type. Added sugars content shall be indented under Total Sugars and shall be prefaced with the word "Includes" followed by the amount (in grams) "Added Sugars" ("Includes 'X' g Added Sugars"). It shall be expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When a mixture of naturally occurring and added sugars is present in the food, and for specific foods containing added sugars, alone or in combination with naturally occurring sugars, where the added sugars are subject to fermentation and/or non-enzymatic browning, the manufacturer must maintain records in accordance with paragraph (h)(8) of this section to verify the declared amount of added sugars in the label and labeling of food.

(iv) "Sugar alcohol" (VOLUNTARY): A statement of the number of grams of sugar alcohols per serving may be declared voluntarily on the label, except that when a claim is made on the label or in labeling about sugar alcohol, total sugars, or added sugars when sugar alcohols are present in the product, sugar alcohol content shall be declared. For nutrition labeling purposes, sugar alcohols are defined as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group and whose use in the food is listed by FDA (e.g., mannitol or xylitol) or is generally recognized as safe (e.g., sorbitol). In lieu of the term "sugar alcohol," the name of the specific sugar alcohol (e.g., "xylitol") present in the product may be used in the nutrition label, provided that only one sugar alcohol is present in the product. Sugar alcohol content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(7) "Protein": A statement of the number of grams of protein per serving, expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When the protein in products represented or

purported to be for adults and children 4 or more years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 20 expressed as a percent, or when the protein in a product represented or purported to be for children greater than 1 but less than 4 years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 40 expressed as a percent, either of the following shall be placed adjacent to the declaration of protein content by weight: The statement “not a significant source of protein,” or a listing aligned under the column headed “%Daily Value” of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the Daily Reference Value (DRV) or Reference Daily Intake (RDI), as appropriate, for protein and expressed as percent of Daily Value. When the protein quality in a product as measured by the Protein Efficiency Ratio (PER) is less than 40 percent of the reference standard (casein) for a product represented or purported to be specifically for infants through 12 months, the statement “not a significant source of protein” shall be placed adjacent to the declaration of protein content. Protein content may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food as determined by appropriate methods of analysis in accordance with § 413.309(h), except when the procedure for a specific food requires a specific factor other than 6.25, that factor shall be used.

(i) A statement of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the RDI or DRV for protein, as appropriate, and expressed as percent of Daily Value, may be placed on the label, except that such a statement shall be given if a protein claim is made for the product, or if the product is represented or purported to be specifically for infants through 12 months of age or children 1 through 3 years of age. When such a declaration is provided, it shall be placed on the label adjacent to the statement of grams of protein and aligned under the column headed “%Daily Value,” and expressed to the nearest whole percent. However, the percentage of the RDI for protein shall not be declared if the product is represented or purported to be specifically for infants through 12 months and the protein quality value is less than 40 percent of the reference standard.

(ii) The “corrected amount of protein (grams) per serving” for products represented or purported to be for adults and children 1 or more years of age is equal to the actual amount of protein (grams) per serving multiplied by the amino acid score corrected for protein digestibility. If the corrected score is above 1.00, then it shall be set at 1.00. The protein digestibility-corrected amino acid score shall be determined by methods given in sections 5.4.1, 7.2.1, and 8.00 in “Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation,” except that when official AOAC procedures described in paragraph (c)(7) of this section require a specific factor other than 6.25, that specific factor shall be used.

For products represented or purported to be specifically for infants through 12 months, the corrected amount of protein (grams) per serving is equal to the actual amount of protein (grams) per serving multiplied by the relative protein quality value. The relative protein quality value shall be determined by dividing the subject product’s protein PER value by the PER value for casein. If the relative protein value is above 1.00, it shall be set at 1.00.

(iii) For the purpose of labeling with a percent of the DRV or RDI, a value of 50 grams of protein shall be the DRV for adults and children 4 or more years of age, a value of 11 grams of protein shall be the RDI for infants through 12 months, a value of 13 grams shall be the DRV for children 1 through 3 years of age, and a value of 71 grams of protein shall be the RDI for pregnant women and lactating women.

(8) Vitamins and minerals: The requirements related to including a statement of the amount per serving of vitamins and minerals are described in this paragraph (c)(8).

(i) For purposes of declaration of percent of Daily Value as provided for in paragraphs (d) through (g) of this section, products represented or purported to be specifically for infants through 12 months, children 1 through 3 years, pregnant women and lactating women shall use the RDIs that are specified for the intended group. For products represented or purported to be specifically for both infants through 12 months and children 1 through 3 years of age, the percent of Daily Value shall be presented by separate declarations according to paragraph (e) of this section based on the RDI values for infants through 12 months and for children 1 through 3 years of age. When such dual declaration is used on any label, it shall be included in all labeling, and equal prominence shall be given to both values in all such labeling. The

percent Daily Value based on the RDI values for pregnant women and lactating women shall be declared on food represented or purported to be specifically for pregnant women and lactating women. All other products shall use the RDI for adults and children 4 or more years of age.

(ii) The declaration of vitamins and minerals as a quantitative amount by weight and percent of the RDI shall include vitamin D, calcium, iron, and potassium in that order, for infants through 12 months, children 1 through 3 years of age, pregnant women, lactating women, and adults and children 4 or more years of age. The declaration of folic acid shall be included as a quantitative amount by weight when added or a claim is made about the nutrient. The declaration of vitamins and minerals in a food as a quantitative amount by weight and percent of the RDI, may include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section. The declaration of vitamins and minerals shall include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section as a statement of the amount per serving of the vitamins and minerals as described in this paragraph, calculated as a percent of the RDI and expressed as a percent of the Daily Value, when they are added, or when a claim is made about them, unless otherwise stated as quantitative amount by weight and percent of the Daily Value. Other vitamins and minerals need not be declared if neither the nutrient nor the component is otherwise referred to on the label or in labeling and the vitamins and minerals are:

(A) Required or permitted in a standardized food (e.g., thiamin, riboflavin, and niacin in enriched flour) and that standardized food is included as an ingredient (i.e., component) in another product; or

(B) Included in a product solely for technological purposes and declared only in the ingredients statement. The declaration may also include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are naturally occurring in the food. The additional vitamins and minerals shall be listed in the order established in paragraph (c)(8)(iv) of this section.

(iii) The percentages for vitamins and minerals shall be expressed to the nearest 2-percent increment up to and including the 10-percent level, the nearest 5-percent increment above 10 percent and up to and including the 50-percent level, and the nearest 10-percent increment above the 50-percent level. Quantitative amounts and percentages

of vitamins and minerals present at less than 2 percent of the RDI are not required to be declared in nutrition labeling but may be declared by a zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table and that is followed by the statement "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients) or "Contains <2 percent of the Daily Value of this (these) nutrients." Alternatively, except as provided for in paragraph (f) of this section, if vitamin D, calcium, iron, or potassium is present in amounts less

than 2 percent of the RDI, label declaration of the nutrient(s) is not required if the statement "Not a significant source of ____ (listing the vitamins or minerals omitted)" is placed at the bottom of the table of nutrient values. Either statement shall be in the same type size as nutrients that are indented. The quantitative amounts of vitamins and minerals, excluding sodium, shall be the amount of the vitamin or mineral included in one serving of the product, using the units of measurement and the levels of significance given in paragraph (c)(8)(iv) of this section, except that zeros

following decimal points may be dropped, and additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts (e.g., the RDI for zinc is given in whole milligrams, but the quantitative amount may be declared in tenths of a milligram).

(iv) The following RDIs, nomenclature, and units of measure are established for the following vitamins and minerals which are essential in human nutrition:

| Nutrient | Unit of measure | RDI | | | |
|-------------------------------|---|------------------------------|--|----------------------------|------------------------------------|
| | | Adults and children ≥4 years | Infants ¹ through 12 months | Children 1 through 3 years | Pregnant women and lactating women |
| Vitamin A | Micrograms RAE ² (mcg) | 900 | 500 | 300 | 1,300 |
| Vitamin C | Milligrams (mg) | 90 | 50 | 15 | 120 |
| Calcium | Milligrams (mg) | 1,300 | 260 | 700 | 1,300 |
| Iron | Milligrams (mg) | 18 | 11 | 7 | 27 |
| Vitamin D | Micrograms (mcg) ³ | 20 | 10 | 15 | 15 |
| Vitamin E | Milligrams (mg) ⁴ | 15 | 5 | 6 | 19 |
| Vitamin K | Micrograms (mcg) | 120 | 2.5 | 30 | 90 |
| Thiamin | Milligrams (mg) | 1.2 | 0.3 | 0.5 | 1.4 |
| Riboflavin | Milligrams (mg) | 1.3 | 0.4 | 0.5 | 1.6 |
| Niacin | Milligrams NE ⁵ (mg) | 16 | 4 | 6 | 18 |
| Vitamin B ₆ | Milligrams (mg) | 1.7 | 0.3 | 0.5 | 2.0 |
| Folate ⁶ | Micrograms DFE ⁷ (mcg) | 400 | 80 | 150 | 600 |
| Vitamin B ₁₂ | Micrograms (mcg) | 2.4 | 0.5 | 0.9 | 2.8 |
| Biotin | Micrograms (mcg) | 30 | 6 | 8 | 35 |
| Pantothenic acid | Milligrams (mg) | 5 | 1.8 | 2 | 7 |
| Phosphorus | Milligrams (mg) | 1,250 | 275 | 460 | 1,250 |
| Iodine | Micrograms (mcg) | 150 | 130 | 90 | 290 |
| Magnesium | Milligrams (mg) | 420 | 75 | 80 | 400 |
| Zinc | Milligrams (mg) | 11 | 3 | 3 | 13 |
| Selenium | Micrograms (mcg) | 55 | 20 | 20 | 70 |
| Copper | Milligrams (mg) | 0.9 | 0.2 | 0.3 | 1.3 |
| Manganese | Milligrams (mg) | 2.3 | 0.6 | 1.2 | 2.6 |
| Chromium | Micrograms (mcg) | 35 | 5.5 | 11 | 45 |
| Molybdenum | Micrograms (mcg) | 45 | 3 | 17 | 50 |
| Chloride | Milligrams (mg) | 2,300 | 570 | 1,500 | 2,300 |
| Potassium | Milligrams (mg) | 4,700 | 700 | 3,000 | 5,100 |
| Choline | Milligrams (mg) | 550 | 150 | 200 | 550 |
| Protein | Grams (g) | N/A | 11 | N/A | ⁸ 71 |

¹ RDIs are based on dietary reference intake recommendations for infants through 12 months of age.

² RAE = Retinol activity equivalents; 1 microgram RAE = 1 microgram retinol, 2 micrograms supplemental β-carotene, 12 micrograms β-carotene, or 24 micrograms α-carotene, or 24 micrograms β-cryptoxanthin.

³ The amount of vitamin D may, but is not required to, be expressed in international units (IU), in addition to the mandatory declaration in mcg. Any declaration of the amount of vitamin D in IU must appear in parentheses after the declaration of the amount of vitamin D in mcg.

⁴ 1 mg α-tocopherol (label claim) = 1 mg α-tocopherol = 1 mg RRR- α-tocopherol = 2 mg *all* *rac*-α-tocopherol.

⁵ NE = Niacin equivalents, 1 mg NE = 1 mg niacin = 60 milligrams tryptophan.

⁶ "Folate" and "Folic Acid" must be used for purposes of declaration in the labeling of conventional foods and dietary supplements. The declaration for folate must be in mcg DFE (when expressed as a quantitative amount by weight in a conventional food or a dietary supplement), and percent DV based on folate in mcg DFE. Folate may be expressed as a percent DV in conventional foods. When folic acid is added or when a claim is made about the nutrient, folic acid must be declared in parentheses, as mcg of folic acid.

⁷ DFE = Dietary Folate Equivalents; 1 DFE = 1 mcg naturally-occurring folate = 0.6 mcg folic acid.

⁸ Based on the reference caloric intake of 2,000 calories for adults and children aged 4 years and older, and for pregnant women and lactating women.

(v) The following synonyms may be added in parenthesis immediately following the name of the nutrient or dietary component:

Calories—Energy

Vitamin C—Ascorbic acid

Thiamin—Vitamin B₁

Riboflavin—Vitamin B₂

(vi) A statement of the percent of vitamin A that is present as *beta*-carotene may be declared voluntarily. When the vitamins and minerals are

listed in a single column, the statement shall be indented under the information on vitamin A. When vitamins and minerals are arrayed horizontally, the statement of percent shall be presented in parenthesis following the declaration

of vitamin A and the percent of Daily Value of vitamin A in the product (e.g., “Percent Daily Value: Vitamin A 50 (90 percent as beta-carotene)”). When declared, the percentages shall be expressed in the same increments as are provided for vitamins and minerals in paragraph (c)(8)(iii) of this section.

(vii) When the amount of folate is declared in the labeling of a product the nutrient name “folate” shall be listed for products containing folate (natural

folate, and/or synthetic folate), folic acid, or a mixture of folate and folic acid. The name of the synthetic form of the nutrient “folic acid”, when added or a claim is made about the nutrient, shall be included in parentheses after this declaration with the amount of folic acid. The declaration must be folate in mcg DFE (when expressed as a quantitative amount by weight) and the percent Daily Value based on folate in mcg DFE, or may be expressed as folate

and the percent DV based on folate in mcg DFE. When declared, folic acid must be in parentheses, mcg of folic acid as shown in paragraph (d)(12) of this section in the display that illustrates voluntary declaration of nutrition information.

(9) The following DRVs, nomenclature, and units of measure are established for the following food components:

| Food component | Unit of measurement | DRV | | | |
|-----------------------------|-----------------------|------------------------------|---------------------------|----------------------------|------------------------------------|
| | | Adults and children ≥4 years | Infants through 12 months | Children 1 through 3 years | Pregnant women and lactating women |
| Fat | Grams (g) | 178 | 30 | 239 | 178 |
| Saturated fatty acids | Grams (g) | 120 | N/A | 210 | 120 |
| Cholesterol | Milligrams (mg) | 300 | N/A | 300 | 300 |
| Total carbohydrate | Grams (g) | 1275 | 95 | 2150 | 1275 |
| Sodium | Milligrams (mg) | 2,300 | N/A | 1,500 | 2,300 |
| Dietary fiber | Grams (g) | 128 | N/A | 214 | 128 |
| Protein | Grams (g) | 150 | N/A | 213 | N/A |
| Added Sugars | Grams (g) | 150 | N/A | 225 | 150 |

¹ Based on the reference caloric intake of 2,000 calories for adults and children aged 4 years and older, and for pregnant women and lactating women.

² Based on the reference caloric intake of 1,000 calories for children 1 through 3 years of age.

(d)(1) Nutrient information specified in paragraph (c) of this section shall be presented on products in the following format, as shown in paragraph (d)(12) of this section, except on foods where the horizontal display is permitted as provided for in paragraph (d)(11) of this section, on which dual columns of nutrition information are declared as provided for in paragraph (e) of this section, on those food products on which the simplified format is permitted to be used as provided for in paragraph (f) of this section, on foods for infants through 12 months of age and children 1 through 3 years of age as provided for in § 413.400(c), and on foods in small or intermediate-sized packages as provided for in paragraph (g) of this section.

(i) The nutrition information shall be set off in a box by use of hairlines and shall be all black or one color type, printed on a white or other neutral contrasting background whenever practical.

(ii) All information within the nutrition label shall utilize:

(A) A single easy-to-read type style,

(B) Upper and lower case letters,

(C) At least one point leading (*i.e.*, space between two lines of text) except that at least four points leading shall be utilized for the information required by paragraphs (d)(7) and (d)(8) of this section, and

(D) Letters should never touch.

(iii) Information required in paragraphs (d)(7) and (d)(8) of this section shall be in type size no smaller than 8 point. Information required in paragraph (d)(5) of this section for the “Calories” declaration shall be highlighted in bold or extra bold and shall be in a type size no smaller than 16 point except the type size for this information required in the tabular displays as shown in paragraphs (d)(11)(iii), (e)(6)(ii), and (g)(1)(i)(A) of this section, and the linear display for small packages as shown in paragraph (g)(1)(i)(B) of this section shall be in a type size no smaller than 10 point. The numeric amount for the information required in paragraph (d)(5) of this section shall also be highlighted in bold or extra bold type and shall be in a type size no smaller than 22 point, except the type size for this information required for the tabular display for small packages as shown in paragraph (g)(1)(i)(A) of this section, and for the linear display for small packages as shown in paragraph (g)(1)(i)(B) of this section no smaller than 14 point. The information required in paragraph (d)(9) of this section shall be in a type size no smaller than 6 point. When provided, the information described in paragraph (d)(10) of this section shall be in a type size no smaller than 6 point.

(iv) The headings required by paragraphs (d)(2), (d)(3)(ii), (d)(4), and (d)(6) of this section (*i.e.*, “Nutrition

Facts,” “Serving Size,” “Amount per serving,” and “% Daily Value”), the names of all nutrients that are not indented according to requirements of paragraph (c) of this section (*i.e.*, “Calories,” “Total Fat,” “Cholesterol,” “Sodium,” “Total Carbohydrate” and “Protein”), and the percentage amounts required by paragraph (d)(7)(ii) of this section shall be highlighted in bold or extra bold type or other highlighting (reverse printing is not permitted as a form of highlighting) that prominently distinguishes it from other information. No other information shall be highlighted.

(v) A hairline rule that is centered between the lines of text shall separate “Nutrition Facts” from the servings per container statement required in paragraph (d)(3)(i) of this section, and shall separate each nutrient and its corresponding percent of Daily Value required in paragraphs (d)(7)(i) and (d)(7)(ii) of this section from the nutrient and percent of Daily Value above and below it, as shown in paragraph (d)(12) of this section.

(2) The information shall be presented under the identifying heading of “Nutrition Facts” which shall be set in a type size no smaller than all other print size in the nutrition label except for the numerical information for “Calories” required in paragraph (d)(5) of this section, and except for labels presented according to the format provided for in paragraphs (d)(11)(iii),

(d)(13)(ii), (e)(6)(ii), (g)(1)(i)(A) and (g)(1)(i)(B) of this section, unless impractical, shall be set the full width of the information provided under paragraph (d)(7) of this section, as shown in paragraph (d)(12) of this section.

(3) Information on servings per container and serving size shall immediately follow the heading as shown in paragraph (d)(12) of this section. Such information shall include:

(i) “___ servings per container”: The number of servings per container, except that this statement is not required on single-serving containers as defined in paragraph (b)(8) of this section or on single-ingredient, raw products that are not ground or chopped products described in § 413.301. The information required in this paragraph shall be located immediately after the “Nutrition Facts” heading and shall be in a type size no smaller than 10 point, except the type size for this information shall be no smaller than 9 point in the tabular display for small packages as shown in paragraph (g)(1)(i)(A) of this section and the linear display for small packages as shown in paragraph (g)(1)(i)(B) of this section. For the linear display for small packages as shown in paragraph (g)(1)(i)(B) of this section, the actual number of servings may be listed after the servings per container declaration.

(ii) “Serving size”: A statement of the serving size as specified in paragraph (b)(9) of this section shall immediately follow the “___ servings per container” declaration. The information required in this paragraph shall be highlighted in bold or extra bold and be in a type size no smaller than 10 point except the type size shall be no smaller than 9 point for this information in the tabular displays as shown in paragraphs (d)(11) and (e)(6)(ii) of this section, the tabular display for small packages as shown in (g)(1)(i)(A) of this section, and the linear display for small packages as shown in paragraph (g)(1)(i)(B) of this section. The serving size amount must be right justified if adequate space is available. If the “Serving size” declaration does not fit in the allocated space a type size of no smaller than 8 point may be used on packages of any size.

(4) A subheading “Amount per serving” shall be separated from serving size information by a bar as shown in paragraph (d)(12) of this section, except this information is not required for the dual column formats shown in paragraphs (e)(5), (e)(6)(i), and (e)(6)(ii) of this section. “Per ___” (e.g., per ½ a burrito)” is required for dual column formats.

(5) Information on calories shall immediately follow the subheading “Amount per serving” and shall be declared in one line. If “Calories from saturated fat” is declared, it shall be indented under “Calories” and shall be in a type size no smaller than 8 point.

(6) The column heading “% Daily Value,” followed by an asterisk (e.g., “% Daily Value*”), shall be separated from information on calories by a bar as shown in paragraph (d)(12) of this section. The position of this column heading shall allow for a list of nutrient names and amounts as described in paragraph (d)(7) of this section to be to the left of, and below, this column heading. The column headings “Percent Daily Value,” “Percent DV,” or “% DV” may be substituted for “% Daily Value.”

(7) Except as provided for in paragraph (g)(1)(i)(B) of this section, and except as permitted by § 413.400(d)(2), nutrient information for both mandatory and any voluntary nutrients listed in paragraph (c) of this section that are to be declared in the nutrition label, except for folic acid in conventional food and voluntarily declared vitamins and minerals expressed as a statement of the amount per serving calculated as a percent of the RDI and expressed as a percent Daily Value, shall be declared as follows:

(i) The name of each nutrient, as specified in paragraph (c) of this section, shall be given in a column and followed immediately by the quantitative amount by weight for that nutrient appended with a “g” for grams or “mg” for milligrams, or “mcg” for micrograms as shown in paragraph (d)(12) of this section. The symbol “<” may be used in place of “less than”.

(ii) A listing of the percent of the DRV as established in paragraphs (c)(7)(iii) and (c)(9) of this section shall be given in a column aligned under the heading “% Daily Value” established in paragraph (d)(6) of this section with the percent expressed to the nearest whole percent for each nutrient declared in the column described in paragraph (d)(7)(i) of this section for which a DRV has been established, except that the percent for protein may be omitted as provided in paragraph (c)(7) of this section. The percent shall be calculated by dividing either the amount declared on the label for each nutrient or the actual amount of each nutrient (*i.e.*, before rounding) by the DRV for the nutrient, except that the percent for protein shall be calculated as specified in paragraph (c)(7)(ii) of this section. The numerical value shall be followed by the symbol for percent (*i.e.*, %).

(8) Nutrient information for vitamins and minerals (except sodium) shall be

separated from information on other nutrients by a bar and shall be arrayed vertically as shown in paragraph (d)(12) of this section (e.g., Vitamin D 2 mcg 10%, Calcium 260 mg 20%, Iron 8 mg 45%, Potassium 235 mg 6%) or may be listed horizontally. When listed horizontally in two columns, vitamin D and calcium should be listed on the first line and iron and potassium should be listed on the second line as shown in paragraph (d)(12) of this section in the side-by-side display. When more than four vitamins and minerals are declared voluntarily as shown in paragraph (d)(12) of this section in the label which illustrates the mandatory plus voluntary provisions of paragraph (d) of this section, they may be declared vertically with percentage listed under the column headed “% Daily Value.”

(9) A footnote, preceded by an asterisk, shall be placed beneath the list of vitamins and minerals and shall be separated from the list by a bar, except that the footnote may be omitted from foods that can use the terms “calorie free,” “free of calories,” “no calories,” “zero calories,” “without calories,” “trivial source of calories,” “negligible source of calories,” or “dietarily insignificant source of calories” on the label or in the labeling of foods as defined in 9 CFR 413.360(b). The first sentence of the footnote: “The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet” may be used on foods than can use the terms “calorie free,” “free of calories,” “no calories,” “zero calories,” “without calories,” “trivial source of calories,” “negligible source of calories,” or “dietarily insignificant source of calories” on the label or in the labeling of foods as defined in 9 CFR 413.360(b). The footnote shall state: “*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.” If the food product is represented or purported to be for children 1 through 3 years of age, the second sentence of the footnote shall substitute “1,000 calories” for “2,000 calories”.

(10) Caloric conversion information on a per gram basis for fat, carbohydrate, and protein may be presented beneath the information required in paragraph (d)(9), separated from that information by a hairline. This information may be presented horizontally (*i.e.* “Calories per gram: Fat 9, Carbohydrate 4, Protein 4”) or vertically in columns.

(11)(i) If the space beneath the information on vitamins and minerals is not adequate to accommodate the information required in paragraph (d)(9)

of this section, the information required in paragraph (d)(9) may be moved to the right of the column required in paragraph (d)(7)(ii) of this section and set off by a line that distinguishes it and sets it apart from the percent of Daily Value information. The caloric conversion information provided for in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(ii) If the space beneath the mandatory declaration of potassium is not adequate to accommodate any remaining vitamins and minerals to be declared or the information required in paragraph (d)(9) of this section, the remaining information may be moved to the right and set off by a line that distinguishes it and sets it apart from the nutrients and the percent of DV information given to the left. The caloric conversion information provided for in paragraph

(d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(iii) If there is not sufficient continuous vertical space (*i.e.*, approximately 3 inches) to accommodate the required components of the nutrition label up to and including the mandatory declaration of potassium, the nutrition label may be presented in a horizontal display as shown in the following sample label.

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(12) The following sample labels illustrate the mandatory provisions and mandatory plus voluntary provisions of

paragraph (d) of this section and the side-by-side display:

| Nutrition Facts | |
|------------------------------|---------------------|
| 8 servings per container | |
| Serving size | 1 cup (245g) |
| Amount per serving | |
| Calories | 60 |
| % Daily Value* | |
| Total Fat 1.5g | 2% |
| Saturated Fat 0.5g | 0% |
| Trans Fat 0g | |
| Cholesterol 10mg | 4% |
| Sodium 560mg | 24% |
| Total Carbohydrate 9g | 3% |
| Dietary Fiber 0g | 0% |
| Total Sugars less than 1gram | |
| Includes 0g Added Sugars | 0% |
| Protein 2g | |
| Vitamin D 0mcg | 0% |
| Calcium 0mcg | 0% |
| Iron 0.5mcg | 2% |
| Potassium 0mcg | 0% |

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to daily diet. 2,000 calories a day is used for general nutrition advice.

| Nutrition Facts | |
|---------------------------------------|----------------------|
| 17 servings per container | |
| Serving size | 3/4 cup (28g) |
| Amount per serving | |
| Calories | 140 |
| % Daily Value* | |
| Total Fat 1.5g | 2% |
| Saturated Fat 0g | 0% |
| Trans Fat 0g | |
| Polyunsaturated Fat 0.5g | |
| Monounsaturated Fat 0.5g | |
| Cholesterol 0mg | 0% |
| Sodium 160mg | 7% |
| Total Carbohydrate 22g | 8% |
| Dietary Fiber 2g | 7% |
| Soluble Fiber <1g | |
| Insoluble Fiber 1g | |
| Total Sugars 9g | |
| Includes 8g Added Sugars | 16% |
| Protein 9g | 18% |
| Vitamin D 2mcg (80 IU) | 10% |
| Calcium 130mg | 10% |
| Iron 4.5mg | 25% |
| Potassium 115mg | 2% |
| Vitamin A 90mcg | 10% |
| Vitamin C 9mg | 10% |
| Thiamin 0.3mg | 25% |
| Riboflavin 0.3mg | 25% |
| Niacin 4mg | 25% |
| Vitamin B ₆ 0.4mg | 25% |
| Folate 200mcg DFE (120mcg folic acid) | 50% |
| Vitamin B ₁₂ 0.6mcg | 25% |
| Phosphorus 100mg | 8% |
| Magnesium 25mg | 6% |
| Zinc 3mg | 25% |

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

(13)(i) Nutrition labeling on the outer label of packages of products that contain two or more products in the same packages (e.g., variety packs) or of packages that are used interchangeably for the same type of food (e.g., meat salad containers, poultry salad

containers) may use an aggregate display.

(ii) Aggregate displays shall comply with format requirements of paragraph (d) of this section to the maximum extent possible, except that the identity of each food shall be specified to the right of the "Nutrition Facts" heading,

and both the quantitative amount by weight (i.e., g/mg/mcg amounts) and the percent Daily Value for each nutrient shall be listed in separate columns under the name of each food. The following sample label illustrates an aggregate display.

| Nutrition Facts | | Smoked Beef Sausage | Smoked Pork Sausage | Smoked Turkey Sausage |
|---|------------------------|----------------------------|----------------------------|------------------------------|
| 8 servings per container | | | | |
| Serving size | 1 link | (34g) | (34g) | (34g) |
| Amount per serving | | | | |
| Calories | | 340 | 260 | 130 |
| | % Daily Value* | % Daily Value* | % Daily Value* | % Daily Value* |
| Total Fat | 32g 41% | 24g 31% | 7g 9% | |
| Saturated Fat | 13g 65% | 8g 40% | 3g 15% | |
| Trans Fat | 0.5g | 0g | 0g | |
| Cholesterol | 70mg 23% | 50mg 17% | 45mg 15% | |
| Sodium | 700mg 30% | 700mg 30% | 1000mg 43% | |
| Total Carbohydrate | 0g 0% | 0g 0% | 0g 0% | |
| Dietary Fiber | 0g 0% | 0g 0% | 0g 0% | |
| Total Sugars | 0g | 1g | 3g | |
| Includes Added Sugars | 0g 0% | 1g 2% | 3g 6% | |
| Protein | 13g | 10g | 13g | |
| * The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice. | | | | |
| | Vitamin D | 0.5mc 2% | 0.9mcg 4% | 0mcg 0% |
| | Calcium | 0mg 0% | 0mg 0% | 0mg 0% |
| | Iron | 1.3mg 8% | 0.5mg 2% | 8mg 45% |
| | Potassium | 200mg 4% | 410mg 8% | 170mg 4% |
| | Vitamin A | 2% | 0% | 4% |
| | Vitamin C | 0% | 0% | 2% |
| | Thiamin | 0% | 15% | 8% |
| | Riboflavin | 8% | 15% | 8% |
| | Niacin | 15% | 15% | 20% |
| | Vitamin B ₆ | 10% | 10% | 20% |

(14) When nutrition labeling appears in a second language, the nutrition information may be presented in a separate nutrition label for each language or in one nutrition label with the information in the second language following that in English. Numeric characters that are identical in both languages need not be repeated (e.g., "Protein/Proteínas 2 g"). All required information must be included in both languages.

(e) Nutrition information may be presented for two or more forms of the same product (e.g., both "as purchased" and "as prepared") or for common combinations of foods as provided for in paragraph (b) of this section, for different units (e.g., per nugget or per 100 grams) as provided for in paragraph (b) of this section, or for two or more groups for which RDIs are established (e.g., both infants through 12 months of age and children 1 through 3 years of age) as shown in paragraph (c)(8)(i) of this section. When such dual labeling is

provided, equal prominence shall be given to both sets of values. Information shall be presented in a format consistent with paragraph (d) of this section, except that:

(1) Following the serving size information there shall be two or more column headings accurately describing the amount per serving size of the form of the same product (e.g., "raw" and "roasted"), the combinations of foods, the units, or the RDI groups that are being declared as shown in paragraph (e)(5) of this section.

(2) The quantitative information by weight as required in paragraph (d)(7)(i) and the information required in (d)(7)(ii) of this section shall be presented for the form of the product as packaged and for any other form of the product (e.g., "as prepared" or combined with another ingredient as shown in paragraph (e)(5) of this section) but may be on the basis of 'as consumed' for single-ingredient, raw products that are not ground or chopped products described in

§ 413.301, and according to the label serving size based on the Reference Amount in § 413.312(b).

(3) When the dual labeling is presented for two or more forms of the same food, for combinations of food, for different units, or for two or more groups for which RDIs are established, quantitative information by weight and the percent Daily Value shall be presented in two columns and the columns shall be separated by vertical lines as shown in paragraph (e)(5) of this section.

(4) Nutrient information for vitamins and minerals (except sodium) shall be separated from information on other nutrients by a bar and shall be arrayed vertically in the following order: Vitamin D, calcium, iron, potassium as shown in paragraph (e)(5) of this section.

(5) The following sample label illustrates the provisions of paragraph (e) of this section:

| Nutrition Facts | | | |
|---|------------------------|------------|----------------------------|
| 8 servings per container | | | |
| Serving Size 4oz (112g, about 84g braised) | | | |
| | Per raw portion | | Per braised portion |
| Calories | 220 | | 210 |
| | % DV* | | % DV* |
| Total Fat | 17g | 22% | 16g 21% |
| Saturated Fat | 5g | 25% | 5g 25% |
| Trans Fat | 0g | | 0g |
| Cholesterol | 60mg | 20% | 80mg 27% |
| Sodium | 1360mg | 59% | 830mg 36% |
| Total Carb. | 0g | 0% | 0g 0% |
| Dietary Fiber | 0g | 0% | 0g 0% |
| Total Sugars | 0g | | 0g |
| Incl. Added Sugars | 0g | 0% | 0g 0% |
| Protein | 17g | | 15g |
| Vitamin D | 0mcg | 0% | 0mcg 0% |
| Calcium | 0mg | 0% | 0mg 0% |
| Iron | 1.9mg | 10% | 1.6mg 8% |
| Potassium | 330mg | 8% | 120mg 2% |

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

(6) When dual labeling is presented for a food on a per serving basis and per container basis as required in paragraph (b)(16)(i) of this section or on a per serving basis and per unit basis as required in paragraph (b)(4)(iv) of this section, the quantitative information by

weight as required in (d)(7)(i) and the percent Daily Value as required in paragraph (d)(7)(ii) shall be presented in two columns, and the columns shall be separated by vertical lines as shown in the displays in paragraph (e)(6)(i) of this section.

(i) Nutrient information for vitamins and minerals shall be separated from information on other nutrients by a bar and shall be arrayed vertically in the following order: Vitamin D, calcium, iron, and potassium as shown in the following sample labels.

| Nutrition Facts | | | |
|--|------------------------|------------|----------------------|
| 12 servings per container | | | |
| Serving Size 1/2 burrito (139g) | | | |
| | Per 1/2 burrito | | Per 1 burrito |
| Calories | 330 | | 660 |
| | % DV* | | % DV* |
| Total Fat | 13g | 17% | 27g 35% |
| Saturated Fat | 4g | 20% | 8g 40% |
| Trans Fat | 0g | | 0.5g |
| Cholesterol | 10mg | 3% | 20mg 7% |
| Sodium | 820mg | 36% | 1630mg 71% |
| Total Carb. | 43g | 16% | 86g 43% |
| Dietary Fiber | 6g | 21% | 12g 43% |
| Total Sugars | 4g | | 8g |
| Incl. Added Sugars | 1g | 2% | 2g 4% |
| Protein | 10g | | 20g |
| Vitamin D | 0mcg | 0% | 0mcg 0% |
| Calcium | 40mg | 4% | 80mg 6% |
| Iron | 2mg | 10% | 4mg 20% |
| Potassium | 190mg | 4% | 380mg 8% |

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

| Nutrition Facts | | | |
|----------------------------------|--------------------|------------|----------------------|
| About 2 servings per container | | | |
| Serving Size 1 cup (243g) | | | |
| | Per serving | | Per container |
| Calories | 100 | | 210 |
| | % DV* | | % DV* |
| Total Fat | 3g | 4% | 6g 8% |
| Saturated Fat | 1.5g | 8% | 3g 15% |
| Trans Fat | 0g | | 0g |
| Cholesterol | 12mg | 4% | 26mg 9% |
| Sodium | 740mg | 32% | 1620mg 70% |
| Total Carb. | 10g | 4% | 21g 8% |
| Dietary Fiber | 2g | 7% | 4g 14% |
| Total Sugars | 1g | | 2g |
| Incl. Added Sugars | 0g | 0% | 0g 0% |
| Protein | 8g | | 16g |
| Vitamin D | 0mcg | 0% | 0mcg 0% |
| Calcium | 27mg | 2% | 58mg 4% |
| Iron | 0.9mg | 6% | 1.9mg 10% |
| Potassium | 280mg | 6% | 620mg 15% |

* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

(ii) The following sample label illustrates the provisions of paragraphs (b)(4)(iv) and (b)(16)(i) of this section for

labels that use the dual column format in the horizontal display.

| Nutrition Facts | | Per serving % DV* | | Per container % DV* | | Per serving % DV* | | Per container % DV* | |
|------------------------------|--|----------------------|-----|------------------------|-----|----------------------|--|------------------------|-----|
| 2 servings per container | | | | | | | | | |
| Serving size 1 cup (255g) | | | | | | | | | |
| Calories | | | | | | | | | |
| 220 | | | | | | | | | |
| per serving | | | | | | | | | |
| 440 | | | | | | | | | |
| per container | | | | | | | | | |
| Total Fat | | 5g | 6% | 10g | 13% | Total Carb. | | 35g | 13% |
| Saturated Fat | | 2g | 10% | 4g | 20% | Dietary Fiber | | 6g | 21% |
| Trans Fat | | 0g | | 0g | | Total Sugars | | 7g | |
| Cholesterol | | 15mg | 5% | 30mg | 10% | Incl. Added Sugars | | 4g | 8% |
| Sodium | | 240mg | 10% | 480mg | 21% | Protein | | 9g | |
| Vitamin D | | 5mcg | 25% | 10mcg | 50% | Iron | | 1mg | 5% |
| Calcium | | 200mg | 15% | 400mg | 30% | Potassium | | 470mg | 10% |
| | | | | | | | | 940mg | 20% |

*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,500 calories a day is used for general nutrition advice.

(f)(1) The declaration of nutrition information may be presented in the simplified format as set forth herein when any required nutrients, other than the core nutrients (*i.e.*, calories, total fat, sodium, total carbohydrate, and protein), are present in insignificant amounts. An insignificant amount shall be defined as that amount that may be rounded to zero in nutrition labeling, except that for total carbohydrate, dietary fiber, total sugars, added sugars, and protein, it shall be an amount less than 1 gram.

(2) The simplified format shall include information on the following nutrients:

(i) Total calories, total fat, sodium, total carbohydrate, and protein;

(ii) Any of the following that are present in more than insignificant amounts: saturated fat, *trans* fat, cholesterol, dietary fiber, total sugars, added sugars, vitamin D, calcium, iron, and potassium; and

(iii) Any vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are added in fortified or fabricated foods.

(3) Other nutrients that are naturally present in the product in more than insignificant amounts may be voluntarily declared as part of the simplified format.

(4) Any required nutrient, other than a core nutrient, that is present in an insignificant amount may be omitted from the columnar listing, provided that the following statement is included at the bottom of the nutrition label, "Not a significant source of ____." The blank shall be filled in with the appropriate nutrient or food component. Alternatively, amounts of vitamins and minerals present in insignificant amounts may be declared by the use of

an asterisk (or symbol) that is placed at the bottom of the table of nutrient values and that is followed by the statement "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)."

(5) Except as provided for in paragraph (g) of this section and in § 413.400(c) and (d), nutrient information declared in the simplified format shall be presented in the same manner as specified in paragraphs (d) or (e) of this section, except that the footnote required in paragraph (d)(9) of this section is not required, and an asterisk shall be placed at the bottom of the label followed by the statement "%DV = %Daily Value" when "Daily Value" is not spelled out in the heading, as shown in the following example that illustrates the simplified display

| Nutrition Facts | |
|---|------------|
| 64 servings per container | |
| Serving size 1 tbsp (14g) | |
| Amount per serving | |
| Calories | 130 |
| | % DV* |
| Total Fat 14g | 18% |
| Saturated Fat 2g | 10% |
| Trans Fat 2g | |
| Polyunsaturated Fat 4g | |
| Monounsaturated Fat 6g | |
| Sodium 0mg | 0% |
| Total Carbohydrate 0g | 0% |
| Protein 0g | |
| Not a significant source of cholesterol, dietary fiber, total sugars, added sugars, vitamin D, calcium, iron, and potassium | |
| * %DV = %Daily Value | |

(g) Foods in packages that have a total surface area available to bear labeling of 40 or less square inches may modify the requirements of paragraphs (c) through (f) of this section and § 413.302(a) by one or more of the following means:

(1)(i) Presenting the required nutrition information in a tabular or linear fashion, rather than in vertical columns if the product has a total surface area available to bear labeling of less than 12 square inches, or if the product has a total surface area available to bear labeling of 40 or less square inches and the package shape or size cannot accommodate a standard vertical column or tabular display on any label panel. Nutrition information may be given in a linear fashion only if the package shape or size will not accommodate a tabular display.

(A) The following sample label illustrates the tabular display for small packages.

| Nutrition Facts | Amount/serving | % DV* | Amount/serving | % DV* |
|---|---|-----------|------------------------|------------|
| | Total Fat 2g | 3% | Total Carb. 15g | 5% |
| 5 servings per container | Sat. Fat 1g | 5% | Fiber 0g | 0% |
| Serving size 1/6 cup (28g) | Trans Fat 0.5g | | Total Sugars 14g | |
| Calories 90 | Cholesterol 10mg | 3% | Incl. 13g Added Sugars | 26% |
| | Sodium 200mg | 9% | Protein 3g | |
| | Vitamin D 0% • Calcium 6% • Iron 6% • Potassium 10% | | | |

(B) The following sample label illustrates the linear display.

Nutrition Facts Serv. size: 1 package,

Amount per serving: **Calories 140**, **Total Fat** 12g (15% DV), Sat. Fat 5g (25% DV), Trans Fat 0g, **Cholest.** 30mg (10% DV), **Sodium** 500mg (22% DV), **Total Carb.** 0g (0% DV), Fiber 0g (0% DV), Total Sugars 0g (Incl. 0g Added Sugars, 0% DV), **Protein** 6g, Vit. D (0% DV), Calcium (0% DV), Iron (2% DV), Potassium (2% DV).

(2) Using any of the following abbreviations:

Serving size—Serv size
Servings per container—Servings
Calories from saturated fat—Sat fat cal
Saturated fat—Sat fat
Monounsaturated fat—Monounsaturated fat
Polyunsaturated fat—Polyunsaturated fat
Cholesterol—Cholest

Total carbohydrate—Total carb. This abbreviation can also be used on dual column displays as shown in paragraphs (e)(5), (e)(6)(i), and (e)(6)(ii).

Dietary fiber—Fiber
Soluble fiber—Sol fiber
Insoluble fiber—Insol fiber
Sugar alcohol—Sugar alc
Vitamin—Vit
Potassium—Potas

Includes—Incl. This abbreviation can also be used on dual column displays as shown in paragraphs (e)(5), (e)(6)(i), and (e)(6)(ii) of this section.

(3) Omitting the footnote statement and placing another asterisk at the bottom of the label followed by the statement “%DV=%Daily Value.”

(4) Presenting the required nutrition information on any other label panel.

(h) Compliance with this section shall be determined as follows:

(1) A production lot is a set of food production consumer units that are from one production shift. Alternatively, a collection of consumer units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, constitutes a production lot.

(2) The sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each

from a production lot. Alternatively, the sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each randomly chosen to be representative of a production lot. In each case, the units may be individually analyzed and the results of the analyses averaged, or the units would be composited and the composite analyzed. In both cases, the results, whether an average or a single result from a composite, will be considered by the Agency to be the nutrient content of a composite. All analyses shall be performed by appropriate methods and procedures used by the Department for each nutrient in accordance with the “Chemistry Laboratory Guidebook,” or, if no USDA method is available and appropriate for the nutrient, by appropriate methods for the nutrient in accordance with the 2016 edition of the “Official Methods of Analysis” of the AOAC International, unless a particular method of analysis is specified in § 413.309(c), or, if no USDA, AOAC, or specified method is available and appropriate, by other reliable and appropriate analytical procedures as so determined by the Agency.

(3) Two classes of nutrients are defined for purposes of compliance:

(i) Class I. Added nutrients in fortified or fabricated foods; and

(ii) Class II. Naturally occurring (indigenous) nutrients. When a nutrient is naturally occurring (indigenous) in a food or an ingredient that is added to a food, the total amount of such nutrient in the final food product is subject to Class II requirements, except that when an exogenous source of the nutrient is also added to the final food product, the

total amount of the nutrient in the final food product (indigenous and exogenous) is subject to Class I requirements.

(4) A product with a label declaration of a vitamin, mineral, protein, total carbohydrate, dietary fiber, soluble fiber, insoluble fiber, polyunsaturated or monounsaturated fat shall be deemed to be misbranded under section 1(n) of the Federal Meat Inspection Act (21 U.S.C. 601(n)(1)) or 4(h) of the Poultry Products Inspection Act (21 U.S.C. 453(h)) unless it meets the following requirements:

(i) When a vitamin, mineral, protein, or dietary fiber meets the definition of a Class I nutrient, the nutrient content of the composite must be formulated to be at least equal to the value for that nutrient declared on the label.

(ii) When a vitamin, mineral, protein, total carbohydrate, polyunsaturated or monounsaturated fat, dietary fiber meets the definition of a Class II nutrient, the nutrient content of the composite must be at least equal to 80 percent of the value for that nutrient declared on the label. Provided, that no regulatory action will be based on a determination of a nutrient value that falls below this level by a factor less than the variability generally recognized for the analytical method used in that product at the level involved.

(5) A product with a label declaration of calories, total sugars, added sugars (when the only source of sugars in the food is added sugars), total fat, saturated fat, trans fat, cholesterol, or sodium shall be deemed to be misbranded under section 1(n) of the Federal Meat Inspection Act (21 U.S.C. 601(n)(1)) or 4(h) of the Poultry Products Inspection

Act (21 U.S.C. 453(h)) if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. Provided, that no regulatory action will be based on a determination of a nutrient value that falls above this level by a factor less than the variability generally recognized for the analytical method used in that product at the level involved, and inherent nutrient variation in a product.

(6) The amount of vitamins, minerals, protein, total carbohydrate, dietary fiber, soluble fiber, insoluble fiber, sugar alcohols, polyunsaturated or monounsaturated fat may vary over labeled amounts within good manufacturing practice. The amount of calories, sugars, added sugars, total fat, saturated fat, *trans* fat, cholesterol, or sodium may vary under labeled amounts within good manufacturing practice.

(7) Compliance will be based on the metric measure specified in the label statement of the serving size.

(8) The management of the official establishment or establishment certified under a foreign inspection system, in accordance with parts 327 and 381, subpart T, of this chapter must maintain records in accordance with parts 320 and 381, subpart Q, of this chapter to support the validity of nutrient declarations contained on product labels including the records in subparagraphs (h)(8)(i)–(vii) of this section for documenting the amount of dietary fiber, soluble fiber, insoluble fiber, added sugars, tocopherol, folate, and folic acid. Such records shall be made available to the inspector or any duly authorized representative of the Agency upon request.

(i) When a mixture of dietary fiber, and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber, is present in the food, a manufacturer must maintain records of the amount of non-digestible carbohydrate(s) added to the food that does not meet the definition of dietary fiber.

(ii) When a mixture of soluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food, a manufacturer must maintain records necessary to verify the amount of the non-digestible carbohydrate(s) added to the food that does not meet the definition of dietary fiber.

(iii) When a mixture of insoluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the food, a manufacturer must maintain records necessary to verify the amount of the non-digestible carbohydrate(s)

added to the food that does not meet the definition of dietary fiber.

(iv) When a mixture of naturally occurring and added sugars is present in the food, a manufacturer must maintain records of the amount of added sugars added to the food during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient).

(v) When the amount of sugars added to food products is reduced through the process of yeast-leavening, non-enzymatic browning or fermentation, manufacturers must:

(A) Maintain records of all relevant scientific data and information relied upon by the manufacturer that demonstrates the amount of added sugars in the food after the process of non-enzymatic browning, yeast-leavening, fermentation, or the manufacture of reaction flavors and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food, provided the data and information used is specific to the type of food that is subject to non-enzymatic browning or fermentation; or

(B) Maintain records of the amount of added sugars added to the food before and during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient) and in no event shall the amount of added sugars declared exceed the amount of total sugars on the label; or

(C) Submit a request to FSIS to use an alternative means of compliance. The request must provide scientific data or other information for why the amount of added sugars in a serving of product is likely to have a significant reduction in added sugars compared to the amount added prior to non-enzymatic browning and/or fermentation. A significant reduction would be where reduction in added sugars after non-enzymatic browning or fermentation may be significant enough to impact the label declaration for added sugars by an amount that exceeds the reasonable deficiency acceptable within good manufacturing practice under § 413.309(h)(6). In addition, the scientific data or other information must include the reason that the manufacturer is unable to determine a reasonable approximation of the amount of added sugars in a serving of their finished product and a description of

the process that they used to come to that conclusion.

(vi) When a mixture of *all rac*- α -tocopherol and *RRR*- α -tocopherol is present in a food, manufacturers must maintain records of the amount of *all rac*- α -tocopherol added to the food and *RRR*- α -tocopherol in the finished food.

(vii) When a mixture of folate and folic acid is present in a food, manufacturers must maintain records of the amount of synthetic folate and/or folic acid added to the food and the amount of naturally-occurring folate in the finished food.

(9) The compliance provisions set forth in paragraph (h)(1) through (8) of this section shall not apply to single-ingredient, raw products that are not ground or chopped products described in § 413.301, including those that have been previously frozen, when nutrition labeling is based on the most current representative data base values contained in USDA's National Nutrient Data Bank or its released form, the USDA National Nutrient Database for Standard Reference as provided in § 413.345(e) and (f).

(i) The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at the office of the FSIS Docket Clerk, Room 8–164A, Patriots Plaza 3, 355 E Street SW., Washington, DC, and is available from the sources indicated below. It is also available for inspection at the National Archives and Records Administration (NARA), call 202–741–6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(1) AOAC Reseller. Techstreet, 6300 Interfirst Dr., Ann Arbor, MI 48108, Toll free in United States: 1–800–699–9277, Outside United States: 1–734–780–8000, Fax: 1–734–780–2046, www.techstreet.com, techstreet.service@thomsonreuters.com. FSIS does not endorse any particular reseller and notes that other resellers also may have the reference for sale.

(i) “Official Methods of Analysis of the AOAC INTERNATIONAL,” 20th Edition, Volumes 1 and 2, 2016.

(ii) [Reserved]

(2) Food and Agriculture Organization of the United Nations/World Health Organization (FAO/WHO), Publications Division, Viale delle Terme di Caracalla, 00100 Rome, Italy.

(i) FAO Food and Nutrition Paper 51, “Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation,” Rome, 1991. <http://>

apps.who.int/iris/bitstream/10665/38133/1/9251030979_eng.pdf.

(ii) [Reserved]

(3) United States Department of Agriculture (USDA), Agricultural Research Service, Washington, DC, Nutrient Data Laboratory, Bldg. 005, Room 105 BARC—West, Beltsville, MD 20705, 301–504–0630. *http://www.ars.usda.gov/News/docs.htm?docid=9447.*

(i) USDA Handbook No. 74, Energy Value of Foods—basis and derivation, by A. L. Merrill and B. K. Watt, (slightly revised, 1973) *http://www.ars.usda.gov/SP2UserFiles/Place/80400525/Data/Classics/ah74.pdf.*

(ii) [Reserved]

§§ 413.310–413.311 [Reserved]

§ 413.312 Reference amounts customarily consumed per eating occasion.

(a) The general principles followed in arriving at the reference amounts customarily consumed per eating occasion (Reference Amounts), as set forth in paragraph (b) of this section, are:

(1) The Reference Amounts are calculated for persons 4 years of age or older to reflect the amount of food customarily consumed per eating occasion by persons in this population group. These Reference Amounts are based on data set forth in appropriate national food consumption surveys.

(2) The Reference Amounts are calculated for an infant or child under 4 years of age to reflect the amount of food customarily consumed per eating occasion by infants through 12 months of age or by children 1 through 3 years of age, respectively. These Reference Amounts are based on data set forth in appropriate national food consumption surveys. Such Reference Amounts are to be used only when the product is specially formulated or processed for use by an infant through 12 months of age or by a child under 4 years of age.

(3) An appropriate national food consumption survey includes a large sample size representative of the demographic and socioeconomic characteristics of the relevant population group and must be based on consumption data under actual conditions of use.

(4) To determine the amount of food customarily consumed per eating occasion, the mean, median, and mode of the consumed amount per eating occasion were considered.

(5) When survey data were insufficient, FSIS took various other sources of information on serving sizes of food into consideration. These other sources of information included:

(i) Serving sizes used in dietary guidance recommendations or recommended by other authoritative systems or organizations;

(ii) Serving sizes recommended in comments;

(iii) Serving sizes used by manufacturers and grocers; and

(iv) Serving sizes used by other countries.

(6) Because they reflect the amount customarily consumed, the Reference Amount and, in turn, the serving size declared on the product label are based on only the edible portion of food, and not bone, seed, shell, or other inedible components.

(7) The Reference Amount is based on the major intended use of the product (e.g., a mixed dish measurable with a cup as a main dish and not as a side dish).

(8) The Reference Amounts for products that are consumed as an ingredient of other products, but that may also be consumed in the form in which they are purchased (e.g., ground beef), are based on use in the form purchased.

(9) FSIS sought to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform Reference Amount.

(b) The following Product Categories and Reference Amounts shall be used as the basis for determining serving sizes for specific products:

TABLE 1—MEAT AND POULTRY PRODUCT REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: FOODS FOR INFANTS AND YOUNG CHILDREN 1 THROUGH 3 YEARS OF AGE ^{1 2 3}

| Product category | Reference amount (g) | Label statement ⁴ |
|---|----------------------|------------------------------------|
| Infant and Toddler Foods: | | |
| Dinner Dry Mix | 15 | __tbsp(s) (__ g); cup(s) (__ g). |
| Dinner, ready-to-serve, strained type | 110 | __cup(s) (__ g); __cup(s) (mL). |
| Dinner, soups, ready-to-serve, junior type | 110 | __cup(s) (__ g); cup(s) (__ mL). |
| Dinner, stew or soup, ready-to-serve young children | 170 | __cup(s) (__ g); cup(s) (__ mL). |
| Plain meats, plain poultry, meat sticks, poultry sticks, ready to serve | 55 | 2 oz (56g); __link(s) (__ g). |

¹ These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture and updated by the U.S. Department of Agriculture based on data from the National Health and Nutrition Examination Survey, 2003–2004, 2005–2006, and 2007–2008 conducted by the Centers for Disease Control and Prevention, in the U.S. Department of Health and Human Services.

² Unless otherwise noted in the Reference Amount column, the Reference Amounts are for the ready-to-serve or almost ready-to-serve form of the product (e.g., heat and serve, brown and serve). If not listed separately, the Reference Amount for the unprepared form (e.g., dehydrated cereal) is the amount required to make one Reference Amount of the prepared form. Prepared means prepared for consumption (e.g., ready to serve).

³ Manufacturers are required to convert the Reference Amount to the label serving size in a household measure most appropriate to their specific product using the procedures established by the regulation.

⁴ The label statements are meant to provide examples of serving size statements that may be used on the label, but the specific wording may be changed as appropriate for individual products. The term “piece” is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (e.g., patty for patties, link for links, etc.).

TABLE 2—MEAT AND POULTRY PRODUCT REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION:
GENERAL FOOD SUPPLY ^{1 2 3 4 5}

| Product category | Reference amount | Reference amount | Label statement ⁶ |
|---|---|--|---|
| | Ready-to-serve | Ready-to-cook | |
| Egg mixtures with meat or poultry; <i>e.g.</i> , western style omelet, soufflé, egg foo young. | 110 g | n/a | 4 oz (112g); __piece(s) (__g). |
| Lard, margarine, shortening | 1 tbsp | n/a | 1 tbsp (__g). |
| Salad and potato toppers; <i>e.g.</i> , bacon bits, poultry bacon bits. | 7 g | n/a | __tbsp (__g). |
| Bacon; <i>e.g.</i> , bacon, beef breakfast strips, pork breakfast strips, pork rinds, pork back fat. | 15 g | 54 g = bacon, pork rinds, pork back fat; 30 g = meat breakfast strips. | __piece(s) (__g) __pieces pan fried (__g). |
| Poultry bacon, poultry breakfast strips | 15 g | 26 g = poultry bacon; 18 g = poultry breakfast strips. | __piece(s) (__g); __pieces pan fried (__g). |
| Dried meat or poultry products; <i>e.g.</i> , jerky, dried beef or poultry, Parma ham, meat or poultry sausage products with a moisture/protein ratio of less than 2:1; <i>e.g.</i> , pepperoni. | 30 g | n/a | __piece(s) (__g); __slice(s) (__g); 2 oz (28g). |
| Snacks; <i>e.g.</i> , meat or poultry snack food sticks | 30 g | n/a | __piece(s) (__g); 2 oz (28g). |
| Luncheon products, luncheon meat, bologna, poultry bologna, Canadian style bacon, poultry Canadian style bacon, meat or poultry pattie crumbles, blood pudding, meat or poultry luncheon loaf, old fashioned loaf, berlinger, bangers, minced luncheon roll, thuringer, liver sausage, mortadella, uncured sausage (franks), ham and cheese loaf, P&P loaf, scrapple souse, head cheese, pizza loaf, olive loaf, pate, deviled ham, sandwich spread, teawurst, cervelat, Lebanon bologna, potted meat or poultry food product, taco fillings, pie fillings. | 55 g | n/a | __slice(s) (__g); __piece(s) (__g); __cup (__g); 2 oz (56g). |
| Linked meat or poultry sausage products, Vienna sausage, frankfurters, poultry franks, pork sausage, imitation frankfurters, bratwurst, kielbasa, Polish sausage, poultry Polish sausage, summer sausage, mettwurst, smoked country sausage, smoked sausage, poultry smoked sausage, smoked pickled meat or poultry meat, pickled pigs feet. | 55 g | n/a | __slice(s) (__g); __piece(s) (__g); __oz (__g). |
| Entrees without sauce; <i>e.g.</i> , cuts of meat or poultry including marinated, tenderized, injected cuts of meat or poultry, patties, corn dogs, croquettes, fritters, cured ham, dry cured ham, dry cured cappicola, cured poultry ham products, corned beef, pastrami, country ham, pork shoulder picnic, meatballs, pureed adult foods. | 85 g | 114 g | __piece(s) (__g); __slice(s) (__g); __oz (__g); __cup (__g). |
| Appetizers, hors d'oeuvres—Mini mixed dishes with meat or poultry; <i>e.g.</i> , mini bagel pizzas, mini egg rolls, dumplings, mini pizza rolls, mini quesadilla, mini quiche. | 85 g (add 35 g for products with gravy or sauce toppings). | n/a | __piece(s) (__g); __piece(s) plus sauce (__g). |
| Appetizers, hors d'oeuvres—Dips with meat or poultry; <i>e.g.</i> , chicken dip, chicken and cheese dip, meat dip. | 2 tbsp. | n/a | 2 tbsp (__g). |
| Canned meats (<i>e.g.</i> , canned beef, canned pork) and Canned Poultry (<i>e.g.</i> , canned chicken, canned turkey). | 85 g | n/a | __cup (__g); 3 oz (84g). |
| Entrees with sauce; <i>e.g.</i> , barbecued meat or poultry in sauce, meat or poultry and gravy. | 140 g | n/a | __cup (__g); 2 oz (56g). |
| Mixed dishes NOT measurable with a cup; <i>e.g.</i> , burrito, egg roll, enchilada, pizza, pizza roll, quiche, all types of sandwiches with meat or poultry, cracker and meat/poultry lunch type packages, gyro, Stromboli, burger on a bun, poultry burger on a bun, frank on a bun, poultry frank on a bun, calzone, taco, stuffed pockets, foldovers, stuffed vegetables with meat or poultry, shish kabobs, empanada, chicken cordon bleu. | 140 g (add 55 g for products with gravy or sauce toppings). | n/a | __piece(s) (__g); __piece(s) plus sauce (__g); 5 oz (140g); __oz (__g). |

TABLE 2—MEAT AND POULTRY PRODUCT REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY ^{1 2 3 4 5}—Continued

| Product category | Reference amount | Reference amount | Label statement ⁶ |
|--|------------------|------------------|--|
| | Ready-to-serve | Ready-to-cook | |
| Mixed dishes measurable with a cup; <i>e.g.</i> , casserole, macaroni and cheese with meat or poultry, pot pie, spaghetti with sauce, poultry spaghetti with sauce, meat or poultry chili, meat or poultry chili with beans, hash, creamed chipped beef, creamed dried poultry, ravioli in sauce, stroganoff, Brunswick stew, goulash, poultry a la king, meat or poultry stew, ragout, meat or poultry lasagna, meat or poultry filled pasta. | 1 cup | n/a | 1 cup (_ g). |
| Salads—pasta or potato, potato salad with bacon, potato salad with poultry, macaroni and meat or poultry salad. | 140 g | n/a | _ cup (_ g). |
| Salads—all other meat salads, all other poultry salads; <i>e.g.</i> , chicken salad, ham salad, turkey salad. | 100 g | n/a | _ cup (_ g). |
| Soups with meat or poultry—all varieties | 245 g | n/a | _ cup (_ g). |
| Major main entrée type sauce; <i>e.g.</i> , spaghetti sauce with meat or poultry, spaghetti sauce with meatballs, spaghetti sauce with poultry meatballs. | 125 g | n/a | _ cup (_ g); _ meatballs plus _ cup sauce (_ g). |
| Minor main entrée sauce; <i>e.g.</i> , pizza sauce with meat or poultry, gravy. | 1/4 c | n/a | 1/4 c (_ g). |
| Seasoning mixes dry, bases, extracts, dried broths and stock/juice, freeze dry trail mix products with meat or poultry. | | | |
| As reconstituted: | | | |
| Amount to make one Reference Amount of the final dish; <i>e.g.</i> , | | | |
| Gravy | 1/4 c | n/a | 1/4 c (_ g); |
| Major main entrée type sauce | 125 g | n/a | _ cup (125 g); |
| Soup | 245 g | n/a | _ cup (245 g); |
| Entrée measurable with a cup | 1 cup | n/a | 1 cup (_ g). |
| Candies with meat or poultry; <i>e.g.</i> , chocolate with bacon, chocolate dipped bacon, chocolate with salami. | 30 g | n/a | _ squares (_ g); _ pieces (_ g); 1 oz (28g). |

¹ These values represent the amount (edible portion) of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture and updated by U.S. Department of Agriculture based on data from the National Health and Nutrition Examination Survey, 2003–2004, 2005–2006 and 2007–2008 conducted by the Centers for Diseases Control and Prevention, in the Department of Health and Human Services.

² Manufacturers are required to convert the Reference Amounts to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.

³ Examples listed under Product Category are not all inclusive or exclusive. Examples are provided to assist manufacturers in identifying appropriate product Reference.

⁴ If packed or canned in liquid, the reference amount is for the drained solids, except for products in which both the solids and liquids are customarily consumed (*e.g.*, canned chicken with broth).

⁵ Pizza sauce is part of the pizza and is not considered to be a sauce topping.

⁶ The label statements are meant to provide examples of serving size statements that may be used on the label, but that the specific wording may be changed as appropriate for individual products. The term “piece” is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (*e.g.*, patty for patties, meatballs for meatballs, link for links, etc.). The guidance provided is for the label statement of products in ready-to-serve or almost ready-to-serve form. The guidance does not apply to the products which require further preparation for consumption (*e.g.*, dry mixes, concentrates) unless specifically stated in the product category, reference amount, or label statement column that it is for these forms of the product. For products that require further preparation, manufacturers must determine the label statement following the rules in § 413.309(b) using the reference amount determined according to § 413.412(b).

(c) For products that have no Reference Amount listed in paragraph (b) of this section for the unprepared or the prepared form of the product and that consist of two or more foods packaged and presented to be consumed together (*e.g.*, lunch meat with cheese and crackers), the Reference Amount for the combined product shall be determined using the following rules:

(1) The reference amount for the combined product must be the reference amount, as established in paragraph (b)

of this section, for the ingredient that is represented as the main ingredient (*e.g.*, lunchmeat) plus proportioned amounts of all minor ingredients.

(2) If the Reference Amounts are in compatible units, the weights or volumes must be summed (*e.g.*, ingredients in equal volumes such as tablespoons). If the Reference Amounts are in incompatible units, all amounts must be converted to weights and summed (*e.g.*, grams of one ingredient

plus gram weight of tablespoons of a second ingredient).

(d) If a product requires further preparation, *e.g.*, cooking or the addition of water or other ingredients, and if paragraph (b) of this section provides a Reference Amount for the product in the prepared form, but not the unprepared form, then the Reference Amount for the unprepared product must be the amount of the unprepared product required to make the Reference Amount for the prepared product as

established in paragraph (b) of this section.

(e) The Reference Amount for an imitation or substitute product or altered product as defined in § 413.313(d), such as a “low calorie” version, shall be the same as for the product for which it is offered as a substitute.

(f) The Reference Amounts set forth in paragraphs (b) through (e) of this section shall be used in determining whether a product meets the criteria for nutritional claims. If the serving size declared on the product label differs from the Reference Amount, and the product meets the criteria for the claim only on the basis of the Reference Amount, the claim shall be followed by a statement that sets forth the basis on which the claim is made. That statement shall include the Reference Amount as it appears in paragraph (b) of this section followed, in parentheses, by the amount in common household measure if the Reference Amount is expressed in measures other than common household measures.

(g) The Administrator, on his or her own initiative or on behalf of any interested person who has submitted a labeling application, may issue a proposal to establish or amend a Product Category or Reference Amount identified in paragraph (b) of this section.

(1) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(2) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(3) The availability for public disclosure of labeling applications, along with supporting documentation,

submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(4) Data accompanying the labeling application, such as food consumption data, shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(5) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(6) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(7) Labeling applications for a new Reference Amount and/or Product Category shall be accompanied by the following data which shall be submitted in the following form to the Director, Labeling and Program Delivery Staff, Office of Policy and Program Development, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 413.312 with respect to Reference Amount and/or Product Category.

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

- (i) A statement of the objective of the labeling application;
- (ii) A description of the product;
- (iii) A complete sample product label including nutrition label, using the format established by regulation;
- (iv) A description of the form in which the product will be marketed;
- (v) The intended dietary uses of the product with the major use identified (*e.g.*, ham as a luncheon meat, turkey as a luncheon meat);
- (vi) If the intended use is primarily as an ingredient in other foods, list of foods or food categories in which the product will be used as an ingredient with information on the prioritization of the use;
- (vii) The population group for which the product will be offered for use (*e.g.*, infants through 12 months, children under 4 years of age);
- (viii) The names of the most closely-related products (or in the case of foods for special dietary use and imitation or substitute foods, the names of the products for which they are offered as substitutes);
- (ix) The suggested Reference Amount (the amount of edible portion of food as consumed, excluding bone, skin or other

inedible components) for the population group for which the product is intended with full description of the methodology and procedures that were used to determine the suggested Reference Amount. In determining the Reference Amount, general principles and factors in paragraph (a) of this section should be followed.

(x) The suggested Reference Amount shall be expressed in metric units. Reference Amounts for foods shall be expressed in grams except when common household units such as cups, tablespoons, and teaspoons are more appropriate or are more likely to promote uniformity in serving sizes declared on product labels. For example, common household measures would be more appropriate if products within the same category differ substantially in density such as mixed dishes measurable with a cup.

(A) In expressing the Reference Amount in grams, the following general rules shall be followed:

(1) For quantities greater than 10 grams, the quantity shall be expressed in nearest 5 grams increment.

(2) For quantities less than 10 grams, exact gram weights shall be used.

(B) [Reserved]

(xi) A labeling application for a new subcategory of food with its own Reference Amount shall include the following additional information:

(A) Data that demonstrate that the new subcategory of food will be consumed in amounts that differ enough from the Reference Amount for the parent category to warrant a separate Reference Amount. Data must include sample size, and the mean, standard deviation, median, and modal consumed amount per eating occasion for the product identified in the labeling application and for other products in the category. All data must be derived from the same survey data.

(B) Documentation supporting the difference in dietary usage and product characteristics that affect the consumption size that distinguishes the product identified in the labeling application from the rest of the products in the category.

(xii) In conducting research to collect or process food consumption data in support of the labeling application, the following general guidelines should be followed.

(A) Sampled population selected should be representative of the demographic and socioeconomic characteristics of the target population group for which the food is intended.

(B) Sample size (*i.e.*, number of eaters) should be large enough to give reliable estimates for customarily consumed amounts.

(C) The study protocol should identify potential biases and describe how potential biases are controlled for or, if not possible to control, how they affect interpretation of results.

(D) The methodology used to collect or process data including study design, sampling procedures, materials used (*e.g.*, questionnaire, interviewer's manual), procedures used to collect or process data, methods or procedures used to control for unbiased estimates, and procedures used to

correct for nonresponse, should be fully documented.

(xiii) A statement concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(8) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(9) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(10) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed Reference Amount or Product Category is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount or Product Category.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of

such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(11) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the **Federal Register** a proposed rule to amend the regulations to authorize the use of the Reference Amount or Product Category. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed Reference Amount or Product Category. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed Reference Amount or Product Category shall be approved for use on the labeling of meat food products or poultry food products.

(i) If the Reference Amount or Product Category is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the Reference Amount or Product Category on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of an answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless,

within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the Reference Amount or Product Category is approved, the Agency shall notify the applicant, in writing, and shall also publish in the **Federal Register** a final rule amending the regulations to authorize the use of the Reference Amount or Product Category.

§ 413.313 Nutrient content claims; general principles.

(a) This section applies to meat, meat food products, or poultry products that are intended for human consumption and that are offered for sale.

(b) A claim which, expressly or by implication, characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling pursuant to § 413.309, may not be made on a label or in labeling of that product unless the claim is made in accordance with the applicable provisions in this part.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the product, e.g., "low sodium" or "contains 100 calories."

(2) An implied nutrient content claim is any claim that:

(i) Describes the product or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"); or

(ii) Suggests that the product, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams (g) of fat").

(3) Except for claims regarding vitamins and minerals described in paragraph (q)(3) of this section, no nutrient content claims may be made on products intended specifically for use by infants through 12 months and children less than 2 years of age unless the claim is specifically provided for in this part.

(4) Reasonable variations in the spelling of the terms defined in applicable provisions in this part and their synonyms are permitted provided these variations are not misleading (e.g., "hi" or "lo").

(c) Information that is required or permitted by § 413.309 to be declared in nutrition labeling, and that appears as

part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

(d) A “substitute” product is one that may be used interchangeably with another product that it resembles, *i.e.*, that it is organoleptically, physically, and functionally (including shelf life) similar to, and that it is not nutritionally inferior to unless it is labeled as an “imitation.”

(1) If there is a difference in performance characteristics that materially limits the use of the product, the product may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j)(2)(iii) of this section, informing the consumer of such difference (*e.g.*, “not recommended for frying”).

(2) This disclaimer shall be in easily legible print or type and in a size no less than that required by § 317.2(h) or § 381.121(c) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than $\frac{1}{16}$ -inch minimum height, except as permitted by § 413.400(d)(2).

(e)(1) Because the use of a “free” or “low” claim before the name of a product implies that the product differs from other products of the same type by virtue of its having a lower amount of the nutrient, only products that have been specially processed, altered, formulated, or reformulated so as to lower the amount of the nutrient in the product, remove the nutrient from the product, or not include the nutrient in the product, may bear such a claim (*e.g.*, “low sodium beef noodle soup”, “low sodium chicken noodle soup”).

(2) Any claim for the absence of a nutrient in a product, or that a product is low in a nutrient when the product has not been specially processed, altered, formulated, or reformulated to qualify for that claim shall indicate that the product inherently meets the criteria and shall clearly refer to all products of that type and not merely to the particular brand to which the labeling attaches (*e.g.*, “lard, a sodium free food”, “chicken breast meat, a low sodium food”).

(f) A nutrient content claim shall be in type size and style no larger than two

times that of the statement of identity and shall not be unduly prominent in type style compared to the statement of identity.

(g) Labeling information required in §§ 413.313, 413.354, 413.356, 413.360, 413.361, 413.362, and 413.380, whose type size is not otherwise specified, is required to be in letters and/or numbers no less than $\frac{1}{16}$ inch in height, except as permitted by § 413.400(d)(2).

(h) [Reserved]

(i) Except as provided in § 413.309 or in paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

(1) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is consistent with a definition for a claim, as provided in this part, for the nutrient that the label addresses. Such a claim might be, “less than 10 g of fat per serving;”

(2) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is not consistent with such a definition, but the label carries a disclaimer adjacent to the statement that the product is not “low” in or a “good source” of the nutrient, such as “only 200 milligrams (mg) sodium per serving, not a low sodium product.” The disclaimer must be in easily legible print or type and in a size no less than required by § 317.2(h) or § 381.121(c) for the net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than $\frac{1}{16}$ -inch minimum height, except as permitted by § 413.400(d)(2);

(3) The statement does not in any way implicitly characterize the level of the nutrient in the product and it is not false or misleading in any respect (*e.g.*, “100 calories” or “5 grams of fat”), in which case no disclaimer is required.

(4) “Percent fat free” claims are not authorized by this paragraph. Such claims shall comply with § 413.362(b)(6).

(j) A product may bear a statement that compares the level of a nutrient in the product with the level of a nutrient in a reference product. These statements shall be known as “relative claims” and include “light,” “reduced,” “less” (or “fewer”), and “more” claims.

(1) To bear a relative claim about the level of a nutrient, the amount of that nutrient in the product must be compared to an amount of nutrient in an

appropriate reference product as specified in this paragraph (j).

(i)(A) For “less” (or “fewer”) and “more” claims, the reference product may be a dissimilar product within a product category that can generally be substituted for one another in the diet or a similar product.

(B) For “light,” “reduced,” and “added” claims, the reference product shall be a similar product, and

(ii)(A) For “light” claims, the reference product shall be representative of the type of product that includes the product that bears the claim. The nutrient value for the reference product shall be representative of a broad base of products of that type; *e.g.*, a value in a representative, valid data base; an average value determined from the top three national (or regional) brands, a market basket norm; or, where its nutrient value is representative of the product type, a market leader. Firms using such a reference nutrient value as a basis for a claim, are required to provide specific information upon which the nutrient value was derived, on request, to consumers and appropriate regulatory officials.

(B) For relative claims other than “light,” including “less” and “more” claims, the reference product may be the same as that provided for “light” in paragraph (j)(1)(ii)(A) of this section or it may be the manufacturer’s regular product, or that of another manufacturer, that has been offered for sale to the public on a regular basis for a substantial period of time in the same geographic area by the same business entity or by one entitled to use its trade name, provided the name of the competitor is not used on the labeling of the product. The nutrient values used to determine the claim when comparing a single manufacturer’s product to the labeled product shall be either the values declared in nutrition labeling or the actual nutrient values, provided that the resulting labeling is internally consistent (*i.e.*, that the values stated in the nutrition information, the nutrient values in the accompanying information, and the declaration of the percentage of nutrient by which the product has been modified are consistent and will not cause consumer confusion when compared), and that the actual modification is at least equal to the percentage specified in the definition of the claim.

(2) For products bearing relative claims:

(i) The label or labeling must state the identity of the reference product and the percent (or fraction) of the amount of the nutrient in the reference product by

which the nutrient has been modified, (e.g., “50 percent less fat than ‘reference product’ ” or “ $\frac{1}{3}$ fewer calories than ‘reference product’ ”); and

(ii) This information shall be immediately adjacent to the most prominent claim in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, that is no less than that required by § 317.2(h) or § 381.121(c) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the referral statement shall be no less than one-half the size of the claim, but no smaller than $\frac{1}{16}$ -inch minimum height, except as permitted by § 413.400(d)(2).

(iii) The determination of which use of the claim is in the most prominent location on the label or labeling will be made based on the following factors, considered in order:

(A) A claim on the principal display panel adjacent to the statement of identity;

(B) A claim elsewhere on the principal display panel;

(C) A claim on the information panel; or

(D) A claim elsewhere on the label or labeling.

(iv) The label or labeling must also bear:

(A) Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving size with that in the reference product; and

(B) This statement shall appear adjacent to the most prominent claim or to the nutrition information.

(3) A relative claim for decreased levels of a nutrient may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the requirement for a “low” claim for that nutrient.

(k) The term “modified” may be used in the statement of identity of a product that bears a relative claim that complies with the requirements of this part, followed immediately by the name of the nutrient whose content has been altered (e.g., “modified fat ‘product’ ”). This statement of identity must be immediately followed by the comparative statement such as “contains 35 percent less fat than ‘reference product.’ ” The label or labeling must also bear the information required by paragraph (j)(2) of this section in the manner prescribed.

(l) For purposes of making a claim, a “meal-type” product will be defined as a product that:

(1) Makes a major contribution to the diet by:

(i) Weighing at least 10 ounces per labeled serving; and

(ii) Containing not less than three 40 gram portions of food, or combinations of foods, from two or more of the following four food groups, except as noted in paragraph (l)(1)(ii)(E) of this section:

(A) Bread, cereal, rice, and pasta;

(B) Fruits and vegetables;

(C) Milk, yogurt, and cheese;

(D) Meat, poultry, fish, dry beans, eggs, and nuts; except that:

(E) These foods will not be sauces (except for foods in the four food groups in paragraph (l)(1)(ii)(A) through (D) of this section, that are in the sauces), gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, or garnishes; and

(2) Is represented as, or is in the form commonly understood to be, a breakfast, lunch, dinner, meal, or entree. Such representations may be made by statements, photographs, or vignettes.

(m) For purposes of making a claim, a main-dish product will be defined as a food that:

(1) Makes a major contribution to the meal by:

(i) Weighing at least 6 ounces per labeled serving; and

(ii) Containing not less than 40 grams of food, or combinations of foods, from two or more of the following four food groups, except as noted in paragraph (m)(1)(ii)(E) of this section.

(A) Bread, cereal, rice, and pasta;

(B) Fruits and vegetables;

(C) Milk, yogurt, and cheese;

(D) Meat, poultry, fish, dry beans, eggs, and nuts; except that:

(E) These foods will not be sauces (except for foods in the four food groups in paragraph (m)(1)(ii)(A) through (D) of this section, that are in the sauces), gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, or garnishes; and

(3) Is represented as, or is in a form commonly understood to be, a main dish (e.g., not a beverage or dessert). Such representations may be made by statements, photographs, or vignettes.

(n) Nutrition labeling in accordance with § 413.309, shall be provided for any food for which a nutrient content claim is made.

(o) Compliance with requirements for nutrient content claims shall be in accordance with § 413.309(h).

(p)(1) Unless otherwise specified, the reference amount customarily consumed set forth in § 413.312(b) through (e) shall be used in determining whether a product meets the criteria for a nutrient content claim. If the serving size declared on the product label differs from the reference amount

customarily consumed, and the amount of the nutrient contained in the labeled serving does not meet the maximum or minimum amount criterion in the definition for the descriptor for that nutrient, the claim shall be followed by the criteria for the claim as required by § 413.312(f) (e.g., “very low sodium, 35 mg or less per 55 grams”).

(2) The criteria for the claim shall be immediately adjacent to the most prominent claim in easily legible print or type and in a size that is no less than that required by § 317.2(h) or § 381.121(c) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the criteria statement shall be no less than one-half the size of the claim but no smaller than $\frac{1}{16}$ -inch minimum height, except as permitted by § 413.400(d)(2).

(q) The following exemptions apply:

(1) Nutrient content claims that have not been defined by regulation and that appear as part of a brand name that was in use prior to November 27, 1991, may continue to be used as part of that brand name, provided they are not false or misleading under section 1(n) of the Federal Meat Inspection Act (21 U.S.C. 601(n)(1)) or 4(h) of the Poultry Products Inspection Act (21 U.S.C. 453(h)).

(2) [Reserved]

(3) A statement that describes the percentage of a vitamin or mineral in the food, including foods intended specifically for use by infants through 12 months and children less than 2 years of age, in relation to a Reference Daily Intake (RDI) as defined in § 413.309 may be made on the label or in the labeling of a food without a regulation authorizing such a claim for a specific vitamin or mineral.

(4) The requirements of this section do not apply to infant formulas and medical foods, as described in 21 CFR 101.13(q)(4).

(5) [Reserved]

(6) Nutrient content claims that were part of the name of a product that was subject to a standard of identity as of November 27, 1991, are not subject to the requirements of paragraph (b) of this section whether or not they meet the definition of the descriptive term.

(7) Implied nutrient content claims may be used as part of a brand name, provided that the use of the claim has been authorized by FSIS. Labeling applications requesting approval of such a claim may be submitted pursuant to § 413.369.

§§ 413.314–413.343 [Reserved]**§ 413.344 Identification of major cuts of meat products and poultry products.**

(a) The major cuts of single-ingredient, raw meat products are: Beef chuck blade roast, beef loin top loin steak, beef rib roast large end, beef round eye round steak, beef round top round steak, beef round tip roast, beef chuck arm pot roast, beef loin sirloin steak, beef round bottom round steak, beef brisket (whole, flat half, or point half), beef rib steak small end, beef loin tenderloin steak, pork loin chop, pork loin country style ribs, pork loin top loin chop boneless, pork loin rib chop, pork spareribs, pork loin tenderloin, pork loin sirloin roast, pork shoulder blade steak, pork loin top roast boneless, ground pork, lamb shank, lamb shoulder arm chop, lamb shoulder blade chop, lamb rib roast, lamb loin chop, lamb leg (whole, sirloin half, or shank half), veal shoulder arm steak, veal shoulder blade steak, veal rib roast, veal loin chop, and veal cutlets.

(b) The major cuts of single-ingredient, raw poultry products are: Whole chicken (without neck and giblets), chicken breast, chicken wing, chicken drumstick, chicken thigh, whole turkey (without necks and giblets; separate nutrient panels for white and dark meat permitted as an option), turkey breast, turkey wing, turkey drumstick, and turkey thigh.

§ 413.345 Nutrition labeling of single-ingredient, raw meat or poultry products that are not ground or chopped products described in § 413.301.

(a)(1) Nutrition information on the major cuts of single-ingredient, raw meat or poultry products identified in § 413.344, including those that have been previously frozen, is required, either on their label or at their point-of-purchase, unless exempted under § 413.400. If nutrition information is presented on the label, it must be provided in accordance with § 413.309. If nutrition information is presented at the point-of-purchase, it must be provided in accordance with the provisions of this section.

(2) Nutrition information on single-ingredient, raw products that are not ground or chopped products described in § 413.301 and are not major cuts of single-ingredient, raw products identified in § 413.344, including those that have been previously frozen, may be provided at their point-of-purchase in accordance with the provisions of this section or on their label, in accordance with the provisions of § 413.309.

(3) A retailer may provide nutrition information at the point-of-purchase by

various methods, such as by posting a sign or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media. If a nutrition claim is made on point-of-purchase materials, all of the format and content requirements of § 413.309 apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials, the requirements of § 413.309 apply, provided, however:

(i) The listing of percent of Daily Value for the nutrients (except vitamins and minerals specified in § 413.309(c)(8)) and footnote required by § 413.309(d)(9) may be omitted; and

(ii) The point-of-purchase materials are not subject to any of the format requirements.

(b) [Reserved]

(c) For the point-of-purchase materials, the declaration of nutrition information may be presented in a simplified format as specified in § 413.309(f).

(d) The nutrition label data for products covered in paragraphs (a)(1) and (a)(2) must be based on either the raw or cooked edible portions of meat cuts with external cover fat at trim levels reflecting current marketing practices or the raw or cooked edible portions of poultry cuts with skin. If data are based on cooked portions, the methods used to cook the products must be specified and should be those which do not add nutrients from other ingredients such as flour, breading, and salt. Additional nutritional data may be presented on an optional basis for the raw or cooked edible portions of the separable lean of meat cuts or the raw or cooked edible portions of the skinless poultry meat.

(e) Nutrient data that are the most current representative data base values contained in USDA's National Nutrient Data Bank or its released form, the USDA National Nutrient Database for Standard Reference, may be used for nutrition labeling of single-ingredient, raw products, including those that have been previously frozen. These data may be composite data that reflect different quality grades of beef or different classes of turkey or other variables affecting nutrient content. Alternatively, data that reflect specific grades or specific classes or other variables may be used, except that if data are used on labels attached to a product which is labeled as to grade of meat or class of poultry or other variables, the data must represent the product in the package when such data

are contained in the representative data base. When data are used on labels attached to a product, the data must represent the edible meat tissues or the edible poultry tissues present in the package.

(f) If the nutrition information is provided in accordance with paragraph (e) of this section, a nutrition label or labeling will not be subject to the Agency compliance review under § 413.309(h), unless a nutrition claim is made on the basis of the representative data base values.

(g) Retailers may use data bases that they believe reflect the nutrient content of single-ingredient, raw products, including those that have been previously frozen; however, such labeling shall be subject to the compliance procedures of paragraph (e) of this section and the requirements specified in this part for the mandatory nutrition labeling program.

§§ 413.346–413.353 [Reserved]**§ 413.354 Nutrient content claims for “good source,” “high,” and “more.”**

(a) *General requirements.* Except as provided in paragraph (e) of this section, a claim about the level of a nutrient in a product in relation to the Reference Daily Intake (RDI) or Daily Reference Value (DRV) established for that nutrient (excluding total carbohydrate) in § 413.309(c), may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 413.313; and

(3) The product for which the claim is made is labeled in accordance with § 413.309.

(b) *“High” claims.* (1) The terms “high,” “rich in,” or “excellent source of” may be used on the label or in labeling of products, except meal-type products as defined in § 413.313(l), and main-dish products as defined in § 413.313(m) provided that the product contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (b)(1) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l), and main-dish product as defined in § 413.313(m) provided that:

(i) The product contains a food that meets the definition of “high” in paragraph (b)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of

the claim (e.g., “the serving of broccoli in this meal is high in vitamin C”).

(c) “*Good Source*” claims. (1) The terms “good source,” “contains,” or “provides” may be used on the label or in labeling of products, except meal-type products as described in § 413.313(l), and main-dish products as defined in § 413.313(m) provided that the product contains 10 to 19 percent of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (c)(1) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l), and main-dish product as defined in § 413.313(m) provided that:

(i) The product contains a food that meets the definition of “good source” in paragraph (c)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., “the serving of sweet potatoes in this meal is a good source of fiber”).

(d) *Fiber claims*. (1) If a nutrient content claim is made with respect to the level of dietary fiber, i.e., that the product is high in fiber, a good source of fiber, or that the product contains “more” fiber, and the product is not “low” in total fat as defined in § 413.362(b)(2) or, in the case of a meal-type product or a main-dish product, is not “low” in total fat as defined in § 413.362(b)(3), then the labeling shall disclose the level of total fat per labeled serving size (e.g., “contains 12 grams (g) of fat per serving”); and

(2) The disclosure shall appear in immediate proximity to such claim and be in a type size no less than one-half the size of the claim.

(e) “*More*” claims. (1) A relative claim using the terms “more” and “added” may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in a product, except meal-type products as defined in § 413.313(l), and main-dish products as defined in § 413.313(m) provided that:

(i) The product contains at least 10 percent more of the RDI or the DRV for protein, vitamins, minerals, dietary fiber, or potassium (expressed as a percent of the Daily Value) per reference amount customarily consumed than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the nutrient is greater relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., “contains 10 percent more of

the Daily Value for fiber than ‘reference product’”); and

(B) Quantitative information comparing the level of the nutrient in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “fiber content of ‘reference product’ is 1 g per serving; ‘this product’ contains 4 g per serving”).

(2) A relative claim using the terms “more” and “added” may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in meal-type products as defined in § 413.313(l), and main-dish products as defined in § 413.313(m) provided that:

(i) The product contains at least 10 percent more of the RDI or the DRV for protein, vitamins, minerals, dietary fiber, or potassium (expressed as a percent of the Daily Value) per 100 g of product than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the nutrient is greater relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., “contains 10 percent more of the Daily Value for fiber per 3 ounces (oz) than does ‘reference product’”), and

(B) Quantitative information comparing the level of the nutrient in the meal-type product or a main-dish product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “fiber content of ‘reference product’ is 2 g per 3 oz; ‘this product’ contains 5 g per 3 oz”).

§ 413.355 [Reserved]

§ 413.356 Nutrient content claims for “light” or “lite.”

(a) *General requirements*. A claim using the terms “light” or “lite” to describe a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 413.313; and

(3) The product for which the claim is made is labeled in accordance with § 413.309.

(b) “*Light*” claims. The terms “light” or “lite” may be used on the label or in labeling of products, except meal-type

products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), without further qualification, provided that:

(1) If the product derives 50 percent or more of its calories from fat, its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to an appropriate reference product as described in § 413.313(j)(1); or

(2) If the product derives less than 50 percent of its calories from fat:

(i) The number of calories is reduced by at least one-third (33 ⅓ percent) per reference amount customarily consumed compared to an appropriate reference product as described in § 413.313(j)(1); or

(ii) Its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to the appropriate reference product as described in § 413.313(j)(1); and

(3) As required in § 413.313(j)(2) for relative claims:

(i) The identity of the reference product and the percent (or fraction) that the calories and the fat were reduced are declared in immediate proximity to the most prominent such claim (e.g., “⅓ fewer calories and 50 percent less fat than the market leader”); and

(ii) Quantitative information comparing the level of calories and fat content in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “lite ‘this product’—200 calories, 4 grams (g) fat; regular ‘reference product’—300 calories, 8 g fat per serving”); and

(iii) If the labeled product contains less than 40 calories or less than 3 g fat per reference amount customarily consumed, the percentage reduction for that nutrient need not be declared.

(4) A “light” claim may not be made on a product for which the reference product meets the definition of “low fat” and “low calorie.”

(c)(1)(i) A product for which the reference product contains 40 calories or less and 3 g fat or less per reference amount customarily consumed may use the terms “light” or “lite” without further qualification if it is reduced by 50 percent or more in sodium content compared to the reference product; and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim (e.g., “50

percent less sodium than the market leader"); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., "lite 'this product'—500 milligrams (mg) sodium per serving; regular 'reference product'—1,000 mg sodium per serving").

(2)(i) A product for which the reference product contains more than 40 calories or more than 3 g fat per reference amount customarily consumed may use the terms "light in sodium" or "lite in sodium" if it is reduced by 50 percent or more in sodium content compared to the reference product, provided that "light" or "lite" is presented in immediate proximity with "in sodium" and the entire term is presented in uniform type size, style, color, and prominence; and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim (e.g., "50 percent less sodium than the market leader"); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., or "lite 'this product'—170 mg sodium per serving; regular 'reference product'—350 mg per serving").

(3) Except for meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), a "light in sodium" claim may not be made on a product for which the reference product meets the definition of "low in sodium."

(d)(1) The terms "light" or "lite" may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product meets the definition of:

(A) "Low in calories" as defined in § 413.360(b)(3); or

(B) "Low in fat" as defined in § 413.362(b)(3); and

(ii)(A) A statement appears on the principal display panel that explains whether "light" is used to mean "low fat," "low calories," or both (e.g., "Light Delight, a low fat meal"); and

(B) The accompanying statement is no less than one-half the type size of the "light" or "lite" claim.

(2)(i) The terms "light in sodium" or "lite in sodium" may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that the product meets the definition of "low in sodium" as defined in § 413.361(b)(5)(i); and

(ii) "Light" or "lite" and "in sodium" are presented in uniform type size, style, color, and prominence.

(3) The term "light" or "lite" may be used in the brand name of a product to describe the sodium content, provided that:

(i) The product is reduced by 50 percent or more in sodium content compared to the reference product;

(ii) A statement specifically stating that the product is "light in sodium" or "lite in sodium" appears:

(A) Contiguous to the brand name; and

(B) In uniform type size, style, color, and prominence as the product name; and

(iii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim; and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information.

(e) Except as provided in paragraphs (b) through (d) of this section, the terms "light" or "lite" may not be used to refer to a product that is not reduced in fat by 50 percent, or, if applicable, in calories by $\frac{1}{3}$ or, when properly qualified, in sodium by 50 percent unless:

(1) It describes some physical or organoleptic attribute of the product such as texture or color and the information (e.g., "light in color" or "light in texture") so stated, clearly conveys the nature of the product; and

(2) The attribute (e.g., "color" or "texture") is in the same style, color, and at least one-half the type size as the word "light" and in immediate proximity thereto.

(f) If a manufacturer can demonstrate that the word "light" has been associated, through common use, with a particular product to reflect a physical or organoleptic attribute to the point where it has become part of the statement of identity, such use of the term "light" shall not be considered a nutrient content claim subject to the requirements in this part.

(g) The term "lightly salted" may be used on a product to which has been added 50 percent less sodium than is normally added to the reference product as described in § 413.313(j)(1)(i)(B) and (j)(1)(ii)(B), provided that if the product is not "low in sodium" as defined in § 413.361(b)(4), the statement "not a low sodium food," shall appear adjacent to the nutrition information and the information required to accompany a relative claim shall appear on the label or labeling as specified in § 413.313(j)(2).

§§ 413.357–413.359 [Reserved]

§ 413.360 Nutrient content claims for calorie content.

(a) *General requirements.* A claim about the calorie or sugar content of a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 413.313; and

(3) The product for which the claim is made is labeled in accordance with § 413.309.

(b) *Calorie content claims.* (1) The terms "calorie free," "free of calories," "no calories," "zero calories," "without calories," "trivial source of calories," "negligible source of calories," or "dietarily insignificant source of calories" may be used on the label or in labeling of products, provided that:

(i) The product contains less than 5 calories per reference amount customarily consumed and per labeled serving size; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms "low calorie," "few calories," "contains a small amount of calories," "low source of calories," or "low in calories" may be used on the label or in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons (tbsp) and does not provide more than 40 calories per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g

or less or 2 tbsp or less and does not provide more than 40 calories per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 413.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the “as prepared” form).

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains 120 calories or less per 100 g of product; and (ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which it attaches.

(4) The terms “reduced calorie,” “reduced in calories,” “calorie reduced,” “fewer calories,” “lower calorie,” or “lower in calories” may be used on the label or in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i) The product contains at least 25 percent fewer calories per reference amount customarily consumed than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the calories differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., lower calorie ‘product’—“33⅓ percent fewer calories than our regular ‘product’”); and

(B) Quantitative information comparing the level of calories in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “calorie content has been reduced from 150 to 100 calories per serving”).

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or in labeling of products if the reference product meets the definition for “low calorie.”

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains at least 25 percent fewer calories per 100 g of product than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the calories differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., “calorie reduced ‘product’, 25% less calories per ounce (oz) (or 3 oz) than our regular ‘product’”); and

(B) Quantitative information comparing the level of calories in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “calorie content has been reduced from 110 calories per 3 oz to 80 calories per 3 oz”).

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or in labeling of products if the reference product meets the definition for “low calorie.”

(c) *Sugar content claims.* (1) Terms such as “sugar free,” “free of sugar,” “no sugar,” “zero sugar,” “without sugar,” “sugarless,” “trivial source of sugar,” “negligible source of sugar,” or “dietarily insignificant source of sugar” may reasonably be expected to be regarded by consumers as terms that represent that the product contains no sugars or sweeteners, e.g., “sugar free,” or “no sugar,” as indicating a product which is low in calories or significantly reduced in calories. Consequently, except as provided in paragraph (c)(2) of this section, a product may not be labeled with such terms unless:

(i) The product contains less than 0.5 g of sugars, as defined in § 413.309(c)(6)(ii), per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product or a main-dish product, less than 0.5 g of sugars per labeled serving size;

(ii) The product contains no ingredient that is a sugar or that is generally understood by consumers to contain sugars unless the listing of the ingredient in the ingredients statement

is followed by an asterisk that refers to the statement below the list of ingredients, which states: “Adds a trivial amount of sugar,” “adds a negligible amount of sugar,” or “adds a dietarily insignificant amount of sugar;” and

(iii)(A) It is labeled “low calorie” or “reduced calorie” or bears a relative claim of special dietary usefulness labeled in compliance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section; or

(B) Such term is immediately accompanied, each time it is used, by either the statement “not a reduced calorie product,” “not a low calorie product,” or “not for weight control.”

(2) The terms “no added sugar,” “without added sugar,” or “no sugar added” may be used only if:

(i) No amount of sugars, as defined in § 413.309(c)(6)(ii), or any other ingredient that contains sugars that functionally substitute for added sugars is added during processing or packaging;

(ii) The product does not contain an ingredient containing added sugars such as jam, jelly, or concentrated fruit juice;

(iii) The sugars content has not been increased above the amount present in the ingredients by some means such as the use of enzymes, except where the intended functional effect of the process is not to increase the sugars content of a product, and a functionally insignificant increase in sugars results;

(iv) The product that it resembles and for which it substitutes normally contains added sugars; and

(v) The product bears a statement that the product is not “low calorie” or “calorie reduced” (unless the product meets the requirements for a “low” or “reduced calorie” product) and that directs consumers’ attention to the nutrition panel for further information on sugar and calorie content.

(3) Paragraph (c)(1) of this section shall not apply to a factual statement that a product, including products intended specifically for infants and children less than 2 years of age, is unsweetened or contains no added sweeteners in the case of a product that contains apparent substantial inherent sugar content, e.g., juices.

(4) The terms “reduced sugar,” “reduced in sugar,” “sugar reduced,” “less sugar,” “lower sugar,” or “lower in sugar” may be used on the label or in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i) The product contains at least 25 percent less sugars per reference amount customarily consumed than an

appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sugars differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., “this product contains 25 percent less sugar than our regular product”); and

(B) Quantitative information comparing the level of the sugar in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “sugar content has been lowered from 8 g to 6 g per serving”).

(5) The terms defined in paragraph (c)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains at least 25 percent less sugars per 100 g of product than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sugars differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., “reduced sugar ‘product’—25% less sugar than our regular ‘product’”); and

(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “sugar content has been reduced from 17 g per 3 oz to 13 g per 3 oz”).

§ 413.361 Nutrient content claims for the sodium content.

(a) *General requirements.* A claim about the level of sodium in a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 413.313; and

(3) The product for which the claim is made is labeled in accordance with § 413.309.

(b) *Sodium content claims.* (1) The terms “sodium free,” “free of sodium,”

“no sodium,” “zero sodium,” “without sodium,” “trivial source of sodium,” “negligible source of sodium,” or “dietarily insignificant source of sodium” may be used on the label or in labeling of products, provided that:

(i) The product contains less than 5 milligrams (mg) of sodium per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product or a main-dish product, less than 5 mg of sodium per labeled serving size;

(ii) The product contains no ingredient that is sodium chloride or is generally understood by consumers to contain sodium unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: “Adds a trivial amount of sodium,” “adds a negligible amount of sodium” or “adds a dietarily insignificant amount of sodium”; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms “very low sodium” or “very low in sodium” may be used on the label or in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons (tbsp) and contains 35 mg or less sodium per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 35 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 413.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the “as prepared” form); and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the

label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains 35 mg or less of sodium per 100 g of product; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms “low sodium,” “low in sodium,” “little sodium,” “contains a small amount of sodium,” or “low source of sodium” may be used on the label and in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 g or greater than 2 tbsp and contains 140 mg or less sodium per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 140 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 413.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the “as prepared” form); and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains 140 mg or less sodium per 100 g of product; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(6) The terms “reduced sodium,” “reduced in sodium,” “sodium reduced,” “less sodium,” “lower

sodium,” or “lower in sodium” may be used on the label or in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i) The product contains at least 25 percent less sodium per reference amount customarily consumed than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., “reduced sodium ‘product’, 50 percent less sodium than regular ‘product’”); and

(B) Quantitative information comparing the level of sodium in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “sodium content has been lowered from 300 to 150 mg per serving”).

(iii) Claims described in paragraph (b)(6) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for “low sodium.”

(7) The terms defined in paragraph (b)(6) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains at least 25 percent less sodium per 100 g of product than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., “reduced sodium ‘product’—30% less sodium per 3 oz than our ‘regular product’”); and

(B) Quantitative information comparing the level of sodium in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “sodium content has been reduced from 220 mg per 3 oz to 150 mg per 3 oz”).

(iii) Claims described in paragraph (b)(7) of this section may not be made on the label or in labeling of products

if the nutrient content of the reference product meets the definition for “low sodium.”

(c) The term “salt” is not synonymous with “sodium.” Salt refers to sodium chloride. However, references to salt content such as “unsalted,” “no salt,” “no salt added” are potentially misleading.

(1) The term “salt free” may be used on the label or in labeling of products only if the product is “sodium free” as defined in paragraph (b)(1) of this section.

(2) The terms “unsalted,” “without added salt,” and “no salt added” may be used on the label or in labeling of products only if:

(i) No salt is added during processing;

(ii) The product that it resembles and for which it substitutes is normally processed with salt; and

(iii) If the product is not sodium free, the statement, “not a sodium free product” or “not for control of sodium in the diet” appears adjacent to the nutrition information of the product bearing the claim.

(3) Paragraph (c)(2) of this section shall not apply to a factual statement that a product intended specifically for infants and children less than 2 years of age is unsalted, provided such statement refers to the taste of the product and is not false or otherwise misleading.

§ 413.362 Nutrient content claims for fat, fatty acids, and cholesterol content.

(a) *General requirements.* A claim about the level of fat, fatty acid, and cholesterol in a product may only be made on the label or in labeling of products if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 413.313; and

(3) The product for which the claim is made is labeled in accordance with § 413.309.

(b) *Fat content claims.* (1) The terms “fat free,” “free of fat,” “no fat,” “zero fat,” “without fat,” “nonfat,” “trivial source of fat,” “negligible source of fat,” or “dietarily insignificant source of fat” may be used on the label or in labeling of products, provided that:

(i) The product contains less than 0.5 gram (g) of fat per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product or a main-dish product, less than 0.5 g of fat per labeled serving size;

(ii) The product contains no added ingredient that is a fat or is generally

understood by consumers to contain fat unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: “Adds a trivial amount of fat,” “adds a negligible amount of fat,” or “adds a dietarily insignificant amount of fat”; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms “low fat,” “low in fat,” “contains a small amount of fat,” “low source of fat,” or “little fat” may be used on the label and in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons (tbsp) and contains 3 g or less of fat per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 3 g or less of fat per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 413.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the “as prepared” form).

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains 3 g or less of total fat per 100 g of product and not more than 30 percent of calories from fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the

particular brand to which the label attaches.

(4) The terms “reduced fat,” “reduced in fat,” “fat reduced,” “less fat,” “lower fat,” or “lower in fat” may be used on the label or in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i) The product contains at least 25 percent less fat per reference amount customarily consumed than an appropriate reference product as described in § 413.313(j)(1); and
(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., “reduced fat—50 percent less fat than our regular ‘product’”); and

(B) Quantitative information comparing the level of fat in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “fat content has been reduced from 8 g to 4 g per serving”).

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for “low fat.”

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains at least 25 percent less fat per 100 g of product than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., “reduced fat ‘product’, 33 percent less fat per 3 oz than our regular ‘product’”); and

(B) Quantitative information comparing the level of fat in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent such claim or to the nutrition information (e.g., “fat content has been reduced from 8 g per 3 oz to 5 g per 3 oz”).

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or in labeling of a product

if the nutrient content of the reference product meets the definition for “low fat.”

(6) The term “_____ percent fat free” may be used on the label or in labeling of products, provided that:

(i) The product meets the criteria for “low fat” in paragraph (b)(2) or (b)(3) of this section;

(ii) The percent declared and the words “fat free” are in uniform type size; and

(iii) A “100 percent fat free” claim may be made only on products that meet the criteria for “fat free” in paragraph (b)(1) of this section, that contain less than 0.5 g of fat per 100 g, and that contain no added fat.

(iv) A synonym for “_____ percent fat free” is “_____ percent lean.”

(c) *Fatty acid content claims.* (1) The terms “saturated fat free,” “free of saturated fat,” “no saturated fat,” “zero saturated fat,” “without saturated fat,” “trivial source of saturated fat,” “negligible source of saturated fat,” or “dietarily insignificant source of saturated fat” may be used on the label or in labeling of products, provided that:

(i) The product contains less than 0.5 g of saturated fat and less than 0.5 g *trans* fatty acids per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product or a main-dish product, less than 0.5 g of saturated fat and less than 0.5 g *trans* fatty acids per labeled serving size;

(ii) The product contains no ingredient that is generally understood by consumers to contain saturated fat unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: “Adds a trivial amount of saturated fat,” “adds a negligible amount of saturated fat,” or “adds a dietarily insignificant amount of saturated fat;” and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms “low in saturated fat,” “low saturated fat,” “contains a small amount of saturated fat,” “low source of saturated fat,” or “a little saturated fat” may be used on the label or in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i) The product contains 1 g or less of saturated fat per reference amount

customarily consumed and not more than 15 percent of calories from saturated fat; and

(ii) If the product meets these conditions without benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (c)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains 1 g or less of saturated fat per 100 g and less than 10 percent calories from saturated fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms “reduced saturated fat,” “reduced in saturated fat,” “saturated fat reduced,” “less saturated fat,” “lower saturated fat,” or “lower in saturated fat” may be used on the label or in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i) The product contains at least 25 percent less saturated fat per reference amount customarily consumed than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the saturated fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., “reduced saturated fat ‘product’, contains 50 percent less saturated fat than the national average for ‘product’”); and

(B) Quantitative information comparing the level of saturated fat in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “saturated fat reduced from 3 g to 1.5 g per serving”).

(iii) Claims described in paragraph (c)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for “low saturated fat.”

(5) The terms defined in paragraph (c)(4) of this section may be used on the

label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains at least 25 percent less saturated fat per 100 g of product than an appropriate reference product as described in § 413.313(j)(1); and

(ii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the saturated fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., “reduced saturated fat ‘product’,” “50 percent less saturated fat than our regular ‘product’”); and

(B) Quantitative information comparing the level of saturated fat in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “saturated fat content has been reduced from 2.5 g per 3 oz to 1.5 g per 3 oz”).

(iii) Claims described in paragraph (c)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for “low saturated fat.”

(d) *Cholesterol content claims.* (1) The terms “cholesterol free,” “free of cholesterol,” “zero cholesterol,” “without cholesterol,” “no cholesterol,” “trivial source of cholesterol,” “negligible source of cholesterol,” or “dietarily insignificant source of cholesterol” may be used on the label or in labeling of products, provided that:

(i) The product contains less than 2 milligrams (mg) of cholesterol per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), less than 2 mg of cholesterol per labeled serving size;

(ii) The product contains no ingredient that is generally understood by consumers to contain cholesterol, unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: “Adds a trivial amount of cholesterol,” “adds a negligible amount of cholesterol,” or “adds a dietarily insignificant amount of cholesterol”;

(iii) The product contains 2 g or less of saturated fat per reference amount customarily consumed or, in the case of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), 2 g or less of

saturated fat per labeled serving size; and

(iv) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which it attaches; or

(v) If the product meets these conditions only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is reduced by 25 percent or more from the reference product it replaces as described in § 413.313(j)(1) and for which it substitutes as described in § 413.313(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share. As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol was reduced are declared in immediate proximity to the most prominent such claim (e.g., “cholesterol free ‘product’,” contains 100 percent less cholesterol than ‘reference product’”); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “contains no cholesterol compared with 30 mg in one serving of ‘reference product’”).

(2) The terms “low in cholesterol,” “low cholesterol,” “contains a small amount of cholesterol,” “low source of cholesterol,” or “little cholesterol” may be used on the label or in labeling of products, except meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i)(A) If the product has a reference amount customarily consumed greater than 30 g or greater than 2 tbsp:

(1) The product contains 20 mg or less of cholesterol per reference amount customarily consumed; and

(2) The product contains 2 g or less of saturated fat per reference amount customarily consumed; or

(B) If the product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less:

(1) The product contains 20 mg or less of cholesterol per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 413.309(f)(1), of all

nutrients per reference amount customarily consumed, the per-50-g criterion refers to the “as prepared” form); and

(2) The product contains 2 g or less of saturated fat per reference amount customarily consumed.

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches; or

(iii) If the product contains 20 mg or less of cholesterol only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is reduced by 25 percent or more from the reference product it replaces as described in § 413.313(j)(1) and for which it substitutes as described in § 413.313(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share. As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., “low cholesterol ‘product’,” contains 85 percent less cholesterol than our regular ‘product’”); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “cholesterol lowered from 30 mg to 5 mg per serving”).

(3) The terms defined in paragraph (d)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product contains 20 mg or less of cholesterol per 100 g of product;

(ii) The product contains 2 g or less of saturated fat per 100 g of product; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms “reduced cholesterol,” “reduced in cholesterol,” “cholesterol reduced,” “less cholesterol,” “lower cholesterol,” or “lower in cholesterol” may be used on the label or in labeling of products or products that substitute for those products as specified in

§ 413.313(d), excluding meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference product it replaces as described in § 413.313(j)(1) and for which it substitutes as described in § 413.313(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share;

(ii) The product contains 2 g or less of saturated fat per reference amount customarily consumed; and

(iii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., “25 percent less cholesterol than ‘reference product’ ”); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., “cholesterol lowered from 55 mg to 30 mg per serving”).

(iv) Claims described in paragraph (d)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for “low cholesterol.”

(5) The terms defined in paragraph (d)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 413.313(l) and main-dish product as defined in § 413.313(m), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference product it replaces as described in § 413.313(j)(1) and for which it substitutes as described in § 413.313(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share;

(ii) The product contains 2 g or less of saturated fat per 100 g of product; and

(iii) As required in § 413.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., “25% less cholesterol than ‘reference product’ ”); and

(B) Quantitative information comparing the level of cholesterol in the product per specified weight with that of the reference product that it replaces

is declared adjacent to the most prominent claim or to the nutrition information (e.g., “cholesterol content has been reduced from 35 mg per 3 oz to 25 mg per 3 oz”).

(iv) Claims described in paragraph (d)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for “low cholesterol.”

(e) “Lean” and “Extra Lean” claims.

(1) The term “lean” may be used on the label or in labeling of a product, provided that the product contains less than 10 g of fat, 4.5 g or less of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m).

(2) The term “extra lean” may be used on the label or in labeling of a product, provided that the product contains less than 5 g of fat, less than 2 g of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined in § 413.313(l) and main-dish products as defined in § 413.313(m).

(f) A statement of the lean percentage may be used on the label or in labeling of ground or chopped products described in § 413.301 when the product does not meet the criteria for “low fat,” defined in § 413.362(b)(2), provided that a statement of the fat percentage is contiguous to and in lettering of the same color, size, type, and on the same color background, as the statement of the lean percentage.

§ 413.363 Nutrient content claims for “healthy.”

(a) The term “healthy,” or any other derivative of the term “health,” may be used on the labeling of any meat, meat food product, or poultry product, provided that the product is labeled in accordance with § 413.309 and § 413.313.

(b)(1) The product shall meet the requirements for “low fat” and “low saturated fat,” as defined in § 413.362, except that single-ingredient, raw products may meet the total fat and saturated fat criteria for “extra lean” in § 413.362.

(2) The product shall not contain more than 60 milligrams (mg) of cholesterol per reference amount customarily consumed, per labeled serving size, and, only for foods with

reference amounts customarily consumed of 30 grams (g) or less or 2 tablespoons (tbsp) or less, per 50 g, and, for dehydrated products that must be reconstituted with water or a diluent containing an insignificant amount, as defined in § 413.309(f)(1), of all nutrients, the per-50-g criterion refers to the prepared form, except that:

(i) A main-dish product, as defined in § 413.313(m), and a meal-type product, as defined in § 413.313(l), and including meal-type products that weigh more than 12 ounces (oz) per serving (container), shall not contain more than 90 mg of cholesterol per labeled serving size; and

(ii) Single-ingredient, raw products may meet the cholesterol criterion for “extra lean” in § 413.362.

(3) The product shall not contain more than 480 mg of sodium per reference amount customarily consumed, per labeled serving size, and, only for foods with reference amounts customarily consumed of 30 g or less or 2 tbsp or less, per 50 g, and, for dehydrated products that must be reconstituted with water or a diluent containing an insignificant amount, as defined in § 413.309(f)(1), of all nutrients, the per-50-g criterion refers to the prepared form, except that:

(i) A main-dish product, as defined in § 413.313(m), and a meal-type product, as defined in § 413.313(l), and including meal-type products that weigh more than 12 oz per serving (container), shall not contain more than 600 mg of sodium per labeled serving size;¹ and

(ii) The requirements of this paragraph (b)(3) do not apply to single-ingredient, raw products.

(4) The product shall contain 10 percent or more of the Reference Daily Intake or Daily Reference Value as defined in § 413.309 for vitamin A, vitamin C, calcium, iron, protein, or fiber per reference amount customarily consumed prior to any nutrient addition, except that:

(i) A main-dish product, as defined in § 413.313(m), and including main-dish products that weigh less than 10 oz per serving (container), shall meet the level for two of the nutrients per labeled serving size; and

¹ This regulation previously provided that, after January 1, 2006, individual meat and poultry products bearing the claim “healthy” (or any derivative of the term “health”) must contain no more than 360 mg of sodium and that meal-type products bearing the claim “healthy” (or any other derivative of the term “health”) must contain no more than 600 mg of sodium. Implementation of these sodium level requirements for products bearing the claim “healthy” (or any derivative of the term “health”) has been deferred indefinitely due to technological barriers and consumer preferences.

(ii) A meal-type product, as defined in § 413.313(l), shall meet the level for three of the nutrients per labeled serving size.

§§ 413.364–413.368 [Reserved]

§ 413.369 Labeling applications for nutrient content claims.

(a) This section pertains to labeling applications for claims, express or implied, that characterize the level of any nutrient required to be on the label or in labeling of product by this part.

(b) Labeling applications included in this section are:

(1) Labeling applications for a new (heretofore unauthorized) nutrient content claim,

(2) Labeling applications for a synonymous term (*i.e.*, one that is consistent with a term defined by regulation) for characterizing the level of a nutrient, and

(3) Labeling applications for the use of an implied claim in a brand name.

(c) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(d) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(e) If nonclinical laboratory studies accompany a labeling application, the applicant shall include, with respect to each nonclinical study included with the application, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in part 58 of chapter 1, title 21, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(f) If clinical investigations accompany a labeling application, the applicant shall include, with respect to each clinical investigation included with the application, either a statement that the investigation was conducted in compliance with the requirements for institutional review set forth in part 56 of chapter 1, title 21, or was not subject to such requirements in accordance with § 56.194 or § 56.105, and that it was conducted in compliance with the requirements for informed consents set forth in part 50 of chapter 1, title 21.

(g) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(h) The data specified under this section to accompany a labeling application shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(i) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(j) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(k)(1) Labeling applications for a new nutrient content claim shall be accompanied by the following data which shall be submitted in the following form to the Director, Labeling and Program Delivery Staff, Office of Policy and Program Development, Food Safety and Inspection Service, Washington, DC 20250.

(Date) _____

The undersigned, _____, submits this labeling application pursuant to 9 CFR 413.369 with respect to (statement of the claim and its proposed use). Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the nutrient content claim and the nutrient that the term is intended to characterize with respect to the level of such nutrient. The statement shall address why the use of the term as proposed will not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also

specify the level at which the nutrient must be present or what other conditions concerning the product must be met for the appropriate use of the term in labels or labeling, as well as any factors that would make the use of the term inappropriate.

(ii) A detailed explanation supported by any necessary data of why use of the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that such claim would describe. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed and why such benefit is not available through the use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, and scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

(iii) Analytical data that demonstrates the amount of the nutrient that is present in the products for which the claim is intended. The assays should be performed on representative samples in accordance with § 413.309(h). If no USDA or AOAC methods are available, the applicant shall submit the assay method used, and data establishing the validity of the method for assaying the nutrient in the particular food. The validation data shall include a statistical analysis of the analytical and product variability.

(iv) A detailed analysis of the potential effect of the use of the proposed claim on food consumption, and any corresponding changes in nutrient intake. The analysis shall specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the analysis shall specifically address the dietary practices of such group, and shall include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it

has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the **Federal Register** a proposed rule to amend the regulations to authorize the use of the nutrient content claim. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed nutrient content claim shall be approved for use on the labeling of meat and meat food products and poultry products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the **Federal Register** a final rule amending the regulations to authorize the use of the claim.

(l)(1) Labeling applications for a synonymous term shall be accompanied by the following data which shall be submitted in the following form to the Director, Labeling and Program Delivery Staff, Office of Policy and Program Development, Food Safety and Inspection Service, Washington, DC 20250:

(Date) _____

The undersigned, _____ submits this labeling application pursuant to 9 CFR 413.369 with respect to (statement of the synonymous term and its proposed use in a nutrient content claim that is consistent with an existing term that has been defined under part 413).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the synonymous term, the existing term defined by a regulation with which the synonymous term is claimed to be consistent, and the nutrient that the term is intended to characterize the level of. The statement shall address why the use of the synonymous term as proposed will not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify whether any limitations not applicable to the use of the defined term are intended to apply to the use of the synonymous term.

(ii) A detailed explanation supported by any necessary data of why use of the proposed term is requested, including whether the existing defined term is inadequate for the purpose of effectively characterizing the level of a nutrient. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through the use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

Yours very truly,

Applicant _____
By _____
(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed synonymous term is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way

of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed synonymous term.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the claim is approved, the Agency shall notify the applicant, in writing, and shall publish in the **Federal Register** a notice informing the public that the synonymous term has been approved for use.

(m)(1) Labeling applications for the use of an implied nutrient content claim in a brand name shall be accompanied by the following data which shall be submitted in the following form to the Director, Labeling and Program Delivery Staff, Office of Policy and Program Development, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 413.369 with respect to (statement of the implied nutrient content claim and its proposed use in a brand name).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the implied nutrient content claim, the nutrient the claim is intended to characterize, the corresponding term for characterizing the level of such nutrient as defined by a regulation, and the brand name of which the implied claim is intended to be a part. The statement shall address why the use of the brand-name as proposed will not be

misleading. The statement shall provide examples of the types of products on which the brand name will appear. It shall also include data showing that the actual level of the nutrient in the food would qualify the label of the product to bear the corresponding term defined by regulation. Assay methods used to determine the level of a nutrient shall meet the requirements stated under labeling application format in paragraph (k)(1)(iii) of this section.

(ii) A detailed explanation supported by any necessary data of why use of the proposed brand name is requested. This explanation shall also state what nutritional benefit to the public will derive from use of the brand name as proposed. If the branded product is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group and scientific data sufficient for such purpose.

Yours very truly,

Applicant _____

By _____

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed implied nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for

a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish a notice of the labeling application in the **Federal Register** seeking comment on the use of the implied nutrient content claim. The notice shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's notice shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the implied nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the implied nutrient content claim shall be approved for use on the labeling of meat food products or for poultry products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the **Federal Register** a notice informing the public that the implied nutrient content claim has been approved for use.

§§ 413.370–413.379 [Reserved]

§ 413.380 Label statements relating to usefulness in reducing or maintaining body weight.

(a) *General requirements.* Any product that purports to be or is represented for special dietary use because of usefulness in reducing body weight shall bear:

(1) Nutrition labeling in conformity with § 413.309 of this part, unless exempt under that section, and

(2) A conspicuous statement of the basis upon which the product claims to be of special dietary usefulness.

(b) *Nonnutritive ingredients.* (1) Any product subject to paragraph (a) of this section that achieves its special dietary usefulness by use of a nonnutritive ingredient (*i.e.*, one not utilized in normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary product may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the product under the applicable law and regulations of this chapter. Any product that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If nutritive sweeteners as well as nonnutritive sweeteners are added, the statement shall indicate the presence of both types of sweetener; *e.g.*, “Sweetened with nutritive sweeteners and nonnutritive sweeteners.”

(c) “*Low calorie*” foods. A product purporting to be “low calorie” must

comply with the criteria set forth for such foods in § 413.360.

(d) “*Reduced calorie*” foods and other comparative claims. A product purporting to be “reduced calorie” or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such foods in § 413.360(b) (4) and (5).

(e) “*Label terms suggesting usefulness as low calorie or reduced calorie foods*”.

(1) Except as provided in paragraphs (e)(2) and (e)(3) of this section, a product may be labeled with terms such as “diet,” “dietetic,” “artificially sweetened,” or “sweetened with nonnutritive sweetener” only if the claim is not false or misleading, and the product is labeled “low calorie” or “reduced calorie” or bears another comparative calorie claim in compliance with the applicable provisions in this part.

(2) Paragraph (e)(1) of this section shall not apply to any use of such terms that is specifically authorized by regulation governing a particular food, or, unless otherwise restricted by regulation, to any use of the term “diet” that clearly shows that the product is offered solely for a dietary use other than regulating body weight, *e.g.*, “for low sodium diets.”

(3) Paragraph (e)(1) of this section shall not apply to any use of such terms on a formulated meal replacement or other product that is represented to be of special dietary use as a whole meal, pending the issuance of a regulation governing the use of such terms on foods.

(f) “*Sugar free*” and “*no added sugar*”. Criteria for the use of the terms “sugar free” and “no added sugar” are provided for in § 413.360(c).

§§ 413.381–413.399 [Reserved]

§ 413.400 Exemptions from nutrition labeling.

(a) The following products are exempt from nutrition labeling:

(1) Food products produced by small businesses, other than the major cuts of single-ingredient, raw products identified in § 413.344 produced by small businesses, provided that the labels for these products bear no nutrition claims or nutrition information, and ground or chopped products described in § 413.301 produced by small businesses that bear a statement of the lean percentage and fat percentage on the label or in labeling in accordance with § 413.362(f), provided that labels or labeling for these products bear no other nutrition claims or nutrition information,

(i) A food product, for the purposes of the small business exemption, is

defined as a formulation, not including distinct flavors which do not significantly alter the nutritional profile, sold in any size package in commerce.

(ii) For purposes of this paragraph, a small business is any single-plant facility, including a single retail store, or multi-plant company/firm, including a multi-retail store operation, that employs 500 or fewer people and produces no more than 100,000 pounds of the product qualifying the firm for exemption from this part.

(iii) For purposes of this paragraph, calculation of the amount of pounds shall be based on the most recent 2-year average of business activity. Where firms have been in business less than 2 years or where products have been produced for less than 2 years, reasonable estimates must indicate that the annual pounds produced will not exceed the amounts specified.

(2) Products intended for further processing, provided that the labels for these products bear no nutrition claim or nutrition information,

(3) Products that are not for sale to consumers, provided that the labels for these products bear no nutrition claims or nutrition information,

(4) Products in small packages that are individually wrapped packages of less than ½ ounce net weight, provided that the labels for these products bear no nutrition claims or nutrition information,

(5) Products custom slaughtered or prepared,

(6) Products intended for export, and

(7) The following products prepared and served or sold at retail provided that the labels or the labeling of these products bear no nutrition claims or nutrition information:

(i) Ready-to-eat products that are packaged or portioned at a retail store or similar retail-type establishment, provided, however, that this exemption does not apply to ready-to-eat ground or chopped products described in § 413.301 that are packaged or portioned at a retail establishment, unless the establishment qualifies for an exemption under (a)(1) of this section;

(ii) Multi-ingredient products (*e.g.*, sausage) processed at a retail store or similar retail-type establishment, provided, however, that this exemption does not apply to multi-ingredient ground or chopped products described in § 413.301 that are processed at a retail establishment, unless the establishment qualifies for an exemption under (a)(1) of this section; and

(iii) Products that are ground or chopped at an individual customer's request.

(b) Restaurant menus generally do not constitute labeling or fall within the scope of these regulations.

(c)(1) Foods represented or purported to be specifically for infants through 12 months of age and children 1 through 3 years of age shall bear nutrition labeling. The nutrients declared for infants through 12 months of age and children 1 through 3 years of age shall include calories, total fat, saturated fat, *trans* fat, cholesterol, sodium, total carbohydrate, dietary fiber, total sugars, added sugars, protein, and the following vitamins and minerals: Vitamin D, calcium, iron, and potassium.

(2) Foods represented or purported to be specifically for infants through 12 months of age shall bear nutrition labeling, except that:

(i) Such labeling shall not declare a percent of Daily Value for saturated fat, *trans* fat, cholesterol, sodium, dietary fiber, total sugars, or added sugars and shall not include a footnote.

(ii) The following sample label illustrates the provisions of paragraph (c)(2) of this section.

| Nutrition Facts | |
|------------------------------|---------------------|
| 4 servings per container | |
| Serving size | 1 pack (70g) |
| Amount per serving | |
| Calories | 25 |
| % Daily Value | |
| Total Fat 0g | 0% |
| Saturated Fat 0g | |
| <i>Trans</i> Fat 0g | |
| Cholesterol 0mg | |
| Sodium 74mg | |
| Total Carbohydrate 5g | 5% |
| Dietary Fiber 1g | |
| Total Sugars 3g | |
| Includes 0g Added Sugars | |
| Protein 0g | 0% |
| Vitamin D 0mcg | 0% |
| Calcium 5mg | 2% |
| Iron 1mg | 10% |
| Potassium 230mg | 35% |

(3) Foods represented or purported to be specifically for children 1 through 3 years of age shall include a footnote that states: “* The %Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 1,000 calories a day is used for general nutrition advice.”

(i) The following sample label illustrates the provisions of paragraph (c)(3) of this section.

| Nutrition Facts | |
|---|--------------------------|
| 1 serving per container | |
| Serving size | 1 container (85g) |
| Amount per serving | |
| Calories | 70 |
| % Daily Value* | |
| Total Fat 15g | 4% |
| Saturated Fat 0.5g | 5% |
| <i>Trans</i> Fat 0g | |
| Cholesterol 10mg | 3% |
| Sodium 240mg | 16% |
| Total Carbohydrate 11g | 7% |
| Dietary Fiber 1g | 7% |
| Total Sugars 1g | |
| Includes 1g Added Sugars | 4% |
| Protein 3g | 23% |
| Vitamin D 0mcg | 0% |
| Calcium 35mg | 6% |
| Iron 0.6mg | 8% |
| Potassium 30mg | 0% |
| * The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 1,000 calories a day is used for general nutrition advice. | |

(ii) [Reserved]

(d)(1) Products in packages that have a total surface area available to bear labeling of less than 12 square inches are exempt from nutrition labeling, provided that the labeling for these products bear no nutrition claims or other nutrition information, except that this exemption does not apply to the major cuts of single-ingredient, raw products identified in § 413.344. The manufacturer, packer, or distributor

shall provide, on the label of packages that qualify for and use this exemption, an address or telephone number that a consumer can use to obtain the required nutrition information (e.g., “For nutrition information call 1-800-123-4567”).

(2) When products bear nutrition labeling, either voluntarily or because nutrition claims or other nutrition information is provided, all required information shall be provided in accordance with 9 CFR 413.309(d) for the linear nutrition display as shown in 9 CFR 413.309(g)(1)(i)(B).

Done at Washington, DC, on: November 28, 2016.

Alfred V. Almanza,
Acting Administrator.

[FR Doc. 2016-29272 Filed 1-18-17; 8:45 am]

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Part III

Department of Energy

10 CFR Part 430

Energy Conservation Program: Energy Conservation Standards for Ceiling Fans; Final Rule

DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket Number EERE-2012-BT-STD-0045]

RIN 1904-AD28

Energy Conservation Program: Energy Conservation Standards for Ceiling Fans

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule.

SUMMARY: The Energy Policy and Conservation Act of 1975 (EPCA), as amended, prescribes energy conservation standards for various consumer products and certain commercial and industrial equipment, including ceiling fans. EPCA also requires the U.S. Department of Energy (DOE) to periodically determine whether more-stringent standards would be technologically feasible and economically justified, and would save a significant amount of energy. In this final rule, DOE amends the energy conservation standards for ceiling fans. It has determined that the amended energy conservation standards for these products would result in significant conservation of energy, and are technologically feasible and economically justified.

DATES: The effective date of this rule is March 20, 2017. Compliance with the amended standards established for ceiling fans in this final rule is required on and after January 21, 2020.

ADDRESSES: The docket for this rulemaking, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at www.regulations.gov. All documents in the docket are listed in the www.regulations.gov index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

A link to the docket web page can be found at https://www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=5. The docket web page contains instructions on how to access all documents, including public comments, in the docket.

For further information on how to review the docket, contact Ms. Lucy deButts at: (202) 287-1604 or by e-mail: ApplianceStandardsQuestions@ee.doe.gov.

FOR FURTHER INFORMATION CONTACT:

Lucy deButts, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE-5B, 1000 Independence Avenue SW., Washington, DC 20585-0121. Telephone: (202) 287-1604. E-mail: ApplianceStandardsQuestions@ee.doe.gov.

Elizabeth Kohl, U.S. Department of Energy, Office of the General Counsel, GC-33, 1000 Independence Avenue SW., Washington, DC 20585-0121. Telephone: (202) 586-7796. E-mail: Elizabeth.Kohl@hq.doe.gov.

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I. Synopsis of the Final Rule

Title III, Part B¹ of the Energy Policy and Conservation Act of 1975 (EPCA or the Act), Public Law 94–163 (42 U.S.C. 6291–6309), established the Energy Conservation Program for Consumer Products Other Than Automobiles.² These products include ceiling fans, which are the subject of this rulemaking.

Pursuant to EPCA, any new or amended energy conservation standard must be designed to achieve the maximum improvement in energy efficiency that DOE determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) Furthermore, the new or amended standard must result in significant conservation of energy. (42 U.S.C. 6295(o)(3)(B))

In accordance with these and other statutory provisions discussed in this document, DOE is adopting amended energy conservation standards for ceiling fans. The amended standards, which are expressed for each product class as the minimum allowable efficiency in terms of cubic feet per minute per watt (CFM/W), as a function of ceiling fan diameter in inches, are shown in Table I.1. These standards

would apply to all ceiling fans listed in Table I.1 and manufactured in, or imported into, the United States on and after January 21, 2020.

TABLE I.1—ENERGY CONSERVATION STANDARDS FOR CEILING FANS
[Compliance starting January 21, 2020]

| Product class | Minimum efficiency equation CFM/W* |
|-----------------------------------|--|
| Very Small-Diameter (VSD). | D ≤ 12 in.: 21 D > 12 in.: 3.16 D – 17.04 |
| Standard | 0.65 D + 38.03 |
| Hugger | 0.29 D + 34.46 |
| High-Speed Small-Diameter (HSSD). | 4.16 D + 0.02 |
| Large Diameter | 0.91 D – 30.00 |

*D is the ceiling fan's blade span, in inches, as determined in Appendix U.

A. Benefits and Costs to Consumers

Table I.2 presents DOE's evaluation of the economic impacts of the adopted standards on consumers of ceiling fans, as measured by the average life-cycle cost (LCC) savings and the simple payback period (PBP).³ The average LCC savings are positive for all product classes, and the PBP is less than the average lifetime of ceiling fans, which is estimated to be 13.8 years for all product classes (see section IV.F.5).

TABLE I.2—IMPACTS OF AMENDED ENERGY CONSERVATION STANDARDS ON CONSUMERS OF CEILING FANS

| Product class | Average LCC savings* (2015\$) | Simple payback period (years) |
|---------------------------------|-------------------------------|-------------------------------|
| Standard | 25.78 | 1.7 |
| Hugger | 21.50 | 1.8 |
| Very Small-Diameter | 4.29 | 9.3 |
| High-Speed Small-Diameter | 19.80 | 6.9 |
| Large-Diameter | 128.90 | 4.1 |

* The calculation excludes consumers with zero LCC savings (no impact).

DOE's analysis of the impacts of the adopted standards on consumers is described in section IV.F of this document.

B. Impact on Manufacturers

The industry net present value (INPV) is the sum of the discounted cash flows to the industry from the reference year through the terminal year of the analysis period (2016–2049). Using a real

discount rate of 7.4 percent, DOE estimates that the INPV for manufacturers of ceiling fans in the case without amended standards is \$1,211.6 million in 2015\$. Under the adopted standards, DOE expects that manufacturers may lose up to 9.9 percent of this INPV, which is approximately \$119.4 million.

DOE's analysis of the impacts of the adopted standards on manufacturers is

described in section IV.J of this document.

C. National Benefits and Costs⁴

DOE's analyses indicate that the adopted energy conservation standards for ceiling fans would save a significant amount of energy. Relative to the case without amended standards (referred to as the “no-new-standards case”), the lifetime energy savings for ceiling fans

¹ For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

² All references to EPCA in this document refer to the statute as amended through the Energy Efficiency Improvement Act of 2015, Public Law 114–11 (April 30, 2015).

³ The average LCC savings are measured relative to the efficiency distribution in the no-new-standards case, which depicts the market in the compliance year in the absence of standards (see section IV.F.7). The simple PBP, which is designed to compare specific ceiling fan efficiency levels, is measured relative to the baseline product (see

section IV.C), which corresponds to the least efficient model available to purchase.

⁴ All monetary values in this document are expressed in 2015 dollars and, where appropriate, are discounted to 2016 unless explicitly stated otherwise.

purchased in the 30-year period that begins in the anticipated first full year of compliance with the amended standards (2020–2049), amount to 2.008 quadrillion British thermal units (Btu), or quads.⁵ This represents a total energy savings of 26 percent across all product classes relative to the energy use of these products in the no-new-standards case.

The cumulative net present value (NPV) of total consumer costs and savings of the standards for ceiling fans ranges from \$4.488 billion (at a 7-percent discount rate) to \$12.123 billion (at a 3-percent discount rate). This NPV expresses the estimated total value of future operating-cost savings minus the estimated increased product costs for ceiling fans purchased in 2020–2049.

In addition, the standards for ceiling fans are projected to yield significant environmental benefits. DOE estimates

that the standards would result in cumulative greenhouse gas emission reductions (over the same period as for energy savings) of 120.2 million metric tons (Mt)⁶ of carbon dioxide (CO₂), 64.0 thousand tons of sulfur dioxide (SO₂), 222.6 thousand tons of nitrogen oxides (NO_x), 530.1 thousand tons of methane (CH₄), 1.3 thousand tons of nitrous oxide (N₂O), and 0.2 tons of mercury (Hg).⁷ The cumulative reduction in CO₂ emissions through 2030 amounts to 18.2 Mt, which is equivalent to the emissions resulting from the annual electricity use of more than 1.9 million homes.

The value of the CO₂ reductions is calculated using a range of values per metric ton (t) of CO₂ (otherwise known as the “Social Cost of Carbon”, or SCC) developed by a Federal interagency working group.⁸ The derivation of the SCC values is discussed in section IV.L. Using discount rates appropriate for

each set of SCC values, DOE estimates that the net present monetary value of the CO₂ emissions reduction (not including CO₂ equivalent emissions of other gases with global warming potential) is between \$0.8 billion and \$11.7 billion, with a value of \$3.8 billion using the SCC central value case represented by \$40.6/metric ton (t) in 2015. DOE also estimates that the present monetary value of the NO_x emissions reduction to be \$0.2 billion at a 7-percent discount rate, and \$0.4 billion at a 3-percent discount rate.⁹ DOE is investigating appropriate valuation of the reduction in other emissions, and did not include any values for other emissions in this rulemaking.

Table I.3 summarizes the economic benefits and costs expected to result from the adopted standards for ceiling fans.

TABLE I.3—SELECTED CATEGORIES OF ECONOMIC BENEFITS AND COSTS OF AMENDED ENERGY CONSERVATION STANDARDS FOR CEILING FANS *

| Category | Present value (billion 2015\$) | Discount rate (%) |
|--|-----------------------------------|----------------------|
| Benefits | | |
| Consumer Operating Cost Savings | 7.0 | 7 |
| CO ₂ Reduction (using mean SCC at 5% discount rate) ** | 16.5 | 3 |
| CO ₂ Reduction (using mean SCC at 3% discount rate) ** | 0.8 | 5 |
| CO ₂ Reduction (using mean SCC at 2.5% discount rate) ** | 3.8 | 3 |
| CO ₂ Reduction (using mean SCC at 2.5% discount rate) ** | 6.1 | 2.5 |
| CO ₂ Reduction (using 95th percentile SCC at 3% discount rate) ** | 11.7 | 3 |
| NO _x Reduction † | 0.2 | 7 |
| | 0.4 | 3 |
| Total Benefits ‡ | 11.0 | 7 |
| | 20.7 | 3 |
| Costs | | |
| Consumer Incremental Installed Costs | 2.5 | 7 |
| | 4.4 | 3 |

⁵ The quantity refers to full-fuel-cycle (FFC) energy savings. FFC energy savings includes the energy consumed in extracting, processing, and transporting primary fuels (i.e., coal, natural gas, petroleum fuels), and, thus, presents a more complete picture of the impacts of energy efficiency standards. For more information on the FFC metric, see section IV.H.1.

⁶ A metric ton is equivalent to 1.1 short tons. Results for emissions other than CO₂ are presented in short tons.

⁷ DOE calculated emissions reductions relative to the no-new-standards-case, which reflects key assumptions in the *Annual Energy Outlook 2015* (AEO 2015).

⁸ United States Government-Interagency Working Group on Social Cost of Carbon. *Technical Support Document: Technical Update of the Social Cost of Carbon for Regulatory Impact Analysis Under*

Executive Order 12866. May 2013. Revised July 2015. Available at <https://www.whitehouse.gov/sites/default/files/omb/inforeg/scc-ts-final-july-2015.pdf>.

⁹ DOE estimated the monetized value of NO_x emissions reductions associated with electricity savings using benefit per ton estimates from the *Regulatory Impact Analysis for the Clean Power Plan Final Rule*, published in August 2015 by EPA's Office of Air Quality Planning and Standards. Available at www.epa.gov/cleanpowerplan/clean-power-plan-final-rule-regulatory-impact-analysis. See section IV.L.2 for further discussion. On February 9, 2016, the U.S. Supreme Court stayed the rule implementing the Clean Power Plan pending disposition of the applicants' petitions for review in the United States Court of Appeals for the District of Columbia Circuit and disposition of the applicants' petition for a writ of certiorari, if such writ is sought. *Chamber of Commerce, et al. v. EPA,*

et al., Order in Pending Case, available at <http://www.chamberlitigation.com/sites/default/files/scotus/files/2016/SCOTUS%20Order%20Granting%20U.S.%20Chamber%2C%20et%20al.%20Stay%20Application%20-%20States%20of%20West%20Virginia%2C%20Texas%2C%20et%20al.%20v.%20EPA%20%28ESPS%29.pdf> (last visited June 22, 2016). Pending the outcome of that litigation, DOE continues to use the benefit-per-ton estimates established in the Regulatory Impact Analysis for the Clean Power Plan. To be conservative, DOE is primarily using a national benefit-per-ton estimate for NO_x emitted from the Electricity Generating Unit sector based on an estimate of premature mortality derived from the ACS study (Krewski *et al.* 2009). If the benefit-per-ton estimates were based on the Six Cities study (Lepuele *et al.* 2011), the values would be nearly two-and-a-half times larger.

TABLE I.3—SELECTED CATEGORIES OF ECONOMIC BENEFITS AND COSTS OF AMENDED ENERGY CONSERVATION STANDARDS FOR CEILING FANS *—Continued

| Category | Present value (billion 2015\$) | Discount rate (%) |
|---|-----------------------------------|----------------------|
| Total Net Benefits | | |
| Including CO ₂ and NO _x Reduction Monetized Value ‡ | 8.5 16.3 | 7 3 |

* This table presents the costs and benefits associated with ceiling fans shipped in 2020–2049. These results include benefits to consumers which accrue after 2049 from the products purchased in 2020–2049. The incremental installed costs include incremental equipment cost as well as installation costs. The CO₂ reduction benefits are global benefits due to actions that occur nationally.

** The interagency group selected four sets of SCC values for use in regulatory analyses. Three sets of values are based on the average SCC from the integrated assessment models, at discount rates of 5 percent, 3 percent, and 2.5 percent. For example, for 2015 emissions, these values are \$12.4/t, \$40.6/t, and \$63.2/t, in 2015\$, respectively. The fourth set (\$118/t in 2015\$ for 2015 emissions), which represents the 95th percentile of the SCC distribution calculated using a 3-percent discount rate, is included to represent higher-than-expected impacts from temperature change further out in the tails of the SCC distribution. The SCC values are emission year specific. See section IV.L.1 for more details.

† DOE estimated the monetized value of NO_x emissions reductions associated with electricity savings using benefit per ton estimates from the *Regulatory Impact Analysis for the Clean Power Plan Final Rule*, published in August 2015 by EPA's Office of Air Quality Planning and Standards. (Available at www.epa.gov/cleanpowerplan/clean-power-plan-final-rule-regulatory-impact-analysis.) See section IV.L.2 for further discussion. To be conservative, DOE is primarily using a national benefit-per-ton estimate for NO_x emitted from the Electricity Generating Unit sector based on an estimate of premature mortality derived from the ACS study (Krewski *et al.* 2009). If the benefit-per-ton estimates were based on the Six Cities study (Lepule *et al.* 2011), the values would be nearly two-and-a-half times larger.

‡ Total Benefits for both the 3-percent and 7-percent cases are presented using only the average SCC with 3-percent discount rate.

The benefits and costs of the adopted standards, for ceiling fans sold in 2020–2049, can also be expressed in terms of annualized values. The monetary values for the total annualized net benefits are the sum of (1) the national economic value of the benefits in reduced consumer operating costs, minus (2) the increases in product purchase prices and installation costs, plus (3) the value of the benefits of CO₂ and NO_x emission reductions, all annualized.¹⁰

The national operating cost savings are domestic private U.S. consumer monetary savings that occur as a result of purchasing the covered products. The national operating cost savings is measured for the lifetime of ceiling fans shipped in 2020–2049. The CO₂ reduction is a benefit that accrues

globally due to decreased domestic energy consumption that is expected to result from this rule. Because CO₂ emissions have a very long residence time in the atmosphere, the SCC values in future years reflect future CO₂-emissions impacts that continue beyond 2100.

Estimates of annualized benefits and costs of the adopted standards are shown in Table I.4. The results under the primary estimate are as follows. Using a 7-percent discount rate for benefits and costs other than CO₂ reduction, (for which DOE used a 3-percent discount rate along with the SCC series that has a value of \$40.6/t in 2015),¹¹ the estimated annualized cost of the standards in this rule is \$245.1 million per year in increased equipment

costs, while the estimated annualized benefits are \$688.1 million in reduced equipment operating costs, \$214.1 million in CO₂ reductions, and \$15.1 million in reduced NO_x emissions. In this case, the annualized net benefit amounts to \$672.2 million per year. Using a 3-percent discount rate for all benefits and costs and the SCC series has a value of \$40.6/t in 2015, the estimated cost of the standards is \$243.2 million per year in increased equipment costs, while the estimated annualized benefits are \$919.0 million in reduced operating costs, \$214.1 million in CO₂ reductions, and \$21.5 million in reduced NO_x emissions. In this case, the annualized net benefit amounts to \$911.4 million per year.

TABLE I.4—SELECTED CATEGORIES OF ANNUALIZED BENEFITS AND COSTS OF AMENDED STANDARDS FOR CEILING FANS *

| | Discount rate | Primary estimate | Low-net-benefits estimate | High-net-benefits estimate |
|--|-----------------------------------|--------------------|---------------------------|----------------------------|
| (million 2015\$/year) | | | | |
| Benefits | | | | |
| Consumer Operating Cost Savings | 7% | 688.1 | 579.7 | 793.5 |
| | 3% | 919.0 | 764.2 | 1081.9 |
| CO ₂ Reduction (using mean SCC at 5% discount rate) ** ... | 5% | 62.8 | 53.7 | 71.0 |
| CO ₂ Reduction (using mean SCC at 3% discount rate) ** ... | 3% | 214.1 | 182.2 | 242.6 |
| CO ₂ Reduction (using mean SCC at 2.5% discount rate) ** ... | 2.5% | 314.2 | 267.2 | 356.3 |
| CO ₂ Reduction (using 95th percentile SCC at 3% discount rate) ** ... | 3% | 652.7 | 555.4 | 739.8 |
| NO _x Reduction † | 7% | 15.1 | 13.1 | 38.1 |
| | 3% | 21.5 | 18.4 | 55.3 |
| Total Benefits ‡ | 7% plus CO ₂ range ... | 766 to 1,356 | 647 to 1,148 | 903 to 1,571 |

¹⁰ To convert the time-series of costs and benefits into annualized values, DOE calculated a present value in 2016, the year used for discounting the NPV of total consumer costs and savings. For the benefits, DOE calculated a present value associated with each year's shipments in the year in which the shipments occur (e.g., 2020 or 2030), and then

discounted the present value from each year to 2016. The calculation uses discount rates of 3 and 7 percent for all costs and benefits except for the value of CO₂ reductions, for which DOE used case-specific discount rates, as shown in Table I.3. Using the present value, DOE then calculated the fixed annual payment over a 30-year period, starting in

the compliance year, that yields the same present value.

¹¹ DOE used a 3-percent discount rate because the SCC values for the series used in the calculation were derived using a 3-percent discount rate (see section IV.L).

TABLE I.4—SELECTED CATEGORIES OF ANNUALIZED BENEFITS AND COSTS OF AMENDED STANDARDS FOR CEILING FANS *—Continued

| | Discount rate | Primary estimate | Low-net-benefits estimate | High-net-benefits estimate |
|--|-----------------------------------|---------------------|---------------------------|----------------------------|
| | | | (million 2015\$/year) | |
| | 7% | 917.3 | 775.0 | 1,074.2 |
| | 3% plus CO ₂ range ... | 1,003 to 1,593 | 836 to 1,338 | 1,208 to 1,877 |
| | 3% | 1,154.6 | 964.8 | 1,379.9 |
| Costs *** | | | | |
| Consumer Incremental Product Costs | 7% | 245.1 | 288.1 | 272.8 |
| | 3% | 243.2 | 298.7 | 273.7 |
| Net Benefits | | | | |
| Total * | 7% plus CO ₂ range ... | 521 to 1,111 | 358 to 860 | 630 to 1,299 |
| | 7% | 672.2 | 487.0 | 801.4 |
| | 3% plus CO ₂ range ... | 760 to 1,350 | 538 to 1,039 | 935 to 1,603 |
| | 3% | 911.4 | 666.1 | 1,106.2 |

* This table presents the annualized costs and benefits associated with ceiling fans shipped in 2020–2049. These results include benefits to consumers which accrue after 2049 from the ceiling fans purchased from 2020–2049. The incremental installed costs include incremental equipment cost as well as installation costs. The CO₂ reduction benefits are global benefits due to actions that occur nationally. The Primary Estimate assumes the Reference case electricity prices and housing starts from AEO 2015 and decreasing product prices for ceiling fans with DC motors, due to price trend on the electronics components. The Low Benefits Estimate uses the Low Economic Growth electricity prices and housing starts from AEO 2015 and no price trend for ceiling fans with DC motors. The High Benefits Estimate uses the High Economic Growth electricity prices and housing starts from AEO 2015 and the same product price decrease for ceiling fans with DC motors as in the Primary Estimate. The methods used to derive projected price trends are explained in section IV.G.4. Note that the Benefits and Costs may not sum to the Net Benefits due to rounding.

** The CO₂ reduction benefits are calculated using 4 different sets of SCC values. The first three use the average SCC calculated using 5-percent, 3-percent, and 2.5-percent discount rates, respectively. The fourth represents the 95th percentile of the SCC distribution calculated using a 3-percent discount rate. The SCC values are emission year specific. See section IV.L.1 for more details.

† DOE estimated the monetized value of NO_x emissions reductions associated with electricity savings using benefit per ton estimates from the *Regulatory Impact Analysis for the Clean Power Plan Final Rule*, published in August 2015 by EPA's Office of Air Quality Planning and Standards. (Available at www.epa.gov/cleanpowerplan/clean-power-plan-final-rule-regulatory-impact-analysis.) See section IV.L.2 for further discussion. For the Primary Estimate and Low Net Benefits Estimate, DOE used national benefit-per-ton estimates for NO_x emitted from the Electric Generating Unit sector based on an estimate of premature mortality derived from the ACS study (Krewski *et al.* 2009). For the High Net Benefits Estimate, the benefit-per-ton estimates were based on the Six Cities study (Lepuele *et al.* 2011); these are nearly two-and-a-half times larger than those from the ACS study.

* Total Benefits for both the 3-percent and 7-percent cases are presented using only the average SCC with 3-percent discount rate. In the rows labeled “7% plus CO₂ range” and “3% plus CO₂ range,” the operating cost and NO_x benefits are calculated using the labeled discount rate, and those values are added to the full range of CO₂ values.

*** For certain assumed design options (e.g., fan optimization) that are included at the selected standard level, DOE estimated no incremental costs to consumers, but did estimate a one-time industry conversion cost to manufacturers to make their products compliant with the selected standards that are not reflected in the Consumer Incremental Product Costs. The one-time industry conversion cost to manufacturers of these design options contribute to a loss in industry net present value of \$4.8 million, which is equivalent to an annualized cost of \$0.4 million/year at a 7.4-percent discount rate over the analysis period.

DOE's analysis of the national impacts of the adopted standards is described in sections IV.H, IV.K, and IV.L of this notice.

D. Conclusion

Based on the analyses culminating in this final rule, DOE found the benefits to the nation of the standards (energy savings, consumer LCC savings, positive NPV of consumer benefit, and emission reductions) outweigh the burdens (loss of INPV and LCC increases for some users of these products). DOE has concluded that the standards in this final rule represent the maximum improvement in energy efficiency that is technologically feasible and economically justified, and would result in significant conservation of energy.

II. Introduction

The following section briefly discusses the statutory authority underlying this adopted rule, as well as some of the relevant historical background related to the establishment of standards for ceiling fans.

A. Authority

Title III, Part B of the Energy Policy and Conservation Act of 1975 (EPCA or the Act), Public Law 94–163 (42 U.S.C. 6291, *et seq.*) established the Energy Conservation Program for Consumer Products Other Than Automobiles, a program covering most major household appliances (collectively referred to as “covered products”), which includes the ceiling fans that are the subject of this rulemaking. (42 U.S.C. 6295(ff)) EPCA, as amended, prescribes energy conservation standards for these products and authorizes DOE to

consider energy efficiency or energy use standards for the electricity used by ceiling fans to circulate air in a room. *Id.*

Under 42 U.S.C. 6295(m), DOE must periodically review its already established energy conservation standards for a covered product. Under this requirement, the next review that DOE would need to conduct must occur no later than 6 years from the issuance of any final rule establishing or amending a standard for a covered product. EPCA also provides that not later than 6 years after issuance of any final rule establishing or amending a standard, DOE must publish either a notice of determination that standards for the product do not need to be amended, or a notice of proposed rulemaking including new proposed energy conservation standards. (42 U.S.C. 6295(m))

Pursuant to EPCA, DOE's energy conservation program for covered products consists essentially of four parts: (1) Testing, (2) labeling, (3) the establishment of Federal energy conservation standards, and (4) certification and enforcement procedures. The Federal Trade Commission (FTC) is primarily responsible for labeling, and DOE implements the remainder of the program. Subject to certain criteria and conditions, DOE is required to develop test procedures to measure the energy efficiency, energy use, or estimated annual operating cost of each covered product. (42 U.S.C. 6295(o)(3)(A) and (r)) Manufacturers of covered products must use the prescribed DOE test procedure as the basis for certifying to DOE that their products comply with the applicable energy conservation standards adopted under EPCA and when making representations to the public regarding the energy use or efficiency of those products. (42 U.S.C. 6293(c) and 6295(s)) Similarly, DOE must use these test procedures to determine whether the products comply with standards adopted pursuant to EPCA. (42 U.S.C. 6295(s)) The DOE test procedures for ceiling fans appear at title 10 of the Code of Federal Regulations (CFR) part 430, subpart B, appendix U, 10 CFR 430.23(w) and 10 CFR 429.32.

DOE must follow specific statutory criteria for prescribing new or amended standards for covered products, including ceiling fans. Any new or amended standard for a covered product must be designed to achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A) and (3)(B)) Furthermore, DOE may not adopt any standard that would not result in the significant conservation of energy. (42 U.S.C. 6295(o)(3)) Moreover, DOE may not prescribe a standard (1) for certain products, including ceiling fans, if no test procedure has been established for the product, or (2) if DOE determines by rule that the standard is not technologically feasible or economically justified. (42 U.S.C. 6295(o)(3)(A)–(B)) In deciding whether a proposed standard is economically justified, DOE must determine whether the benefits of the standard exceed its burdens. (42 U.S.C. 6295(o)(2)(B)(i)) DOE must make this determination after receiving comments on the proposed standard, and by considering, to the greatest extent practicable, the following seven statutory factors:

(1) The economic impact of the standard on manufacturers and

consumers of the products subject to the standard;

(2) The savings in operating costs throughout the estimated average life of the covered products in the type (or class) compared to any increase in the price, initial charges, or maintenance expenses for the covered products that are likely to result from the standard;

(3) The total projected amount of energy (or as applicable, water) savings likely to result directly from the standard;

(4) Any lessening of the utility or the performance of the covered products likely to result from the standard;

(5) The impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from the standard;

(6) The need for national energy and water conservation; and

(7) Other factors the Secretary of Energy (Secretary) considers relevant.

(42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII))

Further, EPCA, as codified, establishes a rebuttable presumption that a standard is economically justified if the Secretary finds that the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the energy savings during the first year that the consumer will receive as a result of the standard, as calculated under the applicable test procedure. (42 U.S.C. 6295(o)(2)(B)(iii))

EPCA, as codified, also contains what is known as an “anti-backsliding” provision, which prevents the Secretary from prescribing any amended standard that either increases the maximum allowable energy use or decreases the minimum required energy efficiency of a covered product. (42 U.S.C. 6295(o)(1)) Also, the Secretary may not prescribe an amended or new standard if interested persons have established by a preponderance of the evidence that the standard is likely to result in the unavailability in the United States in any covered product type (or class) of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States. (42 U.S.C. 6295(o)(4))

Additionally, EPCA specifies requirements when promulgating an energy conservation standard for a covered product that has two or more subcategories. DOE must specify a different standard level for a type or class of products that has the same function or intended use if DOE determines that products within such group (A) consume a different kind of

energy from that consumed by other covered products within such type (or class); or (B) have a capacity or other performance-related feature which other products within such type (or class) do not have and such feature justifies a higher or lower standard. (42 U.S.C. 6295(q)(1)) In determining whether a performance-related feature justifies a different standard for a group of products, DOE must consider such factors as the utility to the consumer of such a feature and other factors DOE deems appropriate. *Id.* Any rule prescribing such a standard must include an explanation of the basis on which such higher or lower level was established. (42 U.S.C. 6295(q)(2))

Federal energy conservation requirements generally supersede State laws or regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297(a)–(c)) DOE may, however, grant waivers of Federal preemption for particular State laws or regulations, in accordance with the procedures and other provisions set forth under 42 U.S.C. 6297(d)).

EPCA also requires that for any final rule for new or amended energy conservation standards promulgated after July 1, 2010, DOE must address standby mode and off mode energy use. (42 U.S.C. 6295(gg)(3)) Specifically, when DOE adopts a standard for a covered product after that date, it must, if justified by the criteria for adoption of standards under EPCA (42 U.S.C. 6295(o)), incorporate standby mode and off mode energy use into a single standard, or, if that is not feasible, adopt a separate standard for such energy use for that product. (42 U.S.C. 6295(gg)(3)(A)–(B)) The amended standards DOE is adopting in this final rule incorporate standby mode and off mode energy use into a single standard.

B. Background

1. Current Standards

The Energy Policy and Conservation Act of 1975 (EPCA) defined and established design standards for ceiling fans. EPCA defined a “ceiling fan” as “a nonportable device that is suspended from a ceiling for circulating air via the rotation of fan blades.” (42 U.S.C. 6291(49)) In a final rule technical amendment published in the on October 18, 2005, DOE codified the statutorily-prescribed design standards for ceiling fans. 70 FR 60407, 60413. These standards are set forth in DOE's regulations at 10 CFR 430.32(s), and require all ceiling fans manufactured on or after January 1, 2007, to have the following features:

1. Fan speed controls separate from any lighting controls;
2. adjustable speed controls (either more than one speed or variable speed); and

3. the capability for reverse action (other than fans sold for industrial or outdoor application or where safety would be an issue)).

(42 U.S.C. 6295(ff)(1)(A) and (6))

2. History of Standards Rulemaking for Ceiling Fans

EPCA established energy conservation standards for ceiling fans as described in Section II.B.1 and authorized DOE to consider, if the requirements of 42 U.S.C. 6295(o) and (p) are met, establishing energy efficiency or energy use standards for the electricity used by ceiling fans to circulate air in a room. (42 U.S.C. 6295(ff))

As noted in section II.B.1, DOE codified the statutorily-prescribed design standards for ceiling fans in the CFR at 10 CFR 430.32(s). 70 FR 60407, 60413 (Oct. 18, 2005). DOE also adopted test procedures for ceiling fans at 10 CFR part 430, subpart B, appendix U and 10 CFR 430.23(w). 71 FR 71340, 71366–67 (Dec. 8, 2006). Sampling and certification requirements for ceiling fans are set forth at 10 CFR 429.32.

On March 15, 2013, DOE published a notice announcing the availability of the framework document, “Energy Conservation Standards Rulemaking Framework Document for Ceiling Fans and Ceiling Fan Light Kits,”¹² and a public meeting to discuss the proposed analytical framework for the energy conservation standards rulemaking. 78 FR 16643. DOE held the public meeting for the framework document on March 22, 2013,¹³ to present the framework document, describe the analyses DOE planned to conduct during the rulemaking, seek comments from interested parties on these subjects, and inform them about and facilitate their involvement in the rulemaking.

On September 29, 2014, DOE published the preliminary analysis for the ceiling fan energy conservation standards rulemaking. 79 FR 58290. DOE posted the preliminary analysis, as well as the complete preliminary technical support document (TSD), on its website.¹⁴ DOE held a public meeting

on November 19, 2014, to present the preliminary analysis, which included presenting preliminary results for the engineering and downstream economic analyses, seek comments from interested parties on these subjects, and facilitate interested parties’ involvement in the rulemaking.

On January 13, 2016, DOE published a notice of proposed rulemaking (NOPR) for the ceiling fans energy conservation standards rulemaking (ceiling fans NOPR). 81 FR 1688. DOE posted the ceiling fans NOPR analysis, as well as the complete NOPR TSD on its Web site.¹⁵ DOE held a public meeting on February 3, 2016 to present the ceiling fans NOPR, which included the engineering analysis, downstream economic analyses, manufacturer impact analysis, and proposed standards. In the public meeting, DOE also sought comments from interested parties on these subjects, and facilitated interested parties’ involvement in the rulemaking. At the public meeting, and during the comment period, DOE received comments that helped DOE identify issues and refine the analyses presented in the ceiling fans NOPR for this final rule. The key changes since the ceiling fans NOPR were the following: (1) The engineering analysis was updated based on additional test data, and (2) the efficiency distribution in the no-new-standards case for the standard and hugger product classes was updated with significantly more market share at the lower efficiency levels based on comments from manufacturers.

This final rule responds to issues raised by commenters in response to the framework document, preliminary analysis, and NOPR.

III. General Discussion

DOE developed this proposal after considering comments, data, and information from interested parties that represent a variety of interests. The following section provides general discussion of the final standards rule; section IV addresses the issues raised by these commenters.

A. Product Classes and Scope of Coverage

1. Scope of Coverage

EPCA defines a “ceiling fan” as “a nonportable device that is suspended from a ceiling for circulating air via the rotation of fan blades.” (42 U.S.C. 6291(49))

¹⁵ The NOPR analysis, NOPR TSD and NOPR public meeting information are available at regulations.gov under docket number EERE–2012–BT–STD–0045–0130.

DOE previously interpreted the definition of a ceiling fan such that it excluded certain types of ceiling fans commonly referred to as hugger fans. 71 FR 71343 (Dec. 8, 2006). Hugger ceiling fans are typically understood to be set flush to the ceiling (e.g., mounted without a downrod). The previous interpretation exempted hugger fans from standards on the basis that they are set flush to the ceiling. However, in the test procedure final rule for ceiling fan light kits, DOE reinterpreted the definition of a ceiling fan to include hugger fans, and clarified that the definition also included ceiling fans capable of producing large volumes of airflow. 80 FR 80209 (Dec. 24, 2015).

The changes in interpretation of the ceiling fan definition discussed above resulted in the applicability of the design standards set forth in EPCA at 42 U.S.C. 6295(ff)(1) to these fan types as of January 25, 2016. DOE research indicates that all ceiling fans currently on the market, including hugger ceiling fans and ceiling fans that produce a large volume of airflow, appear to meet the EPCA design standards. Compliance with requirements related to the ceiling fan reinterpretation was discussed in the Ceiling Fan Light Kit test procedure final rule. 80 FR 80209 (Dec. 24, 2015). Specifically, DOE will not assert civil penalty authority for violations of the applicable standards arising as a result of the reinterpretation of the ceiling fan definition before June 26, 2017.

DOE is also establishing efficiency standards for these fan types, which include hugger ceiling fans and ceiling fans that produce a large volume of airflow, in this ceiling fans final rule. Compliance with those standards, as discussed in the **DATES** section, is January 21, 2020.

Additionally, in the ceiling fan test procedure final rule, DOE provided clarification on those ceiling fans that are not subject to the test procedure. 81 FR 48620 (July 25, 2016). The test procedures do not apply to belt-driven ceiling fans, centrifugal ceiling fans, oscillating ceiling fans, or ceiling fans whose blades’ plane of rotation cannot be within 45 degrees of horizontal. American Lighting Association (ALA) requested that DOE clarify that if the plane of rotation is not within 45 degrees of horizontal, the ceiling fan is not subject to DOE’s proposed efficiency standards, certification requirements or labeling requirements. (ALA, No. 137 at p. 4) DOE confirms that it is not establishing performance standards for ceiling fans whose blades’ plane of rotation cannot be within 45 degrees of horizontal in this final rule. The design standards set forth in EPCA at 42 U.S.C.

¹² The energy conservation standards final rule for ceiling fan light kits was published on January 6, 2016. 81 FR 580.

¹³ The framework document is available at regulations.gov under docket number EERE–2012–BT–STD–0045–0001.

¹⁴ The preliminary analysis, preliminary TSD, and preliminary analysis public meeting information are available at regulations.gov under docket number EERE–2012–BT–STD–0045–0066.

6295(ff) remain applicable to these fans and manufacturers must certify compliance with those design standards to DOE.

In summary, this DOE final rule is not establishing performance standards for belt-driven ceiling fans, centrifugal ceiling fans, oscillating ceiling fans, or ceiling fans whose blades' plane of rotation cannot be within 45 degrees of horizontal. DOE is also not establishing performance standards for highly decorative fans. Manufacturers must continue to submit certification reports to DOE for such fans with respect to the statutory design standards. Both DOE and manufacturers would determine whether a fan met the definition of a highly decorative fan using the final test procedure, though manufacturers would not be required to submit the supporting information, including any test data that supports their highly decorative classification as part of their certification submission to DOE. In addition, manufacturers would be required to test highly-decorative fans according to the test procedure established in the test procedure final rule to make representations of the energy efficiency of such fans (*e.g.*, for the EnergyGuide label)).

2. Product Classes

When establishing energy conservation standards, DOE divides covered products into product classes by the type of energy used or by capacity or other performance-related features that justify differing standards. In making a determination whether a performance-related feature justifies a different standard, DOE must consider such factors as the utility of the feature to the consumer and other factors DOE determines are appropriate. (42 U.S.C. 6295(q))

Currently there are no product classes for ceiling fans, because the previous final rule for ceiling fans published on October 18, 2005 set design standards, but did not establish product classes. 70 FR 60407. In the ceiling fans NOPR, DOE proposed seven product classes and their associated definitions, which included highly-decorative, belt-driven, very small-diameter, hugger, standard, high-speed small-diameter and large-diameter fans. 81 FR 1688 (January 13, 2016). Chapter 3 of the TSD provides additional discussion on the establishment of these product classes pursuant to 42 U.S.C. 6295(q). In the ceiling fans test procedure final rule, DOE finalized the definitions for these types of ceiling fans. 81 FR 48620 (July 25, 2016). In this final rule, DOE is finalizing all seven product classes proposed in the ceiling fans NOPR. For

further details on product classes, see section IV.A.1 of this rulemaking.

B. Test Procedure

EPCA sets forth generally applicable criteria and procedures for DOE's adoption and amendment of test procedures. (42 U.S.C. 6293) Manufacturers of covered products must use these test procedures to certify to DOE that their product complies with energy conservation standards and to quantify the efficiency of their product. (42 U.S.C. 6293, 6295(s)) Similarly, DOE must use these test procedures to determine compliance with its energy conservation standards. (42 U.S.C. 6295(s)) As noted, the test procedures for ceiling fans are provided in 10 CFR 430.23(w) and appendix U to subpart B of 10 CFR part 430. DOE published a NOPR to amend the ceiling fan test procedures on October 17, 2014, 79 FR 62521, and published a supplemental NOPR (SNOPR) on June 3, 2015. 80 FR 31487. DOE finalized the test procedure on July 25, 2016. 81 FR 48620.

With respect to the process of establishing test procedures and standards for a given product, DOE notes that, while not legally obligated to do so, it generally follows the approach laid out in guidance found in 10 CFR part 430, subpart C, Appendix A (Procedures, Interpretations and Policies for Consideration of New or Revised Energy Conservation Standards for Consumer Products). That guidance provides, among other things, that DOE issues final, modified test procedures for a given product prior to publication of the NOPR proposing energy conservation standards for that product. While DOE strives to follow the procedural steps outlined in its guidance, there may be circumstances in which it may be necessary or appropriate to deviate from it. In such instances, the guidance indicates that DOE will provide notice and an explanation for the deviation. Accordingly, DOE has provided notices while it continued to develop the final test procedure for ceiling fans. DOE received comments regarding test methods for ceiling fans for which the plane of rotation of the ceiling fan's blades cannot be within 45 degrees of horizontal, high-volume small-diameter ceiling fans and ceiling fans with blade spans greater than seven feet leading to modification to test methods proposed in the NOPR. (79 FR 62521 (October 17, 2014)). DOE also received comments regarding the variability of results from the test procedures proposed in the SNOPR (80 FR 31487 (June 3, 2015)), based on testing conducted by manufacturers. Lastly, DOE conducted a

thorough review of all available test data, including additional test data supplied by manufacturers, to identify opportunities to decrease testing variation.

DOE attempted to issue the final test procedure prior to the NOPR proposing energy conservation standards. However, additional time to address comments received on the NOPR and SNOPR lead to modification of the test procedure, which caused deviations from the guidance provided in 10 CFR part 430, subpart C, Appendix A.

Currently no energy efficiency performance standards exist for ceiling fans, just design standards for certain ceiling fans. In this final rule, DOE is setting energy efficiency performance standards in terms of a minimum efficiency equation established in the test procedure final rule. 81 FR 48620 (July 25, 2016). The test procedure final rule established test procedures for an integrated efficiency metric measured in cubic feet per minute per watt (CFM/W) that is applicable to all ceiling fans for which DOE establishes energy conservation standards in this final rule.

In the July 2016 test procedure final rule, DOE: (1) Specified new test procedures for large-diameter ceiling fans, multi-mount ceiling fans, ceiling fans with multiple fan heads, and ceiling fans where the airflow is not directed vertically, and (2) adopted the following changes to the current test procedure: (a) Low-speed small-diameter ceiling fans must be tested at high and low speeds; (b) high-speed small-diameter ceiling fans must be tested at high speed only; (c) large-diameter ceiling fans must be tested at up to five speeds; (d) a test cylinder is not to be used during testing; (e) fans that can be mounted at more than one height are to be mounted in the configuration that minimizes the distance between the fan blades and the ceiling; (f) any heater installed with a ceiling fan is to be switched off during testing; (g) small-diameter ceiling fans must be mounted directly to the real ceiling; (h) the allowable measurement tolerance for air velocity sensors is $\pm 5\%$; (i) the allowable mounting distance tolerance for air velocity sensors is $\pm 1/16"$; (j) the air delivery room must be at $70 \text{ F} \pm 5 \text{ F}$ during testing; (k) air delivery room doors and air conditioning vents must be closed and forced-air conditioning equipment turned off during testing; (l) low speed small diameter and HSSD fans capable of operating with single- and multi-phase power be tested with single-phase power, and large diameter fans capable of operating with single- and multi-phase power be tested with multi-phase

power; (m) the supply voltage must be 120 V if the ceiling fan's minimum rated voltage is 120 V or the lowest rated voltage range contains 120 V; 240 V if the ceiling fan's minimum rated voltage is 240 V or the lowest rated voltage range contains 240 V; the ceiling fan's minimum rated voltage (if a voltage range is not given) or the mean of the lowest rated voltage range, in all other cases; (n) measurement axes shall be perpendicular to test room walls; and (o) measurement stabilization requirements shall be met for a valid test (*i.e.*, average air velocity readings in each axis for each sensor are within 5% and average electrical power measurement in each axis for each sensor are within 1%). DOE also determined that belt-driven ceiling fans, centrifugal ceiling fans, oscillating ceiling fans, and ceiling fans for which the plane of rotation of the fan blades cannot be within 45 degrees of horizontal are not subject to the ceiling fan test procedure. Manufacturers of highly decorative ceiling fans must use the test procedure as described in section III.A.1.

C. Technological Feasibility

1. General

In each energy conservation standards rulemaking, DOE conducts a screening analysis based on information gathered on all current technology options and prototype designs that could improve the efficiency of the products or equipment that are the subject of the rulemaking. As the first step in such an analysis, DOE develops a list of technology options for consideration in consultation with manufacturers, design engineers, and other interested parties. DOE then determines which of those means for improving efficiency are technologically feasible. DOE considers technologies incorporated in commercially available products or in working prototypes to be technologically feasible. 10 CFR part 430, subpart C, appendix A, section 4(a)(4)(i)

After DOE has determined that particular technology options are technologically feasible, it further evaluates each technology option in light of the following additional screening criteria: (1) Practicability to manufacture, install, and service; (2) adverse impacts on product utility or availability; and (3) adverse impacts on health or safety. 10 CFR part 430, subpart C, appendix A, section 4(a)(4)(ii)–(iv) Additionally, it is DOE policy not to include in its analysis any proprietary technology that is a unique pathway to achieving a certain

efficiency level. Section IV.B of this notice discusses the results of the screening analysis for ceiling fans, particularly the designs DOE considered, those it screened out, and those that are the basis for the standards considered in this rulemaking. For further details on the screening analysis for this rulemaking, see section IV.B of this notice and chapter 4 of the final rule TSD.

2. Maximum Technologically Feasible Levels

When DOE proposes to adopt an amended standard for a type or class of covered product, it must determine the maximum improvement in energy efficiency or maximum reduction in energy use that is technologically feasible for such product. (42 U.S.C. 6295(p)(1)) Accordingly, in the engineering analysis, DOE determined the maximum technologically feasible (“max-tech”) improvements in energy efficiency for ceiling fans, using the design parameters for the most efficient products available on the market or in working prototypes. The max-tech levels that DOE determined for this rulemaking are described in section IV.C of this proposed rule and in chapter 5 of the final rule TSD.

D. Energy Savings

1. Determination of Savings

For each trial standard level (TSL), DOE projected energy savings from application of the TSL to ceiling fans purchased in the 30-year period that begins in the first full year of compliance with any amended standards (2020–2049).¹⁶ The savings are measured over the entire lifetime of products purchased in the 30-year analysis period. DOE quantified the energy savings attributable to each TSL as the difference in energy consumption between each standards case and the no-new-standards case. The no-new-standards case represents a projection of energy consumption that reflects how the market for a product would likely evolve in the absence of amended energy conservation standards.

DOE used its national impact analysis (NIA) spreadsheet models to estimate national energy savings (NES) from potential amended standards for ceiling fans. The NIA spreadsheet model (described in section IV.H of this rulemaking) calculates energy savings in terms of site energy, which is the energy directly consumed by products at the locations where they are used. Based on

the site energy, DOE calculates NES in terms of primary energy savings at the site or at power plants, and also in terms of full-fuel-cycle (FFC) energy savings. The FFC metric includes the energy consumed in extracting, processing, and transporting primary fuels (*i.e.*, coal, natural gas, petroleum fuels), and thus presents a more complete picture of the impacts of energy conservation standards.¹⁷ DOE's approach is based on the calculation of an FFC multiplier for each of the energy types used by covered products or equipment. For more information on FFC energy savings, see section IV.H.1 of this rulemaking.

2. Significance of Savings

To adopt standards for a covered product, DOE must determine that such action would result in significant energy savings. (42 U.S.C. 6295(o)(3)(B)) Although the term “significant” is not defined in the Act, the U.S. Court of Appeals, for the District of Columbia Circuit in *Natural Resources Defense Council v. Herrington*, 768 F.2d 1355, 1373 (D.C. Cir. 1985), indicated that Congress intended “significant” energy savings in the context of EPCA to be savings that are not “genuinely trivial.” The energy savings for all the TSLs considered in this rulemaking, which range from 0.807 quads to 3.738 quads, are nontrivial, and, therefore, DOE considers them “significant” within the meaning of section 325 of EPCA.

E. Economic Justification

1. Specific Criteria

As noted above, EPCA provides seven factors to be evaluated in determining whether a potential energy conservation standard is economically justified. (42 U.S.C. 6295(o)(2)(B)(i)(I)–(VII)) The following sections discuss how DOE has addressed each of those seven factors in this rulemaking.

a. Economic Impact on Manufacturers and Consumers

In determining the impacts of a potential amended standard on manufacturers, DOE conducts a manufacturer impact analysis (MIA), as discussed in section IV.J. DOE first uses an annual cash-flow approach to determine the quantitative impacts. This step includes both a short-term assessment—based on the cost and capital requirements during the period between when a regulation is issued and when entities must comply with the

¹⁶ DOE also presents a sensitivity analysis that considers impacts for products shipped in a 9-year period.

¹⁷ The FFC metric is discussed in DOE's statement of policy and notice of policy amendment. 76 FR 51282 (August 18, 2011), as amended at 77 FR 49701 (Aug. 17, 2012).

regulation—and a long-term assessment over a 30-year period. The industry-wide impacts analyzed include (1) INPV, which values the industry on the basis of expected future cash flows; (2) cash flows by year; (3) changes in revenue and income; and (4) other measures of impact, as appropriate. Second, DOE analyzes and reports the impacts on different types of manufacturers, including impacts on small manufacturers. Third, DOE considers the impact of standards on domestic manufacturer employment and manufacturing capacity, as well as the potential for standards to result in plant closures and loss of capital investment. Finally, DOE takes into account cumulative impacts of various DOE regulations and other regulatory requirements on manufacturers.

For individual consumers, measures of economic impact include the changes in LCC and payback period (PBP) associated with new or amended standards. These measures are discussed further in the following section. For consumers in the aggregate, DOE also calculates the national net present value of the economic impacts applicable to a particular rulemaking. DOE also evaluates the LCC impacts of potential standards on identifiable subgroups of consumers that may be affected disproportionately by a national standard.

b. Savings in Operating Costs Compared to Increase in Price (LCC and PBP)

EPCA requires DOE to consider the savings in operating costs throughout the estimated average life of the covered product in the type (or class) compared to any increase in the price of, or in the initial charges for, or maintenance expenses of, the covered product that are likely to result from a standard. (42 U.S.C. 6295(o)(2)(B)(i)(II)) DOE conducts this comparison in its LCC and PBP analysis.

The LCC is the sum of the purchase price of a product (including its installation) and the operating cost (including energy, maintenance, and repair expenditures) discounted over the lifetime of the product. The LCC analysis requires a variety of inputs, such as product prices, product energy consumption, energy prices, maintenance and repair costs, product lifetime, and discount rates appropriate for consumers. To account for uncertainty and variability in specific inputs, such as product lifetime and discount rate, DOE uses a distribution of values, with probabilities attached to each value.

The PBP is the estimated amount of time (in years) it takes consumers to

recover the increased purchase cost (including installation) of a more-efficient product through lower operating costs. DOE calculates the PBP by dividing the change in purchase cost due to a more-stringent standard by the change in annual operating cost for the year that standards are assumed to take effect.

For its LCC and PBP analysis, DOE assumes that consumers will purchase the covered products in the first full year of compliance with amended standards. The LCC savings for the considered efficiency levels are calculated relative to the case that reflects projected market trends in the absence of amended standards. DOE's LCC and PBP analysis is discussed in further detail in section IV.F.

c. Energy Savings

Although significant conservation of energy is a separate statutory requirement for adopting an energy conservation standard, EPCA requires DOE, in determining the economic justification of a standard, to consider the total projected energy savings that are expected to result directly from the standard. (42 U.S.C. 6295(o)(2)(B)(i)(III)) As discussed in section IV.H, DOE uses the NIA spreadsheet models to project national energy savings.

d. Lessening of Utility or Performance of Products

In establishing product classes, and in evaluating design options and the impact of potential standard levels, DOE evaluates potential standards that would not lessen the utility or performance of the considered products. (42 U.S.C. 6295(o)(2)(B)(i)(IV)) Based on data available to DOE, the standards adopted in this final rule would not reduce the utility or performance of the products under consideration in this rulemaking.

e. Impact of Any Lessening of Competition

EPCA directs DOE to consider the impact of any lessening of competition, as determined in writing by the Attorney General, that is likely to result from a standard. (42 U.S.C. 6295(o)(2)(B)(i)(V)) It also directs the Attorney General to determine the impact, if any, of any lessening of competition likely to result from a standard and to transmit such determination to the Secretary within 60 days of the publication of a proposed rule, together with an analysis of the nature and extent of the impact. (42 U.S.C. 6295(o)(2)(B)(ii)) To assist the Department of Justice (DOJ) in making such a determination, DOE transmitted copies of its proposed rule and the

NOPR TSD to the Attorney General for review, with a request that the DOJ provide its determination on this issue. In its assessment letter responding to DOE, DOJ concluded that the proposed energy conservation standards for ceiling fans are unlikely to have a significant adverse impact on competition. DOE is publishing the Attorney General's assessment at the end of this final rule.

f. Need for National Energy Conservation

DOE also considers the need for national energy conservation in determining whether a new or amended standard is economically justified. (42 U.S.C. 6295(o)(2)(B)(i)(VI)) The energy savings from the adopted standards may provide improvements to the security and reliability of the nation's energy system. Reductions in the demand for electricity also may result in reduced costs for maintaining the reliability of the Nation's electricity system. DOE conducts a utility impact analysis to estimate how standards may affect the nation's needed power generation capacity, as discussed in section IV.M.

The adopted standards also are likely to result in environmental benefits in the form of reduced emissions of air pollutants and greenhouse gases (GHGs) associated with energy production and use. DOE conducts an emissions analysis to estimate how potential standards may affect these emissions, as discussed in section IV.K; the emissions impacts are reported in section V.B.6 of this rulemaking. DOE also estimates the economic value of emissions reductions resulting from the considered TSLs, as discussed in section IV.L. To date, this accounting for environmental benefits has not had a decisive impact on the outcome of any standards rulemaking, which is also the case for today's final rule.

g. Other Factors

In determining whether an energy conservation standard is economically justified, DOE may consider any other factors that the Secretary deems to be relevant. (42 U.S.C. 6295(o)(2)(B)(i)(VII)) To the extent interested parties submit any relevant information regarding economic justification that does not fit into the other categories described above, DOE could consider such information under "other factors."

2. Rebuttable Presumption

As set forth in 42 U.S.C. 6295(o)(2)(B)(iii), EPCA creates a rebuttable presumption that an energy conservation standard is economically justified if the additional cost to the

consumer of a product that meets the standard is less than three times the value of the first year's energy savings resulting from the standard, as calculated under the applicable DOE test procedure. DOE's LCC and PBP analyses generate values used to calculate the effect potential amended energy conservation standards would have on the payback period for consumers. These analyses include, but are not limited to, the 3-year payback period contemplated under the rebuttable-presumption test. In addition, DOE routinely conducts an economic analysis that considers the full range of impacts to consumers, manufacturers, the Nation, and the environment, as required under 42 U.S.C. 6295(o)(2)(B)(i). The results of this analysis serve as the basis for DOE's evaluation of the economic justification for a potential standard level (thereby supporting or rebutting the results of any preliminary determination of economic justification). The rebuttable presumption payback calculation is discussed in section IV.F.8 of this final rule.

IV. Methodology and Discussion of Related Comments

This section addresses the analyses DOE has performed for this rulemaking with regard to ceiling fans. Separate subsections address each component of DOE's analyses. DOE also responds to comments received on its analyses in this section.

DOE used several analytical tools to estimate the impact of the standards considered in this document. The first tool is a spreadsheet that calculates the LCC savings and PBP of amended energy conservation standards (the Life-Cycle Cost Analysis spreadsheet). The national impacts analysis uses a second spreadsheet set that provides shipments forecasts and calculates national energy savings and net present value of total consumer costs and savings expected to result from potential energy conservation standards (the National Impact Analysis spreadsheet). DOE uses the third spreadsheet tool, the Government Regulatory Impact Model (GRIM), to assess manufacturer impacts of potential standards. These three spreadsheet tools are available on the DOE website for this rulemaking: <https://www.regulations.gov/#/docketDetail;D=EERE-2012-BT-STD-0045>. Additionally, DOE used output from the latest version of EIA's *Annual Energy Outlook* (AEO), a widely known energy forecast for the United States, for the emissions and utility impact analyses.

A. Market and Technology Assessment

DOE develops information in the market and technology assessment that provides an overall picture of the market for the products concerned, including the purpose of the products, the industry structure, manufacturers, market characteristics, and technologies used in the products. This activity includes both quantitative and qualitative assessments, based primarily on publicly-available information. The subjects addressed in the market and technology assessment for this rulemaking include (1) the scope of the rulemaking and product classes, (2) manufacturers and industry structure, (3) existing efficiency programs, (4) shipments information, (5) market and industry trends, and (6) technologies or design options that could improve the energy efficiency of ceiling fans. See chapter 3 of the final rule TSD for further discussion of the market and technology assessment.

DOE received several comments regarding product classes, and the technology options DOE identified that can improve the efficiency of ceiling fans. The comments are discussed in the following sections.

1. Product Classes

DOE divides covered products into classes by: (a) The type of energy used by the product; (b) the capacity of the product; or (c) other performance-related features that justify different standard levels, considering the consumer utility of the feature and other relevant factors. (42 U.S.C. 6295(q))

In the ceiling fans NOPR, DOE proposed seven product classes based on the capacity of the product and other performance-related features that justify a different standard, considering the utility to the consumer. 81 FR 1688. The product classes include: Highly-decorative, belt-driven, very-small-diameter, hugger, standard, high-speed small-diameter and large-diameter ceiling fans. DOE also proposed definitions for these product classes in the ceiling fan energy conservation standard proposed rule. In the ceiling fan test procedure final rule, DOE finalized the definitions for the following types of ceiling fans: highly-decorative, belt-driven, very-small-diameter, hugger, standard, high speed small-diameter and large-diameter ceiling fans. DOE responded to any comments received in response to the ceiling fans NOPR regarding the definitions for these type of ceiling fans in the test procedure final rule. 81 FR 48620 (July 25, 2016).

In this final rule, DOE finalizes the product classes proposed in the ceiling fans NOPR for the energy conservation standards. DOE received several comments to the ceiling fans NOPR regarding the product classes that were proposed. Westinghouse stated that they agree and appreciate the minor changes made to the product class structure, and that the changes make a big difference, particularly regarding safety. (Westinghouse, Public Meeting Transcript, No. 133 at p. 21) ALA commented that they agreed in general with the product class structure proposed in the NOPR. (ALA, No. 137 at p. 4) BAS stated that they are generally supportive of the product class structure. (BAS, No. 138 at p. 2) However, BAS expressed concern that the product classes may be too complex, in particular, comparing the standard fans to HSSD fans. The two different methods of tests may provide some confusion to end users. Specifically, BAS was concerned that HSSD ceiling fans will be tested at one speed, while standard ceiling fans will be tested at two speeds (BAS, Public Meeting Transcript, No. 133 at p. 22) (BAS, No. 138 at p. 2)

DOE finds that HSSD ceiling fans provide different utility to the consumer than standard ceiling fans. HSSD ceiling fans generally operate at much higher speeds (in terms of RPM) than standard ceiling fans, and are installed in commercial applications. HSSD ceiling fans are available in a blade span range similar to standard ceiling fans, but an HSSD fan typically provides more airflow at a given blade span because it runs at much higher RPMs. Additionally, DOE observed that HSSD ceiling fans are generally used in commercial buildings whereas standard fans are installed in residential buildings. Therefore, HSSD and standard ceiling fans provide distinct utility to different end-users and are not market substitutes. As a result, establishing separate product classes and differing test methods should not provide confusion to end-users.

Also, in general, the product class structure was developed to follow the Underwriters Laboratory (UL) ceiling fan existing safety standards (UL Standard 507–1999, “UL Standard for Safety for Electric Fans” (UL 507)).¹⁸ The UL 507 standard uses both blade thickness and maximum tip speed to differentiate fans, such that ceiling fans are safe for use in applications where

¹⁸ Underwriters Laboratories Inc. UL Standard for Safety for Electric Fans, UL 507. 1999. Northbrook, IL. <http://www.comm-2000.com/ProductDetail.aspx?UniqueKey=8782>.

the distance between the fans blades and the floor is 10 feet or less. While standard ceiling fans are used in locations where blades are typically within 10 feet of the floor, HSSD ceiling fans are not and do not have to comply with the UL 507 standard. A product class structure that is consistent with UL 507 provides a method to differentiate standard and HSSD ceiling fans, while still ensuring that the safety standards are in place. Simplifying the product class structure without using the UL507 standard could result in safety issues.

In summary, HSSD ceiling fans provide a different utility to consumers compared to standard fans, and that warrants a separate product class for these ceiling fans. Therefore, in this final rule, DOE continues to define separate product classes for HSSD and standard ceiling fans.

For the reasons discussed above, DOE finalizes the seven product classes proposed in the ceiling fans NOPR in this final rule. The product classes finalized in this final rule are: Highly-decorative, belt-driven, very-small-diameter, hugger, standard, high-speed small-diameter and large-diameter ceiling fans.

In the ceiling fans NOPR, DOE did not propose standards for ceiling fans in the highly-decorative fan and belt-driven ceiling fan product classes. EPCA requires DOE to consider exempting, or setting different standards for, certain product classes for which the “primary standards” are not technically feasible or economically justified. EPCA also requires DOE to consider establishing separate exempted product classes for highly-decorative fans for which air

movement performance is a secondary design feature. (42 U.S.C.6295(ff)(6)(B)(i)–(ii)) DOE did not have data to determine whether standards for belt-driven ceiling fans were technically feasible and economically justified due to the limited number of basic models for belt-driven ceiling fans. DOE did not receive any comments regarding these product classes and has not received any additional data to analyze potential standards for belt-driven ceiling fans. As a result, in this final rule, DOE does not set any standards for highly-decorative and belt-driven ceiling fans.

DOE is also not establishing performance standards for centrifugal ceiling fans, oscillating ceiling fans, or ceiling fans whose blades’ plane of rotation cannot be within 45 degrees of horizontal fans. In the ceiling fan test procedure final rule, DOE stated that those ceiling fans are also not subject to the test procedure. 81 FR 48620 (July 25, 2016).

2. Technology Options

In the NOPR market and technology assessment, DOE identified technology options that would improve the efficiency of ceiling fans, as measured by the DOE test procedure. These technology options fall into four main categories: (1) More efficient motors, which include larger direct-drive single phase induction motors, three-phase induction motors, geared brushless DC motors, gearless brushless DC motors, and brushless DC motors, and; (2) more efficient blades, which include curved blades, airfoil blades, twisted blades, beveled blades, blade attachments, alternative blade materials; (3) ceiling

fan controls, which include occupancy sensors; and (4) fan optimization.

DOE received no comments in opposition to the technology options proposed in the ceiling fans NOPR. However, DOE did receive comments regarding including an additional technology option specific to large-diameter ceiling fans. BAS requested that an additional efficiency level be added to represent a large diameter fan using a premium AC motor instead of a three-phased geared brushless DC motor. BAS stated that premium AC motors are almost as efficient as permanent magnet motors. (BAS, Public Meeting Transcript, No. 133 at pp. 35–36)

In response to BAS’s comment, and for the reasons discussed in section IV.C.3, DOE added premium AC motor as an additional technology option in this final rule to account for the costs and benefits of premium AC motors used in ceiling fans in DOE’s analysis. Further discussion regarding how DOE implemented this technology option in the analysis is provided in chapter 5 of the TSD.

In the absence of adverse comments, DOE analyzed the same technology options from the ceiling fans NOPR, as well as the premium AC motor technology option specific to large-diameter ceiling fans, in this final rule. Table IV.1 provides the list of technology options considered in the analysis and their descriptions. The screening analysis, which is discussed in the next section, provides further discussion on which of these technology options DOE retained as design options for the engineering analysis.

TABLE IV.1—TECHNOLOGY OPTIONS AND DESCRIPTIONS

| Technology option | Description |
|--|---|
| Fan optimization | This represents increasing the efficiency of a fan by adjusting existing fan design features. These adjustments could include changing blade pitch, fine-tuning motor RPM, and/or changing internal motor characteristics. The material, mass, and design/assembly of the motor lamination stack will have an impact on efficiency (via reducing eddy current losses, for example). Similarly, the material, diameter, length, configuration, etc. of the wire in the motor will influence electrical resistance losses inside motor as well as the overall efficiency of the motor. |
| More efficient motors: | |
| Larger direct drive single-phase induction motors. | This represents increasing the mass and/or choosing steel with better energy efficiency characteristics for the stator and rotor stack, improving the lamination design, increasing the cross section and/or length of the copper wiring inside the motor. |
| Three-phase induction motors | Three-phase induction motors have lower thermal energy losses than the single-phase motors typically found in residential line-power applications. They also have a more even torque on the rotor resulting in a more efficient rotation and less motor “hum.” However, three-phase power is extremely uncommon in residential applications. For most residences, these types of motors require electronic drive systems that convert single-phase power into a three-phase power supply. |
| Brushless DC motor | In residential applications, brushless DC motors typically consist of a permanent magnet synchronous AC motor that is driven by a multi-pole electronic drive system. Similar to DC motors, brushless DC motors typically achieve better efficiency than standard AC motors because they too have no rotor energy losses. |

TABLE IV.1—TECHNOLOGY OPTIONS AND DESCRIPTIONS—Continued

| Technology option | Description |
|-----------------------------------|--|
| Geared Brushless DC motor | Brushless DC motor fans with geared motors have fan blades attached to the motor via a geared mechanism, which allows the fan blades to rotate at a different speed from the motor. |
| Premium AC motor | Premium AC motors are NEMA Premium® motors that are highly energy efficient electric motors. A motor can be marketed as a NEMA Premium motor if it meets or exceeds a set of minimum full-load efficiency levels. ¹⁹ Such NEMA motors are available in integral horsepower capacities (<i>i.e.</i> , 1 hp+). |
| Gearless Brushless DC motor | Fans with a brushless DC motor that drive the fan blades directly without the use of a geared mechanism. |
| More efficient blades: | |
| Curved blades | Curved blades are blades for which the centerline of the blade cross section is cambered. Curved blades generally have uniform thickness and no significant internal volume. |
| Airfoil blades | Airfoil blades use curved surfaces to improve aerodynamics, but the thickness is not uniform and the top and bottom surfaces do not follow the same path from leading edge to trailing edge. Airfoil blades typically do not operate as efficiently in reverse, potentially impacting consumer utility on models where reverse flow was an option. |
| Twisted blades | Twisted blades reduce aerodynamic drag and improve efficiency by decreasing the blade pitch or twist from where the blade attaches to the motor casing to the blade tip. |
| Blade attachments | Blade attachments refer to upswept blade tips or other components that can be fastened to a fan blade to potentially increase airflow or reduce drag. |
| Beveled blades | Beveled blades are typically beveled at the blade edges from the motor casing to the blade tip. Beveled fan blades are more aerodynamic than traditional fan blades. |
| Alternative blade materials | Use of alternative materials could enable more complex and efficient blade shapes (plywood vs. MDF vs. injection-molded resin, for example). |
| Ceiling fan controls: | |
| Occupancy sensors | Occupancy sensors use technologies that detect the presence of people through movement, body heat, or other means. Ceiling fans used with an occupancy sensor could power down if they sense that a room is unoccupied. |
| Wind and Temperature Sensors ... | Wind and temperature sensors detect temperature changes in the surrounding space, or potential wind speed reductions below certain thresholds. Ceiling fans could potentially adjust fan speed based on the wind and temperature in the space the ceiling fan is located when coupled with these sensors. |

B. Screening Analysis

DOE uses the following four screening criteria to determine which technology options are suitable for further consideration in an energy conservation standards rulemaking:

(1) *Technological feasibility.*

Technologies that are not incorporated in commercial products or in working prototypes will not be considered further.

(2) *Practicability to manufacture, install, and service.* If it is determined that mass production and reliable installation and servicing of a technology in commercial products could not be achieved on the scale necessary to serve the relevant market at the time of the projected compliance date of the standard, then that technology will not be considered further.

(3) *Impacts on product utility or product availability.* If it is determined that a technology would have significant adverse impact on the utility of the product to significant subgroups of consumers or would result in the unavailability of any covered product type with performance characteristics (including reliability), features, sizes, capacities, and volumes that are

substantially the same as products generally available in the United States at the time, it will not be considered further.

(4) *Adverse impacts on health or safety.* If it is determined that a technology would have significant adverse impacts on health or safety, it will not be considered further. 10 CFR part 430, subpart C, appendix A, 4(a)(4) and 5(b)

In sum, if DOE determines that a technology, or a combination of technologies, fails to meet one or more of the above four criteria, DOE will exclude it from further consideration in the engineering analysis. The reasons for eliminating any technology are discussed below. The subsequent sections include comments from interested parties pertinent to the screening criteria, DOE's evaluation of each technology option against the screening analysis criteria, and whether DOE determined that a technology option should be excluded ("screened out") based on the screening criteria.

Westinghouse agreed in general with the screened in and screened out technologies, and said they appreciated that DOE considered a significant amount of stakeholder feedback. (Westinghouse, Public Meeting Transcript, No. 133 at p. 46) With the exception of brushless DC motors, ALA agreed with DOE's screening analysis

for hugger and standard ceiling fans. (ALA, No. 137 at p. 6) The discussion regarding retaining brushless DC motors as a technology option is provided in section IV.B.2.

1. Screened-Out Technologies

In the ceiling fans NOPR, DOE screened out the following technologies: (1) For standard, hugger and VSD ceiling fans: Three-phase induction motors, occupancy sensors, and blade design elements including airfoil blades, beveled blades, twisted blades, blade attachments, and alternative blade materials; (2) For HSSD ceiling fans: Larger direct-drive single-phase induction motors, three-phase induction motors, twisted blades, blade attachments, alternative blade materials, and occupancy sensors; (3) For large-diameter ceiling fans: Larger direct-drive single-phase induction motors, beveled blades, twisted blades, blade attachments, alternative blade materials, and occupancy sensors. 81 FR 1688, (January 13, 2016).

DOE received several comments regarding the screened-out technologies, specifically occupancy sensors, and wind and temperature sensors. ALA supported screening out occupancy sensors from DOE's analysis. According to ALA, while this technology has the potential to reduce consumer ceiling fan usage, occupancy sensors would be

¹⁹ NEMA Premium Motors Information Page: <https://www.nema.org/Policy/Energy/Efficiency/Pages/NEMA-Premium-Motors.aspx>.

problematic for ceiling fans in bedrooms. (ALA, No. 137 at p. 7) BAS stated that in the Lawrence Berkeley National Laboratory (LBNL) study cited by DOE in the TSD, more than 50 percent of surveyed people indicated there is a ceiling fan operating in an empty room at least half of the time. BAS believes that adding occupancy sensors to those ceiling fans would dramatically reduce the annual energy use of the fan. (BAS, No. 138 at p. 6)

DOE acknowledges that occupancy sensors have the potential to save energy by reducing the number of ceiling fan operating hours. However, available data was insufficient for DOE to evaluate any potential tradeoff between consumer utility and the energy savings of reduced operating hours. DOE also researched the option of introducing occupancy sensors in ceiling fans. DOE did not find data to show that occupancy sensor can be installed reliably market-wide. Therefore, in this final rule, DOE continues to screen out occupancy sensors because DOE cannot satisfactorily evaluate the energy savings potential, technological feasibility and impact on consumer utility of implementing sensors or schedule controls.

In terms of wind and temperature sensors, Center for the Built Environment (CBE) commented that additional research is needed to demonstrate to what degree integrated temperature and wind sensors in a ceiling fan may save energy with current commercial building controls, or standard thermostats found in most homes. (CBE, No. 143 at p. 1) ALA agreed with DOE's decision to not include wind or temperature sensors as technology options. ALA stated they are not aware of any ceiling fans or working prototypes that include integrated wind or temperature sensors, or any data that would indicate that these products could lead to energy savings in real world applications. (ALA, No. 137 at p. 6) BAS stated that many large diameter fan manufacturers offer some sort of speed control based on space temperature (Big Ass Fans' SmartSense). (BAS, No. 138 at pp. 4–5)

Similar to occupancy sensors, DOE acknowledges that wind and temperature sensors have the potential to save energy by reducing the number of ceiling fan operating hours. As BAS stated, there are large-diameter manufacturers that offer some sort of speed control based on space temperature. However, available data is insufficient for DOE to evaluate any potential tradeoff between consumer utility and the energy savings of

reduced operating hours based on implementing controls. DOE also did not find data to show that wind and temperature sensors can be installed reliably market-wide. Therefore, for this final rule, DOE continues to screen out wind and temperature sensors for all ceiling fans because DOE cannot satisfactorily evaluate the energy savings potential, technological feasibility and impact on consumer utility of implementing wind and temperature sensors.

In the absence of any adverse comments regarding the technology options that were screened out in the NOPR, DOE continues to screen-out the same technology options from the NOPR in this final rule. Specifically, DOE screened out the following technologies in this final rule—(1) For standard, hugger and VSD ceiling fans: Three-phase induction motors, and blade design elements including airfoil blades, beveled blades, twisted blades, blade attachments, and alternative blade materials, and occupancy, wind and temperature sensors; (2) For HSSD ceiling fans: More efficient direct-drive single-phase induction motors, three-phase induction motors, twisted blades, blade attachments, alternative blade materials, and occupancy, wind and temperature sensors; (3) For large-diameter ceiling fans: More efficient direct-drive single-phase induction motors, beveled blades, twisted blades, blade attachments, alternative blade materials, and occupancy, wind and temperature sensors.

2. Remaining Technologies

In the ceiling fans NOPR, DOE retained the following technology options—(1) For standard, hugger and VSD ceiling fans: Fan optimization, larger direct-drive single-phase induction motor and brushless DC motors; (2) For HSSD ceiling fans: fan optimization, curved blades, airfoil blades and brushless DC motors; (3) For large-diameter ceiling fans: Fan optimization, airfoil blades, geared brushless DC motors and gearless brushless DC motors. 81 FR 1688 (January 13, 2016).

DOE received several comments regarding the retained technology options. For fan optimization, Westinghouse commented that there are always a few changes that can be made to fans to optimize fans, but not all of the options can be made or it will result in a completely different product. (Westinghouse, Public Meeting Transcript, No. 133 at p. 48) DOE recognizes Westinghouse's concern that making changes to a ceiling fan to improve performance may result in

what the industry or consumer would consider a different fan model. DOE defined “fan optimization” for its analysis as adjusting existing design features. These adjustments include adjusting blade pitch, fine-tuning motor rpm, and changing internal motor characteristics. DOE does not expect any of these adjustments to require significant changes to the appearance, materials, or outputs of the fan. Consequently, the optimized fan should look and feel almost identical to the non-optimized version of the same fan, only consume less energy.

Regal requested that DC motors be referred to as “brushless DC motors” instead of just “DC motors” in the standard. (Regal, Public Meeting Transcript, No. 133 at p. 52) DOE agrees with Regal and recognizes that “brushless DC motors” is a more accurate technical descriptor for these motors. As such, DOE refers to these motors as “brushless DC motors” throughout this final rule notice and accompanying TSD.

For brushless DC motors in standard and hugger ceiling fans, ALA commented that they are concerned about the technological feasibility of DC motors due to concerns about their reliability and their incompatibility with existing wall-mounted controls. (ALA, No. 137 at p. 6) Appliance Standards Awareness Project (ASAP), Alliance to Save Energy (ASE), American Council for an Energy-Efficient Economy (ACEEE), Natural Resources Defense Council (NRDC), and Northwest Energy Efficiency Alliance (herein known as “Advocates”) claimed they were unaware of any data indicating any reliability issues associated with DC motors for ceiling fans. (Advocates, No. 142 at p. 4)

DOE has observed that several ceiling fan manufacturers offer small-diameter ceiling fans that use brushless DC motors, and that these fans are some of the most efficient small-diameter ceiling fans on the market. DOE does acknowledge, however, that brushless DC motors are a relatively new technology. Consequently, most small diameter ceiling fans that use brushless DC motors that are currently installed in the field are early in their expected lifespan and, in turn, any reliability issues may become apparent as these fans age. Nevertheless, their availability in the market indicates to DOE that brushless DC motors meet the screening criteria of technological feasibility, practicability to manufacture, install, and service, and no significant impacts on utility (including reliability and product availability). Consequently, DOE screened in brushless DC motors

for this final rule for standard and hugger fans. DOE accounted for differences in reliability between brushless DC and AC motors in the life cycle cost analyses. In addition, the energy conservation standard efficiency level adopted in this final rule (see section V.C.1 for discussion on TSLs) is consistent with performance achieved by standard and hugger ceiling fans that use larger direct-drive single-phase induction motors. As a result, any issues, if they exist, with the use of brushless DC motors in standard and hugger ceiling fans, should not be influenced by this rule.

For brushless DC motors in VSD ceiling fans, ALA objected to screening in this technology option. ALA stated they are not aware of any brushless DC motor VSD fans on the market, or currently in development, that would provide an acceptable substitute for the functionality of AC motors in VSD fans. (ALA, No. 137 at p. 6) Pacific Gas and Electric Company (PG&E), Southern California Gas Company (SCGC), San Diego Gas and Electric (SDG&E), Southern California Edison (SCE), and Arizona Public Service (APS) (herein known as California Investor Owned Utilities, or CA IOUs), on the other hand, commented that they continue to support the inclusion of brushless DC motor technology for all product classes, including VSD ceiling fans. CA IOUs also identified several VSD models that use brushless DC motors, including Vaxcel F1008, Fanimation MAD3255, and Sunpentown SF-1691C. In addition, CA IOUs stated that several pedestal and desk fans that are similar in technology, utility, and physical dimensions to VSD ceiling fans use brushless DC motors. (CA IOUs, No. 144 at p. 2)

DOE's understanding from manufacturer interviews is that brushless DC motors in VSD ceiling fans could be technologically feasible, as brushless DC motors are used in traditional standard and hugger ceiling fans. DOE reviewed the list provided by CA IOUs regarding VSD ceiling fans with brushless DC motors that are available in the market. The Fanimation MAD 3255 ceiling fan model specifications on the Fanimation website states that the smallest diameter for the model is 44-inches;²⁰ therefore, this fan is not a VSD ceiling fan. The Vaxcel F0018 and the Sunpentown SF-1619C, however, are VSD ceiling fans that have a brushless DC motor. Therefore, DOE confirms that there are VSD ceiling fan in the market with

brushless DC motors. DOE also did some online research regarding pedestal and desk fans that use brushless DC motors, and observed that there are several models available in the market at blade spans 18 inches or less. Desk fans and pedestal fans are similar in utility compared to VSD ceiling fans because they generally provide consumers with targeted airflow, and can be used to provide air to smaller spaces. However, more importantly, these fans have similar physical characteristics to VSD ceiling fans in terms of fan design; the fans typically have similar blade spans, similar airflows, and similar design (*e.g.*, axial blades and a single motor). Additionally, desk fans and VSD fans have similar size constraints for the motor housing. Because DOE has observed that brushless DC motors are commercially available in VSD ceiling fans, and in desk and pedestal fans, DOE concludes that brushless DC motor is practicable to manufacture, install, and service that does not have significant adverse impacts on utility (including reliability and product availability). Therefore, in this final rule, DOE continues to retain brushless DC motors as a technology option for VSD ceiling fans. In addition, the energy conservation standard efficiency level adopted in this final rule (see section V.C.1 for discussion on TSLs) is consistent with performance achieved by VSD ceiling fans that use larger direct-drive single-phase induction motors. As a result, any issues, if they exist, with the use of brushless DC motors in VSD ceiling fans, should not be influenced by this rule.

For the large-diameter product class, BAS requested that an additional efficiency level be added with a premium AC motor instead of the three-phased geared brushless DC motor. (BAS, Public Meeting Transcript, No. 133 at p. 35) DOE acknowledges that for large-diameter ceiling fans, premium AC motors and three-phase geared motors are readily available in the market. Therefore, DOE retained both technology options in the screening analysis because they meet the four screening criteria for this final rule.

Through a review of each technology, DOE concludes that all of the other identified technologies listed in this section meet all four screening criteria to be examined further as design options in DOE's final rule analysis. In summary, DOE retained the following technology options: (1) For standard, hugger and VSD ceiling fans: Fan optimization, larger direct-drive single-phase induction motors and brushless DC motors; (2) For HSSD ceiling fans:

Fan optimization, curved blades, airfoil blades and brushless DC motors; (3) For large-diameter ceiling fans: Fan optimization, airfoil blades, premium AC motors, geared brushless DC motors and gearless brushless DC motors.

DOE determined that these technology options are technologically feasible because they are being used in commercially-available products or working prototypes. DOE also finds that all of the remaining technology options meet the other screening criteria (*i.e.*, practicable to manufacture, install, and service and do not result in adverse impacts on consumer utility, product availability, health, or safety). For additional details, see chapter 4 of the final rule TSD.

C. Engineering Analysis

In the engineering analysis, DOE establishes the relationship between the manufacturer production cost (MPC) and improved ceiling fan efficiency. This relationship serves as the basis for cost-benefit calculations for individual consumers, manufacturers, and the Nation.

In this final rule, for small-diameter ceiling fans (VSD, Standard, Hugger and HSSD ceiling fans), DOE performed its analysis in terms of incremental increases in efficiency due to the implementation of selected design options. DOE selected representative sizes, and for each size, DOE identified a baseline efficiency as a reference point from which to measure changes resulting from each design option. For large-diameter ceiling fans, DOE performed its analysis based on a representative data set of ceiling fan performance data. DOE determined efficiency as observed in the representative dataset by best-fitting lines to the data for fans that incorporate each design option analyzed. Efficiency for all ceiling fans is represented in terms of the metric finalized in the test procedure. 81 FR 48620 (July 25, 2016).

For both small and large-diameter ceiling fans, MPCs for each successive design option are based on reverse-engineering, which includes product teardowns and a bottom-up manufacturing cost assessment. The estimated MPCs also include the costs of controls. DOE then developed the relationship between MPC and ceiling fan efficiency; this relationship is referred to as a cost-efficiency curve. The efficiency ranges from that of the least-efficient ceiling fan sold today (*i.e.*, the baseline) to the maximum-technologically feasible (max-tech) efficiency level.

The following is a summary of the method DOE used to determine the

²⁰ <http://www.fanimation.com/products/index.php/louvre.html>.

cost-efficiency relationship for ceiling fans:

- Perform airflow and power consumption tests on a representative sample of ceiling fans in each product class.
- Develop a detailed BOM for the tested ceiling fans through product teardowns, and construct a ceiling fan cost model.

DOE used a combination of test data, data from spec sheets, the cost model, and feedback from manufacturers to calculate the incremental increase in efficiency and cost increase from baseline to max-tech. Further details can be found in chapter 5 of the TSD.

1. Standard and Hugger Ceiling Fans

In the ceiling fans NOPR, DOE combined the cost-efficiency curves of flat-blade fans and unconventional-blade fans in the standard and hugger product classes to create an aggregate curve for all standard ceiling fans and all hugger ceiling fans. DOE used the following design options to create the curves: Fan optimization, larger direct drive motors, and brushless DC motors. DOE used the maximum efficiency of the unconventional-blade fans as the max-tech for the aggregate curve to ensure that all types of ceiling fans, including designs with unconventional-blades, can achieve the max-tech level of efficiency. DOE received several comments on the engineering analysis specific to the standard and hugger product classes.

Advocates commented that the energy savings associated with EL 4 for standard and hugger fans are likely to be significantly greater than shown in the analysis. They stated that it looks like the analysis is assuming that the power consumption of a flat-blade fan incorporating a DC motor would be equivalent to that of an unconventional-blade fan with a DC motor. In practice, it seems very unlikely that flat-blade fans with DC motors would not significantly exceed the efficiency levels given that DOE's analysis shows that a flat-blade fan with a DC motor is 30% more efficient than an unconventional-blade fan with a DC motor. (Advocates, No. 142 at p. 4)

For the NOPR, because DOE set the max-tech efficiency for standard and hugger ceiling fan product classes as the max-tech efficiency for unconventional-blade fans, DOE also set the power consumption at max-tech as the max-tech power consumption for unconventional-blade fans to match the max-tech efficiency. DOE acknowledges that to comply with the EL 4 efficiency for both flat blade fans and unconventional-blade fans,

manufacturers are likely to employ brushless DC motors. Therefore, at the max-tech efficiency, there is potential for energy savings for the flat-blade fans. For this final rule, DOE adjusted the power consumption at max-tech to include the potential energy savings from the flat-blade fans. DOE used the same weighting between flat and unconventional blade fans at max tech (*i.e.*, unconventional blade fans make up about 2 percent of the market, while flat blade fans are about 98 percent of the market) as at all the other efficiency levels.

In the engineering analysis for standard and hugger ceiling fans, DOE used an aggregate cost-efficiency curve for flat and unconventional blade fans, as opposed to defining two separate product classes, because fans with flat blades and fans with unconventional blades are functionally indistinguishable. Both fan types move air via the rotation of fan blades, improve comfort by this air movement, and can be used in similar spaces (unlike the distinction between standard and hugger fans, where the former cannot be used in rooms with low ceilings). Further, because flat blade and unconventional blade fans on the market appear to operate within the same CFM range, they have the same product capacity. Therefore, when setting the max-tech for the standard and hugger ceiling fan product classes, DOE set it at the max-tech efficiency for unconventional-blade fans, because this ensures that even at max-tech, all types of ceiling fans, including designs with unconventional blades, can achieve this level of efficiency.

Advocates also stated that the costs associated with EL4 for standard and hugger fans are likely to be lower than shown in the analysis, but did not provide supporting data for this statement. (Advocates, No. 142 at p. 4) As described in section IV.C, DOE reverse engineered several ceiling fans at EL4 (with brushless DC motors) to determine the MPC for that EL. To investigate the Advocates' claims, DOE reverse engineered several more brushless DC motor fans, and revisited the cost model to review the costs used in the NOPR. Based on the review, DOE corroborated the costs presented in the NOPR, rather than lower costs. Absent any additional cost data, DOE continues to use the MPC results from the NOPR for EL4 for standard and hugger fans in this final rule.

In summary, in this final rule, DOE continues to use the combined cost-efficiency curves of flat-blade fans and unconventional-blade fans in the standard and hugger product classes to

create an aggregate curve for all standard ceiling fans and all hugger ceiling fans.

Since the NOPR, DOE received additional test data for hugger and standard fans from manufacturers, which was used in the analysis for the final rule. The additional test data was used to update some of the efficiency deltas (*i.e.*, the difference in efficiency for a particular design option) in the analysis. Additionally, the test data informed the conversion factors used to convert efficiencies from ENERGY STAR test method, to efficiencies based on testing small-diameter ceiling fans using the test method in the July 2016 test procedure final rule (*i.e.*, mounting fans directly to the real ceiling). Based on the new test data, DOE increased the conversion factors since the NOPR. DOE then used these conversion factors to determine the efficiency results for the engineering analysis. Further details on the updates to the conversion factor is provided in Chapter 5 of the TSD.

2. VSD and HSSD Ceiling Fans

For the NOPR analysis, DOE was not aware of unconventional blade and flat blade fan variations for VSD and HSSD fans, so DOE did not use an aggregate curve approach for these ceiling fans. DOE used the same design option approach as standard and hugger ceiling fans to determine cost-efficiency relationships for all representative sizes in both VSD and HSSD product classes. DOE used the following design options for VSD ceiling fans to create the curves: Fan optimization, larger direct drive single-phase induction motors, and brushless DC motors. DOE used the following design options for HSSD ceiling fans to create the curves: Fan optimization, curved blades, airfoil blades and brushless DC motors.

DOE did not receive any specific comments on the engineering approach used for the VSD product class. However, DOE received several comments specific to the HSSD engineering analysis. Westinghouse commented that they were concerned with the additive approach used in calculating cost differences for the HSSD efficiency levels. They stated that the approach may not be fully calculating or capturing what the true cost increase will be. (Westinghouse, Public Meeting Transcript, No. 133 at p. 92)

DOE interprets Westinghouse's comment to mean that the full cost for the ELs with multiple design options is not being captured in the engineering analysis. As described in section IV.C, DOE developed the manufacturer production costs based on actual

product teardowns. When actual torn down models were not available for certain design options, DOE estimated costs based on materials and manufacturing processes necessary for each design option, and by using input from manufacturers. DOE performed this analysis through a catalog teardown, which uses published manufacturer product literature and supplementary component data to estimate the costs of major physical differences between the catalog teardown unit and a similar physical teardown unit. Some efficiency levels are consistent with performance of ceiling fans that use multiple design options, such as fan optimization and larger direct-drive single-phase induction motors. When determining the MPCs for efficiency levels that incorporate several design options, DOE's engineering analysis incorporates the costs of all design options included in that efficiency level (*i.e.*, the additive approach) added to the baseline MPC. The result, therefore, includes all of the production costs associated with manufacturing a baseline fan and all the incremental costs of adding or substituting technology options to improve efficiency. Westinghouse did not identify specific costs not captured by DOE's analysis, or provide information to support a contention that the additive approach does not fully calculate or capture the actual cost increase. Absent additional information, DOE concludes that its MPC estimates capture all manufacturing costs applicable to the efficiency levels analyzed. See chapter 5 of the final rule TSD for further discussion on the HSSD ceiling fan engineering analysis, which includes details about the costs included in DOE's MPC estimates. DOE did increase the conversion costs for all ceiling fans as part of the MIA. See section IV.J.2.a for further discussion on manufacturer conversion costs.

Westinghouse also asked if DOE had considered reordering the HSSD efficiency levels to have EL3 with DC motor and with flat metal blade followed by EL4 with DC motor and airfoil blades instead of adding the airfoil blades in EL3 and DC motor in EL4. Westinghouse commented that this is different from hugger and standard fans, where the motor options are what drive the cost. They stated that the airfoil blade is a high cost adder with not the same payback as a motor upgrade would be. (Westinghouse, Public Meeting Transcript, No. 133 at p. 113) Fanimation agreed with Westinghouse's comments. (Fanimation, Public Meeting Transcript, No. 133 at

pp. 113–114) ALA commented that they are skeptical of DOE's estimate of the net benefits that DC motor-based fan provide to consumers, and generally believe that DC motor-based ceiling fan efficiency standards, like DOE's proposed TSL 4-based standard for HSSD fans, are not technologically feasible. Additionally, ALA stated that DOE's proposed max-tech standard is not economically justified because it relies upon the airfoil blade design option, which is not economically justified. ALA stated that if DOE declines to adopt a standard at EL 3 or below for HSSD fans, DOE should consider adopting a standard for HSSD fans based on an efficiency level that corresponds to the fan optimization and DC motor design options, without the use of curved blades or airfoil blades. (ALA, No. 137, pp. 2–3)

Pursuant to EPCA, DOE must adopt standards that achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) To do this, DOE first establishes TSLs by combining specific efficiency levels for each of the product classes analyzed. Higher TSLs generally consist of a combination of higher efficiency levels for each product class, and the highest TSL generally represents the max-tech efficiency level for all product classes. Therefore, higher TSLs typically represent higher potential energy savings. (See section V.A for more details on TSLs chosen for this rulemaking). DOE then considers the impacts of amended standards for ceiling fans at each TSL beginning with the maximum technologically feasible level, to determine whether that level is economically justified. Where the max-tech level is not justified, DOE then “walks down” to the next most efficient level and conducts the same evaluation until it reached the highest efficiency level that is both technologically feasible and economically justified and saves a significant amount of energy.

For this final rule, TSLs 4 and 5 correspond to the max-tech efficiency level for HSSD ceiling fans.²¹ Therefore, when DOE performed a walk-down from TSL 5 and determined that TSL 4 would result in the maximum improvement in energy efficiency that was technologically feasible and economically justified (see section V.C.1), the efficiency level for HSSD ceiling fans still corresponded to the max-tech EL for HSSD ceiling fans.

²¹ For HSSD ceiling fans, the max-tech efficiency level analyzed included fan optimization, airfoil blades and a brushless DC motor as design options on a baseline fan.

Because TSL 4 is justified, EPCA prohibits DOE from considering TSL 3, which included a lower efficiency level for HSSD ceiling fans (EL 3, which included only airfoil blades and fan optimization as design options on a baseline fan). Thus, the change to the order of the efficiency levels for HSSD ceiling fans suggested by Westinghouse would not change the results of DOE's walkdown analysis. Therefore, DOE has not analyzed an alternate EL3 with a brushless DC motor and with flat metal blades in this final rule.

Since the NOPR, DOE received additional test data for hugger and standard fans from manufacturers that was used in the analysis for the final rule. The additional test data was used to update some of the efficiency deltas in the analysis. Because some of the VSD and HSSD efficiency deltas are dependent on the standard and hugger analysis, the engineering results for VSD and HSSD analyses were updated accordingly. Further details on the engineering analysis is provided in Chapter 5 of the TSD.

3. Large-Diameter Ceiling Fans

In the NOPR, DOE used a combination of the reverse-engineering and design option approach for the large-diameter ceiling fan engineering analysis. DOE relied on test data and feedback from manufacturers to determine energy ELs to analyze. DOE estimated baseline ceiling fan efficiencies based on test data for large-diameter ceiling fans at intermediate ELs adjusted by efficiency deltas. After establishing the baseline efficiency for large-diameter ceiling fans, DOE applied efficiency deltas associated with each design option to the baseline to calculate the efficiency consistent with performance of large-diameter ceiling fans that use each design option from baseline to max-tech. In DOE's analysis, efficiency deltas are estimated differences in ceiling fan efficiency based on comparing performance of ceiling fans that use different technology options, but are otherwise identical. This analysis resulted in an efficiency curve, as a function of ceiling fan diameter, for each efficiency level.

During the NOPR public meeting, BAS requested that an additional efficiency level be added to represent large-diameter ceiling fans that use a premium AC motor instead of a three-phased geared brushless DC motor, and stated that the premium AC motors are almost as efficient as permanent magnet motors. (BAS, Public Meeting Transcript, No. 133 at pp. 35–36)

DOE received test data from BAS that included ceiling fans using premium AC

motors. After evaluating the data, DOE confirmed BAS's assertions that large-diameter ceiling fans that use premium AC motors have comparable efficiencies to those that use geared brushless DC motors. In addition, DOE conducted a teardown analysis, which estimated that ceiling fans with a premium AC motor have lower MPC than ceiling fans with a geared brushless DC motor. Therefore, DOE expects that manufacturers would use the lower-cost premium AC motors instead of geared brushless DC motors to meet a standard that is consistent with the performance of ceiling fans that use either of these technologies.

Consequently, DOE replaced the geared brushless DC motor design option with premium AC motors for EL 3 in this analysis to reflect this expectation.

In addition to the test data for fans with premium AC motors, DOE also received additional test data from BAS for the other efficiency levels analyzed in the analysis. With this data, DOE's database of large-diameter fan performance includes 87 ceiling fans at EL 2, EL 3 and EL 4, comprising of ceiling fans from six different manufacturers, and with blade spans of 8, 10, 12, 14, 16, 18, 20 and 24 feet. Due to the large number of ceiling fans, the range of efficiency levels, and the variety of manufacturers, DOE determined that this dataset is representative of the EL 2, EL 3 and EL 4 large-diameter ceiling fans in the market.

A representative dataset allowed DOE to shift from the design option approach used in the NOPR (*i.e.*, evaluating technology pairs to determine efficiency deltas associated with each design option) to an efficiency-level approach (*i.e.*, representing efficiency as observed in the representative dataset by using best-fit lines for each technology option analyzed). In its dataset, DOE observed a broad range of efficiencies in ceiling fans with a gearless brushless DC motor and airfoil blades (*i.e.*, max-tech), and a narrow range of efficiencies in ceiling fans either with airfoil blades (*i.e.*, EL 2) or with a premium AC motor and airfoil blades (*i.e.*, EL3). This change in methodology also updated the engineering results for the large-diameter analysis. Further discussion regarding the efficiency-level approach and the engineering results for large-diameter ceiling fans is provided in chapter 5 of the TSD.

During the NOPR public meeting, BAS recommended that efficiencies be gauged using a CFM/W curve as a function of airflow for each diameter. This would essentially require a CFM per watt standard equation as a function of airflow at every diameter available.

(BAS, Public Meeting Transcript, No. 133 at p. 39) In written comments, BAS stated that the fundamental assumption that all ceiling fans of the same diameter move the same amount of air is untrue, allows inefficient low airflow products to remain on the market, and creates an upper limit to ceiling fan performance at each diameter. (BAS, No. 138 at p. 12) BAS further urged DOE to consider a metric that will not eliminate high efficiency, high utility ceiling fans from the market. BAS recommended that an efficiency metric based on ceiling fan diameter and maximum airflow be used to provide energy savings across all airflows and diameters, while still allowing the continued development of high utility products. (BAS, No. 138 at p. 15) In this discussion, DOE understood BAS' use of the phrase "high utility ceiling fans" to mean ceiling fans with high maximum airflows. The Advocates also encouraged DOE to consider standards for large-diameter ceiling fans that take both diameter and airflow into account. According to the Advocates, by taking only diameter into account in establishing ELs for large-diameter ceiling fans, the standards may have little impact on ceiling fans that deliver relatively low airflow rates, while simultaneously prohibiting ceiling fans of the same diameter that deliver higher airflow rates than those assumed in the analysis. (Advocates, No. 142 at pp. 1–2)

DOE's understanding of both BAS and Advocates concern is that an efficiency standard only based on diameter only could disproportionately impact ceiling fans that deliver higher airflows, compared to those that deliver lower airflows. To investigate this further, DOE analyzed the test data provided by BAS, in addition to DOE's own test data of large-diameter ceiling fans.

DOE began its analysis by confirming that the relationship between diameter and ceiling fan efficiency is an appropriate basis for an energy efficiency standard. DOE plotted a best fit line between diameter and efficiency of all the ceiling fans at max-tech and observed a R^2 correlation of 0.51 between diameter and efficiency. DOE conducted a similar exercise for ceiling fans at EL 2 and EL 3. At these ELs, however, DOE observed a narrower range of efficiencies at each diameter, which resulted in better R^2 correlations of 0.87 and 0.97 for EL 2 and EL 3, respectively, compared to max-tech. Therefore, the greater variation in max-tech test data suggests that the variation in efficiency with airflow is much greater for ceiling fans with gearless brushless DC motors than those with AC

motors. DOE realizes that the data for EL 4 ceiling fans is more scattered meaning that not all ceiling fans produce the same amount of airflow and that airflow has a direct effect on the efficiency of ceiling fans. However, for EL 2 and EL 3, the tight range of efficiency and airflow data at EL 2 and EL 3 suggests that the slope from the best fit line is a good representation of the relationship between efficiency and diameter.

For this final rule, the energy conservation standard efficiency level adopted is consistent with performance achieved by large-diameter ceiling fans with EL 3 characteristics. See section V.C.1 for discussion on TSLs. Therefore, DOE believes that the relationship between diameter and efficiency is an appropriate basis for an energy efficiency standard. However, based on the data, DOE did observe that there were some high airflow ceiling fans that might be disproportionately disadvantaged based on a standard using the best fit line. Therefore, to preserve consumer utility that require ceiling fans with high airflow, DOE decreased the y-intercept of the best fit equations, while maintaining the slopes. DOE aimed to preserve consumer utility by maintaining the maximum airflow produced at each diameter, or identify a close alternative, by shifting the equation downwards.

For each of the eight diameters analyzed (ranging from 8–24 feet), DOE identified the ceiling fan with the maximum tested airflow from all efficiency levels. At two of the eight diameters, a ceiling fan at EL 2 produces the largest airflow, and at the other six diameters, a ceiling fan at EL 3 produces the maximum airflow. At three of the eight diameters, the fan with the highest airflow achieves the efficiency level established in this final rule.

For the other five diameters, where the highest airflow ceiling fan does not meet the established standard level, DOE identified the ceiling fan with the highest airflow that achieves the standard level and compared it to the ceiling fan with the maximum airflow at that diameter. DOE calculated the percentage of maximum airflow for these ceiling fans to determine whether the EL 3 standard is still achievable with an EL 3 ceiling fan, without eliminating ceiling fans with high maximum airflows. DOE further investigated any diameter where the maximum airflow ceiling fan did not achieve the standard level, in order to see if the maximum airflow or a close alternative could be achieved. At two of the remaining five diameters, the ceiling fan with the highest airflow that achieved the standard level produced 99

percent of the airflow recorded for the ceiling fan with the maximum airflow. At two other diameters, the ceiling fans that meet the standard produced 90 percent of airflow of the highest airflow ceiling fan. For the last diameter, the highest airflow of a ceiling fan achieving the standard was 85 percent of the ceiling fan with the maximum airflow. The lower percentages at the three diameters may be a representation of smaller sample size, and not an outcome of the stringency of the standard.

For the reasons mentioned, DOE believes that the high efficiency, high airflow ceiling fans will not be eliminated from the market when using the shifted best fit equation. Therefore, DOE continued with the methodology outlined in the NOPR by adopting a standard equation that is only a function of diameter, and not airflow.

BAS commented that the repair costs should be separated for the geared and gearless versions for DC motors used in the large-diameter analysis. BAS stated that the gearless DC motor will take more hours to service than the geared motor because the entire fan assembly has to be removed to repair the gearless motor. (BAS, Public Meeting Transcript, No. 133 at p. 99) BAS also stated that efficiency losses resulting from gearboxes are generally less than 5 percent, not 20 percent. (BAS, Public Meeting Transcript, No. 133 at p. 31)

In the final rule, DOE replaced the geared brushless DC motor with the premium AC motor for efficiency level 3. Therefore, these comments do not affect the large-diameter analysis in the final rule.

4. Reducing Fan Speed To Improve Efficiency

In the NOPR analysis, DOE had requested comments on what an acceptable reduction of fan speed may be to improve ceiling fan efficiency such that it does not affect consumer utility for each of the proposed product classes. DOE received several comments regarding this topic.

CBE stated that, based on CBE laboratory tests, at least one ceiling fan tested is more efficient at lower speed. However, limiting the maximum air speed would not satisfy human comfort at higher temperatures. CBE suggested that one way to avoid this may be setting a limit for the maximum air speed for a ceiling fan, while requiring that the energy efficiency standard be met as well. (CBE, No. 143 at p. 1) BAS commented that a decrease of 50% in airflow nets an approximate gain of 220% on efficiency, but would result in a dramatic reduction in cooling effect and consumer utility. BAS stated that

the impact of the reduced performance will likely not be known to the consumer because there are no guidelines, equations or standards that allow consumers to translate CFM into cooling effect. BAS felt this would be especially true if the labeling requirements do not prominently display the maximum CFM of the fan. (BAS, No. 138 at p. 7) ALA stated they do not believe that reducing fan speeds available to a consumer is a viable way to improve efficiency because reducing fan speed directly impairs consumer utility. ALA therefore agreed with DOE's statement in the NOPR, that "manufacturers will not reduce airflow to levels that are unacceptable when other cost-justified pathways to compliance are available." (ALA, No. 137 at p. 7) CA IOUs asked whether companies may simply reduce their fans' RPMs in order to meet the efficiency standard, and ASAP suggested that in such a case, consumers may run their fans at higher speeds, thereby reducing the energy savings from the standard. (CA IOUs, Public Meeting Transcript, No. 133 at p. 159; ASAP, Public Meeting Transcript, No. 133 at pp. 154–155) Westinghouse responded by suggesting that manufacturers that try to meet the standard by reducing the utility (*i.e.*, airflow) of their fans would lose business. (Westinghouse, Public Meeting Transcript, No. 133 at pp. 155–156) In addition, Westinghouse noted that if a manufacturer tried to make an obsolete product simply to meet the standard, demand for the product would wane over time and competition would publicize how that manufacturer's products are lacking in performance. (Westinghouse, Public Meeting Transcript, No. 133 at pp. 158–159)

DOE understands that slowing down a fan can significantly reduce energy consumption. However, DOE also recognizes that airflow, which diminishes at lower fan speeds, factors heavily into consumer utility. DOE observes that the airflow produced by commercially available fans of the same diameter varies. While DOE interprets this to mean that some variation in airflow at a given diameter is acceptable to the market and does not represent a reduction in utility, DOE did not include slowing down the fan as a design option to avoid setting standards that may result in reduced utility. Leaving out reducing fan speed as a design option ensures that manufacturers can meet the level adopted by this final rule in a cost-justified manner without reducing fan speed. While manufacturers may opt to

do so, it is unlikely that many will due to the market pressures identified by Westinghouse. In addition, the FTC is primarily responsible for labeling, and issued amendments to the ceiling fan label for all ceiling fans except large-diameter and HSSD ceiling fans on September 15, 2016. 81 FR 63634. The ceiling fan label includes a prominent display of the CFM based on typical use of a ceiling fan. The FTC is planning to seek comments on the need for, and content of, fan labels for large-diameter and HSSD ceiling fans in a separate notice. 81 FR 63634, 63637.

5. Standard Level Equations

In the ceiling fans NOPR, DOE proposed best-fit linear standard level equations in terms of ceiling fan diameter, based on the efficiency results for the representative sizes analyzed for each product classes. The linear standard level equations were established so that the proposed minimum efficiencies could be calculated for all ceiling fan diameters within a product class. DOE received a comment regarding the standard level equations proposed.

In general, ALA commented that DOE should, in adopting final efficiency standards for ceiling fans, clarify that the efficiency equation found in the table in proposed 10 CFR § 430.32(s)(2) represents minimum ceiling fan efficiency. (ALA, No. 137 at p. 3) DOE appreciates the comment from ALA, and has updated references to the standard level equations in this final rule to clarify that it represents minimum ceiling fan efficiency.

In this final rule, DOE continues to develop standard level equations based on diameter for all product classes. As discussed in the ceiling fans NOPR, DOE believes that blade diameter is a better proxy for utility than airflow. The size of a fan determines the cooling area, impacts room aesthetics, and determines if a fan physically fits into a room. Literature published by manufacturers clearly indicates that blade span is an important criterion for consumer fan selection. Manufacturers include sizing guides in published product literature to instruct consumers on how to properly size a fan for a given room size. These fan sizing guides specify the affected square footage of a room based on fan blade diameter. DOE did not find such guides for other ceiling fan characteristics such as airflow.

Therefore, based on the updates to the engineering analyses described in sections IV.C.1 through IV.C.3 for all product classes, DOE also updated the best-fit linear standard level equations.

DOE is not aware of commercially available VSD fan models below 12 inches in diameter. However, extending a best-fit linear equation below 12 inches for VSD would result in minimum ceiling fan efficiency standards below 0 CFM/Watt at near 0 inch diameters. In this final rule, DOE is continuing to use a best-fit linear equation for VSD fans 12 inches in diameter and above (the range in which all known commercially-available VSD models currently exist). However, DOE is extending the minimum ceiling fan efficiency required at 12 inches to all VSD fans below 12 inches in diameter to avoid standards 0 CFM/Watt and below for any VSD models that may exist in this range.

D. Markups Analysis

The markups analysis develops appropriate markups (*e.g.*, manufacturer markups, retailer markups, distributor markups, contractor markups) in the distribution chain and sales taxes to convert the MPC estimates derived in the engineering analysis to consumer prices, which are then used in the LCC and PBP analysis and in the manufacturer impact analysis. At each step in the distribution channel, the markups are multipliers that are applied to the purchase cost to cover business costs and profit margin.

DOE characterized four distribution channels to describe how standard, hugger and VSD ceiling fans pass from manufacturers to consumers. These four distribution channels can be characterized as follows:

Manufacturer → Home Improvement Center → Consumer
 Manufacturer/Home Improvement Center (in-store label) → Consumer
 Manufacturer → Wholesaler → Contractor → Consumer
 Manufacturer → Showroom → Consumer

DOE developed separate markups for home improvement centers that have their in-store label ceiling fans and for those that sell independent-label ceiling fans. As indicated in the market assessment, two of the top three ceiling fan brands in the market are the in-store brands for two home improvement centers. These home improvement centers therefore serve as both in-store brand manufacturers and home improvement centers that carry both store-brand and independent-brand ceiling fans. For in-store label ceiling fans, DOE developed an overall markup that encompasses the margins for manufacturing as well as selling the product. For the independent-label ceiling fans sold through home centers,

separate markups were developed for the brand manufacturer and for the home improvement centers which serve only as a retailer.

For large-diameter and HSSD ceiling fans, the two distribution channels that DOE considered can be characterized as follows:

Manufacturer → Dealer → Customer
 Manufacturer → In-house Dealer → Customer

The second distribution channel for large-diameter and HSSD ceiling fans is a direct sale channel where the manufacturer sells the product directly to a customer through its in-house dealer. DOE assumed the markup for in-house dealers is the same as the conventional dealer markup; therefore, the overall markup for these two distribution channels is the same.

To account for manufacturers' non-production costs and profit margin, DOE applied the manufacturer markup to the full MPC derived in the engineering analysis. The resulting manufacturing selling price (MSP) is the price at which the manufacturer can recover all production and non-production costs and earn a profit. To meet new or amended energy conservation standards, manufacturers typically introduce design changes to their product lines, which increase manufacturer production costs. As production costs increase, manufacturers typically incur additional overhead.

To calculate the manufacturer markups, DOE reviewed 10-K reports²² submitted to the U.S. Securities and Exchange Commission (SEC) by publicly-owned ceiling fan companies. The financial figures necessary for calculating the manufacturer markup are net sales, costs of sales, and gross profit. Few ceiling fan manufacturing companies are publicly owned, and most of the publicly-owned ceiling fan manufacturing companies are subsidiaries of more diversified parent companies, so the financial information summarized may not be exclusively for the ceiling fan portion of their business and can also include financial information from other product sectors. DOE discussed the manufacturer markup with manufacturers during interviews, and used product specific feedback on market share, markups and cost structure from manufacturers to adjust the manufacturer markup calculated through review of SEC 10-K reports.

²² U.S. Securities and Exchange Commission, Annual 10-K Reports (various years between 2007 and 2013), available at <http://sec.gov>.

To develop markups for the market participants involved in the distribution of ceiling fans, DOE utilized several sources, including: (1) The SEC 10-K reports and U.S. Census Bureau's annual retail trade survey for building material and supplier dealer industry²³ (to develop home improvement center markups); (2) the U.S. Census Bureau's annual wholesale trade report for electrical and electronic appliance, television, and radio set merchant wholesaler industry²⁴ (to develop wholesaler markups); (3) 2014 RSMeans Electrical Cost Data²⁵ (to develop contractor markups); and (4) the SEC 10-K reports (to develop dealer markups).

To develop the markups when home centers serve as both brand manufacturer and retailer, DOE relied upon input from an industry expert.²⁶

For each of the market participants, DOE developed baseline and incremental markups based on the product markups at each step in the distribution chain. The baseline markup relates the change in the MSP of baseline models to the change in the consumer purchase price. The incremental markup relates the change in the MSP of higher-efficiency models (the incremental cost increase) to the change in the consumer purchase price.

In addition to the markups, DOE derived state and local taxes from data provided by the Sales Tax Clearinghouse.²⁷ These data represent weighted average taxes that include county and city rates. DOE derived shipment-weighted average tax values for each region considered in the analysis.

Chapter 6 of the final rule TSD provides details on DOE's development of markups for ceiling fans.

E. Energy Use Analysis

The purpose of the energy use analysis is to determine the annual energy consumption of ceiling fans at different efficiency levels in

²³ U.S. Census Bureau. *2012 Annual Retail Trade Survey*. Building Material and Supplier Dealer. 2012 (Last Accessed April 22, 2015) http://www.census.gov/retail/arts/historic_releases.html.

²⁴ U.S. Bureau of the Census. *2012 Annual Wholesale Trade Report, NAICS 423620: Electrical and Electronic Appliance, Television and Radio Set Merchant Wholesaler*. 2012. Washington, DC. (Last Accessed April 22, 2015) <http://www.census.gov/wholesale/index.html>.

²⁵ RS Means Company Inc. *Electrical Cost Data: 36th Annual Edition*. 2014. Kingston, MA.

²⁶ Mehta, V. Independent ceiling fan industry consultant. Personal communication. E-mail to Colleen Kantner, LBNL, November 24, 2013.

²⁷ Sales Tax Clearinghouse Inc., *State Sales Tax Rates Along with Combined Average City and County Rates* (2014) available at <http://thesc.com/STrates.stm> (last accessed May 27, 2014).

representative U.S. homes and commercial buildings, and to assess the energy savings potential of increased ceiling fan efficiency. To develop annual energy use estimates, DOE multiplied ceiling fan input power by the number of hours of use (HOU) per year. The energy use analysis estimates the range of operating hours of ceiling fans in the field (*i.e.*, as they are actually used by consumers). The energy use analysis provides the basis for other analyses that DOE performed, particularly assessments of the energy savings and the savings in consumer operating costs that could result from adoption of amended standards.

1. Inputs for Standard, Hugger, and VSD Ceiling Fans

a. Sample of Purchasers

As in the NOPR analysis, DOE has included only residential applications in the energy use analysis of standard, hugger, and VSD ceiling fans. DOE used the Energy Information Administration (EIA) 2009 Residential Energy Consumption Survey (RECS)²⁸ to choose a random sample of households in which new ceiling fans could be installed. RECS is a national sample survey of housing units that collects statistical information on the consumption of, and expenditures for, energy in housing units, along with data on energy-related characteristics of the housing units and occupants. RECS collected data on 12,083 housing units, and was constructed by EIA to be a national representation of the household population in the United States.

In creating the sample of RECS households, DOE used the subset of RECS records that met the criterion that the household had at least one ceiling fan. DOE chose a sample of 10,000 households from RECS to estimate annual energy use for standard, hugger, and VSD ceiling fans. Because RECS provides no means of determining the type of ceiling fan in a given household, DOE used the same sample for the standard, hugger, and VSD product classes.

b. Operating Hours

As in the NOPR analysis, DOE used data from an LBNL study²⁹ that surveyed ceiling fan owners to estimate

the total daily operating hours for each sampled RECS household. In that study, the authors asked a nationally representative sample of more than 2,500 ceiling fan users to report their ceiling fan operating hours for high, medium, and low speeds. The LBNL study reported a distribution of operating hours, with an average of 6.45 hours of operation per day. The operating hours for each sample household were drawn from the distribution of operating hours reported in the LBNL study, and further apportioned into operating hours at different fan speeds.

As in the NOPR analyses, DOE estimated that the average fraction of time that standard, hugger, and VSD ceiling fans were operated at each speed was equal to the simple average of the fractions reported by the LBNL survey and an AcuPOLL³⁰ survey submitted by ALA in response to the ceiling fan test procedure NOPR. This average yields an estimate of 33 percent of time spent in active mode on high speed, 38 percent on medium speed, and 29 percent on low speed. In written comments received in response to the NOPR, Westinghouse and ALA indicated agreement with these estimated average hours of use for standard, hugger, and VSD ceiling fans. (Westinghouse, Public Meeting Transcript, No. 133 at p. 79; ALA, No. 137 at p. 8)

For the final rule, DOE refined the NOPR approach by accounting for a distribution in operating hours spent at each speed.³¹ Specifically, for each sampled household, the fraction of time that the fan spends at each of low and medium speed was drawn from a uniform distribution over the interval between zero and twice the average fraction of time for that speed. Since the sum of fractions of time spent at each speed must equal one, the fraction of time spent at high speed is simply given by the remaining fraction. DOE then used these fractions to apportion the total hours of use into hours of use at high, medium and low speeds.

c. Power Consumption at Each Speed and Standby

DOE determined the power consumption at high, medium, and low speed for each representative fan size in the engineering analysis. These values

are shown in chapter 5 of the final rule TSD. DOE estimated that all ceiling fans with brushless DC motors expend standby power, and that 7 percent of standard, hugger, and VSD ceiling fans with AC motors come with a remote, and therefore consume power while in standby mode. DOE further estimated 0.7 watts as the power consumption value for standby for all representative fans belonging to the standard, hugger, and VSD product classes, based on testing conducted in association with developing the engineering analysis.

BAS commented that the percentage energy savings for ceiling fans with occupancy sensors will be similar to that of lighting systems with occupancy sensors and that this similarity could be used to estimate savings from ceiling fans with occupancy sensors. (BAS, No. 138 at p. 5) DOE acknowledges that occupancy sensors have the potential to have an impact on the energy consumption of ceiling fans. However, available data is insufficient for DOE to determine what impact occupancy sensors may have on energy use in practice. In the absence of supporting data or evidence to substantiate energy savings, DOE does not believe it is appropriate to assume ceiling fans and lighting systems to have similar percentage energy savings. Furthermore, occupancy sensors have been screened out of the final rule analysis (see section IV.B.1), and it is unclear if fans with occupancy sensors will make up a non-negligible portion of the market in the future, especially in the residential sector.

The CA IOUs indicated that many hugger, standard, and VSD ceiling fans with brushless DC motors have six speeds, not three speeds. Therefore, the CA IOUs recommended that DOE consider incorporating the advantages of six-speed ceiling fans by averaging the performance characteristics at the lowest two speeds, the middle two speeds, and the highest two speeds as proxies for the currently-proposed low-speed setting, middle-speed setting, and high-speed setting, respectively. (CA IOUs, No. 144 at p. 3) As previously mentioned, in the energy use analysis, DOE used the power consumption estimates developed for each representative fan in the engineering analysis. In the engineering analysis, power consumption estimates at high, medium, and low speed were developed based on the test method set forth in the test procedure final rule (CITE). Consistent with the test procedure final rule, testing was conducted at the lowest and highest speed for fans for with brushless DC motors. Testing was not conducted at the other four fan

²⁸ U.S. Department of Energy—Energy Information Administration. 2009 RECS Survey Data. (Last accessed May 3, 2016.) <http://www.eia.gov/consumption/residential/data/2009/>.

²⁹ Kantner, C. L. S., S. J. Young, S. M. Donovan, and K. Garbesi. *Ceiling Fan and Ceiling Fan Light Kit Use in the U.S.—Results of a Survey on Amazon Mechanical Turk*. 2013. Lawrence Berkeley National Laboratory: Berkeley, CA. Report No. LBNL-6332E. <http://www.escholarship.org/uc/item/3r67c1f9>.

³⁰ AcuPOLL® Precision Research, Inc. *Survey of Consumer Ceiling Fan Usage and Operations*. 2014.

³¹ For the final rule, DOE used a distribution of operating hours at each speed, rather than an average, to better represent the distribution of impacts on a sample of 10,000 households. The average time at each speed from the distribution is unchanged from average value used in the NOPR analysis.

speeds. Power consumption at medium speed for such fans was estimated based on scaling the power consumption at the middle speed setting from representative fans with three speeds. The specific distribution of time between the six fan speeds commonly had by DC-motor fans is unknown, but DOE concludes that the current approach should be a representative estimate of overall energy use for DC-motor ceiling fans.

2. Inputs for Large-Diameter and High-Speed Small-Diameter Ceiling Fans

a. Sample of Purchasers

As in the NOPR analysis, DOE has included only commercial and industrial applications in the energy use analysis of large-diameter and HSSD ceiling fans. Although some large-diameter and HSSD fans are used in residential applications, they represent a very small portion of the total market for large-diameter and HSSD ceiling fans. Similar to standard, hugger, and VSD ceiling fans, DOE developed a sample of 10,000 fans to represent the range of large-diameter and HSSD ceiling fan energy use. The sample captured variations in operating hours.

b. Operating Hours

In the NOPR analysis, DOE used feedback from manufacturers to estimate total hours of operation for HSSD ceiling fans. Manufacturers suggested a range of possible hours of operation, depending on industry and application, with 12 hours per day as a representative value. To represent a range of possible operating hours around this representative value, DOE drew 10,000 samples from a uniform distribution between 6 hours per day and 18 hours per day when calculating the energy use of HSSD fans. DOE also used manufacturer feedback to determine the proportion of operating time spent at each speed, estimating that, on average, HSSD fans spend approximately 10 percent of the time at high or low speed, and the rest of their time (approximately 80 percent) at a medium speed.

Westinghouse and ALA agreed with the average hours of use estimate for HSSD fans in the NOPR analysis, and no stakeholders expressed disagreement. (Westinghouse, Public Meeting Transcript, No. 133 at p. 79; ALA, No. 137 at p. 8) Accordingly, DOE assumed for this final rule that HSSD fans operate for 12 hours a day on average when conducting analysis for the final rule, and has maintained its assumptions regarding the operating hours distribution.

In the energy conservation standards NOPR analysis, DOE's estimate of the daily total hours of operation for large-diameter fans was consistent with total hours of operation estimate from the test procedure SNOPR. (80 FR 31487 (Jun. 3, 2015)) In the test procedure SNOPR, to weight the performance results of the ceiling fans at each of the five speeds, DOE took a simple average of the total daily hours-of-use estimate of 18 hours per day provided by MacroAir and an example of the fraction of time spent at each speed from BAS that DOE assumed implicitly agreed with the 12 hours per day estimate from the October 2014 test procedure NOPR, which yielded an average value of 15 hours per day. *Id.* BAS took issue with DOE's assumption and, therefore, disagreed with DOE's estimate of 15 hours of use per day (BAS, No. 138 at p. 6)

To estimate the energy consumption of large-diameter ceiling fans, DOE must make an estimate of average operating hours for such fans. Based on the available data on daily operating hours, for the final rule DOE estimated 12 hours of use per day in active mode for large-diameter ceiling fans, consistent with the hours of use estimate for HSSD fans, which are also used in commercial and industrial applications, and also consistent with estimate from the test procedure final rule (CITE).

In the NOPR analysis, DOE also modeled the fraction of time spent at each of five speeds by large-diameter ceiling fans in an approach aligned with the ceiling fans test procedure SNOPR, which proposed to test all large-diameter ceiling fans at maximum speed, 80% speed, 60% speed, 40% speed, and 20% speed. 80 FR 31487 (June 3, 2015). Taking the average of manufacturer inputs yielded the following hours of use distribution for the NOPR analysis: 1.8 hours at maximum speed, 3.5 hours at 80% speed, 3.6 hours at 60% speed, 2 hours at 40% speed, and 4.1 hours at 20% speed. BAS clarified that the input on distribution of time at different speeds was intended as an example and not as an estimate to be used in calculations. (BAS, No. 138 at p. 8) BAS further commented that there is insufficient data to assign operating hours or estimate percentages of operation. (BAS, Public Meeting Transcript, No. 133 at pp. 83–84) BAS recommended against the use of an average of two sets of operating hours in deriving operating hours for large-diameter ceiling fans and recommended measuring at high speed only or using a metric that includes equal weighting at the five proposed operating speeds. (BAS, No. 138 at p. 6)

For the final rule, based on lack of available data to suggest otherwise, DOE gave equal weighting to each of the five speeds from the test procedure, consistent with BAS's suggestion and consistent with the approach in the test procedure final rule. (CITE)

c. Power Consumption at Each Speed and Standby

For the large-diameter ceiling fan product class, the power consumption for a given representative fan was determined by the weighted average of power consumption at the five speeds discussed previously, where each speed was weighted by an equal fraction of time spent at that speed, as detailed in chapter 5 of the final rule TSD.

For the HSSD ceiling fan product class, as in the NOPR analysis, DOE determined power consumption at high speed for each representative fan in the engineering analysis. To estimate the power consumption at medium speed, DOE multiplied the high-speed power by the average ratio between high-speed power and medium-speed power in the standard, hugger, and VSD fans engineering analysis. DOE used the same approach for low-speed power, using the average ratio between high-speed power and low-speed power from the standard, hugger, and VSD fans engineering analysis.

As in the NOPR analysis, in this final rule DOE considered all HSSD fans at the efficiency levels with a brushless DC motor to have standby power, assuming a remote control was included for all such fans. DOE estimated 0.7 watts as the standby power value for all representative fans in the HSSD product class. Because these fans also have standby power as a result of a remote control receiver, this is the same value used for standard, hugger and VSD fans, as discussed in section IV.E.1.c.

DOE also considered large-diameter fans to have standby power, because available information indicated that the majority of large-diameter ceiling fans in the market use a variable-frequency drive and/or are operated by remote control, which consumes standby power. The standby power for large-diameter ceiling fans was estimated to be 7 watts in the engineering analysis (see chapter 5 of the final rule TSD).

For HSSD and large-diameter ceiling fans with standby power consumption, DOE assumed that all hours not spent in active mode were in standby mode.

3. Impact on Air Conditioning or Heating Equipment Use

DOE did not account for any interaction between ceiling fans and air conditioning or heating equipment in

the NOPR analyses. In DOE's estimation it appeared unlikely that consumers would substantially increase air conditioning use, or forego purchasing a ceiling fan in lieu of an air conditioning unit, due to a modest increase in the initial cost of a ceiling fan due to an amended energy conservation standard. Therefore the interaction between ceiling fan use and air conditioning use would be unlikely to be different in the case of amended standards than it would be in the no-new-standards case.

ASAP, et al. and the CA IOUs agree that the interaction between ceiling fan and air conditioning use would be negligible on a national level. (ASAP, et al., No. 142 at p. 5) The CA IOUs also agreed with DOE's decision not to include the air conditioning interaction in its analyses for this rule, based on the lack of available data. (CA IOUs, No. 144 at p. 2) ALA suggested that DOE's proposed ceiling fan efficiency standards could result in increased air conditioning use, because many ceiling fan consumers already have air conditioning units—which provide substitutionary cooling at no additional cost—and will therefore be more price sensitive to the price of ceiling fans. (ALA, No. 137 at p. 8) BAS pointed out that shipments projections do not directly reflect the possibility of consumers increasing their air conditioning set point and using the ceiling fan at high speeds. (BAS, Public Meeting Transcript, No. 133 at pp. 77–78)

As noted in the NOPR, DOE agrees that ceiling fans have the theoretical potential to be an inexpensive and effective replacement for air conditioning use; however, the interaction between ceiling fan use and air conditioning use is unlikely to be different in the case of amended standards than it would be in the no-new-standards case. The shipments analysis projects a modest change of shipments for standard, hugger, and VSD fans of less than 1% under the adopted standard level, and it is unclear what would motivate consumers to change their air conditioner's set point or otherwise change their air-conditioning behavior if they own a ceiling fan regardless of whether there is a new or amended standard. DOE did not account for such interaction in the final rule analyses.

The Center for the Built Environment at the University of California, Berkeley (CBE) agreed with DOE that a modest increase in ceiling fan price is unlikely to increase air conditioning use, but suggested that DOE conduct analyses on the building level rather than only considering ceiling fan cost savings.

(CBE, No. 143 at p. 2) BAS cited three projects using building automation systems to vary ceiling fan speed that resulted in a reduction or elimination of air conditioning use. (BAS, No. 138 at p. 10) It was reported in one of the projects cited by BAS that the use of ceiling fans in a school can provide up to 4 °F of “additional effective” or “perceived” cooling. In the other two projects, the use of ceiling fans resulted in expanded temperature ranges in buildings, such as from a 72 °F to 75 °F range to a 68 °F to 82 °F range.

While DOE appreciates the provision of quantifiable outcomes, it is not clear if and how such cooling translates to applications beyond the specific cases cited, which may not be representative of ceiling fan usage in general. Moreover, as discussed previously, the interaction between ceiling fan use and air conditioning use is unlikely to be significantly different in the case of amended standards than it would be in the no-new-standards case. Customers who would purchase ceiling fans as a cost-effective substitute are for air-conditioning or heating equipment are free to do so regardless of whether there is any amended standard.

F. Life-Cycle Cost and Payback Period Analysis

DOE conducts LCC and PBP analyses to evaluate the economic impacts on individual consumers of potential energy conservation standards. The effect of new or amended energy conservation standards on individual consumers usually involves a reduction in operating cost and an increase in purchase cost. DOE uses the following two metrics to measure consumer impacts:

- The LCC (life-cycle cost) is the total consumer expense of an appliance or product over the life of that product, consisting of total installed cost (manufacturer selling price, distribution chain markups, sales tax, and installation costs) plus operating costs (expenses for energy use, maintenance, and repair). To compute the operating costs, DOE discounts future operating costs to the time of purchase and sums them over the lifetime of the product.
- The PBP (payback period) is the estimated amount of time (in years) it takes consumers to recover the increased purchase cost (including installation) of a more-efficient product through lower operating costs. DOE calculates the PBP by dividing the change in purchase cost at higher efficiency levels by the change in annual operating cost for the year that amended or new standards are assumed to take effect.

For any given efficiency level, DOE measures the change in LCC relative to the LCC in the no-new-standards case, which reflects the estimated efficiency distribution of ceiling fans in the absence of new or amended energy conservation standards. In contrast, the PBP for a given efficiency level is measured relative to the baseline product.

DOE calculated the LCC and PBP for each considered efficiency level for a nationally representative consumer sample for each of the product classes. DOE developed consumer samples that account for variation in factors such as geographic location. Two types of consumer samples were created: one for the standard, hugger and VSD group of fans and another for the HSSD and large-diameter group. This was done to capture the variability in energy consumption, discount rates and energy prices associated with the different groups of ceiling fans.

For VSD, hugger, and standard ceiling fans, DOE created a sample in a manner similar to that outlined in section IV.E.1. Due to a lack of data on the location of HSSD and large-diameter fans, DOE assumed that the geographic distribution of HSSD and large-diameter fan purchasers is similar to that of standard, hugger, and VSD ceiling fan purchasers. Therefore, DOE chose the location of HSSD and large-diameter fan purchasers according to the geographic distribution of households in RECS. For each consumer in the sample used for HSSD and large-diameter fans, DOE determined the energy consumption of ceiling fans and the appropriate electricity price for the location and sector.

The calculation of the total installed cost includes MPCs, manufacturer markups, retailer and distributor markups, and sales taxes. Installation costs were assumed not to vary by efficiency level, and therefore were not considered in the analysis.

Inputs to the calculation of operating expenses include annual energy consumption, energy prices and price projections, repair and maintenance costs, product lifetimes, and discount rates.

DOE created distributions of values for product lifetime, discount rates, and sales taxes, with probabilities attached to each value, to account for their uncertainty and variability.

The computer model DOE uses to calculate the LCC and PBP relies on a Monte Carlo simulation to incorporate uncertainty and variability into the analysis. The Monte Carlo simulations randomly sample input values from the probability distributions and ceiling fan

user samples. The model calculated the LCC and PBP for products at each efficiency level for a sample of 10,000 consumers per simulation run.

DOE calculated the LCC and PBP for all consumers as if each were to purchase a new product in the expected first full year of compliance with

amended standards. The final rule is expected to publish in late 2016, with a compliance date in late 2019. For this final rule, DOE analyzes LCC results for 2020, the first full year of compliance with final rule.

Table IV.2 summarizes the approach and data DOE used to derive inputs to

the LCC and PBP calculations. The subsections that follow provide further discussion. Details of the spreadsheet model, and of all the inputs to the LCC and PBP analyses, are contained in chapter 8 and its appendices of the final rule TSD.

TABLE IV.2—SUMMARY OF INPUTS AND METHODS FOR THE LCC AND PBP ANALYSES *

| Inputs | Source/method |
|-------------------------------|--|
| Purchase Price | DOE estimated the purchase price of ceiling fans (CF) by combining the different cost components along the production, import, distribution and retail chain. DOE further used a price trend to project prices of CF with brushless DC motors to the compliance year. |
| Sales Tax | Derived 2020 population-weighted-average tax values for each reportable domain based on Census population projections and sales tax data from Sales Tax Clearinghouse. |
| Energy Use | Derived in the energy use analysis, and takes into account variations in factors such as operating hours. Variation in geographic location is taken into account for certain product classes. |
| Energy Prices | Electricity: Based on 2014 marginal electricity price data from the Edison Electric Institute. Variability: Electricity prices vary by season, U.S. region, and baseline electricity consumption level. |
| Energy Price Trends | Based on AEO 2015 price forecasts. |
| Product Lifetime | Derived a mean ceiling fan life time of 13.8 years from a best-fit model based on the Weibull distribution. |
| Discount Rates | Approach involves identifying all possible debt or asset classes that might be used to purchase the considered appliances, or might be affected indirectly. Primary data source was the Federal Reserve Board's Survey of Consumer Finances. |
| Efficiency Distribution | Current efficiency distribution for standard and hugger ceiling fans is based on feedback from manufacturers. Current efficiency distribution for VSD, HSSD and large-diameter ceiling fans is based on on-line model counts. Efficiency distribution for the compliance year is estimated by the market-share module of shipments model. See chapter 9 of the final rule TSD for details. |
| Assumed Compliance Date | 2019.** |

* References for the data sources mentioned in this table are provided in the sections following the table and in chapter 8 of the final rule TSD.

** The compliance date was assumed to be in late 2019, so the LCC analysis was conducted for 2020, the first full year of compliance.

1. Purchase Price

DOE estimates the purchase price by combining manufacturing and production cost, manufacturer markups, tariffs, import costs, retail markups, and sales tax. Section IV.D provides the details of the markups analysis.

DOE used a price trend to account for changes in the incremental brushless DC motor price that are expected to occur between the time for which DOE has data for brushless DC motor prices (2014) and the first full year after the assumed compliance date of the rulemaking (2020). DOE estimated a 6 percent price decline rate associated with the electronics used to control brushless DC motor fans based on an analysis of the Producer Price Index (PPI) of semiconductor components.³² This rate is applied only to the incremental cost between a brushless DC motor and an AC motor and not to the price of the entire ceiling fan. For details on the price trend analysis, see section IV.G.

DOE applied sales tax, which varies by geographic location, to the total product cost. DOE collected sales tax

data from the Sales Tax Clearinghouse³³ and used population projections from the Census bureau³⁴ to develop population-weighted-average sales tax values for each state in 2020.

In the final rule analyses, as in the NOPR analysis, DOE assumed that installation costs are the same regardless of efficiency level and do not affect the LCC or PBP. Westinghouse, ALA, and BAS agreed that installation costs are not based on efficiency level of fan technology. (Westinghouse, Public Meeting Transcript, No. 133 at p. 96; ALA, No. 137 at p. 8; BAS, No. 138 at p. 10)

Lutron estimated that, conservatively, there are approximately 20 million ceiling fan speed controls installed in the U.S. that generally work well with AC-motor ceiling fans. Because controls for DC-motor ceiling fans are more complicated, requiring brushless DC motors for standard, hugger, and VSD ceiling fans would unintentionally force consumers with high-cost, integrated

control systems (*i.e.*, control systems intended to control ceiling fan operation in addition to other appliances) to replace those controls systems, which is expensive and would remove energy savings potential. (Lutron, No. 141 at p. 2)

Regarding the estimate of 20 million installed speed controls for ceiling fans with AC motors, DOE notes that brushless DC-motor ceiling fans are assumed to be sold with a remote control and that the cost of the associated control is included in DOE's analyses. Therefore, consumer ability to control fan speed is preserved for ceiling fans with brushless DC motors. Regarding high-cost integrated control systems, DOE acknowledges that there may be a higher installation cost for consumers who purchase a DC-motor ceiling fan and need to upgrade from an existing integrated control system that only works with AC-motor ceiling fans to an integrated control system that works with DC-motor ceiling fans; however it is unclear what fraction of AC-motor standard, hugger, and VSD ceiling fans are currently operated by high-cost integrated control systems. DOE's best estimate is that this fraction

³³ <https://thesc.com/STRates.stm>. Last accessed May 7th 2015.

³⁴ U.S. Census Bureau, Population Division, Interim State Population Projections, 2005. Table A1: Interim Projections of the Total Population for the United States and States: April 1, 2000 to July 1, 2030.

³² PCU334413334413.

is negligibly small.³⁵ Furthermore, DOE notes that the standard adopted for standard, hugger, and VSD ceiling fans by this final rule does not require the usage of DC-motor ceiling fans.

The CA IOUs suggested that DOE remove the remote control cost from the installed cost, as the remote control is not an essential component for a ceiling fan. Alternatively, if DOE decides to include the cost of remote controls, the CA IOUs encourage DOE to consider adding the cost for wall mount controls for AC ceiling fans. (CA IOUs, No. 144 at p. 4)

DOE clarifies that in the final rule analysis, the cost of the basic means of control has been accounted for in the engineering analysis at all efficiency levels for all product classes (see section IV.C). For standard, hugger and VSD fans with an AC motor, the means of control are assumed to be electromechanical, *e.g.*, a pull chain or wall-mounted controls, as the vast majority of AC-motor ceiling fans are operated with these types of controls. For fans with a brushless DC motor, the means of control is assumed to be a remote control, as the vast majority of ceiling fans with a brushless DC motor are operated by remote control. Chapter 5 of the final TSD provides more detail on the assumptions and costs regarding the means of control. In the case of standard, hugger and VSD fans, DOE will continue to estimate, as in the NOPR analysis, that 7 percent of fans with AC motors are operated with a remote control, which is accounted for separately when calculating the purchase price.

2. Electricity Prices

In the final rule analysis, as in the NOPR analysis, DOE used average electricity prices to characterize energy costs associated with the baseline efficiency level and marginal electricity prices to characterize incremental energy costs associated with the other efficiency levels considered. Marginal electricity prices are used to characterize incremental energy costs because they capture more accurately the small, incremental cost or savings associated with a change in energy use relative to the consumer's bill in the reference case, and may provide a better representation of consumer costs than average electricity prices. In the LCC

analysis, the marginal electricity prices vary by season, region, and baseline household electricity consumption level. DOE estimated these prices using data published with the Edison Electric Institute (EEI) Typical Bills and Average Rates reports for summer and winter 2014.³⁶ DOE assigned seasonal marginal prices to each LCC sample based on the location and the baseline monthly electricity consumption for an average summer or winter month associated with that sample. DOE approximated the electricity prices for the industrial sector using the commercial sector prices. This approximation was made as the type of industrial facility that uses ceiling fans typically occupies a regular building, rather than a heavy industrial complex. For a detailed discussion of the development of electricity prices, see appendix 8B of the final rule TSD.

3. Electricity Price Trends

To arrive at average and marginal electricity prices in future years, DOE multiplied the average and marginal electricity prices in the reference year (2014) by the forecast of annual residential or commercial electricity price changes for each Census division from EIA's *AEO 2015*, which has an end year of 2040.³⁷ To estimate the trends after 2040, DOE used the average rate of change during 2025–2040.

For each fan purchase sampled, DOE applied the projection for the Census division in which the purchase was located. The AEO electricity price trends do not distinguish between marginal and average prices, so DOE used the *AEO 2015* trends for the marginal prices. DOE reviewed the EEI data for the years 2007 to 2014 and determined that there is no systematic difference in the trends for marginal vs. average electricity prices in the data.

DOE used the electricity price trends associated with the AEO Reference case scenarios for the nine Census divisions. The Reference case is a business-as-usual estimate, given expected market, demographic, and technological trends. DOE also included prices from AEO high-growth and AEO low-growth scenarios in the analysis. The high- and low-growth cases show the projected effects of alternative economic growth assumptions on energy markets.

³⁶ Edison Electric Institute. *Typical Bills and Average Rates Report*. Winter 2014 published April 2014, Summer 2014 published October 2014. See <http://www.eei.org/resourcesandmedia/products/Pages/Products.aspx>.

³⁷ U.S. Department of Energy-Energy Information Administration, *Annual Energy Outlook 2015 with Projections to 2040* (Available at: <http://www.eia.gov/forecasts/aeo/>).

4. Repair Costs

In the NOPR analysis, DOE used information on repairs and installation from manufacturer interviews to estimate the cost to consumers of repairing a ceiling fan. DOE also assumed that 2.5 percent and 9 percent of AC-motor and DC-motor ceiling fans incurred repair costs, respectively. DOE based these assumptions on repair rate estimates provided by a ceiling fan technical expert.³⁸

CA IOUs and ASAP commented that the repair rate for brushless DC motors in ceiling fans may actually be lower than the repair rate for AC motors. (CA IOUs, Public Meeting Transcript, No. 133 at p. 98; ASAP, Public Meeting Transcript, No. 133 at p. 98) The CA IOUs and ASAP disagreed with the repair cost increase for brushless DC motor ceiling fans due to a lack of supporting data, and ASAP further noted that this may have caused the economic results presented in the NOPR to be underestimated. (CA IOUs, No. 144 at p. 5; ASAP, Public Meeting Transcript, No. 133 at pp. 12–13; ASAP, No. 142 at p. 4)

DOE reexamined this issue and found no suitable data with which to update its assumption that the excess rate of failure for brushless DC motors, above the repair rate for AC motors, is 6.5 percent of purchases. Because brushless DC motors incorporate electronics that AC motors do not have, the reliability of AC motors is likely to exceed brushless DC motors. Hence, DOE has continued to use the same assumptions in the final rule analyses.

5. Product Lifetime

DOE estimated ceiling fan lifetimes by fitting a survival probability function to data of historical shipments and the 2012 age distributions of installed stock. Data on the age distribution for the installed standard, hugger, and VSD ceiling fan stock in 2012 was available from the LBNL study.³⁹ By combining data from the LBNL study with historic data on standard, hugger, and VSD ceiling fan shipments from NPD, ENERGY STAR and Appliance Magazine (see chapter 3 for more information on historical shipments), DOE estimated the percentage of appliances of a given age that are still in operation. This survival function, which DOE assumed has the form of a cumulative Weibull distribution,⁴⁰ provides a mean of 13.8 years and a

³⁸ Mehta, V. Personal communication. E-mail to Mohan Ganeshalingam, LBNL. January 14, 2014.

³⁹ Kantner, *et al.* (2013), *op. cit.*

⁴⁰ Weibull distributions are commonly used to model appliance lifetimes.

³⁵ In the aforementioned LBNL study, only 1 percent of ceiling fan owners indicated that their ceiling fans were operated via means other than pull chain/chord, wall switch (on-off only), wall control (on-off and variable speed control, and remote control (battery operated). Integrated controls such as the ones mentioned here are assumed to fall into the "other" category.

median of 13.0 years for ceiling fan lifetime and is the same distribution employed in the preliminary and NOPR analyses. Shipment data were available only for standard, hugger, and VSD ceiling fans, so DOE assumed the survival probability function of large-diameter and HSSD ceiling fans is the same as that for standard, hugger, and VSD ceiling fans.

Westinghouse and ALA agreed with the ceiling fan survival function used by DOE in the NOPR analysis, but Westinghouse commented that commercial building “turning” (i.e., where a building is repurposed for a new business) can shorten the service life of commercial fans. (Westinghouse, Public Meeting Transcript, No. 133 at p. 101; ALA, No. 137 at p. 8) CA IOUs added that there is qualitative online information suggesting that ceiling fans with brushless DC motors last longer than ceiling fans with AC motors. (CA IOUs, Public Meeting Transcript, No. 133 at p. 102) The CA IOUs also indicated that DC-motor ceiling fans may last longer than AC-motor ceiling fans, and that consumers are less likely to discard DC-motor ceiling fans prior to the end of their useful life when compared to AC-motor ceiling fans. (CA IOUs, No. 144 at p. 3) BAS added that the average lifetime for large-diameter fans is on the order of 15–20 years, with a large spread in the distribution of expected lifetimes. (BAS, No. 138 at p. 11) Finally, HKC commented that the service life of ceiling fans can be shortened by changing design trends. (HKC, Public Meeting Transcript, No. 133 at pp. 103–104)

DOE acknowledges that ceiling fans that use different technologies and belong to product classes may have different technical lifetimes. However, in its analyses, DOE considers the service lifetime of ceiling fans, including the types of effects mentioned by HKC and Westinghouse. The survival function used in the NOPR and final rule analyses inherently incorporates factors other than product failure, such as home renovation rates or design trend changes, by virtue of its derivation from the actual age distribution of installed ceiling fans in the stock. Therefore, the technical possibility of ceiling fans with brushless DC motors lasting longer than ceiling fans with AC motors should not significantly alter the survival function.

With respect to large-diameter ceiling fans, given that the general survival function DOE used results in and a median lifetime of 13 years and an average lifetime of 13.8 years—which does not drastically differ from the average lifetime suggested by BAS—and that DOE is unaware of any data to

support an increase in average lifetime for large-diameter ceiling fans, in this final rule DOE used the same survival function proposed in the NOPR for all product classes.

6. Discount Rates

In calculating the LCC, DOE applies discount rates appropriate to consumers to estimate the present value of future operating costs. To identify appropriate discount rates for purchasers, DOE estimated the percentage of HSSD and large-diameter fan purchasers in the commercial and industrial sectors. For HSSD fans, DOE estimated the ratio in floor space between likely building types where a fan would be installed in commercial settings to that in industrial settings. Manufacturer interviews informed DOE of the likely locations of CF installations. Floor space estimates by building type were taken from the 2010 U.S. Lighting Market Characterization,⁴¹ which extrapolates estimates for commercial floor space from the 2003 Commercial Buildings Energy Consumption Survey (CBECS) and industrial floor space from the 2006 Manufacturing Energy Consumption Survey (MECS) to 2010 values using measured growth trends. The ratio suggests that 80 percent of HSSD installations are in the commercial sector and 20 percent are in the industrial sector. For large-diameter fans, DOE used manufacturer feedback about common applications for these fans. DOE estimated that 20 percent of large-diameter ceiling fan installations are in the commercial sector and 80 percent are in the industrial sector.

For residential consumers, DOE estimated a distribution of discount rates for ceiling fans based on consumer financing costs and opportunity cost of funds related to appliance energy cost savings and maintenance costs. First, DOE identified all relevant household debt or asset classes to approximate a consumer's opportunity cost of funds related to appliance energy cost savings. It estimated the average percentage shares of the various types of debt and equity by household income group using data from the Federal Reserve Board's Survey of Consumer Finances⁴² (SCF) for 1995, 1998, 2001, 2004, 2007, 2010 and 2013. Using the SCF and other sources, DOE developed a distribution

of rates for each type of debt and asset by income group to represent the rates that may apply in the year in which amended standards would take effect. DOE assigned each sample household, based on its income group, a specific discount rate drawn from one of the distributions. The average rate across all types of household debt and equity and income groups, weighted by the shares of each type, is 4.4 percent. See chapter 8 of the final rule TSD for further details on the development of residential discount rates.

To establish discount rates for commercial and industrial users, DOE estimated the cost of capital for companies that purchase ceiling fans. The weighted average cost of capital is commonly used to estimate the present value of cash flows to be derived from a typical company project or investment. Most companies use both debt and equity capital to fund investments, so their cost of capital is the weighted average of the cost to the firm of equity and debt financing, as estimated from financial data for publicly traded firms in the sectors that purchase ceiling fans. For this analysis, DOE used Damodaran online⁴³ as the source of information about company debt and equity financing. The average rate across all types of companies, weighted by the shares of each type, is 5.0 percent. See chapter 8 of the final rule TSD for further details on the development of commercial and industrial sector discount rates.

7. Efficiency and Blade Span Distribution in the No-New-Standards Case

To estimate the share of consumers that would be affected by a potential energy conservation standard at a particular efficiency level, DOE's LCC analysis considered the projected distribution (market shares) of product efficiencies in the no-new-standards case (i.e., the case without new efficiency performance standards).

Shipments data for ceiling fans disaggregated by efficiency level are not available, so it is not possible to derive the current shipments-weighted efficiency distribution. Instead, for the NOPR analysis, DOE developed the current efficiency market share distributions for the standard, hugger, and VSD product classes using online data from a ceiling fan retailer⁴⁴ and data obtained from in-store visits of major retailers. Ceiling fan models were

⁴¹ Navigant Consulting, Inc. *Final Report: 2010 U.S. Lighting Market Characterization*. January 2012. (Last Accessed May 7, 2016.) <http://apps1.eere.energy.gov/buildings/publications/pdfs/ssl/2010-lmc-final-jan-2012.pdf>.

⁴² Board of Governors of the Federal Reserve System. *Survey of Consumer Finances*. 1995, 1998, 2001, 2004, 2007, 2010 and 2013. (Last accessed May 7, 2016.) <http://www.federalreserve.gov/econresdata/scf/scfindex.htm>.

⁴³ Damodaran, A. *Cost of Capital by Sector*. January 2014. (Last accessed May 7, 2016.) http://people.stern.nyu.edu/adamodar/New_Home_Page/datafile/wacc.htm.

⁴⁴ <http://www.hansenwholesale.com/>.

binned according to their efficiency to arrive at the current distributions. To estimate the efficiency distributions in 2019, DOE applied a consumer-choice model sensitive only to the first cost of options representative of each efficiency level given by the engineering analysis.

Westinghouse commented at the NOPR public meeting that the fraction of hugger fans currently estimated to meet EL 3 appeared to be too high. Westinghouse and ALA also commented that model counts of ceiling fans are not representative of market share. (Westinghouse, Public Meeting Transcript, No. 133 at p. 107–110; ALA, No. 139 at pp. 2–3) ALA estimated that approximately 70 percent of standard and hugger ceiling fan models do not meet the standard level proposed in the NOPR based on test results of sample products, and added that higher sales-volume ceiling fan models are less likely to meet that standard than lower sales-volume models. For certain manufacturers, ALA estimated that over 90 percent of shipments would not

comply with the proposed standards (ALA, No. 139 at pp. 2–3) DOE understands that model counts are not necessarily representative of market share. With respect to the estimate that 90 percent of shipments would not comply with the proposed standards for certain manufacturers, DOE notes that any given manufacturer’s efficiency distribution may differ from the efficiency distribution of the entire market. For the 70 percent of standard and hugger sample products that did not meet the proposed standard level based on recent testing results, it is unclear how representative these sample products are of the entire ceiling fan market without corresponding shipments data. However, in the absence of a shipments-weighted efficiency distribution, for this final rule DOE has adopted an updated 2015 efficiency distribution with 70 percent of shipments of standard and hugger ceiling fans below the proposed standard level in the NOPR. Because no market share distribution was suggested by ALA amongst the three efficiency

levels below the proposed standard level, market shares were assumed to be split evenly between EL0, EL1, and EL2. The efficiency distribution for 2020 was then projected using the consumer-choice model described in section IV.G.3. No comments were received regarding the efficiency distribution for VSD ceiling fans, so DOE has maintained its approach from the NOPR analysis for the VSD product class. For HSSD and large-diameter ceiling fans, DOE developed the current efficiency distributions using model counts available on HSSD and large-diameter fan manufacturer websites. DOE assumed the current distribution observed in 2015 would also be representative of the efficiency distribution in 2020. The estimated market shares for the no-new-standards case for all ceiling fans are shown in Table IV.3. See chapter 8 of the final rule TSD for further information on the derivation of the efficiency distributions.

TABLE IV.3.—MARKET EFFICIENCY DISTRIBUTION FOR THE NO-NEW-STANDARDS CASE IN 2020

| Product class | EL 0 (%) | EL 1 (%) | EL 2 (%) | EL 3 (%) | EL 4 (%) | Total * (%) |
|----------------------|----------|----------|----------|----------|----------|-------------|
| Standard | 22.7 | 22.7 | 22.7 | 28.9 | 3.1 | 100 |
| Hugger | 22.6 | 22.6 | 22.6 | 28.8 | 3.4 | 100 |
| VSD | 4.1 | 0.0 | 96.0 | 0.0 | | 100 |
| HSSD | 44.7 | 44.7 | 0.0 | 2.7 | 8.0 | 100 |
| Large-Diameter | 5.1 | 5.1 | 58.3 | 14.1 | 17.3 | 100 |

* Rows may not sum to 100% due to rounding.

DOE also developed size distributions within each product class to determine the likelihood that a given purchaser would select each of the representative fan sizes from the engineering analysis. For the NOPR, DOE estimated the distribution of diameters for standard, hugger, HSSD and large-diameter ceiling fans using the distribution of models currently seen on the market. In particular, DOE estimated that the current market share for 36-inch and 56-inch HSSD ceiling fans are 7 percent and 93 percent, respectively. A limited pool of available VSD fan models

indicated a rough split of market share between the two representative blade spans, so DOE assumed that the VSD market was evenly split between the two blade spans. Westinghouse agreed with the proposed market shares for 36” and 56” high-speed small-diameter ceiling fans in the NOPR, as well as the market shares by diameter for hugger, standard, and very-small diameter low-volume ceiling fans. (Westinghouse, Public Meeting Transcript, No. 133 at p. 91, 117) In the absence of additional data or comments to support an alternative

approach, DOE retained the same methodology for the final rule analysis to estimate the blade span distribution for all the product classes. DOE estimated the blade span distribution by using the distribution of models currently seen on the market for the final rule. Table IV.4 presents the blade span distribution of each of the product classes. (For the NIA, DOE assumed that blade size distribution remains constant over the years considered in the analysis.)

TABLE IV.4.—BLADE SPAN DISTRIBUTION

| Product class | Standard | | | Hugger | | VSD | | HSSD | | Large-Diameter | | |
|---------------------------|----------|------|-----|--------|------|------|------|------|------|----------------|------|------|
| Blade Span (inches) | 44 | 52 | 60 | 44 | 52 | 13 | 16 | 36 | 56 | 96 | 144 | 240 |
| Market Share (%) | 21.1 | 72.5 | 6.5 | 46.2 | 53.8 | 50.0 | 50.0 | 7.0 | 93.0 | 22.0 | 27.0 | 51.0 |

8. Payback Period Analysis

The payback period is the amount of time it takes the consumer to recover the

additional installed cost of more-efficient products, compared to baseline products, through energy cost savings.

Payback periods are expressed in years. Payback periods that exceed the life of the product mean that the increased

total installed cost is not recovered in reduced operating expenses.

The inputs to the PBP calculation for each efficiency level are the change in total installed cost of the product and the change in the first-year annual operating expenditures relative to the baseline. The PBP calculation uses the same inputs as the LCC analysis, except that discount rates are not needed.

EPCA, as amended, establishes a rebuttable presumption that a standard is economically justified if the Secretary finds that the additional cost to the consumer of purchasing a product complying with an energy conservation standard level will be less than three times the value of the first year's energy savings resulting from the standard, as calculated under the applicable test procedure. (42 U.S.C. 6295(o)(2)(B)(iii)) For each considered efficiency level, DOE determined the value of the first year's energy savings by calculating the energy savings in accordance with the applicable DOE test procedure, and multiplying those savings by the average energy price forecast for the year in which compliance with the amended standards would be required.

G. Shipments Analysis

DOE uses projections of product shipments to calculate the national impacts of potential amended energy conservation standards on energy use, NPV, and future manufacturer cash flows. Historical shipments data are used to build up an equipment stock, and to calibrate the shipments model to project shipments over the course of the analysis period based on the estimated future demand for ceiling fans. Details of the shipments analysis are described in chapter 9 of the final rule TSD.

The shipments model projects total shipments and market-share efficiency distributions in each year of the 30-year analysis period for the no-new-standards case and each of the standards cases, calibrated using historical shipments. This final rule is expected to publish in late 2016 with a compliance date in late 2019. DOE begins its shipments analysis for the final rule in 2020, the first full year of compliance, and extends over 30 years until 2049. The shipments model consists of three main components: (1) A shipments demand model that determines the total demand for new ceiling fans in each year of the analysis period, (2) a stock model that tracks the age distribution of the stock over the analysis period, and (3) a model that determines the market shares of purchased ceiling fans across efficiency levels. For standard, hugger, and VSD ceiling fans, DOE used a consumer-choice model sensitive to

ceiling fan first cost to estimate market shares across efficiency level. For HSSD and large-diameter ceiling fans, DOE used a roll-up approach to estimate the efficiency distribution in each standards case.

1. Shipments Demand Model

DOE used historical shipment data of hugger, standard, and VSD fans from Appliance Magazine's Statistical Review from 1991 to 2006,⁴⁵ data from ENERGY STAR annual reports from 2003 to 2013,⁴⁶ and data purchased from NPD Research group from 2007–2011.⁴⁷ Figure 9.3.1 in Chapter 9 of this final rule TSD displays the historical time series used for DOE's shipments analysis.

As the data were not disaggregated by product class, DOE estimated the relative split between standard, hugger, and VSD product classes. In the NOPR analysis, DOE used online and in-store ceiling fan data and applied a price-weighting approach based on market share data as a function of retail price for ceiling fans collected by the NPD Group from 2007 to 2011. These data inform the price-weighting scheme, which apportions more market share to ceiling fans with lower first costs. DOE calculated 48.7 percent and 51.3 percent current market shares for hugger and standard ceiling fans, respectively. DOE's calculation assumed that multi-mount ceiling fan installations are split 27 percent/73 percent as hugger and standard ceiling fans, respectively.

Westinghouse agreed with DOE's estimates for the market split between standard, hugger, and VSD ceiling fans in the NOPR analyses. (Westinghouse, Public Meeting Transcript, No. 133 at p. 91, 117) DOE retains this methodology for estimating market share by product class for the final rule.

DOE's estimate for HSSD historical shipments is based on scaling historical shipments of standard, hugger, and VSD ceiling fans using a scaling factor estimated from feedback from manufacturer interviews. DOE's estimate for large-diameter fans is based on matching a linear shipments trend to an estimate of 2013 installed stock assuming large-diameter fans were introduced to the market in 2000.

Shipments for standard, hugger, and VSD ceiling fans are calculated for the residential sector. Shipments for HSSD and large-diameter fans are calculated

for the commercial and industrial sectors. As all of the inputs used in the downstream analyses are the same for both sectors, DOE does not distinguish between shipments to the commercial or industrial sector.

The ceiling fan shipments demand model considers four market segments that affect the net demand for total shipments: replacements for retired stock, additions due to new building construction, additions due to expanding demand in existing buildings, and reductions due to building demolitions, which erodes demand from replacements and existing buildings.

2. Stock-Accounting Model

The stock accounting model tracks the age (vintage) distribution of the installed ceiling fan stock. The age distribution of the stock impacts both the national energy savings (NES) and NPV calculations, because the operating costs for any year depend on the age distribution of the stock. Older, less efficient units may have higher operating costs, while newer, more efficient units have lower operating costs. The stock accounting model is initialized using historical shipments data and accounts for additions to the stock (*i.e.*, shipments) and retirements. The age distribution of the stock in 2012 is estimated using results from a recent survey of ceiling fan owners.⁴⁸ The stock age distribution is updated for subsequent years using projected shipments and retirements determined by the stock age distribution and a product retirement function.

3. Market-Share Projections

The consumer-choice model used for standard, hugger, and VSD ceiling fans estimates the market shares of purchases in each year in the analysis period for each efficiency level presented in the engineering analysis. DOE assumed that each of these product classes provides a specific utility and consumers do not choose between options in different product classes. The consumer-choice module selects which ceiling fans are purchased within a product class in any given year based on consumer sensitivity to first cost, as well as on the ceiling fan options available, which were determined in the engineering analysis. Deviations from purely cost-driven behavior are accounted for using factors found by calibrating the model to observed historical data.

Westinghouse agreed with DOE's NOPR assumption that consumers of standard, hugger, and VSD ceiling fans

⁴⁵ Appliance® Statistical Review, Annual Report, Appliance Magazine (1991–2006).

⁴⁶ United States Environmental Protection Agency, *ENERGY STAR® and Other Climate Protection Partnerships: Annual Report* (2003–2013).

⁴⁷ NPD Group, 2007–2011.

⁴⁸ Kantner, *et al.* (2013), *op. cit.*

are most sensitive to first cost. (Westinghouse, Public Meeting Transcript, No. 133 at p. 123) DOE maintains this assumption for the consumer-choice model in the final rule.

In the NOPR analysis, DOE assumed the no-new-standards case efficiency distribution for HSSD and large-diameter ceiling fans remained fixed at the estimated 2015 efficiency distribution over the shipments analysis period. In the standards cases, market shares for those levels that do not meet the standard roll up to the standard level, and shares above the standard level are unchanged. In the NOPR analysis, DOE assumed no product class switching between the HSSD and large-diameter product classes.

Westinghouse and BAS agreed with the roll-up approach DOE used in its NOPR analysis, but BAS added that large-diameter ceiling fan manufacturers are likely to meet the minimum efficiency by reducing the utility of their fans (i.e., by reducing the maximum airflow). (Westinghouse, Public Meeting Transcript, No. 133 at pp. 123–124; BAS, Public Meeting Transcript, No. 133 at p. 126)

For this final rule, DOE continues to use the roll-up approach for HSSD and large-diameter ceiling fans. As discussed in section IV.C.3, DOE adjusted the efficiency equation associated with the considered standard levels to ensure that high airflow ceiling fans would be preserved under the standard level in this final rule.

4. Price Trend

The consumer-choice model uses ceiling fan prices, which change over time in some cases. There is considerable evidence of learning-by-doing lowering the cost of new technologies along with increases in production of the new technology. The concept behind this empirical phenomenon is that as the new technology is produced in greater numbers, employees and firms will find ways to lower costs. Brushless DC motors are a relatively new technology

for use in ceiling fans, and thus DOE expects price declines. Given the absence of data on cumulative shipments of brushless DC motors, DOE models learning lowering costs, and thus prices, with time. In the NOPR analysis, DOE adopted a price decline rate of 6 percent applied to the incremental (not total) cost associated with a brushless DC motor, based on information from a technical expert for standard, hugger, and VSD ceiling fans.⁴⁹ ASAP agreed with DOE’s approach to apply price learning only to the electronic component of brushless DC motors, as opposed to applying price learning to the entire product. (ASAP, Public Meeting Transcript, No. 133 at p. 122) DOE continues to use this methodology for applying price trends to brushless DC motors in this final rule.

5. Impact of a Standard on Shipments

DOE assumes that any increase in the average price of a ceiling fan due to a standard would result in a decrease in shipments. For this final rule analysis, DOE uses a relative price elasticity of demand of -0.34, which is the value DOE has typically used for residential appliances.

DOE notes that an increase in the price of ceiling fan light kits due to the adopted ceiling fan light kit standard will also impact the shipments of ceiling fans sold with ceiling fan light kits. The ceiling fan final rule analysis included the impact on ceiling fan shipments from the estimated ceiling fan light kit price change due to the adopted ceiling fan light kit standard. (81 FR 580 (Jan. 6, 2016)) The impact from a ceiling fan light kit standard to ceiling fan shipments is applied to both the no ceiling fan standards case and the ceiling fan standards case shipments.

H. National Impact Analysis

The NIA assesses the national energy savings (NES) and the net present value (NPV) from a national perspective of total consumer costs and savings that would be expected to result from new or amended standards at specific efficiency levels. (“Consumer” in this

context refers to consumers of the product being regulated.) DOE calculates the NES and NPV based on projections of annual product shipments, along with the annual energy consumption, total installed cost, and repair costs. For the final rule analysis, DOE projected the energy savings, operating cost savings, product costs, and NPV of consumer benefits over the lifetime of ceiling fans shipped from 2020 through 2049, beginning with the first full year of compliance with a potential standard.

DOE evaluates the impacts of new and amended standards by comparing a case without such standards with standards-case projections. The no-new-standards case projection characterizes energy use and consumer costs for each product class in the absence of new or amended energy conservation standards. For this projection, DOE considers historical trends in efficiency and various forces that are likely to affect the mix of efficiencies over time. DOE compares the no-new-standards case with projections characterizing the market for each product class if DOE adopted new or amended standards at specific energy efficiency levels (i.e., the TSLs or standards cases) for that class. For the standards cases, DOE considers how a given standard would likely affect the market shares of products with efficiencies greater than the standard when ceiling fans that do not meet the TSL being analyzed are excluded as options available to the consumer.

DOE uses a spreadsheet model to calculate the energy savings and the national consumer costs and savings from each TSL. Interested parties can review DOE’s analyses by changing various input quantities within the spreadsheet. The NIA spreadsheet model uses typical values (as opposed to probability distributions) as inputs.

Table IV.5 summarizes the inputs and methods DOE used for the NIA analysis for the final rule. Discussion of these inputs and methods follows the table. See chapter 10 of the final rule TSD for further details.

TABLE IV.5—SUMMARY OF INPUTS AND METHODS FOR THE NATIONAL IMPACT ANALYSIS

| Inputs | Method |
|--|--|
| Shipments | Annual shipments from shipments model. |
| Assumed Compliance Date of Standard | 2019.* |
| No Standard-Case Forecasted Efficacies | Estimated by market-share module of shipments model. |
| Standards-Case Forecasted Efficacies | Estimated by market-share module of shipments model. |

⁴⁹ Mehta, V. Personal communication. E-mail to Mohan Ganeshalingam, LBNL. January 14, 2014.

TABLE IV.5—SUMMARY OF INPUTS AND METHODS FOR THE NATIONAL IMPACT ANALYSIS—Continued

| Inputs | Method |
|---|--|
| Annual Energy Consumption per Unit | Annual weighted-average values are a function of energy use at each EL. |
| Total Installed Cost per Unit | Annual weighted-average values are a function of cost at each EL. Incorporates projection of future product prices based on historical data. |
| Annual Energy Cost per Unit | Annual weighted-average values as a function of the annual energy consumption per unit and energy prices. |
| Repair and Maintenance Cost per Unit | DC motor fans have a 6.5% higher failure rate compared to AC motor fans. |
| Energy Prices | AEO 2015 forecasts (to 2040) and extrapolation thereafter. |
| Energy Site-to-Primary and FFC Conversion | A time-series conversion factor based on AEO 2015. |
| Discount Rate | Three and seven percent. |
| Present Year | 2016. |

* The compliance date was assumed to be in late 2019, so the shipments analysis was conducted for products shipped from 2020–2049, beginning with the first full year of compliance.

1. National Energy Savings

The national energy savings analysis involves a comparison of national energy consumption of the considered products between each potential standards case and the case with no new or amended energy conservation standards. DOE calculated the national energy consumption by multiplying the number of units (stock) of each product (by vintage or age) by the unit energy consumption (also by vintage). DOE calculated annual NES based on the difference in national energy consumption for the no-new-standards case and for the case where a standard is set at each TSL. DOE estimated energy consumption and savings based on site energy and converted the electricity consumption and savings to primary energy (*i.e.*, the energy consumed by power plants to generate site electricity) using annual conversion factors derived from AEO 2015. Cumulative energy savings are the sum of the NES for each year over the timeframe of the analysis.

In 2011, in response to the recommendations of a committee on “Point-of-Use and Full-Fuel-Cycle Measurement Approaches to Energy Efficiency Standards” appointed by the National Academy of Sciences, DOE announced its intention to use full-fuel-cycle (FFC) measures of energy use and greenhouse gas and other emissions in the national impact analyses and emissions analyses included in future energy conservation standards rulemakings. 76 FR 51281 (Aug. 18, 2011). After evaluating the approaches discussed in the August 18, 2011 notice, DOE published a statement of amended policy in which DOE explained its determination that EIA’s National Energy Modeling System (NEMS) is the most appropriate tool for its FFC analysis and its intention to use NEMS

for that purpose. 77 FR 49701 (Aug. 17, 2012). NEMS is a public domain, multi-sector, partial equilibrium model of the U.S. energy sector⁵⁰ that EIA uses to prepare its *Annual Energy Outlook*. The approach used for deriving FFC measures of energy use and emissions is described in appendix 10B of the final rule TSD.

The rebound effect accounts for increased usage of an appliance by consumers after the implementation of a standard, reducing the energy savings attributed to a standard. DOE generally accounts for the direct rebound effect in its estimates of the national energy savings when available data suggest consumers may increase product usage in the event of a standard which acts to decrease the average power associated with the product. In the case of ceiling fans, DOE found no data pertaining to a rebound effect associated with more efficient products and also received comments in response to the Framework document from ALA indicating that they did not believe a rebound effect due to a ceiling fan standard was likely. (ALA, No 39, at pg. 39) In this final rule, DOE assumes no rebound effect in its reference scenario. Nevertheless, DOE performed a sensitivity scenario assuming a rebound of 3-percent to examine the implications of rebound. The rebound sensitivity reduces national energy savings at each TSL by 3 percent without impacting NPV results. The full results of this sensitivity analysis can be found in appendix 10C of this final rule TSD. The rebound effect explored in this sensitivity analysis can reduce expected savings in energy costs to consumers in the standards case.

⁵⁰ For more information on NEMS, refer to *The National Energy Modeling System: An Overview* 2009, DOE/EIA-0581(2009), October 2009. Available at <http://www.eia.gov/forecasts/aeo/index.cfm>.

2. Net Present Value Analysis

The inputs for determining the NPV of the total costs and benefits experienced by consumers are (1) total annual installed cost, (2) total annual operating costs savings, and (3) a discount factor to calculate the present value of costs and savings. DOE calculates net savings each year as the difference between the no-new-standards case and each standards case in terms of total savings in operating costs versus total increases in installed costs. DOE calculates operating cost savings over the lifetime of each product shipped during the forecast period.

The operating cost savings are primarily energy cost savings, which are calculated using the estimated energy savings in each year and the projected price of electricity. To estimate electricity prices in future years, DOE multiplied the average regional energy prices by the forecast of annual national-average residential energy price changes in the Reference case from AEO 2015, which has an end year of 2040. To estimate price trends after 2040, DOE used the average annual rate of change in prices from 2020 through 2040. As part of the NIA, DOE also analyzed scenarios that used inputs from the AEO 2015 Low Economic Growth and High Economic Growth cases. NIA results based on these cases are presented in appendix 10C of the final rule TSD.

DOE estimated the range of potential impacts of amended standards by considering four sensitivity scenarios: a high-benefit scenario, a low-benefit scenario, and a scenario that includes a 3-percent rebound effect. In the high benefits scenario, DOE used the AEO 2015 high economic growth case estimates for new housing starts and electricity prices along with its reference price trend for DC motor fans. As discussed in section IV.G.4, price

trend is only applied to the price premium between a DC motor and a direct drive AC motor. In the low benefits scenario, DOE used the low economic growth *AEO 2015* estimates for housing starts and electricity prices, along with no price trend. In the 3-percent rebound scenario, DOE assumed that there would be increased ceiling fan usage due to the decreased operating cost savings associated with a standard. As noted previously, DOE assumes any operating cost incurred by increased usage due to the rebound effect is offset by the economic value associated with that increased usage. The NIA results based on these alternative scenarios are presented in appendix 10C of the final rule TSD.

In calculating the NPV, DOE multiplies the net savings in future years by a discount factor to determine their present value. For this final rule, DOE estimated the NPV of consumer benefits using both a 3-percent and a 7-percent real discount rate. DOE uses these discount rates in accordance with guidance provided by the Office of Management and Budget (OMB) to Federal agencies on the development of regulatory analysis.⁵¹ The discount rates for the determination of NPV are in contrast to the discount rates used in the LCC analysis, which are designed to reflect a consumer's perspective. The 7-percent real value is an estimate of the average before-tax rate of return to private capital in the U.S. economy. The 3-percent real value represents the "social rate of time preference," which is the rate at which society discounts future consumption flows to their present value.

I. Consumer Subgroup Analysis

In analyzing the potential impact of new or amended energy conservation standards on consumers, DOE evaluates the impact on identifiable subgroups of consumers that may be disproportionately affected by a new or amended national standard. The purpose of a subgroup analysis is to determine the extent of any such disproportional impacts. DOE evaluates impacts on particular subgroups of consumers by analyzing the LCC impacts and PBP for those particular consumers from alternative standard levels. For this final rule, DOE analyzed the impacts of the considered standard levels on low-income households and small businesses that purchase ceiling fans. DOE used the LCC and PBP

spreadsheet model to estimate the impacts of the considered efficiency levels on these subgroups.

DOE calculated the LCC and PBP results for standard, hugger, and VSD fans based on a sample of low-income households or consumers who were identified in the RECS 2009 survey as being at or below the "poverty line." The poverty line varies with household size, head of household age, and family income.

In the case of the HSSD and large-diameter fans, DOE conducted a subgroup analysis based on small businesses that purchase ceiling fans by applying the small company discount rate distributions for each sector in the LCC and PBP calculation, instead of the discount rate associated with the entire industry.

Chapter 11 in the final rule TSD describes the consumer subgroup analysis.

J. Manufacturer Impact Analysis

1. Overview

DOE conducted an MIA for ceiling fans to estimate the financial impact of amended standards on manufacturers of ceiling fans. The MIA has both quantitative and qualitative aspects. The quantitative part of the MIA relies on the GRIM, an industry cash-flow model customized for the ceiling fans covered in this rulemaking. The key GRIM inputs are data on the industry cost structure, MPCs, shipments, and assumptions about manufacturer markups, and conversion costs. The key MIA output is INPV. DOE used the GRIM to calculate cash flows using standard accounting principles and to compare changes in INPV between the no-new-standards case and various TSLs (the standards cases). The difference in INPV between the no-new-standards case and the standards cases represents the financial impact of amended energy conservation standards on ceiling fan manufacturers. Different sets of assumptions (scenarios) produce different INPV results. The qualitative part of the MIA addresses factors such as manufacturing capacity; characteristics of, and impacts on, any particular subgroup of manufacturers, including small manufacturers; and impacts on competition.

DOE conducted the MIA for this rulemaking in three phases. In the first phase, DOE prepared an industry characterization based on the market and technology assessment, preliminary manufacturer interviews, and publicly available information. In the second phase, DOE estimated industry cash flows in the GRIM using industry

financial parameters derived in the first phase and the shipments derived in the shipment analysis. In the third phase, DOE conducted interviews with a variety of ceiling fan manufacturers that account for more than 30 percent of domestic ceiling fan sales covered by this rulemaking. During these interviews, DOE discussed engineering, manufacturing, procurement, and financial topics specific to each company, and obtained each manufacturer's view of the ceiling fan industry as a whole. The interviews provided information that DOE used to evaluate the impacts of amended standards on manufacturers' cash flows, manufacturing capacities, and direct domestic manufacturing employment levels. See section V.B.2.b of this final rule for the discussion on the estimated changes in the number of domestic employees involved in manufacturing ceiling fans covered by standards.

During the third phase, DOE used the results of the industry characterization analysis in the first phase and feedback from manufacturer interviews to group manufacturers that exhibit similar production and cost structure characteristics. DOE identified one manufacturer subgroup for a separate impact analysis; small businesses. DOE determined that ceiling fan manufacturing falls under the North American Industry Classification System (NAICS) code 335210, small electrical appliance manufacturing. The U.S. Small Business Administration (SBA) defines a small business as having less than 1,500 total employees for manufacturing operating under this NAICS code. This threshold includes all employees in a business' parent company and any other subsidiaries. Based on this classification, DOE identified six domestic ceiling fan businesses that manufacturer ceiling fans in the United States and qualify as small businesses per the SBA threshold. DOE analyzed the impact on the small business subgroup in the complete MIA, which is presented in chapter 12 of the final rule TSD, and in the Regulatory Flexibility analysis required by the Regulatory Flexibility Act, 5 U.S.C. 601, et. seq., presented in section VI.B of this final rule.

2. GRIM Analysis and Key Inputs

DOE uses the GRIM to quantify the changes in cash flows over time due to amended energy conservation standards. These changes in cash flows result in either a higher or lower INPV for the standards case compared to the no-new-standards case. The GRIM uses standard annual cash-flow analysis that incorporates MPCs, manufacturer

⁵¹ United States Office of Management and Budget, *Circular A-4: Regulatory Analysis*, September 17, 2003. Section E. Available at www.whitehouse.gov/omb/memoranda/m03-21.html.

markups, shipments, and industry financial information as inputs. It then models changes in MPCs, investments, and manufacturer margins that may result from analyzed amended energy conservation standards. The GRIM uses these inputs to calculate a series of annual cash flows beginning with the reference year of the analysis, 2016, and continuing to the terminal year of the analysis, 2049. DOE computes INPV by summing the stream of annual discounted cash flows during the analysis period. DOE used a real discount rate of 7.4 percent for ceiling fan manufacturers. This is the same discount rate used in the NOPR analysis. Many of the GRIM inputs come from the engineering analysis, the shipment analysis, manufacturer interviews, and other research conducted during the MIA. The major GRIM inputs are described in detail in the following sections.

a. Capital and Product Conversion Costs

DOE expects amended ceiling fan energy conservation standards to cause manufacturers to incur conversion costs by bringing their tooling and product designs into compliance with amended standards. For the MIA, DOE classified these conversion costs into two major groups: (1) Capital conversion costs and (2) product conversion costs. Capital conversion costs are investments in property, plant, and equipment necessary to adapt or change existing tooling equipment so new product designs can be fabricated and assembled. Product conversion costs are investments in research, development, testing, marketing, certification, and other non-capitalized costs necessary to make product designs comply with amended standards.

ALA commented that DOE underestimated conversion costs due to an understated percentage of shipments that will meet the standard in the compliance year (ALA, No. 139, p. 2–4). ALA maintains that conversion costs would be doubled had DOE used the efficiency distribution estimated by ALA.

For the final rule, DOE revised the shipment efficiency distribution in the shipment analysis for standard and hugger ceiling fans based on feedback from ALA. The MIA used the shipment efficiency distribution when calculating the industry conversion costs. Conversion costs significantly increased from the NOPR to the final rule due to these changes in the efficiency distribution.

ALA went on to comment that conversion costs are further understated due to their exclusion of additional

financing costs that could be incurred by some manufacturers to purchase manufacturing equipment needed to produce ceiling fans that comply with the standard (ALA, No. 139, p. 4). Also, Westinghouse commented that they were concerned DOE's analysis may not be fully calculating or capturing what the true cost increase for manufacturers will be. (Westinghouse, Public Meeting Transcript, No. 133 at p. 92)

DOE increased the per model capital and product conversion costs associated with converting a failing ceiling fan model into a compliant model, based on ALA and Westinghouse's comments. This per model conversion cost increase resulted in higher overall conversion costs from the NOPR to the final rule. This increase in per model conversion costs was in addition to the increase in the number of models needed to be converted due to the changes in the efficiency distribution previously described.

b. Manufacturer Production Costs

Manufacturing a more efficient product is typically more expensive than manufacturing a lower efficient product due to the use of more complex components, which are typically more costly than less efficient components. The increases in the MPCs of the analyzed products can affect the revenues, gross margins, and cash flow of the industry, making these product costs key inputs for the GRIM and the MIA.

In the MIA, DOE used the MPCs calculated in the engineering analysis, as described in section IV.C and further detailed in chapter 5 of the final rule TSD. To calculate MPCs for ceiling fans, DOE updated the MPCs used in the NOPR analysis based on manufacturer feedback for the final rule analysis. The MIA used these updated MPCs for the final rule analysis.

c. Shipment Scenarios

INPV, which is the key GRIM output, depends on industry revenue, which depends on the quantity and prices of ceiling fans shipped in each year of the analysis period. Industry revenue calculations require forecasts of: (1) Total annual shipment volume of ceiling fans; (2) the distribution of shipments across the product class (because prices vary by product class); and, (3) the distribution of shipments across ELs (because prices vary with ceiling fan efficiency).

DOE modeled the no-new-standards case ceiling fan shipments and the growth of ceiling fan shipments using replacement shipments of failed ceiling fan units, new construction starts as

projected by *AEO 2015*, and the number of additions to existing buildings due to expanding demand throughout the analysis period taking into account demolitions in the housing stock.

DOE updated the initial 2015 efficiency distribution for the final rule analysis for standard and hugger fans based on feedback from manufacturers. To estimate the distribution of shipments across ELs over the analysis period for standard, hugger, and VSD ceiling fans, a consumer-choice model was used to project consumer purchases based on consumer sensitivity to first cost. For HSSD and large-diameter ceiling fans, a roll-up approach was used, in which consumers who would have purchased ceiling fans that fail to meet the new standards in the no-new-standards case purchase the least efficient, compliant ceiling fans in the standards cases. Consumers that would have purchased compliant ceiling fans in the no-new-standards case continue to purchase the exact same ceiling fans in the standards cases.

For all ceiling fans, DOE also included price elasticity in the shipments analysis for all standards cases. When price elasticity is included in the shipment analysis, the total number of ceiling fans declines as the average price of a ceiling fan increases due to standards. For a complete description of the shipments, see the shipments analysis discussion in section IV.G of this final rule.

d. Markup Scenarios

As discussed in section IV.J.2.b, the MPCs for ceiling fans are the manufacturers' costs for those units. These costs include materials, labor, depreciation, and overhead, which are collectively referred to as the cost of goods sold (COGS). The MSP is the price received by ceiling fan manufacturers from the first sale, typically to a distributor, regardless of the downstream distribution channel through which the ceiling fans are ultimately sold. The MSP is not the cost the end-user pays for ceiling fans, because there are typically multiple sales along the distribution chain and various markups applied to each sale. The MSP equals the MPC multiplied by the manufacturer markup. The manufacturer markup covers all the ceiling fan manufacturer's non-production costs (*i.e.*, selling, general, and administrative expenses [SG&A]; research and development [R&D]; interest) as well as profit. Total industry revenue for ceiling fan manufacturers equals the MSPs at each efficiency level multiplied by the number of shipments at that efficiency level.

Modifying these manufacturer markups in the standards cases yields a different set of impacts on ceiling fan manufacturers than in the no-new-standards case. For the MIA, DOE modeled three standards case markup scenarios for ceiling fans to represent the uncertainty regarding the potential impacts on prices and profitability for ceiling fan manufacturers following the implementation of amended standards. The three scenarios are: (1) A preservation of gross margin markup scenario; (2) a preservation of operating profit markup scenario; and (3) a two-tiered markup scenario. Each scenario leads to different manufacturer markup values, which, when applied to the inputted MPCs, result in varying revenue and cash-flow impacts on ceiling fan manufacturers.

The manufacturer markups for the preservation of operating profit and two-tiered markup scenarios depend on the efficiency distribution of shipments calculated in the shipment analysis. Therefore, the manufacturer markups for the preservation of operating profit and two-tiered markup scenarios are slightly different in the final rule than those in the NOPR analysis.

3. Discussion of Comments

Only ALA and Westinghouse commented on the assumptions and results of the NOPR MIA. These comments addressed the capital and product conversion costs and are addressed in section IV.J.2.a. No further comments on the NOPR were submitted regarding the MIA.

4. Manufacturer Interviews

DOE conducted additional interviews with manufacturers following the preliminary analysis as part of the NOPR analysis. DOE outlined the key issues for ceiling fan manufacturers in the NOPR. 81 FR 1689 (January 13, 2016). DOE considered the information received during these interviews in the development of the NOPR and this final rule. DOE did not receive any comments regarding the key issues described in the NOPR analysis.

a. Shift to Air Conditioning

Several manufacturers stated that ceiling fan energy conservation standards could cause residential consumers to forgo the purchase of a ceiling fan in lieu of an air conditioner due to the price increase, or could cause residential ceiling fan owners to run their air conditioners more frequently instead of using their ceiling fan. Manufacturers assert that if residential consumers instead use their air conditioner to cool their homes, this

could result in more energy use, as ceiling fans tend to be more efficient at cooling rooms than air conditioners.

Manufacturers also stated that overly stringent ceiling fan standards could force manufacturers to reduce the aesthetic quality of some ceiling fans to comply with energy conservation standards. This could cause some residential consumers to forgo the purchase of these ceiling fans because the aesthetic appearance of ceiling fans is an important factor when residential consumers purchase ceiling fans. Manufacturers claim this reduction in aesthetic quality could again result in more energy use, because residential consumers who do not purchase ceiling fans would need to use air conditioners to cool their homes. DOE addresses this issue in section IV.E.3 of this final rule.

b. Testing Burden

Manufacturers are concerned about the additional testing burden associated with complying with amended energy conservation standards. Most manufacturers use third-party testing facilities for testing and reporting purposes, which can be expensive. Manufacturers stated that ceiling fan standards would significantly increase the amount that they already invest in testing each year. DOE includes the additional testing and certification costs that manufacturers must make due to standards as part of the MIA. DOE calculates the total industry conversion costs for manufacturers, which includes the additional testing and certification costs of complying with amended standards. These conversion costs impact the INPV at each TSL. Industry cash flow analysis results are discussed in detail in section V.B.2.a.

c. Utility of Brushless and Gearless DC Motors for Residential Consumers

Manufacturers stated that amended energy conservation standards that required the use of brushless DC motors in residential ceiling fans would limit the overall utility of the fan and increase maintenance costs. Manufacturers claim that brushless DC motors require significantly more maintenance and have a higher warranty factor compared to ceiling fans with AC motors. Additionally, ceiling fans with brushless DC motors require the use of a handheld remote, which manufacturers claim is not preferred by many residential consumers. Therefore, manufacturers stated any ceiling fan standard that required the use of a brushless DC motor would significantly reduce the overall utility of ceiling fans to residential consumers.

For the HSSD and large-diameter product classes, which are expected to represent less than three percent of all covered ceiling fan shipments in 2020, manufacturers stated that the use of brushless DC motors in HSSD ceiling fans and gearless DC motors in large-diameter ceiling fans will not significantly impact consumer utility. HSSD and large-diameter ceiling fans are typically used in commercial and industrial applications as opposed to in residential applications. Most manufacturers indicated that commercial and industrial consumers do not dislike using a handheld remote that is required when operating a ceiling fan with a brushless or gearless DC motor, and in some applications it is preferable. Also, these commercial and industrial consumers tend to be better equipped to respond to the increased maintenance costs associated with owning and operating ceiling fans with brushless or gearless DC motors because these consumers are more likely to repair their own products and equipment than residential consumers are.

DOE conducted a screening analysis as part of this final rule analysis and concluded that brushless or gearless DC motors should be considered as a viable technology for all respective product classes of covered ceiling fans for the engineering analysis. See section IV.B of this final rule for a detailed discussion of the screening analysis. Additionally, DOE did include the additional repair costs of ceiling fans using brushless or gearless DC motors as part of the LCC analysis. See section IV.F.4 for a complete description of the repair cost assumptions of brushless and gearless DC motors.

K. Emissions Analysis

The emissions analysis consists of two components. The first component estimates the effect of potential energy conservation standards on power sector and site (where applicable) combustion emissions of CO₂, NO_x, SO₂, and Hg. The second component estimates the impacts of potential standards on emissions of two additional greenhouse gases, CH₄ and N₂O, as well as the reductions to emissions of all species due to “upstream” activities in the fuel production chain. These upstream activities consist of extraction, processing, and transporting fuels to the site of combustion. The associated emissions are referred to as upstream emissions.

The analysis of power sector emissions uses marginal emissions factors that were derived from data in *AEO 2015*, as described in section IV.M.

Details of the methodology are described in the appendices to chapters 13 and 15 of the final rule TSD.

Combustion emissions of CH₄ and N₂O are estimated using emissions intensity factors published by the EPA-GHG Emissions Factors Hub.⁵² The FFC upstream emissions are estimated based on the methodology described in chapter 15 of the final rule TSD. The upstream emissions include both emissions from fuel combustion during extraction, processing, and transportation of fuel, and “fugitive” emissions (direct leakage to the atmosphere) of CH₄ and CO₂.

The emissions intensity factors are expressed in terms of physical units per MWh or MMBtu of site energy savings. Total emissions reductions are estimated using the energy savings calculated in the national impact analysis.

For CH₄ and N₂O, DOE calculated emissions reduction in tons and also in terms of units of carbon dioxide equivalent (CO₂eq). Gases are converted to CO₂eq by multiplying each ton of gas by the gas’ global warming potential (GWP) over a 100-year time horizon. Based on the Fifth Assessment Report of the Intergovernmental Panel on Climate Change,⁵³ DOE used GWP values of 28 for CH₄ and 265 for N₂O.

The AEO incorporates the projected impacts of existing air quality regulations on emissions. AEO 2015 generally represents current legislation and environmental regulations, including recent government actions, for which implementing regulations were available as of [October 31, 2014]. DOE’s estimation of impacts accounts for the presence of the emissions control programs discussed in the following paragraphs.

SO₂ emissions from affected electric generating units (EGUs) are subject to nationwide and regional emissions cap-and-trade programs. Title IV of the Clean Air Act sets an annual emissions cap on SO₂ for affected EGUs in the 48 contiguous States and the District of Columbia (D.C.). (42 U.S.C. 7651 *et seq.*) SO₂ emissions from 28 eastern States and D.C. were also limited under the

Clean Air Interstate Rule (CAIR). 70 FR 25162 (May 12, 2005). CAIR created an allowance-based trading program that operates along with the Title IV program. In 2008, CAIR was remanded to EPA by the U.S. Court of Appeals for the District of Columbia Circuit, but it remained in effect.⁵⁴ In 2011, EPA issued a replacement for CAIR, the Cross-State Air Pollution Rule (CSAPR). 76 FR 48208 (Aug. 8, 2011). On August 21, 2012, the D.C. Circuit issued a decision to vacate CSAPR,⁵⁵ and the court ordered EPA to continue administering CAIR. On April 29, 2014, the U.S. Supreme Court reversed the judgment of the D.C. Circuit and remanded the case for further proceedings consistent with the Supreme Court’s opinion.⁵⁶ On October 23, 2014, the D.C. Circuit lifted the stay of CSAPR.⁵⁷ Pursuant to this action, CSAPR went into effect (and CAIR ceased to be in effect) as of January 1, 2015.

EIA was not able to incorporate CSAPR into AEO 2015, so it assumes implementation of CAIR. Although DOE’s analysis used emissions factors that assume that CAIR, not CSAPR, is the regulation in force, the difference between CAIR and CSAPR is not significant for the purpose of DOE’s analysis of emissions impacts from energy conservation standards.

The attainment of emissions caps is typically flexible among EGUs and is enforced through the use of emissions allowances and tradable permits. Under existing EPA regulations, any excess SO₂ emissions allowances resulting from the lower electricity demand caused by the adoption of an efficiency standard could be used to permit offsetting increases in SO₂ emissions by any regulated EGU. In past rulemakings, DOE recognized that there was uncertainty about the effects of efficiency standards on SO₂ emissions covered by the existing cap-and-trade system, but it concluded that negligible reductions in power sector SO₂ emissions would occur as a result of standards.

Beginning in 2016, however, SO₂ emissions will fall as a result of the Mercury and Air Toxics Standards (MATS) for power plants. 77 FR 9304 (Feb. 16, 2012). In the MATS rule, EPA established a standard for hydrogen chloride as a surrogate for acid gas hazardous air pollutants (HAP), and also established a standard for SO₂ (a non-HAP acid gas) as an alternative equivalent surrogate standard for acid gas HAP. The same controls are used to reduce HAP and non-HAP acid gas; thus, SO₂ emissions will be reduced as a result of the control technologies installed on coal-fired power plants to comply with the MATS requirements for acid gas. AEO 2015 assumes that, in order to continue operating, coal plants must have either flue gas desulfurization or dry sorbent injection systems installed by 2016. Both technologies, which are used to reduce acid gas emissions, also reduce SO₂ emissions. Under the MATS, emissions will be far below the cap established by CAIR, so it is unlikely that excess SO₂ emissions allowances resulting from the lower electricity demand would be needed or used to permit offsetting increases in SO₂ emissions by any regulated EGU.⁵⁸ Therefore, DOE believes that energy conservation standards will generally reduce SO₂ emissions in 2016 and beyond.

CAIR established a cap on NO_x emissions in 28 eastern States and the District of Columbia.⁵⁹ Energy conservation standards are expected to have little effect on NO_x emissions in those States covered by CAIR because excess NO_x emissions allowances resulting from the lower electricity demand could be used to permit offsetting increases in NO_x emissions from other facilities. However, standards would be expected to reduce NO_x emissions in the States not affected by the caps, so DOE estimated NO_x emissions reductions from the standards

⁵⁸ DOE notes that the Supreme Court remanded EPA’s 2012 rule regarding national emission standards for hazardous air pollutants from certain electric utility steam generating units. See *Michigan v. EPA* (Case No. 14–46, 2015). DOE has tentatively determined that the remand of the MATS rule does not change the assumptions regarding the impact of energy efficiency standards on SO₂ emissions. Further, while the remand of the MATS rule may have an impact on the overall amount of mercury emitted by power plants, it does not change the impact of the energy efficiency standards on mercury emissions. DOE will continue to monitor developments related to this case and respond to them as appropriate.

⁵⁹ CSAPR also applies to NO_x and it supersedes the regulation of NO_x under CAIR. As stated previously, the current analysis assumes that CAIR, not CSAPR, is the regulation in force. The difference between CAIR and CSAPR with regard to DOE’s analysis of NO_x emissions is slight.

⁵² Available at www2.epa.gov/climateleadership/center-corporate-climate-leadership-ghg-emission-factors-hub.

⁵³ Intergovernmental Panel on Climate Change. Anthropogenic and Natural Radiative Forcing. In *Climate Change 2013: The Physical Science Basis. Contribution of Working Group I to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change*. Chapter 8. 2013. Stocker, T.F., D. Qin, G.-K. Plattner, M. Tignor, S.K. Allen, J. Boschung, A. Nauels, Y. Xia, V. Bex, and P.M. Midgley, Editors. Cambridge University Press: Cambridge, United Kingdom and New York, NY, USA.

⁵⁴ See *North Carolina v. EPA*, 550 F.3d 1176 (D.C. Cir. 2008); *North Carolina v. EPA*, 531 F.3d 896 (D.C. Cir. 2008).

⁵⁵ See *EME Homer City Generation, LP v. EPA*, 696 F.3d 7, 38 (D.C. Cir. 2012), cert. granted, 81 U.S.L.W. 3567, 81 U.S.L.W. 3696, 81 U.S.L.W. 3702 (U.S. June 24, 2013) (No. 12–1182).

⁵⁶ See *EPA v. EME Homer City Generation*, 134 S. Ct. 1584, 1610 (U.S. 2014). The Supreme Court held in part that EPA’s methodology for quantifying emissions that must be eliminated in certain States due to their impacts in other downwind States was based on a permissible, workable, and equitable interpretation of the Clean Air Act provision that provides statutory authority for CSAPR.

⁵⁷ See *Georgia v. EPA*, Order (D.C. Cir. filed October 23, 2014) (No. 11–1302).

considered in this final rule for these States.

The MATS limit mercury emissions from power plants, but they do not include emissions caps and, as such, DOE's energy conservation standards would likely reduce Hg emissions. DOE estimated mercury emissions reduction using emissions factors based on *AEO 2015*, which incorporates the MATS.

L. Monetizing Carbon Dioxide and Other Emissions Impacts

As part of the development of this rule, DOE considered the estimated monetary benefits from the reduced emissions of CO₂ and NO_x expected to result from each of the TSLs considered. To make this calculation analogous to the calculation of the NPV of consumer benefit, DOE considered the reduced emissions expected to result over the lifetime of products shipped in the forecast period for each TSL. This section summarizes the basis for the monetary values used for CO₂ and NO_x emissions and presents the values considered in this final rule.

For this final rule, DOE relied on a set of values for the social cost of carbon (SCC) that was developed by a Federal interagency process. The basis for these values is summarized in the next section, and a more detailed description of the methodologies used is provided as an appendix to chapter 14 of the final rule TSD.

1. Social Cost of Carbon

The SCC is an estimate of the monetized damages associated with an incremental increase in carbon emissions in a given year. It is intended to include (but is not limited to) climate-change-related changes in net agricultural productivity, human health, property damages from increased flood risk, and the value of ecosystem services. Estimates of the SCC are provided in dollars per metric ton of CO₂. A domestic SCC value is meant to reflect the value of damages in the United States resulting from a unit change in CO₂ emissions, while a global SCC value is meant to reflect the value of damages worldwide.

Under section 1(b)(6) of Executive Order 12866, "Regulatory Planning and Review," 58 FR 51735 (Oct. 4, 1993), agencies must, to the extent permitted by law, "assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs." The purpose of the SCC estimates presented here is to allow agencies to

incorporate the monetized social benefits of reducing CO₂ emissions into cost-benefit analyses of regulatory actions. The estimates are presented with an acknowledgement of the many uncertainties involved and with a clear understanding that they should be updated over time to reflect increasing knowledge of the science and economics of climate impacts.

As part of the interagency process that developed these SCC estimates, technical experts from numerous agencies met on a regular basis to consider public comments, explore the technical literature in relevant fields, and discuss key model inputs and assumptions. The main objective of this process was to develop a range of SCC values using a defensible set of input assumptions grounded in the existing scientific and economic literatures. In this way, key uncertainties and model differences transparently and consistently inform the range of SCC estimates used in the rulemaking process.

a. Monetizing Carbon Dioxide Emissions

When attempting to assess the incremental economic impacts of CO₂ emissions, the analyst faces a number of challenges. A report from the National Research Council⁶⁰ points out that any assessment will suffer from uncertainty, speculation, and lack of information about (1) future emissions of GHGs, (2) the effects of past and future emissions on the climate system, (3) the impact of changes in climate on the physical and biological environment, and (4) the translation of these environmental impacts into economic damages. As a result, any effort to quantify and monetize the harms associated with climate change will raise questions of science, economics, and ethics and should be viewed as provisional.

Despite the limits of both quantification and monetization, SCC estimates can be useful in estimating the social benefits of reducing CO₂ emissions. The agency can estimate the benefits from reduced (or costs from increased) emissions in any future year by multiplying the change in emissions in that year by the SCC values appropriate for that year. The NPV of the benefits can then be calculated by multiplying each of these future benefits by an appropriate discount factor and summing across all affected years.

It is important to emphasize that the interagency group is committed to

updating these estimates as the science and economic understanding of climate change and its impacts on society improves over time. In the meantime, the interagency group will continue to explore the issues raised by this analysis and consider public comments as part of the ongoing interagency process.

b. Development of Social Cost of Carbon Values

In 2009, an interagency process was initiated to offer a preliminary assessment of how best to quantify the benefits from reducing carbon dioxide emissions. To ensure consistency in how benefits are evaluated across Federal agencies, the Administration sought to develop a transparent and defensible method, specifically designed for the rulemaking process, to quantify avoided climate change damages from reduced CO₂ emissions. The interagency group did not undertake any original analysis. Instead, it combined SCC estimates from the existing literature to use as interim values until a more comprehensive analysis could be conducted. The outcome of the preliminary assessment by the interagency group was a set of five interim values: Global SCC estimates for 2007 (in 2006\$) of \$55, \$33, \$19, \$10, and \$5 per metric ton of CO₂. These interim values represented the first sustained interagency effort within the U.S. government to develop an SCC for use in regulatory analysis. The results of this preliminary effort were presented in several proposed and final rules.

c. Current Approach and Key Assumptions

After the release of the interim values, the interagency group reconvened on a regular basis to generate improved SCC estimates. Specially, the group considered public comments and further explored the technical literature in relevant fields. The interagency group relied on three integrated assessment models commonly used to estimate the SCC: The FUND, DICE, and PAGE models. These models are frequently cited in the peer-reviewed literature and were used in the last assessment of the Intergovernmental Panel on Climate Change (IPCC). Each model was given equal weight in the SCC values that were developed.

Each model takes a slightly different approach to model how changes in emissions result in changes in economic damages. A key objective of the interagency process was to enable a consistent exploration of the three models, while respecting the different approaches to quantifying damages

⁶⁰ National Research Council. *Hidden Costs of Energy: Unpriced Consequences of Energy Production and Use*. 2009. National Academies Press: Washington, DC.

taken by the key modelers in the field. An extensive review of the literature was conducted to select three sets of input parameters for these models: Climate sensitivity, socio-economic and emissions trajectories, and discount rates. A probability distribution for climate sensitivity was specified as an input into all three models. In addition, the interagency group used a range of scenarios for the socio-economic parameters and a range of values for the discount rate. All other model features were left unchanged, relying on the

model developers' best estimates and judgments.

In 2010, the interagency group selected four sets of SCC values for use in regulatory analyses. Three sets of values are based on the average SCC from the three integrated assessment models, at discount rates of 2.5, 3, and 5 percent. The fourth set, which represents the 95th percentile SCC estimate across all three models at a 3-percent discount rate, was included to represent higher-than-expected impacts from climate change further out in the

tails of the SCC distribution. The values grow in real terms over time.

Additionally, the interagency group determined that a range of values from 7 percent to 23 percent should be used to adjust the global SCC to calculate domestic effects,⁶¹ although preference is given to consideration of the global benefits of reducing CO₂ emissions. Table IV.6 presents the values in the 2010 interagency group report,⁶² which is reproduced in appendix 14A of the final rule TSD.

TABLE IV.6—ANNUAL SCC VALUES FROM 2010 INTERAGENCY REPORT, 2010–2050
[2007\$ per metric ton CO₂]

| Year | Discount rate | | | |
|------------|---------------|---------|---------|-----------------|
| | 5% | 3% | 2.5% | 3% |
| | Average | Average | Average | 95th percentile |
| 2010 | 4.7 | 21.4 | 35.1 | 64.9 |
| 2015 | 5.7 | 23.8 | 38.4 | 72.8 |
| 2020 | 6.8 | 26.3 | 41.7 | 80.7 |
| 2025 | 8.2 | 29.6 | 45.9 | 90.4 |
| 2030 | 9.7 | 32.8 | 50.0 | 100.0 |
| 2035 | 11.2 | 36.0 | 54.2 | 109.7 |
| 2040 | 12.7 | 39.2 | 58.4 | 119.3 |
| 2045 | 14.2 | 42.1 | 61.7 | 127.8 |
| 2050 | 15.7 | 44.9 | 65.0 | 136.2 |

The SCC values used for this document were generated using the most recent versions of the three integrated assessment models that have been published in the peer-reviewed literature, as described in the 2013 update from the interagency working group (revised July 2015).⁶³ Table IV.7

shows the updated sets of SCC estimates from the latest interagency update in 5-year increments from 2010 through 2050. The full set of annual SCC estimates from 2010 through 2050 is reported in appendix 14B of the final rule TSD. The central value that emerges is the average SCC across

models at the 3-percent discount rate. However, for purposes of capturing the uncertainties involved in regulatory impact analysis, the interagency group emphasizes the importance of including all four sets of SCC values.

TABLE IV.7—ANNUAL SCC VALUES FROM 2013 INTERAGENCY UPDATE (REVISED JULY 2015), 2010–2050
[2007\$ per metric ton CO₂]

| Year | Discount rate | | | |
|------------|---------------|---------|---------|-----------------|
| | 5% | 3% | 2.5% | 3% |
| | Average | Average | Average | 95th percentile |
| 2010 | 10 | 31 | 50 | 86 |
| 2015 | 11 | 36 | 56 | 105 |
| 2020 | 12 | 42 | 62 | 123 |
| 2025 | 14 | 46 | 68 | 138 |
| 2030 | 16 | 50 | 73 | 152 |
| 2035 | 18 | 55 | 78 | 168 |
| 2040 | 21 | 60 | 84 | 183 |
| 2045 | 23 | 64 | 89 | 197 |
| 2050 | 26 | 69 | 95 | 212 |

⁶¹ It is recognized that this calculation for domestic values is approximate, provisional, and highly speculative. There is no *a priori* reason why domestic benefits should be a constant fraction of net global damages over time.

⁶² United States Government-Interagency Working Group on Social Cost of Carbon. *Social*

Cost of Carbon for Regulatory Impact Analysis Under Executive Order 12866. February 2010. <https://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/Social-Cost-of-Carbon-for-RIA.pdf>.

⁶³ United States Government-Interagency Working Group on Social Cost of Carbon. *Technical*

Support Document: Technical Update of the Social Cost of Carbon for Regulatory Impact Analysis Under Executive Order 12866. May 2013. Revised July 2015. <https://www.whitehouse.gov/sites/default/files/omb/inforeg/scc-td-final-july-2015.pdf>.

It is important to recognize that a number of key uncertainties remain, and that current SCC estimates should be treated as provisional and revisable because they will evolve with improved scientific and economic understanding. The interagency group also recognizes that the existing models are imperfect and incomplete. The National Research Council report mentioned previously points out that there is tension between the goal of producing quantified estimates of the economic damages from an incremental ton of carbon and the limits of existing efforts to model these effects. There are a number of analytical challenges that are being addressed by the research community, including research programs housed in many of the Federal agencies participating in the interagency process to estimate the SCC. The interagency group intends to periodically review and reconsider those estimates to reflect increasing knowledge of the science and economics of climate impacts, as well as improvements in modeling.⁶⁴

In summary, in considering the potential global benefits resulting from reduced CO₂ emissions, DOE used the values from the 2013 interagency report (revised July 2015), adjusted to 2015\$ using the implicit price deflator for gross domestic product (GDP) from the Bureau of Economic Analysis. For each of the four sets of SCC cases specified, the values for emissions in 2015 were \$12.4, \$40.6, \$63.2, and \$118 per metric ton avoided (values expressed in 2015\$). DOE derived values after 2050 based on the trend in 2010–2050 in each of the four cases.

DOE multiplied the CO₂ emissions reduction estimated for each year by the SCC value for that year in each of the four cases. To calculate a present value of the stream of monetary values, DOE discounted the values in each of the four cases using the specific discount rate that had been used to obtain the SCC values in each case.

2. Social Cost of Other Air Pollutants

As noted previously, DOE has estimated how the considered energy conservation standards would reduce site NO_x emissions nationwide and

decrease power sector NO_x emissions in those 22 States not affected by the CAIR.

DOE estimated the monetized value of NO_x emissions reductions from electricity generation using benefit per ton estimates from the *Regulatory Impact Analysis for the Clean Power Plan Final Rule*, published in August 2015 by EPA's Office of Air Quality Planning and Standards.⁶⁵ The report includes high and low values for NO_x (as PM_{2.5}) for 2020, 2025, and 2030 using discount rates of 3 percent and 7 percent; these values are presented in appendix 14C of the final rule TSD. DOE primarily relied on the low estimates to be conservative.⁶⁶ DOE assigned values for 2021–2024 and 2026–2029 using, respectively, the values for 2020 and 2025. DOE assigned values after 2030 using the value for 2030. DOE developed values specific to the end-use category for ceiling fans using a method described in appendix 14C of the final rule TSD.

DOE multiplied the emissions reduction (in tons) in each year by the associated \$/ton values, and then discounted each series using discount rates of 3 percent and 7 percent as appropriate.

DOE is evaluating appropriate monetization of avoided SO₂ and Hg emissions in energy conservation standards rulemakings. DOE has not included monetization of those emissions in the current analysis.

M. Utility Impact Analysis

The utility impact analysis estimates several effects on the electric power generation industry that would result from the adoption of new or amended energy conservation standards. The utility impact analysis estimates the changes in installed electrical capacity

and generation that would result for each TSL. The analysis is based on published output from the NEMS associated with *AEO 2015*. NEMS produces the *AEO* Reference case, as well as a number of side cases that estimate the economy-wide impacts of changes to energy supply and demand. DOE uses published side cases to estimate the marginal impacts of reduced energy demand on the utility sector. These marginal factors are estimated based on the changes to electricity sector generation, installed capacity, fuel consumption and emissions in the *AEO* Reference case and various side cases. Details of the methodology are provided in the appendices to chapters 13 and 15 of the final rule TSD.

The output of this analysis is a set of time-dependent coefficients that capture the change in electricity generation, primary fuel consumption, installed capacity and power sector emissions due to a unit reduction in demand for a given end use. These coefficients are multiplied by the stream of electricity savings calculated in the NIA to provide estimates of selected utility impacts of new or amended energy conservation standards.

N. Employment Impact Analysis

DOE considers employment impacts in the domestic economy as one factor in selecting a standard. Employment impacts from new or amended energy conservation standards include both direct and indirect impacts. Direct employment impacts are any changes in the number of employees of manufacturers of the products subject to standards, their suppliers, and related service firms. The MIA addresses those impacts. Indirect employment impacts are changes in national employment that occur due to the shift in expenditures and capital investment caused by the purchase and operation of more-efficient appliances. Indirect employment impacts from standards consist of the net jobs created or eliminated in the national economy, other than in the manufacturing sector being regulated, caused by (1) reduced spending by end users on energy, (2) reduced spending on new energy supply by the utility industry, (3) increased consumer spending on new products to which the new standards apply, and (4) the effects of those three factors throughout the economy.

One method for assessing the possible effects on the demand for labor of such shifts in economic activity is to compare sector employment statistics developed by the Labor Department's Bureau of Labor Statistics (BLS). BLS regularly

⁶⁵ Available at www.epa.gov/cleanpowerplan/clean-power-plan-final-rule-regulatory-impact-analysis. See Tables 4A–3, 4A–4, and 4A–5 in the report. The U.S. Supreme Court has stayed the rule implementing the Clean Power Plan until the current litigation against it concludes. *Chamber of Commerce, et al. v. EPA, et al.*, Order in Pending Case, 577 U.S. ____ (2016). However, the benefit-per-ton estimates established in the Regulatory Impact Analysis for the Clean Power Plan are based on scientific studies that remain valid irrespective of the legal status of the Clean Power Plan.

⁶⁶ For the monetized NO_x benefits associated with PM_{2.5}, the related benefits are primarily based on an estimate of premature mortality derived from the ACS study (Krewski *et al.* 2009), which is the lower of the two EPA central tendencies. Using the lower value is more conservative when making the policy decision concerning whether a particular standard level is economically justified. [Include this explanation the first time/previous times where these two cites are referenced.] If the benefit-per-ton estimates were based on the Six Cities study (Lepule *et al.* 2012), the values would be nearly two-and-a-half times larger. (See chapter 14 of the final rule TSD for citations for the studies mentioned above.)

⁶⁴ In November 2013, OMB announced a new opportunity for public comment on the interagency technical support document underlying the revised SCC estimates. 78 FR 70586. In July 2015 OMB published a detailed summary and formal response to the many comments that were received: This is available at <https://www.whitehouse.gov/blog/2015/07/02/estimating-benefits-carbon-dioxide-emissions-reductions>. It also stated its intention to seek independent expert advice on opportunities to improve the estimates, including many of the approaches suggested by commenters.

publishes its estimates of the number of jobs per million dollars of economic activity in different sectors of the economy, as well as the jobs created elsewhere in the economy by this same economic activity. Data from BLS indicate that expenditures in the utility sector generally create fewer jobs (both directly and indirectly) than expenditures in other sectors of the economy.⁶⁷ There are many reasons for these differences, including wage differences and the fact that the utility sector is more capital-intensive and less labor-intensive than other sectors. Energy conservation standards have the effect of reducing consumer utility bills. Because reduced consumer expenditures for energy likely lead to increased expenditures in other sectors of the economy, the general effect of efficiency standards is to shift economic activity from a less labor-intensive sector (*i.e.*, the utility sector) to more labor-intensive sectors (*e.g.*, the retail and service sectors). Thus, the BLS data suggest that net national employment may increase due to shifts in economic activity resulting from energy conservation standards.

DOE estimated indirect national employment impacts for the standard levels considered in this final rule using an input/output model of the U.S. economy called Impact of Sector Energy Technologies version 3.1.1 (ImSET).⁶⁸ ImSET is a special-purpose version of the “U.S. Benchmark National Input-Output” (I-O) model, which was designed to estimate the national employment and income effects of energy-saving technologies. The ImSET software includes a computer-based I-O model having structural coefficients that characterize economic flows among 187 sectors most relevant to industrial, commercial, and residential building energy use.

DOE notes that ImSET is not a general equilibrium forecasting model, and

understands the uncertainties involved in projecting employment impacts, especially changes in the later years of the analysis. Because ImSET does not incorporate price changes, the employment effects predicted by ImSET may over-estimate actual job impacts over the long run for this rule. Therefore, DOE generated results for near-term timeframes (2020 and 2025), where these uncertainties are reduced. For more details on the employment impact analysis, see chapter 16 of the final rule TSD.

V. Analytical Results and Conclusions

The following section addresses the results from DOE’s analyses with respect to the considered energy conservation standards for ceiling fans. It addresses the TSLs examined by DOE, the projected impacts of each of these levels if adopted as energy conservation standards for ceiling fans, and the standards levels that DOE is adopting in this final rule. Additional details regarding DOE’s analyses are contained in the final rule TSD supporting this rulemaking.

A. Trial Standard Levels

In the NOPR analysis, DOE had six TSLs with TSL 6 corresponding to maximum technologically feasible (max tech) efficiency level, TSL 5 corresponding to maximum NPV (at a 7 percent discount rate), and TSL 4 corresponding to maximum NPV (at a 7 percent discount rate) with positive LCC savings. For the final rule, DOE now has five TSLs with TSL 5 corresponding to both max tech and maximum NPV, and TSL 4 corresponding to maximum NPV with an AC motor for all product classes other than HSSD fans, and maximum NPV for HSSD fans. The criteria for TSLs 1–3 remains unchanged.

The TSLs for the final rule were developed by combining specific efficiency levels for each of the product

classes analyzed by DOE. DOE presents the results for the TSLs in this document, while the results for all efficiency levels that DOE analyzed are in the final rule TSD.

Table V.1 presents the TSLs and the corresponding efficiency levels for ceiling fans. TSL 5 represents the max-tech energy efficiency for all product classes.

TSL 4 corresponds to maximum NPV with an AC motor for all product classes other than HSSD fans, and maximum NPV for HSSD fans. In addition, at this TSL, less than 50 percent of consumers experience a net cost, and large-diameter ceiling fans that provide high levels of airflow are not disproportionately impacted. Specifically, for large-diameter ceiling fans, while max-tech provides LCC savings and NPV that are both positive, max-tech has potential unintended consequence of disproportionately impacting large diameter fans that provide high levels of airflow. DOE does not have enough data to be certain that large-diameter ceiling fans at the current max CFM levels offered on the market at all diameters can meet the max-tech level, even when using brushless DC motors. Therefore, if large-diameter ceiling fans that provide the highest levels of airflow in today’s market cannot meet the max tech level even when using brushless DC motors, these fans could be unintentionally eliminated from the market, diminishing product availability and utility.

TSL 3 corresponds to the highest efficiency level that can be met with a standard (AC) motor for all product classes. TSL 2 corresponds to the fan-optimization design-option efficiency level. TSL 1 corresponds to the first non-baseline efficiency level (*i.e.*, EL 1).

TABLE V.1—TRIAL STANDARD LEVELS FOR CEILING FANS

| | VSD | Hugger | Standard | HSSD | Large-diameter |
|-------------|------|--------|----------|------|----------------|
| TSL 1 | EL 1 | EL 1 | EL 1 | EL 1 | EL 1 |
| TSL 2 | EL 1 | EL 2 | EL 2 | EL 1 | EL 1 |
| TSL 3 | EL 2 | EL 3 | EL 3 | EL 3 | EL 3 |
| TSL 4 | EL 2 | EL 3 | EL 3 | EL 4 | EL 3 |
| TSL 5 | EL 3 | EL 4 | EL 4 | EL 4 | EL 4 |

⁶⁷ See U.S. Department of Commerce—Bureau of Economic Analysis. *Regional Multipliers: A User Handbook for the Regional Input-Output Modeling System (RIMS II)*. 1997. U.S. Government Printing Office: Washington, DC. Available at <http://www.bea.gov/scb/pdf/regional/perinc/meth/rims2.pdf>.

⁶⁸ J.M. Roop, M.J. Scott, and R.W. Schultz. *ImSET 3.1: Impact of Sector Energy Technologies*. 2009.

Pacific Northwest National Laboratory: Richland, WA. PNNL-18412. Available at www.pnl.gov/main/publications/external/technical_reports/PNNL-18412.pdf.

B. Economic Justification and Energy Savings

1. Economic Impacts on Individual Consumers

DOE analyzed the economic impacts on ceiling fans consumers by looking at the effects potential amended standards at each TSL would have on the LCC and PBP. DOE also examined the impacts of potential standards on consumer subgroups. These analyses are discussed below.

a. Life-Cycle Cost and Payback Period

In general, higher-efficiency products affect consumers in two ways: (1) Purchase price increases and (2) annual

operating costs decrease. Inputs used for calculating the LCC and PBP include total installed costs (*i.e.*, product price plus installation costs), and operating costs (*i.e.*, annual energy use, energy prices, energy price trends, repair costs, and maintenance costs). The LCC calculation also uses product lifetime and a discount rate. Chapter 8 of the final rule TSD provides detailed information on the LCC and PBP analyses.

Table V.2 through Table V.11 show the LCC and PBP results for the TSL efficiency levels considered for each product class. In the first of each pair of tables, the simple payback is measured relative to the baseline product. In the

second table, the impacts are measured relative to the efficiency distribution in the in the no-new-standards case in the compliance year (see section IV.F.7 of this notice). Because some consumers purchase products with higher efficiency in the no-new-standards case, the average savings are less than the difference between the average LCC of EL 0 and the average LCC at each TSL. The savings refer only to consumers who are affected by a standard at a given TSL. Those who already purchase a product with efficiency at or above a given TSL are not affected. Consumers for whom the LCC increases at a given TSL experience a net cost.

TABLE V.2—AVERAGE LCC AND PBP RESULTS BY EFFICIENCY LEVEL FOR STANDARD FANS

| EL | Average costs (2015\$) | | | | Simple payback (years) | Average lifetime (years) |
|---------|------------------------|-----------------------------|-------------------------|--------|------------------------|--------------------------|
| | Installed cost | First year's operating cost | Lifetime operating cost | LCC | | |
| 0 | 113.49 | 16.99 | 190.29 | 303.79 | | 13.8 |
| 1 | 113.49 | 12.75 | 144.06 | 257.55 | 0.0 | 13.8 |
| 2 | 113.49 | 11.48 | 130.20 | 243.70 | 0.0 | 13.8 |
| 3 | 124.95 | 10.33 | 117.58 | 242.53 | 1.7 | 13.8 |
| 4 | 158.01 | 5.86 | 75.92 | 233.93 | 4.0 | 13.8 |

Note: The results for each EL represent the average result if all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

TABLE V.3—AVERAGE LCC SAVINGS RELATIVE TO THE NO-NEW-STANDARDS CASE EFFICIENCY DISTRIBUTION FOR STANDARD FANS

| EL | Life-cycle cost savings | |
|---------|---|-------------------------------|
| | Percent of consumers that experience net cost | Average LCC savings* (2015\$) |
| | | |
| 1 | 0.0 | 46.61 |
| 2 | 0.0 | 37.20 |
| 3 | 27.5 | 25.78 |
| 4 | 50.4 | 26.80 |

* The calculation excludes consumers with zero LCC savings (no impact).

TABLE V.4—AVERAGE LCC AND PBP RESULTS BY EFFICIENCY LEVEL FOR HUGGER FANS

| EL | Average costs (2015\$) | | | | Simple payback (years) | Average lifetime (years) |
|---------|------------------------|-----------------------------|-------------------------|--------|------------------------|--------------------------|
| | Installed cost | First year's operating cost | Lifetime operating cost | LCC | | |
| 0 | 100.39 | 15.05 | 168.74 | 269.13 | | 13.8 |
| 1 | 100.39 | 11.30 | 127.78 | 228.17 | 0.0 | 13.8 |
| 2 | 100.39 | 10.17 | 115.51 | 215.90 | 0.0 | 13.8 |
| 3 | 110.63 | 9.24 | 105.27 | 215.90 | 1.8 | 13.8 |
| 4 | 139.90 | 5.52 | 71.83 | 211.73 | 4.1 | 13.8 |

Note: The results for each EL represent the average result if all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

TABLE V.5—AVERAGE LCC SAVINGS RELATIVE TO THE NO-NEW-STANDARDS CASE EFFICIENCY DISTRIBUTION FOR HUGGER FANS

| EL | Life-cycle cost savings | |
|---------|---|--------------------------------|
| | Percent of consumers that experience net cost | Average LCC savings * (2015\$) |
| 1 | 0.0 | 39.02 |
| 2 | 0.0 | 31.75 |
| 3 | 27.8 | 21.50 |
| 4 | 51.4 | 19.20 |

* The calculation excludes consumers with zero LCC savings (no impact).

TABLE V.6—AVERAGE LCC AND PBP RESULTS BY EFFICIENCY LEVEL FOR VSD FANS

| EL | Average costs (2015\$) | | | | Simple payback (years) | Average lifetime (years) |
|---------|------------------------|-----------------------------|-------------------------|--------|------------------------|--------------------------|
| | Installed cost | First year's operating cost | Lifetime operating cost | LCC | | |
| 0 | 268.25 | 14.12 | 158.25 | 426.50 | | 13.8 |
| 1 | 268.25 | 12.72 | 142.90 | 411.15 | 0.0 | 13.8 |
| 2 | 289.30 | 11.87 | 133.65 | 422.95 | 9.3 | 13.8 |
| 3 | 352.51 | 7.82 | 96.53 | 449.04 | 13.4 | 13.8 |

Note: The results for each EL represent the average result if all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

TABLE V.7—AVERAGE LCC SAVINGS RELATIVE TO THE NO-NEW-STANDARDS CASE EFFICIENCY DISTRIBUTION FOR VSD FANS

| EL | Life-cycle cost savings | |
|---------|---|--------------------------------|
| | Percent of consumers that experience net cost | Average LCC savings * (2015\$) |
| 1 | 0.0 | 16.10 |
| 2 | 2.1 | 4.29 |
| 3 | 75.8 | −25.94 |

* The calculation excludes consumers with zero LCC savings (no impact).

TABLE V.8—AVERAGE LCC AND PBP RESULTS BY EFFICIENCY LEVEL FOR HSSD FANS

| EL | Average costs (2015\$) | | | | Simple payback (years) | Average lifetime (years) |
|---------|------------------------|-----------------------------|-------------------------|--------|------------------------|--------------------------|
| | Installed cost | First year's operating cost | Lifetime operating cost | LCC | | |
| 0 | 145.28 | 20.27 | 204.44 | 349.72 | | 13.8 |
| 1 | 145.28 | 18.24 | 184.24 | 329.52 | 0.0 | 13.8 |
| 2 | 169.20 | 17.05 | 172.35 | 341.55 | 7.4 | 13.8 |
| 3 | 177.92 | 16.92 | 177.65 | 355.56 | 9.8 | 13.8 |
| 4 | 227.81 | 8.38 | 92.49 | 320.30 | 6.9 | 13.8 |

Note: The results for each EL represent the average result if all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

TABLE V.9—AVERAGE LCC SAVINGS RELATIVE TO THE NO-NEW-STANDARDS CASE EFFICIENCY DISTRIBUTION FOR HSSD FANS

| EL | Life-cycle cost savings | |
|----|---|--------------------------------|
| | Percent of consumers that experience net cost | Average LCC savings * (2015\$) |
| 1 | 0.0 | 20.17 |
| 2 | 58.8 | – 1.90 |
| 3 | 70.0 | – 15.81 |
| 4 | 38.7 | 19.80 |

* The calculation excludes consumers with zero LCC savings (no impact).

TABLE V.10.—AVERAGE LCC AND PBP RESULTS BY EFFICIENCY LEVEL FOR LARGE-DIAMETER FANS

| EL | Average costs (2015\$) | | | | Simple payback (years) | Average lifetime (years) |
|----|------------------------|-----------------------------|-------------------------|---------|------------------------|--------------------------|
| | Installed cost | First year's operating cost | Lifetime operating cost | LCC | | |
| 0 | 4119.72 | 292.21 | 2921.38 | 7041.10 | | 13.8 |
| 1 | 4119.72 | 262.99 | 2632.90 | 6752.62 | 0.0 | 13.8 |
| 2 | 4261.44 | 239.08 | 2396.87 | 6658.31 | 2.7 | 13.8 |
| 3 | 4458.32 | 210.14 | 2110.93 | 6569.25 | 4.1 | 13.8 |
| 4 | 4706.71 | 156.42 | 1624.11 | 6330.82 | 4.3 | 13.8 |

Note: The results for each EL represent the average result if all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

TABLE V.11—AVERAGE LCC SAVINGS RELATIVE TO THE NO-NEW-STANDARDS CASE EFFICIENCY DISTRIBUTION FOR LARGE-DIAMETER FANS

| EL | Life-cycle cost savings | |
|----|---|--------------------------------|
| | Percent of consumers that experience net cost | Average LCC savings * (2015\$) |
| 1 | 0.0 | 291.52 |
| 2 | 1.0 | 247.21 |
| 3 | 23.3 | 128.90 |
| 4 | 16.2 | 347.93 |

* The calculation excludes consumers with zero LCC savings (no impact).

DOE conducted a sensitivity analysis to determine the potential impacts to consumers for a scenario in which manufacturers increase their selling price in order to pass through to consumers their conversion costs at TSL 1 and TSL 2. At TSL 1 and TSL 2, DOE estimates no incremental installed costs to consumers because the assumed design options (e.g., fan optimization) implemented at those levels would not result in incremental MPC or differences in installation costs based on manufacturer interviews. However, DOE estimates that manufacturers will incur conversion costs at TSL 1 and TSL 2 to make their products compliant. To provide a high estimate of the potential

cost impacts on consumers, DOE passed through these product conversion costs at TSL 1 and TSL 2 to the higher TSL levels and presents the results in appendix 8.E of the TSD. For this sensitivity, the LCC savings are positive and the PBPs are less than the lifetime of the products for each product class at the chosen TSL level.

b. Consumer Subgroup Analysis

In the consumer subgroup analysis, DOE estimated the impact of the considered TSLs on low-income households and small businesses. Table V.12 through

Table V.16 compare the average LCC savings and PBP at each efficiency level for the two consumer subgroups, along

with the average LCC savings for the entire sample for all the product classes. For standard, hugger, and VSD ceiling fans, the average LCC savings and PBP for low-income households at the considered efficiency levels are not substantially different from the averages for all households. For HSSD and large-diameter ceiling fans, the average savings and PBP for small businesses at the considered efficiency levels show moderate differences from the averages for all businesses, but the differences are not significant enough to recommend a different standard level be adopted. Chapter 11 of the final rule TSD presents the complete LCC and PBP results for the subgroups.

TABLE V.12—COMPARISON OF LCC SAVINGS AND PBP FOR LOW-INCOME HOUSEHOLDS AND ALL HOUSEHOLDS FOR STANDARD FANS

| EL | Average LCC savings * (2015\$) | | Simple payback period (years) | |
|---------|-----------------------------------|------------|----------------------------------|------------|
| | All | Low-income | All | Low-income |
| 1 | 46.61 | 42.26 | 0.0 | 0.0 |
| 2 | 37.20 | 34.65 | 0.0 | 0.0 |
| 3 | 25.78 | 23.73 | 1.7 | 1.7 |
| 4 | 26.80 | 24.99 | 4.0 | 4.0 |

* The calculation excludes consumers with zero LCC savings (no impact).

TABLE V.13—COMPARISON OF LCC SAVINGS AND PBP FOR LOW-INCOME HOUSEHOLDS AND ALL HOUSEHOLDS FOR HUGGER FANS

| EL | Average LCC savings * (2015\$) | | Simple payback period (years) | |
|---------|-----------------------------------|------------|----------------------------------|------------|
| | All | Low-income | All | Low-income |
| 1 | 39.02 | 40.04 | 0.0 | 0.0 |
| 2 | 31.75 | 33.22 | 0.0 | 0.0 |
| 3 | 21.50 | 22.49 | 1.8 | 1.8 |
| 4 | 19.20 | 19.56 | 4.1 | 4.2 |

* The calculation excludes consumers with zero LCC savings (no impact).

TABLE V.14—COMPARISON OF LCC SAVINGS AND PBP FOR LOW-INCOME HOUSEHOLDS AND ALL HOUSEHOLDS FOR VSD FANS

| EL | Average LCC savings * (2015\$) | | Simple payback period (years) | |
|---------|-----------------------------------|------------|----------------------------------|------------|
| | All | Low-income | All | Low-income |
| 1 | 16.10 | 16.90 | 0.0 | 0.0 |
| 2 | 4.29 | 5.99 | 9.3 | 9.5 |
| 3 | -25.94 | -27.10 | 13.4 | 13.6 |

* The calculation excludes consumers with zero LCC savings (no impact).

TABLE V.15—COMPARISON OF LCC SAVINGS AND PBP FOR SMALL BUSINESSES AND ALL BUILDINGS FOR HSSD FANS

| EL | Average LCC savings * (2015\$) | | Simple payback period (years) | |
|---------|-----------------------------------|------------------|----------------------------------|------------------|
| | All | Small businesses | All | Small businesses |
| 1 | 20.17 | 17.49 | 0.0 | 0.0 |
| 2 | -1.90 | -4.96 | 7.4 | 7.4 |
| 3 | -15.81 | -18.39 | 9.8 | 9.7 |
| 4 | 19.80 | 6.08 | 6.9 | 6.9 |

* The calculation excludes consumers with zero LCC savings (no impact).

TABLE V.16—COMPARISON OF LCC SAVINGS AND PBP FOR SMALL BUSINESSES AND ALL BUILDINGS FOR LARGE-DIAMETER FANS

| EL | Average LCC savings * (2015\$) | | Simple payback period (years) | |
|---------|-----------------------------------|------------------|----------------------------------|------------------|
| | All | Small businesses | All | Small businesses |
| 1 | 291.52 | 250.66 | 0.0 | 0.0 |
| 2 | 247.21 | 191.28 | 2.7 | 2.6 |
| 3 | 128.90 | 80.70 | 4.1 | 4.1 |
| 4 | 347.93 | 254.52 | 4.3 | 4.3 |

* The calculation excludes consumers with zero LCC savings (no impact).

c. Rebuttable Presumption Payback

As discussed in section IV.F.8, EPCA establishes a rebuttable presumption that an energy conservation standard is economically justified if the increased purchase cost for a product that meets the standard is less than three times the value of the first-year energy savings resulting from the standard. In calculating a rebuttable presumption payback period for each of the considered TSLs, DOE used discrete

values, and, as required by EPCA, based the energy use calculation on the DOE test procedures for ceiling fans. In contrast, the PBPs presented in section V.B.1.a were calculated using distributions that reflect the range of energy use in the field. Table V.17 presents the rebuttable-presumption payback periods for the considered TSLs for ceiling fans. While DOE examined the rebuttable-presumption criterion, it considered whether the standard levels considered

for this rule are economically justified through a more detailed analysis of the economic impacts of those levels, pursuant to 42 U.S.C. 6295(o)(2)(B)(i), that considers the full range of impacts to the consumer, manufacturer, Nation, and environment. The results of that analysis serve as the basis for DOE to evaluate the economic justification for a potential standard level, thereby supporting or rebutting the results of any preliminary determination of economic justification.

TABLE V.17—REBUTTABLE PRESUMPTION PAYBACK PERIOD RESULTS

| EL | Standard | Hugger | VSD | HSSD | Large-diameter |
|----|----------|--------|------|------|----------------|
| 1 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| 2 | 0.0 | 0.0 | 9.4 | 3.5 | 2.9 |
| 3 | 1.5 | 1.5 | 12.6 | 4.2 | 4.5 |
| 4 | 3.2 | 3.3 | | 3.2 | 4.7 |

2. Economic Impacts on Manufacturers

DOE performed an MIA to estimate the impact of amended energy conservation standards on manufacturers of ceiling fans. This section describes the expected impacts on manufacturers at each TSL. Chapter 12 of the final rule TSD explains the analysis in further detail.

a. Industry Cash Flow Analysis Results

Table V.18 through Table V.20 present the financial impacts, represented by changes in INPV, of amended standards on ceiling fan manufacturers as well as the conversion costs that DOE estimates ceiling fan manufacturers would incur at each TSL. To evaluate the range of cash-flow impacts on the ceiling fan industry, DOE modeled three manufacturer markup scenarios that correspond to the range of anticipated market responses to amended standards. Each scenario results in a unique set of cash flows and corresponding industry values at each TSL.

In the following discussion, the INPV results refer to the difference in industry value between the no-new-standards case and each TSL in the standards cases. INPV is calculated by summing the discounted cash flows from the reference year (2016) through the end of the analysis period (2049). INPV values vary by the manufacturer markup scenario modeled to produce them. DOE believes that these manufacturer markup scenarios are most likely to capture the range of impacts on ceiling fan manufacturers as a result of the amended energy conservation standards. The results also discuss the

difference in cash flows between the no-new-standards case and the standards cases in the year before the compliance date of amended standards. This difference in cash flow represents the size of the required conversion costs at each TSL relative to the cash flow generated by the ceiling fan industry in the absence of amended energy conservation standards.

To assess the upper (less severe) bound on the range of potential impacts on ceiling fan manufacturers, DOE modeled a preservation of gross margin, or flat, markup scenario. This scenario assumes that in the standards cases, manufacturers would be able to pass along the higher production costs required for more efficient products to their consumers. Specifically, the industry would be able to maintain its average no-new-standards case gross margin (as a percentage of revenue) despite the higher product costs in the standards cases. In general, the larger the product price increases, the less likely manufacturers are to achieve the cash flow from operations calculated in this manufacturer markup scenario because it is less likely that manufacturers would be able to fully mark up these larger cost increases.

To assess the lower (more severe) bound on the range of potential impacts on ceiling fan manufacturers, DOE modeled two additional manufacturer markup scenarios; a preservation of operating profit markup scenario and a two-tiered markup scenario. In the preservation of operating profit markup scenario manufacturers are not able to yield additional operating profit from higher production costs and the

investments that are required to comply with amended ceiling fan energy conservation standards, but instead are only able to maintain the same operating profit in the standards cases that was earned in the no-new-standards case. This scenario represents a potential lower bound on the range of impacts on manufacturers because manufacturers are only able to maintain the operating profit that they would have earned in the no-new-standards case despite higher production costs and investments. Manufacturers must therefore, reduce margins as a result of this manufacturer markup scenario, which reduces profitability.

DOE also modeled a two-tiered markup scenario as a potential lower (more severe) bound on the range of potential impacts on ceiling fan manufacturers. In this manufacturer markup scenario, manufacturers have two tiers of markups that are differentiated, in part, by efficiency level. The higher efficiency tiers typically earn premiums (for the manufacturer) over the baseline efficiency tier. Several manufacturers suggested that amended standards would lead to a reduction in premium markups and reduce the profitability of higher efficiency products. During the MIA interviews, manufacturers provided information on the range of typical efficiency levels in those tiers and the change in profitability at each level. DOE used this information to estimate markups for ceiling fans under a two-tiered pricing strategy in the no-new-standards case. In the standards cases, DOE modeled the situation in which standards result in less product

differentiation, compression of the markup tiers, and an overall reduction in profitability.

TABLE V.18—MANUFACTURER IMPACT ANALYSIS FOR CEILING FANS—PRESERVATION OF GROSS MARGIN MARKUP SCENARIO

| | Units | No-new-standards case | Trial standard levels | | | | |
|--------------------------------|-----------------------|-----------------------|-----------------------|---------|---------|---------|---------|
| | | | 1 | 2 | 3 | 4 | 5 |
| INPV | 2015\$ millions | 1,211.6 | 1,214.6 | 1,227.2 | 1,213.2 | 1,206.8 | 1,265.3 |
| Change in INPV | 2015\$ millions | | 3.0 | 15.6 | 1.6 | (4.8) | 53.8 |
| | % | | 0.2 | 1.3 | 0.1 | (0.4) | 4.4 |
| Product Conversion Costs | 2015\$ millions | | 5.1 | 9.4 | 31.7 | 33.2 | 46.5 |
| Capital Conversion Costs | 2015\$ millions | | 7.1 | 13.1 | 63.0 | 66.7 | 109.5 |
| Total Conversion Costs | 2015\$ millions | | 12.3 | 22.5 | 94.7 | 99.9 | 155.9 |

TABLE V.19—MANUFACTURER IMPACT ANALYSIS FOR CEILING FANS—PRESERVATION OF OPERATING PROFIT MARKUP SCENARIO

| | Units | No-new-standards case | Trial standard levels | | | | |
|--------------------------------|-----------------------|-----------------------|-----------------------|---------|---------|---------|---------|
| | | | 1 | 2 | 3 | 4 | 5 |
| INPV | 2015\$ millions | 1,211.6 | 1,200.8 | 1,188.6 | 1,107.9 | 1,092.1 | 926.7 |
| Change in INPV | 2015\$ millions | | (10.7) | (23.0) | (103.7) | (119.4) | (284.8) |
| | % | | (0.9) | (1.9) | (8.6) | (9.9) | (23.5) |
| Product Conversion Costs | 2015\$ millions | | 5.1 | 9.4 | 31.7 | 33.2 | 46.5 |
| Capital Conversion Costs | 2015\$ millions | | 7.1 | 13.1 | 63.0 | 66.7 | 109.5 |
| Total Conversion Costs | 2015\$ millions | | 12.3 | 22.5 | 94.7 | 99.9 | 155.9 |

TABLE V.20—MANUFACTURER IMPACT ANALYSIS FOR CEILING FANS—TWO-TIERED MARKUP SCENARIO

| | Units | No-new-standards case | Trial standard levels | | | | |
|--------------------------------|-----------------------|-----------------------|-----------------------|---------|---------|---------|---------|
| | | | 1 | 2 | 3 | 4 | 5 |
| INPV | 2015\$ millions | 1,211.6 | 1,232.8 | 1,275.8 | 1,123.8 | 1,116.6 | 1,164.2 |
| Change in INPV | 2015\$ millions | | 21.2 | 64.3 | (87.7) | (95.0) | (47.3) |
| | % | | 1.8 | 5.3 | (7.2) | (7.8) | (3.9) |
| Product Conversion Costs | 2015\$ millions | | 5.1 | 9.4 | 31.7 | 33.2 | 46.5 |
| Capital Conversion Costs | 2015\$ millions | | 7.1 | 13.1 | 63.0 | 66.7 | 109.5 |
| Total Conversion Costs | 2015\$ millions | | 12.3 | 22.5 | 94.7 | 99.9 | 155.9 |

TSL 1 sets the efficiency level at EL 1 for all ceiling fans. At TSL 1, DOE estimates that impacts on INPV range from –\$10.7 million to \$21.2 million, or changes in INPV of –0.9 percent to 1.8 percent. At TSL 1, industry free cash flow (operating cash flow minus capital expenditures) is expected to decrease by approximately 6.3 percent to \$69.9 million, compared to the no-new-standards case value of \$74.6 million in 2019, the year leading up to the standards.

Percentage impacts on INPV are slightly negative to slightly positive at TSL 1. DOE estimates that 77 percent of standard and hugger ceiling fan shipments, 96 percent of VSD ceiling fan shipments, 55 percent of HSSD ceiling fan shipments, and 95 percent of large-diameter ceiling fan shipments would meet or exceed the efficiency levels required at TSL 1.

DOE expects conversion costs to be small at TSL 1 because most of the

ceiling fan shipments, on a total volume basis, already meet or exceed the efficiency levels required at TSL 1. DOE estimates that ceiling fan manufacturers will incur a total of \$12.3 million in conversion costs at TSL 1 based on estimates for product conversion costs and capital conversion costs. DOE estimates that ceiling fan manufacturers will incur \$5.1 million in product conversion costs as they must develop and redesign any ceiling fan models that do not meet the efficiency levels required at TSL 1. DOE estimates that manufacturers will incur \$7.1 million in capital conversion costs at TSL 1, as ceiling fan manufacturers most likely will need to purchase new tooling for any redesigned models.

At TSL 1, the shipment-weighted average MPC for all ceiling fans increases by approximately 1.5 percent relative to the no-new-standards case shipment-weighted average MPC for all ceiling fans in 2020, the year of

compliance for amended ceiling fan energy conservation standards. In the preservation of gross margin markup scenario, manufacturers are able to fully pass on this slight cost increase to consumers. The slight increase in the shipment-weighted average MPC for all ceiling fans outweighs the \$12.3 million in conversion costs, causing a slightly positive change in INPV at TSL 1 under the preservation of gross margin markup scenario.

Under the preservation of operating profit markup scenario, manufacturers earn the same operating profit as would be earned in the no-new-standards case, but manufacturers do not earn additional profit from their investments. The average manufacturer markup for both the preservation of operating profit and two-tiered markup scenarios is calculated by averaging the ceiling fan industry manufacturer markup, for all ceiling fan product classes in aggregate, from the year of compliance (2020) until

the terminal year (2049). In this scenario, the 1.5 percent increase in the shipment-weighted average MPC for all ceiling fans results in a slight reduction in average manufacturer markup, from 1.370 in the no-new-standards case to 1.368 at TSL1. The slight reduction in average manufacturer markup and \$12.3 million in conversion costs causes a slightly negative change in INPV at TSL 1 under the preservation of operating profit markup scenario.

Under the two-tiered markup scenario, where manufacturers earn different markups for more efficient products, the average manufacturer markup increases from 1.370 in the no-new-standards case to 1.373 at TSL 1 as more shipments are purchased at the higher markup efficiency tiers. The increase in the average manufacturer markup and the increase in the shipment-weighted average MPC for all ceiling fans outweigh the \$12.3 million in conversion costs, causing a slightly positive change in INPV at TSL 1 under the two-tiered markup scenario.

TSL 2 sets the efficiency level at EL 1 for VSD, HSSD, and large-diameter ceiling fans and EL 2 for standard and hugger ceiling fans. At TSL 2, DOE estimates that impacts on INPV range from –\$23.0 million to \$64.3 million, or changes in INPV of –1.9 percent to 5.3 percent. At this TSL, industry free cash flow is estimated to decrease by approximately 11.5 percent to \$66.0 million, compared to the no-new-standards case value of \$74.6 million in 2019.

Percentage impacts on INPV range from slightly negative to slightly positive at TSL 2. DOE projects that in 2020, 55 percent of standard and hugger ceiling fan shipments, 96 percent of VSD ceiling fan shipments, 55 percent of HSSD ceiling fan shipments, and 95 percent of large-diameter ceiling fan shipments would meet or exceed the efficiency levels required at TSL 2.

DOE expects conversion costs to be moderate at TSL 2 because most of the ceiling fan shipments, on a total volume basis, currently meet or exceed the efficiency levels analyzed at TSL 2. DOE estimates that manufacturers will incur a total of \$22.5 million in conversion costs at TSL 2. DOE estimates that manufacturers will incur \$9.4 million in product conversion costs at TSL 2 as manufacturers must develop and redesign any ceiling fan models that do not meet the efficiency levels required at TSL 2. Capital conversion costs are estimated to be \$13.1 million at TSL 2. Capital conversion costs at TSL 2 are driven by investments in tooling needed to further optimize standard and hugger

ceiling fans to meet the efficiency levels required at TSL 2.

At TSL 2, the shipment-weighted average MPC for all ceiling fans increases by approximately 4.2 percent relative to the no-new-standards case shipment-weighted average MPC for all ceiling fans in 2020. In the preservation of gross margin markup scenario, manufacturers are able to recover their \$22.5 million in conversion costs over the course of the analysis period through the increase in the shipment-weighted MPC for all ceiling fans, causing a slightly positive change in INPV at TSL 2 under the preservation of gross margin markup scenario.

Under the preservation of operating profit markup scenario, the 4.2 percent increase in the shipment-weighted average MPC for all ceiling fans results in a slight reduction in the average manufacturer markup, from 1.370 in the no-new-standards case to 1.365 at TSL 2. The slight reduction in the average manufacturer markup and \$22.5 million in conversion costs cause a slightly negative change in INPV at TSL 2 under the preservation of operating profit markup scenario.

Under the two-tiered markup scenario, the average manufacturer markup increases from 1.370 in the no-new-standards case to 1.377 at TSL 2 as more shipments are purchased at the higher markup efficiency tiers. The increase in the average manufacturer markup and the increase in the shipment-weighted average MPC for all ceiling fans outweigh the \$22.5 million in conversion costs, causing a slightly positive change in INPV at TSL 2 under the two-tiered markup scenario.

TSL 3 sets the efficiency level at EL 2 for VSD ceiling fans and EL 3 for standard, hugger, HSSD, and large-diameter ceiling fans. At TSL 3, DOE estimates that impacts on INPV range from –\$103.7 million to \$1.6 million, or changes in INPV of –8.6 percent to 0.1 percent. At this level, industry free cash flow is estimated to decrease by approximately 50.1 percent to \$37.2 million, compared to the no-new-standards case value of \$74.6 million in 2019.

Percentage impacts on INPV range from moderately negative to slightly positive at TSL 3. DOE projects that in 2020, 32 percent of standard and hugger ceiling fan shipments, 96 percent of VSD ceiling fan shipments, 11 percent of HSSD ceiling fan shipments, and 31 percent of large-diameter ceiling fan shipments would meet or exceed the efficiency levels analyzed at TSL 3.

DOE expects higher conversion costs at TSL 3 than at lower TSLs because manufacturers will be required to

redesign and retest a significant portion of their ceiling fan models that do not meet the efficiency levels required at this TSL. DOE estimates that manufacturers will incur \$31.7 million in product conversion costs at TSL 3 as manufacturers must research, develop, and redesign numerous ceiling fan models to meet the efficiency levels required at TSL 3. Capital conversion costs are estimated to be \$63.0 million at TSL 3. Capital conversion costs at TSL 3 are driven by retooling costs associated with producing redesigned standard, hugger, and VSD ceiling fans with larger direct drive motors; HSSD ceiling fans with air foil blades; and large-diameter ceiling fans with premium AC motors and airfoil blades.

At TSL 3, the shipment-weighted average MPC increases by approximately 11.5 percent for all ceiling fans relative to the no-new-standards case MPC in 2020. In the preservation of gross margin markup scenario, manufacturers are able to recover their \$94.7 million in conversion costs through the moderate increase in MPC over the course of the analysis period causing a slightly positive change in INPV at TSL 3 under the preservation of gross margin markup scenario.

Under the preservation of operating profit markup, the 11.5 percent MPC increase for all ceiling fans results in a reduction in manufacturer markup after the compliance year, from 1.370 in the no-new-standards case to 1.356 at TSL 3. This reduction in manufacturer markup and \$94.7 million in conversion costs incurred by manufacturers cause a moderately negative change in INPV at TSL 3 under the preservation of operating profit scenario.

Under the two-tiered markup scenario, the average manufacturer markup decreases from 1.370 in the no-new-standards case to 1.359 at TSL 3. At TSL 3 under the two-tiered markup scenario, manufacturers reduce their markups on their more efficient shipments, as these premium products are no longer able to earn higher markups as they become the baseline due to standards. The decrease in the average manufacturer markup and the \$94.7 million in conversion costs incurred by manufacturers outweighs the moderate increase in the shipment-weighted average MPC for all ceiling fans, causing a moderately negative change in INPV at TSL 3 under the two-tiered markup scenario.

TSL 4 sets the efficiency level at EL 2 for VSD ceiling fans; EL 3 for standard, hugger, and large-diameter ceiling fans; and EL 4 for HSSD ceiling fans. At TSL 4, DOE estimates impacts

on INPV range from –\$119.4 million to –\$4.8 million, or decreases in INPV of –9.9 percent to –0.4 percent. At this level, industry free cash flow is estimated to decrease by approximately 52.9 percent to \$35.1 million, compared to the no-new-standards case value of \$74.6 million in 2019.

Percentage impacts on INPV range from moderately negative to slightly negative at TSL 4. DOE projects that in 2020, 32 percent of standard and hugger ceiling fan shipments, 96 percent of VSD ceiling fan shipments, 8 percent of HSSD ceiling fan shipments, and 31 percent of large-diameter ceiling fan shipments would meet or exceed efficiency levels analyzed at TSL 4.

For TSL 4, DOE concluded that manufacturers would likely use DC motors in the HSSD ceiling fan product class. DOE estimates that manufacturers will incur a total of \$99.9 million in conversion costs at TSL 4. DOE estimates that manufacturers will incur \$33.2 million in product conversion costs at TSL 4 as manufacturers must research, develop, and redesign numerous ceiling fan models to meet the efficiency levels required at TSL 4. Capital conversion costs are estimated to be \$66.7 million at TSL 4. Capital conversion costs at TSL 4 are driven by retooling costs associated with producing redesigned standard, hugger, and VSD ceiling fans with larger direct drive motors; HSSD ceiling fans with DC motors and airfoil blades; and large-diameter ceiling fans with premium AC motors and airfoil blades.

At TSL 4, the shipment-weighted average MPC for all ceiling fans increases by approximately 12.8 percent relative to the no-new-standards case shipment-weighted average MPC for all ceiling fans in 2020. In the preservation of gross margin markup scenario, manufacturers are not able to recover their \$99.9 million in conversion costs over the course of the analysis period through the moderate increase in the shipment-weighted average MPC for all ceiling fans, causing a slightly negative change in INPV at TSL 4 under the preservation of gross margin markup scenario.

Under the preservation of operating profit markup scenario, the 12.8 percent increase in the shipment-weighted average MPC for all ceiling fans results in a reduction of the average manufacturer markup, from 1.370 in the no-new-standards case to 1.355 at TSL 4. The reduction of the average manufacturer markup and \$99.9 million in conversion costs cause a moderately negative change in INPV at TSL 4 under the preservation of operating profit scenario.

Under the two-tiered markup scenario, the increase in the shipment-weighted average MPC for all ceiling fans results in a reduction of the average manufacturer markup, from 1.370 in the no-new-standards case to 1.359 at TSL 4. At TSL 4 under the two-tiered markup scenario, manufacturers reduce their markups on their more efficient shipments, as these premium products are no longer able to earn higher markups as they become the baseline due to standards. The decrease in the average manufacturer markup and the \$99.9 million in conversion costs outweigh the increase in the shipment-weighted average MPC for all ceiling fans, causing a moderately negative change in INPV at TSL 4 under the two-tiered markup scenario.

TSL 5 represents max-tech for all ceiling fan product classes. This TSL sets the efficiency level at EL 3 for VSD ceiling fans and EL 4 for standard, hugger, HSSD, and large-diameter ceiling fans. At TSL 5, DOE estimates that impacts on INPV range from –\$284.8 million to \$53.8 million, or changes in INPV of –23.5 percent to 4.4 percent. At this level, industry free cash flow is estimated to decrease by approximately 83.4 percent to \$12.4 million, compared to the no-new-standards case value of \$74.6 million in 2019.

Percentage impacts on INPV range from significantly negative to slightly positive at TSL 5. DOE projects that in 2020, 3 percent of standard ceiling fan shipments, 4 percent of hugger ceiling fan shipments, no VSD ceiling fan shipments, 8 percent of HSSD ceiling fan shipments, and 17 percent of large-diameter ceiling fan shipments would meet the efficiency levels analyzed at TSL 5.

DOE estimates that manufacturers will incur a total of \$155.9 million in conversion costs at TSL 5. DOE estimates that manufacturer will incur \$46.5 million in product conversion costs at TSL 5 as manufacturers must research, develop, and redesign the vast majority of their ceiling fan models to meet the efficiency levels required at TSL 5. Capital conversion costs are estimated to be \$109.5 million at TSL 5, driven by retooling costs associated with producing redesigned, max-tech standard, hugger, and VSD ceiling fans with DC motors; and HSSD and large-diameter ceiling fans with DC motors and airfoil blades.

At TSL 5, the shipment-weighted average MPC for all ceiling fans significantly increases by approximately 45.1 percent relative to the no-new-standards case shipment-weighted average MPC for all ceiling fans in 2020.

In the preservation of gross margin markup scenario, manufacturers are able to recover their \$155.9 million in conversion costs over the course of the analysis period through the significant increase in the shipment-weighted average MPC for all ceiling fans, causing a positive change in INPV at TSL 5 under the preservation of gross margin markup scenario.

Under the preservation of operating profit markup scenario, the 45.1 percent increase in the shipment-weighted MPC for all ceiling fans results in a reduction of the average manufacturer markup, from 1.370 in the no-new-standards case to 1.332 at TSL 5. The reduction of the average manufacturer markup and \$155.9 million in conversion costs cause a significantly negative change in INPV at TSL 5 under the preservation of operating profit markup scenario.

Under the two-tiered markup scenario, the 45.1 percent increase in the shipment-weighted average MPC for all ceiling fans results in a reduction of the average manufacturer markup, from 1.370 in the no-new-standards case to 1.359 at TSL 5. At TSL 5 under the two-tiered markup scenario, manufacturers reduce their markups on their more efficient shipments, as these premium products are no longer able to earn higher markups as they become the baseline due to standards. The decrease in the average manufacturer markup and \$155.9 million in conversion costs outweigh the increase in the shipment-weighted average MPC for all ceiling fans, causing a slightly negative change in INPV at TSL 5 under the two-tiered markup scenario.

b. Impacts on Employment

DOE quantitatively assessed the impacts of amended energy conservation standards on direct employment in the ceiling fan industry. DOE used the GRIM to estimate the domestic labor expenditures and number of domestic production workers in the no-new-standards case and at each TSL from 2016 to 2049. DOE used statistical data from the U.S. Census Bureau's 2014 Annual Survey of Manufacturers, the results of the engineering analysis, and interviews with manufacturers to determine the inputs necessary to calculate industry-wide labor expenditures and domestic employment levels. Labor expenditures involved with the manufacturing of the product are a function of the labor intensity of the product, the sales volume, and an assumption that wages remain fixed in real terms over time.

In the GRIM, DOE used the labor content of ceiling fans and the MPCs to estimate the annual labor expenditures

in the industry. DOE used Census data and interviews with manufacturers to estimate the portion of the total labor expenditures that is attributable to domestic labor.

The production worker estimates in this section only cover workers up to the line-supervisor level directly involved in fabricating and assembling a product within a manufacturing facility. Workers performing services that are closely associated with production operations, such as material handing with a forklift, are also included as production labor. DOE's estimates account for production workers who manufacture only the specific products covered by this rulemaking.

Table V.21 represents the potential impacts the amended standards could

have on domestic production employment. The upper bound of the results estimates the maximum change in the number of production workers that could occur after compliance with amended energy conservation standards when assuming that manufacturers continue to produce the same scope of covered products in the same production facilities. It also assumes that domestic production does not shift to lower labor-cost countries. Because there is a real risk of manufacturers evaluating sourcing and production facility location decisions in response to amended energy conservation standards, the lower bound of the employment results estimate the maximum decrease in domestic production workers in the industry if some or all existing production was

moved outside of the United States. While the results present a range of estimates, the following sections also include qualitative discussions of the employment impacts at the various TSLs. Finally, the domestic production employment impacts shown are independent of the employment impacts from the broader U.S. economy, documented in chapter 17 of the final rule TSD.

DOE estimates that in the absence of amended energy conservation standards, there would be approximately 33 domestic production workers involved in manufacturing ceiling fans in 2020. Table V.21 presents the range of potential impacts of amended energy conservation standards on U.S. production workers in the ceiling fan industry.

TABLE V.21—POTENTIAL CHANGES IN THE TOTAL NUMBER OF DOMESTIC CEILING FAN PRODUCTION WORKERS IN 2020

| | No-new-standards case | Trial standard level | | | | |
|---|-----------------------|----------------------|--------|----------|----------|----------|
| | | 1 | 2 | 3 | 4 | 5 |
| Total Number of Domestic Production Workers in 2020 (without changes in production locations) | 33 | 33 | 33 | 32 | 32 | 28 |
| Potential Changes in Domestic Production Workers in 2020 * | | 0–(33) | 0–(33) | (1)–(33) | (1)–(33) | (5)–(33) |

* DOE presents a range of potential employment impacts. Numbers in parentheses indicate negative numbers.

At the upper end of the employment impact range, DOE expects there to be slight or no negative impacts on domestic production employment at each of the TSLs. Slight negative impacts on domestic production employment at higher TSLs are driven by the reduction in total ceiling fan shipments. DOE included price elasticity as part of the shipments analysis, so as the average price of ceiling fans increases due to amended standards, fewer ceiling fans would be sold. Therefore, the amount of labor associated with these fewer shipments also decreases. It is important to note that while the average total MPC increases for more efficient ceiling fans, the increase in MPC is almost entirely attributed to the increase in the material costs used to produce more efficient fans. The amount of labor associated with producing more efficient ceiling fans remains virtually the same even as the total MPC of a ceiling fan increases at higher efficiency levels.

At the lower end of the range, DOE models a situation where all domestic employment associated with ceiling fan production moves abroad as a result of energy conservation standards. The majority of manufacturers that have domestic production produce large-diameter ceiling fans. Moving production of large-diameter fans

abroad would result in significantly high shipping costs. Based on the prohibitive shipping costs and manufacturer feedback, DOE does not expect the impacts on domestic production employment to approach the lower bound at any TSL.

At TSL 4, the TSL adopted in today's final rule, DOE concludes that, based on the shipment analysis, manufacturer interviews, and the results of the direct domestic employment analysis, manufacturers could face a slight negative impact on domestic production employment due to a slight reduction in overall ceiling fan shipments in 2020.

c. Impacts on Manufacturing Capacity

Ceiling fan manufacturers stated that they anticipate manufacturing capacity constraints if all ceiling fans are required to use DC motors to comply with the amended energy conservation standards. DOE learned during interviews that manufacturers primarily source motors for ceiling fans from either ceiling fan original equipment manufacturers or directly from motor manufacturers and then insert them into their ceiling fan models. During interviews, manufacturers stated that demand for DC motors may outpace supply if DC motors are required for all ceiling fans to comply with amended standards. Manufacturers expressed

concern during interviews that currently only a few ceiling fan shipments incorporate DC motors, and there would be major sourcing concerns if all ceiling fan were required to use DC motors.

Manufacturers would most likely meet the standard required at TSL 4 for the HSSD ceiling fans by using DC motors, HSSD ceiling fans only account for less than 3 percent of all ceiling fan shipments. Therefore, DOE does not anticipate a manufacturer capacity constraint on the supply of DC motors for this small portion of the overall ceiling fan market. DOE expects that the motor manufacturers that supply ceiling fan manufacturers with DC motors would be able to increase production of DC motors in the 3 years from the publication of the final rule to the compliance date of the final rule to meet demand for ceiling fans that require DC motors due to amended standards. DOE does not anticipate any significant impact on the manufacturing capacity as a result of the adopted amended energy conservation standards in this final rule. See section V.C.1 for more details on the standard adopted in this rulemaking.

d. Impacts on Subgroups of Manufacturers

Using average cost assumptions to develop an industry cash-flow estimate may not be adequate for assessing

differential impacts among manufacturer subgroups. Small manufacturers, niche product manufacturers, and manufacturers exhibiting cost structures substantially different from the industry average could be affected disproportionately. DOE identified only one manufacturer subgroup that required a separate analysis in the MIA; small businesses. DOE analyzes the impacts on small businesses in a separate analysis in section VI.B. DOE did not identify any other adversely impacted manufacturer subgroups for ceiling fans for this rulemaking based on the results of the industry characterization.

e. Cumulative Regulatory Burden

While any one regulation may not impose a significant burden on manufacturers, the combined effects of recent or impending regulations may have serious consequences for some manufacturers, groups of manufacturers, or an entire industry. Assessing the impact of a single regulation may overlook this cumulative regulatory burden. Multiple regulations affecting the same manufacturer can strain profits and lead companies to abandon product lines or markets with lower expected future returns than competing products. For these reasons, DOE conducts a cumulative regulatory burden analysis as part of its rulemaking for ceiling fans.

DOE identified a number of requirements, in addition to amended

energy conservation standards for ceiling fans, that ceiling fan manufacturers will face for products they manufacture approximately three years leading up to and three years following the compliance date of these amended standards. The following section addresses key related concerns that manufacturers raised during interviews regarding cumulative regulatory burden.

Manufacturers raised concerns about existing regulations and certifications separate from DOE's energy conservation standards that ceiling fan manufacturers must meet. These include California Title 20, which has the same energy conservation standards to DOE's existing ceiling fan standards, but requires an additional certification, and California Air Resources Board Standards limiting the amount of formaldehyde in composite wood used to make fan blades, among others.

DOE discusses these and other requirements in chapter 12 of the final rule TSD, which lists the estimated compliance costs of those requirements when available. In considering the cumulative regulatory burden, DOE evaluates the timing of regulations that affect the same product, because the coincident requirements could strain financial resources in the same profit center and consequently affect capacity. DOE also identified the ceiling fan light kit standards rulemaking as a source of

additional cumulative regulatory burden on ceiling fan manufacturers.

DOE has published a final rule pertaining to energy conservation standards for ceiling fan light kits. 81 FR 581 The ceiling fan light kit standard affects the majority of ceiling fan manufacturers and will require manufacturers impacted by both standards to make investments to bring both ceiling fan light kits and ceiling fans into compliance during the same time period. Additionally, redesigned ceiling fan light kits could potentially require adjustments to ceiling fan redesigns that are separate from those potentially required by the amended ceiling fan rule.

In addition to the amended energy conservation standards on ceiling fans, several other existing and pending Federal regulations may apply to other products produced by ceiling fan manufacturers. DOE acknowledges that each regulation can affect a manufacturer's financial operations. Multiple regulations affecting the same manufacturer can strain manufacturers' profit and possibly cause them to exit particular markets. Table V.22 presents other DOE energy conservation standards that could also affect ceiling fan manufacturers in the three years leading up to and after the compliance date of amended energy conservation standards for these products.

TABLE V.22—OTHER DOE REGULATIONS POTENTIALLY AFFECTING CEILING FAN MANUFACTURERS

| Regulation | Number of manufacturers * | Approximate compliance date | Estimated industry total conversion expenses | Annual industry revenue | Number of manufacturers from today's rule affected ** |
|---|---------------------------|-----------------------------|--|--------------------------------|---|
| Electric Motors, 79 FR 30933 (May 29, 2014) | 7 | 2016 | \$84.6 million (2013\$) | \$3,880 million (2013\$) | 1 |
| General Service Fluorescent Lamps, 80 FR 4042 (January 26, 2015). | 47 | 2018 | \$26.6 million (2013\$) | \$2,820 million (2013\$) | 1 |
| Ceiling Fan Light Kits, 81 FR 580 (January 6, 2016) | 67 | 2019 | \$18.9 million (2014\$) | \$310 million (2014\$) | 53 |
| Commercial Industrial Fans and Blowers † | † 242 | † 2019 | TBD † | TBD † | † 8 |
| General Service Lamps, 81 FR 14528 (NOPR) March 17, 2016 †. | † 142 | † 2020 | \$509.0 million (2014\$) † | 1,903 million (2014\$) † | † 1 |

* The number of manufacturers listed in the final rule for the energy conservation standard that is contributing to cumulative regulatory burden

** The number of manufacturers producing ceiling fans that are affected by the listed energy conservation standards

† The final rule for this energy conservation standard has not been published.

DOE did not receive any data on other regulatory costs that affect the industry modeled in the cash-flow analysis.

3. National Impact Analysis

a. Significance of Energy Savings

To estimate the energy savings attributable to potential standards for

ceiling fans, DOE compared their energy consumption under the no-new-standards case to their anticipated energy consumption under each TSL. The savings are measured over the entire lifetime of products purchased in the 30-year period that begins in the first full year of anticipated compliance

with amended standards (2020–2049). Table V.23 presents DOE's projections of the national energy savings for each TSL considered for ceiling fans. The savings were calculated using the approach described in section IV.H.1 of this notice.

TABLE V.23—CUMULATIVE NATIONAL ENERGY SAVINGS FOR CEILING FANS; 30 YEARS OF SHIPMENTS
[2020–2049]

| | Trial standard level | | | | |
|----------------------|----------------------|-------|-------|-------|-------|
| | 1 | 2 | 3 | 4 | 5 |
| | <i>Quads</i> | | | | |
| Primary energy | 0.772 | 1.205 | 1.760 | 1.921 | 3.577 |
| FFC energy | 0.807 | 1.260 | 1.839 | 2.008 | 3.738 |

OMB Circular A–4⁶⁹ requires agencies to present analytical results, including separate schedules of the monetized benefits and costs that show the type and timing of benefits and costs. Circular A–4 also directs agencies to consider the variability of key elements underlying the estimates of benefits and costs. For this rulemaking, DOE undertook a sensitivity analysis using nine, rather than 30, years of

product shipments. The choice of a 9-year period is a proxy for the timeline in EPCA for the review of certain energy conservation standards and potential revision of and compliance with such revised standards.⁷⁰ The review timeframe established in EPCA is generally not synchronized with the product lifetime, product manufacturing cycles, or other factors specific to ceiling fans. Thus, such results are

presented for informational purposes only and are not indicative of any change in DOE's analytical methodology. The NES sensitivity analysis results based on a 9-year analytical period are presented in Table V.24. The impacts are counted over the lifetime of ceiling fans purchased in 2020–2028.

TABLE V.24—CUMULATIVE NATIONAL ENERGY SAVINGS FOR CEILING FANS; 9 YEARS OF SHIPMENTS
[2020–2028]

| | Trial standard level | | | | |
|----------------------|----------------------|-------|-------|-------|-------|
| | 1 | 2 | 3 | 4 | 5 |
| | <i>quads</i> | | | | |
| Primary energy | 0.221 | 0.332 | 0.465 | 0.510 | 1.068 |
| FFC energy | 0.231 | 0.347 | 0.486 | 0.533 | 1.116 |

b. Net Present Value of Consumer Costs and Benefits

DOE estimated the cumulative NPV of the total costs and savings for

consumers that would result from the TSLs considered for ceiling fans. In accordance with OMB's guidelines on regulatory analysis,⁷¹ DOE calculated NPV using both a 7-percent and a 3-

percent real discount rate. Table V.25 shows the consumer NPV results with impacts counted over the lifetime of products purchased in 2020–2049.

TABLE V.25—CUMULATIVE NET PRESENT VALUE OF CONSUMER BENEFITS FOR CEILING FANS; 30 YEARS OF SHIPMENTS
[2020–2049]

| Discount rate | Trial standard level (billion 2015\$) | | | | |
|-----------------|--|-------|--------|--------|--------|
| | 1 | 2 | 3 | 4 | 5 |
| 3 percent | 6.464 | 9.286 | 11.389 | 12.123 | 21.006 |
| 7 percent | 2.700 | 3.744 | 4.228 | 4.488 | 7.454 |

The NPV results based on the aforementioned 9-year analytical period are presented in Table V.26. The impacts are counted over the lifetime of

products purchased in 2020–2028. As mentioned previously, such results are presented for informational purposes only and are not indicative of any

change in DOE's analytical methodology or decision criteria.

⁶⁹ U.S. Office of Management and Budget. *Circular A–4: Regulatory Analysis*. September 17, 2003. www.whitehouse.gov/omb/circulars_a004_a-4/.

⁷⁰ Section 325(m) of EPCA requires DOE to review its standards at least once every 6 years, and requires, for certain products, a 3-year period after any new standard is promulgated before

compliance is required, except that in no case may any new standards be required within 6 years of the compliance date of the previous standards. While adding a 6-year review to the 3-year compliance period adds up to 9 years, DOE notes that it may undertake reviews at any time within the 6 year period and that the 3-year compliance date may yield to the 6-year backstop. A 9-year analysis

period may not be appropriate given the variability that occurs in the timing of standards reviews and the fact that for some products, the compliance period is 5 years rather than 3 years.

⁷¹ U.S. Office of Management and Budget. *Circular A–4: Regulatory Analysis*. September 17, 2003. www.whitehouse.gov/omb/circulars_a004_a-4/.

TABLE V.26—CUMULATIVE NET PRESENT VALUE OF CONSUMER BENEFITS FOR CEILING FANS; 9 YEARS OF SHIPMENTS [2020–2028]

| Discount rate | Trial standard level (billion 2015\$) | | | | |
|-----------------|--|-------|-------|-------|-------|
| | 1 | 2 | 3 | 4 | 5 |
| 3 percent | 2.302 | 3.165 | 3.556 | 3.752 | 6.298 |
| 7 percent | 1.312 | 1.753 | 1.814 | 1.904 | 2.895 |

The above results reflect the use of a default trend to estimate the change in price for ceiling fans over the analysis period (see section IV.G of this document). DOE also conducted a sensitivity analysis that considered one scenario with no price decline. The results of these alternative cases are presented in appendix 10C of the NOPR TSD.

c. Indirect Impacts on Employment

DOE expects energy conservation standards for ceiling fans to reduce energy bills for consumers of those products, with the resulting net savings being redirected to other forms of economic activity. These expected shifts in spending and economic activity could affect the demand for labor. As described in section IV.N of this document, DOE used an input/output model of the U.S. economy to estimate indirect employment impacts of the TSLs that DOE considered in this rulemaking. DOE understands that there are uncertainties involved in projecting employment impacts, especially changes in the later years of the analysis. Therefore, DOE generated results for near-term timeframes (2020–2025), where these uncertainties are reduced.

The results suggest that the adopted standards are likely to have a negligible impact on the net demand for labor in the economy. The net change in jobs is so small that it would be imperceptible in national labor statistics and might be offset by other, unanticipated effects on

employment. Chapter 16 of the final rule TSD presents detailed results regarding anticipated indirect employment impacts.

4. Impact on Utility or Performance of Products

Based on testing and teardowns conducted in support of this rule as discussed in section IV.C of this notice, DOE has concluded that the standards adopted in this final rule would not reduce the utility or performance of the ceiling fans under consideration in this rulemaking. Manufacturers of these products currently offer units that meet or exceed the adopted standards.

5. Impact of Any Lessening of Competition

DOE considered any lessening of competition that would be likely to result from new or amended standards. As discussed in section III.E.1.e, the Attorney General of the United States (Attorney General) to determine the impact, if any, of any lessening of competition likely to result from a proposed standard and to transmit such determination in writing to the Secretary within 60 days of the publication of a proposed rule, together with an analysis of the nature and extent of the impact. To assist the Attorney General in making this determination, DOE provided the Department of Justice (DOJ) with copies of the NOPR and the TSD for review. In its assessment letter responding to DOE, DOJ concluded that the proposed energy conservation standards for ceiling fans

are unlikely to have a significant adverse impact on competition. DOE is publishing the Attorney General's assessment at the end of this final rule.

6. Need of the Nation To Conserve Energy

Enhanced energy efficiency, where economically justified, improves the Nation's energy security, strengthens the economy, and reduces the environmental impacts (costs) of energy production. Reduced electricity demand due to energy conservation standards is also likely to reduce the cost of maintaining the reliability of the electricity system, particularly during peak-load periods. As a measure of this reduced demand, chapter 15 in the final rule TSD presents the estimated reduction in generating capacity, relative to the no-new-standards case, for the TSLs that DOE considered in this rulemaking.

Energy conservation resulting from amended standards for ceiling fans is expected to yield environmental benefits in the form of reduced emissions of air pollutants and greenhouse gases. Table V.27 provides DOE's estimate of cumulative emissions reductions expected to result from the TSLs considered in this rulemaking. The table includes both power sector emissions and upstream emissions. The emissions were calculated using the multipliers discussed in section IV.K. DOE reports annual emissions reductions for each TSL in chapter 13 of the final rule TSD.

TABLE V.27—CUMULATIVE EMISSIONS REDUCTION FOR CEILING FANS SHIPPED IN 2020–2049

| | Trial standard level | | | | |
|---|----------------------|-------|--------|--------|--------|
| | 1 | 2 | 3 | 4 | 5 |
| Power Sector Emissions | | | | | |
| CO ₂ (million metric tons) | 45.79 | 71.38 | 104.07 | 113.66 | 212.43 |
| SO ₂ (thousand tons) | 25.38 | 39.50 | 57.48 | 62.75 | 117.87 |
| NO _x (thousand tons) | 51.65 | 80.54 | 117.49 | 128.34 | 239.51 |
| Hg (tons) | 0.09 | 0.15 | 0.21 | 0.23 | 0.44 |
| CH ₄ (thousand tons) | 3.67 | 5.71 | 8.31 | 9.08 | 17.03 |
| N ₂ O (thousand tons) | 0.52 | 0.81 | 1.17 | 1.28 | 2.40 |

TABLE V.27—CUMULATIVE EMISSIONS REDUCTION FOR CEILING FANS SHIPPED IN 2020–2049—Continued

| | Trial standard level | | | | |
|---|----------------------|---------|----------|----------|----------|
| | 1 | 2 | 3 | 4 | 5 |
| Upstream Emissions | | | | | |
| CO ₂ (million metric tons) | 2.64 | 4.12 | 6.02 | 6.58 | 12.23 |
| SO ₂ (thousand tons) | 0.49 | 0.76 | 1.11 | 1.22 | 2.26 |
| NO _x (thousand tons) | 37.87 | 59.12 | 86.36 | 94.31 | 175.36 |
| Hg (tons) | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| CH ₄ (thousand tons) | 209.18 | 326.60 | 477.10 | 521.03 | 968.66 |
| N ₂ O (thousand tons) | 0.02 | 0.04 | 0.06 | 0.06 | 0.11 |
| Total FFC Emissions | | | | | |
| CO ₂ (million metric tons) | 48.43 | 75.50 | 110.09 | 120.24 | 224.66 |
| SO ₂ (thousand tons) | 25.87 | 40.26 | 58.59 | 63.97 | 120.13 |
| NO _x (thousand tons) | 89.51 | 139.66 | 203.85 | 222.65 | 414.87 |
| Hg (tons) | 0.10 | 0.15 | 0.22 | 0.24 | 0.44 |
| CH ₄ (thousand tons) | 212.85 | 332.31 | 485.41 | 530.11 | 985.69 |
| CH ₄ (thousand tons CO ₂ eq) * | 5959.68 | 9304.79 | 13591.50 | 14843.04 | 27599.41 |
| N ₂ O (thousand tons) | 0.54 | 0.84 | 1.23 | 1.34 | 2.51 |
| N ₂ O (thousand tons CO ₂ eq) * | 143.43 | 223.33 | 325.12 | 354.94 | 665.94 |

* CO₂eq is the quantity of CO₂ that would have the same global warming potential (GWP).
Negative values refer to an increase in emissions.

As part of the analysis for this rule, DOE estimated monetary benefits likely to result from the reduced emissions of CO₂ and NO_x that DOE estimated for each of the considered TSLs for ceiling fans. As discussed in section IV.L of this document, for CO₂, DOE used the most recent values for the SCC developed by an interagency process. The four sets of SCC values for CO₂ emissions reductions in 2015 resulting from that process (expressed in 2015\$) are represented by \$12.4/t (the average

value from a distribution that uses a 5-percent discount rate), \$40.6/t (the average value from a distribution that uses a 3-percent discount rate), \$63.2/t (the average value from a distribution that uses a 2.5-percent discount rate), and \$118/t (the 95th-percentile value from a distribution that uses a 3-percent discount rate). The values for later years are higher due to increasing damages (public health, economic, and environmental) as the projected magnitude of climate change increases.

Table V.28 presents the global value of CO₂ emissions reductions at each TSL. For each of the four cases, DOE calculated a present value of the stream of annual values using the same discount rate as was used in the studies upon which the dollar-per-ton values are based. DOE calculated domestic values as a range from 7 percent to 23 percent of the global values; these results are presented in chapter 14 of the final rule TSD.

TABLE V.28—ESTIMATES OF GLOBAL PRESENT VALUE OF CO₂ EMISSIONS REDUCTION FOR PRODUCTS SHIPPED IN 2020–2049

| TSL | SCC case * | | | |
|-------------------------------|---------------------------|---------------------------|-----------------------------|-----------------------------------|
| | 5% discount rate, average | 3% discount rate, average | 2.5% discount rate, average | 3% discount rate, 95th percentile |
| Million 2015\$ | | | | |
| Power Sector Emissions | | | | |
| 1 | 321.5 | 1472.2 | 2338.6 | 4486.8 |
| 2 | 498.5 | 2287.8 | 3635.9 | 6973.5 |
| 3 | 722.5 | 3324.3 | 5286.2 | 10134.5 |
| 4 | 789.6 | 3632.1 | 5775.3 | 11072.8 |
| 5 | 1500.9 | 6854.9 | 10882.2 | 20887.5 |
| Upstream Emissions | | | | |
| 1 | 18.2 | 84.1 | 133.9 | 256.6 |
| 2 | 28.3 | 131.0 | 208.5 | 399.5 |
| 3 | 41.2 | 190.7 | 303.7 | 581.7 |
| 4 | 45.0 | 208.3 | 331.8 | 635.5 |
| 5 | 85.0 | 391.1 | 621.8 | 1192.4 |
| Total FFC Emissions | | | | |
| 1 | 339.8 | 1556.4 | 2472.5 | 4743.4 |
| 2 | 526.8 | 2418.8 | 3844.4 | 7373.0 |
| 3 | 763.6 | 3515.0 | 5589.9 | 10716.3 |

TABLE V.28—ESTIMATES OF GLOBAL PRESENT VALUE OF CO₂ EMISSIONS REDUCTION FOR PRODUCTS SHIPPED IN 2020–2049—Continued

| TSL | SCC case * | | | |
|---------|---------------------------|---------------------------|-----------------------------|-----------------------------------|
| | 5% discount rate, average | 3% discount rate, average | 2.5% discount rate, average | 3% discount rate, 95th percentile |
| | Million 2015\$ | | | |
| 4 | 834.6 | 3840.4 | 6107.1 | 11708.4 |
| 5 | 1585.9 | 7246.0 | 11503.9 | 22079.9 |

* For each of the four cases, the corresponding SCC value for emissions in 2015 is \$12.4, \$40.6, \$63.2, and \$118 per metric ton (2015\$). The values are for CO₂ only (*i.e.*, not CO_{2eq} of other greenhouse gases).

DOE is well aware that scientific and economic knowledge about the contribution of CO₂ and other GHG emissions to changes in the future global climate and the potential resulting damages to the world economy continues to evolve rapidly. Thus, any value placed on reduced CO₂ emissions in this rulemaking is subject to change. DOE, together with other Federal agencies, will continue to review various methodologies for estimating the monetary value of reductions in CO₂ and other GHG emissions. This ongoing

review will consider the comments on this subject that are part of the public record for this and other rulemakings, as well as other methodological assumptions and issues. However, consistent with DOE's legal obligations, and taking into account the uncertainty involved with this particular issue, DOE has included in this rule the most recent values and analyses resulting from the interagency review process.

DOE also estimated the cumulative monetary value of the economic benefits associated with NO_x emissions

reductions anticipated to result from the considered TSLs for ceiling fans. The dollar-per-ton values that DOE used are discussed in section IV.L of this document. Table V.29 presents the cumulative present values for NO_x emissions for each TSL calculated using 7-percent and 3-percent discount rates. This table presents values that use the low dollar-per-ton values, which reflect DOE's primary estimate. Results that reflect the range of NO_x dollar-per-ton values are presented in Table V.31.

TABLE V.29—ESTIMATES OF PRESENT VALUE OF NO_x EMISSIONS REDUCTION FOR CEILING FANS SHIPPED IN 2020–2049 *

| TSL | 3% discount rate | 7% discount rate |
|------------------------|------------------|------------------|
| | Million 2015\$ | |
| Power Sector Emissions | | |
| 1 | 86.2 | 35.2 |
| 2 | 133.4 | 54.0 |
| 3 | 193.7 | 77.6 |
| 4 | 213.4 | 85.6 |
| 5 | 404.6 | 166.6 |
| Upstream Emissions | | |
| 1 | 69.9 | 27.9 |
| 2 | 108.5 | 43.0 |
| 3 | 157.5 | 61.7 |
| 4 | 172.1 | 67.5 |
| 5 | 326.3 | 131.4 |
| Total FFC Emissions | | |
| 1 | 156.1 | 63.1 |
| 2 | 241.9 | 96.9 |
| 3 | 351.2 | 139.4 |
| 4 | 385.5 | 153.1 |
| 5 | 730.9 | 297.9 |

* Results are based on the low benefit-per-ton values.

7. Other Factors

The Secretary of Energy, in determining whether a standard is economically justified, may consider any other factors that the Secretary deems to be relevant. (42 U.S.C.

6295(o)(2)(B)(i)(VII)) No other factors were considered in this analysis.

8. Summary of National Economic Impacts

The NPV of the monetized benefits associated with emissions reductions

can be viewed as a complement to the NPV of the consumer savings calculated for each TSL considered in this rulemaking. Table V.30 presents the NPV values that result from adding the estimates of the potential economic benefits resulting from reduced CO₂ and

NO_x emissions in each of four valuation scenarios to the NPV of consumer savings calculated for each TSL

considered in this rulemaking, at both a 7-percent and 3-percent discount rate. The CO₂ values used in the columns of

each table correspond to the 2015 values in the four sets of SCC values discussed above.

TABLE V.30—NET PRESENT VALUE OF CONSUMER SAVINGS COMBINED WITH PRESENT VALUE OF MONETIZED BENEFITS FROM CO₂ AND NO_x EMISSIONS REDUCTIONS

| TSL | Consumer NPV at 3% discount rate added with: | | | |
|----------------|---|---|---|--|
| | SCC case \$12.4/t and 3% low NO _x values | SCC case \$40.6/t and 3% low NO _x values | SCC case \$63.2/t and 3% low NO _x values | SCC case \$118/t and 3% low NO _x values |
| Billion 2015\$ | | | | |
| 1 | 6.960 | 8.177 | 9.093 | 11.364 |
| 2 | 10.055 | 11.947 | 13.372 | 16.901 |
| 3 | 12.502 | 15.254 | 17.329 | 22.455 |
| 4 | 13.343 | 16.349 | 18.615 | 24.217 |
| 5 | 23.323 | 28.983 | 33.241 | 43.817 |
| TSL | Consumer NPV at 7% discount rate added with: | | | |
| | SCC case \$12.4/t and 7% low NO _x values | SCC case \$40.6/t and 7% low NO _x values | SCC case \$63.2/t and 7% low NO _x values | SCC case \$118/t and 7% low NO _x values |
| 1 | 3.103 | 4.320 | 5.236 | 7.507 |
| 2 | 4.367 | 6.259 | 7.685 | 11.213 |
| 3 | 5.131 | 7.882 | 9.957 | 15.083 |
| 4 | 5.475 | 8.481 | 10.748 | 16.349 |
| 5 | 9.338 | 14.998 | 19.256 | 29.832 |

Note: The SCC case values represent the global SCC in 2015, in 2015\$ per metric ton (t), for each case.

In considering the above results, two issues are relevant. First, the national operating cost savings are domestic U.S. monetary savings that occur as a result of market transactions, while the value of CO₂ reductions is based on a global value. Second, the assessments of operating cost savings and the SCC are performed with different methods that use different time frames for analysis. The national operating cost savings is measured for the lifetime of products shipped in 2020–2049. Because CO₂ emissions have a very long residence time in the atmosphere,⁷² the SCC values in future years reflect future climate-related impacts that continue beyond 2100.

C. Conclusion

When considering new or amended energy conservation standards, the standards that DOE adopts for any type (or class) of covered product must be designed to achieve the maximum improvement in energy efficiency that the Secretary determines is technologically feasible and economically justified. (42 U.S.C. 6295(o)(2)(A)) In determining whether a

standard is economically justified, the Secretary must determine whether the benefits of the standard exceed its burdens by, to the greatest extent practicable, considering the seven statutory factors discussed previously. (42 U.S.C. 6295(o)(2)(B)(i)) The new or amended standard must also result in significant conservation of energy. (42 U.S.C. 6295(o)(3)(B))

For this final rule, DOE considered the impacts of amended standards for ceiling fans at each TSL, beginning with the maximum technologically feasible level, to determine whether that level was economically justified. Where the max-tech level was not justified, DOE then considered the next most efficient level and undertook the same evaluation until it reached the highest efficiency level that is both technologically feasible and economically justified and saves a significant amount of energy.

To aid the reader as DOE discusses the benefits and/or burdens of each TSL, tables in this section present a summary of the results of DOE's quantitative analysis for each TSL. In addition to the quantitative results presented in the tables, DOE also considers other burdens and benefits that affect economic justification. These include the impacts on identifiable subgroups of consumers who may be disproportionately affected by a national standard and impacts on employment.

DOE also notes that the economics literature provides a wide-ranging discussion of how consumers trade off upfront costs and energy savings in the absence of government intervention. Much of this literature attempts to explain why consumers appear to undervalue energy efficiency improvements. There is evidence that consumers undervalue future energy savings (or appear to do so) as a result of (1) a lack of information; (2) a lack of sufficient salience of the long-term or aggregate benefits; (3) a lack of sufficient savings to warrant delaying or altering purchases; (4) excessive focus on the short term, in the form of inconsistent weighting of future energy cost savings relative to available returns on other investments; (5) computational or other difficulties associated with the evaluation of relevant tradeoffs; and (6) a divergence in incentives (for example, between renters and owners, or builders and purchasers). Having less than perfect foresight and a high degree of uncertainty about the future, consumers may trade off these types of investments at a higher than expected rate between current consumption and uncertain future energy cost savings.

In DOE's current regulatory analysis, potential changes in the benefits and costs of a regulation due to changes in consumer purchase decisions are included in two ways. First, if consumers forego the purchase of a

⁷² The atmospheric lifetime of CO₂ is estimated of the order of 30–95 years. Jacobson, M.Z. Correction to "Control of fossil-fuel particulate black carbon and organic matter, possibly the most effective method of slowing global warming." *J. Geophys. Res.* 2005, 110: D14105. doi: 10.1029/2005JD005888.

product in the standards case, this decreases sales for product manufacturers, and the impact on manufacturers attributed to lost revenue is included in the MIA. Second, DOE accounts for energy savings attributable only to products actually used by consumers in the standards case; if a regulatory option decreases the number of products purchased by consumers, this decreases the potential energy savings from an energy conservation standard. DOE provides estimates of shipments and changes in the volume of product purchases in chapter 9 of the final rule TSD. However, DOE's current analysis does not explicitly control for heterogeneity in consumer preferences, preferences across subcategories of products or specific features, or

consumer price sensitivity variation according to household income.⁷³

While DOE is not prepared at present to provide a fuller quantifiable framework for estimating the benefits and costs of changes in consumer purchase decisions due to an energy conservation standard, DOE is committed to developing a framework that can support empirical quantitative tools for improved assessment of the consumer welfare impacts of appliance standards. DOE has posted a paper that discusses the issue of consumer welfare impacts of appliance energy conservation standards, and potential enhancements to the methodology by which these impacts are defined and estimated in the regulatory process.⁷⁴ DOE welcomes comments on how to more fully assess the potential impact of

energy conservation standards on consumer choice and how to quantify this impact in its regulatory analysis in future rulemakings.

1. Benefits and Burdens of TSLs Considered for Ceiling Fan Standards

Table V.31 and Table V.32 summarize the quantitative impacts estimated for each TSL for ceiling fans. The national impacts are measured over the lifetime of ceiling fans purchased in the 30-year period that begins in the anticipated first full year of compliance with amended standards (2020–2049). The energy savings, emissions reductions, and value of emissions reductions refer to full-fuel-cycle results. The efficiency levels contained in each TSL are described in section V.A of this notice.

TABLE V.31—SUMMARY OF ANALYTICAL RESULTS FOR CEILING FANS TSLs: NATIONAL IMPACTS

| Category | TSL 1 | TSL 2 | TSL 3 | TSL 4 | TSL 5 |
|--|----------------|----------------|-----------------|-----------------|-------------------|
| Cumulative FFC National Energy Savings (quads) | | | | | |
| quads | 0.807 | 1.260 | 1.839 | 2.008 | 3.738. |
| NPV of Consumer Costs and Benefits (billion 2015\$) | | | | | |
| 3% discount rate | 6.464 | 9.286 | 11.388 | 12.123 | 21.006. |
| 7% discount rate | 2.700 | 3.744 | 4.228 | 4.488 | 7.454. |
| Cumulative FFC Emissions Reduction (Total FFC Emission) | | | | | |
| CO ₂ (million metric tons) | 48.43 | 75.50 | 110.09 | 120.24 | 224.66. |
| SO ₂ (thousand tons) | 25.87 | 40.26 | 58.59 | 63.97 | 120.13. |
| NO _x (thousand tons) | 89.51 | 139.66 | 203.85 | 222.65 | 414.87. |
| Hg (tons) | 0.10 | 0.15 | 0.22 | 0.24 | 0.44. |
| CH ₄ (thousand tons) | 212.85 | 332.31 | 485.41 | 530.11 | 985.69. |
| CH ₄ (thousand tons CO ₂ eq) * | 5,959.68 | 9,304.79 | 13,591.50 | 14,843.04 | 27,599.41. |
| N ₂ O (thousand tons) | 0.54 | 0.84 | 1.23 | 1.34 | 2.51. |
| N ₂ O (thousand tons CO ₂ eq) * | 143.43 | 223.33 | 325.12 | 354.94 | 665.94. |
| Value of Emissions Reduction (Total FFC Emissions) | | | | | |
| CO ₂ (billion 2015\$) ** | 0.340 to 4.743 | 0.527 to 7.373 | 0.764 to 10.716 | 0.835 to 11.708 | 1.586 to 22.080. |
| NO _x —3% discount rate (million 2015\$) | 156.1 to 355.9 | 241.9 to 551.6 | 351.2 to 800.7 | 385.5 to 878.9 | 730.9 to 1,666.3. |
| NO _x —7% discount rate (million 2015\$) | 63.1 to 142.2 | 96.9 to 218.5 | 139.4 to 314.2 | 153.1 to 345.3 | 297.9 to 671.8. |

Parentheses indicate negative (–) values.

* CO₂eq is the quantity of CO₂ that would have the same global warming potential (GWP).

** Range of the economic value of CO₂ reductions is based on estimates of the global benefit of reduced CO₂ emissions.

TABLE V.32—SUMMARY OF ANALYTICAL RESULTS FOR CEILING FANS TSLs: MANUFACTURER AND CONSUMER IMPACTS

| Category | TSL 1 * | TSL 2 * | TSL 3 * | TSL 4 * | TSL 5 * |
|--|-----------------|-----------------|-----------------|-----------------|-------------------|
| Manufacturer Impacts | | | | | |
| Industry NPV (million 2015\$) (No-new-standards case INPV = 1,211.6) | 1,200.8–1,232.8 | 1,188.6–1,275.8 | 1,107.9–1,213.2 | 1,092.1–1,206.8 | 926.7 to 1,265.3. |
| Industry NPV (% change) | (0.9)–1.8 | (1.9)–5.3 | (8.6)–0.1 | (9.9)–(0.4) | (23.5) to 4.4. |
| Consumer Average LCC Savings ** (2015\$) | | | | | |
| Standard | 46.61 | 37.20 | 25.78 | 25.78 | 26.80. |
| Hugger | 39.01 | 31.75 | 21.50 | 21.50 | 19.20. |
| Very Small-Diameter | 16.10 | 16.10 | 4.29 | 4.29 | (25.94). |
| High-Speed Small-Diameter | 20.17 | 20.17 | (15.81) | 19.80 | 19.80. |
| Large-Diameter | 291.52 | 291.52 | 128.90 | 128.90 | 347.93. |
| Consumer Simple PBP *** (years) | | | | | |
| Standard | 0.0 | 0.0 | 1.7 | 1.7 | 4.0. |

⁷³ P.C. Reiss and M.W. White. Household Electricity Demand, Revisited. *Review of Economic Studies*. 2005. 72(3): pp. 853–883. doi: 10.1111/0034-6527.00354.

⁷⁴ Sanstad, A.H. *Notes on the Economics of Household Energy Consumption and Technology Choice*. 2010. Lawrence Berkeley National Laboratory. https://www1.eere.energy.gov/buildings/appliance_standards/pdfs/consumer_ee_theory.pdf.

TABLE V.32—SUMMARY OF ANALYTICAL RESULTS FOR CEILING FANS TSLs: MANUFACTURER AND CONSUMER IMPACTS—Continued

| Category | TSL 1 * | TSL 2 * | TSL 3 * | TSL 4 * | TSL 5 * |
|--|---------|---------|---------|---------|---------|
| Hugger | 0.0 | 0.0 | 1.8 | 1.8 | 4.1. |
| Very Small-Diameter | 0.0 | 0.0 | 9.3 | 9.3 | 13.4. |
| High-Speed Small-Diameter | 0.0 | 0.0 | 9.8 | 6.9 | 6.9. |
| Large-Diameter | 0.0 | 0.0 | 4.1 | 4.1 | 4.3. |
| Percent of Consumers that Experience a Net Cost | | | | | |
| Standard | 0.0 | 0.0 | 27.5 | 27.5 | 50.4. |
| Hugger | 0.0 | 0.0 | 27.8 | 27.8 | 51.4. |
| Very Small-Diameter | 0.0 | 0.0 | 2.1 | 2.1 | 75.8. |
| High-Speed Small-Diameter | 0.0 | 0.0 | 70.0 | 38.7 | 38.7. |
| Large-Diameter | 0.0 | 0.0 | 23.3 | 23.3 | 16.2. |

* Parentheses indicate negative (–) values. The entry “n.a.” means not applicable because there is no change in the standard at certain TSLs.

** The calculation excludes consumers with zero LCC savings (no impact).

*** Simple PBP results are calculated assuming that all consumers use products at that efficiency level. The PBP is measured relative to the baseline product.

DOE first considered TSL 5, which represents the max-tech efficiency levels. TSL 5 would save 3.738 quads of energy, an amount DOE considers significant. Under TSL 5, the NPV of consumer benefit would be \$7.454 billion using a discount rate of 7 percent, and \$21.006 billion using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 5 are 224.66 Mt of CO₂, 120.13 thousand tons of SO₂, 414.87 thousand tons of NO_x, 0.44 ton of Hg, 985.69 thousand tons of CH₄, and 2.51 thousand tons of N₂O. The estimated monetary value of the CO₂ emissions reduction at TSL 5 ranges from \$1.586 billion to \$22.080 billion.

At TSL 5, the average LCC impact for affected consumers is a cost of \$25.94 for VSD ceiling fans and a savings of \$19.20, \$26.80, \$19.80, and \$347.93 for hugger, standard, HSSD and large-diameter ceiling fans, respectively. The simple payback period is 13.4 years for VSD ceiling fans, 4.1 years for hugger ceiling fans, 4.0 years for standard ceiling fans, 6.9 years for HSSD ceiling fans, and 4.3 years for large-diameter ceiling fans. The fraction of consumers experiencing a net LCC cost is 76 percent for VSD ceiling fans, 51 percent for hugger ceiling fans, 50 percent for standard ceiling fans, 39 percent for HSSD ceiling fans, and 16 percent for large-diameter ceiling fans.

At TSL 5, the projected change in INPV ranges from a decrease of \$284.8 million to an increase of \$53.8 million, which represents a decrease of 23.5 percent and an increase of 4.4 percent.

At TSL 5, the corresponding efficiency levels for all product classes are the max-tech efficiency levels. Specifically for the VSD, hugger, and standard ceiling fan product classes, the percentages of consumers that experience net cost are greater than 50 percent. Additionally, specific to the

VSD ceiling fan product class, the average LCC savings in 2015\$ for all consumers, and affected consumers relative to no standards case is negative. Manufacturers may experience a loss in INPV of up to 23.5 percent.

The Secretary concludes that at TSL 5, the benefits of energy savings, positive NPV of consumer benefits, emission reductions, and the estimated monetary value of the emissions reductions would be outweighed by the percentage of consumers that experience net cost for the VSD, hugger, and standard ceiling fan product classes, the negative average LCC savings for the VSD ceiling fan product class, and the potential reduction in manufacturer industry value. Consequently, the Secretary has tentatively concluded that TSL 5 is not economically justified.

DOE then considered TSL 4, which corresponds to the maximum NPV with an AC motor for all product classes other than HSSD fans, and maximum NPV for HSSD fans. At this TSL, less than 50 percent of consumers experience a net cost, and large-diameter ceiling fans that provide high levels of airflow are not disproportionately impacted. TSL 4 would save 2.008 quads of energy, an amount DOE considers significant. Under TSL 4, the NPV of consumer benefit would be \$4.488 billion using a discount rate of 7 percent, and \$12.123 billion using a discount rate of 3 percent.

The cumulative emissions reductions at TSL 4 are 120.24 Mt of CO₂, 63.97 thousand tons of SO₂, 222.65 thousand tons of NO_x, 0.24 ton of Hg, 530.11 thousand tons of CH₄, and 1.34 thousand tons of N₂O. The estimated monetary value of the CO₂ emissions reduction at TSL 4 ranges from \$0.835 billion to \$11.708 billion.

At TSL 4, the average LCC impact for affected consumers is a savings of \$4.29

for VSD ceiling fans, \$21.50 for hugger ceiling fans, \$25.78 for standard ceiling fans, \$19.80 for HSSD ceiling fans, and \$128.90 for large-diameter ceiling fans. The simple payback period is 9.3 years for VSD ceiling fans, 1.8 years for hugger ceiling fans, 1.7 years for standard ceiling fans, 6.9 years for HSSD ceiling fans, and 4.1 years for large-diameter ceiling fans. The fraction of consumers experiencing a net LCC cost is 2 percent for VSD ceiling fans, 28 percent for hugger ceiling fans, 27 percent for standard ceiling fans, 39 percent for HSSD ceiling fans, and 23 percent for large-diameter ceiling fans.

At TSL 4, the projected change in INPV ranges from decreases of \$119.4 million to \$4.8 million, which represent decreases of 9.9 percent and 0.4 percent, respectively.

For TSL 4, the efficiency levels for each product class correspond to the following: max-tech for HSSD ceiling fan product class, EL 3 for the hugger, standard, and large-diameter ceiling fan product classes, and EL 2 for the very-small diameter ceiling fan product class. Within large-diameter ceiling fans, TSL 4 does not disproportionately impact fans that provide high levels of airflow. At TSL 4, the average LCC savings in 2015\$ are positive for all product classes. Also, the fraction of consumers that experience net savings at TSL 4 is greater than the fraction of consumers that experience a net cost. Manufacturers may experience a loss in INPV of up to 9.9 percent.

After considering the analysis and weighing the benefits and burdens, the Secretary has concluded that at TSL 4 for ceiling fans, the benefits of energy savings, positive NPV of consumer benefits, emission reductions, the estimated monetary value of the emissions reductions, and positive average LCC savings would outweigh the negative impacts on some

consumers and on manufacturers, including the conversion costs that could result in a reduction in INPV for manufacturers. Accordingly, the Secretary has concluded that TSL 4 would offer the maximum improvement in efficiency that is technologically feasible and economically justified, and would result in the significant conservation of energy.

Therefore, based on the above considerations, DOE adopts the energy conservation standards for ceiling fans at TSL 4. The amended energy conservation standards for ceiling fans, which are expressed as minimum CFM/W, are shown in Table V.33.

TABLE V.33—AMENDED ENERGY CONSERVATION STANDARDS FOR CEILING FANS

| Product class | Minimum efficiency equation (CFM/W)* |
|----------------------------|---|
| Very Small-Diameter (VSD). | D ≤ 12 in.: 21 D > 12 in.: 3.16 D – 17.04 |
| Standard | 0.65 D + 38.03 |
| Hugger | 0.29 D + 34.46 |

TABLE V.33—AMENDED ENERGY CONSERVATION STANDARDS FOR CEILING FANS—Continued

| Product class | Minimum efficiency equation (CFM/W)* |
|-----------------------------------|--------------------------------------|
| High-Speed Small-Diameter (HSSD). | 4.16 D + 0.02 |
| Large Diameter | 0.91 D – 30.00 |

*D is the ceiling fan's blade span, in inches, as determined in Appendix U.

2. Summary of Annualized Benefits and Costs of the Adopted Standards

The benefits and costs of the adopted standards can also be expressed in terms of annualized values. The annualized net benefit is the sum of (1) the annualized national economic value (expressed in 2015\$) of the benefits from operating products that meet the adopted standards (consisting primarily of operating cost savings from using less energy, minus increases in product purchase costs, and (2) the annualized monetary value of the benefits of CO₂ and NO_x emission reductions.⁷⁵

Table V.34 shows the annualized values for ceiling fans under TSL 4,

expressed in 2015\$. The results under the primary estimate are as follows.

Using a 7-percent discount rate for benefits and costs other than CO₂ reductions (for which DOE used a 3-percent discount rate along with the average SCC series corresponding to a value of \$40.6/t in 2015 (2015\$)), the estimated cost of the adopted standards for ceiling fans is \$245.1 million per year in increased equipment costs, while the estimated benefits are \$688.1 million per year in reduced equipment operating costs, \$214.1 million per year in CO₂ reductions, and \$15.1 million per year in reduced NO_x emissions. In this case, the net benefit amounts to \$672.2 million per year.

Using a 3-percent discount rate for all benefits and costs and the average SCC series corresponding to a value of \$40.6/t in 2015 (in 2015\$), the estimated cost of the adopted standards for ceiling fans is \$243.2 million per year in increased equipment costs, while the estimated annual benefits are \$919.0 million in reduced operating costs, \$214.1 million in CO₂ reductions, and \$21.5 million in reduced NO_x emissions. In this case, the net benefit amounts to \$911.4 million per year.

TABLE V.34—SELECTED CATEGORIES OF ANNUALIZED BENEFITS AND COSTS OF ADOPTED STANDARDS (TSL 4) FOR CEILING FANS

| | Discount rate | Primary estimate | Low-net-benefits estimate | High-net-benefits estimate |
|---|-----------------------------------|----------------------|---------------------------|----------------------------|
| Million 2015\$/year | | | | |
| Benefits | | | | |
| Consumer Operating Cost Savings | 7% | 688.1 | 579.7 | 793.5. |
| | 3% | 919.0 | 764.2 | 1081.9. |
| CO ₂ Reduction (using mean SCC at 5% discount rate) ** ... | 5% | 62.8 | 53.7 | 71.0. |
| CO ₂ Reduction (using mean SCC at 3% discount rate) ** ... | 3% | 214.1 | 182.2 | 242.6. |
| CO ₂ Reduction (using mean SCC at 2.5% discount rate) ** ... | 2.5% | 314.2 | 267.2 | 356.3. |
| CO ₂ Reduction (using 95th percentile SCC at 3% discount rate) **. | 3% | 652.7 | 555.4 | 739.8. |
| NO _x Reduction † | 7% | 15.1 | 13.1 | 38.1. |
| | 3% | 21.5 | 18.4 | 55.3. |
| Total Benefits ‡ | 7% plus CO ₂ range ... | 766 to 1,356 | 647 to 1,148 | 903 to 1,571. |
| | 7% | 917.3 | 775.0 | 1,074.2. |
| | 3% plus CO ₂ range ... | 1,003 to 1,593 | 836 to 1,338 | 1,208 to 1,877. |
| | 3% | 1,154.6 | 964.8 | 1,379.9. |
| Costs *** | | | | |
| Consumer Incremental Product Costs | 7% | 245.1 | 288.1 | 272.8. |
| | 3% | 243.2 | 298.7 | 273.7. |
| Net Benefits | | | | |
| Total ‡ | 7% plus CO ₂ range ... | 521 to 1,111 | 358 to 860 | 630 to 1,299. |
| | 7% | 672.2 | 487.0 | 801.4. |
| | 3% plus CO ₂ range ... | 760 to 1,350 | 538 to 1,039 | 935 to 1,603. |

⁷⁵ To convert the time-series of costs and benefits into annualized values, DOE calculated a present value in 2014, the year used for discounting the NPV of total consumer costs and savings. For the benefits, DOE calculated a present value associated

with each year's shipments in the year in which the shipments occur (2020, 2030, etc.), and then discounted the present value from each year to 2015. The calculation uses discount rates of 3 and 7 percent for all costs and benefits except for the

value of CO₂ reductions, for which DOE used case-specific discount rates. Using the present value, DOE then calculated the fixed annual payment over a 30-year period, starting in the compliance year that yields the same present value.

TABLE V.34—SELECTED CATEGORIES OF ANNUALIZED BENEFITS AND COSTS OF ADOPTED STANDARDS (TSL 4) FOR CEILING FANS—Continued

| | Discount rate | Primary estimate | Low-net-benefits estimate | High-net-benefits estimate |
|--|---------------|------------------|---------------------------|----------------------------|
| | 3% | 911.4 | 666.1 | 1,106.2. |

* This table presents the annualized costs and benefits associated with ceiling fans shipped in 2020–2049. These results include benefits to consumers which accrue after 2049 from the ceiling fans purchased from 2020–2049. The incremental installed costs include incremental equipment cost as well as installation costs. The CO₂ reduction benefits are global benefits due to actions that occur nationally. The Primary Estimate assumes the Reference case electricity prices and housing starts from AEO 2015 and decreasing product prices for ceiling fans with DC motors, due to price trend on the electronics components. The Low Benefits Estimate uses the Low Economic Growth electricity prices and housing starts from AEO 2015 and no price trend for ceiling fans with DC motors. The High Benefits Estimate uses the High Economic Growth electricity prices and housing starts from AEO 2015 and the same product price decrease for ceiling fans with DC motors as in the Primary Estimate. The methods used to derive projected price trends are explained in section IV.G.4. Note that the Benefits and Costs may not sum to the Net Benefits due to rounding.

** The CO₂ reduction benefits are calculated using 4 different sets of SCC values. The first three use the average SCC calculated using 5-percent, 3-percent, and 2.5-percent discount rates, respectively. The fourth represents the 95th percentile of the SCC distribution calculated using a 3-percent discount rate. The SCC values are emission year specific. See section IV.L.1 for more details.

† DOE estimated the monetized value of NO_x emissions reductions associated with electricity savings using benefit per ton estimates from the *Regulatory Impact Analysis for the Clean Power Plan Final Rule*, published in August 2015 by EPA's Office of Air Quality Planning and Standards. (Available at www.epa.gov/cleanpowerplan/clean-power-plan-final-rule-regulatory-impact-analysis.) See section IV.L.2 for further discussion. For the Primary Estimate and Low Net Benefits Estimate, DOE used national benefit-per-ton estimates for NO_x emitted from the Electric Generating Unit sector based on an estimate of premature mortality derived from the ACS study (Krewski *et al.* 2009). For the High Net Benefits Estimate, the benefit-per-ton estimates were based on the Six Cities study (Lepuele *et al.* 2011); these are nearly two-and-a-half times larger than those from the ACS study.

‡ Total Benefits for both the 3-percent and 7-percent cases are presented using only the average SCC with 3-percent discount rate. In the rows labeled “7% plus CO₂ range” and “3% plus CO₂ range,” the operating cost and NO_x benefits are calculated using the labeled discount rate, and those values are added to the full range of CO₂ values.

*** For certain assumed design options (e.g. fan optimization) that are included at the selected standard level, DOE estimated no incremental costs to consumers, but did estimate a one-time industry conversion cost to manufacturers to make their products compliant with the selected standards that are not reflected in the Consumer Incremental Product Costs. The one-time industry conversion cost to manufacturers of these design options contribute to a loss in industry net present value of \$4.8 million, which is equivalent to an annualized cost of \$0.4 million/year at a 7.4-percent discount rate over the analysis period.

VI. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866 and 13563

Section 1(b)(1) of Executive Order 12866, “Regulatory Planning and Review,” 58 FR 51735 (Oct. 4, 1993), requires each agency to identify the problem that it intends to address, including, where applicable, the failures of private markets or public institutions that warrant new agency action, as well as to assess the significance of that problem. The problems that the adopted standards for ceiling fans are intended to address are as follows:

(1) Insufficient information and the high costs of gathering and analyzing relevant information leads some consumers to miss opportunities to make cost-effective investments in energy efficiency.

(2) In some cases the benefits of more efficient equipment are not realized due to misaligned incentives between purchasers and users. An example of such a case is when the equipment purchase decision is made by a building contractor or building owner who does not pay the energy costs.

(3) There are external benefits resulting from improved energy efficiency of appliances that are not captured by the users of such equipment. These benefits include externalities related to public health, environmental protection and national

energy security that are not reflected in energy prices, such as reduced emissions of air pollutants and greenhouse gases that impact human health and global warming. DOE attempts to qualify some of the external benefits through use of social cost of carbon values.

The Administrator of the Office of Information and Regulatory Affairs (OIRA) in the OMB has determined that the regulatory action in this document is a significant regulatory action under section (3)(f) of Executive Order 12866. Accordingly, pursuant to section 6(a)(3)(B) of the Order, DOE has provided to OIRA: (i) The text of the draft regulatory action, together with a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need; and (ii) an assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with a statutory mandate. DOE has included these documents in the rulemaking record.

In addition, the Administrator of OIRA has determined that the regulatory action is an “economically” significant regulatory action under section (3)(f)(1) of Executive Order 12866. Accordingly, pursuant to section 6(a)(3)(C) of the Order, DOE has provided to OIRA an assessment, including the underlying analysis, of benefits and costs

anticipated from the regulatory action, together with, to the extent feasible, a quantification of those costs; and an assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, and an explanation why the planned regulatory action is preferable to the identified potential alternatives. These assessments can be found in the technical support document for this rulemaking.

DOE has also reviewed this regulation pursuant to Executive Order 13563, issued on January 18, 2011. 76 FR 3281, Jan. 21, 2011. EO 13563 is supplemental to and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, agencies are required by Executive Order 13563 to (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including

potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

DOE emphasizes as well that Executive Order 13563 requires agencies to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. In its guidance, OIRA has emphasized that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. For the reasons stated in the preamble, DOE believes that this final rule is consistent with these principles, including the requirement that, to the extent permitted by law, benefits justify costs.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of a final regulatory flexibility analysis (FRFA) for any final rule where the agency was first required by law to publish a proposed rule for public comment. As required by Executive Order 13272, "Proper Consideration of Small Entities in Agency Rulemaking," 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's website (<http://energy.gov/gc/office-general-counsel>). DOE has prepared the following FRFA for the products that are the subject of this rulemaking.

1. Need for, and Objectives of, the Rule

A description of the need for, and objectives of, this rule is set forth

elsewhere in the preamble and not repeated here.

2. Significant Comments in Response to the IRFA

DOE did not receive comments in response to the IRFA. Comments on the economic impacts of amended standards are addressed in section IV.J.2.a and section IV.J.3 and did not result in significant changes to the FRFA.

3. Comments Filed by the Chief Counsel for Advocacy

The SBA's Chief Counsel for Advocacy did not submit comments on this rulemaking.

4. Description and Estimate of the Number of Small Entities Affected

For manufacturers of ceiling fans, the SBA has set a size threshold, which defines those entities classified as "small businesses" for the purposes of the statute. DOE used the SBA's small business size standards to determine whether any small entities would be subject to the requirements of the rule. See 13 CFR part 121. The size standards are listed by North American Industry Classification System (NAICS) code and industry description available at: https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf. Ceiling fan manufacturing is classified under NAICS code 335210, "Small Electrical Appliance Manufacturing." The SBA sets a threshold of 1,500 employees or less for an entity to be considered as a small business for this category.

To estimate the number of companies that manufacture ceiling fans covered by this rulemaking, DOE conducted a market survey using publicly available information. DOE first attempted to identify all ceiling fan manufacturers by researching industry trade associations (e.g., ALA⁷⁶), information from previous rulemakings, individual company websites, and SBA's database. DOE then attempted to gather information on the location and number of employees to see if these companies met SBA's definition of a small business for each potential ceiling fan

manufacturer by reaching out directly to those potential small businesses and using market research tools (e.g., www.hoovers.com, www.manta.com, glassdoor.com, www.linkedin.com, etc.). DOE also asked interested parties and industry representatives if they were aware of any small businesses during manufacturer interviews and DOE public meetings. DOE used information from these sources to create a list of companies that manufacture or sell ceiling fans and would be affected by this rulemaking.

For ceiling fans, DOE identified 66 companies that sell ceiling fans covered by this rulemaking. 25 of these companies are large businesses with more than 1,500 total employees or are foreign-owned and operated. DOE determined that of the remaining 41 companies with less than 1,500 employees, only six companies are small businesses that maintain domestic production facilities.

5. Description of Compliance Requirements

There are six small domestic ceiling fan manufacturers identified. Four small businesses manufacture HSSD ceiling fans and three small businesses manufacture large-diameter ceiling fans (one of these small businesses manufactures both HSSD and large-diameter ceiling fans and are therefore counted in each of these small business counts). To estimate conversion costs for small manufacturers, DOE multiplied an estimate of the number of platforms that would need to be redesigned at TSL 4 by the per-platform conversion cost estimated for the respective type of conversion cost, efficiency level, and product class for each manufacturer. Additionally, DOE obtained company revenue information from publicly available databases such as Hoovers⁷⁷ and Manta.⁷⁸

Leveraging these assumptions, DOE estimated total conversion costs and conversion costs relative to small ceiling fan manufacturers' annual revenues. DOE presents the estimated total conversion costs incurred by small domestic ceiling fan manufacturers at TSL 4 in Table VI.1.

⁷⁶ ALA. Membership Directory and Buyer's Guide 2015. Last Accessed June 9, 2015. http://www.lightrays-digital.com/lightrays/2015_membership_directory#pg1.

⁷⁷ www.hoovers.com.

⁷⁸ www.manta.com.

TABLE VI.1—CONVERSION COSTS FOR SMALL CEILING FAN MANUFACTURERS AT THE ADOPTED TRIAL STANDARD LEVEL [TSL 4]

| Product conversion costs (2015\$ millions) | Capital conversion costs (2015\$ millions) | Total conversion costs (2015\$ millions) | Average total conversion costs as a percentage of annual revenue |
|---|---|---|---|
| \$0.7 | \$1.6 | \$2.3 | 2.6 |

There are four small manufacturers that make HSSD fans. For one of these small manufacturers, their entire HSSD product offerings use DC motors and they should be able to meet the HSSD standard without any modifications to their product offerings. For the other three HSSD small manufacturer, two only offer one HSSD ceiling fan and one only offers five HSSD ceiling fans. These small manufacturers primarily sell commercial, industrial, and/or agricultural fans not covered by this rulemaking. DOE does not believe that HSSD ceiling fan sales significantly contribute to these companies' revenue. HSSD small manufacturers either make compliant HSSD ceiling fans or these HSSD ceiling fans do not comprise a significant portion of their company's revenue. If these manufacturers decide not to invest in making compliant HSSD ceiling fans, DOE does not believe their revenue will be significantly reduced.

There are three small manufacturers that make large-diameter fans. Two of these small manufacturers primarily make ceiling fans that have DC motors and exceed the efficiency levels required for large-diameter ceiling fans at the adopted standard. The last small manufacturer has eight large-diameter ceiling fans that would have to be converted to comply with the adopted standards for this product class. This would require replacing the motor on these eight large-diameter ceiling fans with a more efficient AC motor.

6. Significant Alternatives Considered and Steps Taken To Minimize Significant Economic Impacts on Small Entities

The discussion in section VI.B.5 analyzes impacts on small businesses that would result from DOE's adopted final rule, TSL 4. In reviewing alternatives to the adopted rule, DOE examined energy conservation standards set at higher and lower efficiency levels; TSL 1, TSL 2, TSL 3, and TSL 5.

DOE considered TSL 5, but determined that the 86 percent increase in the energy savings and 66 percent increase in NPV compared to TSL 4 did not justify the total industry conversion costs of \$155.9 million, the potential loss of up to 23.5 percent of INPV, and

increased burden on small manufacturers.

DOE also considered TSLs lower than the TSL adopted. At TSL 1, the energy savings was reduced by 60 percent and consumer NPV was reduced by 40 percent compared to TSL 4. At TSL 2, the energy savings was reduced by 37 percent and consumer NPV was reduced by 17 percent compared to TSL 4. At TSL 3, the energy savings was reduced by 8 percent and consumer NPV was reduced by 6 percent compared to TSL 4. DOE concludes that establishing standards at TSL 4 balances the benefits of the energy savings and consumer NPV with the potential burdens placed on ceiling fan manufacturers, including small businesses. Accordingly, DOE is declining to adopt one of the other TSLs, or the other policy alternatives detailed as part of the regulatory impacts analysis included in chapter 17 of the final rule TSD.

Additional compliance flexibilities may be available through other means. For example, individual manufacturers may petition for a waiver of the applicable test procedure (see 10 CFR 430.27). Further, EPCA provides that a manufacturer whose annual gross revenue from all of its operations does not exceed \$8 million may apply for an exemption from all or part of an energy conservation standard for a period not longer than 24 months after the effective date of a final rule establishing the standard. Additionally, Section 504 of the Department of Energy Organization Act, 42 U.S.C. 7194, provides authority for the Secretary to adjust a rule issued under EPCA in order to prevent "special hardship, inequity, or unfair distribution of burdens" that may be imposed on that manufacturer as a result of such rule. Manufacturers should refer to 10 CFR part 430, subpart E, and 10 CFR part 1003 for additional details.

C. Review Under the Paperwork Reduction Act

Manufacturers of ceiling fans must certify to DOE that their products comply with any applicable energy conservation standards. In certifying compliance, manufacturers must test their products according to the DOE test procedures for ceiling fans, including any amendments adopted for those test

procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including ceiling fans. 76 FR 12422 (March 7, 2011); 80 FR 5099 (Jan. 30, 2015). The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement has been approved by OMB under OMB control number 1910–1400. Public reporting burden for the certification is estimated to average 30 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

D. Review Under the National Environmental Policy Act of 1969

Pursuant to the National Environmental Policy Act (NEPA) of 1969, DOE has determined that the rule fits within the category of actions included in Categorical Exclusion (CX) B5.1 and otherwise meets the requirements for application of a CX. (See 10 CFR part 1021, App. B, B5.1(b); 1021.410(b) and App. B, B(1)–(5).) The rule fits within this category of actions because it is a rulemaking that establishes energy conservation standards for consumer products or industrial equipment, and for which none of the exceptions identified in CX B5.1(b) apply. Therefore, DOE has made a CX determination for this rulemaking, and DOE does not need to prepare an Environmental Assessment or Environmental Impact Statement for this rule. DOE's CX determination for this rule is available at <http://energy.gov/nepa/categorical-exclusion-cx-determinations-cx>.

E. Review Under Executive Order 13132

Executive Order 13132, "Federalism," 64 FR 43255 (Aug. 10, 1999) imposes

certain requirements on Federal agencies formulating and implementing policies or regulations that preempt State law or that have Federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this rule and has determined that it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this final rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297) Therefore, no further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. 61 FR 4729 (Feb. 7, 1996). Regarding the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation (1) clearly specifies the preemptive effect, if any, (2) clearly specifies any effect on existing Federal law or regulation, (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction, (4) specifies the retroactive effect, if any, (5) adequately defines key terms, and (6) addresses other important issues affecting clarity

and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a "significant intergovernmental mandate," and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE's policy statement is also available at http://energy.gov/sites/prod/files/gcprod/documents/umra_97.pdf.

DOE has concluded that this final rule may require expenditures of \$100 million or more in any one year by the private sector. Such expenditures may include (1) investment in research and development and in capital expenditures by ceiling fans manufacturers in the years between the final rule and the compliance date for the new standards and (2) incremental additional expenditures by consumers to purchase higher-efficiency ceiling fans, starting at the compliance date for the applicable standard.

Section 202 of UMRA authorizes a Federal agency to respond to the content requirements of UMRA in any other

statement or analysis that accompanies the final rule. (2 U.S.C. 1532(c)) The content requirements of section 202(b) of UMRA relevant to a private sector mandate substantially overlap the economic analysis requirements that apply under section 325(o) of EPCA and Executive Order 12866. The **SUPPLEMENTARY INFORMATION** section of this document and chapter 17 of the TSD for this final rule respond to those requirements.

Under section 205 of UMRA, the Department is obligated to identify and consider a reasonable number of regulatory alternatives before promulgating a rule for which a written statement under section 202 is required. (2 U.S.C. 1535(a)) DOE is required to select from those alternatives the most cost-effective and least burdensome alternative that achieves the objectives of the rule unless DOE publishes an explanation for doing otherwise, or the selection of such an alternative is inconsistent with law. As required by 42 U.S.C. 6295(d), (f), and (o), 6313(e), and 6316(a), In accordance with the statutory provisions discussed in this document, this final rule establishes amended energy conservation standards for ceiling fans that are designed to achieve the maximum improvement in energy efficiency that DOE has determined to be both technologically feasible and economically justified. A full discussion of the alternatives considered by DOE is presented in chapter 17 of the TSD for this final rule.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

Pursuant to Executive Order 12630, "Governmental Actions and Interference with Constitutionally Protected Property Rights," 53 FR 8859 (March 18, 1988), DOE has determined that this rule would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for Federal agencies to review most disseminations of information to the public under information quality guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use," 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OIRA at OMB, a Statement of Energy Effects for any significant energy action. A "significant energy action" is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that (1) is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

DOE has concluded that this regulatory action, which sets forth amended energy conservation standards for ceiling fans, is not a significant energy action because the standards are not likely to have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as such by the Administrator at OIRA. Accordingly, DOE has not prepared a Statement of Energy Effects on this final rule.

L. Review Under the Information Quality Bulletin for Peer Review

On December 16, 2004, OMB, in consultation with the Office of Science and Technology Policy (OSTP), issued its Final Information Quality Bulletin for Peer Review (the Bulletin). 70 FR 2664 (Jan. 14, 2005). The Bulletin

establishes that certain scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal Government, including influential scientific information related to agency regulatory actions. The purpose of the bulletin is to enhance the quality and credibility of the Government's scientific information. Under the Bulletin, the energy conservation standards rulemaking analyses are "influential scientific information," which the Bulletin defines as "scientific information the agency reasonably can determine will have, or does have, a clear and substantial impact on important public policies or private sector decisions." Id at FR 2667.

In response to OMB's Bulletin, DOE conducted formal in-progress peer reviews of the energy conservation standards development process and analyses and has prepared a Peer Review Report pertaining to the energy conservation standards rulemaking analyses. Generation of this report involved a rigorous, formal, and documented evaluation using objective criteria and qualified and independent reviewers to make a judgment as to the technical/scientific/business merit, the actual or anticipated results, and the productivity and management effectiveness of programs and/or projects. The "Energy Conservation Standards Rulemaking Peer Review Report" dated February 2007 has been disseminated and is available at the following Web site: www.energy.gov/eere/buildings/peer-review.

M. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this rule prior to its effective date. The report will state that it has been determined that the rule is a "major rule" as defined by 5 U.S.C. 804(2).

VII. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this final rule.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Intergovernmental relations, Reporting and recordkeeping requirements, and Small businesses.

Issued in Washington, DC, on November 21, 2016.

David J. Friedman,

Acting Assistant Secretary, Energy Efficiency and Renewable Energy.

For the reasons set forth in the preamble, DOE amends part 430 of chapter II, subchapter D, of title 10 of the Code of Federal Regulations, as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. Section 430.32 is amended by:
 ■ a. Redesignating paragraphs (s)(2), (3), (4) and (5) as (s)(3), (4), (5) and (6), respectively; and
 ■ b. Adding a new paragraph (s)(2) to read as follows:

§ 430.32 Energy and water conservation standards and their compliance dates.

* * * * *

(s) * * *
 (2)(i) Ceiling fans manufactured on or after January 21, 2020 shall meet the requirements shown in the table:

| Product class as defined in Appendix U | Minimum efficiency (CFM/W) ¹ |
|--|--|
| Very small-diameter (VSD). | D ≤ 12 in.: 21 D > 12 in.: 3.16 D – 17.04 |
| Standard | 0.65 D + 38.03 |
| Hugger | 0.29 D + 34.46 |
| High-speed small-diameter (HSSD). | 4.16 D + 0.02 |
| Large-diameter | 0.91 D – 30.00 |

¹ D is the ceiling fan's blade span, in inches, as determined in Appendix U of this part.

(ii) The provisions in this appendix apply to ceiling fans except:

(A) Ceiling fans where the plane of rotation of a ceiling fan's blades is not less than or equal to 45 degrees from horizontal, or cannot be adjusted based on the manufacturer's specifications to be less than or equal to 45 degrees from horizontal;

(B) Centrifugal ceiling fans, as defined in Appendix U of this part;

(C) Belt-driven ceiling fans, as defined in Appendix U of this part;

(D) Oscillating ceiling fans, as defined in Appendix U of this part; and

(E) Highly-decorative ceiling fans, as defined in Appendix U of this part.

* * * * *

Note: The following letter will not appear in the Code of Federal Regulations.

U.S. DEPARTMENT OF JUSTICE

Antitrust Division:

William J. Baer,

Assistant Attorney General, Main Justice Building, 950 Pennsylvania Avenue NW., Washington, DC 20530-0001, (202) 514-2401/(202) 616-2645 (Fax).

March 21, 2016

Anne Harkavy,

Deputy General Counsel for Litigation, Regulation and Enforcement U.S. Department of Energy, Washington, DC 20585.

Dear Deputy General Counsel Harkavy:

I am responding to your January 21, 2016, letter seeking the views of the Attorney General about the potential impact on competition of proposed energy conservation standards for ceiling fans.

Your request was submitted under Section 325(o)(2)(B)(i)(V) of the Energy Policy and Conservation Act, as amended, 42 U.S.C. 6295(o)(2)(B)(i)(V), which requires the Attorney General to make a determination of

the impact of any lessening of competition that is likely to result from the imposition of proposed energy conservation standards. The Attorney General's responsibility for responding to requests from other departments about the effect of a program on competition has been delegated to the Assistant Attorney General for the Antitrust Division in 28 CFR 0.40(g).

In conducting its analysis, the Antitrust Division examines whether a proposed standard may lessen competition, for example, by substantially limiting consumer choice or increasing industry concentration. A lessening of competition could result in higher prices to consumers.

We have reviewed the proposed standards contained in the Notice of Proposed Rulemaking (81 FR. 1688, January 13, 2016) and the related Technical Support Document. We have also reviewed supplementary information submitted to the Attorney General by the Department of Energy, as well as materials presented at the public meeting held on the proposed standards on February

3, 2016, and have conducted interviews with industry representatives.

Based on the information currently available, we do not believe that the proposed energy conservation standards for ceiling fans are likely to have a significant adverse effect on competition. Our opinion is subject to some uncertainty, in part because manufacturers indicated to us that they cannot reliably determine which of their products will be able to comply with the new standards. The manufacturers understand that a new test procedure will likely be used to determine ceiling fan efficiency performance, and believe that there is insufficient test data using this new test procedure for the manufacturers to be able to predict their ceiling fans' compliance with the proposed standards, particularly in the popular "Standard" and "Hugger" categories.

Sincerely,
William J. Baer

[FR Doc. 2017-00474 Filed 1-18-17; 8:45 am]

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Part IV

Department of Health and Human Services

42 CFR Parts 70 and 71

Control of Communicable Diseases; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Parts 70 and 71

[CDC Docket No. CDC–2016–0068]

RIN 0920–AA63

Control of Communicable Diseases

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is issuing this final rule (FR) to amend its regulations governing its domestic (interstate) and foreign quarantine regulations to best protect the public health of the United States. These amendments have been made to aid public health responses to outbreaks of new or re-emerging communicable diseases and to accord due process to individuals subject to Federal public health orders. In response to public comment received, the updated provisions in this final rule clarify various safeguards to prevent the importation and spread of communicable diseases affecting human health into the United States and interstate.

DATES: This rule is effective February 21, 2017.

FOR FURTHER INFORMATION CONTACT: Director, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–E03, Atlanta, GA 30329, or email dgmqpolicyoffice@cdc.gov.

SUPPLEMENTARY INFORMATION: Based on public comment received to the Notice of Proposed Rulemaking (NPRM) (81 FR 54230) this final rule, among other things: Withdraws a provision regarding “Agreements” as proposed in the NPRM, requires CDC to issue a federal order within 72 hours after apprehending an individual, increases the threshold for those who may be considered “indigent” to 200% of the applicable poverty guideline, adds a definition for “Secretary,” adds a requirement for CDC to provide legal counsel for isolated or quarantined individuals qualifying as indigent who request a medical review, modifies the definition of “non-invasive,” includes “known or possible exposure” in the list of information that may be collected during a public health risk assessment, and strengthens due process protections by ensuring that CDC will arrange for translation or interpretation services for

public health orders and medical reviews as needed. In implementing quarantine, isolation, or other public health measures under this Final Rule, HHS/CDC will seek to use the least restrictive means necessary to prevent the spread of communicable disease.

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I. Executive Summary

A. Purpose of the Action

HHS/CDC has statutory authority (42 U.S.C. 264, 265) to promulgate regulations that protect U.S. public health from communicable diseases, including quarantinable communicable diseases as specified in an Executive Order of the President. *See* Executive Order 13295 (April 4, 2003), as amended by Executive Order 13375 (April 1, 2005) and Executive Order 13674 (July 31, 2014). The need for this rulemaking was reinforced during HHS/CDC’s response to the largest outbreak of Ebola virus disease (Ebola) on record, followed by the recent outbreak of Middle East Respiratory Syndrome (MERS), both quarantinable communicable diseases, and repeated outbreaks and responses to measles, a non-quarantinable communicable disease of public health concern. This

final rule will enhance HHS/CDC's ability to prevent the introduction, transmission, and spread of communicable diseases into the United States and interstate by clarifying and providing greater transparency regarding its response capabilities and practices.

B. Summary of Major Provisions

Both the domestic and foreign portions of this regulation include new proposed public health definitions; new regulatory language implementing HHS/CDC's activities concerning non-invasive public health prevention measures (*i.e.*, traveler health screening) at U.S. ports of entry and other U.S. locations (*i.e.*, railway stations, bus terminals); and provisions affording due process to persons served with a Federal public health order (*e.g.*, isolation, quarantine), including requiring that HHS/CDC explain the reasons for issuing the order, administrative processes for appealing the order, and a mandatory reassessment of the order.

The domestic portion of this final rule includes a requirement that commercial passenger flights report deaths or illnesses to the CDC. It also includes a provision requiring that individuals apply for a travel permit if they are under a Federal quarantine, isolation, or conditional release order (unless the specific travel is authorized by the Federal conditional release order) or if a State or local public health department requests CDC assistance in enforcing a State or local quarantine or isolation order. Additionally, the domestic portion of this final rule includes new regulatory language clarifying when an individual who is moving between U.S. states is "reasonably believed to be infected" with a quarantinable communicable disease in a "qualifying stage." These determinations are made when the CDC considers the need to apprehend or examine an individual for potential infection with a quarantinable communicable disease. The foreign portion of this final rule includes new regulatory authority permitting the CDC Director to prohibit the importation of animals or products that pose a threat to public health.

HHS/CDC has also changed the text of the regulation to reflect modern terminology, technology, and plain language used by private industry, public health partners, and the public. The final rule also authorizes public health monitoring through electronic or internet-based means of communication for individuals under a Federal conditional release order who are reasonably believed to be exposed to or

infected with a quarantinable communicable disease. This would include communication through email and webcam application tools. Finally, while neither modifying nor authorizing additional criminal penalties for violations of quarantine rules and regulations, this final rule updates regulatory language to align with existing criminal penalties set forth in statute.

C. Summary of Costs and Benefits

The regulatory impact analysis quantitatively addresses the costs and benefits associated with this final rule. The economic impact analysis of this final rule is subdivided into two sections.

The first analysis summarizes the economic impact of changes to 42 CFR 70.1, 42 CFR 71.1/71.4/71.5 for which the primary costs for submitting passenger and crew information to HHS/CDC are incurred by airlines and vessel operators and the primary benefit is improved public health responsiveness to assess and offer post-exposure prophylaxis to travelers potentially exposed to communicable diseases of public health concern. The most likely estimates of annual costs to airlines, vessel operators, the United States government, and public health departments are low (\$32,622, range \$10,959 to \$430,839) because the final rule primarily codifies existing practice or improves alignment between existing regulatory text and the International Civil Aviation Organization (ICAO)'s guidelines for symptoms to report. The cost estimates in this final rule are based on (1) an anticipated small increase in the number of illness reports delivered by airlines and processed by HHS/CDC and (2) increased costs for airlines and vessel operators to comply with HHS/CDC orders for traveler and crew contact data, to the extent that such information is readily available and already maintained, and not already transmitted to the U.S. Customs and Border Protection (CBP). The cost estimate also includes an increase in costs for public health departments to contact more exposed travelers due to the availability of improved contact data.

The best estimate of the annual quantified benefits of the final rule are \$110,045 (range \$26,337 to \$297,393) and mostly result from increased efficiencies for HHS/CDC and State and local public health departments to conduct contact investigations among travelers on an aircraft exposed to communicable diseases of public health concern, especially for measles and tuberculosis. To the extent that improved responsiveness of airlines to

HHS/CDC traveler data orders may result from the implementation of the provisions in this final rule, HHS/CDC may become better able to respond to infectious diseases threats and (1) reduce case-loads during infectious disease outbreaks, (2) reduce public anxiety during disease outbreaks, (3) mitigate economic impacts on businesses as a consequence of reduced public anxiety associated with quarantinable communicable disease outbreaks initiated by international travelers (such as have been observed during outbreak of severe acute respiratory syndrome in Canada or Middle East respiratory syndrome in South Korea), and (4) reduce the amount of personnel labor time to conduct large-scale contact investigations in response to a new infectious disease or one with larger scale public health and medical consequences like Ebola.

The second analysis in this final rule is of a number of provisions that aim to improve transparency of how HHS/CDC uses its regulatory authorities to protect public health. HHS/CDC believes that improving the quality of its regulations by providing clearer explanations of its policies and procedures is an important public benefit. However, HHS/CDC is not able to attach a dollar value to this added benefit in a significant way.

II. Public Participation

On August 15, 2016, HHS/CDC published a notice of proposed rulemaking (NPRM) (81 FR 54299) to amend 42 CFR part 70 (interstate) and 42 CFR part 71 (foreign) quarantine regulations. The public was invited to comment on these amendments. The comment period ended October 14, 2016. In the NPRM, HHS/CDC specifically requested public comment on the following:

- Whether the use of the standard definition of "indigent" is an appropriate threshold to determine whether an individual cannot afford representation and therefore should be appointed a medical representative at the government's expense and whether the public believes that there may be non-indigent individuals, as defined in the NPRM, who may have difficulty affording a representative;
- The definition of *public health emergency* and its utility in identifying communicable diseases that "would be likely to cause a public health emergency if transmitted to other individuals" under 42 U.S.C. 264(d)(2)(B);

- Requirements relating to travelers under a Federal order of isolation, quarantine, or conditional release; specifically, on whether stakeholders

have concerns regarding the requirement imposed on conveyance operators to not “knowingly” transport individuals under a Federal order and the feasibility of this requirement and the application of this provision to individuals under State/local order as well as individuals traveling entirely within a State.

- Public health prevention measures and whether the public has any concerns regarding the mandatory health screening of passengers using non-invasive means as defined in the proposal or the collection of personal information from screened individuals for the purposes of contact tracing;
- Payment for care and treatment, and whether there are any concerns that all third party payments be exhausted prior to the Federal reimbursement of medical care or treatment for individuals placed under a Federal order for quarantine, isolation, or conditional surveillance;
- The application of requirements relating to issuance of a Federal order for quarantine, isolation or conditional release as it applies to groups and whether this provision sufficiently informs the public of the important details concerning circumstances during which HHS/CDC would issue to groups or individuals Federal orders for quarantine, isolation, and conditional release and the duration and conditions of such orders;
- Whether 72 hours is the necessary amount of time to conduct a reassessment after a Federal order is first issued, or if the reassessment should take place earlier or later;
- Whether or not the public sees a role for the Federal government to ensure that basic living conditions, amenities, and standards are satisfactory when placing individuals under Federal orders;
- Whether the definition of “non-invasive” aligns with common perceptions of what constitutes non-invasive procedures that may be conducted outside of a traditional clinical setting;
- Whether the penalties proposed, and the circumstances under which such penalties may be imposed, were clearly explained;
- The applicability of the December 13, 2007 system of records notice (SORN) to the activities proposed (72 FR 70867), and whether the SORN sufficiently addresses the public’s concerns related to maintenance and protection of the data elements proposed;
- The request for a passenger and crew manifest within 24 hours and whether the provision grants operators

of airlines sufficient time for operators to respond to manifests orders;

- The likelihood that the passenger and crew data elements requested are already collected and maintained by airline operators for transmission to CDC;
- Any industry concerns regarding whether proposed section 71.63 sufficiently details the circumstances under which HHS/CDC may impose an embargo on the importation of animals, articles, or things, including how such an embargo would be implemented, as well as any concerns regarding coordination with other Federal agencies.

The public comment period for the proposed rule ended on October 14, 2016 and HHS/CDC received 15,800 comments from individuals, stakeholders, and groups. A summary of those comments and responses to those comments are found at Section IV, below.

II. Background

A. Legal Authority

The primary legal authorities supporting this rulemaking are sections 361 and 362¹ of the Public Health Service Act (42 U.S.C. 264, 265). HHS/CDC also believes that the following Public Health Service Act sections are relevant with respect to this rulemaking: section 311 (42 U.S.C. 243), section 321 (42 U.S.C. 248), section 322 (42 U.S.C. 249), section 365 (42 U.S.C. 268), and sections 367–69 (42 U.S.C. 270–72). A detailed explanation of these legal authorities was provided in the NPRM published at 81 FR 54230 (Aug. 15, 2016).

B. Regulatory History

On August 15, 2016, HHS/CDC published a Notice of Proposed Rulemaking to update 42 CFR 70 (domestic) and 42 CFR 71 (foreign) quarantine regulations. These amendments were proposed to aid public health responses to outbreaks of communicable disease, such as the largest outbreak of Ebola virus disease (Ebola) on record, Middle East Respiratory Syndrome (MERS), both quarantinable communicable diseases, and repeated outbreaks of measles in the United States, a non-quarantinable communicable disease of public health concern. (81 FR 54299). Communicable diseases of public health concern are those diseases that because of their

potential for spread, particularly during travel, may require a public health intervention. The provisions contained within the proposal were designed to enhance HHS/CDC’s ability to prevent the further importation and spread of communicable diseases into the United States and interstate by clarifying HHS/CDC’s response capabilities, practices, and making them more transparent.

III. Summary of the Final Rule

Upon consideration of public comment, the following is a section-by-section summary of the changes from the proposed text that HHS/CDC made to parts 70 and 71:

A. General References to “CDC” and “Director” in Parts 70 and 71

Throughout the regulatory text in parts 70 and 71, references to “CDC” or “HHS/CDC” have been replaced with “Director.” This is in keeping with the common practice that federal agencies act through employees and officials to whom the authority involved has been delegated. *Director* is currently defined in sections 70.1 and 71.1 to mean “the Director, Centers for Disease Control and Prevention, Department of Health and Human Services, or another authorized representative as approved by the CDC Director or the Secretary of HHS.” Where it is necessary to exclude CDC employees or officials from undertaking certain functions this has been indicated by use of parenthesis, e.g., “Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order).” This is a stylistic change from the NPRM, but does not result in a substantive change in the final rule.

B. Definitions (Sections 70.1 and 71.1(b))

- The definition of *Agreements* has been removed.
- The definition of *Electronic or internet-based monitoring* has been modified to include “communication through” these means and “audio” conference.
- The definition of *Indigent* has been modified to increase the threshold to 200% of the applicable poverty guidelines.
- The definition of *Ill person* under section 71.1 has been modified to include a person who “Has a fever that has persisted for more than 48 hours” or “Has acute gastroenteritis, which means either diarrhea, defined as three or more episodes of loose stools in a 24-hour period or what is above normal for the individual, or vomiting accompanied by one or more of the following: One or more episodes of loose stools in a 24-

¹ Section 3 of Executive Order 13295 (April 4, 2003) states that the functions of the President under sections 362 and 364(a) of the Public Health Service Act (42 U.S.C. 265 and 267(a)) are assigned to the HHS Secretary.

hour period, abdominal cramps, headache, muscle aches, or fever (temperature of 100.4 °F [38°C] or greater).” This language was quoted verbatim in the preamble of the NPRM at 81 FR 54305 but was inadvertently omitted from the proposed regulatory text.

- The definition of *Medical Examination* has been modified to indicate that the health worker conducting the assessment must be “licensed.”

- The definition of *Medical Representative* has been changed to *Representatives* and now includes for an indigent individual the additional appointment of “an attorney who is knowledgeable of public health practices” if the indigent individual requests a medical review.

- The definition of *Non-invasive* has been modified to: (1) Replace “physical examination” with “visual examination;” (2) specify that the individual performing the assessment must be a “public health worker (*i.e.*, an individual with education and training in the field of public health);” and (3) remove “auscultation, external palpation, external measurement of blood pressure.”

- A definition for *Secretary* has been added. *Secretary* means the Secretary of Health and Human Services (HHS) or any other officer or employee of that Department to whom the authority involved has been delegated. We note that while the NPRM did not propose this definition, the NPRM referenced the *Secretary* in defining *Public Health Emergency*. Thus, HHS/CDC considers it useful to also define the term *Secretary*.

C. Apprehension and Detention of Persons With Quarantinable Communicable Diseases (Section 70.6)

This provision is has been finalized as proposed, with the exception that references to CDC have been replaced with Director throughout this section. HHS/CDC has also added a requirement that the Director arrange for adequate food and water, appropriate accommodation, appropriate medical treatment, and means of necessary communication, for individuals who are apprehended or held in quarantine or isolation. Similar language has been added to an analogous provision at Section 71.33(a).

D. Medical Examinations (Sections 70.12 and 71.36)

These provisions are finalized as proposed, with the exception that references to CDC have been replaced with Director throughout this section. HHS/CDC has also added a requirement

that the Director, as part of the Federal order, advise the individual that the medical examination shall be conducted by an authorized and licensed health worker with prior informed consent.

E. Requirements Relating to the Issuance of a Federal Order for Quarantine, Isolation, or Conditional Release (§§ 70.14 and 71.37)

Paragraphs (a)(5) and (a)(4) of these provisions have been modified, respectively, to require that the Federal order include an explanation that the Federal order will be reassessed no later than 72 hours after it has been served and an explanation of the right to request a medical review, present witnesses and testimony at the medical review, and to be represented at the medical review by either an advocate (*e.g.*, an attorney, family member, or physician) at the individual’s own expense, or, if indigent, to have representatives appointed at the government’s expense. Paragraph (b) of these provisions has been modified to require that a Federal public health order be served within 72 hours of an individual’s apprehension. Paragraph (c) has been modified to require that the Director arrange for translation or interpretation services of the Federal order as needed. References to CDC have been replaced with Director throughout this section.

F. Mandatory Reassessment of a Federal Order for Quarantine, Isolation, or Conditional Release (§§ 70.15 and 71.38)

These provisions have been modified to include paragraph (g) which states that the Director shall arrange for translation or interpretation services of the Federal order as needed. References to CDC have been replaced with Director throughout this section.

G. Medical Review of a Federal Order for Quarantine, Isolation, or Conditional Release (§§ 70.16 and 71.39)

Paragraph (f) of these provisions has been modified to reference “Representatives,” consistent with the change in definition. Paragraph (f) of these provisions has also been modified to remove, “and cannot afford a medical representative” because this language is duplicative and unnecessary if the individual has already qualified as indigent. Paragraph (k) of these provisions has been modified to state: “The medical review shall be conducted by telephone, audio or video conference, or through other means that the medical reviewer determines in his/her discretion are practicable for allowing the individual under

quarantine, isolation, or conditional release to participate in the medical review.” These provisions have also been modified to include paragraph (q) which states that the Director shall arrange for translation or interpretation services as needed for purposes of this section. References to CDC have been replaced with Director throughout this section.

H. Administrative Records Relating to a Federal Order for Quarantine, Isolation, or Conditional Release (§§ 70.17 and 71.29)

These sections have been modified to remove paragraphs (5) regarding agreements between CDC and the individual.

I. Payment for Care and Treatment (§§ 70.13 and 71.30)

These provisions have been finalized as proposed, with the exception that references to CDC have been replaced with Director throughout this section.

J. Agreements (§§ 70.18 and 71.40)

These provisions have been removed.

K. Penalties (§§ 70.18 and 71.2)

The content of these provisions has been finalized as proposed. Proposed § 70.19 *Penalties* has been moved to § 70.18, since proposed § 70.18 *Agreements* has been removed from this final rule.

L. Public Health Prevention Measures To Detect Communicable Disease (§§ 70.10 and 71.20)

Paragraph (b) has been modified to include “known or possible exposure” information to the list of information that may be collected. References to CDC have been replaced with Director throughout this section.

M. Requirements Relating to Travelers Under a Federal Order of Isolation, Quarantine, or Conditional Release (Section 70.5)

Paragraph (a), (a)(4), (b)(1), (b)(2), and (c) of this provision have been modified to remove “agreements.” Paragraph (d) has been modified to add “to individuals traveling entirely intrastate and to conveyances that may transport such individuals.” The language in paragraph (d) was discussed in the NPRM at 81 FR 54243 and public comment concerning intrastate application of this provision was explicitly solicited. The language, however, was inadvertently omitted from the regulatory text. References to CDC have also been replaced with Director throughout this section. In response to public comments, HHS/CDC

has included a requirement that the Director respond to a request for a travel permit within five (5) business days and to an appeal under this section within three (3) business days. Public comments concerning this provision are addressed below.

N. Report of Death or Illness Onboard Aircraft Operated by an Airline (§ 70.11)

This provision has been finalized as proposed, with the exception that references to CDC have been replaced with Director throughout this section.

O. Requirements Relating to Transmission of Airline and Vessel Passenger, Crew, and Flight and Voyage Information for Public Health Purposes (§ 71.4 and 71.5)

These provisions have been finalized as proposed, with the exception that the title has been modified to remove references to collection and storage of information to more accurately reflect the requirements under this section and references to CDC have been replaced with Director throughout this section.

P. Suspension of Entry of Animals, Articles, or Things From Designated Foreign Countries and Places Into the United States (§ 71.63)

This provision has been finalized as proposed with the exception that references to CDC have been replaced with Director throughout this section.

Q. Report of Death or Illness (§ 71.21)

The title of this provision has been finalized as proposed, to remove the word "Radio."

V. Overview of Public Comments to the 2016 NPRM

On August 15, 2016 HHS/CDC published a Notice of Proposed Rulemaking proposing to amend the current interstate (domestic) and foreign quarantine regulations for the control of communicable diseases. The NPRM included a 60-day public comment period and during this time, HHS/CDC received 15,800 comments from individuals, groups, organizations, industry, and unions. Comments were both in support of and in opposition to the regulation. Many public comments expressed concern that these updated regulations sought to compel medical treatment or vaccination without patient consent. One association stated its strong objection "to the coercive imposition of treatment, including vaccination, without the genuine consent of the patient."

HHS/CDC begins this section by stating that these regulations do not compel vaccination or involuntary

medical treatment. In keeping with current practice, HHS/CDC will continue to recommend care and treatment, including post-exposure prophylaxis when indicated, to individuals who are either sick with or at risk of disease following exposure to a communicable disease of public health concern.

HHS/CDC also received comments relating to immigration policy and regulations, issues of citizenship, border security, religion, personal testimony regarding adverse vaccine events, and requests to apply these regulations only to individuals who are not citizens of the United States. These comments are beyond the scope of this final rule and have not been included in this discussion. However, HHS/CDC notes that it will continue to apply communicable disease control and prevention measures uniformly to all individuals in the United States, regardless of citizenship, religion, race, or country of residency.

HHS/CDC also received public comment regarding disinsection (*i.e.*, measures to control or kill insect vectors of disease) and fumigation procedures, citing HHS/CDC's statutory authorities relating to inspection, fumigation, and pest extermination. We note that while HHS/CDC maintains regulations at 42 CFR 70.2 and 71.32(b) implementing this statutory authority, such comments are outside of the scope of this final rule, which did not include proposed changes to these regulatory provisions.

The following is a discussion of public comments received that are applicable and within the scope of the regulation. Topics including: Accountability, Administrative Records, Agreements, Apprehension, Authority (including Scope), Conditional Release, Constitutional Issues (including Amendments, Court Cases, and Habeas Corpus), Data Collection, Definitions, Detention, Due Process, Economic Impact, Electronic Monitoring, Exposure, Informed Consent, Least Restrictive Means, Minors, Medical Assessments, Examination, Notice, Penalties, Privacy, Qualifying Stage, Quarantine, Quarantinable Communicable Diseases List, and others are discussed.

A summary of comments and a response to those comments are found below, organized by general and specific comments that apply to both parts 70 and 71, comments that only apply to part 70 (interstate), and comments that only apply to part 71 (foreign).

A. Provisions Applicable to Both Parts 70 and 71

a. General Comments

Since posting the proposed regulation on August 15, 2016, HHS/CDC received 15,800 public comments. HHS/CDC received several comments from individuals, groups, or industry requesting to extend the 60-day comment period. In light of the number of comments submitted, HHS/CDC has determined that a 60-day comment period was both fair and sufficient to adequately inform the public of the contents of this rulemaking, allow the public to carefully consider the rulemaking, and receive informed public feedback. Thus, HHS/CDC declines to reopen the comment period.

Several commenters requested that HHS/CDC withdraw the NPRM in its entirety. A non-profit organization stated that the "NPRM would be, if adopted, a direct and onerous infringement of the personal liberties of Americans and an unnecessary aggressive method of assisting in the control of communicable disease." Another commenter said that the "NPRM is premature." HHS/CDC disagrees and declines to withdraw the proposal in its entirety because it contains important measures that will aid the public health response to prevent the introduction, transmission, and spread of communicable diseases into and within the United States. Moreover, in the spirit of transparency, these measures, which are largely current practice, are being published and codified to make the public aware of their use.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations stating that it should promulgate a separate rule guaranteeing humane conditions of confinement. HHS/CDC disagrees that such a separate rule is needed and believes that the current final rule adequately addresses these concerns, as discussed in detail below.

HHS/CDC received a comment that the proposed rule does not comply with Executive Order 12866 because there is no public need for the rule and it did not adequately assess the costs and benefits of the rule, including the alternative of not regulating. HHS/CDC disagrees. As discussed in detail below, this rule describes the public health measures that may be used in response to outbreaks of communicable diseases, such as the recent largest recorded outbreak of Ebola. The economic impact analysis has been clarified to more clearly differentiate quarantinable and non-quarantinable diseases. The

economic impact analysis also examines the costs and benefits of the Final Rule measured against current practices (*i.e.*, a status quo baseline). Both the costs and benefits of this Final Rule are small because the provisions set forth are primarily a codification of current practices, based on existing regulatory authorities.

A public health research center commented that there is no evidence that measures employed at points of entry were effective during the response to the 2014–2016 Ebola outbreak and that HHS/CDC is attempting to codify these ineffective practices for use in future disease outbreaks. They further noted that despite greater than 99% complete monitoring, zero cases of Ebola were detected among those monitored. HHS/CDC appreciates this comment and recognizes the challenges presented by measuring the benefits of prevention in public health.

HHS/CDC disagrees that the measures employed in response to the 2014–16 Ebola outbreak were ineffective and that it is seeking to codify ineffective measures. HHS/CDC considers more than 99% complete monitoring a successful effort in State and Federal cooperation in response to an unprecedented outbreak of Ebola. Second, rather than the number of cases detected, HHS/CDC considers the key metrics of effectiveness to be the number of people who were able to continue to travel safely without fear of disease spread and the ability to facilitate rapid isolation and evaluation of the approximately 1400 individuals who developed illness compatible with Ebola during the 21-day monitoring period. Finally, we note that this commenter limited his or her statement to HHS/CDC measures put into place at U.S. ports of entry during the Ebola response.

The enhanced public health risk assessment protocol put into place at U.S. ports of entry in response to the Ebola outbreak was one part of a layered risk mitigation program to prevent the importation and spread of Ebola within the United States, which included exit screening in the affected countries as recommended by the World Health Organization (WHO) (see Statement on the 1st meeting of the International Health Regulations [IHR] Emergency Committee on the 2014 Ebola outbreak in West Africa 8/8/2014) and a reliance on air industry partners for detection and reporting of potentially ill travelers prior to arrival.

The enhanced entry risk assessment process was instituted after an individual infected with Ebola entered the United States and transmitted the

disease. This case demonstrated that the processes then in place to prevent departure of individuals exposed to or infected with Ebola in affected West African countries could not detect persons who were exposed but were unaware of or denied such exposure and were potentially incubating the infection. To further reduce the risk of introduction and spread, HHS/CDC recommended monitoring of all potentially exposed individuals by a public health authority through the 21-day risk period after potential exposure, rather than relying on previously recommended self-monitoring. Monitoring was viewed as the least restrictive alternative to widespread quarantine and travel bans demanded by some members of the public that would ultimately have hampered the response efforts in West Africa and domestically. HHS/CDC, along with its Federal and State partners, implemented an entry process by which individuals identified as having recently traveled to, from, or through an affected country entered through five ports of entry where public health staff and partners were stationed, submitted accurate and complete contact information, were checked for symptoms, and were provided answers to Ebola risk assessment questions.

This was done for several reasons:

- To ensure that any individual entering the United States who could have been exposed to or infected with Ebola in a country experiencing an Ebola outbreak was identified and reported to the State and local health department of final destination so that, if the individual became ill, State or local health departments could rapidly notify healthcare providers prior to the individual's arriving at a hospital. This process was designed specifically to prevent unknowing individuals from exposing others such as occurred in Texas when a patient exposed two healthcare workers.

- While HHS/CDC acknowledges that a public health worker may be unlikely to encounter someone with symptoms at the moment of entry because of the 21-day incubation period, individuals coming from the outbreak countries frequently traveled for well over 24 hours and in many cases had itineraries that involved interstate movement within the United States. The odds of developing symptoms during that travel, and potential onward travel, were considered non-trivial, and public health measures to detect symptoms upon entry were considered warranted given the serious morbidity and costs associated with Ebola.

- The risk assessment at the limited ports of entry provided an important opportunity for HHS/CDC to stratify the risk of developing Ebola for every individual who entered from the affected countries. It allowed HHS/CDC to work with State and local health departments in implementing the least restrictive means of monitoring individuals for development of symptoms. HHS/CDC notes that there were no Federal quarantine orders issued because of the availability of monitoring options provided by State and local authorities under the *Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure*.

- The encounter also provided an opportunity to provide travelers with educational materials, orientate them to the monitoring program (Check and Report Ebola (CARE)), and facilitate reporting of the traveler's health status to State and local health departments.

The enhanced entry risk assessment and monitoring process described above was developed in response to the epidemiological profile of Ebola and the complexities of a 21-day incubation period. However, in the event of an outbreak of a different communicable disease requiring enhanced assessment or monitoring of travelers (whether quarantinable or non-quarantinable), HHS/CDC, in concert with Federal and State partners, may implement a different system of risk assessment and monitoring. HHS/CDC would tailor the program in accordance with the scientific evidence of the situation and the utility and feasibility of the program given the availability of resources.

The same public health research center commented that employing non-evidence-based measures is contrary to the United States' international legal agreements, specifically mentioning the public health measures implemented during the response to Ebola as they pertain to the International Health Regulations (IHR 2005). The commenter further stated that given the absence of evidence to support the use of travel monitoring and quarantine, HHS/CDC should proceed cautiously before employing these measures in the future.

Having addressed the commenter's concern regarding the evidence of the effectiveness of public health measures at ports of entry above, HHS/CDC concurs with the commenter that the use of quarantine and travel restrictions, in the absence of evidence of their utility, is detrimental to efforts to combat the spread of communicable disease. However, HHS/CDC disagrees that it used non-evidence based measures in contravention of the IHR.

To the contrary, HHS/CDC used the best available science and risk assessment procedures in designing a port of entry risk assessment and management program that took into account available resources, circumstances in the countries with Ebola outbreaks, and principles of least restrictive means to successfully ensure that measures to ban travel between the United States and the affected countries were unnecessary. These measures would have negatively impacted the efforts to combat Ebola in the region and would have had dramatic negative implications for travelers and industry.

Furthermore, the measures did not unduly affect travel or trade beyond the voluntary changes made by industry and travelers. HHS/CDC believes that CDC's entry risk assessment and management program was appropriate, commensurate with the risk, and consistent with the following WHO recommendation: "[Member] States should be prepared to detect, investigate, and manage Ebola cases; this should include assured access to a qualified diagnostic laboratory for Ebola and, where appropriate, the capacity to manage travelers originating from known Ebola-infected areas who arrive at international airports or major land crossing points with unexplained febrile illness." *WHO Statement on the 1st meeting of the IHR Emergency Committee on the 2014 Ebola outbreak in West Africa* (Aug. 8, 2014). Travelers were assessed for risk on an individual basis upon entry; and any individual who met the pre-defined symptom threshold (based on exposure level) was medically evaluated and referred to care as needed. No Federal quarantine orders were issued for the duration of the response because HHS/CDC in coordination with State and local public health authorities was able to tailor its interventions to allow onward travel.

Future outbreaks may necessitate a different combination of public health measures at ports of entry. In those circumstances, HHS/CDC will use the best available science to assess the risk of importation and spread within the United States.

One commenter suggested that if HHS/CDC were to apply the "Precautionary Principle," it would not promulgate these regulations. HHS/CDC notes first that the "precautionary principle," often described as the avoidance of harm when there is scientific uncertainty about risks, originated in environmental contexts and remains largely associated with environmental issues. Invoking the precautionary principle in an environmental context, for instance,

places the onus on those considering a potentially harmful action, such as drilling or mining near a watershed, to prove its safety in advance. The principle may be used by policy makers to justify discretionary decisions in situations where there is the possibility of harm from making a certain decision (e.g. taking a particular course of action) when extensive scientific knowledge on the matter is lacking.

HHS/CDC disagrees that this regulation will have harmful effect or that these measures lack a scientific basis for protecting public health. In fact, as described above regarding the response efforts to the 2014–2016 Ebola response, HHS/CDC has successfully employed the measures outlined in this regulation for many years. Again, the provisions outlined through this regulation are not new practices, nor new authorities, but a codification of HHS/CDC practice to protect public health.

One commenter suggested that education on healthy practices would be more effective than regulatory provisions. Another commenter stated that our immune systems would ward off communicable disease if we encourage clean water, adequate shelter, effective sewage treatment, and nutritious food. HHS/CDC agrees that these necessities are important to public health, and we rely on health communication often to educate the public on how to protect themselves and others from certain communicable diseases. For example, HHS/CDC routinely advises people with seasonal influenza to stay home from work and school, to cover their coughs and sneezes, and to wash their hands. HHS/CDC also works with State, local, and airport authorities in posting health education materials for the public. However, in certain circumstances, when a communicable disease poses a severe health threat to others, additional measures may be needed to protect the public's health. This is particularly important in situations when the infectious individual has disregarded public health recommendations by, for example, refusing to take prescribed medications to treat infectious tuberculosis or traveling while infectious. In such situations, it may be necessary to use public health authorities to require the individual to remain in isolation or to prevent travel to protect the public's health.

HHS/CDC received a few comments suggesting that publication of the NPRM in the **Federal Register** was not sufficient to inform the public of these proposed updates. One comment questioned why the proposed

regulations were not more widely disseminated through media outlets. In response, HHS/CDC notes that Federal courts have long recognized that publication in the **Federal Register** is legally sufficient for giving affected persons notice of proposed rulemaking. *See Federal Crop Ins. Corp. v. Merrill*, 332 U.S. 380, 385 (1947) ("Congress has provided that the appearance of rules and regulations in the **Federal Register** gives legal notice of their contents."). The **Federal Register**, within the National Archives and Records Administration, is the official publication for all Federal agency rules, proposed rules, and notices of Federal agencies and organizations, as well as for Executive Orders and certain other presidential documents. Individuals interested in obtaining more information regarding HHS/CDC's regulatory processes, including input provided by persons and organizations, may examine the regulatory docket or submit a request through the Freedom of Information Act.

HHS/CDC received a comment stating that HHS/CDC should, by regulation, provide sufficient public health justification for screening practices to support its proposed public health prevention measures at ports of entry. While HHS/CDC agrees that it should provide sufficient public health justification for large-scale screening practices, HHS/CDC disagrees that this justification should be formalized in regulations. During the 2014–2016 Ebola epidemic, HHS/CDC issued *Interim U.S. Guidance for Monitoring and Movement of Persons with Potential Ebola Virus Exposure* to assist HHS/CDC staff and public health partners engaged in the response. The guidance provided public health authorities and partners with recommendations for monitoring people potentially exposed to Ebola and for evaluating their intended travel, including the application of movement restrictions when necessary. From August 2014–December 2015, the guidance was accessed online approximately 334,000 times, with more than 88,000 views during the first 4 days after the October 2014 update that added recommendations for active monitoring and clarified travel and movement restriction recommendations. Updates to the guidance to accommodate new information and changes in the outbreak situation continued through 2015. The guidance was retired on February 19, 2016, when more than 45 days had passed since Guinea was declared free of Ebola virus transmission, signaling widespread human-to-human transmission in the

affected countries was at an end. Formalizing this guidance in regulation would have deprived HHS/CDC of the needed flexibility to respond to public health events as they occurred, would have proved administratively burdensome and unnecessary, and would have potentially delayed prevention measures therefore resulting in a less effective response. HHS/CDC will consider the need for similar guidance during future outbreaks taking into account the extent of the outbreak and the risk of importation and spread of disease into the United States.

HHS/CDC received several comments suggesting that the proposed regulations were not written in plain language and were therefore difficult to understand. One commenter also noted errors in the document such as hyperlinks, references, and footnotes. This commenter also reviewed the NPRM for inconsistencies, conflicts, missing definitions, misleading language, and ambiguities. HHS/CDC thanks these commenters for the input. We have developed communication materials and published them to our Web site to help facilitate the review and comprehension of these documents. Interested persons should see <http://www.cdc.gov/quarantine/notice-proposed-rulemaking-control-communicable-diseases.html>.

One commenter opposed the rule because of a perceived negative social impact upon individuals placed under a public health order. We respond that one compelling reason for the publication of this final rule is to make the public aware of these measures so that the words, purposes, and meanings of “quarantine” and “isolation” become more familiar and less likely to cause public anxiety and stigmatization.

HHS/CDC received comments suggesting that, to best prevent the introduction of communicable diseases into the U.S., individuals who travel to or originate in countries with high risk of communicable disease should not be allowed to enter (or return to) the United States. On March 27, 2015, HHS/CDC published a Notice in the **Federal Register** titled *Criteria for Recommending Federal Travel Restrictions for Public Health Purposes, Including for Viral Hemorrhagic Fevers*. See 80 FR 16400 (Mar. 27, 2015). The Notice describes the tools the Federal government has to ensure that people who pose a public health risk do not board flights or enter the United States without a public health evaluation. See 80 FR 16400 (Mar. 27, 2015). It is the policy of HHS/CDC to work with the Department of State, and any other relevant Federal and State agencies to

ensure infected U.S. citizens seeking to return to the U.S. do so in a manner that does not place the public at risk.

A few commenters expressed concern, as parents or guardians, about their rights with respect to children or minors. Specifically, these commenters wondered whether children/minors would be separated from parents/guardians during a public health risk assessment. HHS/CDC thanks the commenters for these questions and appreciates the opportunity to respond. In response, HHS/CDC notes that these regulations do not limit the rights that parents or guardians may have over minor children, including the right to make medical decisions. Notwithstanding, children are included in the definition of “individuals” as used in these regulations and thus minor children may be subject to apprehension, detention, examination, and conditional release for quarantinable communicable diseases to the same extent as adults. In such rare circumstances, HHS/CDC will work with the child’s parent or guardian to ensure that the rights accorded to any individual subject to Federal isolation or quarantine, such as the opportunity for an administrative medical review, are adequately protected.

In addition, and in keeping with standard public health practice, parents or guardians while in the presence of infected minor children may be required to adhere to infection control precautions for their own protection. Such protections may include wearing personal protective equipment (such as a mask) while in close proximity to the child/minor to avoid further transmission of the illness. In extremely rare circumstances, such as a child infected with Ebola, the risk may be too great to allow a parent to remain with a child; however, every effort will be made to facilitate communication between a parent and a minor child through the least restrictive means, for example, through the use of technology.

One commenter asked about HHS/CDC obtaining the consent of a parent or legal guardian prior to the medical examination, quarantine, or treatment of minors. We respond that HHS/CDC will adhere to all applicable laws regarding the medical examination or treatment of minors. If minors are traveling unaccompanied by a parent or legal guardian and are believed to be infected with or exposed to a quarantinable communicable disease, HHS/CDC will use its best efforts to contact a parent or guardian to obtain consent prior to medical examination. In addition, HHS/CDC will not restrict a minor’s ability to communicate with family or legal

counsel hired by the minor’s parent or legal guardian. As explained further below, HHS/CDC will appoint representatives, including a medical representative and an attorney, if the individual (including a minor’s parent or legal guardian) is indigent and requests a medical review. HHS/CDC clarifies, however, that the public health measures included in this final rule, including apprehension, examination, quarantine, and isolation, do not require a parent or legal guardian’s consent as a prerequisite to their application. However, in response to concerns about informed consent, HHS/CDC has added regulatory language requiring that the Director advise the individual that if a medical examination is required as part of a Federal order that the examination will be conducted by an authorized and licensed health worker with prior informed consent.

b. Scope and Authority

HHS/CDC received comments from the public questioning whether HHS/CDC is a part of the Federal government and has the authority to propose and promulgate regulations, or whether the Agency is a private entity. The “Communicable Disease Center” became part of the U.S. Public Health Service on July 1, 1946 and is an Agency within the U.S. Department of Health and Human Services. For more information on the history of CDC, please see <http://www.cdc.gov/museum/timeline/index.html>.

HHS/CDC received numerous comments from the public seeking clarity on the scope of authority the Agency has to take actions described in this regulation. Specifically, HHS/CDC received comments questioning whether the authority to detain an individual may be exercised by a Federal agency of government, instead of the U.S. President or Congress. Several commenters specifically questioned whether the wording of the regulation was too “general” and expressed concern over its potential for abuse. A public health organization recommended that HHS/CDC’s authority should be limited only to those diseases listed by Executive Order as quarantinable communicable diseases. An association suggested that the proposed rule would vastly increase the authority of HHS/CDC. One individual stated that this regulation is an attempt by HHS/CDC to evade Congress. One organization speculated that HHS/CDC plans to request that the list of quarantinable communicable diseases be expanded “to include measles and other vaccine targeted diseases for the purpose of

apprehending and quarantining travelers entering the US or traveling between States, who have not been vaccinated with MMR (measles-mumps-rubella vaccine) and other Federally recommended vaccines.”

In response, HHS/CDC first notes that it cannot—and will not—act beyond the scope of authority granted by Congress in statute; HHS/CDC offers the following clarifications. Under section 361(a) of the Public Health Service Act (42 U.S.C. 264(a)), the HHS Secretary is authorized to make and enforce regulations as in the Secretary’s judgment are necessary to prevent the introduction, transmission, or spread of all communicable diseases from foreign countries into the States or possessions of the United States and from one State or possession into any other State or possession. Under section 361(b)(42 U.S.C. 264(b)), the authority to issue regulations authorizing the apprehension, examination, detention, and conditional release of individuals is limited to those communicable diseases specified in an Executive Order of the President, *i.e.*, “quarantinable communicable diseases.” The authority for carrying out these regulations has been delegated from the HHS Secretary to the CDC Director, who in turn delegated these authorities to HHS/CDC’s Division of Global Migration & Quarantine (DGMQ). These quarantinable communicable diseases are currently limited to cholera, diphtheria, infectious tuberculosis (TB), plague, smallpox, yellow fever, and viral hemorrhagic fevers (such as Marburg, Ebola, Lassa fever, and Crimean-Congo), severe acute respiratory syndromes, and influenza caused by novel or re-emergent influenza viruses that are causing or have the potential to cause a pandemic. *See* Executive Order 13295 (April 4, 2003), as amended by Executive Order 13375 (April 1, 2005) and Executive Order 13674 (July 31, 2014). Changes to the list of quarantinable communicable diseases are beyond the scope of this regulation. And again, we reemphasize that HHS/CDC does not intend, through these regulations, to mandate vaccination or compulsory medical treatment of individuals.

One commenter supported the international proposals (part 71), but urged HHS/CDC to remove the domestic portion (part 70) of this regulation. We disagree. HHS/CDC’s authorities apply to all travelers in the United States, regardless of citizenship or residency, and are intended to complement State authorities within their jurisdictions by providing a mechanism to prevent importation of communicable disease

from other countries as well as spread of communicable disease between States and between States and territories. Thus, HHS/CDC’s and States’ authorities together create a comprehensive system to protect the public from communicable disease threats including in situations such as interstate travel when a single State’s authorities may be inadequate to address the communicable disease threat.

Several commenters suggested that HHS/CDC has the authority to unilaterally change or update the list of quarantinable communicable diseases. Other commenters requested that the list be narrowed to only those diseases with a “high mortality rate.” HHS/CDC reemphasizes that, as prescribed by statute, the list of quarantinable communicable diseases may only be changed by Executive Order of the President and that such suggestions are beyond the scope of this final rule.

HHS/CDC received several comments on the Agency’s accountability system, encouraging that a “strong system of checks and balances” should be in place for this regulation to be implemented. HHS/CDC agrees that there should be accountability and oversight regarding the agency’s activities. We note that these regulations do not affect the ability of Congress to conduct its oversight activities or affect the jurisdiction of federal courts to review federal agency actions under the Administrative Procedure Act (5 U.S.C. 704).

HHS/CDC received a comment that there is no court supervision of HHS/CDC activities. We disagree. These regulations do not affect the jurisdiction of the Federal courts or the statutory rights of individuals to obtain judicial review of CDC’s actions and decisions through appropriate mechanisms such as the habeas corpus statute (28 U.S.C. 2241) or the Administrative Procedure Act (5 U.S.C. 704).

Some commenters questioned the need for HHS/CDC to use its authorities if the threat of death is minimal compared with the size of the population, listing illnesses such as chickenpox, pertussis, Zika, the common cold and flu, and leprosy. One organization suggested that, through the language of the NPRM, HHS/CDC was “equating” non-quarantinable diseases with quarantinable diseases. Another commenter suggested that HHS/CDC’s authority to act should be based on the mortality of the illness, rather than whether or not it appears on the list of quarantinable communicable diseases. HHS/CDC thanks the commenters for

consideration of the proposal as well as the input provided.

First, we note that HHS/CDC only has authority to quarantine or isolate individuals who have illnesses that are listed by Executive Order of the President as quarantinable communicable diseases. HHS/CDC does not have the ability or authority to unilaterally modify the list of quarantinable communicable diseases. Second, because HHS/CDC also has statutory authority to prevent the “introduction, transmission, and spread” of communicable diseases, HHS/CDC may take actions other than quarantine or isolation to protect the public’s health. These other actions may include contact tracing investigations to notify individuals to seek proper treatment if they have been exposed to a communicable disease, even if the disease is not listed by Executive Order as quarantinable. HHS/CDC does not seek to compel vaccination or medical treatment. In keeping with current practice, HHS/CDC recommends certain vaccines for post-exposure prophylaxis and individuals may choose to follow these recommendations as they deem appropriate.

Other commenters questioned why diseases such as Ebola, measles, and Zika—three very different diseases with three very different effects on individuals—are used to support the same regulatory provisions. One organization quoted the NPRM, citing correctly that while measles is not a quarantinable communicable disease, it was used in the NPRM to support the need for this updated regulation. HHS/CDC welcomes the opportunity to provide further clarification.

The proposed rule provides HHS/CDC with a number of options for public health interventions based on a public health risk assessment of the communicable disease in question and the situation at hand. These interventions could include conducting a contact investigation on an airplane or vessel if a person with a serious communicable disease was known to have traveled on the airplane or vessel. These contact investigations are similar to those conducted by health departments in community settings. In addition to these interventions, for the nine communicable diseases currently designated by Executive Order as quarantinable communicable diseases, HHS/CDC may apprehend, detain, examine, quarantine, isolate, or conditionally release individuals for purposes of preventing communicable disease spread. Ebola and infectious tuberculosis are examples of quarantinable communicable diseases.

HHS/CDC also provides the public with recommendations to address other communicable diseases of public health concern. Zika is a good example of a disease of public health concern because of the ways it can be spread, e.g., through mosquitoes, sexual transmission, and maternal-fetal transmission. Therefore, HHS/CDC has recommended avoiding mosquito bites, protecting against sexual transmission, and for pregnant women to avoid travel to areas where Zika is spreading. Another example is seasonal influenza, which is very contagious but also very common; therefore, HHS/CDC makes recommendations for people sick with flu-like symptoms to stay home from work or school and take basic precautions such as covering their coughs and sneezes and washing their hands. In all situations, HHS/CDC considers how common and severe the communicable disease is, how it is transmitted, and what interventions are available and appropriate before making recommendations or taking action to protect the health of the public.

One commenter questioned why HHS/CDC was not able to currently control all communicable diseases, specifically leprosy. While HHS/CDC works regularly and continuously with other Federal, State, local and tribal health departments to eliminate the introduction, transmission and spread of all communicable disease, outbreaks can and do still occur. HHS/CDC staff have experienced first-hand the impact of globalization on public health. The rapid speed and tremendous volume of international and transcontinental travel, commerce, and human migration enable microbial threats to disperse worldwide in 24 hours—less time than the incubation period of most communicable diseases. These and other forces intrinsic to modern technology and ways of life favor the emergence of new communicable diseases and the reemergence or increased transmission of known communicable diseases.

HHS/CDC received many comments regarding measles and the need to apply public health measures to prevent the transmission and spread of the disease. We note also that while measles may be transmissible during travel, it is not one of the quarantinable communicable diseases listed by Executive Order of the President. Therefore, while HHS/CDC may recommend post-exposure prophylaxis, or other ways to manage and prevent spread, we do not have the authority to apprehend, examine, detain, or conditionally release individuals who may have measles, nor those who may have been exposed. See

80 FR 16,400 (Mar. 27, 2015)(describing air travel restrictions that may be applicable to a passenger who would represent a threat to public health).

HHS/CDC believes that requesting that DHS restrict the air travel of persons with measles is warranted because measles is a serious and highly contagious communicable disease that would pose a public health threat during travel. People exposed to measles who are not immune to the infection and have not been vaccinated following the exposure are advised to delay their travel voluntarily until they are no longer at risk of becoming infectious.

A number of commenters suggested that the proposed regulations are unconstitutional or in violation of the “Nuremberg Code,” the United Nations Educational, Scientific and Cultural Organization (UNESCO), the Universal Declaration on Bioethics and Human Rights, the Geneva Convention, human rights in general, and/or civil liberties in general because they ostensibly authorize compulsory medical treatment without informed consent. Commenters also cited numerous Supreme Court cases purportedly in support of these claims, such as *Mills v. Rogers*, 457 U.S. 291 (1982), (curtailing the involuntary administration of anti-psychotic drugs to mental patients); *Vacco v. Quill*, 521 U.S. 793 (1997) (constitutionality of an assisted suicide ban); *Washington v. Harper*, 494 U.S. 210 (1990) (involuntary administration of anti-psychotic drugs to prison inmates); *Sell v. United States*, 539 U.S. 166 (2003)(upholding certain strict due process protections before any involuntary administration of anti-psychotic drugs to incarcerated prisoners can be made); and *Canterbury v. Spence*, 409 U.S. 1064 (1972)(duty of doctors to obtain informed consent). HHS/CDC disagrees and re-asserts that this final rule does not authorize compulsory medical treatment, including compulsory vaccination, without informed consent.

These regulations do not violate or take away any recognized rights guaranteed by the U.S. Constitution or applicable international agreements. While HHS/CDC has successfully responded to outbreaks of communicable diseases, such as Ebola, these regulations will improve HHS/CDC’s future ability to prevent the introduction, transmission, and spread of communicable diseases, through such mechanisms as improved reporting of illnesses and public health prevention measures at airports. While many of these activities have been carried out in the past through internal operating

procedures, these regulations improve the public’s awareness and understanding of HHS/CDC’s activities to protect the public’s health.

One commenter expressed concerns about religious exemptions for mandatory vaccination or treatment. In response, HHS/CDC notes that these regulations do not authorize compulsory vaccinations or medical treatment. While HHS/CDC will implement these regulations in a manner consistent with respecting the religious rights of individuals, religion is not a basis for exempting individuals from the provisions of these regulations, including those provisions relating to quarantine and isolation.

One commenter raised similar concerns that the regulations may lead to apprehensions based on factors unrelated to public health such as wearing of religious garb or reading of certain newspapers. HHS/CDC agrees that public health actions should not be taken based on factors unrelated to protecting the public’s health and these regulations do not authorize such actions. Additionally, these regulations strike the appropriate balance between individual liberties and public health protection.

Several commenters questioned whether quarantine and isolation may be carried out consistent with the Fourth Amendment to the U.S. Constitution. One commenter also suggested that implementation of public health prevention measures at airports would lead to “unreasonable searches and seizures” under the Fourth Amendment. HHS/CDC disagrees with these assertions. The Fourth Amendment protects the rights of persons to be free in their persons, houses, papers, and effects, against unreasonable government searches and seizures. HHS/CDC notes that at ports of entry, routine apprehensions and examinations related to quarantine and isolation may fall under the border-search doctrine, which provides that, in general, searches conducted by CBP officers at the border are not subject to the requirements of first establishing probable cause or obtaining a warrant. See *United States v. Roberts*, 274 F.3d 1007, 1011 (5th Cir. 2001); see also *United States v. Bravo*, 295 F.3d 1002, 1006 (9th Cir. 2002) (noting that only in circumstances involving extended detentions or intrusive medical examinations have courts required that border searches be premised upon reasonable suspicion). Similarly, apprehensions and examination of persons traveling interstate under this rule are authorized under the special-needs doctrine articulated by the

Supreme Court in *Skinner v. Railway Labor Executives' Ass'n*, 489 U.S. 602 (1989) because of the "special need" in preventing communicable disease spread. Furthermore, to the extent that "probable cause," rather than "special needs," would be the applicable Fourth Amendment standard, HHS/CDC contends that meeting the requirements of 42 U.S.C. 264 satisfies this standard. See *Villanova v. Abrams*, 972 F.2d 792, 795 (7th Cir.1992)(noting that probable cause for emergency civil commitment exists where "there are reasonable grounds for believing that the person seized is subject to the governing legal standard."). HHS/CDC further acknowledges that any searches and seizures of individuals must be reasonable under the circumstances. HHS/CDC reiterates that this final rule does not authorize compulsory medical treatment, including vaccination, without informed consent.

HHS/CDC received a comment citing *Missouri v. McNeely*, where the U.S. Supreme Court ruled that police must generally obtain a warrant before subjecting a drunken-driving suspect to a blood test, and that the natural metabolism of blood alcohol does not establish a *per se* exigency that would justify a blood draw without consent. In response, HHS/CDC notes that courts have recognized that while the requirements for probable cause and a warrant generally apply in a criminal context, these standards do not apply when the government is conducting a non-law enforcement related activity. See *Nat'l Treasury Employees Union v. Von Raab*, 489 U.S. 665 (1989) (reaffirming the general principle that a government search may be conducted without probable cause and a warrant when there is a special governmental need, beyond the normal need for law enforcement). HHS/CDC reiterates that the special-needs doctrine articulated by the Supreme Court in *Skinner v. Railway Labor Executives' Ass'n*, 489 U.S. 602 (1989) provides the appropriate legal standard under the Fourth Amendment for apprehensions and detentions under this final rule.

Several commenters also questioned whether the regulations are consistent with the requirements of the Fifth and Sixth Amendments to the U.S. Constitution. We note at the outset that the Sixth Amendment only applies to criminal proceedings and thus would be inapplicable to isolation and quarantine decisions which are public health protection measures unrelated to the normal needs of law enforcement. Furthermore, HHS/CDC asserts that this final rule is consistent with the requirements of due process embodied

in the Fifth Amendment to the U.S. Constitution. Specifically, procedural safeguards contained in the final rule include: (1) A requirement for written orders of quarantine, isolation, or conditional release, including translation or interpretation services as needed; (2) mandatory review of the Federal order after the first 72 hours; (3) notifying individuals through the written order of their right to request a medical review; (4) an opportunity at the medical review for the detained individual to be heard through an attorney or other advocate hired at their own expense, present experts or other witnesses, submit documentary or other evidence; and confront and cross-examine any government witnesses; (5) a decision-maker independent of those who authorized the original isolation, quarantine, or conditional release; (6) a written statement by the fact-finder of the evidence relied upon and the reasons for the decision; (7) appointment of representatives, including a medical representative and an attorney, if the individual is indigent and requests a medical review; and (8) timely notice of the preceding rights. See *Vitek v. Jones*, 445 U.S. 480 (1980); *Mathews v. Eldridge*, 424 U.S. 319 (1976).

HHS/CDC also received a comment that quarantine violates the guarantees of substantive due process under the 5th Amendment to the U.S. Constitution. HHS/CDC disagrees. In addition to a guarantee of fair procedures, the U.S. Supreme Court has interpreted the Fifth Amendment's Due Process Clause as containing a substantive component barring certain arbitrary, wrongful government actions regardless of the fairness of the procedures used to implement them. See *Zinermon v. Burch*, 494 U.S. 113, 125 (1990). HHS/CDC notes that the quarantine of individuals who have been exposed to a communicable disease, but are not yet capable of transmission is a well-known and accepted public health strategy of long standing. See *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905) (recognizing the power of States to issue "quarantine laws and health laws of every description"); *Compagnie Francaise de Navigation a Vapeur v. State Bd. of Health, Louisiana*, 186 U.S. 380, 396 (1902) (discussing the 1893 Federal quarantine statute). The restrictions on individuals authorized under this regulation are justified by the benefits to the public health.

HHS/CDC received a comment that quarantine and isolation are State police powers that should not be exercised at the Federal level. While HHS/CDC acknowledges that the States have

primary authority for quarantine and isolation within their borders, the Federal government has an important and longstanding role in preventing communicable disease spread at ports of entry and interstate. This authority is reflected in 42 U.S.C. 264 and consistent with principles of Federalism.

HHS/CDC received one comment stating that it should conduct a Federalism analysis because implementing the rule will require working with State health officials and resources. Under Executive Order 13132, a Federalism analysis is required if a rulemaking has federalism implications, would limit or preempt State or local law, or imposes substantial direct compliance costs on State or local governments. Under such circumstances, a Federal agency must consult with State and local officials. Federalism implications is defined as having substantial direct effects on State or local governments, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Under 42 U.S.C. 264(e), Federal public health regulations do not preempt State or local public health regulations, except in the event of a conflict with the exercise of Federal authority. Other than to restate this statutory provision, this rulemaking does not alter the relationship between the Federal government and State/local governments as set forth in 42 U.S.C. 264. While HHS/CDC acknowledges that portions of this rule may involve HHS/CDC "working with State health officials" to better coordinate public health responses, the rule is consistent with 42 U.S.C. 264(e) and there are no provisions that impose direct compliance costs on State and local governments. The longstanding provision on preemption in the event of a conflict with Federal authority (42 CFR 70.2) is left unchanged by this rulemaking. Therefore, HHS/CDC believes that the rule does not warrant additional consultation under Executive Order 13132.

HHS/CDC received several questions asking who would be responsible for the enforcement of these regulations. One commenter questioned whether HHS/CDC would use "militarized police or create [an] armed Federal police force to carry out these actions." As explained elsewhere, in keeping with current practice and existing law, law enforcement support for quarantine or isolation orders will generally be provided by U.S. Customs and Border Protection, U.S. Coast Guard, or other Federal law enforcement programs, but

HHS/CDC may also accept voluntary State and local assistance in enforcing its Federal orders. HHS/CDC will also continue to enforce its regulations in a manner consistent with the Fourth Amendment and other provisions of the U.S. Constitution.

c. Definitions

Agreements

HHS/CDC received many comments on the definition of *Agreement*, largely expressing confusion and concern that such agreements would not be truly voluntary. The intent of this provision was to provide HHS/CDC with an additional tool to facilitate cooperation from individuals in regard to recommended public health actions. In response to public comments, however, HHS/CDC has withdrawn this definition and will not issue the proposed provisions on “Agreements.”

Airline

HHS/CDC did not receive public comment on the proposed definition of *Airline*. However, consistent with HHS/CDC's intent that this definition apply to common air carriers, to improve clarity, we have removed the phrase “including scheduled or public charter passenger operations operating in air commerce within the United States” and removed the reference to 49 U.S.C. 40102(a)(3).

Apprehension

HHS/CDC received many comments on the proposed definition and provision regarding *Apprehension*; a discussion of these comments is in the section below titled, “Apprehension and Detention of Persons with Quarantinable Communicable Diseases.” The definition is finalized as proposed.

Commander

HHS/CDC did not receive public comment on the proposed definition of *Commander*. Therefore, this definition is finalized as proposed.

Communicable Stage

HHS/CDC received a comment seeking clarity regarding the definition of *Communicable Stage*. The commenter stated that the definition for *communicable stage* may unnecessarily restrict social distancing powers because it appears limited to human-to-human transmission and does not include human transmission via an intermediate vector, such as mosquitoes or flea bites. HHS/CDC disagrees. The definition of communicable stage includes transmission of an infectious agent either “directly or indirectly from

an infected individual to another individual.” Thus, HHS/CDC clarifies that indirect transmission of an infectious agent may include transmission via an insect vector as described by the commenter. This definition is finalized as proposed.

Conditional Release

HHS/CDC received many comments on the proposed definition and provision regarding *Conditional Release*; a substantive discussion of these comments is presented in the section below titled *Requirements Relating to Issuance of a Federal Order for Quarantine, Isolation, or Conditional Release*.

HHS/CDC is modifying the definition of *Conditional Release* under section 70.1 to remove the cross-reference to the definition of surveillance as that term appears in current section 71.1. The definition of *Conditional Release* under section 70.1 tracks the definition of surveillance under section 71.1 and means “the temporary supervision by a public health official (or designee) of an individual or group, who may have been exposed to a quarantinable communicable disease to determine the risk of disease spread and includes public health supervision through in-person visits, telephone, or through electronic or internet-based monitoring.” HHS/CDC is making this change to improve clarity and remove the need for the public to cross-reference the definition of surveillance to understand the definition of *Conditional Release* as used in section 70.1.

This definition of *Conditional Release* under section 71.1 is finalized as proposed.

Contaminated Environment

HHS/CDC did not receive public comment on the proposed definition of *Contaminated Environment*. Therefore, this definition is finalized as proposed.

Conveyance

HHS/CDC did not receive public comment on the proposed definition of *Conveyance*. Therefore, this definition is finalized as proposed.

Electronic or Internet-Based Monitoring

HHS/CDC received many comments on the proposed definition and provision regarding *Electronic or Internet-based monitoring*. We have modified this definition as follows: “mechanisms or technologies allowing for the temporary public health supervision of an individual under conditional release and may include communication through electronic mail,

SMS texts, video or audio conference, webcam technologies, integrated voice-response systems, or entry of information into a web-based forum; wearable tracking technologies; and other mechanisms or technologies as determined by the Director or supervising State or local health authority.”

Several commenters expressed privacy concerns because conditional release of exposed or ill individuals may be accomplished over the internet or through electronic monitoring. Other commenters expressed concerns about privacy, having misunderstood the proposed rule as authorizing HHS/CDC to conduct invasive surveillance of personal communications such as emails, text messages, and telephone calls. Commenters also expressed concerns related to the use of webcams and wearable tracking technologies as an option for monitoring of exposed people. One association viewed this proposed provision as an expansion of CDC's “electronic monitoring of personal information, under the guise of protecting the public against rare, isolated outbreaks of disease.”

HHS/CDC appreciates the opportunity to address these concerns. CDC's intent was to describe mechanisms that HHS/CDC or other public health authorities can use to communicate with individuals for the purpose of conducting monitoring following exposure to a quarantinable communicable disease. These mechanisms are intended as alternatives to in-person interviews because of the inconvenience and logistical problems that may arise when meeting in-person.

During the 2014–2016 Ebola response, HHS/CDC recommended “active monitoring” defined as daily communication between public health authorities and the individuals being monitored. HHS/CDC did not specify how this communication should occur, and health departments used a variety of electronic technologies for this purpose including those listed in the regulation. HHS/CDC also recommended “direct active monitoring” for people with certain higher levels of exposure. This involved having a public health official check in with the person through direct observation rather than relying on phone calls or electronic communications. Webcams were used by some health departments as an alternative to in-person visits to observe the person taking his or her temperature. The webcam was only operational during this scheduled public health “visit.” The use of webcams proved convenient for both

the health departments and the people being monitored, especially if the people lived in remote areas. Webcams are also used routinely by health departments for “directly observed therapy” for diseases like tuberculosis (TB), in order to watch patients take their TB medications. HHS/CDC has clarified the regulatory text to state that these technologies will be used for communicating with the individual and not as a means of monitoring the individual’s personal communications.

One commenter asked whether HHS/CDC would “assist with payment for internet services” if webcam communications was required. In keeping with current practice, if an individual does not have access to internet services, HHS/CDC may use alternative methods to assist with communication, such as the issuance of a cellular phone. Some organizations also expressed concerns about the use of technologies such as cellular phones or wearable tracking technologies for the purpose of electronic monitoring. HHS/CDC acknowledges that the use of wearable tracking technology may be necessary in rare situations when a person does not comply with the required monitoring or when it is necessary to know the physical whereabouts of the person to ensure that they are not in a public place. While HHS/CDC acknowledges that public health surveillance of ill or exposed individuals through electronic monitoring may raise some privacy concerns, HHS/CDC believes that protecting the public’s health outweighs these concerns.

HHS/CDC is committed to protecting the privacy of personally identifiable information collected and maintained under the Privacy Act of 1974. As detailed in the preamble of the proposed rule, on December 13, 2007, HHS/CDC published a notice of a new system of records under the Privacy Act of 1974 for its conduct of activities under this final rule (72 FR 70867). HHS/CDC accepted public comment on its proposed new system of records at that time. As required under the Privacy Act, HHS/CDC described in its notice the proposed system of records, the purpose for the collection of the system data, the proposed routine uses (*i.e.*, disclosures of system data that are compatible to the purpose for the data collection), the benefits and need for the routine use of this data, our agency’s policies, procedures, and restrictions on the routine use disclosure of this information, and, most importantly, our safeguards to prevent its unauthorized use.

Under this system of records, CDC will only release data collected under this rule and subject to the Privacy Act to authorized users as legally permitted. HHS/CDC will take precautionary measures including implementing the necessary administrative, technical and physical controls to minimize the risks of unauthorized access to medical and other private records. In addition, HHS/CDC will make disclosures from the system only with the consent of the subject individual or, in accordance with the routine uses published at 72 FR 70867, or as allowed under an exception to the Privacy Act. Furthermore, HHS/CDC will apply the protections of the SORN to all travelers regardless of citizenship or nationality. Finally, such records will be stored and maintained in keeping with the official Records Control Schedule as set forth by the National Archives and Records Administration. For more information, please see <https://www.archives.gov/records-mgmt/rcs>.

Ill Person

We have modified the definition of *Ill person* under 71.1 to include a person who “(b)(2) Has a fever that has persisted for more than 48 hours; or (b)(3) Has acute gastroenteritis, which means either diarrhea, defined as three or more episodes of loose stools in a 24-hour period or what is above normal for the individual, or vomiting accompanied by one or more of the following: One or more episodes of loose stools in a 24-hour period, abdominal cramps, headache, muscle aches, or fever (temperature of 100.4 °F [38 °C] or greater).” This language was quoted verbatim in the preamble of the NPRM at 81 FR 54305 but was inadvertently omitted from the proposed regulatory text.

HHS/CDC received comments regarding the updated definition of *Ill person* which flight crews use to report to the CDC occurrences of illnesses in passengers or crew during travel. Specifically, commenters expressed concern that “non-medical personnel” such as flight attendants would report such observations; others questioned whether the definition is too broad and may result in over-reporting of non-threatening illnesses; others worried that it could lead to unnecessary apprehensions of individuals. One commenter claimed to be “chemical sensitive,” and worried that he or she may be penalized for having a reaction from sitting next to someone on a plane wearing a “strong fragrance.” HHS/CDC thanks the commenters for considering the proposal and providing feedback.

HHS/CDC clarifies that the purpose of the *ill person* definition is to align with current global and accepted detection and reporting practices so that onboard deaths and illnesses are reported by airlines and, where necessary, investigated by HHS/CDC. We note that the *ill person* definition in this final rule is consistent with the internationally recognized and accepted illness reporting guidelines published by the International Civil Aviation Organization (ICAO). This practice is not new, but has been used successfully for many years by aircraft and vessel crews to assist public health officials in preventing further transmission and spread of communicable disease.

HHS/CDC also does not intend to apprehend individuals based solely on their meeting the definition of an *ill person*. The purpose of an illness report is to allow trained HHS/CDC public health and medical officers to determine whether an illness occurring onboard a flight or voyage necessitates a public health response. In contrast, an apprehension of an individual is based on a variety of criteria in addition to an illness report including: Clinical manifestations, contact or suspected contact with infected individuals, host susceptibility, travel to affected countries or places, or other evidence of exposure to or infection with a quarantinable communicable disease. Thus, HHS/CDC disagrees that the *ill person* definition will lead to unnecessary apprehensions of individuals.

Several commenters noted that the symptoms listed in HHS/CDC’s definition of an *ill person* are common symptoms of many non-threatening conditions, and thus questioned their inclusion in the definition. HHS/CDC appreciates the opportunity to respond to these concerns. The symptoms listed in HHS/CDC’s *ill person* definition are provided for airlines and vessels to report to HHS/CDC so that HHS/CDC can make a public health risk assessment; *the symptoms alone would not result in issuance of a public health order*. In making such an assessment, HHS/CDC medical and public health officers consider the symptoms as well as the medical history of the person and any possible exposures that could indicate that the person may be infected with a quarantinable communicable disease.

A few commenters stated that the definition of *ill person* appears to expand the scope of HHS/CDC’s authority beyond the list of quarantinable communicable diseases specified through an Executive Order of the President. HHS/CDC disagrees. The

purpose of the ill person definition is to help facilitate the identification, particularly by flight crews, of communicable diseases of public health concern. Thus, HHS/CDC has defined *ill person* in such a way that the term may be understood by non-medically trained crewmembers. While the reporting of an ill person onboard a flight may trigger a public health evaluation by a trained quarantine officer in consultation with an HHS/CDC medical officer, such reporting does not expand the basis upon which an ill person may be subject to apprehension, detention, or conditional release. As noted by the commenter, such public health actions are limited to those quarantinable communicable diseases specified through an Executive Order of the President (e.g., cholera, diphtheria, infectious tuberculosis, yellow fever, viral hemorrhagic fevers, Severe Acute Respiratory Syndromes, and pandemic influenza).

A public health association suggested that any changes to the list of signs and symptoms within the definition of *ill person* should be made available for public comment. HHS/CDC assumes this comment is in reference to section (3) of the definition which provides for reporting of “symptoms or other indications of communicable disease, as the HHS/CDC may announce through posting of a notice in the **Federal Register**.” HHS/CDC appreciates the opportunity to clarify the purpose of this section. Section (3) of the *ill person* definition is intended to apply only to new, emerging, and imminent threats to public health. We expect it will only be relied on in emergency situations where a quick response is required to protect the public. Other circumstances, where the list of signs and symptoms may change due to evolving science or technology, will be made available for public comment, through a similar process as this rulemaking—Notices in the **Federal Register**—and may also request input from the public.

A number of commenters noted that symptoms listed in HHS/CDC’s definition of an *ill person* are common symptoms of many conditions, particularly “appears obviously unwell” which many commenters requested be removed from the definition. HHS/CDC appreciates the opportunity to clarify that, with the exception of acute gastroenteritis on vessels, HHS/CDC only requires reporting of an ill traveler on an aircraft or vessel if fever “accompanied by one or more of the following” other symptoms listed are present. Therefore, as an example, headache alone would not be sufficient to require reporting, but rather fever

plus headache, fever plus cough, fever plus persistent vomiting, fever plus persistent diarrhea, etc. These symptoms combined with fever are frequently seen in communicable diseases that could pose a public health risk to others during travel. Because a person with fever who also appears obviously unwell could have a serious communicable disease, HHS/CDC feels it is appropriate to retain this symptom, and further notes that its inclusion better aligns with Note 1 to the guidelines set forth by the International Civil Aviation Organization in paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation.

One public health organization commented that the definition of *ill person* was broad and would be better issued through agency guidance rather than a rule. In response, HHS/CDC notes that the existing regulation contains an outdated and overly narrow definition of *ill person* that does not reflect current knowledge of communicable diseases, and that the reporting of ill travelers has been managed through a combination of regulation and agency guidance. This combination of “required” and “requested” reporting has proven confusing to some airline and vessel employees and this rule seeks to mitigate such confusion by including all relevant symptom clusters in the rule. Further, HHS/CDC notes that the change in the *ill person* definition better aligns with guidelines set forth by the International Civil Aviation Organization and is supported in comments received from the airline industry.

One public health organization commented on the different definitions of *ill person* for aircraft and vessels and recommended that the definitions be combined and not depend on the mode of transport. In response, HHS/CDC wishes to point out three crucial differences between aircraft and vessels which HHS/CDC feels justify the different definitions. One difference, additionally noted by the commenting organization, is the difference in time that a traveler spends on an aircraft and a vessel which makes the time frame (24 hours) specified in the definition of acute gastroenteritis for vessels relevant and minimizes the reporting of travelers with a single episode of loose stool that subsequently resolves, a common occurrence. The second is the high risk of spread of gastrointestinal infections onboard vessels that is unlikely to occur on aircraft; for this reason, reporting of diarrheal illnesses on aircraft includes the presence of fever which is more likely to indicate a serious

communicable disease, whereas the definition on vessels includes diarrheal illness without fever to allow for the reporting of viral gastrointestinal illnesses that typically do not cause fever but have been known to cause large outbreaks on cruise vessels. The third difference is the presence onboard cruise vessels of medical facilities capable of making a diagnosis of pneumonia which allows the inclusion of pneumonia in the vessel definition. In all other respects, the definitions are the same. HHS/CDC adds that combining the definitions would be confusing to industry professionals responsible for conducting this reporting.

One public health organization provided a recommendation to modify the description of the “rash” component in the definition of ill person to ensure that the term fully encompassed the range of potential skin rash symptoms. The organization’s recommendation for revisions was as follows: “The individual has areas on the skin that are red or purple, flat or bumps; with multiple red bumps; red, flat spots; or blister-like bumps filled with fluid or pus that are intact, draining, or partly crusted over; or dry and scaling patches. The rash may be discrete or run together, and may include one area of the body, such as the face, or more than one area.”

HHS/CDC responds that it will not change the regulatory text of the ill person definition with this language because we are concerned that this might add too much complexity to the regulatory definition. However, consistent with the regulatory definition of “ill person,” HHS/CDC will update its reporting guidance for aircraft and vessels to include this revised description. Current guidance may be found at: <http://www.cdc.gov/quarantine/air/reporting-deaths-illness/guidance-reporting-onboard-deaths-illnesses.html>.

An air industry commenter suggested another change to the ill person definition. The proposed definition included “headache with stiff neck,” and the commenter suggested that this be modified to “severe headache of recent onset with stiff neck.” While HHS/CDC will not change the regulatory definition of ill person to accommodate this change, HHS/CDC believes this is a useful modification to make in ill person reporting guidance to aircraft and vessels.

Incubation Period

HHS/CDC did not receive any comments on the proposed definition of *Incubation period*. However, upon a

review of the definition, we have decided that the definition should more closely track the definition of *Precommunicable stage*. For quarantinable communicable diseases, the *Incubation period* is defined as the *Precommunicable stage* of the disease. Thus, we have determined that the two definitions should more closely align. A substantive discussion of comments received concerning the definition of *Precommunicable stage* appears below.

Accordingly, we have modified the definition of *Incubation period* to add “or, if signs and symptoms do not appear, the latest date signs and symptoms could reasonably be expected to appear.” Other aspects of this definition are finalized as proposed.

Indigent

HHS/CDC received comments relating to the proposed definition of *Indigent* which is used to determine whether a detained individual qualifies for appointment at government expense of representatives to assist him/her during a medical review. One comment from a public health department suggested raising the threshold for indigent status to at least 200% of the applicable poverty guideline. HHS/CDC agrees and has made this change in the final regulation.

One commenter opposed including a definition for indigents and indicated that HHS/CDC should assume all costs whenever an individual is placed into Federal isolation or quarantine. HHS/CDC disagrees that assuming such costs without regard to indigence is necessary or appropriate.

Other substantive comments relating to the appointment at government expense of representatives to assist detained indigent individuals during a medical review are discussed below.

Master or Operator

HHS/CDC did not receive any comments on the definition of *Master or operator*. Accordingly, this definition is finalized as proposed.

Medical Examination

In response to comments received regarding medical examinations under sections 70.12 and 71.36, we have modified the definition of *Medical Examination* to indicate that the health worker conducting the assessment must be “licensed.” Comments regarding sections 70.12 and 71.36 are addressed below.

HHS/CDC received a comment regarding the definition of *Medical Examination*. The commenter stated that the definition of medical examination should include a mental

health assessment because a mental health condition may impact an individual’s appreciation of his or her public health risk to others. While HHS/CDC acknowledges that a mental health assessment may be useful as part of an individual’s medical care and treatment and that such an assessment may be ordered as needed by a treating clinician, HHS/CDC declines to make such assessments a formal part of the medical examination process. Specifically, because a mental health assessment is not generally needed to diagnose or confirm the presence or extent of infection with a quarantinable communicable disease, HHS/CDC disagrees that it is necessary or appropriate to require such an assessment as part of a Federal public health order.

Medical Representative

HHS/CDC received several comments relating to the proposed definitions of *Medical Representative* and *Medical Reviewer* as well as the potential use of HHS/CDC employees as representatives or medical reviewers. One commenter suggested that it would be less problematic for HHS/CDC to allow and pay for outside participants to serve in these capacities. First, HHS/CDC notes that the definition of *Medical representative* has been changed to *Representatives* and revised as detailed below. HHS/CDC disagrees with this comment and notes that the definition of both *Representatives* and *Medical reviewer* would in fact allow for the appointment of non-HHS/CDC employees in these capacities as suggested by the commenter. For this reason, both *Representatives* and *Medical reviewer* are broadly defined in terms of the occupational qualifications of these individuals. HHS/CDC also does not consider it problematic to rely on internal reviewers and notes that it is not unusual, for instance, for hospitals to rely on internal decision-makers when determining whether to commit a mental health patient on an emergency basis.

HHS/CDC received a comment that the “definition of medical exemption is not apparent.” In response, HHS/CDC notes that no clarification of what is meant by “medical exemption” is provided by the commenter and that HHS/CDC did not propose adding such a definition. While these regulations do not authorize compulsory vaccination or medical treatment, there is no recognized “medical exemption” from quarantine, isolation, or conditional release and HHS/CDC declines to create one.

Non-Invasive

HHS/CDC received several comments concerning the definition of *Non-invasive*, including support from a public health association regarding the definition. However, several individuals disagreed with the proposed definition. In response to public comment that the definition of “non-invasive” allowed too much physical contact between the individual and public health officer, HHS/CDC has replaced “physical” with “visual” and removed “auscultation; external palpation; external measurement of blood pressure” from the definition. While HHS/CDC continues to believe that these procedures qualify as *Non-invasive* under the definition, after considering public comment and a review of standard operating procedures, HHS/CDC finds such procedures to be unlikely to be conducted during a public health risk assessment. Such procedures may be conducted at a port of entry by emergency medical service personnel as part of a medical assessment to determine the need for emergency medical care. We also modified the definition to clarify that the individual conducting the public health risk assessment will be a “public health worker.” Public health workers are individuals who have education and training in the field of public health.

One commenter mentioned that the new definition of *Non-invasive* states that the HHS/CDC could order laboratory testing under certain conditions. The commenter further asserted that forced laboratory testing, without the option of quarantine instead, is an invasive measure, and questioned how this could be in line with the concept of non-invasive. HHS/CDC responds that the definition of non-invasive applies to procedures conducted during a public health risk assessment at a port of entry and that this definition does not authorize forcible or invasive procedures to extract human biological samples for laboratory testing. Should laboratory testing be needed for a person reasonably believed to be infected with a quarantinable communicable disease, such testing would be done as part of a medical examination conducted at a healthcare facility and performed with the patient’s informed consent. HHS/CDC has added language to the regulatory text requiring that the Director advise individuals of their right to have medical testing and examination conducted by an authorized and licensed health worker and with prior informed consent. While this regulation does not authorize forcible testing,

HHS/CDC may require laboratory test results demonstrating that a symptomatic individual is no longer infectious prior to rescinding a Federal isolation order.

Precommunicable Stage

HHS/CDC received comments relating to the definition of *Precommunicable stage*. One commenter suggested that persons in the “precommunicable stage” of a quarantinable communicable disease pose no direct threat to the public’s health. A public health organization also stated that this definition should not apply to non-symptomatic people who have been exposed to Ebola. HHS/CDC disagrees with both comments. For instance, a patient diagnosed with multidrug-resistant or extensively drug-resistant tuberculosis who is not currently infectious, but who has not been adequately treated and is thus at high risk for relapse would be considered to be in the “precommunicable stage” of the disease and pose a direct threat to the public’s health. Similarly, an individual who is reasonably believed to have been exposed to Ebola poses a direct threat.

Several public health organizations additionally expressed concerns regarding the use of the “precommunicable stage” definition to justify quarantine of healthcare workers caring for patients with quarantinable communicable diseases such as Ebola or severe acute respiratory syndromes, including healthcare workers providing care in the United States or in other countries. One such organization further requested clarification of whether the rule provides for the needs and protection of healthcare workers who voluntarily self-quarantine while providing care for patients with the quarantinable communicable diseases noted above.

In response, HHS/CDC states that it does not recommend quarantine or occupational restrictions of healthcare workers who follow recommended infection control precautions while providing care for patients with quarantinable communicable diseases. Healthcare workers who do not follow infection control precautions or who have had unprotected exposures to patients with a quarantinable communicable disease may be subject to quarantine or occupational restrictions; these individuals would be afforded the same due process protections as other exposed individuals.

Several commenters also questioned CDC’s proposed definition for *Precommunicable stage* stating that it may result in an apprehension of an

individual who displays no symptoms of a communicable illness. In response, HHS/CDC states that it has defined *Precommunicable stage* consistent with the public health practice of quarantine. Quarantine refers to the public health practice of separating and restricting the movement of individuals who are reasonably believed to have been exposed to a communicable disease, but are not yet ill. In contrast, isolation refers to the public health practice of separating and restricting the movement of individuals who have been exposed to a communicable disease and are symptomatic from those who are not sick.

The definition of *Precommunicable stage* is finalized as proposed.

Public Health Emergency

HHS/CDC received several comments relating to the definition of *Public health emergency*. One commenter stated that use of the term is duplicative and unnecessary because the term is used elsewhere in the Public Health Service Act (42 U.S.C. 247d) and appears in State-based legislation based on the Model State Emergency Health Powers Act. This commenter suggested that to avoid confusion the term should be renamed “Public Health Exigency.” HHS/CDC disagrees. Section 361(d) of the Public Health Service Act (42 U.S.C. 264(d)(1)) authorizes the apprehension and examination of individuals traveling interstate who are in the “precommunicable stage” of a quarantinable communicable disease, but only if the disease “would be likely to cause a public health emergency if transmitted to other individuals.” Thus, section 361(d) is unique and differs from how the term public health emergency is used in other statutes or provisions of the Public Health Service Act because it authorizes application of specific public health measures (apprehension and examination) to specific individuals (those in the precommunicable stage of a quarantinable communicable disease), but only if the disease would be likely to cause a public health emergency. Thus, HHS/CDC considers it essential to define public health emergency because the existence of such an emergency is a necessary prerequisite to the apprehension and examination of individuals in the precommunicable stage of a quarantinable communicable disease.

This commenter also suggested that the definition of public health emergency contains an oversight because it does not mention the potential for an infectious condition being highly likely to cause “short- or

long-term disability.” HHS/CDC disagrees because the definition includes infectious diseases that are highly likely to cause “serious illness” if not properly controlled. HHS/CDC clarifies that “short- or long-term disability” caused by an infectious agent would be considered a “serious illness.”

This commenter further suggested that in addition to referencing a public health emergency declaration by the HHS Secretary, the definition should also include similar declarations by the President under the Stafford Act or under the National Emergencies Act. HHS/CDC disagrees. We note first that the definition of public health emergency is not limited to those emergencies declared by the HHS Secretary. Second, in the event of a man-made or natural disaster that also affects public health, the HHS Secretary may issue a separate declaration under the Public Health Service Act as was done in response to the terrorist attacks of September 11, 2001 and in response to Hurricane Katrina. Thus, HHS/CDC does not see a need to also reference Presidential declarations as suggested by the commenter.

This commenter also requested clarification concerning whether the World Health Organization’s (WHO) declaration of a Public Health Emergency of International Concern (PHEIC) could continue to serve as the basis for a “public health emergency” if the President or HHS Secretary disagreed with the declaration of a PHEIC on legal, epidemiologic, or policy grounds. In response, HHS/CDC notes that the scenario proposed by the commenter is unlikely, but that CDC remains a component of HHS, subject to the authority and supervision of the HHS Secretary and President of the United States.

HHS/CDC also received a comment objecting to referencing the WHO’s declaration of a Public Health Emergency of International Concern (PHEIC) in the definition of “public health emergency” because this ostensibly relinquishes U.S. sovereignty. HHS/CDC disagrees. By including references to a PHEIC, HHS/CDC is not constraining its actions or making its actions subject to the dictates of the WHO. Rather, the declaration or notification of a PHEIC is only one way for HHS/CDC to define when the precommunicable stage of a quarantinable communicable disease may be likely to cause a public health emergency if transmitted to other individuals. While HHS/CDC will give consideration to the WHO’s declaration of a PHEIC or the circumstances under which a PHEIC may be notified to the

WHO, HHS/CDC will continue to make its own independent decisions regarding when a quarantinable communicable disease may be likely to cause a public health emergency if transmitted to other individuals. Thus, HHS/CDC disagrees that referencing the WHO determination of a PHEIC results in any relinquishment of U.S. sovereignty.

The International Health Regulations are an international legal instrument that sets out the roles of WHO and State parties in identifying, responding to, and sharing information about public health emergencies of international concern. HHS/CDC believes that it would be unlikely for the United States to formally object to the WHO's declaration of a PHEIC, but that CDC remains a component of HHS, subject to the authority and supervision of the HHS Secretary and President of the United States.

Also regarding the definition of "public health emergency," one public health association expressed concern that *any* disease considered to be a public health emergency may qualify it as quarantinable. Another commenter noted that some PHEICs "most certainly do not qualify as public health emergencies" under the proposed definition. HHS/CDC appreciates the opportunity to clarify. Only those communicable diseases listed by Executive Order of the President may qualify as quarantinable communicable diseases. For example, Zika virus infection, which although the current epidemic was declared a PHEIC by WHO, is not a quarantinable communicable disease. The definition of *Public health emergency* is finalized as proposed.

Public Health Prevention Measures

HHS/CDC received one comment relating to the definition of *Public health prevention measures*. The commenter stated that the second use of "and other non-invasive means" should be deleted from the definition of *public health prevention measures* as redundant. HHS/CDC disagrees because "observation, questioning, review of travel documents, and records review" as cited in the definition appears to materially differ from "other non-invasive means" that may be used as a part of public health prevention measures such as temperature checks, visual observation, or visual examination of the ear, nose, or mouth. Accordingly, HHS/CDC believes that the updated definition provides greater clarity as written. Further information, including a discussion regarding comments received on these proposed

provisions, is discussed in the section below titled *Public Health Prevention Measures to Detect Communicable Disease*. The definition is finalized as proposed.

Qualifying Stage

HHS/CDC received several comments relating to *Qualifying stage*. Several commenters, including one public health organization, expressed concern that the definition was either too vague, too broad, or too confusing. One commenter suggested that the definition for *Qualifying stage* is confusing because it splits communicable diseases into a "precommunicable stage" and a "communicable stage" and that a communicable disease would not be on the list of Federal quarantinable communicable diseases if its spread did not already have some potential to cause a public health emergency. In response, HHS/CDC notes that the term "qualifying stage" is defined under 42 U.S.C. 264(d)(2) to include both a "precommunicable stage" and a "communicable stage" and that this definition explicitly references diseases "likely to cause a public health emergency." Thus, while HHS/CDC may clarify and explain statutory terms through regulation, it has no authority to change the language of the statute.

One public health organization recommended that HHS/CDC policy implementing the *Qualifying stage* definition acknowledge that a one-size fits all protocol is not appropriate because different diseases have different transmission patterns and the need for isolation and quarantine may differ. HHS/CDC agrees that the need for isolation and quarantine may differ based on the disease and adds that it conducts a public health risk assessment before issuing Federal public health orders. For example, HHS/CDC does not typically issue Federal public health orders for cholera, a quarantinable communicable disease as defined by Executive Order because the sanitation infrastructure in the United States makes cholera transmission unlikely. HHS/CDC further notes that it typically conducts the public health risk assessment in coordination with the State or local health department of jurisdiction before issuing a Federal public health order.

Public health organizations and other commenters cautioned against apprehending individuals or issuing public health orders when the risk of communicable disease spread during the precommunicable period is low. HHS/CDC agrees and further adds that it will typically conduct a public health risk assessment in coordination with

State and local public health officials to ensure that any restrictions imposed on an individual are commensurate with the degree of risk and using the least restrictive means available.

The definition of *Qualifying stage* is finalized as proposed.

Reasonably Believed To Be Infected, as Applied to Individuals

HHS/CDC received several comments regarding the definition of *Reasonably believed to be infected, as applied to an individual*. Several public health organizations expressed concern there could be undue burden placed on healthcare facilities or health departments by greatly expanding the number of individuals requiring health screening, medical examination and testing, or placed under Federal isolation of quarantine orders. HHS/CDC disagrees. This rule represents a codification of current practice and decisions regarding the need for medical examination of individuals suspected of being infected with a quarantinable communicable disease, including during an outbreak or public health emergency, will generally be based on published disease-specific case definitions for PUIs (persons under investigation) that incorporate clinical and epidemiologic factors. Furthermore, decisions regarding the issuance of Federal public health orders or medical examination for a suspected quarantinable communicable disease would typically be made in coordination with a State or local health department of jurisdiction. Therefore, HHS/CDC does not anticipate placing an undue burden on healthcare facilities or health departments as a result of these definitions.

One commenter stated that the *Reasonably believed to be infected, as applied to an individual* definition allows for apprehension, quarantine, or isolation based solely on reasonable inferences that the person was exposed somehow or in some way to infectious agents. HHS/CDC disagrees because as stated in the definition reasonable inferences may only be drawn from "specific articulable facts" that an individual has been exposed to an infectious agent such as through "contact with an infected person or an infected person's bodily fluids, a contaminated environment, or through an intermediate host or vector." Thus, HHS/CDC disagrees that this standard does not comport with standard public health practice.

HHS/CDC received a comment from a public health agency expressing concern that travel to other countries where transmission of a quarantinable

communicable disease has likely occurred would be the sole basis upon which HHS/CDC would form a reasonable belief that an individual may be infected with a quarantinable communicable disease. In response, HHS/CDC clarifies that travel to other countries was simply used as an illustrative example. The decision to place an individual into isolation or quarantine will ordinarily be based on several factors, including travel, contact with an infected person or an infected person's bodily fluids, host susceptibility, and clinical manifestations. HHS/CDC believes that this definition is clear and that no further changes are necessary.

The definition of *Reasonably believed to be infected as applied to an individual* is finalized as proposed.

Secretary

HHS/CDC has added a definition for *Secretary* meaning the Secretary of Health and Human Services (HHS) or any other officer or employee of that Department to whom the authority involved has been delegated. We note that while the NPRM did not propose this definition, the NPRM referenced the *Secretary* in defining *Public Health Emergency*. Thus, HHS/CDC considers it useful to also define the term *Secretary*.

After consideration of comments regarding *Definitions*, HHS/CDC has made the following changes in the final rule:

- The definition of *Agreements* has been withdrawn.
- The definition of *Conditional Release* under section 70.1 has been modified to remove the internal cross-reference to the definition of surveillance under section 71.1. The definition of *Conditional Release* under section 70.1 has been further modified to align with the definition of surveillance under section 71.1 and means “the temporary supervision by a public health official (or designee) of an individual or group, who may have been exposed to a quarantinable communicable disease to determine the risk of disease spread and includes public health supervision through in-person visits, telephone, or through electronic or internet-based monitoring.”
- The definition of *Electronic or internet-based monitoring* has been modified to indicate “communication through” such means, and include “audio” conference.
- The definition of *Incubation period* has been modified to add “or, if signs and symptoms do not appear, the latest date signs and symptoms could reasonably be expected to appear.” This

aligns the definition with the *Precommunicable stage* definition.

- The definition of *Indigent* has been modified to increase the threshold to 200% of the applicable poverty guidelines.
- The definition of *Medical Examination* has been modified to indicate that the health worker conducting the assessment must be “licensed.”
- The definition of *Medical Representative* has been changed to *Representatives* and now includes in addition to the appointment of a medical professional, the appointment of “an attorney who is knowledgeable of public health practices.”
- The definition of *Non-invasive* has been modified to (1) replace “physical examination” with “visual examination,” (2) specify that the individual performing the assessment must be a “public health worker (*i.e.*, an individual with education and training in the field of public health)” and (3) remove “auscultation, external palpation, external measurement of blood pressure.”
- A definition for *Secretary* has been added and means “the Secretary of Health and Human Services (HHS) or any other officer or employee of that Department to whom the authority involved has been delegated.”

d. Public Health Prevention Measures To Detect Communicable Disease

HHS/CDC received support from commenters on screening individuals entering the U.S. from parts of the world where highly infectious diseases are common. One such commenter requested to know the criteria HHS/CDC uses when deciding whether to detain an individual. Another commenter stated that travel history “should be a prerequisite for Federal orders to quarantine” and “medical exam should be a prerequisite for Federal orders to isolate.” HHS/CDC thanks these commenters and welcomes the opportunity to explain this process.

HHS/CDC's decision to detain an individual is based on several criteria, including: Clinical manifestations: Signs and symptoms consistent with those of a quarantinable communicable disease; known or suspected contact with cases, *i.e.*, patients either confirmed or suspected to be infected with a quarantinable communicable disease; epidemiologic information/evidence (travel history, exposure to animals); other documentary or physical evidence in the individual's possession, such as a physician's note documenting infection with or medication for treatment of a quarantinable disease;

and/or public health authorities having notified HHS/CDC that the individual is known or suspected to be infected with a quarantinable communicable disease and likely non-adherent with public health recommendations.

HHS/CDC has modified paragraph (b) of the provisions relating to public health prevention measures to detect communicable disease (§§ 70.10 and 71.20) to include information about “known or possible exposure,” in response to comments requesting further clarity of CDC's criteria.

One organization from the airline industry was generally supportive of 70.10 and 71.20, *public health prevention measures to detect communicable disease*, and requested that any measures, such as screening, occur prior to individuals boarding an aircraft, and preferably prior to arrival at the gate. HHS/CDC thanks these commenters for their support. In response, while an operational plan for each location has not yet been finalized, HHS/CDC expects such measures to occur prior to the boarding of an aircraft, and to the extent possible, prior to arrival at the gate. One airline organization insisted that airline operators should not be financially responsible for any costs associated with screening. HHS/CDC responds that it does not expect airlines and airline operators to assume direct costs associated with public health screening, such as providing additional personnel to conduct the screening. However, indirect costs such as missed flights of passengers who are detained may occur.

Another airline organization requested that HHS/CDC ensure wait-times in lines are not impacted by screening, and encouraged HHS/CDC to take into account the needs of all stakeholders. HHS/CDC feels strongly that in these rare circumstances, which would only occur should a threat to public health exist, preventing airline employees and other passengers from being exposed to a detained or delayed individual provides a greater benefit than the monetary loss of airfare. In keeping with current practice, HHS/CDC will work together with public health partners, carriers, and all who have equities, to ensure insofar as possible that the least restrictive and time-consuming measures are implemented. Finally, commenters requested that individuals who refuse to undergo a public health risk assessment prior to travel be denied boarding of an aircraft. In response, HHS/CDC notes that individuals may be denied boarding for public health reasons pursuant to the criteria published at 80 FR 16,400 (Mar. 27, 2015) titled *Criteria for Requesting*

Federal Travel Restrictions for Public Health Purposes, Including for Viral Hemorrhagic Fevers.

HHS/CDC received a comment expressing concern about conducting public health prevention measures at “other locations” besides U.S. ports of entry because the commenter found this language vague. HHS/CDC clarifies that this term is meant to include all locations where individuals may enter the United States from a foreign country (i.e., border crossings) or gather for the purposes of engaging in interstate travel (e.g., airports, seaports, railway stations, bus terminals), regardless of whether such places are formally designated as such.

One public health organization requested clarification regarding what information or event would justify triggering the screening of travelers. CDC’s response is that, while specific triggers cannot be defined at this time, screening of travelers may generally be conducted during a public health emergency if HHS/CDC determined that monitoring of potentially exposed travelers was needed to protect the public’s health.

One public health organization and many individual commenters asserted that people exposed to measles should not be “tracked” through the use of Federal public health orders. First, we reiterate that because measles is not a quarantinable communicable disease, HHS/CDC does not have the authority to issue a public health order for this illness. Second, it is not HHS/CDC’s policy to monitor people following measles exposures. Rather, HHS/CDC notifies State or local health departments regarding people in their jurisdictions who may have been exposed to measles. The State or local health departments, in turn, choose to notify people regarding their measles exposure, assess their immunity to measles and, if they are not immune, offer vaccination with MMR vaccine to prevent infection. State or local health authorities may choose to monitor people following exposures to measles based on their own criteria.

One commenter asked whether mandatory health screenings at airports would be conducted privately, whether processes would comply with HIPAA, and how data would be protected at airports. In response, HHS/CDC states that, in all situations, HHS/CDC strives to protect the privacy of individuals subject to screening, collection of information, or the issuance of Federal public health orders under HHS/CDC’s authority. While some aspects of the entry risk assessment process conducted during the 2014–2016 Ebola epidemic

were performed in areas of the airport that are not considered private, these were limited to collection of contact information, noncontact temperature measurement, observation for visible signs of illness, and superficial screening questions that did not collect sensitive information. Any more detailed public health assessment would be done in a private area.

HHS/CDC is bound by the Privacy Act to protect personally identifiable data collected and maintained in accordance with that Act. Furthermore, HHS/CDC will apply the protections of the SORN to all travelers regardless of citizenship or nationality. Personally identifiable data collected by HHS/CDC at airports are maintained in a secure database and shared only for official purposes on a need to know basis using secure methods as described in CDC’s System of Records Notice published at 72 FR 70867. HHS is also a hybrid entity under HIPAA, but only those parts of HHS that have been determined to be health care components are subject to the HIPAA Privacy Rule. CDC is generally not a health care component treated as a “covered entity” under the HIPAA Privacy Rule. However, certain specific offices of HHS, CDC, and the National Institute for Occupational Safety and Health (NIOSH) performing activities related to the World Trade Center Health Program are considered health care components of HHS and must comply with HIPAA and the Privacy Rule.

One public health organization recommended that the rulemaking specify that individuals undergoing a public health risk assessment only be asked to provide contact tracing information if the risk assessment leads to a reasonable belief that the individual may become infected. It is CDC’s policy to conduct conveyance-related contact investigations for confirmed cases of communicable diseases. In instances when confirmation cannot be obtained, HHS/CDC may investigate contacts based on reasonable belief of infection following a public health risk assessment which is typically conducted in coordination with the State or local health department of jurisdiction. Such operational details are generally defined in internal protocols. State or local authorities may conduct community-based contact investigations within their jurisdictions based on their own criteria.

After consideration of these comments, HHS/CDC has modified paragraph (b) the provisions relating to *Public Health Prevention Measures to Detect Communicable Disease* (§§ 70.10 and 71.20) to include information about

“known or possible exposure” in the list of information that may be collected.

e. Apprehension and Detention of Persons With Quarantinable Communicable Diseases

HHS/CDC received several comments relating to the “apprehension” of an individual. One public health association and a public health department suggested that HHS/CDC not use the term “apprehension” because this may create social stigma. HHS/CDC uses this term in these regulations to align with the statutory terminology used in 42 U.S.C. 264(b) which authorizes the “apprehension, detention, or conditional release” of individuals coming into a State or possession from a foreign country or possession for purposes of preventing the introduction, transmission, and spread of quarantinable diseases. Similarly, 42 U.S.C. 264(d) authorizes the “apprehension and examination” of any individual in the qualifying stage of a quarantinable communicable disease who is moving or about to move between States or constitutes a probable source of infection to individuals moving between States. While HHS/CDC can clarify and explain this term, only Congress has the authority to change statutory language. In addition to being a term specifically used in statute under 42 U.S.C. 264, HHS/CDC has determined that this term best conveys that HHS/CDC may, based on public health grounds, assume physical custody of individuals. Furthermore, using alternative terminology, may reduce public understanding and transparency regarding HHS/CDC’s legal authorities.

One commenter stated that not every social distancing technique needs to involve taking physical custody of individuals and that using more voluntary-based options would be advisable. HHS/CDC agrees that attempting to obtain voluntary compliance with public health measures is more advisable than assuming legal custody, but believes that maintaining the authority to apprehend individuals who may pose a public health risk is a necessary tool to protect the public’s health. HHS/CDC received a comment regarding the “burden of proof” for an apprehension. In response, HHS/CDC notes that the applicable standard for an apprehension of an interstate traveler is “reason to believe” that the individual is in the qualifying stage of a quarantinable communicable disease. HHS/CDC notes that *Reasonably believed to be infected as applied to an individual* is defined under this final rule.

Several commenters expressed concern that because the “apprehension” period is not explicitly time-limited, that HHS/CDC may “apprehend” an individual indefinitely without providing the individual with a written public health order or a medical review. One commenter noted that HHS/CDC used the term “generally” in the preamble of the NPRM and felt it was too vague, stating “setting a firm timeframe is vital.” A partnership of public health legal scholars and organizations stated that because HHS/CDC did not explicitly limit how long an individual could remain apprehended that such apprehensions could turn into the functional equivalent of a quarantine thus potentially raising Fourth and Fifth Amendment concerns. In response to these concerns, HHS/CDC has added language requiring that it serve an apprehended individual with a public health order within 72 hours of that individual’s apprehension.

HHS/CDC received several other comments relating to the sections authorizing the apprehension and detention of persons with quarantinable communicable diseases. A partnership of public health legal scholars and organizations suggested two public health frameworks for apprehension and detention, one for implementation during non-exigent circumstances and a second for exigent circumstances. As described, the primary distinction between the non-exigent and exigent framework, is that in the former HHS/CDC would be required to hold a due process hearing prior to the imposition of an isolation or quarantine, while in the latter HHS/CDC may briefly detain the individual prior to holding a hearing. While HHS/CDC appreciates the input provided by this partnership, HHS/CDC declines to adopt this suggestion. Importantly, unlike State and local public health authorities who have primary responsibility for the imposition of public health measures occurring within their jurisdictions, HHS/CDC acts in time-sensitive circumstances to prevent communicable disease spread, such as at ports of entry, upon the request of a State or local public health authority of jurisdiction, or when State or local control is inadequate. Furthermore, unlike State and local public health authorities who generally have broad police-power authority to protect the public’s health, HHS/CDC’s statutory authority with respect to isolation and quarantine is limited to only those small, subset of communicable diseases specified through an Executive Order of the

President as quarantinable. Accordingly, HHS/CDC does not foresee sufficient “non-exigent” circumstances where it would be necessary for it to issue a Federal isolation or quarantine order and thus declines to establish the suggested alternative framework on this basis.

The circumstances under which HHS/CDC may apprehend and detain individuals is limited by the terms of 42 U.S.C. 264. HHS/CDC may only isolate, quarantine, or conditionally release an individual if it reasonably believes that the individual is infected with a quarantinable communicable disease and the individual is either arriving into the U.S. from a foreign country, moving between States, or constitutes a probable source of infection to others who may then move between States.

Accordingly, the circumstances under which CDC is would issue a quarantine or isolation order are “exigent” because the individual constitutes a communicable disease risk and is actively engaged in travel or constitutes a source of infection to others engaged in travel. It is thus unnecessary and impractical to provide a “pre-deprivation” hearing prior to quarantining or isolating the individual because he/she if released from custody may be lost to public health follow-up and may expose others. HHS/CDC would not quarantine or isolate an arriving traveler from a foreign country where a single case of a communicable disease such as Ebola exists unless it reasonably believes that the traveler arriving into the U.S. is infected with a quarantinable communicable disease.

Commenters stated that individuals must receive notice of their suspected exposure and be permitted to speak with legal counsel or have legal counsel appointed to them. HHS/CDC agrees that individuals should be adequately notified of the basis for their detention and directs this commenter to sections 70.14 and 71.37, which detail the specific factual content that must be included in a Federal order for quarantine, isolation, or conditional release. We have also modified these sections to explicitly require that the federal order include an explanation of the right to request a medical review, present witnesses and testimony at the medical review, and to be represented at the medical review by either an advocate (e.g., family member, physician, or attorney) at the individual’s own expense, or, if indigent, to have representatives appointed at the government’s expense.

As previously stated, consistent with principles of preventing communicable disease spread, HHS/CDC will also take

measures (such as ensuring phone access) to allow apprehended individuals to have contact with family or legal counsel whom they hire at their own expense. As explained further below, HHS/CDC will also appoint representatives, including a medical representative and an attorney, if the individual is indigent and requests a medical review. Individuals who do not qualify as indigent may also choose to be represented at the medical review by an advocate (e.g., an attorney, physician, family member) and present a reasonable number of medical experts, of their own choosing and at their own expense. HHS/CDC, however, rejects as impractical the notion that indigent individuals should have representatives appointed to them *at the moment of apprehension* because most illnesses of public health concern can be ruled out based on a short interview with a quarantine officer involving an assessment of symptoms and travel history. Thus, the expected length of an apprehension will be very short and not justify the appointment of representatives.

This commenter also requested clarity on what legal recourse may be available to apprehended individuals. While HHS/CDC does not express an opinion regarding what form of legal action an aggrieved individual should pursue, we note that these regulations do not impact the constitutional or statutory rights of individuals to seek judicial redress for detention.

HHS/CDC received comments from the public regarding HHS/CDC’s authority to “arrest” individuals. One commenter stated that individuals should only be detained when a crime has been committed. One association objected to HHS/CDC’s “power to detain an individual for 72 hours and longer without any Federal court order.” Some commenters also worried that any person showing signs of a “common cold” may be held. To be clear, HHS/CDC is not a law enforcement agency, it has no legal authority to “arrest” individuals, but rather has been granted the authority by Congress to “apprehend and detain” individuals for the purposes of preventing the introduction, transmission and spread of quarantinable communicable disease as specified in an Executive Order of the President. 42 U.S.C. 264(b). This provision further provides that “regulations may provide that if upon examination any such individual is found to be infected, he may be detained for such time and in such manner as may be reasonably necessary.” 42 U.S.C. 264(d)(1). HHS/CDC strongly believes that these

authorities may be implemented in a manner consistent with the U.S. Constitution. Furthermore, during the period of apprehension, HHS/CDC will arrange for adequate food and water, appropriate accommodation, appropriate medical treatment, and means of necessary communication.

HHS/CDC received comments from the public inquiring about the criteria that HHS/CDC uses to determine whether an individual should be detained and assessed. As provided for in the regulation, HHS/CDC may apprehend, examine, isolate, and quarantine such individuals to protect the public's health. In determining whether an individual poses a threat to public health, HHS/CDC has developed and uses the following criteria: Clinical manifestations: Signs and symptoms consistent with those of a quarantinable disease; known or suspected contact with a case, *i.e.*, patients either confirmed or suspected to be infected with a quarantinable disease; epidemiologic information/evidence (travel history, exposure to animals); other documentary or physical evidence in the individual's possession, such as a physician's note documenting infection with or medication for treatment of a quarantinable communicable disease; and/or public health authorities have notified HHS/CDC that the individual is known or suspected to be infected with a quarantinable communicable disease and non-adherent with public health recommendations. This determination is typically made in consultation and coordination with State and local public health authorities, as well as the treating health care physician (when available). One public health association agreed that travel history (entering the U.S. from a country where quarantinable diseases occur) made sense for screening, but not for a quarantine or isolation order. HHS/CDC responds that the criteria listed above, as well as those within the NPRM, are examples of factors that HHS/CDC takes into consideration when determining the totality of the circumstances—not one criterion does, should, or will, decide if the individual requires a public health order.

One commenter questioned whether, regarding the list of quarantinable communicable diseases listed by Executive Order of the President, a “common cold” would qualify as a “severe acute respiratory syndrome” and therefore subject the ill individual to a public health order. In response, we note that Executive Order 13295 (April 4, 2003), as amended by Executive Order 13375 (April 1, 2005) and

Executive Order 13674 (July 31, 2014), explicitly excludes “influenza” from the definition of severe acute respiratory syndrome.

HHS/CDC received several comments from a flight attendant union relating to apprehension and detention of a flight crew. These comments include that the flight attendant's employer should be made aware of the apprehension, that HHS/CDC should limit the personal health information that is shared with the employer, that the employer should treat this information as confidential, and that those apprehended should be able to notify families and their union. In response, HHS/CDC notes that it works closely with the airline industry regarding potential occupational exposures to communicable diseases. Furthermore, HHS/CDC notes that personally identifiable health information collected and maintained under the Privacy Act will be disclosed only with the consent of the subject individual, in accordance with the routine uses published in HHS/CDC's system of records notice (72 FR 70867), or under an applicable exception to the Privacy Act. While these regulations do not mandate how employers should treat the personal health information of their employees, HHS/CDC agrees that such information should be treated as confidential. Lastly, consistent with principles of preventing communicable disease spread, HHS/CDC will allow persons detained in accordance with these regulations to communicate with family, union representatives, legal counsel whom they hire at their own expense, and others of their choosing. HHS/CDC will also appoint representatives, including a medical representative and an attorney, if the individual is indigent and requests a medical review.

One commenter asked about provisions for people detained under HHS/CDC's authority who require emergency medical care, and whether the need to conduct a public health assessment could impede such care resulting in harm to the individual. In response, HHS/CDC states that public health officers at ports of entry work closely with emergency medical service (EMS) personnel and that emergency medical care takes precedence over the public health risk assessment. When an individual suspected of being infected with a quarantinable communicable disease requires emergency care, the individual would be transported immediately by EMS to a medical facility, using appropriate infection control precautions. The public health risk assessment would be completed subsequently using information

provided by the examining health care provider in coordination with the health department of jurisdiction.

After consideration of these comments, HHS/CDC has finalized the *Apprehension and Detention of Persons With Quarantinable Communicable Diseases* (§ 70.6) provision as proposed, with the exception that Federal public health orders must be served on the individual within 72 hours of an apprehension. As further detailed below, the 72-hour period was determined based on public comment from health departments familiar with the process, as well as CDC's previous experience of the time necessary to conduct a medical examination, collect and package laboratory specimens, transport the specimens to an appropriate laboratory (when necessary), and conduct the testing.

f. Medical Examinations

HHS/CDC received several comments relating to medical examinations. HHS/CDC received a comment from a public health agency stating that when an individual agrees to submit to a medical examination, it may be more appropriate to medically examine the patient during the “apprehension” period. In response, HHS/CDC notes that these regulations do not prohibit voluntary compliance with public health recommendations in the absence of a public health order. Notwithstanding, HHS/CDC believes that the ability to order a medical examination as part of an order for isolation, quarantine, or conditional release is an important tool to protect the public's health. This agency also stated that the definitions of “health status” and “public health risk” should be modified to ensure that the medical examination contains the minimum requirements needed to assess the communicable disease of public health concern. In response, HHS/CDC clarifies that its sole purpose in ordering a medical examination would be to determine the presence, absence, or extent of infection with a quarantinable communicable disease. HHS/CDC notes, however, that the medical examination is conducted by clinical staff who have primary responsibility for the patient's medical care and treatment and that a medical examination would thus ordinarily include the taking of a medical history and physical examination. HHS/CDC believes that this definition is clear and that no further modifications are needed.

HHS/CDC received a comment expressing concern that an individual would not be able to choose his or her own clinical healthcare provider if

ordered to undergo a medical examination. One commenter raised concerns about the possibility of medical examinations being conducted by “unqualified” or “non-medical personnel.” In response, HHS/CDC clarifies that, in keeping with current practice, any medical evaluation required by HHS/CDC would be conducted at a healthcare facility by a licensed healthcare practitioner. Furthermore, HHS/CDC has determined that it would be impractical to allow individuals to choose their own medical examiners. HHS/CDC notes that among other considerations, it must ensure that the healthcare facility where the medical examination will be conducted has appropriate containment facilities, that necessary laboratory samples will be properly collected, and that it is HHS/CDC’s practice to coordinate closely with State and local public health authorities in the choosing of clinical healthcare providers. Accordingly, we have concluded that the public interest is best served by having HHS/CDC, in coordination with the local health authority and EMS, choose the healthcare facility where the medical examination will be conducted and not the detained individual.

One commenter expressed concern that nonmedical personnel may be allowed to make a determination of illness resulting in actions being taken based on potential misdiagnosis. HHS/CDC appreciates the opportunity to clarify this point. Decisions to issue Federal public health orders are based on the assessment of qualified and licensed physicians. These decisions are based on all available evidence, including clinical presentation, medical and exposure history, and the results of medical evaluation and laboratory testing. Treatment decisions are made by the individual’s treating physician with guidance from public health subject-matter experts.

One commenter suggested that medical examinations should be conducted only with the informed consent of the individual and should not “forcibly” be required. HHS/CDC clarifies that it may require a medical examination under 42 U.S.C. 264(d) because this section, among other things, authorizes the “apprehension and examination” of individuals reasonably believed to be infected with quarantinable communicable diseases in a qualifying stage. CDC, however, agrees that medical examinations may not be conducted “forcibly.” Furthermore, because medical examinations will typically occur in a hospital setting and be performed by clinical staff, it will be incumbent upon clinical staff to obtain

the patient’s informed consent consistent with established standards of medical practice.

Public health organizations provided several comments regarding medical examinations, including that they be performed promptly so as not to curtail liberty, include only minimal components necessary to establish the diagnosis of or rule out the quarantinable communicable disease of concern, and that specimens obtained during such examinations not be used for purposes other than diagnostic testing without informed consent. In response, HHS/CDC states that it agrees with all of these points and that CDC, in keeping with current practice, has a commitment to upholding the highest ethical standards for both medical care and research.

One public health organization asked for clarification of whether hospital staff would be involved in obtaining consent for medical examinations authorized under this rule. In response, HHS/CDC states that, while a public health order authorizes that a medical examination be conducted, should any invasive procedures be determined by the treating clinician to be necessary for diagnostic or treatment purposes, consent for such procedures should be obtained by medical staff in accordance with established standards.

One organization asked for clarification of the location where medical examinations would be conducted, including whether inpatient or ambulatory-care facilities would be included. HHS/CDC responds that it will coordinate with State or local health departments of jurisdiction concerning such operational details as the exact locations where medical examinations may be conducted.

Several public health organizations commented on whether the issuance of public health orders is needed prior to medical examination if individuals agree voluntarily to such examinations, noting that a requirement for the issuance of orders could impede or delay the medical examination and that the examination, itself, could determine whether such orders are needed. In response, HHS/CDC notes that it may choose not to exercise its authority to issue public health orders if an individual complies voluntarily with HHS/CDC’s requirements, including the requirement of a medical examination. However, HHS/CDC retains the right to issue an order requiring a medical examination should an individual not comply voluntarily. Of note, one public health organization supported the use of Federal public health orders in requiring medical examinations, stating

that such orders had been used effectively in the past to facilitate timely examination.

One public health organization requested that language be added to the rule stating that medical examinations will be performed with proper adherence to worker safety and health policies and protocols. HHS/CDC responds that such occupational health protections are beyond the scope of this regulation and are covered by regulations of the Occupational Safety and Health Administration (OSHA).

HHS/CDC received several comments from a flight attendant union relating to medical examinations. This organization stated that the regulations should mandate that an employer pay a flight attendant’s salary and per diem and that no flight attendant should incur discipline as a result of being absent from work. This organization further commented that any changes in the employer-employee relationship should be addressed through joint guidance between government and industry groups. This group also commented that “promptly” should be defined in terms of the length of time that may be needed to arrange for a medical exam and that no more than five hours would be reasonable. This group further stated that “reasonably believed” should be defined to require specific, articulable facts that a trained medical professional can articulate.

HHS/CDC responds that these regulations do not alter, define, or mandate the employer-employee relationship between flight attendants and their employers. In regard to the timeframe for arranging a medical examination, HHS/CDC rejects a specific 5-hour timeframe as too prescriptive, but agrees that the medical examination should be arranged as quickly as possible based on the circumstances of the event. HHS/CDC further notes that the definition of “reasonably believed to be infected” already requires the existence of “specific articulable facts” articulated by a public health officer. Such specific, articulable facts would, for instance, include “contact with an infected person or an infected person’s bodily fluids, a contaminated environment, or through an intermediate host or vector.”

HHS/CDC received a comment from a partnership of public health legal scholars and organizations expressing concern that the regulations do not appear to limit the invasiveness of a medical examination, so long as the examination itself is needed to diagnose or determine the presence or extent of infection with a quarantinable communicable disease. HHS/CDC

welcomes this opportunity to provide further clarifications. HHS/CDC notes that because medical examinations will occur in a hospital setting and be performed by the hospital's clinical staff, it will be incumbent upon clinical staff to obtain the patient's informed consent consistent with established standards of medical practice prior to any examination occurring and that such examinations may not be forcibly conducted. HHS/CDC has also added a requirement that the Director, as part of the Federal order, the individual that the medical examination shall be conducted by an authorized and licensed health worker with prior informed consent. Furthermore, HHS/CDC will implement this provision consistent with U.S. constitutional requirements and Articles 23 and 31 of the International Health Regulations, which requires that parties apply "the least intrusive and invasive medical examination that would achieve the public health objective."

After consideration of these comments, HHS/CDC has finalized the provisions relating to *Medical Examination* (§§ 70.12 and 71.36) as proposed, with the exception that the Director as part of the Federal order must advise the individual that the medical examination will be conducted by an authorized and licensed health worker with prior informed consent.

g. Requirements Relating to Issuance of a Federal Order for Quarantine, Isolation, or Conditional Release

HHS/CDC received several comments relating to the issuance of Federal orders for isolation or quarantine. A flight attendant union commented that crew lists should not be published as part of a quarantine order posted in a conspicuous location. This group further stated that quarantine orders for flight attendants should be treated differently than those applicable to passengers or other airline personnel because flight attendants are health and safety personnel trained in how to perform CPR and operate defibrillators. In response, HHS/CDC notes that if a public health order is publicly posted, the order will be written to refer to a group of individuals, such as all individuals onboard a particular affected interstate or international flight. Under such circumstances, HHS/CDC expects that all members of the group will receive individual copies of the public health order. In some circumstances, CDC anticipates that issuance of a group federal order to an individual may not be feasible—such as when the location of the individual is unknown. Thus, HHS/CDC does not

expect to publish the names of individual passengers or crew as part of a publicly posted quarantine order. Furthermore, while HHS/CDC agrees that flight attendants provide an important public health and safety role, HHS/CDC disagrees that acknowledging this role requires the issuance of different public health orders than those issued to other affected persons.

HHS/CDC received several comments requesting the "least restrictive" means with respect to quarantine and isolation. HHS/CDC agrees and clarifies that in all situations involving quarantine, isolation, or other public health measures, it seeks to use the least restrictive means necessary to prevent spread of disease. Regarding quarantine, as an example, during the 2014–2016 Ebola epidemic, HHS/CDC recommended monitoring of potentially exposed individuals rather than quarantine. Most of these people were free to travel and move about the community, as long as they maintained daily contact with their health department. For some individuals with higher levels of exposure, HHS/CDC recommended enhanced monitoring (involving direct observation) and, in some cases restrictions on travel and being in crowded places, but did not recommend quarantine. HHS/CDC has the option of "conditional release" as a less restrictive alternative to issuance of an order of quarantine or isolation. Under a conditional release order, the person would not be confined as long as the terms of the order were followed. Should a quarantine or isolation order be deemed necessary, home quarantine or isolation would be considered as a less restrictive option to confinement in a guarded facility as long as this was determined to be safe for other household members, appropriate based on the individual's ability and willingness to follow all necessary precautions, and based on the individual's history of compliance with public health recommendations.

One public health organization requested that HHS/CDC specify the types of locations of Federal quarantine and asked clarification of whether this would occur on lands or property under Federal jurisdiction, and whether Federal or State standards would apply to an individual quarantined on lands or property not under Federal control. In response, HHS/CDC notes that operational issues such as the exact location of a quarantine and whether Federal, State, and local orders would be issued separately or concurrently would depend on individual facts and circumstances unique to each case. HHS/CDC notes, however, that it is not

unusual for the Federal government to exercise jurisdiction concurrently with State and local governments.

One public health organization noted the longstanding difficulties faced by Federal, State and local authorities in identifying suitable facilities for quarantining of large groups of people (approximately 350, representing the potential complement of travelers onboard an international flight), including the immediate availability of such facilities in the event of an emergency. HHS/CDC acknowledges these difficulties and affirms that it is actively working with Federal partners to identify suitable locations to accommodate large groups of people while under a Federal public health order.

One commenter stated, "If this is enacted . . . everyone who works with diseases . . . CDC, WHO, Labs, Drs., nurses etc. would have to be arrested as potential carriers." HHS/CDC disagrees with this assertion. HHS/CDC is not a law enforcement agency and does not have authority to arrest individuals. HHS/CDC's authority to issue Federal public health orders is limited to those diseases defined by Executive Order as quarantinable communicable diseases. Furthermore, HHS/CDC does not recommend restriction of movement for healthcare workers, laboratory workers, or others whose occupations involve working with infectious pathogens as long as the recommended infection control precautions are followed. Workers who do not take the necessary precautions or have unprotected exposures to a quarantinable communicable disease may be subject to restrictions if they meet the requirements for issuance of Federal public health orders.

Some commenters indicated that vaccination or treatment should not be "conditions" under "conditional release." HHS/CDC confirms that this final rule does not compel mandatory vaccination or medical treatment of individuals. HHS/CDC clarifies that when medically appropriate, vaccination or treatment, may be "conditions" of an individual's release from quarantine or isolation. Individuals consent to these conditions.

A public health agency commented that HHS/CDC should consider the conditions of confinement to ensure that certain minimum requirements, such as access to telephones, and reasonable accommodation of dietary restrictions, are observed. Specifically, such conditions should be considered at different stages including as part of the issuance of an order, during the mandatory reassessment, and as a part

of the medical review. In response, HHS/CDC notes that in addition to implementing these regulations consistent with U.S. constitutional requirements, CDC's implementation will also be consistent with Article 32 of the International Health Regulations which, among other things, requires that in implementing health measures under the IHR the gender, sociocultural, ethnic and religious concerns of the traveler be taken into consideration. Furthermore, Article 32 requires arranging for adequate food and water, protection for baggage and other possessions, appropriate accommodation, appropriate medical treatment, and means of necessary communication for those subject to public health orders. Furthermore, as stated in the regulations, as part of a mandatory reassessment and medical review, HHS/CDC will consider whether the least restrictive means are being used to protect the public health. HHS/CDC, however, does not believe that it is necessary for "conditions of confinement" to be formally considered as part of an administrative review because many conditions of confinement, such as availability of entertainment or other amenities, may be raised through informal means such as making one's concern known to the facility where the individual is being housed.

HHS/CDC received a comment from a public health agency noting that it should assume the responsibility of providing translation and interpretation services when issuing an order for quarantine, isolation, or conditional release, or when conducting a medical review. HHS/CDC agrees and has incorporated these changes into the regulatory text.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations requesting clarification as to whether personal service will occur when a quarantine order is issued on a group basis and posted in a conspicuous location. In response, HHS/CDC notes that if a public health order is publicly posted, the order will be written to refer to a group of individuals, such as all individuals onboard a particular affected interstate or international flight. Under such circumstances, HHS/CDC expects that all members of the group will receive individual copies of the public health order, thus addressing any concerns about adequacy of notice. Because HHS/CDC, however, cannot foresee all of the circumstances that may arise in an emergency situation, HHS/CDC believes that it is appropriate for these regulations to authorize service

through posting or publication, but only when individual service is "impracticable."

After consideration of these comments, HHS/CDC has modified the provisions regarding requirements relating to *issuance of a Federal order for quarantine, isolation, or conditional release* (§§ 70.14 and 71.37). Paragraphs (a)(5) and (4) of these provisions have been modified, respectively, to require that the federal order include an explanation of the right to request a medical review, present witnesses and testimony at the medical review, and to be represented at the medical review by either an advocate (e.g., family member, physician, or attorney) at the individual's own expense, or, if indigent, to have representatives appointed at the government's expense. Paragraph (b) of these provisions has been modified to require that a Federal public health order be served within 72 hours of an individual's apprehension. A new provision, paragraph (c), has been added requiring that the Director arrange for translation and interpretation services of the Federal order as needed.

h. Mandatory Reassessment of a Federal Order for Quarantine, Isolation, or Conditional Release

A number of commenters were confused regarding the 72-hour period, believing this period referred to the period of apprehension pending the issuance of a Federal public health order and asked why 72 hours were needed. The 72-hour period proposed referred to the timeframe in which HHS/CDC must conduct a mandatory reassessment of the continued need for isolating or quarantining an individual following the service of a Federal public health order. However, in response to public comments HHS/CDC has also added in sections 70.14(b) and 71.37(b) a requirement that it serve the individual with a Federal public health order within 72 hours of that individual's apprehension.

Some commenters, including a public health association, supported the mandatory 72-hour reassessment provision guaranteed by these regulations. One of these commenters also suggested the time be re-evaluated periodically in the event that technology provides a way of speeding up the diagnosis process; another suggested the time frame be expanded to five days to account for weekends; one more commenter noted that circumstances may arise where an additional 72 hours may be needed; and another commenter stated that a second 72-hour reassessment should be required. HHS/

CDC is committed to performing a reassessment within 72 hours of the federal public health order being served on the individual. If, at that time, HHS/CDC determines that the order was properly issued and that a public health risk continues to exist, the order would either be continued or HHS/CDC would work with the State and local health department to transfer custody. In the event that HHS/CDC continues the order, the individual may request a medical review at that time.

A few commenters stated that the reassessment of HHS/CDC's orders should be conducted in a shorter time period than 72 hours such as within 12 hours, performed electronically and conducted by a 3rd party. While HHS/CDC appreciates the input provided by these commenters, HHS/CDC finds these suggestions impractical. Medical examination to confirm or rule out infection with a quarantinable communicable disease may require up to 72 hours to allow for laboratory testing. While some communicable diseases (typically viral infections) may be diagnosed using molecular tests such as polymerase chain reaction (PCR) that take several hours to perform, others require that the organism be cultured to make a confirmed diagnosis or to conduct antimicrobial sensitivity testing in order to provide appropriate treatment. This is typically needed for bacterial infections, such as diphtheria or plague, and may take 48–72 hours (or longer) to complete. For some infectious tuberculosis cases, laboratory confirmation may take several weeks although preliminary molecular testing may assist in conducting an assessment of risk sufficient to continue or rescind the order. Specimen transportation time may also need to be factored in as testing for certain diseases is only available at state public health laboratories or CDC.

While HHS/CDC is required by this provision to reassess the need for a Federal public health order within 72 hours, HHS/CDC will immediately release individuals from detention if at any time it receives information confirming the absence of infection with a quarantinable communicable disease. We note that while the medical assessment is intended primarily as a review of available medical records and other relevant information, these regulations do not prohibit HHS/CDC from conducting the review electronically, for instance by relying on electronic medical records. Furthermore, HHS/CDC disagrees that relying on internal decision-makers for the reassessment is inappropriate or undesirable and thus does not consider

it necessary to rely on a “3rd party.” However, the CDC official or employee conducts the reassessment will not be the same person who issued the quarantine, isolation, or conditional release order. Following the reassessment, the detained individual may also request a medical review as described in these regulations.

HHS/CDC received a comment from a public health agency requesting clarification as to whether all individuals within a group will receive individual due process when a group order is issued. This agency also questioned the feasibility of providing a mandatory reassessment and medical review for large groups. In response, HHS/CDC confirms that if a group order is issued, all individuals within that group will be accorded due process. Furthermore, HHS/CDC has provided flexibility in the regulations to allow for a mandatory reassessment of the group order and consolidation of medical reviews where appropriate.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations stating that while the rule requires consideration of least restrictive means upon reassessment of an order and as part of the medical review, HHS/CDC must also consider least restrictive means prior to the issuance of a quarantine or isolation order. HHS/CDC agrees that all means short of assuming legal custody of the individual including attempting to obtain voluntary compliance with public health measures should be explored. HHS/CDC notes, however, that an isolation or quarantine order is typically issued in time-sensitive situations where because of the exigent circumstances surrounding the risk of communicable disease spread it is not immediately possible to explore all available less restrictive means, including the appropriateness of a home environment, instead of a hospital. For this reason, HHS/CDC has chosen the mandatory reassessment and medical review as the appropriate time to conduct a formal assessment of least restrictive means. To the extent that the commenters suggest that due process requires more, we disagree. *See Yin v. California*, 95 F.3d 864, 870 (9th Cir. 1996) (recognizing that in searches and seizures justified by special needs, the government does not have to use the least restrictive means to further its interests); *Stockton v. City of Freeport, Texas*, 147 F.Supp.2d 642, 647 (S.D. Tex. 2001) (recognizing that the Fourth Amendment does not require that a search or seizure be conducted through the least restrictive means, but rather that the alleged personal invasion be

reasonable under all of the circumstances).

After consideration of these comments, HHS/CDC has finalized the provisions relating to *mandatory reassessment of a Federal order for quarantine, isolation, or conditional release* (§§ 70.15 and 71.38) as proposed.

i. Medical Review of a Federal Order for Quarantine, Isolation, or Conditional Release

HHS/CDC received several comments arguing that its proposed medical review procedures are deficient. Specifically, one commenter stated that assessment procedures should be clearly communicated to all affected persons; that HHS/CDC should more clearly delineate “less restrictive alternatives;” that affected individuals should have a right to legal representation; and that access to independent judicial review is essential.

HHS/CDC agrees that it should clearly communicate review procedures to individuals subject to Federal isolation, quarantine, or conditional release. We note that sections 70.14 and 71.37 have been modified to require that the federal order authorizing isolation, quarantine, or conditional release include an explanation that the federal order will be reassessed 72 hours after it is served on the individual and of the right to request a medical review, present witnesses and testimony at the medical review, and to be represented at the medical review by either an advocate (e.g., family member, physician, or attorney) at the individual’s own expense, or, if indigent, to have representatives appointed at the government’s expense. We further note that the provisions relating to medical reviews, sections 70.16 and 71.39 have been revised to include new paragraphs (q) which states that “The Director shall arrange for translation or interpretation services as needed for purposes of this section.”

Similarly, in regard to minor children or adults with a cognitive disability, HHS/CDC will work with a competent guardian to ensure that procedures are clearly communicated. In regard to less restrictive alternatives, HHS/CDC believes that it is not possible to delineate with specificity all of the less restrictive options that may be available because such determinations will inevitably be based on the individual circumstances of each case, including the severity of the particular disease-causing agent, availability of treatment options should the disease not be adequately contained, the patient’s particular level of infectivity or

communicability, appropriateness of the home environment, and the individual patient’s understanding, ability, and willingness to comply with less restrictive alternatives. For this reason, HHS/CDC has made consideration of less restrictive alternatives a part of the medical review proceeding where evidence may be submitted into the record, testimony obtained, and a recommendation provided by the medical reviewer. As a general matter, however, HHS/CDC clarifies that less restrictive alternatives would refer to reasonable and available alternatives that are adequate to protect the public’s health other than confinement in a guarded facility, such as home quarantine, directly observed therapy, or other forms of supervised release.

In response to concerns about legal representation, HHS/CDC has amended the definition of “Medical representative” to “Representatives” and will now appoint “an attorney knowledgeable of public health practices” in addition to a “physician, nurse practitioner, or similar medical professional qualified in the diagnosis and treatment of infectious diseases.” HHS/CDC hopes that by appointing both an attorney and a qualified medical professional for indigent individuals it will alleviate concerns expressed by the public regarding the medical review process. We note that an attorney may become “knowledgeable of public health practices” in a number of ways, for instance, through prior representation of a public health agency or advocacy organization, training provided by a public health or advocacy organization or other training that would ordinarily occur through a Continuing Legal Education (CLE) event, law school coursework, or through independent study. We further note that for individuals qualifying as indigent, HHS/CDC intends to provide independent legal counsel from outside of the agency. In doing so, HHS/CDC may employ a variety of mechanisms, such as through agreements or memorandums of understanding with law school legal clinics, State or local bar associations, or public interest groups representing indigent clients. Individuals who do not qualify as indigent may choose to be represented at the medical review by an advocate (e.g., an attorney, physician, family member) and present a reasonable number of medical experts, of their own choosing and at their own expense.

HHS/CDC also agrees that access to independent judicial review is essential and assures the public that this final rule does not affect the constitutional or statutory rights of individual to seek

judicial review through such traditional mechanisms as a petition for a writ of habeas corpus under 28 U.S.C. 2241. As a Federal agency, however, HHS/CDC would lack the legal authority through regulation to grant Federal courts with jurisdiction that they would not otherwise possess because only Congress may expand a Federal court's jurisdiction.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations stating that the CDC Director should not have unfettered discretion to accept or reject the medical reviewer's decision, but rather should only be allowed to reject a decision based on lack of substantial evidence. HHS/CDC believes that it would be inappropriate to mandate through regulation that the decision of a medical reviewer (which may include an HHS or CDC employee) should displace the decision of the CDC Director, particularly where the statute and delegation of authority have provided otherwise.

HHS/CDC received several comments stating that a medical representative should be appointed to anyone regardless of their ability to pay. HHS/CDC disagrees and notes that appointment of a representative at the government's expense without regard to the patient's indigence is not required. The status of "indigent" is self-reported as HHS/CDC will not require access to an individual's financial records. Those who self-identify as indigent may be required to sign an affidavit or declaration under penalty of perjury stating they meet the threshold of at least 200% of the applicable poverty guidelines.

HHS/CDC received a comment from a non-profit organization contending that the medical review does not comport with due process because there is no limit on the number of reviews that may be consolidated into a single proceeding, no access to legal counsel, no independence of the reviewer from the initial decision-maker, no confrontation or cross-examination of witnesses, no compulsory process for obtaining evidence or testimony, and no judicial review. This group contends that any detention that is non-exigent should occur only based on the "informed explicit written consent" of the patient or "utilize the existing legal procedures for involuntary commitment of persons."

HHS/CDC disagrees that the medical review as described and set forth in the regulations does not comport with due process. While HHS/CDC acknowledges that there is no numerical limit to the number of medical reviews that may be

consolidated, HHS/CDC believes that the circumstances giving rise to the need for consolidation will be exceedingly rare and that medical reviews will generally be conducted on an individual basis.

HHS/CDC also disagrees that there is no access to legal counsel because HHS/CDC will, consistent with principles of preventing communicable disease spread, allow persons subject to public health orders to communicate with family and legal counsel whom they hire at their own expense. Furthermore, as described above, the regulations have been amended to require the appointment of *both* an attorney *and* a medical professional if the detained individual qualifies as an indigent and requests a medical review. Individuals who do not qualify as indigent may also choose to be represented at the medical review by an advocate (*e.g.*, an attorney, physician, family member) and present a reasonable number of medical experts, of their own choosing and at their own expense.

HHS/CDC further believes that reliance on internal reviewers does not violate due process and notes that it is not unusual, for instance, for hospitals to rely on internal decision-makers when determining whether to commit a mental health patient on an emergency basis. The regulations, moreover, explicitly state that the medical reviewer will not be the same individual who initially authorized the quarantine or isolation order. We note further that the definition of both "representatives" and "medical reviewer" would in fact allow for the appointment of non-HHS/CDC employees in these capacities because both terms are broadly defined in terms of the professional qualifications and not employment status of these individuals. Thus, these regulations do not prohibit the CDC Director from appointing personnel from outside of the agency to assist in conducting a medical review. For individuals qualifying as indigent, HHS/CDC intends, generally, to provide independent legal counsel from outside of the agency.

HHS/CDC also clarifies that during the course of a medical review, a detained individual will be permitted to present witnesses and question any witnesses offered by HHS/CDC. Any "confrontation" of witnesses, however, will be conducted in a manner consistent with principles of preventing communicable disease spread. HHS/CDC, as a Federal agency, however lacks the legal authority to allow a detained individual to use compulsory processes, such as a subpoena, to compel the presence of witnesses. HHS/CDC will

nevertheless make reasonable efforts to produce any HHS/CDC employees that would be critical to a detained individual's presentation of evidence during a medical review.

HHS/CDC also disagrees that there is no judicial review and notes that these regulations do not impact an individual's constitutional or statutory rights to contest their Federal detention through such traditional mechanisms as a petition for a writ of habeas corpus under 28 U.S.C. 2241. To the extent, however, that the commenter contends that HHS/CDC should follow legal procedures other than those set forth through the Federal quarantine statute at 42 U.S.C. 264, we disagree. HHS/CDC notes that as a Federal agency it lacks the ability to rewrite Federal statutes or grant Federal courts with legal jurisdiction that they do not already possess. HHS/CDC also rejects as impractical and as insufficient to protect public health, the notion that isolation or quarantine should only occur based upon the consent of the subject individual.

HHS/CDC received a comment from a flight attendant union that as an important "safety net" HHS/CDC should pay for "second medical opinions." HHS/CDC declines to extend payment to medical examinations beyond those required as part of a public health order, but notes that as part of a medical review individuals may submit additional evidence into the record concerning their health status and potential public health risk to others.

One commenter noted language in the NPRM stating that the "medical review is not intended to address the concerns of individuals who take issue with amenities of their confinement . . .," interpreting this to mean that "no provision is made for those who must use a CPAP (continuous positive airway pressure) at night or who need orthopedic appliances, or who have food allergies, to name a few." In response, HHS/CDC states that, when confinement of an individual under Federal public health authorities is needed, HHS/CDC will ensure that such confinement will occur in a location and with necessary amenities to ensure the health and safety of the individual, including provision for medical or dietary requirements. Issues related to health and safety will be addressed at the time of the issuance of the order, or as soon as HHS/CDC is made aware of them, but are beyond the scope of the medical review which is intended to re-evaluate the continued need for the Federal public health order based on a review of the medical and other evidence submitted into the record.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations stating that it should provide for an oral hearing whenever practical. HHS/CDC agrees that an oral hearing is appropriate and has modified the language to state: “The medical review shall be conducted by telephone, audio or video conference, or through other means that the medical reviewer determines in his/her discretion are practicable for allowing the individual under quarantine, isolation, or conditional release to participate in the medical review.”

HHS/CDC received a comment from a partnership of public health legal scholars and organizations that the CDC Director’s written order, which constitutes final agency action, must advise individuals of their rights to appeal to Federal court. We note that the commenters specifically cite the Administrative Procedures Act (APA, 5 U.S.C. 704), which provides that “final agency action for which there is no other adequate remedy in a court are subject to judicial review.” While HHS/CDC agrees that independent judicial review of agency decisions is available, it takes no position as to whether such reviews should occur under the APA (as suggested by the commenters) or through other traditional mechanisms as a petition for a writ of habeas corpus under 28 U.S.C. 2241. For this reason, HHS/CDC believes that due process is satisfied by designating the Director’s written order as “final agency action” without further speculation as to the exact form of further legal review. However, to clarify HHS/CDC’s intended we have added the following language to the regulatory text: “Nothing in these regulations shall affect the constitutional or statutory rights of individuals to obtain judicial review of their federal detention.”

Accordingly, after consideration of these comments, HHS/CDC has modified paragraph (f) of the provisions regarding *medical review of a Federal order for quarantine, isolation, or conditional release* (§§ 70.16 and 71.39) to include the revised definition of “Representatives,” which now requires HHS/CDC to appoint both a medical professional and an attorney “to assist the individual for purposes of the medical review upon a request and certification, under penalty of perjury, by that individual that he or she is indigent and cannot afford a representative.”

j. Administrative Records Relating to a Federal Order for Quarantine, Isolation, or Conditional Release

HHS/CDC received a comment from a flight attendant union concerning whether an overlap existed between CDC’s maintenance of administrative records relating to the issuance of Federal public health orders and an employee’s access to exposure and medical records under OSHA (29 CFR 1910.1020). We note that since HHS/CDC is not a flight attendant’s employer, HHS/CDC would not be covered by this particular OSHA standard under these circumstances. Furthermore, because these regulations do not alter, define, or mandate the employer-employee relationship between flight attendants and their employers, to the extent that this question seeks input regarding an employer’s obligations under OSHA, HHS/CDC views the question as outside the scope of the rulemaking.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations stating that the regulations should require quarterly reporting to Congress to facilitate transparency and oversight. While CDC recognizes the additional transparency that direct reporting of details related to quarantine activities may provide to the public, CDC notes that historically, the issuance of Federal orders is rare (*i.e.*, one to two orders issued per year). Thus, publication of the specifics surrounding individual quarantine cases may raise significant privacy concerns related to the individuals placed under federal orders.

CDC does routinely describe its practices in published Morbidity and Mortality Weekly Reports (MMWR) when new methods, technologies, or other changes make it possible to revise and improve programs (*e.g.* DNB, M&M guidance, change in air contact investigation algorithms), which all serve to enhance transparency. Such information is also found on CDC’s Web site and publicly available standard operating procedures.

After consideration of comments received and as further explained below, HHS/CDC has modified the provisions regarding *Administrative Records* relating to a Federal order for quarantine, isolation, or conditional release (§§ 70.17 and 71.29) to remove paragraphs (5) regarding agreements entered into between HHS/CDC and the individual.

k. Other Due Process Concerns

HHS/CDC received many additional comments from the public concerned over whether this regulation violates

rights guaranteed by the U.S. Constitution, such as Due Process and specifically during the medical review process. HHS/CDC disagrees that the regulations are insufficient to protect the constitutional rights of individuals. In regard to medical reviews, HHS/CDC asserts that allowing individuals to choose at the government’s expense who will conduct the medical review is not required by due process and that there is no conflict of interest in allowing the CDC Director to appoint who will conduct the medical review on the agency’s behalf. HHS/CDC asserts, however, that individuals will be allowed to submit relevant information, including information provided by outside doctors or other medical specialists during the medical review. HHS/CDC will further preserve relevant agency documents for purposes of ensuring a competent legal review in the event that the individual seeks judicial redress of their quarantine or isolation. As explained elsewhere, law enforcement support for quarantine or isolation orders will generally be provided by U.S. Customs and Border Protection, U.S. Coast Guard, or other Federal law enforcement programs, but HHS/CDC may also accept voluntary state and local assistance in enforcing its Federal orders.

HHS/CDC received public comment expressing concern with regard to potential language barriers experienced by foreign nationals during travel. HHS/CDC responds that it has revised those sections of the regulations dealing with issuance of Federal orders to require that HHS/CDC arrange for translation or interpretation services of the Federal order as needed. In circumstances where it would be impractical to provide a line-by-line translation of the order, HHS/CDC may take other steps to reasonably apprise individuals of the contents of the order, for example, by arranging for oral translation services.

One public health organization questioned the feasibility of CDC’s conducting the mandatory reassessment or medical review of a group quarantine order within the specified time frame. In response, HHS/CDC states that a group quarantine order would be issued on the basis of a shared exposure for all individuals in the group; therefore, the mandatory reassessment or medical review could be conducted based on the shared exposure, unless certain individuals in the group were determined to be immune to the quarantinable communicable disease in question. Part of the reassessment would include a determination of whether the group order should be revised as individual orders.

HHS/CDC also received a comment that the duration of a quarantine, isolation, or conditional release period is not adequately defined. HHS/CDC disagrees because the regulations limit these actions to only those who would pose a public health threat, for instance, by being in the “qualifying stage” or a quarantinable communicable disease. The “qualifying stage” of the disease is defined as a communicable stage of the disease or a precommunicable stage, but only if the disease would be likely to cause a public health emergency if transmitted to other individuals. We note that HHS/CDC’s “Health Information for International Travel” (also known as the Yellow Book) provides the public with general guidance regarding the expected length of communicability for many quarantinable communicable diseases. For more information, please see <http://wwwnc.cdc.gov/travel/yellowbook/2016/table-of-contents>.

HHS/CDC received a comment that the qualifications of who may issue a quarantine or isolation order are not defined leading to concerns that such orders will be issued by non-medically trained personnel. In regard to the qualifications of who may issue a Federal public health order, HHS/CDC notes that all orders are issued under the authority of the CDC Director, but that in practice such determinations are made only by personnel trained in public health and licensed to practice medicine in the United States.

One organization requested that HHS/CDC provide notification to the appropriate embassy if a foreign national is placed under a Federal order. In regard to non-resident foreign nationals, HHS/CDC clarifies that it will coordinate closely with the U.S. Department of State to ensure that all rights and obligations under the Vienna Convention on Consular Relations and bilateral agreements will be observed. Because of the complexity of this issue, including reliance on the interpretation of treaties and bilateral agreements, HHS/CDC believes that it is best to ensure compliance through operational procedures, rather than to formalize such obligations through regulatory text.

One commenter requested that HHS/CDC clarify its handling of issues relating to diplomatic immunity. HHS/CDC recognizes that under the Vienna Convention on Diplomatic Relations, diplomats are not liable to any form of “detention.” It is HHS/CDC’s policy to coordinate closely with the U.S. Department of State regarding any public health issues arising in regards to diplomats and HHS/CDC will continue to do so under these regulations.

One public health organization recommended that HHS/CDC include written notification to individuals under public health orders of the duration that the order will be in effect. HHS/CDC responds that it will provide information on the incubation and communicability period of the quarantinable communicable disease, if known, but that the duration of the public health order may depend on a variety of factors, such as demonstration of non-infectiousness through repeated laboratory testing. Thus, HHS/CDC is unable to provide an exact numerical limit (in terms of days or hours) that a public health order will remain in effect.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations stating that in exigent circumstances HHS/CDC may isolate or quarantine an individual, but should then be required to hold a mandatory due process hearing within 48 hours before a neutral decision-maker. At the outset, HHS/CDC agrees with the commenters that the appropriate framework for determining the adequacy of due process procedures are the factors articulated by the Supreme Court in *Mathews v. Eldridge*, 424 U.S. 319 (1976). These factors include: (1) The private interest affected by the government’s actions; (2) the risk of erroneous deprivation of such private interest through the procedures used and the probable value, if any, of additional or substitute procedures; and (3) the government’s interest, including the function involved and the fiscal and administrative burden of proposed additional or substitute procedures. Concerning the private interest at stake, HHS/CDC disagrees that this interest should be measured solely in terms of the physical liberty of the individual, but notes that the private interest also includes an interest in receiving medical treatment and in not harming others, as would occur if the individual was communicable. The Federal government’s interest, moreover, is particularly strong because it is not simply guarding the welfare of a single individual or even a small group of individuals, but rather protecting the public at large against the spread of a quarantinable communicable disease. Most importantly, HHS/CDC believes that mandatory administrative hearings are unlikely to significantly guard against erroneous deprivations. Unlike subjective determinations of behavior which typically form the basis of a mental health “civil commitment,” isolation and quarantine decisions are based on objective criteria such as

manifestations of physical illness or laboratory test results. Thus, weighing these factors, HHS/CDC disagrees that due process requires it to adopt a system of mandatory administrative hearings in the absence of the individual requesting a medical review.

Regarding the use of a “neutral” decision maker, HHS/CDC restates that the definition of both “representatives” and “medical reviewer” would in fact allow for the appointment of non-HHS/CDC employees in these capacities. The regulations, moreover, explicitly state that the medical reviewer will not be the same individual who initially authorized the quarantine or isolation order. Accordingly, HHS/CDC has determined that the procedures it has adopted for medical reviews comport with due process.

1. Privacy

Several people commented on the private nature of the doctor-patient relationship. HHS/CDC appreciates the opportunity to respond to this concern. HHS/CDC is charged with protecting the health of the public. At times, this requires obtaining private information about people’s health or exposure history and taking certain actions to protect others from becoming sick with a communicable disease. HHS/CDC works closely with State and local health departments to ensure that ill people detained or isolated under Federal orders receive appropriate care and treatment. HHS/CDC is also bound by the Privacy Act to protect personally identifiable information collected and maintained under that Act. For a more detailed explanation of how such information is protected, please see <http://www.cdc.gov/sornnotice/09-20-0171.htm>. For information on the retention and maintenance of such records, please see <https://www.archives.gov/records-mgmt/rcs>.

HHS/CDC received a comment from a professor of public health law and ethics stating that HHS/CDC should address how the HIPAA Privacy Rule, Americans with Disabilities Act (ADA), and Administrative Procedure Act (APA) counterbalance the powers set forth in the proposal and reflect “appropriate social distancing practices.” The commenter did not highlight which specific provisions of these laws HHS/CDC should address or the relationship that these laws have to social distancing. Notwithstanding, HHS/CDC may generally state that these regulations will be carried out consistent with Federal law.

We note that HHS is a hybrid entity under HIPAA, but only those parts of the Department that have been

determined to be health care components are subject to the HIPAA Privacy Rule. CDC is generally not a health care component treated as a “covered entity” under the HIPAA Privacy Rule. However, certain specific offices of HHS, CDC, and the National Institute for Occupational Safety and Health (NIOSH) performing activities related to the World Trade Center Health Program are considered health care components of HHS and must comply with HIPAA and the Privacy Rule.

CDC most often acts as a public health authority under the HIPAA Privacy Rule. During the course of a public health investigation it may seek the support of a covered entity, such as a hospital or private physician. The HIPAA Privacy Rule permits the disclosure of public health information to public health authorities, such as the CDC, and their authorized agents for public health purposes including but not limited to public health surveillance, investigations, and interventions. More information concerning the HIPAA Privacy Rule may be found here: <http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm>.

Similarly, we note that this final rule while formalizing administrative policies and practices, does not affect the rights of individuals under the ADA or APA, which are statutes enacted by Congress. One commenter opined that collection of contact information as part of public health prevention measures and maintenance of administrative records raise privacy concerns and that HHS/CDC should consider “super-enhanced privacy protections” consistent with the Model State Public Health Privacy Act of 1999. HHS/CDC disagrees. As a Federal agency, HHS/CDC must abide by the laws established by Congress for the protection of records, specifically the Privacy Act of 1974, 5 U.S.C. 552. On December 13, 2007, HHS/CDC published a system of records notice (72 FR 70867) under the Privacy Act describing, among other things, safeguards for preventing the unauthorized use of information collected from travelers. HHS/CDC will make disclosures from this system only with the consent of the subject individual, in accordance with routine uses published in its system notice, or in accordance with an applicable exception under the Privacy Act.

m. Payment for Care and Treatment

HHS/CDC received several comments relating to payment for medical expenses. One commenter stated that HHS/CDC should assume payment for

all related medical expenses, housing costs, and other necessities for individuals or groups subject to deprivations of liberty and that it is “ethically unfair” for HHS/CDC to be the “payer of last resort.” Another commenter stated that “CDC must guarantee financial help after third party payments are exhausted.” While HHS/CDC acknowledges that it has an ethical, moral, and legal obligation to provide care and treatment for individuals under a Federal quarantine or isolation order, HHS/CDC disagrees that it is “ethically unfair” to excuse a medical insurer or other entity with a contractual obligation from paying for medical expenses. Accordingly, HHS/CDC has determined that it is appropriate for it to maintain and affirm its status as a “payer of last resort.”

Two public health organizations asked whether nonmedical costs such as training of staff, replenishing of personal protective equipment, managing and disposing of biological waste and contaminated supplies, etc., are also subject to HHS/CDC payment authorization. While the costs of care and treatment of individual patients under Federal public health orders are authorized by this rule, these additional costs to the extent that they are unrelated to the individual patient’s treatment and care would not be covered by this rule.

HHS/CDC received a comment suggesting that the regulations allow for charging detainees the medical and hospital costs of nonconsensual treatment. HHS/CDC disagrees and first, clarifies that these regulations do not authorize compulsory medical treatment. HHS/CDC further acknowledges that constitutional principles and medical ethics require that those detained under isolation or quarantine have access to adequate nourishment, appropriate accommodation, and medical treatment. However, HHS/CDC has determined that its obligation to pay for medical care and treatment should be secondary to the obligation of any third party, such as a medical insurer that may have a pre-existing contractual obligation with the patient to pay for hospital expenses. Accordingly, HHS/CDC declines to make any changes to the provisions authorizing payment for medical care and treatment.

A flight attendant union commented that HHS/CDC should pay for any outside costs that the flight attendant would normally incur relating to medical treatment, e.g., copayments, deductibles. HHS/CDC declines this suggestion and notes that while it is not HHS/CDC’s intent to unduly burden

individuals with the costs of their own isolation or quarantine, payment for expenses will be made consistent with constitutional and ethical obligations to provide for the basic necessities, e.g., food, medical treatment, for those subject to such public health orders. Furthermore, these regulations do not alter, define, or modify the contractual relationship between insurance companies and the insured.

After consideration of these comments, HHS/CDC has finalized the provisions relating to payment for care and treatment (§§ 70.13 and 71.30) as proposed.

n. Agreements

HHS/CDC received comments relating to the intention and use of agreements. Commenters worried that such “agreements” may be coerced, and individuals would be compelled to submit to involuntary testing or “research projects.” One commenter stated that the definition of agreement is circular and confusing because the word “agreement” appears in the definition. This commenter also suggested that what HHS/CDC proposes should more aptly be labeled as an “Affidavit” or “Affirmation” because the definition as proposed by HHS/CDC lacks bilateral obligations on both parties.

Due to the number of public comments received expressing confusion over this public health measure, HHS/CDC has removed the provisions on *Agreements* (70.18 and 71.40), and modified other provisions of the final rule (70.1, 71.1(b), and 70.5) to remove references to “agreements.”

o. Penalties

Many commenters expressed concern over the penalties provisions contained within the proposed regulation. Specifically, one association objected to “CDC’s proposed increase in penalties.” Another stated that “CDC is not qualified to decide upon the punishment.” HHS/CDC takes this time to better explain that the penalties listed in today’s final rule, which have been codified as proposed, are set forth by Congress via statutory language and codified into regulation to reflect current practice. This regulation serves to notify the public of the existing statutory penalties for violation of quarantine regulations, which HHS/CDC has no authority to change.

One organization requested that language be added to rules regarding the issuance of penalties if an employer provides an “unsafe work or unhealthful working condition.” HHS/CDC responds that such penalties are beyond the scope of this rule and refers

the commenter to regulations of the Occupational Safety and Health Administration.

HHS/CDC received a comment from a flight attendant union regarding criminal penalties stating that HHS/CDC should provide further clarification as to what constitutes a violation and clarify that flight attendants who act in accordance with their company's practices, policies, or procedures should not be held criminally liable. In response, HHS/CDC notes that while the text of the regulation is being updated, these regulations do not increase the criminal penalties that may be imposed for violations of quarantine regulations or alter the manner in which liability may be assessed. Rather, these regulations serve to inform the public of the criminal penalties that currently exist in statute (42 U.S.C. 271 and 18 U.S.C. 3571). Furthermore, HHS/CDC clarifies that criminal penalties, if any, would be assessed by a court of law based on an indictment or information filed by an Assistant U.S. Attorney based on individualized facts and circumstances, and would not be determined administratively by the CDC.

HHS/CDC offers the following explanation to inform the public regarding this section. As prescribed in section 368 (42 U.S.C. 271) and under 18 U.S.C. 3559 and 3571(c), criminal sanctions exist for violating regulations enacted under sections 361 and 362 (42 U.S.C. 264 and 265). 18 U.S.C. 3559 defines an offense (not otherwise classified by letter grade) as a "Class A misdemeanor" if the maximum term of imprisonment is "one year or less but more than six months." 18 U.S.C. 3571 provides that individuals found guilty of an offense may be sentenced to a fine. Specifically, an individual may be fined "not more than the greatest of"—(1) the amount specified in the law setting forth the offense; or (2) for a misdemeanor resulting in death, not more than \$250,000; or (3) for a Class A misdemeanor that does not result in death, not more than \$100,000. Similarly, an organization, found guilty of an offense may be fined "not more than the greatest of"—(1) the amount specified in the law setting forth the offense; or (2) for a misdemeanor resulting in a death, not more than \$500,000; or (3) for a Class A misdemeanor that does not result in death, not more than \$200,000. 42 U.S.C. 271 sets forth statutory penalties of up to 1 year in jail and a fine of \$1,000. Therefore, it is classified as a Class A misdemeanor under 18 U.S.C. 3559. Because the alternate fines set forth under 18 U.S.C. 3571 are greater

than the \$1,000 set forth under 42 U.S.C. 271 (which sets a maximum penalty of not more than \$1,000 or one year of jail, or both for violation of quarantine laws), and because 42 U.S.C. 271 does not exempt its lower penalties from 18 U.S.C. 3571(e), HHS/CDC has chosen to codify the greater penalties of 18 U.S.C. 3571(b)(5) and (c)(5) and to remove the lower penalties as stated in 42 CFR 71.2 from the regulation.

After consideration of these comments, HHS/CDC has finalized the provisions relating to *Penalties* (70.18 and 71.2) as proposed. *Penalties* has been moved to section 70.18, since proposed 70.18 *Agreements* has been removed from this final rule.

p. Economic Impact

Within the analysis published with the NPRM, HHS/CDC solicited public comment regarding the cost and benefit estimates for airlines and vessel operators associated with improved provision of traveler contact data. While HHS/CDC received support for the data collection from two public health associations, HHS/CDC received a comment from industry who misread the proposals to mean that aircraft operators would be required to develop new capacity and processes to capture and store a comprehensive set of sensitive data, archive this data, and then provide it to CDC.

HHS/CDC restates and clarifies that today's final rule does not impose any new burdens upon the airline industry but rather, codifies the current practice of receiving a passenger manifest order (if needed, as CDC currently collects passenger information from CBP via APIS and PNR) and providing HHS/CDC with any data in an airline's possession. This regulatory impact analysis has been revised to clarify that the rule does not require an airline to solicit or store additional data. Therefore, HHS/CDC does not expect that formalizing its current data collection practices will increase costs. Neither airlines nor U.S. Customs and Border Protection (CBP) will need to develop new data systems nor will travelers need to provide data as part of the "check in process."

The same industry organization also commented that they have been complying effectively with the existing requirements, but have, on occasion found it difficult to locate, extract, compile, format and transmit available information within the timeframe specified in orders from HHS/CDC. They note that delays sometimes arise because the manifest order may contain incorrect flight or passenger information. The discussion in the regulatory impact analysis section has

been revised to note that delays in compliance with manifest order requirements may result from HHS/CDC having incorrect traveler information in the manifest order.

The same industry organization also reports that all of the data available to them related to passengers are currently transmitted as Advance Passenger Information System (APIS), and potentially under Passenger Name Record (PNR), data to the Department of Homeland Security (DHS) and that there is no reason to burden airlines with an order for passenger data. HHS/CDC recognizes that industry does submit certain passenger data to DHS and it is not our intent to burden industry with duplicative requirements, but rather to effectively and efficiently protect public health. In the experience of the HHS/CDC, queries from APIS/PNR rarely result in full sets of contact information (*i.e.* the record includes all five additional data fields as outlined in the final rule). The data fields that are most commonly missing from the records are email addresses (missing 90 percent of the time), secondary phone number (missing 90 percent of the time), and street addresses (missing or insufficient for public health contact tracing up to 50 percent of the time). These data elements are vital to a contact tracing investigation. In looking at a random sample of 20% of the compiled international air travel manifests for 2015, those including a compiled data set from NTC and the airlines, 100% were missing at least one of the 5 data fields. Email address and secondary phone number were among those most frequently missing. For context, there were approximately 760,000 scheduled flights that arrived into the United States in 2015. In 2015, CDC issued passenger manifest requests for 64 international flights arriving into the United States. As noted in the RIA of the final rule, from 2010 to 2015, CDC conducted an average of 77 contact investigations per year involving arriving international flights.

Airlines are contacted for the majority of contact investigations using a manifest order document. At a minimum, CDC needs to confirm the ill traveler was on the flight and where the individual sat in relation to other travelers to determine risk of exposure.

In CDC's experience the following has been true:

- Only airlines can quickly and efficiently produce a partial manifest targeting affected rows;
- only airlines can confirm identity of "babes in arms" and their co-travelers (Parent); this is important for measles cases;

- only airlines can quickly confirm whether an individual actually flew (in instances where individuals deplane and do not re-board during a layover); and

- only airlines can confirm a plane's configuration if there is a question with the provided row numbers. Different aircraft have different seating arrangements depending on carrier and layout. It is important to know if a certain seat is separated by a bulkhead or is a window seat.

In addition, HHS/CDC only requires a partial manifest, e.g. 5 rows for travelers with infectious tuberculosis, so that NTC and HHS/CDC staff can limit the investigation to only those passengers at risk and supplement/cross reference with APIS and PNR data. If a partial manifest is not available from the airlines, then each passenger record must be researched individually to find a seat number, and then the configuration of an entire plane must be populated to determine where the index case sat in relation to other at-risk passengers. For large flights from Asia, this can pose a tremendous burden to NTC and CDC staff while slowing the ability of CDC to provide important contact information to state and local health departments. Manually populating multiple 300+ person flights is not feasible in a timely manner.

As part of its plan for retrospective analysis under E.O. 13563, HHS/CDC intends to synthesize, analyze, and report within the next two years on strategies to reduce duplication of the collection of passenger/crew manifest information in coordination with DHS/CBP. The report will include any recommendations (e.g., IT systems improvements to facilitate enhanced search capabilities of passenger data, increased efficiency to relay passenger data, improvements to the existing CDC-CBP MOU) to ensure that the collection of passenger or crew manifest information do not unduly burden airlines, vessels, and other affected entities. HHS/CDC intends to seek public comment on the report and any recommendations regarding the costs and benefits of activities implemented in 42 CFR parts 71.4 and 71.5. Estimates of both costs and benefits in the NPRM regulatory impact analysis were not very large because HHS/CDC is not implementing a new data collection requirement. The regulatory impact analysis for the final rule has been revised to reflect that HHS/CDC will work with CBP to search for responsive data to avoid duplicative data requirements. Estimates of costs in the revised regulatory impact analysis have not been revised because the airline

industry did not provide any new information regarding costs to search for responsive data when receiving manifest orders. The benefit estimate has been revised and is lower than the estimate for the NPRM to indicate that the airlines may not have any more contact data than is already provided in APIS or PNR data submitted to DHS.

HHS/CDC received a number of comments from the general public that compared the relatively small number of measles cases in any given year to the total numbers of vaccine-associated adverse events and health department spending to contain measles outbreaks. Based on this comparison, commenters believed that HHS/CDC and health departments spend too much money on communicable disease control and that resources would be better allocated to other activities. Some commenters suggested that the costs of these adverse events should be included in a Small Business Regulatory Enforcement Fairness Act analysis. In general, this type of analysis is outside the scope of this regulatory impact analysis because this final rule does not require measles vaccination. HHS/CDC's recommended vaccine schedule will not be affected by this final rule. Although HHS/CDC recommends that health departments offer measles vaccine to non-immune individuals exposed during travel, measles is not a quarantinable communicable disease and this final rule does not require any individual to receive a measles vaccine. Because health departments offer measles vaccines to exposed, non-immune travelers, HHS/CDC estimates that the final rule will only result in a small number (6) of additional measles vaccines. The costs of procuring and administering these vaccines is included in the analysis.

As noted in the regulatory impact analysis, there are only 564 travelers exposed to measles during international travel in a given year. Most of these travelers will already have immunity to measles and the final rule is only expected to have a small impact on the ability of health departments to contact travelers. The total costs of all measles vaccine-associated adverse events is outside the scope of the analysis for this final rule as mentioned above.

One commenter suggested that the cost estimates for the NPRM were too low because the analysis did not account for reduced willingness to travel if vaccines against measles and other communicable diseases are required to travel. HHS/CDC disagrees with this suggestion because vaccination is not a requirement in this final rule. HHS/CDC has on occasion

requested that DHS/TSA restrict interstate or international air travel for people known to be infectious with measles who were noncompliant with public health recommendations not to travel. However, HHS/CDC does not recommend restricting the air travel of persons who have not received the measles vaccine.

One commenter questioned whether the estimated value of statistical life (\$9.4 million) should be multiplied by the total number of measles vaccine-associated adverse events in the United States. HHS/CDC appreciates this thoughtful comment. This would result in a larger estimate in the cost of measles vaccine-associated adverse events. However, this is not a correct usage of the value of statistical life, which should only be multiplied by an estimated number of deaths. The regulatory impact analysis has been revised to better explain this distinction.

Another commenter suggested that public health department measles response costs were overestimated by using a model-based approach rather than estimating the cost of hiring of additional staff to deal with measles outbreaks. HHS/CDC addressed the comment in the regulatory impact analysis by clarifying that the analysis is a published model-based analysis and that the cost estimate is based on the opportunity cost of public health personnel and is not based on the cost of hiring additional staff.

HHS/CDC received comments from the airline industry indicating that the definition of ill person under 71.1 does align with Note 1 to Standard 8.15 of ICAO's Annex 9 to the Convention on International Civil Aviation. HHS/CDC also received comments from the airline industry regarding the change to the definition of ill person under 70.1 for interstate flights contending that these changes would increase costs. Specifically, the airline industry reported that not only does the expansion of the definition of *ill person* place a greater burden on airline staff, the ambiguity of that definition amplifies the burden or at least raises questions as to the particular obligations of the flight crew to determine if someone is an "ill person." Moreover, the airline industry wanted to know whether flight crews have an obligation to conduct a physical examination of the passenger to determine fever. The airline industry also noted that under the OSHA blood borne pathogens standard, employers are prohibited from exposing crewmembers to blood or other potentially infectious materials. The airline industry also questioned whether the fever-related illness

reporting in the proposal would require that all carriers have the equipment (thermometers) onboard to determine fever. The proposal, as noted, has two other ways to identify fever (warm to touch or history of fever) which the airline industry wanted to ensure would remain viable options within the final rule.

HHS/CDC notes that there is no expectation that flight crews should perform physical examinations as part of illness reporting. HHS/CDC also notes that the non-thermometer (warm to touch or history of fever) remain in the final rule. Regarding the potential for increased costs associated with the change in illness reporting for interstate flights, HHS/CDC notes that the current illness reporting requirements for interstate travel appear in 42 CFR 70.4 and state that “The master of any vessel or person in charge of any conveyance engaged in interstate traffic, on which a case or suspected case of a communicable disease develops shall, as soon as practicable, notify the local health authority at the next port of call, station, or stop, and shall take such measures to prevent the spread of the disease as the local health authority directs.” Communicable disease is defined in current 42 CFR 70.1 as “illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through an intermediate plant or animal host, vector, or the inanimate environment.”

The changes in this final rule will not result in substantially increased costs because airlines would either: (1) Be complying with the current regulatory requirement and report all cases or suspected cases of communicable disease to local health departments; or (2) report illnesses according to HHS/CDC guidance available at <http://www.cdc.gov/quarantine/air/reporting-deaths-illness/guidance-reporting-onboard-deaths-illnesses.html>, which is codified in this final rule. HHS/CDC notes that changes in this final rule align the symptoms requested for international and interstate illness reporting. In addition, according to guidance, reports received by HHS/CDC would be considered sufficient to satisfy the requirement to report to local health departments because HHS/CDC will coordinate response activities with the local health department after receiving an illness report. In response to these comments, HHS/CDC increased the expected number of illness reports in the upper bound analysis regulatory impact analysis for the final rule. This

upper bound analysis finds that a 100% increase in info-only reports and 50% increase in reports requiring response would result in a marginal cost of \$20,573 for airlines and vessel operators. This cost is negligible compared to the annual revenue of the international air and maritime travel markets. HHS/CDC also received a comment to include the cost of training for illness reporting in the regulatory impact analysis. HHS/CDC notes that illness reporting is already required under existing regulations and the changes in this final rule more closely align with ICAO guidance for illness reporting for international flights and represent a reduction in burden for interstate flights, where reporting of all cases or suspected cases of communicable diseases is required. HHS/CDC added an estimate of training costs to the upper bound cost analysis for airlines (an annualized \$356,000 per year).

HHS/CDC received a comment from a local health department concerning the rationale for reporting all illnesses and deaths that occur on interstate flights. This health department asked whether evaluating illnesses and deaths that occur on interstate flights may lead to an increase in costs for State and local health departments. HHS/CDC does not anticipate an increase in costs for State and local health departments because evaluating illnesses and deaths occurring on interstate flights is consistent with existing HHS/CDC guidance and represents a less restrictive alternative compared to the existing reporting requirement in 42 CFR 70.4. Furthermore, the costs to State and local health departments may decrease if HHS/CDC is able to filter out reports that do not require a public health response, which airlines would have previously reported directly to the health departments under 42 CFR 70.4. If there is an increase in the number of illness reports requiring a public health response, HHS/CDC believes the costs to health departments may decrease if the health department is notified earlier.

A public health research center questioned the value of nonmedical personnel being able to differentiate Ebola, Middle East respiratory syndrome (MERS) or measles from other medical issues. HHS/CDC appreciates the concern and notes that the final rule aligns the illness reporting requirement with international guidelines and represents a reduced burden for illness reporting on interstate flights compared to current regulatory language as mentioned above. The intent of illness reporting is not to diagnose disease during flight, but rather to identify a

limited number of instances in which it would be advantageous to follow up with ill travelers for an assessment upon disembarkation. The current numbers of illness reports received are summarized in the regulatory impact analysis and the number of reports is not expected to increase significantly because the regulatory text will better align with publically available HHS/CDC guidance.

A number of comments from the public questioned whether there would be a huge cost resulting from the broad definition of *ill person*. These commenters expressed concern that misdiagnosis by non-medically trained personnel would lead to reduced travel based on the public's fear of being wrongly detained by public health officials. HHS/CDC notes that illness reporting is already required for both interstate and international travel. We note that travelers are not placed under public health orders simply as a result of an illness report. Rather, orders are issued only if a licensed medical officer based on a public health risk assessment has sufficient reason to believe that the individual is infected with a quarantinable communicable disease. In addition, the new definition is consistent with existing international guidelines and HHS/CDC guidance. Thus, HHS/CDC does not believe the changes to illness reporting will result in a large burden to the general public. The cost analysis in the regulatory impact analysis has been updated to include the cost to travelers involved in public health follow-up after an illness report.

One commenter opposed the rule because of a perceived negative economic and/or social impact upon individuals placed under a public health order. Regarding the social impact of the individual who may be ostracized, HHS/CDC notes that public health measures such as quarantine and isolation are not new concepts or practices, HHS/CDC has been implementing these measures to protect public health for many years. We reemphasize that one compelling reason for the publication of this final rule is to make “quarantine” and “isolation” better understood by the public so that these terms, its purposes, and meanings become more familiar and thereby decrease public anxiety over these important protections. For the same reason, HHS/CDC does not believe the provisions in the final rule will increase or decrease the cost of isolation or quarantine. HHS/CDC does provide an estimate of traveler cost in the sections describing Ebola entry enhanced risk assessment and management and illness

reports in the regulatory impact analysis.

One commenter suggested that the costs incurred by airlines would be passed along to the general U.S. population purchasing tickets for air travel. HHS/CDC concurs and mentions this possibility in the regulatory impact analysis. However, changes included in this final rule are a codification of a current practice and estimated total costs are only \$11,000 to \$431,000 per year. Thus, significant changes in ticket prices are not expected.

One commenter suggested that changes in infectious disease caseloads would not result in cost savings to public health agencies or individuals because there is already a public health workforce in place. HHS/CDC calculates such costs based on the opportunity cost of public health staff under the presumption that such staff would be involved in other productive activities if not spending time addressing outbreaks.

HHS/CDC solicited comment from the public regarding potential public willingness to pay to be contacted in the event of an exposure to a communicable disease during travel. This was done to help estimate the potential benefit to the public of HHS/CDC's efforts to work with health departments to contact travelers exposed to meningococcal disease, viral hemorrhagic fevers, MERS or other severe acute respiratory syndromes, measles, and tuberculosis, among other diseases. HHS/CDC received a number of comments from several individuals that they believe public health measures to mitigate measles transmission are unnecessary. Some individuals also noted that Ebola and MERS cases in the United States have not led to widespread transmission. These commenters either indicated or inferred that they would be unwilling to pay to be informed of potential communicable disease exposures during travel. The discussion in the regulatory impact analysis has been updated to incorporate this feedback.

HHS/CDC solicited public comment on willingness to pay to reduce Ebola risk in the United States to near zero if another international outbreak of Ebola with widespread transmission occurs in the future. HHS/CDC received comments from an organization representing flight attendants indicating that they believe it is in the public interest to reduce Ebola risk in the United States to near zero in the event of a future outbreak. They indicated that there is no reason to believe that achieving this objective would require unsustainable levels of funding. HHS/CDC incorporated this comment

regarding public willingness to pay in the regulatory impact analysis.

HHS/CDC also received comments from several individuals regarding the high cost of the measures taken to reduce the risk of Ebola transmission in the United States during the 2014–2016 Ebola epidemic in West Africa. Several of these commenters indicated they had zero willingness to pay for future public health measures in the event of a large Ebola outbreak.

Many commenters stressed the need to reassess whether to implement such activities in the event of a future Ebola outbreak. An example of such comments is provided by a research center studying international response efforts to emerging infectious disease threats, who noted that despite 99% complete active monitoring by health departments, there was no evidence of incident Ebola cases among individuals traveling from Ebola-affected countries. This does not include the two incident cases that preceded active monitoring. The commenters state that given this evidence it is not advisable for HHS/CDC to recommend active monitoring in the event of future Ebola outbreaks.

In addition, a public health research center cautioned against extrapolating costs and benefits calculation methods for measles and tuberculosis to Ebola, MERS, and other rare diseases. The research center further noted that countermeasures for Ebola and MERS do not exist (other than isolation and quarantine). They suggest that this would limit the effectiveness of point of entry measures. These researchers also point to the fact that transmission of Ebola and MERS has not occurred during air travel. They noted that point of entry risk assessment programs may increase anxiety (and costs) if cases are detected in the community after the implementation of point of entry measures. Finally, the research center noted that the costs for State and local health departments to actively monitor all arriving travelers for 21 days were not included in the analysis.

In response to these comments, HHS/CDC concurs that it would not be wise to directly extrapolate approaches for measles and tuberculosis to rare diseases and has tried to provide as much information as possible around the decision to implement the Ebola risk assessment program and recommendations for active monitoring. HHS/CDC did not simply extrapolate the analysis for measles and tuberculosis to Ebola.

HHS/CDC does not have data on State and local spending to achieve the objective of the 21-day active monitoring program and concedes that

the cost of active monitoring would likely exceed the costs incurred at the airports. However, HHS/CDC did provide an estimate of total Federal spending for both domestic and international efforts to attempt to quantify the cost of these efforts. Federal money was used to support State/local surveillance efforts. Federal money was also used to support improvements in laboratory capacity by States and hospital infection control efforts, which should have benefits beyond the 2014–2016 Ebola epidemic. In addition, Federal funding supported research into potential Ebola vaccines and medicines. The cost for the Ebola enhanced entry risk assessment program was just a portion of these costs and HHS/CDC acknowledges that risk assessment program at airports by itself would have limited potential to reduce risk. However, HHS/CDC also notes that the costs of Ebola entry risk assessment at points of entry included efforts to (1) stratify travelers by risk level so that health departments could focus more intense monitoring efforts on travelers at higher risk and (2) educate travelers on Ebola risk factors and symptoms and provide informational materials, a thermometer, and a telephone to all travelers to improve compliance with active monitoring efforts. This led to a higher cost, but more effective program relative to an alternative in which travelers would only be screened once at the airport, such as occurred in other countries implementing screening programs during the 2003 Severe Acute Respiratory Syndrome (SARS) epidemic.

HHS/CDC believes that the risk of Ebola infection in the U.S. population was potentially reduced because of the combination of measures to protect against Ebola transmission in the United States, including risk assessment at ports of entry. HHS/CDC acknowledges the risk was probably very low in the absence of domestic activities.

HHS/CDC further notes that it recommended active monitoring of travelers as a less restrictive alternative to more stringent measures such as quarantines that were being demanded by some members of the public. Widespread implementation of quarantine, particularly for healthcare workers crucial to the response efforts in West Africa and the United States, would have greatly hampered outbreak control measures by providing a strong disincentive to healthcare workers participating in the response.

To estimate the potential benefits of the Ebola risk assessment program at ports of entry, HHS/CDC provided a cost comparison of the incident Ebola cases

that occurred in Texas compared to New York to estimate the difference in costs between an Ebola case that was detected quickly and treated in a pre-selected hospital identified to be capable of Ebola treatment in comparison to an Ebola infection that was not initially suspected to be Ebola leading to community exposures and hospital exposures in a hospital that was not a pre-selected hospital capable of Ebola treatment.

HHS/CDC also examined the recent MERS outbreak in South Korea to demonstrate that even relatively small outbreaks of rare diseases such as MERS and Ebola can have large economic costs despite a relatively small number of cases and deaths. HHS/CDC found that the number of international travelers (non-Korean citizens traveling to South Korea) decreased by 40–50% during the peak months of the 2015 MERS outbreak. HHS/CDC further notes that these declines in travel occurred in the absence of widespread travel restrictions. The costs incurred by South Korea during the outbreak were used to demonstrate the potential costs of a larger Ebola outbreak in the United States.

Given the evidence from the programs implemented to mitigate risk during the 2014–16 Ebola epidemic, *i.e.*, the small number of international air travelers from countries with widespread Ebola transmission that later developed Ebola and the very limited risk of transmission by asymptomatic individuals with Ebola infection, HHS/CDC may not elect to implement an Ebola entry risk assessment program in the event of a future outbreak or to recommend 21-day active monitoring of travelers from countries with widespread transmission.

HHS/CDC emphasizes that it will continue to consider cost and work with multiple U.S. government agencies, as well as with airport authorities and health departments in U.S. States and territories, to apply the latest evidence to future decision-making. In addition, HHS/CDC will try to employ the least restrictive measures to achieve public health objectives. HHS/CDC notes that, during the period that the Ebola entry risk assessment and monitoring program was in effect, only 0.08% (29/38,344) of travelers assessed at U.S. airports were recommended for medical evaluation at hospitals and that no Federal quarantine or isolation orders were issued during the epidemic, although some States did issue such orders under their own authorities. These considerations have been added to the regulatory impact analysis in the final rule. Since this analysis concerns a codification of

existing authorities, this analysis has been moved to a separate appendix after incorporating public feedback.

A number of commenters suggested that HHS/CDC did not include the cost for people participating in the Ebola enhanced risk assessment program. However, HHS/CDC did provide such an analysis of these costs. One public commenter suggested that the psychological cost of quarantine should be considered in the economic impact analysis. Although HHS/CDC generally concurs with the idea of accounting for all of the costs associated with time spent in quarantine, HHS/CDC's authority to issue quarantine orders will not change with the publication of this final rule. Thus, this final rule does not incur new psychological costs for persons under quarantine orders.

HHS/CDC notes the opportunity costs for persons undergoing risk assessment at airports and/or evaluation at hospitals during the 2014–16 Ebola entry risk assessment and management program. HHS/CDC estimates their opportunity costs based on average wage rates, but did not have additional data to estimate a marginal psychological cost. Opportunity costs were also estimated for a more restrictive option compared to the Ebola entry risk assessment and management program, *i.e.* a suspension of entry for 21 days after having been in an Ebola-affected country.

One commenter suggested that this rulemaking does not represent the “least burden on society” because HHS/CDC has failed to clearly identify a “compelling public need” for the rule. HHS/CDC appreciates the comment and responds that the regulatory impact analysis cites a specific market failure addressed by this final rule. The market failure is that the costs associated with the spread of communicable diseases impacts the entire U.S. population, not just the group of persons currently infected with communicable diseases. Since this final rule is primarily implementing current practice, HHS/CDC does not anticipate major new benefits or costs.

One commenter stated that the cost/benefit analyses was very vague, meaning that there is no accountability or way to measure whether or not the final rule will achieve its intended result of preventing the spread of quarantinable communicable diseases via travel, which the commenter stated was already an extremely low risk. HHS/CDC concurs that there is uncertainty in the regulatory impact analysis. However, HHS/CDC has tried to indicate that one of the reasons for this uncertainty is that this final rule is primarily implementing current

practice. Thus, where possible, HHS/CDC tried to provide data on the current burden of the provisions that are being updated in this final rule. HHS/CDC does not expect any major changes in practice as a result of this final rule.

One commenter suggests that the cost/benefit analyses was confusing because quarantinable and non-quarantinable diseases were not clearly identified. HHS/CDC appreciates this feedback and has updated the analyses to more clearly differentiate quarantinable and non-quarantinable diseases.

One commenter suggested that HHS/CDC took an unnecessarily extreme position in analyzing an alternative of removing all enforcement of current regulations. HHS/CDC used this as an alternative because this final rule is a codification of current practice and does not impose new regulatory burdens.

q. Paperwork Reduction Act

HHS/CDC published notices related to modifications and a new information collection in the Notice of Proposed Rulemaking. Those information collections are as follows:

(1) Foreign Quarantine Regulations (42 CFR part 71) (OMB Control No. 0920–0134)—Nonmaterial/non-substantive change—National Center for Emerging, and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

(2) Restrictions on Interstate Travel of Persons (42 CFR part 70) (OMB Control No. 0920–0488)—Nonmaterial/non-substantive change—National Center for Emerging, and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

(3) Airline and Vessel and Traveler Information Collection (42 CFR part 71)—New Information Collection Request—National Center for Emerging, and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

One commenter stated that there are no estimates of additional information collection requirements resulting in a clear violation of the Paperwork Reduction Act. The commenter further stated that requesting information when HHS/CDC has no idea of the impact is not a well thought out or planned rulemaking. This commenter further questioned the value of providing comment when the agency purportedly has no idea what additional burden it is imposing on the public. HHS/CDC disagrees with these assessments.

The focus of the final rule is to codify current practices and to update currently approved information collections to better align with operational procedures and other

industry guidance related to illness reporting on aircraft and vessels. Those information collections are currently approved under OMB control numbers 0920–0134 (Foreign Quarantine Regulations), 0920–0488 (Restrictions on Interstate Travel of Persons), and the new information collection request Airline and Vessel and Traveler Information Collection (42 CFR part 71), which is currently pending OMB approval. The estimates of the burden provided in the Paperwork Reduction Act section of the NPRM were based on previous experience with particular information collections solicited or required from the public or industry in the past. In some cases, larger estimates of the burden to account for an increased number of reports to HHS/CDC during disease outbreaks or public health emergencies were included. There are no information collections requirements that are wholly new, unreasonably burdensome, or outside the scope of historical HHS/CDC practices implemented to prevent the introduction or spread of communicable disease into or within the United States.

Another commenter suggested that training in recognizing ill travelers is a burden that was not adequately considered. HHS/CDC disagrees because it does not mandate specific training for recognition of ill travelers. HHS/CDC is seeking to better align the ill person definition with the ICAO standard and thus is not the only organization that has this requirement. HHS/CDC provides specific guidance for how to recognize ill travelers and report to HHS/CDC on its Web site. HHS/CDC also believes this training is most likely already part of the training process for flight crews. An analysis of potential training costs has been added to the upper bound cost analysis in the Regulatory Impact Analysis. The upper bound annualized costs for additional training are estimated at \$356,000.

Finally, HHS/CDC is re-inserting “Has a fever that has persisted for more than 48 hours” as a component in the definition of *Ill person* in § 70.1 General definitions and “Has acute gastroenteritis, which means either diarrhea, defined as three or more episodes of loose stools in a 24-hour period or what is above normal for the individual, or vomiting accompanied by one or more of the following: One or more episodes of loose stools in a 24-hour period, abdominal cramps, headache, muscle aches, or fever (temperature of 100.4 °F [38 °C] or greater)” in § 71.1 General definitions. This language was quoted verbatim in the preamble of the NPRM at 81 FR

54305 but was inadvertently omitted from the proposed regulatory text.

B. Provisions Applicable Only to Part 70 Only (Domestic)

a. General

HHS/CDC received comments from the public asserting that State and local public health regulations already in place are sufficient to protect individuals without the need for Federal involvement. HHS/CDC agrees that State and local authorities play an integral role in protecting public health, but disagrees that there is no Federal role. HHS/CDC’s DGMQ maintains quarantine stations at major U.S. ports of entry that fulfill a primary purpose in preventing the introduction of communicable diseases into the United States, but also play an important role in containing the interstate spread of communicable disease. There are several broad areas of cooperation between quarantine field staff and State and local health agencies, such as contact tracing, which provide a framework for responding to communicable disease threats arising from interstate travel and at the local level. It is through these networks and established partnerships, in keeping with current practice, that the provisions of the final rule will be successfully implemented.

HHS/CDC received a comment to the effect that quarantine specifically should be left to the States. HHS/CDC received another comment stating that Federal authority should not take precedence over State authority. In contrast, a public health association suggested that these regulations should indicate that Federal public health measures “supersede activities taken by States.” We respond that while HHS/CDC works closely with State and local public health authorities, the Federal government has a traditional role in preventing introductions and spread of communicable diseases at ports of entry and interstate. HHS/CDC also disagrees with the suggestion that it should not intervene in the event of inadequate local control or lacks authority to protect the public’s health within the authority granted to it by Congress. Under 42 U.S.C. 264(e), Federal public health regulations do not preempt State or local public health regulations, except in the event of a conflict with the exercise of Federal authority. Other than to restate this statutory provision, this rulemaking does not alter the relationship between the Federal government and State/local governments as set forth in 42 U.S.C. 264. Under, 42 CFR 70.2, HHS/CDC

make take action to prevent the interstate spread of communicable diseases in the event that the CDC Director determines that inadequate local control exists. This longstanding provision on preemption in the event of a conflict with Federal authority is left unchanged by this rulemaking.

One public health organization requested clarification of the process to transfer an individual from Federal to State custody and further stipulated that the State authority should require an independent State assessment of risk under State law. In response, HHS/CDC notes that the issuance of Federal public health orders is coordinated with State and, when appropriate, local public health authorities. Transfer of an individual from Federal to State custody would be similarly coordinated such that the State would need to agree to assume custody and the State’s order would need to be in place prior to HHS/CDC’s rescinding the Federal order. When custody of an individual is transferred to a State authority, the State may choose, but would not be under a Federal mandate, to conduct an independent assessment of risk pursuant to its own policies and procedures. Furthermore, once the transfer of custody has occurred, the State’s laws and standards for due process would apply.

Another public health authority asked for clarification of how jurisdictional issues regarding transfers of authority affecting more than one State would be handled for individuals under Federal quarantine. HHS/CDC responds that if more than one State is affected by the transfer of authority, HHS/CDC will work with all relevant States to determine the most appropriate State or local jurisdiction to accept custody of the individual. If it is necessary to transport the individual to another State, for example to the individual’s State of residence, HHS/CDC will work with the affected States to facilitate such a transfer under Federal orders.

One public health organization requested clarification of the procedures HHS/CDC would use to rescind a public health order. HHS/CDC responds that it would issue the detained individual a written order rescinding the isolation, quarantine, or conditional release. This would be based on either one of two criteria: The individual is determined to no longer pose a public health threat or custody of the individual has been transferred to a State or local public health authority.

HHS/CDC received a comment from a public health department stating that the regulations should include language that HHS/CDC will coordinate with

State and local public health authorities and law enforcement regarding any intended surveillance and enforcement activities. HHS/CDC strongly believes that coordination with State and local public health authorities, as well as relevant law enforcement entities, is essential to the public health response to individual cases as well as outbreaks of communicable disease. On the few occasions that HHS/CDC has issued Federal isolation orders for travelers with infectious tuberculosis, HHS/CDC has worked closely with State and local health departments to coordinate transportation, medical evaluation, and treatment of the ill traveler, including law enforcement when needed. During the 2014–2016 Ebola epidemic, HHS/CDC issued guidance and alerted health care and EMS workers to consider a diagnosis of Ebola if patients had compatible symptoms and had visited an affected country within the previous three weeks. HHS/CDC and State and local health departments worked closely to assess any potentially exposed individuals with symptoms compatible with Ebola to determine whether medical evaluation was needed and, if so, to ensure safe transportation to a medical facility designated by the health department. In light of HHS/CDC's history of close coordination with State and local public health authorities, including cooperating law enforcement entities when needed, HHS/CDC has determined that specific regulatory language is unnecessary.

b. Requirements Relating to Travelers Under a Federal Order of Isolation, Quarantine, or Conditional Release

Some commenters questioned HHS/CDC's authority, as well as the need, to restrict the movement of individuals who are not ill but have been exposed. HHS/CDC thanks these commenters for their review and input. Some quarantinable communicable diseases, such as novel pandemic influenza strains, may be contagious before the infected person becomes symptomatic. Therefore, in these situations, it may be necessary to restrict the movement of asymptomatic exposed people to make sure they do not expose others inadvertently while they are not aware that they are contagious. It may also be necessary to restrict movement of an exposed person if public health authorities are unable to ensure appropriate monitoring of the person, for example, if an individual is known to have a history of noncompliance with public health recommendations. Exposed people whose movement is restricted through quarantine or other means may be offered vaccination, if a

vaccine is available, but only with informed consent.

One commenter noted that the regulation allows HHS/CDC to issue interstate travel permits to an infected individual conditioned upon the individual taking "precautionary measures" as prescribed by HHS/CDC. This commenter requested that HHS/CDC clarify what precautionary measures may be prescribed and stated that such conditions should not be based on factors unrelated to the individual's health condition, *e.g.*, socio-economic, ethnic status. While HHS/CDC agrees that the issuance of a travel permit should not be based on such factors as race, gender, ethnicity, or socio-economic status, we note that the issuance of a travel permit may be conditioned on such factors as the individual's ability and willingness to comply with the terms of the permit. Furthermore, while the exact precautionary measures prescribed may vary based on the infectious agent, such measures, for instance, may include: Agreeing to minimize time in congregate settings while traveling; avoiding eating in restaurants or other enclosed public places; traveling with no other people in the vehicle or, if other people are needed to safely operate the vehicle, agreeing to wear a mask and ensure good ventilation; and reporting to the local health department upon arrival or on route as needed.

This commenter also requested clarification of the legal impact of a person who is denied a permit or has had a permit revoked. We note that per the terms of the regulation persons denied a travel permit or who have had a travel permit revoked may submit a written appeal. The right to a written appeal, as well as the means by which an appeal may be requested, will be addressed in the written order denying the request for a travel permit or revoking an existing permit. The appeal will be decided by an HHS/CDC official who is senior to the employee who denied or revoked the permit. HHS/CDC declines to speculate as to what else this commenter may be referring to by the term "legal impact," but notes that the regulation does not impair the ability of persons to seek judicial review of final agency actions through the Administrative Procedure Act.

This commenter also requested clarification of how long an individual may be restricted in his or her travel under a Federal travel permit. We note first that the restriction only applies to those under a Federal public health order or under a State or local order if the State or local health department of jurisdiction requests Federal assistance

or there is inadequate local control. In further response, HHS/CDC notes that the restriction would remain in place so long as the individual is infected or capable of infecting others. This commenter further requested clarification of the impact of a disagreement between HHS/CDC and State or local public health authorities. We note that by the terms of 42 U.S.C. 264(e), Federal public health regulations do not preempt State or local public health regulations except in the event of a conflict with the exercise of Federal authority. Moreover, per the terms of 42 CFR 70.2, HHS/CDC may take action to prevent the interstate spread of communicable diseases in the event that the CDC Director determines that inadequate local control exists.

HHS/CDC received a comment from a flight attendant union requesting clarification as to whether an employee could be held criminally liable for knowingly transporting someone in violation of the terms of a travel permit as specified under section 70.5. In response, HHS/CDC clarifies that the term "operator" is defined under 70.1 consistent with 14 CFR 1.1 and with respect to an aircraft means, "any person who uses, causes to use or authorizes to use an aircraft, with or without the right of legal control (as owner, lessee, or otherwise)." We further note that criminal liability, if any, will be determined by a court of law and not administratively by HHS/CDC. Accordingly, we decline to speculate as to whether employees who knowingly violate the terms of a travel permit may be held criminally liable.

One public health organization asked for clarification of how local health departments would be engaged in conducting communicable disease screening activities or enforcing Federal public health travel restrictions for individuals traveling interstate, given that HHS/CDC staff are not present at many points of interstate travel. HHS/CDC acknowledges this limitation in their presence at some ports of entry and in regard to interstate travel and intends to address this through future guidance and discussion with stakeholders.

In regard to interstate air travel, HHS/CDC clarifies that the Federal public health Do Not Board tool will deny boarding of persons known to pose a public health risk to other air travelers. This tool is applicable to persons boarding a commercial aircraft with an origin or destination in the United States, including interstate travel. *See* 80 FR 16400 (Mar. 27, 2015).

For other modes of travel, HHS/CDC does not have a systematic mechanism

of denying boarding and these situations may need to be addressed on a case-by-case basis, either through direct communication with a conveyance operator or through application of other movement restrictions such as the issuance of State or Federal public health orders. Such situations will likely require the participation of State or local public health authorities; however, as noted by the commenting organization, the Federal and State/local costs and resources required during such operations are not known. The specific roles of State or local health departments will be addressed through future guidance or stakeholder discussion.

HHS/CDC received a comment contending that the extension of travel permits to intrastate travel is in violation of the Commerce Clause. HHS/CDC disagrees. We note that HHS/CDC will only require intrastate travel permits when a State or local health authority of jurisdiction requests federal assistance or in the event that State and local actions are inadequate to prevent interstate communicable disease spread. Under 42 U.S.C. 264, Congress acting pursuant to its Commerce Clause jurisdiction, has authorized HHS/CDC to take measures to prevent the foreign introduction and interstate spread of communicable diseases. It is well established that the Federal government may act to protect interstate commerce, even though the threat may come entirely from intrastate activities. *See United States v. Lopez*, 514 U.S. 549, 558–559 (1995).

One commenter requested that HHS/CDC replace the word “traveler” with “passenger” with respect to mandatory public health assessments, as a traveler could be taken to mean “anybody in a private vehicle lined up at a toll booth.” In response, HHS/CDC states that the use of the word “traveler” with respect to conveyances is intended to include both passengers and crew. Furthermore, HHS/CDC states that its authority extends to all individuals engaging in interstate travel including those traveling by private vehicle, particularly if they are in the “qualifying stage” of a quarantinable communicable disease.

HHS/CDC received a comment from a partnership of public health legal scholars and organizations expressing concern that requiring application for a travel permit may be unduly burdensome because individuals who are served with a conditional release order at an airport would then need to apply for a separate travel permit to travel to their home State of residence. HHS/CDC disagrees because under such circumstances the conditional release

order itself would include authorization for these individuals to continue travel to their home State of residence provided that they subsequently report to public health authorities as needed. For example, during the response to Ebola, CDC worked with state public health authorities to allow certain individuals who met certain risk thresholds to travel in private vehicles to their place of residence while maintaining a focus on protecting public health. This was done on a case by case basis, depending on distance of travel and risk of exposure, and distance from a health care facility with adequate capacity to treat and contain Ebola. CDC would make similar assessments in the event that conditional release orders are needed for other quarantinable communicable diseases. We note that the conditional release order itself would provide permission to travel and have added clarifying language to the text.

HHS/CDC clarifies, however, that after arriving in their home State, should the individuals wish to engage in further travel, a travel permit may be needed at that time. In response to comments from this partnership organization, HHS/CDC also clarifies that the travel permit, as provided for in the regulations, will only be required under circumstances where the individual is already under a Federal, State or local order of quarantine, isolation, or conditional release. Because the travel permit requirement is only applicable to individuals who are already under a Federal, State, or local public health order, HHS/CDC believes that this provision does not impermissibly restrict an individual’s right to travel.

In response to comments regarding the time with which CDC may consider a travel permit request, the CDC Director shall respond to a request for a travel permit within 5 business days. Likewise, one public health association suggested that, in the event a travel permit is denied, these regulations should state the timeframe that HHS/CDC will issue a response to the appeal; another proposed the time period for CDC’s response to be 72 hours. In response to these comments, HHS/CDC has added a requirement in the regulation that in the event that a request for a travel permit is denied, it must decide an appeal from that denial within three (3) business days. HHS/CDC believes that this timeframe is appropriate because this provision only applies to individuals who already have had their travel restricted through the issuance of a public health order and deciding an

appeal may involve coordination with affected state or local jurisdictions.

After consideration of comments received, HHS/CDC has modified paragraphs (a), (b)(1), (b)(2), and (c) of the provision concerning *Requirements Relating to Travelers Under a Federal Order of Isolation, Quarantine, or Conditional Release* (§ 70.5) to remove “agreements,” referring to agreements entered into by the CDC. We have also modified paragraph (a)(5) to require that HHS/CDC must issue a written response to an appeal within three (3) business days. Other provisions of this section are finalized as proposed.

c. Report of Death or Illness Onboard Aircraft Operated by an Airline

Several commenters expressed concern that the new regulations remove the requirement for a local health authority to be notified when a passenger falls ill or dies on board a flight. The commenters insisted that this could interfere with effective local response to important communicable disease threats. They propose that local authorities should be notified in a timely manner, such as within one hour of initial reporting, and that HHS/CDC should consult with local health authorities on the necessary steps to contain the spread of communicable diseases. In contrast, one airline supported the direct reporting to HHS/CDC.

HHS/CDC carefully considered these comments and responds that it will continue its long standing partnership with local authorities. The rationale behind asking airlines to submit reports of deaths or reportable illnesses directly to HHS/CDC as opposed to local authorities is to simplify and streamline the reporting process for these airlines. Under the final rule, airlines will not be required to know the current points of contact for multiple local jurisdictions, but rather may report to HHS/CDC as a single point of contact. HHS/CDC will continue to share public health information with State and local health departments through approved electronic disease reporting networks such as the Epidemic Information Exchange (Epi-X), HHS/CDC’s secure, Web-based system. HHS/CDC may also notify State or local authorities via phone calls.

Some commenters questioned whether HHS/CDC has adequate resources to be the first responder at the local level. HHS/CDC responds that it regularly coordinates with Federal, State and local agencies and other partners in the airport environment. HHS/CDC intends to continue working closely with Federal, State, and local partners,

including first responders such as EMS and State and local health agencies, when assistance is needed.

One commenter suggested that the reporting of ill travelers “would be an invasion of our liberty and privacy.” HHS/CDC disagrees. The report of illness or death on board a carrier is a longstanding regulatory provision and practice. This final rule only changes to whom the report is made (directly to HHS/CDC), rather than to the local health department of destination. We further note that personally identifiable information collected and maintained under the Privacy Act will be handled in accordance with that Act and CDC’s system of records notice published at 72 FR 70867.

Another commenter worried that “having flight reservations require health reports will significantly impede air travel.” It is not HHS/CDC practice, nor a requirement under this regulation, for individuals to submit health reports prior to or after making a flight or vessel reservation. The only instance when health documents may be required prior to travel, is if a person is known to be infectious with a communicable disease that could spread during travel and has been placed on the Federal Public Health Do Not Board described in 80 FR 16400 (Mar. 27, 2015). Because this practice is not new, HHS/CDC believes it will not impede air travel.

A flight attendant association suggested that HHS/CDC should adopt training and awareness requirements for airline employers to provide to flight attendants concerning “what entails a qualifying stage.” Industry also expressed concern that flight crews may be held responsible and penalized for missed illness identification. HHS/CDC understands that the statutory definition of “qualifying stage” may be confusing to lay persons and does not expect air or vessel crewmembers to be trained in the nuances of such language. Instead, we have crafted a definition of *ill person* to focus, in plain language, on the signs and symptoms of communicable diseases of public health concern and quarantinable communicable diseases, while taking into account the medical resources available to aircrew. HHS/CDC intends to enforce this provision consistent with how reports of deaths and illnesses are currently handled in regard to foreign arrivals. We note that flight crews have not been penalized in the past for missed reports of illness.

HHS/CDC received comments from industry that the report of death or illness should not be limited only to the pilot in command, given the many duties already under his/her responsibility. HHS/CDC disagrees. We

clarify first that this domestic provision was proposed to mirror the current foreign provision under 42 CFR 71.21(b)—which HHS/CDC did not propose to change—and which states “the commander of an aircraft destined for a U.S. airport shall report immediately . . . any death or ill person among passengers or crew.” While we acknowledge the many duties of the pilot in command, because this individual is directly responsible and has final authority over the operation of the aircraft, in keeping with the practice already established through regulation under 42 CFR 71.21(b), we believe that the responsibility for reporting ill persons onboard should ultimately rest with the pilot in command as stated in the regulation. Thus, the text of the regulation has not changed from the proposal.

One industry group commented that the role of flight attendants in identifying sick travelers on board should be addressed through guidance developed in conjunction with HHS/CDC and industry. HHS/CDC responds that it routinely issues guidance for flight crews, including standard guidance for the recognition and reporting of ill travelers and disease- or situation-specific guidance during outbreaks. Such guidance is published on HHS/CDC’s Web site and disseminated through established list serves, industry associations, and any other available means. HHS/CDC will coordinate with industry partners to determine whether additional guidance may be needed and, if necessary, work with these partners to develop such guidance.

One industry organization commented that the proposed rule failed to recognize that airlines employ intermediary professional medical personnel. HHS/CDC responds that it recognizes the role of intermediary professional medical personnel in assisting flight crews in managing an ill traveler onboard and references such personnel in industry guidance issued at <http://www.cdc.gov/quarantine/air/index.html>.

It is not HHS/CDC’s intent for the public health assessment conducted by HHS/CDC public health officers to replace this role in medical management. However, HHS/CDC restates that the reporting of ill travelers to HHS/CDC is the ultimate responsibility of the pilot in command as noted above.

One association requested that the report of deaths on board a carrier be modified and limited to those deaths which resulted from a possible communicable disease. HHS/CDC

disagrees. In keeping with current practice, HHS/CDC will continue to require and receive the reports of *all* deaths that occur on board a carrier, regardless of the suspected cause, to allow a public health official to conduct an assessment.

One public health organization raised concerns about replacing reporting to local health authorities with reporting to HHS/CDC. In response, HHS/CDC notes that extensive input was sought in 2012 from the Association of State and Territorial Health officers (ASTHO) and National Association of County and City Health Officials (NACCHO). Representatives from those organizations recommended that requirements and protocols should be the same for international and interstate flights and procedures should be outlined describing how this would occur. These representatives recommended that airlines should report ill persons on domestic flights to HHS/CDC and that HHS/CDC should subsequently notify State or local health departments. Subsequently, HHS/CDC posted guidance to this effect on its Web site and has continued response planning and development of standard operating procedures to implement these recommendations. Thus, this rulemaking codifies the current practice and is consistent with recommendations provided by ASTHO and NACCHO.

One commenter stated that it appears HHS/CDC is “attempting to move towards mandatory reporting by carriers and border personnel, requiring reporting of persons with signs of illness as they cross borders, as opposed to having to do large-scale individual contact interviews and investigations after an outbreak occurs.” In response, HHS/CDC states that reporting by carriers is already required under the existing regulations and that this regulation only codifies current practice and guidance. In addition, DHS notifies HHS/CDC of ill travelers detected by border personnel. HHS/CDC and DHS agreed to this notification process in a memorandum of understanding and therefore changes to this regulation are unnecessary. HHS/CDC additionally coordinates notification and investigation of contacts during exposure or outbreak situations when necessary based on a public health risk assessment. Such investigations are standard public health practice and not mutually exclusive of reporting by carriers or notifications by border personnel.

After consideration of these comments, the title of the *Radio Report of Death or Illness* (71.21) in the provision has been finalized as

proposed to remove the word “Radio,” and now reads *Report of Death or Illness*.

C. Provisions Applicable to Part 71 Only (Foreign)

One commenter questioned the seriousness of communicable disease spread on aircraft and vessels. Another commenter noted an “extreme unlikelihood of contracting any communicable disease while traveling” and that, therefore, HHS/CDC failed to prove a “compelling need” for the proposed regulations. HHS/CDC appreciates the opportunity to respond to these comments. The spread of communicable diseases on aircraft and vessels is well documented. There are numerous reports in the medical and public health literature of spread of measles, tuberculosis, SARS-coronavirus, and influenza virus on aircraft. Outbreaks of varicella (chickenpox), influenza, and gastrointestinal viruses such as norovirus are common on cruise ships, and spread of other diseases such as measles, rubella (German measles), tuberculosis, and other gastrointestinal diseases has also been reported. Aircraft and vessels have people together in confined spaces for prolonged periods of time. Therefore, conducting contact investigations for certain communicable diseases identified on aircraft or vessels is standard public health practice, both in the United States and internationally, similar to public health practice in community settings.

HHS/CDC received comments from industry regarding ongoing efforts with DHS/CBP to improve passenger data collection, as announced in the NPRM. Several commenters stated that HHS/CDC should delay this final rule until DHS/CBP has published a regulation to ensure that a coordinated system is put in place. HHS/CDC thanks these commenters for their input but disagrees that this final rule should be delayed. This comprehensive regulation seeks to protect public health, by implementing, among other things, current passenger and crew data collection practices.

One commenter objected to the collection of health information prior to using public transportation. Another commenter opposed the idea of carriers being “forced to collect and report 17 data elements on American travelers.” A public health association also insisted that data elements should only be collected from people if there is a reasonable belief that the person is infected. This final rule does not require carriers to collect or transmit any data elements that are not currently collected and transmitted to CBP via APIS and

PNR as a result of normal operating procedures. We also take this time to emphasize two important points. First, passengers are not required by HHS/CDC to submit specific data elements provided by passengers. Second, HHS/CDC will only seek this information from CBP or the airline in the event of a confirmed or suspected communicable disease on board a carrier which requires contacting fellow passengers to inform them of possible exposure.

While HHS/CDC received support for the data collection from two public health associations, a commenter misread the proposals to mean that aircraft operators would be required to develop new capacity and processes to capture and store a comprehensive set of sensitive data, archive this data, and then provide it to HHS/CDC. HHS/CDC takes this opportunity to restate and clarify that these final regulations do not impose any new burdens upon the airline industry but rather, codify the current practice of receiving a passenger manifest order (as needed) and providing HHS/CDC with any data in an airline’s possession. This rule places no requirement on the airline to solicit or store additional data than current practices allow. Therefore, HHS/CDC does not expect this formalization of current practice to have an impact on operations, including “check-in process.” If an airline does not have in its possession the five additional data elements, it is not required to collect or submit them to CDC.

One airline industry group commented that the collection of information from screened individuals for the purpose of contact tracing should apply only to passengers because crewmember information would be provided by the employer. HHS/CDC responds that this may be the case operationally; however, HHS/CDC reserves the right to collect information directly from crew members if necessary.

HHS/CDC received a comment expressing concern that individuals may provide false contact information, *e.g.* emails and telephone numbers, to airlines, and thus that HHS/CDC would lack the means of contacting individuals. In response, HHS/CDC notes that airlines are not required to verify the accuracy of information collected and HHS/CDC takes no position on what consequences the airline may impose if a traveler refuses to provide information or provides inaccurate information.

One public health organization commented on the scope of HHS/CDC’s protocols for when contact investigations are conducted and how

exposed contacts are defined following exposures to measles or varicella on aircraft or vessels. HHS/CDC appreciates the comment but seeks to clarify that these protocols were mentioned in the NPRM solely for the purposes of providing context for the economic analysis and that the content of the protocols themselves is beyond the scope of this rulemaking.

One public health organization commented on the fact that buses and trains typically do not maintain or have access to passenger manifests that would allow for the collection of information by HHS/CDC for the purpose of contact tracing. HHS/CDC agrees with this comment and notes that these regulations do not require operators of buses or trains to maintain passenger manifests for purposes of contact tracing. The organization also commented on the utility of the requirement that operators of buses or trains not knowingly transport individuals subject to a Federal public health order. In response, HHS/CDC notes that it is useful to prohibit conveyance operators from knowingly transporting someone under a Federal public health order without a travel permit or in violation of the terms of a permit because this may limit communicable disease spread. This prohibition, however, would only apply in circumstances where the operator would know or have reason to know that a travel permit is required, for instance, if the conveyance operator has been directly informed by the HHS/CDC or another cooperating Federal, State, or local agency.

A non-profit organization also commented that requiring airlines to disclose passenger information, upon request, but without a warrant, for purposes of notifying passengers of their potential exposure to a communicable disease violates the Fourth Amendment to the U.S. Constitution. This organization also contends that HHS/CDC lacks the legal authority to require that travelers provide certain contact information, such as information concerning their intended destination, health status, and travel history as part of a public health investigation. Specifically, this group contends that “examination” as used in 42 U.S.C. 264(d)(1) should be understood as referring only to an “inspection” not an “interrogation.” This group further contends that because HHS/CDC lacks the legal authority to collect information under 42 U.S.C. 264 it also lacks the authority to collect information under the Privacy Act of 1974. Lastly, this group contends that any compulsory questioning of travelers about “acts of

assembly or association” violates the First Amendment to the U.S. Constitution.

HHS/CDC disagrees with these comments. HHS/CDC notes that the requirement of a judicial warrant is not applicable to requiring passenger and crew information from air carriers. Rather, this activity is permitted without a warrant under the special-needs doctrine articulated by the Supreme Court in *Skinner v. Railway Labor Executives’ Ass’n*, 489 U.S. 602 (1989) because of the “special need” in preventing communicable disease spread. Furthermore, requiring passenger information from airlines and questioning travelers is authorized under 42 U.S.C. 264(a), which allows for the promulgation of regulations necessary for preventing the spread of communicable diseases from foreign countries into the United States and interstate. In carrying out and enforcing these regulations, 42 U.S.C. 264(a), authorizes “inspection” and “other measures” as may be necessary which allows for inspection of airline records and questioning of travelers regarding their health status and travel history. While 42 U.S.C. 264(d)(1) is not directly implicated in questioning of travelers because such questioning may occur without a specific reason to believe that the individual traveler may be infected with a quarantinable communicable disease, we note that the commenter’s suggestion that an “examination” excludes “interrogation” is not supported by common understanding or language usage. We note that Merriam Webster defines “examination” among other things as “a formal interrogation.” Thus, this commenter’s suggestion that because HHS/CDC purportedly lacks the legal authority to collect traveler information under 42 U.S.C. 264 it also lacks authority to collect information under the Privacy Act is without merit.

HHS/CDC also rejects the suggestion that questioning of travelers violates their rights to free association under the First Amendment. The U.S. Supreme Court has recognized a “freedom of association” in only two distinct areas: (1) Choices to enter into and maintain certain personal human relationships (as an element of personal liberty); and (2) a right to associate for the purpose of engaging in other activities protected by the First Amendment, *i.e.*, speech, assembly, petition for redress of grievances, exercise of religious freedom. *City of Dallas v. Stanglin*, 490 U.S. 19, 23–24 (1989). The purpose of this proposed requirement is to protect the vital health interests of passengers and crew so that individuals who have been exposed to a communicable

disease during travel may be contacted, informed, and provided with appropriate public health follow-up. HHS/CDC measures to prevent the introduction, transmission, or spread of communicable diseases do not implicate any of these constitutionally-protected areas.

HHS/CDC further notes that its purpose in collecting passenger information is to notify passengers who have been potentially exposed to communicable diseases of public health concern. For some of these diseases, there are preventive medications or vaccines that the individual may be made aware of and wish to obtain to keep from becoming sick. Therefore, HHS/CDC considers the collection of passenger locating information to be of benefit to these passengers and in keeping with standard public health practice to prevent further communicable disease transmission.

After considering these comments, HHS/CDC has finalized these provisions (71.4 and 71.5) as proposed, with the exception that the title has been modified to remove references to “collection” and “storage” of information to more accurately reflect the requirements under this section. References to the CDC have also been replaced with Director throughout these sections.

a. Suspension of Entry of Animals, Articles, or Things From Designated Foreign Countries and Places Into the United States

Regarding provision 71.63 *Suspension of entry of animals, articles, or things from designated foreign countries and places into the United States*, one public health association proposed that the restriction of animals should include an exception for ports of entry that could provide for physical inspection. In response, HHS/CDC clarifies that if the CDC Director determines an imported animal (or product) poses a significant public health threat, this provision requires the Director to designate the period of time and conditions under which entry into the United States shall be suspended, which may include limiting entries to certain ports where physical inspections are available. In keeping with current practice, HHS/CDC will implement public health protection measures that strike the appropriate balance between protecting the public’s health and continued importation and trade.

HHS/CDC received a comment that the term “thing” as used in 71.63 authorizing the suspension of “animals, articles, or things,” based on the existence of communicable disease in a

foreign country is unduly vague. In response, we explain that HHS/CDC may take public health measures in regard to animals, articles, or things, to prevent the introduction, transmission, and spread of communicable diseases into the United States and interstate. “Article” generally refers to an article of commerce, such as a specific product that someone wishes to import into the United States or move between States that poses a public health risk. In contrast, a “thing” simply refers to a material object that poses a public health risk regardless of whether there is a specific intent to import or move between States. For instance, on July 10, 2001, CDC issued an order under the authority of section 71.32(b) requiring that imports of “lucky bamboo” (a decorative plant) shipped in standing water be prohibited from entering the United States because the water (*i.e.*, the method of packing the lucky bamboo) constituted a potential vector for mosquito-borne illnesses. *See* 66 FR 35984 (July 10, 2001). In contrast, shipments of “lucky bamboo” that were packed dry (not in standing water) were permitted entry into the United States. In this case, “lucky bamboo” (the decorative plant) would constitute the “article” and the standing water would constitute the “thing.”

HHS/CDC received a question regarding the fate of animals or articles denied entry under this regulation, stating that “articles might presumably be forfeited and pets will be executed,” and questioning whether this provision aligns with due process, particularly with respect to the right to appeal. In response, HHS/CDC states that the provision authorizing temporary suspension of entry of certain animals, articles and things based on the existence of a communicable disease in a foreign country and to protect the public’s health is intended to prevent the arrival of these items at a U.S. port of entry. Therefore, HHS/CDC will seek to ensure travelers are informed of the restriction and will also work with carriers to prevent these animals or items from being loaded onto aircraft or vessels traveling to the United States. If such animals or items do arrive at a U.S. port of entry, HHS/CDC will take measures as needed to protect the public’s health. Such measures will be determined on a case-by-case basis and may include, at the owner’s expense, confinement, re-exportation, or destruction. Re-exportation may be considered if there is no public health risk during travel. HHS/CDC would also consider euthanasia of animals if there

are no other reasonable alternatives to protect the public's health.

In response to the concern expressed about an "appeal," HHS/CDC notes that the Director's suspension order would ordinarily constitute "final agency action" under the Administrative Procedure Act, 5 U.S.C. 704. However, HHS/CDC will consider the appropriateness of offering an administrative appeal as it develops the relevant suspension order.

After considering these comments, HHS/CDC has finalized the *Suspension of Entry of Animals, Articles, or Things From Designated Foreign Countries and Places Into the United States* (71.63) provision as proposed.

VI. Alternatives Considered

Under Executive Order 13563 agencies are asked to consider all feasible alternatives to current practice and the rulemaking as drafted. One less restrictive alternative would be for HHS/CDC to stop enforcing its regulations and make compliance with current regulations voluntary. Under this scenario, HHS/CDC would not obtain contact data from airlines or provide such data to health departments in order to conduct contact investigations. HHS/CDC would not require illness and death reports on aircraft or vessels, but would still follow-up with airlines and vessel operators upon request. This alternative would put travelers at greater risk of becoming infected with communicable diseases, reduce the ability of public health departments to offer post-exposure prophylaxis or other measures to prevent communicable disease spread from travelers known to have been exposed, and generally increase the risk of communicable disease transmission in the United States.

Another alternative, is to extend the scope of the regulations by closing U.S. borders and ports of entry to incoming traffic from countries experiencing widespread transmission of quarantinable communicable diseases to protect public health is also analyzed based on the 2014–16 Ebola outbreak in West Africa as well as recent importations of Middle East respiratory syndrome. HHS/CDC believes this approach is neither practicable nor is it desirable.

In a separate appendix, alternatives are considered to increase or decrease HHS/CDC's required payments for care and treatment for individuals under Federal orders as specified in 42 CFR 70.13 and 42 CFR 71.30. Also in a separate appendix, alternatives are also considered in which HHS/CDC does not implement temporary animal import

embargos (less restrictive) or does not allow importation of animals under temporary embargos for science, education, and exhibition when accompanied by a special permit.

We believe the regulations described above and set forth below in text offer the best solutions for protecting U.S. public health while allowing for continued travel. HHS/CDC believes that this rulemaking complies with Executive Order 13563; all of these changes provide good alternatives to the current baseline.

VII. Required Regulatory Analyses

A. Executive Orders 12866 and 13563

HHS/CDC has examined the impacts of the final rule under Executive Order 12866, Regulatory Planning and Review (58 FR 51735, October 4, 1993)² and Executive Order 13563, Improving Regulation and Regulatory Review, (76 FR 3821, January 21, 2011).³ Both Executive Orders direct agencies to evaluate any rule prior to promulgation to determine the regulatory impact in terms of costs and benefits to United States populations and businesses. Further, together, the two Executive Orders set the following requirements: Quantify costs and benefits where the new regulation creates a change in current practice; define qualitative costs and benefits; choose approaches that maximize net benefits including potential economic, environmental, public health and safety, and other advantages; support regulations that protect public health and safety; and minimize the adverse impact of regulation. HHS/CDC has analyzed the final rule as required by these Executive Orders and has determined that it is consistent with the principles set forth in the Executive Orders and the Regulatory Flexibility Act,⁴ as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA)⁵ and that, relative to the status quo, the final rule will not be economically significant because the sum of

annualized costs and benefits are estimated to be much less than \$100 million in any given year.

However, there is uncertainty about the appropriate analytic baseline, and relative to some possible baselines, the effects of the rule are non-negligible. For example, if in the absence this rule, some aspects of future HHS/CDC screening or risk assessment activities are found to be legally impermissible, then the status quo baseline would not represent a reasonable approximation of the state of the world without the rule. Relative to a non-status quo baseline, the rule would lead to activities (e.g., the 2014–16 Ebola risk assessment and management program) that have both substantial costs and substantial benefits. Analyses relative to this non-status quo baseline are presented in a separate appendix.

This Regulatory Impact Analysis (RIA) section presents the anticipated costs and benefits that are quantified where possible are relative to the status quo baseline. Where quantification is not possible, a qualitative discussion is provided of the costs and/or benefits that HHS/CDC anticipates from issuing these regulations.

Need for Rule

The 2014–2016 Ebola response highlights the inadequacies and limitations of the current regulatory provisions on the traveler data collection process in which CDC must request traveler manifests from airlines and manually search for contact data in order to know *who* enters the United States, *where* they go, and *how* to contact them.

Airlines have been slow to respond to HHS/CDC requests for traveler manifests:

- 30% arrive more than three days after a request,
- 15% arrive more than six days late.

In addition, available locating information is usually incomplete: HHS/CDC receives only the name and seat number for 61% of travelers, and one or more additional pieces of information for 39% of travelers. This final rule clarifies HHS/CDC's existing authority to request any available contact data from airlines and vessel operators, which may improve the timeliness and completeness of future requests from airlines or vessel operators for data not already submitted to the Department of Homeland Security.

Some traveler contact data is available in the APIS/PNR dataset already submitted by airlines to CBP. In the experience of the HHS/CDC, queries from APIS/PNR rarely result in full sets

² Executive Order 12866 of September 30, 1993: Regulatory Planning and Review. **Federal Register**. Monday, October 4, 1993; 58(190). <http://www.archives.gov/federal-register/executive-orders/pdf/12866.pdf>. Accessed January 2016.

³ Executive Order 13563 of January 18, 2011: Improving Regulation and Regulatory Review. **Federal Register**. Friday, January 21, 2011; 76(14). <http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf>. Accessed January 2016.

⁴ U.S. Small Business Administration. Regulatory Flexibility Act. <http://www.sba.gov/advocacy/823>. Accessed January 2016.

⁵ Summary of the Unfunded Mandates Reform Act. 2 U.S.C. 1501 *et seq.* (1995). <http://www2.epa.gov/laws-regulations/summary-unfunded-mandates-reform-act>. Accessed January 2016.

of contact information (*i.e.* the record includes all five additional data fields as outlined in the final rule). The data fields that are most commonly missing from the records are email addresses (missing 90 percent of the time), secondary phone number (missing 90 percent of the time), and street addresses (missing or insufficient for public health contact tracing up to 50 percent of the time). These data elements are vital to a contact tracing investigation. In looking at a random sample of 20% of the compiled international air travel manifests for 2015, those including a compiled data set from NTC and the airlines, 100% were missing at least one of the 5 data fields. Email address and secondary phone number were among those most frequently missing. For context, there were approximately 760,000 scheduled flights that arrived into the United States in 2015. In 2015, HHS/CDC issued passenger manifest requests for 64 international flights arriving into the United States. As noted in the RIA of the final rule, from 2010 to 2015, HHS/CDC conducted an average of 77 contact investigations per year involving arriving international flights.

Airlines are contacted for the majority of contact investigations using a manifest order document. At a minimum, HHS/CDC needs to confirm the ill traveler was on the flight and where the individual sat in relation to other travelers to determine risk of exposure. Further, in HHS/CDC's experience, only airlines can:

- Quickly and efficiently produce a partial manifest targeting affected rows
- confirm identity of "babes in arms" and their co-travelers (Parent); this is important for measles cases;
- quickly confirm whether an individual actually flew (in instances where individuals deplane and do not re-board during a layover); and
- confirm a plane's configuration if there is a question with the provided row numbers. Different aircraft have different seating arrangements depending on carrier and layout. It is important to know if a certain seat is separated by a bulkhead or is a window seat.

In addition, HHS/CDC only requires a partial manifest, *e.g.* 5 rows for travelers with infectious tuberculosis, so that NTC and HHS/CDC staff can limit the investigation to only those passengers at risk and supplement/cross reference with APIS and PNR data. If a partial manifest is not available from the airlines, then each passenger record must be researched individually to find a seat number, and then the configuration of an entire plane must be

populated to determine where the index case sat in relation to other at-risk passengers. For large flights from Asia, this can pose a tremendous burden to NTC and CDC staff while slowing the ability of CDC to provide important contact information to state and local health departments. Manually populating multiple 300+ person flights is not feasible in a timely manner.

Finally, CDC wishes to reiterate its desire for the above-described operations to be published in regulation to provide the public, as well as industry, with understanding of the efforts made by CDC to protect public health.

The other change to the economic baseline that may result from this final rule was the need to change the definition of an "ill person" to better match HHS/CDC guidance and the guidelines contained in Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation. Where possible, the marginal costs and benefits of these changes relative to the status quo baseline are monetized.

In addition, HHS/CDC believes that there is a need to better communicate to the public the actions that it has taken in accordance with its regulatory authority under *42 CFR 70.6 Apprehension and detention of persons with specific diseases*, *42 CFR 71.32 Persons, carriers, and things*, and *§ 71.33—Persons: Isolation and surveillance*. HHS/CDC believes it is necessary for the public to better understand actions that may be taken to prevent the importation of communicable diseases and to explain the due process available to individuals under Federal orders for isolation, quarantine, or conditional release. HHS/CDC also believes it is important to explain when HHS/CDC may authorize payment for the care and treatment of individuals subject to medical examination, quarantine, isolation and conditional release.

Finally, HHS/CDC believes it is important to explain its regulatory authority to suspend entry of animals, articles or things from designated foreign countries and places into the United States when importation increases the risk of the introduction and/or transmission of a communicable disease within the United States.

The specific market failure addressed by these regulations is that the costs associated with the spread of communicable diseases impacts the entire U.S. population, not just the group of persons currently infected with communicable diseases or with business interests in providing interstate or

international travel to persons or animals infected with communicable diseases.

The economic impact analysis of this final rule is subdivided into four sections:

1. An analysis of *42 CFR 70.1*, *42 CFR 71.1/71.4/71.5*, for which the primary costs may be incurred by aircraft and vessel operators and the primary benefit is improved public health responsiveness to assess and provide post-exposure prophylaxis to travelers exposed to communicable diseases of public health concern.

2. An analysis of a number of provisions that aim to improve transparency of how HHS/CDC uses regulatory authorities to protect public health. These changes are not intended to provide HHS/CDC with new regulatory authorities, but rather to clarify the agency's standard operating procedures and policies, and due process rights for individuals. HHS/CDC believes that improving the quality of its regulations by providing clearer explanations of its policies and procedures is an important public benefit. However, HHS/CDC is not able to attach a dollar value to this added benefit in a significant way. In a separate appendix, HHS/CDC analyzes the costs and benefits associated with the 2014–2016 Ebola enhanced risk assessment and management program are used to illustrate the costs and benefits of implementation of some of these authorities, and are especially relevant when analyzing the effects of the rule relative to a non-status quo baseline.

3. In a separate appendix, HHS/CDC provides an analysis of the revisions to *42 CFR 70.13/71.30: Payment for care and treatment*, which are not expected to lead to a change in HHS/CDC policy under which HHS/CDC may act as the payer of last resort for individuals subject to medical examination, quarantine, isolation, and conditional release under Federal orders. The primary benefit of codification is increased transparency around HHS/CDC policies to assist in paying for treatment or transportation for individuals under Federal orders. The analysis for these provisions is an examination in potential transfer payments between HHS/CDC and healthcare facilities that provide treatment to individuals under Federal orders or to other payers.

4. In a separate appendix, HHS/CDC provides an analysis of *42 CFR 71.63: Suspension of entry of animals, articles, or things from designated foreign countries and places into the United States*. In this final rule, HHS/CDC is

explaining its existing regulatory authority. HHS/CDC cannot predict how often such authority may be used in the future or for what purpose. HHS/CDC previously exercised this authority on June 11, 2003, when under 42 CFR 71.32(b), HHS/CDC implemented an immediate embargo on the importation

of all rodents from Africa (order Rodentia).⁶ A simple economic impact analysis of this embargo is performed to demonstrate the costs and benefits of one example, but HHS/CDC does not anticipate an increase in frequency of such actions based on the provisions included in this final rule. The primary

purpose of the analysis is to demonstrate potential costs and benefits using a realistic example.

Table 1 provides a summary of whether quantitative or qualitative analyses were performed for each of the provisions in the final rule.

TABLE 1—SUMMARY OF PROVISIONS INCLUDED IN THIS FINAL RULE

| Provision | Qualitative impacts only | Codification of existing authority |
|--|--------------------------|--|
| § 70.1/§ 71.1 General Definitions | No ^a | Yes (except definition of “ill person”). |
| § 70.5 Requirements relating to travelers under a federal order of isolation, quarantine, or conditional release | Yes | Yes. |
| § 70.6 Apprehension and detention of persons with specific diseases; § 71.32 Persons, carriers, and things (no change to title). | Yes | Yes. |
| § 70.10/§ 71.20 Public health prevention measures to detect communicable disease | Yes ^b | Yes. |
| § 70.11 Report of death or illness onboard aircraft operated by an airline | Yes | Yes. |
| § 70.12/§ 71.36 Medical examinations | Yes | Yes. |
| § 70.13/§ 71.30 Payment for Care and Treatment | Yes ^c | Yes. |
| § 70.14/§ 71.37 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release. | Yes | Yes. |
| § 70.15/§ 71.38 Mandatory reassessment of a federal order for quarantine, isolation, or conditional release ... | Yes | Yes. |
| § 70.16/§ 71.39 Medical review of a federal order for quarantine, isolation, or conditional release | Yes | Yes. |
| § 70.17/§ 71.29 Administrative records relating to federal quarantine, isolation, or conditional release | Yes | Yes. |
| § 70.18/§ 71.2 Penalties | Yes | Yes. |
| § 71.4 Requirements relating to collection, storage and transmission of airline passenger, crew and flight information for public health purposes. | No ^a | Yes. |
| § 71.5 Requirements relating to collection, storage and transmission of vessel passenger, crew, and voyage information for public health purposes. | No ^a | Yes. |
| § 71.33 Persons: Isolation and surveillance | Yes | Yes. |
| § 71.63 Suspension of entry of animals, articles, or things from designated foreign countries and places into the United States. | Yes ^d | Yes. |

^a Analyzed in RIA.

^b The costs and benefits associated with the 2014–2016 Ebola enhanced risk assessment and management program are used to illustrate the costs and benefits in a separate appendix.

^c In a separate appendix, an analysis of previous HHS/CDC payments for care and treatment is provided. However, the provisions in the Final Rule are not expected to lead to a change in HHS/CDC policy under which HHS/CDC may act as the payer of last resort for individuals subject to medical examination, quarantine, isolation, and conditional release under Federal orders.

^d In a separate appendix, HHS/CDC provides an analysis of this provision based on past experience when HHS/CDC implemented an immediate embargo on the importation of all rodents from Africa.

Executive Summary of the Costs and Benefits of 42 CFR 70.1, 42 CFR 71.1/ 71.4/71.5

Estimated Costs

The quantified costs and benefits of the final rule are estimated for the following stakeholders: Air and maritime conveyance operators, State and local public health departments (PHDs), individuals exposed to communicable diseases during travel and United States Government (USG). The most likely estimates of primary costs are low (\$32,622, range \$10,959 to \$430,839) because the final rule primarily codifies existing practice or improves alignment between regulatory text and the symptoms reporting guidelines provided by the International Civil Aviation Organization (ICAO). The

cost estimates are based on an increase in:

- The number of illness reports delivered by airlines and vessel operators to CDC, relay of air illness reports to CDC by the Federal Aviation Administration (FAA) when such reports are received by FAA air traffic service units, illness reports processed by HHS/CDC and time for travelers;
- increased costs for airlines and vessel operators to comply with HHS/CDC requests for traveler contact data;
- increased costs for State and local public health departments to follow up with a larger number of travelers exposed to communicable diseases during travel;
- The upper bound cost estimate also includes a substantial increase in training costs for the changes to illness reporting.

Estimated Benefits

The best estimate of quantified benefits of the final rule is also relatively small \$110,045 (range \$26,337 to \$297,393). This estimate is based on expected improvements in illness reporting and in the timeliness, completeness, and accuracy of contact data. These improvements should result in increased efficiencies for HHS/CDC and State and local public health departments in conducting contact investigations among travelers exposed to communicable diseases on aircraft and vessels and reduced illness costs associated with the reduced risk of measles and tuberculosis morbidity and mortality in exposed travelers.

Other potential but non-quantified benefits of the final rule would be associated with future outbreaks of

infectious disease cases for which improved compliance by airlines and vessel operators to provide available traveler contact data would reduce onward spread of disease in the destination communities of exposed travelers. In addition, the change to the definition of “ill person” may also increase reporting of communicable diseases of public health concern onboard conveyances. Reduction in onward spread would also lead to the ability of the public health establishment to reduce effects of disease outbreaks, *e.g.*, delay the spread of disease until a vaccine is available or limit the numbers of outbreaks and cases or reduce public anxiety associated with the risk of transmission. There may also be a reduction in the economic costs of many business sectors such as avoidance of costs to the travel and tourism industry^{7,8} when a disease is contained in its early stages.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of [\$146,000,000 in 2015 USD] or more.” Not only will this final rule not cost State, local and tribal governments any expenditure, it is possible that these stakeholders who might be engaged in contact tracing may see a reduction in costs if the final rule is implemented and there is an improvement in airline compliance with HHS/CDC requests to provide traveler data.

The Final Rule

Traveler contact information will only be requested by HHS/CDC after a case of serious communicable disease (index case) is reported in a person who traveled on a commercial airline or vessel while contagious. Examples of serious communicable diseases include measles, novel influenzas, and viral hemorrhagic fevers such as Ebola among others. This type of situation necessitates identifying and locating passengers seated near the index case in order to conduct a contact investigation (CI). This final rule would lead to better health outcomes if public health departments are more quickly and

effectively able to contact persons potentially exposed to the index case on an aircraft or vessel. These increased efficiencies should lead to smaller infectious disease outbreaks and fewer public health resources needed to control an outbreak.

There are multiple communicable diseases including quarantinable (*e.g.*, tuberculosis, MERS, and Ebola) and non-quarantinable (*e.g.*, measles, varicella, pertussis, rabies, meningococcal, and rubella) diseases that may necessitate a contact investigation to prevent spread of disease in the community. HHS/CDC notes that for non-quarantinable diseases, HHS/CDC efforts would primarily be limited to assisting health departments to notify individuals of their potential exposures. HHS/CDC was unable to quantify the benefits of preventing the spread of all diseases as a group because of differences in the characteristics of each disease. The differences with respect to potential spread and impact make it difficult to assess the benefits that may accrue from reduced spread of all diseases. The quantified analysis focuses on the two diseases that generate the greatest number of contacts to follow up: Measles and tuberculosis.

The ongoing persistence of measles in the United States provides a good example of the need for this final rule. In 2000, measles was declared no longer endemic in the United States due to high vaccination rates. Cases and outbreaks of measles continue to occur, however, as a result of importation from other countries and lack of adherence to the recommendation for measles vaccination (<http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/mmr.html>). The United States is currently discovering the greatest number of measles cases that have been identified since the declaration of measles elimination; 97% of recent cases were associated with importations from other countries. Of 45 direct importations, 40 occurred in U.S. citizens after traveling abroad.⁹

Among air travelers exposed to measles during flights, post-exposure prophylaxis (PEP) with measles-containing vaccine (within 72 hours) or immune globulin (within 6 days) can prevent onset of disease,¹⁰ halting outbreaks before they begin. However,

without accurate and timely contact data, it is frequently difficult to intervene within these timelines. A recent analysis showed that 9 cases likely occurred as a result of exposure during 108 flights with 74 case-travelers over 3 years. Although there was no onward transmission from these 9 cases,¹¹ future cases may lead to larger outbreaks.

Measles outbreaks can have substantial associated costs. One model-based analysis showed that 16 outbreaks with 107 confirmed measles cases cost an estimated \$2.7 million to \$5.3 million U.S. dollars for public health departments to contain.¹² The estimate is based on outbreak-specific travel expenses and the opportunity cost of diverting public health staff to outbreak response activities and is not based on the cost of hiring additional staff. This corresponds to an average cost per outbreak of about \$250,000 in 2015 USD. In comparison, a total of 125 cases occurring in 8 States and three countries were associated with a single measles outbreak that originated in late December 2014 in amusement theme parks in Orange County, California.¹³ Thus, the number of cases in this one outbreak exceeded the total number of outbreak-associated cases identified in 16 outbreaks during 2011. The source of the initial exposure has not been identified so it is not possible to determine where this index case was exposed. However, this example demonstrates the speed with which communicable diseases can be transmitted and the importance of quickly identifying persons that may have been exposed during air or maritime travel. It is possible that the costs of this one outbreak, which spread across 8 States, exceeded the total costs of all 16 outbreaks that occurred in 2011 and were estimated to cost public health departments a total of \$2.7 million to \$5.4 million dollars.¹⁴

In the absence of interventions by public health departments, travelers

¹¹ Nelson, K., Marienau, K.J., Schembri, C. and Redd, S. (2013). “Measles transmission during air travel, United States.” *Travel Medicine and Infectious Disease* (2013) 11, 81e89 11: 81–89.

¹² Ortega-Sanchez, I.R., M. Vijayaraghavan, A.E. Barskey and G.S. Wallace (2012). “The economic burden of sixteen measles outbreaks on United States public health departments in 2011.” *Vaccine* 32(11).

¹³ Jennifer Zipprich, Kathleen Winter, Jill Hacker, Dongxiang Xia, James Watt, Kathleen Harriman. (2015) Measles Outbreak—California, December 2014–February 2015. *MMWR/February 20, 2015/ Vol. 64/No. 6*: 153–154.

¹⁴ Ortega-Sanchez, I.R., M. Vijayaraghavan, A.E. Barskey and G.S. Wallace (2012). “The economic burden of sixteen measles outbreaks on United States public health departments in 2011.” *Vaccine* 32(11).

⁷ Rassy D, Smith RD. The economic impact of H1N1 on Mexico's tourist and pork sectors. *Health Econ.* 2013;22(7):824–34. doi: 10.1002/hec.2862. PubMed PMID: 23744805.

⁸ Keogh-Brown MR, Smith RD. The economic impact of SARS: How does the reality match the predictions? *Health Policy.* 2008;88(1):110–20.

⁹ Gastañaduy, P.A., S.B. Redd, A.P. Fiebelkorn, J.S. Rota, P.A. Rota, W.J. Bellini, J.F. Seward and G.S. Wallace (2014). “Measles—United States, January 1–May 23, 2014.” *MMWR* 63(22): 496–499.

¹⁰ Nelson, K., Marienau, K.J., Schembri, C. and Redd, S. (2013). “Measles transmission during air travel, United States.” *Travel Medicine and Infectious Disease* (2013) 11, 81e89 11: 81–89.

infected with measles during international travel would be as likely as any other individuals to initiate a measles outbreak. In the absence of HHS/CDC efforts to retrieve and transmit contact data, public health departments would not be able to contact travelers to offer post-exposure prophylaxis and to recommend self-monitoring for potential measles symptoms.

Summary of Quantifiable and Qualitative Results of the Regulatory Impact Analysis

The Summary Table provides estimated total monetary results for stakeholders' costs and benefits of implementing the final rule. The Summary Table (Table 2) includes estimates associated with changes to the definition of 'ill person' in 42 CFR 70.1/71.1 and the codification of international traveler data collection processes of aircraft and vessel contact investigations under 42 CFR 71.4/71.5. The best estimates of annual costs are \$32,622 compared to the best estimate of annual benefits at \$110,045. The upper bound annual quantified costs are

\$430,839 and the upper bound quantified benefits are \$297,393. Lower bound quantified costs are \$10,959 and benefits are \$26,337.

The measles and tuberculosis examples should not be considered a complete estimate of non-quantified benefits associated with this final rule, because the impact of this final rule to mitigate many different types of infectious disease outbreaks cannot be quantified. It just provides examples based on the two diseases for which contact investigations are most frequently undertaken. Besides communicable diseases commonly reported in the United States (e.g., measles, tuberculosis), this final rule may also improve HHS/CDC's ability to respond to diseases that are infrequently diagnosed in the United States (e.g., Ebola, novel influenza, Middle East Respiratory Syndrome). For example, it is possible that HHS/CDC may need to prepare to address both Ebola and another disease such as novel influenza or Middle East Respiratory Syndrome (MERS) occurring in two separate countries or regions during a given year.

For example, in 2014, two international travelers on commercial flights from the Middle East arrived in the United States while infected with MERS and two international travelers on commercial flights from West Africa arrived while infected with Ebola. Regardless of the infectious disease scenarios faced by HHS/CDC in a given year, this final rule should improve HHS/CDC's ability to mitigate infectious diseases in the future. To the extent that the final rule would lead to improved responsiveness of airlines and vessel operators to HHS/CDC traveler data requests via manifest orders, HHS/CDC may become better able to respond to infectious diseases threats and (1) reduce case-loads during infectious disease outbreaks, (2) reduce public anxiety during disease outbreaks, (3) mitigate economic impacts on businesses as a consequence of reduced public anxiety, and (4) reduce the amount of personnel labor time to conduct large-scale contact investigations in response to a new infectious disease or one with serious public health and medical consequences like Ebola.

TABLE 2—SUMMARY OF MONETIZED AND QUALITATIVE BENEFITS AND COSTS OF THE FINAL RULE
[2015 USD]

| Category | Most likely estimate | Lower bound estimate | Upper bound estimate | Source citation (RIA, preamble, etc.) |
|---|--|----------------------|----------------------|---------------------------------------|
| BENEFITS | | | | |
| Annual monetized routine benefits from reduced effort by CDC and health department to search for exposed contacts (0% discount rate). | \$12,218 | \$0 | \$12,218 | RIA. |
| Annual monetized routine benefits from reduced illness (0% discount rate) | \$97,828 | \$26,337 | \$272,958 | RIA. |
| Total annual monetized routine benefits (0% discount rate) | \$110,045 | \$26,337 | \$285,175 | RIA. |
| Qualitative (unquantified benefits) | To the extent that airlines or vessel operators have data available and improve responsiveness of airlines and vessel operators to HHS/ CDC traveler data requests results from the implementation of the provisions in this final rule, HHS/CDC may become better able to respond to infectious diseases threats and (1) reduce case-loads during infectious disease outbreaks, (2) reduce public anxiety during disease outbreaks, (3) mitigate economic impacts on businesses as a consequence of reduced public anxiety, and (4) reduce the amount of personnel labor time to conduct large-scale CIs in response to a new infectious disease or one with serious public health and medical consequences like Ebola. | | | RIA. |
| COSTS | | | | |
| Annual monetized costs for changes to illness reporting (airlines and vessel operators, 0% discount rate) *. | \$0 | \$0 | \$376,554 | RIA. |
| Annual monetized costs for changes to codification of manifest order process (airlines and vessel operators), 0% discount rate) *. | \$12,654 | \$0 | \$25,308 | RIA. |
| Annual monetized costs for additional activities by health department contacting individuals exposed to communicable diseases during international travel (0% discount rate). | \$19,968 | \$10,959 | \$28,977 | RIA. |
| Total annual monetized routine costs (0% discount rate) | \$32,622 | \$10,959 | \$430,839 | RIA. |

TABLE 2—SUMMARY OF MONETIZED AND QUALITATIVE BENEFITS AND COSTS OF THE FINAL RULE—Continued
[2015 USD]

| Category | Most likely estimate | Lower bound estimate | Upper bound estimate | Source citation (RIA, preamble, etc.) |
|---|----------------------|----------------------|----------------------|---------------------------------------|
| Annual quantified, but unmonetized, costs | | None | | RIA. |
| Qualitative (unquantified) costs | | None | | RIA. |

The second analysis in this final rule is of a number of provisions that aim to improve transparency of how HHS/CDC uses its regulatory authorities to protect public health. These changes are not intended to provide HHS/CDC with new regulatory authorities, but rather to clarify the agency's standard operating procedures and policies with regard to pre-existing regulations in 42 CFR parts 70 and 71 including due process rights for individuals under Federal orders. HHS/CDC believes that improving the quality of its regulations by providing clearer explanations of its policies and

procedures is an important public benefit. However, HHS/CDC is not able to attach a dollar value to this added benefit in a significant way.

Economic Baseline

Regulated Entities: Airlines and Vessel Operators

The group of entities that may be affected by this final rule would include international and interstate aircraft operators, vessel operators, travelers, State or local health departments and the Federal government agencies that interact with these groups. Since this

final rule primarily updates regulatory requirements to better match current practice, the economic impacts are marginal changes to current practice that result from codification of current practices.

The North American Industry Classification System (NAICS) is used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy. A summary of the total numbers of each entity is summarized in Table 3.

TABLE 3—SUMMARY OF THE NUMBER OF FIRMS ENGAGED IN INTERSTATE AND INTERNATIONAL AIR AND MARITIME TRAVEL

| NAICS codes | NAICS description | Number of firms in industry |
|--------------|--|-----------------------------|
| 481111 | Scheduled Passenger Air Transportation | 264 |
| 481112 | Scheduled Freight Air Transportation | 212 |
| 481219 | Other Nonscheduled Air Transportation | 516 |
| 483111 | Deep Sea Freight Transportation | 191 |
| 483112 | Deep Sea Passenger Transportation | 54 |
| 483113 | Coastal and Great Lakes Freight Transportation | 337 |
| 483114 | Coastal and Great Lakes Passenger Transportation | 110 |
| 483211 | Inland Water Freight Transportation | 318 |
| 483212 | Inland Water Passenger Transportation | 193 |

Statistics of U.S. Businesses, 2013 U.S. all industries.¹⁵
2012 North American Industry Classification System (NAICS).¹⁶

According to a report by the Federal Aviation Administration, in 2012, U.S. civil aviation-related economic activity generated \$1.5 trillion and supported 11.8 million jobs with \$459.4 billion in earnings.¹⁷ In 2015, the domestic U.S. market for air travel included 696 million passengers and the international market included another 198 million travelers.¹⁸

In 2011, there were approximately 11 million North American cruise ship passengers spending 71.8 million passenger nights on board vessels. The cruise ship market was highly concentrated with four firms accounting for 98% of the total market.¹⁹ In total, approximately 18 million travelers enter the United States each year via cruise or cargo ships.²⁰

The domestic/international air carrier market is an ever-shifting corporate

landscape. Both U.S. and foreign airlines engage in “code-sharing” arrangements, whereby the marketing carrier places its call sign (or code) on the operating carrier's flight. For purposes of this rule, reporting duty would require the operating carrier to report on *all* passengers and crewmembers, whether traveling on the operator's code or another carrier's.

The complexity of the domestic/foreign airline-corporations' legal and financial arrangements makes it very difficult to ascertain exactly how each and every domestic and foreign airline would be affected by the implementation costs associated with this final rule; presumably, some of the costs might be passed along to the carrier putting its code on the operating carrier, pursuant to the particular terms of each applicable contract.

¹⁵ <http://www.census.gov/econ/susb/>.

¹⁶ <https://www.census.gov/cgi-bin/sssd/naics/naicsrch>.

¹⁷ U.S. Department of Transportation, Federal Aviation Administration (January 2015) The Economic Impact of Civil Aviation on the U.S. Economy: Economic Impact of Civil Aviation by State. http://www.faa.gov/air_traffic/publications/media/2015-economic-impact-report.pdf (Accessed 5/2/2016).

¹⁸ Bureau of Transportation Statistics T-100 Market data. <http://www.transtats.bts.gov/DataElements.aspx?Data=1> (Accessed 5/2/2016).

¹⁹ U.S. Department of Transportation Maritime Administration (March 2012) North American Cruise Statistical Snapshot, 2011 http://www.marad.dot.gov/wp-content/uploads/pdf/North_American_Cruise_Statistics_Quarterly_Snapshot.pdf (Accessed 5/2/2016).

²⁰ According to the U.S. Department of Homeland Security, 54,236 passengers and crew arrive via vessel each day, which correspond to approximately 18 million per year. <https://www.transportation.gov/policy/aviation-policy/us-international-air-passenger-and-freight-statistics-report> Accessed on 5/2/2106.

Under this final rule, the operator of any airline operating a flight arriving into the United States must make certain contact information described below available within 24 hours of a request by HHS/CDC, to the extent that such data are available to the operator. This requirement also applies to the operator of any vessel carrying 13 or more passengers (excluding crew) and, which is not a ferry as defined in under 46 U.S.C. 2101 and U.S. Coast Guard (USCG) regulations (46 CFR 2.10–25). This requirement is a codification of current practice, and applies to any of the data elements that the airline or vessel operator may have available and authorizes the airline or vessel operator to transmit the contact information in any format and through any system available and acceptable to both the airline and HHS/CDC. Again, because this is a codification of current practices, HHS/CDC assumes airlines and vessel operators will continue to submit data through current mechanisms, although HHS/CDC will accept others that are mutually acceptable.

To simplify the analysis and to develop conservative cost estimates, HHS/CDC assumed that all costs to airlines and vessel operators would be passed along to U.S.-based airlines, vessel operators, or U.S. consumers.

Diseases Affected by the Rule

HHS/CDC has gathered statistics, or reported information on, a number of notifiable and quarantinable diseases (Table 4) that form the basis for estimates of quantitative and qualitative benefits. The final rule provides CDC with the authority to take certain actions with regard to both quarantinable and non-quarantinable diseases. For non-quarantinable diseases, efforts would be primarily limited to early identification and notification of exposed individuals and transmission of contact data to local and State health departments. For

quarantinable diseases, efforts could include issuance of Federal orders for quarantine, isolation, or conditional release of exposed/infected individuals.

TABLE 4—DISEASES ANALYZED

| Non-quarantinable | Quarantinable |
|---|---|
| Measles Pertussis Rabies Meningococcal disease Varicella Rubella | Tuberculosis. Viral Hemorrhagic Fevers. Middle East Respiratory Syndrome Coronavirus (MERS). |

In addition, these diseases for which HHS/CDC currently issues manifest orders and conducts contact investigations can also be subdivided to identify those encountered with some frequency (routine diseases): Tuberculosis, measles, meningococcal disease, pertussis and rubella. Among these diseases, only tuberculosis is a quarantinable disease. The second class is a group of new or emerging diseases, or diseases with serious public health and medical consequences, that are not currently prevalent, but are foreseeable as a future threat, *e.g.*, severe acute respiratory syndromes (including SARS and MERS), Ebola. This second group only includes quarantinable diseases, which may be updated in the future by Executive Order, but which are not being updated as a part of the final rule. Although HHS/CDC may help identify travelers ill with or exposed to measles, meningococcal disease, pertussis, rubella, rabies, and varicella, HHS/CDC does not have the authority to place any travelers with such illnesses or exposures under Federal orders. For quarantinable diseases, illness reporting could lead to issuance of Federal orders if travelers are reasonably believed to be infected with a quarantinable communicable disease in a qualifying stage. Such restrictions would not occur based simply on an illness report by

airline or vessel operator staff and would require a medical assessment by a public health professional.

Contact Investigations and Diseases—Interstate and International

The number of travelers exposed to an index case that are subject to a contact investigation (CI) varies by disease and may include only the two passengers sitting adjacent to the index case (meningococcal disease or pertussis) or as much as the entire aircraft (*e.g.*, initial investigations of cases of MERS or Ebola) (Table 5). The entire aircraft or vessel may be subject to CI if the disease is new and transmission patterns are not well understood (*e.g.*, MERS) or if the disease is felt to have serious medical or public health consequences (*e.g.*, Ebola). Some CIs are only initiated for long-duration travel (*e.g.*, tuberculosis for flights of 8 hours or longer). For other diseases (*e.g.*, measles, MERS), CIs are undertaken regardless of duration.

The table also includes criteria to be considered a contact for persons exposed on vessels. In contrast to air contact investigations, most maritime contact investigations are undertaken before travelers disembark from vessels. Another difference between air and maritime contact investigations is that varicella contact investigations are frequently undertaken among maritime travelers on vessels, but are not pursued for air travelers. In addition, HHS/CDC has not yet had to conduct a contact investigation for Middle East Respiratory Syndrome or viral hemorrhagic fever for travelers exposed on vessels. The criteria listed in Table 5 are current as of October 2016, but may be updated in the future based on reviews of the effectiveness of contact investigations. For example, HHS/CDC stopped providing contact data to health departments for mumps investigations after reviewing evidence of the effectiveness of mumps contact investigations.

TABLE 5—CONTACT INVESTIGATION CRITERIA BY DISEASE, PHD FOLLOW UP

| Disease | CI initiated if | Persons contacted, aircraft | Persons contacted, vessels | Recommended activities |
|------------------------|-----------------|--|---|---|
| Ebola (Quarantinable). | All cases | All passengers and crew as of April 2016. In the future, the recommendation may change to include fewer passengers and crew. | Cruise vessel—any passenger or crew who made have come into contact with the index case's body fluids while the index case was symptomatic. Cargo vessel—all on board the vessel while the index case was symptomatic. | Monitoring for 21 days after last potential exposure. |

TABLE 5—CONTACT INVESTIGATION CRITERIA BY DISEASE, PHD FOLLOW UP—Continued

| Disease | CI initiated if | Persons contacted, aircraft | Persons contacted, vessels | Recommended activities |
|---|---|---|--|--|
| Measles (Non-quarantinable). | All cases if notification received within 21 days of flight. | Passengers seated within 2 rows either direction of the index case, all babies-in-arms, crew in same cabin. All passengers and crew on flights with <50 seats. | Direct face-to-face contact or shared confined space >1 hour with symptomatic case-patient. | Offer MMR vaccination if non-immune and <72 hrs. since exposure; immune globulin if indicated and within 6 days of exposure. |
| Meningo-coccal disease (Non-quarantinable). | Case meets the definition of meningococcal disease within 14 days of travel. For air travel: Flight >8 hrs. (or shorter flights if direct exposure reported). | Passengers or crew sitting directly to the left and right of the index case or with potential for direct contact with oral or respiratory secretions. | Cruise vessels—Cabin mates of or potential for direct contact with oral or respiratory secretions of case-patient during the 7 days prior to symptom onset until 24 hours after implementation of effective antimicrobial therapy. Cargo vessels—All on board the vessel during the 7 days prior to symptom onset of case-patient until 24 hours after implementation of effective antimicrobial therapy. | Post-exposure chemoprophylaxis. |
| New or re-emerging influenza viruses (Quarantinable). | All cases during early stages of international spread. | All passengers and crew | All crew and passengers | Monitoring for 10 days after last potential exposure; possible serologic testing. |
| Pertussis (Non-quarantinable). | All cases if notification is received within 21 days of travel. | Passengers sitting next to index case. | Direct face-to-face contact or shared confined space >1 hour with symptomatic case-patient. | Post-exposure chemoprophylaxis. |
| Rubella (Non-quarantinable). | All cases if notification is received within 60 days of travel. | Passengers seated within 2 rows + crew in same cabin. All passengers and crew on flights with <50 seats. | Direct face-to-face contact or shared confined space >1 hour with symptomatic case-patient. | Serologic testing and guidance for pregnant women. |
| Severe Acute Respiratory Syndromes (Quarantinable). | All cases | SARS-Coronavirus: All passengers and crew. MERS: All passengers and crew contacted during 2014 CIs. Future CIs will include passengers seated within 2 rows of index case. | Cruise vessel—any passenger or crew who had direct face-to-face contact or shared confined space >1 hour with symptomatic case-patient. Cargo vessel—all on board the vessel while the index case was symptomatic. | Monitoring for 10–14 days after last potential exposure; potential serologic testing. |
| TB (Quarantinable). | Notification received within 3 months of travel, clinical criteria met For air travel: Flight >8 hrs. | Passengers seated within 2 rows. | Cargo vessel: All crew members within 3 months of diagnosis who worked with case-patient. Cruise vessel: Passenger travel companions or crew working in close proximity/ sharing living quarters. | Aircraft: Testing for latent TB infection; chest radiograph if the LTBI test is positive. Vessels: Clinical assessment for symptoms and chest radiograph. |
| Varicella (Non-quarantinable). | All cases on vessels | NA | Any person who has had ≥5 minutes of direct face-to-face contact with a varicella case during the infectious period. | Varicella vaccination if unvaccinated/non-immune and <3 days since exposure (possibly up to 5 days). High-risk contacts evaluated Varicella Zoster immune globulin if <10 days after exposure. |

The Quarantine Activity Reporting System (QARS), which contains, among other data, information collected under OMB Control Numbers 0920–0134, 0920–0488, 0920–0821, and 0920–0900, is a web-based and secure electronic system that supports collection of data for ill persons on inbound or interstate

flights and vessels and at land border crossings; infectious disease threats, and follow-up actions. Currently, HHS/CDC Quarantine Stations at U.S. ports of entry are using the system to record their daily activities. All CIs undertaken by HHS/CDC are documented in QARS.

CIs for international flights from January 2010 through December 2015 are summarized in Table 6. More than half (73.2%) were initiated as a result of tuberculosis cases. Measles is the next most common disease (20.8%). The remaining 6% are subdivided across rubella, pertussis, meningococcal

disease and other diseases. This table also includes CIs undertaken for MERS.

TABLE 6—INTERNATIONAL AIR CONTACT INVESTIGATIONS, AVERAGE NUMBER OF ANNUAL INVESTIGATIONS AND CONTACTS BY DISEASE, JAN 2010 THROUGH DEC 2015

[QARS data]^a

| Disease | Total investigations | Total contacts | Average investigations per year | Average contacts per year | Percent of total contacts |
|-------------------------------------|----------------------|----------------|---------------------------------|---------------------------|---------------------------|
| Influenza, avian | 0 | 0 | 0.0 | 0.0 | 0.0 |
| MERS Coronavirus ^b | 2 | 270 | 0.3 | 45.0 | 1.7 |
| Measles | 94 | 3,381 | 15.7 | 563.5 | 20.8 |
| Meningococcal disease | 8 | 9 | 1.3 | 1.5 | 0.1 |
| Other | 3 | 97 | 0.5 | 16.2 | 0.6 |
| Pertussis | 11 | 18 | 1.8 | 3.0 | 0.1 |
| Rabies | 3 | 4 | 0.5 | 0.7 | 0.0 |
| Rubella | 17 | 532 | 2.8 | 88.7 | 3.3 |
| TB (clinically active) | 318 | 11,928 | 53.0 | 1,988.0 | 73.2 |
| Viral hemorrhagic fever | 7 | 53 | 1.2 | 8.8 | 0.3 |
| Total | 463 | 16,292 | 77.2 | 2,715 | |

^aIn May 2011, CIs were discontinued for international outbound flights. To give a better picture of what CIs will look like under this new protocol, flights from January 2010 to May 2011 have been excluded from the above-reported counts. In addition, CIs for mumps have been discontinued. Prior to discontinuation, there were approximately 25 contacts per year investigated for mumps.

^bFor these CIs, contact information for the entire flight was required.

In rare instances, a disease is ruled out after a CI has happened.

HHS/CDC also requests traveler contact data to support contact investigations for travelers exposed to infectious diseases on interstate flights. The numbers of investigations and contacts during 2010–15 are

summarized in Table 7. In contrast to international flights, very few contact investigations for tuberculosis were undertaken on interstate flights, because most interstate flights do not meet the 8-hour time requirement for

tuberculosis contact investigations (Table 5). The majority of contacts were investigated after exposure to measles cases (76%) followed by MERS (8.4%) and viral hemorrhagic fevers including Ebola (8.0%).

TABLE 7—INTERSTATE AIR CONTACT INVESTIGATIONS, AVERAGE NUMBER OF ANNUAL INVESTIGATIONS AND CONTACTS BY DISEASE, JANUARY 2010 THROUGH DECEMBER 2015

[QARS data]

| Disease | Total investigations | Total contacts | Average number of investigations per year | Average number of contacts per year | Percent of total contacts |
|-------------------------------------|----------------------|----------------|---|-------------------------------------|---------------------------|
| Measles | 72 | 3033 | 12.0 | 505.5 | 76.1 |
| Meningococcal disease | 1 | 1 | 0.2 | 0.2 | 0.0 |
| MERS Coronavirus ^a | 2 | 334 | 0.3 | 55.7 | 8.4 |
| Other | 0 | 0 | 0.0 | 0.0 | 0.0 |
| Pertussis | 43 | 83 | 7.2 | 13.8 | 2.1 |
| Rabies | 3 | 3 | 0.5 | 0.5 | 0.1 |
| Rubella | 8 | 172 | 1.3 | 28.7 | 4.3 |
| TB (clinically active) | 2 | 40 | 0.3 | 6.7 | 1.0 |
| Viral hemorrhagic fever | 4 | 319 | 0.7 | 53.2 | 8.0 |
| Total | 135 | 3,985 | 22.5 | 664.2 | |

Notes:

^aFor these CIs, contact information for the entire flight was required.

In rare instances, a disease is ruled out after a CI has happened.

The numbers of contacts for maritime contact investigations are summarized in Table 8. For maritime investigations, the majority of contacts were investigated for varicella (~79%) followed by tuberculosis (~13%) and

measles (~6%). Most of the varicella and measles contact investigations were initiated while travelers were still on vessels. Besides the investigations listed in Table 8, gastrointestinal illness cases on cruise vessels carrying 13 or more

passengers are reported to HHS/CDC's Vessel Sanitation Program and cases of Legionnaires' disease are reported directly to HHS/CDC's Respiratory Diseases Branch.

TABLE 8—MARITIME PASSENGER DATA COLLECTION, AVERAGE NUMBER OF ANNUAL CONTACTS BY DISEASE
[January 2010–December 2015]

| Passengers per voyage | Total investigations | Total contacts | Average number of investigations per year | Average number of contacts per year | Percent of total contacts |
|---|----------------------|----------------|---|-------------------------------------|---------------------------|
| Measles | 5 | 288 | 0.83 | 48 | 6.3 |
| Meningococcal disease | 3 | 22 | 0.5 | 3.67 | 0.5 |
| MERS Coronavirus ** | 0 | 0 | 0 | 0 | 0.0 |
| Other | 1 | 9 | 0.17 | 1.5 | 0.2 |
| Pertussis | 3 | 14 | 0.5 | 2.33 | 0.3 |
| Rabies | 0 | 0 | 0 | 0 | 0.0 |
| Rubella | 2 | 26 | 0.33 | 4.33 | 0.6 |
| TB (clinically active) | 50 | 585 | 8.3 | 97.5 | 12.8 |
| Viral hemorrhagic fever | 0 | 0 | 0 | 0 | 0.0 |
| Varicella (chickenpox) ^a | 206 | 3,627 | 34.3 | 604.5 | 79.3 |
| Total | 270 | 4,571 | 45 | 761.8 | 100.0 |

^aOne CI for varicella involved entire crew of the vessel (1224).

Traveler Manifest Orders for Airlines

Contact tracing is most effective at reducing cases of communicable disease at the early stages of a potential outbreak as soon after initial exposure as possible. Therefore, if an efficient contact system is not in place when the first ill travelers arrive, the benefits of contact tracing are greatly diminished.

Contact data requests only occur after a case of serious communicable disease (index case) is reported in a person who traveled on a commercial airline or vessel while contagious. This type of situation necessitates identifying and locating travelers seated near the index case in order to conduct a CI.

At present, HHS/CDC uses a multi-step process to obtain traveler contact information from airlines. HHS/CDC issues a written order to the airline that requires the airline to provide HHS/CDC with contact information about the index case and traveler contacts. The order cites current regulatory language in 42 CFR 71.32(b), as authorized by 42 U.S.C. 264. HHS/CDC requires that the airline provide it with the traveler's first and last name, seat number, two phone numbers and email address. HHS/CDC instructs airlines and vessel operators to provide data when available or to report when data are unavailable. The time it takes for HHS/CDC to obtain the available traveler contact data can range from a few hours to a few days. From 2010 through May 2015, about 70% of manifests from airlines arrived within 3 days of the request, 15% arrived between 3 and 6 days after a request, 15% arrived after more than six days, and nine requests took more than a month or were never received by HHS/CDC.

At present, HHS/CDC requests that airlines and vessels provide available traveler contact data within 24 hours for

“urgent” manifest requests. In current practice, requests for contact data are only considered “non-urgent” for contact investigations in which travelers had rubella (for which there is no available prophylaxis) or tuberculosis or for situations in which HHS/CDC is not notified of travelers diagnosed with some communicable diseases until after a certain amount of time during which prophylaxis would be effective (*e.g.*, for measles: 6 days). If the analysis is limited to diseases where requests for traveler contact data are marked “urgent” by HHS/CDC (measles, meningococcal disease, MERS, viral hemorrhagic fevers, and rabies), performance improved such that 51% arrived within 24 hours of a request, 33% arrived between 1–3 days after a request, 13% between 3–6 days and only 3% arrived after 6 days. HHS/CDC notes that there may be instances where CDC may not have included the correct information in a manifest order (*e.g.*, flight number or port of entry). The provision of incorrect flight information may have caused delay submission in some of the instances cited above.

While HHS/CDC requires that all information be provided upon first order for information, HHS/CDC has consistently seen that the information provided by a majority of airlines appears limited to frequent flyer information, or other limited contact information. Overall, the completeness of data provided by airlines varied such that airlines generally fell into two categories. Some airlines always provided only the passenger name and seat number. Other airlines would provide some additional contact information for passengers. However, even among these airlines, contact data for some of the passengers only included names and seat numbers.

Considering all requests from 2014, at least one additional piece of contact information was provided for only about 39% of passengers. If the sample were restricted to only flights for which any contact information was provided (1,270 out of 2,411 total passengers), the fraction of passengers with at least one piece of contact information beyond name and seat number increased from 39% to 73.9%. This contact information would include U.S. address for 41.7% of passengers and one phone number for 45% of passengers. As a result of HHS/CDC's use of available information and technology and its partnerships with other Federal agencies, contact tracing of exposed travelers can now be accomplished more rapidly than would be possible if only the contact data provided by airlines were used. However, if airlines or vessel operators have additional data relative to what is currently provided to DHS, the efficiency of contact investigations could improve.

Change to Definition of an “Ill Person”

HHS/CDC is updating the definition of “ill person” in 42 CFR 70.1 and 71.1 to better facilitate identification of communicable diseases of public health concern aboard flights and voyages. However, HHS/CDC currently requests that aircraft and vessels report several of the symptoms included in the revised definition of ill person. Besides aircraft and vessel operators, quarantine stations also receive illness reports from U.S. Customs and Border Protection, U.S. Coast Guard, State and local health departments, and health facilities. These reports are not included in this analysis, which focuses on reporting during travel.

HHS/CDC has crafted the definition of “ill person” in such a way that it should

be understood by non-medically trained crewmembers and used to discern illnesses of public health interest that HHS/CDC would like to be made aware of according to 42 CFR 70.4 from those that it does not (e.g., common cold), while more closely aligning the definition with the symptoms reporting guidelines published by ICAO in *Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation*. To further assist flight crewmembers (and vessel crewmembers under part 71) in identifying individuals with a reportable illness, HHS/CDC provides the following in-depth explanations and examples of the communicable diseases that such signs and symptoms might indicate. Note that these explanations also apply to the definition of “ill person” under part 71 and are discussed in the preamble of this final rule.

The current illness reporting requirements for interstate travel are summarized in 42 CFR 70.4 and state that “The master of any vessel or person in charge of any conveyance engaged in interstate traffic, on which a case or suspected case of a communicable disease develops shall, as soon as practicable, notify the local health authority at the next port of call, station, or stop, and shall take such measures to prevent the spread of the disease as the local health authority directs.” Communicable disease is defined in 42 CFR 70.1 as “illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or

indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment.”

Thus, the changes in this final rule would amount to fewer illness reports than may be anticipated under the current regulation. However, in practice, according to CDC guidance available at <http://www.cdc.gov/quarantine/air/reporting-deaths-illness/guidance-reporting-onboard-deaths-illnesses.html>, the symptoms requested for international and interstate illness reporting are the same subset. In addition, according to guidance, reports received by HHS/CDC would be considered sufficient to satisfy the requirement to report to local health departments since HHS/CDC would coordinate any response activities with the local health department after receipt of the illness report.

This final rule would align the definition from CDC guidance with regulatory text by requiring reports of ill travelers with fever and persistent cough, persistent vomiting, difficulty breathing, headache with stiff neck, decreased consciousness, travelers appearing obviously unwell, or unexplained bleeding. In practice, the codification of such guidance may increase costs to some or all airlines and vessel operators who submit illness reports based only upon symptoms currently identified in 42 CFR 71.1 and not based on HHS/CDC guidance. For illness reports from aircraft, DOT/FAA may also incur additional costs if the number of illness reports made by aircraft pilots in command to air traffic control and reported to HHS/CDC via the Domestic Events Network increases.

For aircraft, the updated definition better aligns with symptoms reporting guidelines published by ICAO in *Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation*. Therefore, HHS/CDC does not anticipate much additional burden on airlines and vessel operators to report ill travelers during travel.

Although HHS/CDC estimates the net change will be no cost to airline or vessel operators, it may be possible to examine the potential increase using simple assumptions. Table 9 shows the number of reports by pilots in command during flights and recorded in HHS/CDC's Quarantine Activity Reporting System (QARS). These include reports of illness that fit the illness definition specified in current 42 CFR 71.1, reports based on HHS/CDC's guidance for airlines and vessel operators, reports made based on the guidelines in *Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation*, or illness reports unrelated to current regulation or guidance. Such reports can also be subdivided into reports requiring HHS/CDC response (“response reports”) and reports that HHS/CDC receives, but which do not require an HHS/CDC response (“info-only reports”). Info-only reports may include symptoms included in HHS/CDC guidance, but for which the underlying condition can easily be diagnosed not to be a communicable disease of public health concern (e.g., influenza-like illness on an aircraft). Info-only reports can also be based on illnesses not requested by HHS/CDC guidance (e.g., motion sickness).

TABLE 9—TOTAL NUMBERS OF REPORTS MADE DURING FLIGHT BY AIRCRAFT OPERATORS, 2011 TO 2015
[HHS/CDC QARS data]

| Year | Category | Based on symptoms included in current regulation | Based on symptoms included in final rule | Reports not based on symptoms included in either current regulation or final rule | Total |
|--------------------|-----------|--|--|---|-------|
| 2015 | Info-only | 30 | 55 | 43 | 128 |
| | Response | 33 | 22 | 15 | 70 |
| 2014 | Info-only | 33 | 61 | 42 | 136 |
| | Response | 19 | 36 | 12 | 67 |
| 2013 | Info-only | 31 | 46 | 29 | 106 |
| | Response | 21 | 25 | 4 | 50 |
| 2012 | Info-only | 34 | 58 | 38 | 130 |
| | Response | 12 | 18 | 2 | 32 |
| 2011 | Info-only | 27 | 39 | 25 | 91 |
| | Response | 25 | 29 | 13 | 67 |
| Average, Info-only | | 31 | 51.8 | 35.4 | 118.2 |
| Average Response | | 22 | 26 | 9.2 | 57.2 |
| Average, total | | 53 | 77.8 | 44.6 | 175.4 |

In addition to illness reports, HHS/CDC receives an average of 10 death reports during air travel each year. Since death reporting requirements are not changing, these are not analyzed.

Table 9 shows that HHS/CDC already receives a number of reports based on symptoms included in HHS/CDC guidance that will be codified with this final rule. On average, among the total 175 illness reports per year, about 78 annual reports are based on symptoms included in the final rule, but not in current regulations compared to 53 reports based on symptoms already listed in current regulations. The remaining 45 reports would include those based on fever alone or based on

symptoms not included either in current regulatory text or in this final rule.

The number of illness reports from master of vessels during voyages is summarized in Table 10. Compared to the breakdown in reports for aircraft, the vast majority of illness reports during voyages are for response as opposed to info-only. There may be greater specificity in reports from cruise vessels because of the presence of medical officers onboard vessels. On average, there were about 208 reports requiring

follow-up and 10.6 info-only reports each year. In contrast to reports from aircraft, most of the reporting for vessels pertains to symptoms included in the current regulation (175 per year) as opposed to those specified in this final rule (32 per year). Very few reports from vessels (3.4 per year) were based on fever only or based on symptoms not included in either current regulation or specified in this final rule.

TABLE 10—TOTAL NUMBERS OF ILLNESS REPORTS (EXCLUDING INFLUENZA-LIKE ILLNESS) MADE DURING VOYAGE BY MASTERS OF VESSELS, 2011 TO 2015
[HHS/CDC QARS data]

| Year | Type of report | Based on symptoms included in current regulation | Based on symptoms included in final rule | Reports not based on symptoms included in either current regulation or final rule | Total |
|--------------------------|-----------------|--|--|---|-------|
| 2015 | Info-only | 5 | 4 | 4 | 13 |
| | Response | 179 | 21 | 1 | 201 |
| 2014 | Info-only | 6 | 3 | 3 | 12 |
| | Response | 168 | 21 | 12 | 201 |
| 2013 | Info-only | 1 | 1 | 3 | 5 |
| | Response | 145 | 48 | 11 | 204 |
| 2012 | Info-only | 5 | 7 | 3 | 15 |
| | Response | 167 | 19 | 1 | 187 |
| 2011 | Info-only | 1 | 3 | 4 | 8 |
| | Response | 196 | 32 | 19 | 247 |
| Average, Info-only | | 3.6 | 3.6 | 3.4 | 10.6 |
| Average Response | | 171 | 28.2 | 8.8 | 208 |
| Average, total | | 174.6 | 31.8 | 12.2 | 218.6 |

In addition to the illness reports reported in the table, HHS/CDC receives about 115 reports of death during maritime travel each year. In addition, HHS/CDC requests, but not require reporting of influenza-like-illness from cruise vessels (also not included in above table).

Baseline Contact Investigation Process for Routinely Imported Diseases

This section reports the primary steps of CIs for routine diseases:

- A traveler (the index case) is identified as ill either during the flight or voyage with a reportable illness or after with a notifiable disease. The aircraft pilot in command or master of vessel may report the illness directly to HHS/CDC. Illnesses on aircraft may also be reported indirectly to HHS/CDC via air traffic control. The FAA then passes the report to CDC through the Domestic Event Network. If the report occurs after travel, a healthcare facility would then report the illness either to HHS/CDC or public health departments (PHDs).

- If CI criteria are met, HHS/CDC contacts the airlines for

- a manifest to determine where the index case was seated in relation to other passengers or crew members,

- HHS/CDC then requests information available from DHS' databases to verify or obtain passenger contact information not included in the manifest.

- If data are not available in DHS databases, HHS/CDC will require (as part of the manifest order) for the airlines to provide any available traveler contact information. The number of travelers for which contact data will be requested is based on the disease-specific criteria listed in Table 5.

Once HHS/CDC has the traveler contact information and flight-seating chart, the CI begins. Current CI procedures are cumbersome, in part because of the difficulties associated with obtaining traveler contact information. HHS/CDC staff may contact airlines more than once to obtain traveler contact data including email address, one or two phone numbers, and address in the United States for U.S. citizens and permanent residents.

When passenger contact information is delayed or partial, State/local public health departments are delayed in starting CIs and, depending on the disease, this delay could make it impossible to prevent illness and/or the transmission of disease. Further, PHDs

could have improved success contacting passengers with more accurate or timelier data.

The model for estimating the benefits of CIs is: Current number of CIs × (reduction in HHS/CDC and health department staff time/resources per contact) × value of staff time.

The rest of this section reports both the quantifiable benefits arising from streamlining the CI process and a discussion of health benefits. The differential impacts of the various diseases make it hard to summarize the final rule's effects given uncertainty around future probabilities of case(s) of multiple such notifiable disease(s). The timeliness of contact investigations could also be improved if improvements in illness reporting led to earlier diagnoses of communicable diseases.

Estimating the Number of Infected Travelers

Most air travelers with illness are not identified in flight, but rather seek medical care and are identified as an

index case after their travel is completed. Compared to air travelers, maritime travelers spend more time on vessels during voyages and medical officers may be employed on cruise vessels.

When communicable diseases are diagnosed after travel, the medical practitioner should notify HHS/CDC or a PHD if the diagnosed disease is on either the list of quarantinable communicable diseases or the list of notifiable diseases. If HHS/CDC can draw upon improved contact information based on the codification of requests for traveler contact data to aircraft and vessel operators as set forth in this final rule, the risk of onward disease transmission can be reduced. By contacting ill travelers more quickly, HHS/CDC may slow the spread and the severity of the outbreak. The benefits therefore depend on:

- How many infected travelers are expected to enter the United States;
- How many quarantinable or notifiable diseases are detected either on-board the aircraft/vessel or reported to HHS/CDC by PHDs;
- How many exposed travelers will become ill as a result of exposure during travel;
- How the infection will be transmitted within the U.S. population;
- How effective public health agency contact tracing will be with and without the final rule.

In addition to improved efficiencies associated with more timely or more complete provision of traveler contact data by airlines and vessel operators, there may also be an increase in the number of reports of ill travelers during travel that require HHS/CDC follow-up. Under the most likely scenario, there will not be a change in these reports, since the new definition better corresponds to reporting guidelines published by ICAO in Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation and current HHS/CDC guidance. However, there may be an increase in illness reports depending on whether airlines and vessel operators increase reporting for required rather than recommended symptoms.

Contact Investigations Supported by CDC and Undertaken by Partners at State and Local Health Departments

The change to the definition of an “ill person” for the purposes of illness reporting and the codification of HHS/CDC requests from airlines and vessel operators for traveler contact data may improve HHS/CDC’s ability to respond effectively and mitigate infectious disease outbreaks. There are a number

of intermediate steps between either an illness report or receiving more complete or timelier traveler data and stopping an infectious disease outbreak. For example, the travelers exposed to the infectious disease would have to be contacted by health departments and comply with recommended public health measures, which could include some form of public health or medical follow up to mitigate their risk of becoming ill, or self-monitoring/quarantine to mitigate the risk of transmitting that disease to other individuals.

The amount of time HHS/CDC staff spend per air or maritime contact varies with the size of the CI because some tasks are CI-specific, such as filling out reports or obtaining manifests, and some are contact-specific such as determining a specific traveler’s contact information. The CI-specific labor time costs less per contact when an investigation includes more contacts, *e.g.*, a manifest that takes 60 minutes of HHS/CDC staff time to obtain for 2 contacts is the equivalent of 30 minutes-staff-time-per-contact while the same manifest listing 30 contacts is the equivalent of 2 minutes-staff-time-per-contact. On the other hand, the traveler-specific time tends to increase-per-contact with less information and decrease-per-contact with more information.²¹ Further, the QARS system used to document and follow up on CIs requires full-time personnel to maintain the system, pull regular reports, and monitor follow-up of travelers contacted during CIs. Finally, HHS/CDC has two full-time persons regularly assigned as liaisons to DHS whose duties include gathering contact information from DHS systems. Therefore, for HHS/CDC staff time to initiate and follow up on different sized CIs, to track down traveler contact information from multiple sources, to work with PHDs, document and report on CIs, update and train in systems, and manage the staff involved in CIs, a cost of \$180 per contact is estimated. This is the equivalent of 2 hours of a HHS/CDC staff person’s being paid the salary of a GS–13, step 4 plus 100% for benefits and employee overhead costs (Table 11).

For PHD resources, HHS/CDC also estimated a cost-per-contact of \$180, which is consistent with HHS/CDC costs and a recent publication adjusted to 2015 dollars.²² PHD processes vary greatly from State to State and at the

local level within a State. A couple of examples:

- One State assigns 2 registered nurses (RNs) who perform 5 CIs or fewer per year for the entire State another State assigns 3 RNs, a Public Health Service Medical Officer, a physician, and a data analyst and conducts about 25 CIs a year.²³

- When one State receives information about passenger contacts from HHS/CDC, the State epidemiologist creates several documents to fax to the relevant county health departments, a team of an epidemiologist and RNs at the county then either call or visit the contacts if there is an address. But the State epidemiologist will make every effort to locate travelers even if their final destination is unclear.²⁴

Finally, different diseases may elicit different levels of response at the PHD level, with a more rapid response for highly infectious diseases like measles that can be prevented with timely post-exposure prophylaxis and a more measured response for less infectious diseases like TB. By using the same cost for HHS/CDC and for PHDs, HHS/CDC believes the potential reductions in cost from reduced effort for PHDs to locate infectious disease contacts are conservatively estimated.

TABLE 11—COST-PER-CONTACT

| CDC | PHD |
|-------------|-------|
| \$180 | \$180 |

Infectious Disease Transmission During International Travel

For some diseases, there is empirical data from which onboard transmission can be estimated. According to a published analysis of the outcomes of measles contact investigations (74 case-travelers on 108 flights resulting in 3,399 contacts) in the United States between December 2008 and December 2011, HHS/CDC could not assign 9% of measles contacts (322) to a health department due to insufficient contact data. Another 12% of these contacts (397) were believed to be outside the United States.²⁵ After HHS/CDC provides contact data to State health departments, HHS/CDC requests, but does not require health departments to

²³ Personal communication from states to Dr. Margaret S. Coleman 2010.

²⁴ Discussion between Dr. Brian Maskery, Dr. Margaret S. Coleman and State and County Health Department contacts 11/21/2014.

²⁵ Nelson, K., Marienau, K.J., Schembri, C. and Redd, S. (2013). “Measles transmission during air travel, United States.” *Travel Medicine and Infectious Disease* (2013) 11, 81e89 11: 81–89.

²¹ Margaret S. Coleman, unpublished data.

²² Coleman, M.S., Marienau, K.J., Marano, N., Marks, S.M., Cetron, M.S. (2014). “Economics of United States tuberculosis airline contact investigation policies: a return on investment analysis.” *TMAID* 12(1):63–71.

provide data on the outcomes of their attempts to follow-up with travelers. Among the 2,673 contacts assigned to U.S. public health departments in 2008–11, HHS/CDC only received outcome data for 1,177 out of the 2,673 assigned contacts. This outcome data included reports from State health departments that 225 out of the 1,177 assigned contacts could not be located (19%). Among the 952 contacts for which HHS/CDC received measles outcome data from health departments, there were 9 lab-confirmed measles cases (1%). Since there may be reporting bias from health departments (*i.e.* health departments would be more likely to report outcome data for contacts that developed measles than for other exposed travelers that did not develop measles, HHS/CDC considers a range of measles incidence rates among exposed travelers from 9 cases/2,673 contacts assigned to health departments (0.34%) to 9 cases/952 exposed contacts with outcome data reported to HHS/CDC (0.95%). This probability could overstate or understate the true transmission rate depending on the length of the flight and seating configuration. On the other hand, it may understate the probability if cases were not reported or occurred overseas.

The majority of travelers exposed to measles on aircraft (~74%) had pre-existing immunity based on past measles immunization, past measles illness, or being born prior to 1957 and thus likely to have measles immunity even if they do not recall experiencing the disease.²⁶ Among the 952 exposed travelers, 8 cases occurred in the 247 contacts (3.2%) without known pre-existing immunity compared to 1 case in the 705 contacts with past history of vaccination or measles illness (0.1%). The median age of measles cases in exposed air traveler contacts was 1.6 years.

Intervention by public health departments mitigates the risk of measles transmission in two ways. First, exposed travelers without measles immunity may be offered voluntary post-exposure prophylaxis with measles-containing vaccine (within 72 hours) or immune globulin (within 6 days),²⁷ which can prevent onset of disease, halting outbreaks before they begin. Under the status quo, relatively few exposed travelers receive post-exposure prophylaxis (just 11 out of 248

travelers with no history of measles immunization or infection). Second, exposed travelers would be counseled by health departments to self-isolate and seek treatment if they started to experience symptoms consistent with measles onset. For example infants exposed during travel and too young to be vaccinated could arrange for special precautions if they visit a pediatrician after becoming ill with measles-like symptoms to minimize the transmission to other unvaccinated infants. Both activities will limit the possibility of measles transmission to family members or others in the community. The attack rate for measles is estimated to be 90%, but the high background immunization rate and high efficacy of measles vaccine attenuates the burden of measles outbreaks in the United States.

In summary, the potential size of a measles outbreak occurring depends on:

- The number of persons contacted by the infectious measles patient
- Background immunity among persons contacted
- Survey estimates have shown considerable heterogeneity in background vaccination rates such that 80% of unvaccinated children live in counties comprising 40% of the total population.²⁸

For tuberculosis, it is difficult to estimate the transmission rate on an aircraft or vessel. A modeling study suggests that the risk of infection is about 1/1000 on an 8.7 hour flight and that persons seated closer to the index case are at greater risk of infection.²⁹ Only 5–10% of persons infected with the bacteria *Mycobacterium tuberculosis* will go on to develop active, infectious disease and the risk of progression is greatest within the first two years after infection.³⁰

An analysis of the epidemiology and outcomes of HHS/CDC-led flight-related tuberculosis contact investigations conducted in the United States from January 2007 to June 2008 examined 131 case-travelers and 4,550 passenger-contacts.³¹ Among 3,375 (74%)

passenger-contacts whose information was provided to health departments, HHS/CDC received results for 861 (26%). HHS/CDC found that 103/861 (12%) had a previous history of a positive TB screening test result or treatment for latent tuberculosis or active disease and were not re-tested. Of the remaining 758 passenger contacts, 182 (24%) tested positive. The majority of travelers with data about TB risk factors (other than exposure to cases during air travel) had at least one risk factor (130/142 or 92%). Risk factors included having been born or lived in a country with high TB prevalence (prevalence >100 per 100,000 population). Although passenger-contacts with risk factors were more likely to have pre-existing latent tuberculosis infection, the authors could not exclude the possibility that infection was acquired during the flights when the travelers were exposed.

Furthermore, because outcomes data were reported for only 26% of passenger contacts forwarded to U.S. health departments (19% of all passenger contacts) the precise determination of in-flight transmission risk of *M. tuberculosis* was not feasible.³²

The results from this investigation were used in a cost-effectiveness study to estimate the return on investment for tuberculosis CIs. The authors examined a range of latent tuberculosis prevalence rates among exposed travelers that varied between 19% and 24% for two different HHS/CDC CI protocols for flight-related TB investigations. The return on investment was calculated based on the likelihood that travelers with latent tuberculosis infection would initiate and complete a treatment regimen to clear the infection, the average cost of tuberculosis treatment, a tuberculosis case fatality rate of 5% and a conservative value of statistical life estimate of \$4.2 million (in 2009 USD) to account for the value of mortality risk reduction from avoided tuberculosis disease. The return on investment depended on the probability assumed for persons with latent TB infection to develop active disease (5–10%) and variation in the costs to health departments to locate exposed travelers (\$28 to \$164). Using the expected latent tuberculosis prevalence rate of 19% in travelers identified for contact investigations on flights and a health department cost per contact of \$164, the return on investment was estimated to

²⁶ Nelson, K., Marienau, K.J., Schembri, C. and Redd, S. (2013). "Measles transmission during air travel, United States." *Travel Medicine and Infectious Disease* (2013) 11, 81e89 11: 81–89.

²⁷ Nelson, K., Marienau, K.J., Schembri, C. and Redd, S. (2013). "Measles transmission during air travel, United States." *Travel Medicine and Infectious Disease* (2013) 11, 81e89 11: 81–89.

²⁸ Smith P, Marcuse E, Seward J, Zhao Z, WA O. Children and Adolescents Unvaccinated Against Measles: Geographic Clustering, Parents' Beliefs, and Missed Opportunities. *Public Health Rep.* 2015;5:485–504.

²⁹ Ko G, Thompson KM, Nardell EA. Estimation of tuberculosis risk on a commercial airliner. *Risk Anal* 2004;24:379e88.

³⁰ Marienau KJ, Cramer EH, Coleman MS, Marano N, Cetron MS. Flight related tuberculosis contact investigations in the United States: comparative risk and economic analysis of alternate protocols. *Travel Med Infect Dis.* 2014;12(1):54–62.

³¹ Marienau KJ, Burgess GW, Cramer E, et al. Tuberculosis investigations associated with air travel: US Centers for Disease Control and Prevention, January 2007–June 2008. *Travel Med Infect Dis* 2010;8:104e12.

³² Marienau KJ, Burgess GW, Cramer E, et al. Tuberculosis investigations associated with air travel: US Centers for Disease Control and Prevention, January 2007–June 2008. *Travel Med Infect Dis* 2010;8:104e12.

vary between \$1.01 and \$3.20. The return on investment formula was calculated based on (Expected benefits – Expected costs)/Expected costs. Thus, for each \$1 in Federal and State resources spent on contact investigations and offering treatment to persons infected with latent tuberculosis infections would result in benefits in excess of costs equal to \$1.01 to \$3.20^{33 34} on average. At the upper bound latent tuberculosis prevalence estimate (24%), the return on investment was estimated to vary between \$1.35 and \$3.92.

There is also empirical data for SARS infections occurring on an aircraft. A study reported that 37 infections resulted from 40 flights with infectious passengers on board. Of the 40 flights, four have documented aircraft sizes. They average 127 passengers per plane.³⁵ Therefore the on board transmission rate could be estimated to be 0.73% among all travelers. In comparison, there is no evidence of transmission of MERS Coronavirus or

viral hemorrhagic fevers during travel on aircraft or vessels. However, there have not been enough observations to determine that there is no risk.

For the remainder of the diseases, empirical data does not exist. Like measles, immunizations are recommended to prevent pertussis, rubella, and meningococcal disease. Since meningococcal conjugate vaccine was more recently added to the United States vaccination schedule, it is likely that background immunity is much lower relative to measles, rubella or pertussis.

In the absence of data for some diseases, the infection rate of measles is used to estimate the infection rates by using the ratio of basic reproduction numbers (R_0). The basic reproduction number is a measure of disease infectiousness. Specifically, it is an estimate of new infections in a completely susceptible population. For example, rubella has an R_0 of 9 to 10 while measles has an R_0 of 15 to 17.³⁶ The infection rate of measles is

multiplied (0.0034 to 0.0095) by the ratio of the average basic reproductive numbers (9.5/16) to arrive at a transmission rate (0.002 to 0.006) for rubella on airplanes. This rate is approximately 60% of the rate for measles. The estimated transmission rates for some diseases are reported in Table 12. The exceptions are for meningococcal disease and tuberculosis. For meningococcal disease, the risk of transmission in household contacts 0.002 to 0.004³⁷ is used in the absence of other data and taking account that CIs are only performed for travelers sitting adjacent to the index case or in the event of other known exposures. For tuberculosis, the probability that exposed travelers have latent tuberculosis³⁸ (19%–24%) is used, although infection may have occurred prior to air travel. For the purposes of evaluating the economic impact of tuberculosis investigations, it does not matter if travelers were infected during travel or before.

TABLE 12—ESTIMATED TRANSMISSION RATE ON PLANE FOR EXPOSED TRAVELERS

| Disease | R_0 | Estimated transmission rate on aircraft to exposed passengers | |
|---|----------------|---|-------------|
| | | Lower bound | Upper bound |
| Diphtheria (quarantinable) | 11 to 14 | 0.0026 | 0.0074 |
| Measles (non-quarantinable) | 15 to 17 | 0.0034 | 0.0095 |
| Meningococcal Disease (non-quarantinable) | NA | <2/1000 | <4/1000 |
| Pertussis (non-quarantinable) | 4 to 5 | 0.001 | 0.003 |
| Rubella (non-quarantinable) | 9 to 10 | 0.002 | 0.006 |
| TB (quarantinable) | NA | 0.19 | 0.24 |

Estimated Number of Cases in Traveler Contacts

The number of potential contacts for each disease can be multiplied by the estimated transmission rate by disease in Table 12 to generate a rough estimate of the annual number of cases among traveler contacts. These numbers of contacts for each disease are summarized in Tables 6 and 7 for interstate and international CIs

respectively. Contact investigations on vessels are excluded for this analysis. Based on this analysis, tuberculosis (19 to 48) and measles cases (3.6 to 10.1) are the most likely diseases that will be diagnosed among contacts exposed during travel (Table 13). Tuberculosis contact investigations only occur for international flights with the very rare exception of a domestic flight with a duration greater than 8 hours. The numbers of contacts and outcomes are

much more uncertain for other diseases. The number of tuberculosis cases are adjusted from the number of contacts with tuberculosis by assuming that only 5% (lower bound) to 10% (upper bound) of infected contacts will go on to develop clinical disease.³⁹

For viral hemorrhagic fevers and MERS, there is no evidence of transmission, but there have not been very many observations.

³³ Coleman M, Marienau K, Marano N, Marks S, Cetron M, Dis TMI. Economics of United States Tuberculosis Airline Contact Investigation Policies. Travel Medicine and Infectious Disease. 2014;12:63–71.

³⁴ Marienau KJ, Burgess GW, Cramer E, et al. Tuberculosis investigations associated with air travel: US Centers for Disease Control and Prevention, January 2007–June 2008. Travel Med Infect Dis 2010;8:104e12.

³⁵ Mangili A, Gendreau MA. Transmission of infectious diseases during commercial air travel. Lancet. 2005;365:989–96.

³⁶ Anderson RM. The concept of herd immunity and the design of community-based immunization programmes. Vaccine. 1992;10(13):928–35.

³⁷ Chapter 14. Meningococcal Disease, The Pink Book, CDC <http://www.cdc.gov/vaccines/pubs/pinkbook/mening.html> Accessed 5/2/2016.

³⁸ Marienau KJ, Burgess GW, Cramer E, et al. Tuberculosis investigations associated with air travel: US Centers for Disease Control and Prevention, January 2007–June 2008. Travel Med Infect Dis 2010;8:104e12.

³⁹ Coleman M, Marienau K, Marano N, Marks S, Cetron M, Dis TMI. Economics of United States Tuberculosis Airline Contact Investigation Policies. Travel Medicine and Infectious Disease. 2014;12:63–71.

TABLE 13—ANNUAL ESTIMATED NUMBER OF CASES AMONG INTERNATIONAL PASSENGER CONTACTS BY DISEASE

| Passengers per flight | Number of contacts | Expected incidence among contacts (lower bound) | Expected incidence among contacts (upper bound) | Expected number of new cases (lower bound) | Expected number of new cases (upper bound) |
|---|--------------------|---|---|--|--|
| MERS Coronavirus (quarantinable) | 101 | Insufficient data | | | |
| Measles (non-quarantinable) | 1,069 | 0.0034 | 0.0095 | 3.6 | 10.1 |
| Meningococcal Disease (non-quarantinable) | 1.7 | 0.00200 | 0.00400 | 0.0033 | 0.0067 |
| Pertussis (non-quarantinable) | 16.8 | 0.001 | 0.003 | 0.02 | 0.04 |
| Rubella (non-quarantinable) | 117 | 0.002 | 0.006 | 0.2 | 0.7 |
| TB ^a (quarantinable) | 1,995 | ^b 0.19 | ^b 0.24 | ^c 18.9 | ^c 47.90 |
| Viral Hemorrhagic Fever (quarantinable) | 62.0 | Insufficient data | | | |
| Total | 3,362 | | | 22.8 | 58.7 |

^a For tuberculosis, travelers contacts are typically found to test positive for infection, but do not have active disease.

^b These probabilities indicate the likelihood that a contact will test positive for infection.

^c The expected numbers of cases adjust for the finding that only 5–10% of individuals that test positive for infection will go on to develop clinical disease.

These estimates of cases may be a lower bound, because potential cases resulting from flights in which contact investigations were not performed are not included. Especially for tuberculosis cases, many international travelers may return to their home countries before seeking treatment and such cases may not lead to contact investigations if HHS/CDC is not informed.

Marginal Costs of Final Rule

Data Collection

Since the final rule does not change the timeframe or amount of data requested from airlines or vessel operators, the most likely economic impact is a small change in the amount of effort for airlines to provide more complete and timely information. To the extent that airlines would respond more quickly or with additional data, it would require some airline information technology staff to expedite requests or to search in more depth for available data. HHS/CDC estimates this may require one hour of staff time per request. HHS/CDC has no way to predict how much more complete, timely, or accurate contact from airlines would become as a result of this final rule. On

average, HHS/CDC acted upon 77 requests per year to airlines for international traveler contact data between 2010 and 2015 (Table 6). In addition, HHS/CDC made 22.5 requests per year for interstate traveler data (Table 7) over the same period. There were 45 contact investigations per year among travelers on vessels (Table 8); however, most of these were undertaken before travelers disembarked vessels in which case contact data could be collected directly from exposed travelers as part of the investigation. The number of maritime contact investigations requiring manifest requests after disembarkation is estimated to be less than 10 per year.

Overall, including international air and maritime activities, the estimated number of contact data requests after disembarkation was estimated at 100 to account for the fact that HHS/CDC sometimes requests traveler contact data for infectious disease events prior to confirmed diagnoses. On occasion, it turns out that travelers are not infected with diseases that require a public health response. This rounding up should also account for a year in which there is a significant increase in the

number of contact investigations among exposed air or maritime travelers. HHS/CDC notes the manifest order process for interstate flights is not codified in the final rule. The data is provided here for completeness.

The average wages for computer and information systems managers (occupation code 11–3021) reported in the Bureau of Labor Statistics, May 2015 Occupational Employment Statistics⁴⁰ were \$63.27 per hour. On average, under the baseline, HHS/CDC assumes that it would require 6 hours of work by airlines to search databases and provide data. For the final rule, HHS/CDC assumes that a management-level computer specialist will spend additional time to provide the best possible contact data for potentially exposed travelers. The base salary is multiplied by an overhead multiplier of 100% to account for non-wage benefits and other overhead costs for supporting each employee (Table 14). The lower bound estimate (\$0) is no change from current practice, while the upper bound estimate assumes 2 hours of time instead of one (\$25,308). These costs are applied to an estimated 100 manifest requests per year.

TABLE 14—ESTIMATE OF COSTS FOR AIRLINES AND VESSEL OPERATORS TO IMPROVE COMPLIANCE WITH HHS/CDC REQUESTS FOR TRAVELER CONTACT DATA, 2015 USD

| | Average number of manifest requests per year | Increased effort to provide more complete or timelier passenger contact data (hrs.) | Average hourly wage rate of IT staff (2015 USD) | Overhead multiplier (%) | Total cost |
|---------------------|--|---|---|-------------------------|------------|
| Baseline | 100 | 6 | \$63.27 | 100 | \$75,924 |
| Best estimate | 100 | 1 | 63.27 | 100 | 12,654 |

⁴⁰ http://www.bls.gov/oes/current/oes_nat.htm.

TABLE 14—ESTIMATE OF COSTS FOR AIRLINES AND VESSEL OPERATORS TO IMPROVE COMPLIANCE WITH HHS/CDC REQUESTS FOR TRAVELER CONTACT DATA, 2015 USD—Continued

| | Average number of manifest requests per year | Increased effort to provide more complete or timelier passenger contact data (hrs.) | Average hourly wage rate of IT staff (2015 USD) | Overhead multiplier (%) | Total cost |
|-------------------|--|---|---|-------------------------|------------|
| Lower bound | 100 | 0 | 63.27 | 100 | 0 |
| Upper bound | 100 | 2 | 63.27 | 100 | 25,308 |

Illness Reporting Costs

When reports are received, public health officers at Quarantine Stations perform case assessments, may request follow-up information, and may consult with HHS/CDC medical officers to determine if additional action such as a contact investigation, onboard response, or notification to State and local health departments is warranted. Under one assumed upper bound scenario, the change in the definition of “ill person” included in the final rule could result in a 100% increase in the number of info-only reports from airlines and a 25% increase from vessels. On average, there are 129 info-only reports for aircraft and vessels each year and these increases would correspond to an annual increase of 119 info-only reports on aircraft and 3 info-only reports on vessels (Table 15). If the average time for each report is estimated to be 2 minutes for aircraft pilots in command or masters of vessels to make the report, 10 minutes for a traveler to discuss the illness with

public health officer, and 60 minutes for HHS/CDC to document the info-only report, the estimated cost of the additional reports can be estimated based on the opportunity cost of time for each type of personnel. In addition to the time required for aircraft pilots in command and masters of vessels to make reports, the personnel in the Department of Transportation’s Federal Aviation Administration (DOT/FAA) may incur additional costs to relay reports of suspected cases of communicable disease received by air traffic control to CDC through the Domestic Events Network. The amount of DOT/FAA staff time is estimated at 26 minutes for a government employee at GS-level 15, step 6 based in Washington, DC. In reality, there would be three DOT/FAA employees involved including 1 GS–15/16 level employee at air traffic control (10 minutes), 1 GS–15 level employee at the Domestic Events Network (10 minutes), and 1 GS–14 level employee at DOT/FAA’s

Washington Operations Center Complex (6 minutes).⁴¹

For aircraft pilots in command or masters of vessels (occupation codes 53–2011 and 53–5021) and travelers (average across all occupations code 00–0000), their opportunity cost is estimated from Bureau of Labor Statistics, May 2015 Occupational Employment Statistics⁴² based on the average salary of aircraft pilots or copilots (\$57.35 per hour), traveler (\$23.23 per hour) or vessel captain, mate, or pilot (\$39.95 per hour). For HHS/CDC employees, the average wage rate is based on the Federal government’s general salary scale for a GS–12, step 5 employee based in Atlanta, GA). Base salaries are multiplied by an overhead multiplier of 100% to account for non-wage benefits and other overhead costs for supporting each employee. Travelers do not have overhead costs. The annual quantified costs of 122 additional info-only reports would be \$17,471.

TABLE 15—CHANGES IN NUMBERS OF INFO-ONLY REPORTS AND ASSOCIATED COSTS FOR THE FINAL RULE UPPER BOUND, 2015 USD

| Employee type | Change in number of info-only reports | Amount of time required per report (min) | Estimated wage rate (2015 USD per hr.) | Overhead multiplier (%) | Estimated cost |
|--|---------------------------------------|--|--|-------------------------|----------------|
| Aircraft: | | | | | |
| Aircraft Pilots or Copilots | 119 | 2 | \$57.35 | 100 | \$455 |
| CDC employee | 119 | 60 | 39.83 | 100 | 9,480 |
| DOT/FAA employees | 119 | 26 | 70.57 | 100 | 7,278 |
| Traveler | 119 | 10 | 23.23 | 0 | 461 |
| Air total | | | | | 17,213 |
| Vessels: | | | | | |
| Air or maritime conveyance officer | | | | | |
| Captains, Mates, and Pilots of Water Vessels | 3 | 2 | 39.95 | 100 | 8 |
| CDC employee | 3 | 60 | 439.83 | 100 | 239 |
| Traveler | 3 | 10 | 23.23 | 0 | 12 |
| Maritime total | | | | | 259 |
| Total costs, aircraft and vessels | | | | | 17,471 |

Notes: Assumes 100% increase in info-only reports from airlines and 25% from vessel operators.

⁴¹ Personal communication between Dr. Brian Maskery and DOT/FAA.

⁴² http://www.bls.gov/oes/current/oes_nat.htm.

Besides the possible change in costs of info-only reports, the other potential change would be an increase in the number of reports that require HHS/CDC follow-up. Under the most likely scenario, there will not be a change in these reports since the new definition better corresponds to HHS/CDC guidance and to reporting guidelines published by ICAO in Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation. However, there may be an increase in the number of reports requiring a response. Under this scenario, there may be an increase in costs for air or masters of vessels to report illnesses. The upper bound increase in reports requiring response is assumed to be 50% of the average annual illness reports from airlines and a 10% increase from vessels (refer to Tables 10 and 11 for baseline number of

reports): 29 reports per year on aircraft and 21 reports per year on vessels. HHS/CDC assumes that the time required to submit illness reports and for DOT/FAA staff to relay reports requiring responses is the same as for info-only reports (2 minutes for pilots in command and masters of vessels and 26 minutes for DOT/FAA to relay reports, Table 16). Further, HHS/CDC assumes that travelers could spend up to 60 minutes talking to HHS/CDC and/or State and local public health officers for reports requiring response. The upper bound estimate of total costs associated with the increase in the number of illness reports requiring response is estimated to be \$3,102.

There would likely be no change or a decrease in HHS/CDC costs because earlier reporting would lead to a more efficient HHS/CDC response relative to an alternative in which the illness was

not reported during travel, but instead was later reported by a public health department to HHS/CDC. In addition, the public health response to the illness would likely be more efficient because exposed travelers could be contacted earlier. In rare situations, such travelers may potentially be informed of their potential exposure at the gate after disembarking the aircraft or vessel. Such actions should not result in significant delays by holding travelers on board.

HHS/CDC did not include any training costs because the change in the "ill person" definition in this final rule is consistent with the internationally recognized and accepted illness reporting guidelines published by ICAO for international travelers and represents a reduced burden compared to the previous illness reporting regulations for interstate travelers.

TABLE 16—CHANGES IN ANNUAL NUMBERS OF REPORTS REQUIRING RESPONSE AND ASSOCIATED COSTS FOR THE FINAL RULE UPPER BOUND, 2015 USD

| Employee type | Change in number of reports | Amount of time required per report (min) | Estimated wage rate (2015 USD per hr.) | Overhead multiplier (%) | Estimated cost (2015 USD) |
|--|-----------------------------|--|--|-------------------------|---------------------------|
| Aircraft: | | | | | |
| Aircraft Pilots or Copilots | 29 | 2 | \$57.35 | 100 | \$111 |
| CDC employee | 29 | 0 | 39.83 | 100 | 0 |
| DOT/FAA employee | 29 | 26 | 70.57 | 100 | 1,774 |
| Traveler | 29 | 60 | 23.23 | 0 | 674 |
| Total | | | | | 2,558 |
| Vessels: | | | | | |
| Captains, Mates, and Pilots of Water Vessels | 21 | 2 | 39.95 | 100 | 56 |
| CDC employee | 21 | 0 | 39.83 | 100 | 0 |
| Traveler | 21 | 60 | 23.23 | 0 | 488 |
| Total | | | | | 544 |
| Total | | | | | 3,102 |

Notes: Assume 50% increase in air illness and a 10% increase in maritime illness reports requiring response (international and interstate).

There may also be a one-time cost associated with updating training to reflect the new regulatory text. As noted above, HHS/CDC reiterates that the change to regulatory text is a codification of HHS/CDC guidance and better aligns with international guidance (Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation). Further for interstate travel, these changes result in relaxed illness reporting compared to status quo regulatory text. Thus any airlines using either ICAO or HHS/CDC guidance to support training efforts for illness reporting should not need to change training materials. At most, it may be necessary to clarify that some symptoms that were previously requested are now required. However, for some airlines or

vessel operators, it may be necessary to revise training materials.

The cost of training was estimated based on the number of pilots and flight attendants and their average wage rates as reported in the Bureau of Labor Statistics, May 2015 Occupational Employment Statistics.⁴³ HHS/CDC assumes that the opportunity cost of employee time spent in training would be the primary cost as opposed to the cost of developing training materials. As an upper bound, HHS/CDC assumed the cost of training could be estimated based on assuming that all employees would require 10 minutes of training to summarize the changes. As noted above, since this change aligns regulatory text

with existing HHS/CDC and ICAO guidance documents, this change may not result in a new training requirement for all airlines since some presumably already use HHS/CDC guidance in training. This 10 minute estimate does not necessarily mean all 230,000 pilots and flight attendants each require 10 minutes of training. For example, 50% of each could require 20 minutes of training, while the other 50% may already conduct training in accordance with either CDC or ICAO guidance. The total cost of the one-time change in training is about \$3.1 million. If this cost is annualized over 10 years, the average annual cost depends on the discount rate assumed and varies from \$313,000 per year (7% discount rate) to \$416,000 (0% discount rate). These

⁴³ http://www.bls.gov/oes/current/oes_nat.htm.

results are summarized in Table 17. These costs (3% discount rate) are added to the upper bound cost estimate

for illness reporting. The lower bound and best estimates are \$0 since the

changes to the definition better align with existing CDC and ICAO guidance.

TABLE 17—ESTIMATED COSTS FOR ONE-TIME TRAINING ABOUT CHANGES IN ILLNESS REPORTING FOR AIRLINES, 2015 USD

| Employee type | | Number of employees | Amount of time required for training per employee (minutes) | Estimated wage rate (2015 USD per hr.) | Overhead multiplier (%) | Estimated cost or benefit (2015 USD) |
|---|----------------------|---------------------|---|--|-------------------------|--------------------------------------|
| Aircraft Pilots or Copilots | | 121,110 | 10 | 57.35 | 100 | 2,315,220 |
| Flight attendants | | 108,510 | 10 | 22.46 | 100 | 812,465 |
| Total | | | | | | 3,127,685 |
| Annualized cost over 10-year time horizon | 3% discount rate ... | \$355,981 | 0% discount rate ... | \$416,179 | 7% discount rate ... | \$312,768 |

The monetized annual costs resulting from the change in the definition of “ill

person” are summarized in Table 18. The benefits in regard to reductions in

communicable disease transmission are summarized in a subsequent section.

TABLE 18—BEST ESTIMATE, LOWER BOUND AND UPPER BOUND OF THE CHANGES IN ANNUAL MONETIZED BENEFITS AND COSTS AS A RESULT OF THE CHANGE TO THE REPORTABLE ILLNESS DEFINITION, 2015 USD

| | Best estimate | Lower bound | Upper bound |
|----------------|---------------|-------------|-------------|
| Costs | | | |
| Final Rule: | | | |
| Aircraft | \$0 | \$0 | \$375,751 |
| Vessels | 0 | 0 | 802 |
| Total | 0 | 0 | 376,554 |

The total costs of the final rule are summarized in Table 19 and include the

costs of the change to the definition of an “ill person” and the codification of

the requirement for airlines to provide passenger contact data for the final rule.

TABLE 19—TOTAL COSTS AND BENEFITS RESULTING FROM CODIFICATION OF TRAVELER DATA COLLECTION (71.4 AND 71.5) AND CHANGE TO DEFINITION OF “ILL PERSON” (70.1 AND 71.1)

| | Best estimate | Lower bound | Upper bound |
|---|---------------|-------------|-------------|
| Costs | | | |
| Final Rule: | | | |
| 71.4 and 71.5 Passenger data collection | \$12,654 | \$0 | \$25,308 |
| 70.1 and 71.1 Change in definition of an “ill person” | 0 | 0 | 376,554 |
| Total costs | 12,654 | 0 | 401,862 |

Benefits From Streamlining the CI Process for Routinely Imported Diseases

This section reports the benefits that HHS/CDC anticipates from implementation of the final rule in avoiding the costs incurred annually for CIs of infectious diseases. The model for estimating the benefits of CIs is: Current number of CIs × (reduction in HHS/CDC and health department staff time/resources per contact) × value of staff time.

HHS/CDC obtained the total number of contacts traced (2,715 per year, Table

6) for all diseases reported on international flights. International flight data were extracted for this analysis because the codification of the requirements to provide timelier and more complete contact data is limited to international arrivals. In comparison, HHS/CDC requests contact information for approximately 664 contacts per year on interstate flights (Table 7). HHS/CDC also supports contact investigations affecting an average of 762 contacts per year for illnesses on board vessels (Table 8); however, many of these investigations occur before travelers

disembark vessels. By limiting the analysis to contacts on international flights, HHS/CDC conservatively estimates the potential benefits associated with this final rule. HHS/CDC multiplied the average annual number of contacts on international flights by the cost-per-contact for HHS/CDC and PHDs (Table 11) to estimate the costs of CIs under the current baseline.

To estimate the benefits (Tables 20 and 21), HHS/CDC assumed a percent reduction in staff time for CIs at HHS/CDC (0–3%) and PHD levels (0–2%)

based on internal conversations with personnel directly involved in the CI process. The reduction in staff time that would result from implementation of this final rule would arise from the ability of HHS/CDC to have a better starting point with which to provide traveler contact data to State and local health departments as a result of the receipt of more complete and timely traveler contact data from airlines. The impact of codification is expected to be limited and would depend on instances in which airlines have more data than what is currently provided to DHS. Better data would improve HHS/CDC's ability to transmit information to destination States more quickly and for States to contact exposed travelers earlier. This would allow States to start their investigations more quickly, contact more travelers faster to conduct public health assessments and potentially offer preventive medications

or vaccines in a more timely fashion or to recommend self-monitoring to mitigate onward transmission. In addition, it would be less likely that HHS/CDC would send incorrect contact data to States. With all of the preceding factors in mind, HHS/CDC estimated that the final rule would reduce labor time by between 0% to 3% at HHS/CDC, and 0% to 2% at PHDs. The higher percentage of avoided costs at HHS/CDC reflect reduced efforts by HHS/CDC to search for accurate contact data for travelers due to untimely or inaccurate data. The lower percentage of avoided costs at PHDs reflects a more diffuse (e.g., multiple local PHDs in a State) infrastructure and the more labor-intensive tasks of following up on individuals. These estimates are small because the change is a clarification and codification of a current practice authorized under broad statutory and regulatory authority rather than a new

regulatory requirement. In addition, the change to the definition of "ill person" may lead to the earlier diagnoses of some travelers with communicable disease, which may lead to earlier and more efficient public health responses.

HHS/CDC annual costs to engage in international air, interstate air, and maritime CIs are about \$745,000 or roughly the equivalent of 3.8 HHS/CDC full-time employees (FTEs) at the wage level of GS-13, step 4 plus benefits and overhead (Table 21). The final rule should have the greatest effect on the international air CIs. The annual reduction in contact tracing costs from implementing the final rule (Table 22) for HHS/CDC ranged from \$0 to \$14,661 based on a 0–3% reduction in effort on international CIs. For PHDs, the reduction in costs ranged from \$0 at the lower bound to \$9,774 at the upper bound (Table 22).

TABLE 20—ANNUALLY FOR HHS/CDC AND PHD: BASELINE COSTS

| | Annual number contacts | HHS/CDC | PHD costs | Total costs |
|--|------------------------|-----------|-----------|-------------|
| HHS/CDC and PHD Baseline Costs (Current Practice) | | | | |
| International air contacts | 2,715 | \$488,700 | \$488,700 | \$977,400 |
| Interstate air contacts | 664 | 119,520 | 119,520 | 239,040 |
| Maritime contacts | 762 | 137,160 | 137,160 | 274,320 |
| Total baseline costs | 4,141 | 745,380 | 745,380 | 1,490,760 |
| Viral hemorrhagic fever, MERS, and SARS contacts | 163 | 29,340 | 29,340 | 58,680 |

TABLE 21—ANNUAL FOR HHS/CDC AND PHDs: BASELINE COSTS, FINAL RULE COSTS, BENEFITS WITH THE FINAL RULE (NUMBER CONTACTS ANNUALIZED FROM JANUARY 2010 TO DECEMBER 2015), 2015 USD

| HHS/CDC and PHD Baseline Costs (Current Practice) | | | | |
|--|--|-----------------|---|-----------------|
| | Annual number contacts | HHS/CDC | PHD | |
| International contacts | 2,715 | \$488,700 | \$488,700 | |
| HHS/CDC and PHD Costs With the Final Rule | | | | |
| | Estimated Costs for HHS/CDC After Efficiency Improvement with Final Rule | | Estimated Costs for PHDs After Efficiency Improvement with Final Rule | |
| | 0%, Lower bound | 3%, Upper bound | 0%, Lower bound | 2%, Upper bound |
| International contacts costs assuming reduction in time (2,715) | \$488,700 | \$474,039 | \$488,700 | \$478,926 |
| Benefits From Implementing the Final Rule | | | | |
| | HHS/CDC 0% and 3% Reduction in effort | | PHD (0% and 2% Reduction in effort) | |
| Benefits (Reduced costs) | \$0 | \$14,661 | \$0 | \$9,774 |

The best estimate of benefits are the midpoint of the lower bound and upper bound estimates for both HHS/CDC and

PHDs (\$12,218). The lower bound (\$0) and upper bound estimates (\$24,435) for

both entities are also reported in Table 22.

TABLE 22—BEST ESTIMATE, LOWER BOUND AND UPPER BOUND OF BENEFITS FROM INCREASED EFFICIENCIES FOR HHS/ CDC AND PHDS TO CONDUCT CONTACT INVESTIGATIONS WITH PROVISION OF BETTER DATA FROM AIRLINES (FINAL RULE), 2015 USD

| | HHS/CDC benefits | PHD benefits | Total |
|---------------------|------------------|--------------|----------|
| Best estimate | \$7,331 | \$4,887 | \$12,218 |
| Lower bound | 0 | 0 | 0 |
| Upper bound | 14,661 | 9,774 | 24,435 |

The total annual monetized benefits by stakeholder from the potential reduced effort for contact investigations are summarized in Table 23.

TABLE 23—BEST ESTIMATE, LOWER BOUND AND UPPER BOUND OF BENEFITS FROM INCREASED EFFICIENCIES FOR HHS/ CDC AND PHDS TO CONDUCT CONTACT INVESTIGATIONS WITH PROVISION OF BETTER DATA FROM AIRLINES, 2015 USD

| | HHS/CDC benefits, USD | PHD benefits, USD | Airlines, USD | Total |
|---------------------|-----------------------|-------------------|---------------|----------|
| Best estimate | \$7,331 | \$4,887 | \$0 | \$12,218 |
| Lower bound | 0 | 0 | 0 | 0 |
| Upper bound | 14,661 | 9,774 | 0 | 24,435 |

Marginal Impact of Final Rule—Measles Health Outcome Benefits

On average, HHS/CDC identified 564 travelers exposed to measles cases on international flights during 2010–2015 (Table 6). The final rule may affect the cost for health departments to implement public health measures in two ways: (1) Health departments may contact exposed travelers more quickly and (2) health departments may be able to contact a higher percentage of exposed travelers. For the first set of travelers that are contacted earlier with the final rule than under the status quo, the cost to both the contacted travelers and to health departments should be less than under the status quo. For measles contacts, earlier follow-up with public health departments should lead to more travelers being offered voluntary measles vaccines within 72 hours. This would potentially reduce the cost of following up with exposed travelers at which time health departments could offer to administer immune globulin or health departments may monitor travelers that have been located after the 72-hour window in

which measles vaccination would reduce their risk of developing symptomatic measles. At present, very few travelers receive post-exposure prophylaxis, 11/248 or 4.4%.⁴⁴ In addition, health departments have implemented quarantine (usually voluntary) for unvaccinated, high risk measles exposures.⁴⁵ HHS/CDC notes that measles is not a quarantinable communicable disease under Federal regulations, but may be quarantinable under a State's authorities. HHS/CDC also notes that measles vaccine is recommended for all persons lacking immunity. Thus, the costs of vaccination for exposed travelers as part of the contact investigation may have been incurred at a later date if travelers' health care providers recommended measles vaccination at a more routine health care visit in the future.⁴⁶ However, to be conservative, HHS/CDC includes the full additional cost to administer such vaccines to persons contacted.

Among the contacts, HHS/CDC estimates that approximately 25% (141 contacts per year) cannot be located by

public health departments (Table 24), either because HHS/CDC cannot assign the contacts to health departments or because the information provided by HHS/CDC is not sufficient to enable health departments to locate contacts after assignment from HHS/CDC. Among these contacts, HHS/CDC assumes that 10% of all contacts (56) are not located because HHS/CDC cannot assign contacts to State health departments due to insufficient data. For these contacts, health departments would not incur any contact tracing costs because such contacts would not be assigned. HHS/CDC assumes a 15% improvement from baseline as a result of this final rule (Table 24). This would result in 8.5 additional contacts per year assigned to health departments for contact tracing. As shown in Table 11, HHS/CDC estimates that health departments incur an estimated cost of \$180 per contact. The marginal cost incurred from this final rule for additional measles contacts assigned to health departments would be $180 \times 8.5 = \$1,530$ per year (Table 25).

TABLE 24—ESTIMATED MARGINAL IMPROVEMENT IN THE NUMBERS OF MEASLES CONTACTS WHO COULD BE TREATED WITH FINAL RULE

| Description | n | Reference |
|--|-----|-----------------------------------|
| Average contacts per year for measles, (a) | 564 | Table 6. |
| Estimated number of contacts for which HHS/CDC cannot assign to a health department, (b) = $10\% \times (a)$. | 56 | Nelson et al. 2013. ⁴⁷ |

⁴⁴ Nelson K, Marienau K, Schembri C, Redd S. Measles transmission during air travel, United States. *Travel Medicine and Infectious Disease* (2013) 11, 81e89. 2013;11:81–9.

⁴⁵ P Kutty, J Rota, W Bellini, SB Redd, A Barskey, G Wallace. (2014) Manual for the Surveillance of Vaccine-Preventable Diseases: Chapter 7 Measles. <http://www.cdc.gov/vaccines/pubs/surv-manual/chpt07-measles.html> Accessed 5/8/2016.

⁴⁶ CDC (2015) Epidemiology and Prevention of Vaccine-Preventable Diseases: Measles. <http://www.cdc.gov/vaccines/pubs/pinkbook/meas.html> Accessed 5/8/2016.

TABLE 24—ESTIMATED MARGINAL IMPROVEMENT IN THE NUMBERS OF MEASLES CONTACTS WHO COULD BE TREATED WITH FINAL RULE—Continued

| Description | n | Reference |
|--|-----|-------------------------------|
| Estimated improvement in HHS/CDC's ability to assign contacts to health department (c) = 15% × (b). | 8.5 | Assumption. |
| Numbers of people who are not currently contacted due to lack of contact information, (d) = (a) × 25%. | 141 | Nelson et al. 2013. |
| Expected numbers of people who could be contacted with final rule, (e) = (d) × 15% | 21 | Assumption. |
| Among those contacted, 70% would have evidence of measles immunity (f) = (e) × 70% | 15 | Nelson et al. 2013 (Table 2). |
| Among those contacted, 30% may be susceptible to measles (g) = (e) × 30% | 6 | Nelson et al. 2013 (Table 2). |

⁴⁷ Nelson, K., Marienau, K.J., Schembri, C. and Redd, S. (2013). "Measles transmission during air travel, United States." *Travel Medicine and Infectious Disease* (2013) 11, 81e89 11: 81–89.

TABLE 25—ESTIMATED MARGINAL COSTS FOR HEALTH DEPARTMENTS TO CONTACT EXPOSED TRAVELERS AND OFFER MEASLES POST-EXPOSURE PROPHYLAXIS (VACCINATION), 2015 USD

| | |
|---|---------|
| Number of additional names sent to health department, (c) | 8.5 |
| Additional cost per contact to health department to search for and examine contacts (USD per contact) (h) | \$180 |
| Additional cost to health department to search for contacts, total (USD), (i) = (c) × (h) | \$1,530 |
| MMR vaccine price per dose (USD) (j) | \$39 |
| Vaccine administration (k) | \$31 |
| Estimated cost prophylactic measles vaccine per person (USD), (l) = (j) + (k) | \$70 |
| Number of individuals who may receive measles vaccine, (g) | 6 |
| Cost of measles vaccination, total (USD) (m) = (g) × (l) | \$420 |
| Total additional annual cost to follow up with more contacts (USD), (i) + (m) | \$1,950 |

In addition, HHS/CDC assumes that the final rule could improve health departments' abilities to contact 15% of those who could not be currently contacted because of insufficient contact information (21 contacts per year). HHS/CDC does not have any data to measure the magnitude of improvement and applies a range of 10% to 20% to calculate lower and upper bounds. If airlines and vessel operators do not have any additional data besides what is already transmitted to DHS, there will

be very little improvement. Among the 21 additional exposed travelers that would be contacted, 70% of them (15 per year) are expected to have measles immunity because they were born before 1957, had history of measles, or received one or more doses of measles vaccine. The remaining 6 travelers per year without proven measles immunity would incur additional costs if they are vaccinated (vaccine costs + vaccine administration, Table 25).

To be conservative, HHS/CDC assumes that all 6 exposed travelers

would be adults and would be vaccinated with the measles-mumps-rubella (MMR) vaccine. The vaccine price for adults is estimated from the Vaccines for Children vaccine price archives (July 2014 and July 2015)⁴⁸ based on the public sector price for the vaccine. Vaccine administration costs are estimated from Healthcare Solutions' 2015 Physicians' Fee & Coding Guide (CPT 90471).⁴⁹ Total costs resulting from the final rule are summarized in Table 26.

TABLE 26—MARGINAL IMPACT OF FINAL RULE TO IMPROVE CONTACT INVESTIGATIONS

| Marginal cost for measles investigations | Additional names provided to health departments | Addition contacts reached by health departments | Number of travelers provided post-exposure prophylaxis | Number of travelers identified earlier | Average probability that contact is infected |
|--|---|---|--|--|--|
| \$1,950 | 8.5 | 21 | 6 | Unknown | 0.0035–0.0095 |

In the absence of interventions by public health departments, travelers infected with measles during international travel would be as likely as any other individuals to spark a measles outbreak. In the absence of HHS/CDC efforts to retrieve and transmit contact data, public health departments would not be able to contact travelers to offer post-exposure prophylaxis and/or to recommend self-

monitoring for potential measles symptoms.

For measles in 2011, 16 outbreaks occurred leading to 107 cases. An outbreak was defined based on 3 or more cases in a cluster.⁵⁰ The remaining 113 cases reported in 2011 resulted in one or two cases per cluster. Thus, the probability that any individual measles index case leads to an outbreak was between $16/(16+113) = 12.4\%$ and $16/$

$(16+57) = 20.1\%$. The lower bound represents an assumption that all of the 113 cases unassociated with outbreaks of 3 or more cases occurred in clusters with just one case each. The upper bound represents a scenario with 56 clusters of two cases each with one cluster with one case. Thus, the probability that any individual measles case could spark an outbreak of 3 or more cases is 12.4% to 20.1%. The

⁴⁸ <http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/archive.html> Accessed 5/2/2016.

⁴⁹ InGauge Healthcare Solutions. 2015 Physicians' Fee & Coding Guide. Atlanta GA2013.

⁵⁰ Ortega-Sanchez IR, Vijayaraghavan M, Barskey AE, Wallace GS. The economic burden of sixteen

measles outbreaks on United States public health departments in 2011. *Vaccine*. 2012;32(11).

average cost to public health departments per measles outbreak is \$250,000 and the upper bound cost is \$1 million.⁵¹

HHS/CDC assumes that the probability that a measles case resulting from exposure during travel and that is not contacted by a public health department is as likely as any other measles case to initiate a measles outbreak of 3 or more cases, which occurs at an approximate probability of 12.4% to 21.9%. The average cost to health departments is \$250,000 for each of these outbreaks and the average outbreak size is about 7 cases (107 cases/16 outbreaks).

The estimated illness costs for measles are \$300 (\$86–\$515) for outpatient cases and \$24,500 (\$3,900–\$45,052) for inpatient cases.⁵² The probability of hospitalization is estimated to be 44.3%.⁵³ A range of hospitalization rates is estimated based on 50% to 150% of this base case estimate (22%–66%). The measles case fatality rate has been estimated to be 0.2%.⁵⁴ HHS/CDC assumes that the value of statistical life is \$9.4 million (range \$4.3 million to \$14.2 million). This value is an estimate of the average willingness to pay to reduce one's mortality risk by a small increment not an estimate of the value of any specific

person's life. For example if 1,000 people were willing to pay \$1,000 each to reduce their risk of death by 1/1,000, the value of statistical life would be equal to \$1,000/0.001 change in risk of death = \$1 million. Alternatively 1,000 people each experiencing a mortality risk reduction of 0.001 would correspond to 1,000 people \times 0.001 mortality risk reduction = 1 statistical life; 1,000 people each willing to pay \$1,000 = 1,000 \times \$1,000 = \$1 million to avert that one statistical death. Using these estimates, the average illness costs associated with a measles case (Table 27) is about \$30,000 (\$9,500 to \$58,000).

TABLE 27—ESTIMATED ILLNESS AND MORTALITY COSTS PER MEASLES CASE

| | Best estimate | Lower bound | Upper bound |
|--|---------------|-------------|--------------|
| Outpatient cost, a | \$300 | \$86 | \$515 |
| Inpatient cost, b | \$24,500 | \$3,943 | \$45,052 |
| Hospitalization rate, c | 44.30% | 22.0% | 66.0% |
| Case fatality rate, d | 0.2% | 0.2% | 0.2% |
| VSL, e | \$9,400,000 | \$4,300,000 | \$14,200,000 |
| Total cost per case ($b \times c + a \times (1 - c) + d \times e$) | \$29,821 | \$9,535 | \$58,309 |

The estimated number of measles cases that will occur in contacts exposed during travel (3.6 to 10.1) can be multiplied by the probability of an outbreak with 3 or more cases (12.4% to 21.7%) to estimate the expected number

of outbreaks in the absence of public health intervention to conduct contact investigations in exposed travelers. For each outbreak, HHS/CDC assumes that an average of 6 additional cases occur with associated morbidity and mortality

costs. The estimated costs of measles outbreaks in the absence of contact investigations for exposed travelers is presented in Table 28.

TABLE 28—ESTIMATED ILLNESS, MORTALITY, PUBLIC HEALTH RESPONSE COSTS ASSOCIATED WITH MEASLES OUTBREAKS

| | Best estimate | Lower bound | Upper bound |
|---|---------------|-------------|-------------|
| Estimated number of measles cases among contacts, a | 6.85 | 3.6 | 10.1 |
| Probability of measles outbreak, b | 17 | 12.4 | 21.9 |
| Number of additional cases per outbreak, c | 6 | 6 | 6 |
| Estimated number of outbreaks, $d = a \times b$ | 1.18 | 0.45 | 2.22 |
| Estimated number of outbreak cases, $e = a \times b \times c$ | 7.06 | 2.68 | 13.29 |
| Estimated health department costs per outbreak, f | 250,000 | 250,000 | 250,000 |
| Estimated health department costs, $g = f \times d$ | 293,989 | 111,607 | 553,758 |
| Average cost per case, h | 29,821 | 9,535 | 58,309 |
| Estimated illness costs, $i = h \times e$ | 210,406 | 25,539 | 774,944 |
| Estimated total costs, $g + i$ | 504,395 | 137,146 | 1,328,703 |

HHS/CDC has not received any reports of large measles outbreaks associated with measles cases in patients exposed during travel and contacted by State or local public health departments. As a result, HHS/CDC believes that when measles cases occur in contacts reached by health departments, the probability of an

outbreak is significantly mitigated by pre-warning of exposure before disease onset. Given that HHS/CDC estimates that health departments are able to reach approximately 75% of contacts under the status quo, HHS/CDC assumes that the risk of an outbreak has been reduced by at least 60% under the status quo. Further, HHS/CDC assumes that

the provisions in the final rule further improve health departments' ability to prevent measles outbreaks in cases that occur among travelers exposed during flights. A modest improvement of 15% is assumed (range 10%–20%) resulting in estimated benefits of about \$45,000 (\$8,000 to \$159,000) in Table 29.

⁵¹ Ortega-Sanchez IR, Vijayaraghavan M, Barskey AE, Wallace GS. The economic burden of sixteen measles outbreaks on United States public health departments in 2011. *Vaccine*. 2012;32(11).

⁵² Zhou F, Shefer A, Wenger J, Messonnier M, Wang LY, Lopez A, et al. Economic Evaluation of the Routine Childhood Immunization Program in

the United States, 2009. *Pediatrics*. 2014;133:577–85.

⁵³ Mason WH, Ross LA, Lanson J, Wright HT. Epidemic measles in the postvaccine era: evaluation of epidemiology, clinical presentation, and complications during an urban outbreak. *Pediatr Infect Dis J*. 1993;12:42–8.

⁵⁴ Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases, 13th Edition—Measles April 2015 <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/meas.pdf>. Accessed 6/13/2016.

TABLE 29—ESTIMATED BENEFITS ASSOCIATED WITH IMPROVEMENT OF MEASLES CONTACT INVESTIGATIONS AS A RESULT OF THIS FINAL RULE

| | Best estimate | Lower bound | Upper bound |
|---|---------------|-------------|-------------|
| Estimated total costs without intervention, $j = g + i$ | \$504,395 | \$137,146 | \$1,328,703 |
| Estimated effectiveness of outbreak prevention baseline, k | 60% | 60% | 60% |
| Estimated cost of measles outbreaks under baseline, $j \times (1 - k)$ | \$201,758 | \$54,858 | \$531,481 |
| Estimated effectiveness of outbreak prevention with final rule, l | 69% | 66% | 72% |
| Estimated cost of measles outbreaks with final rule, $m = j \times (1 - l)$ | \$156,363 | \$46,630 | \$372,037 |
| Estimated benefit associated with final rule, $n = j - m$ | \$45,396 | \$8,229 | \$159,444 |

Marginal Impact on Tuberculosis Investigations

Although measles is not a quarantinable disease and tuberculosis is a quarantinable disease, HHS/CDC's and health departments' approaches to contact investigations are relatively similar. However, HHS/CDC may issue isolation orders for individuals with active tuberculosis in some situations, but would not have authority to issue isolation (or quarantine orders) for individuals with measles. The expected benefits associated with reduced tuberculosis morbidity and mortality of contact investigations for exposed travelers are based on a previous analysis, which estimated a return on investment of \$1.01 to \$3.20 for the baseline situation in which an estimated 19% of exposed contacts are found to

have latent tuberculosis infection.⁵⁵ The contact rate for exposed tuberculosis contacts is probably higher than for measles because the vast majority of tuberculosis contacts are exposed during international travel as exposed to measles contacts, which are approximately evenly divided between interstate and international travel.

The estimated costs to provide testing and treatment to contacts that test positive for latent tuberculosis infection are estimated to be \$1,044 for infected contacts that complete a full course of treatment and \$591 for infected contacts that discontinue treatment after 30 days.⁵⁶ Following the assumptions in the article, an estimated 28% of persons who test positive for latent tuberculosis infection do not start treatment. An estimated 46% start and complete

treatment and the remaining 26% start, but do not complete treatment. The authors estimated that the risk of progression to active tuberculosis is reduced by 80% for those that complete treatment. The authors assumed that there is no effect for individuals that start, but do not complete treatment. HHS/CDC assumes that under the status quo that health departments are able to contact 75% of exposed travelers (based on the reported outcomes from measles contact investigations).⁵⁷

The costs to provide treatment for latent tuberculosis infections under the status quo are summarized in Table 30. In total, the costs are almost \$900,000 including about \$720,000 to locate contacts and about \$180,000 to provide treatment to individuals with latent tuberculosis infection.

TABLE 30—BASELINE ESTIMATED COSTS TO CONDUCT TUBERCULOSIS CONTACT INVESTIGATIONS AND TO PROVIDE TREATMENT

| | Number of contacts | Estimated cost per contact | Estimated cost | Notes |
|---|--------------------|----------------------------|----------------|--|
| Estimated cost of contact investigations | 1,995 | \$360 | \$718,092 | Number of contacts from Table 13 and cost per contact from Table 11. |
| Estimated number of contacts reached by health departments (75%). | 1,496 | NA | | Estimated at 75% similar to measles from Table 24. |
| Estimated number of contacts reached by health departments and have latent TB infection (19% of 75%). | 284 | NA | | Estimated 19% of contacts have LTBI (Table 13). |
| Number of contacts that never start treatment (28%). | 79.6 | 0 | 0 | 28% of 284 contacts with LTBI. |
| Number of contacts that complete treatment (46%). | 130.8 | 1,044 | 136,506 | 46% of 284 contacts with LTBI. |
| Number of contacts that start, but not complete treatment, (26%). | 73.9 | 591 | 43,677 | 26% of 284 contacts with LTBI. |
| Total cost | | | 898,275 | |

The benefits associated with tuberculosis contact investigations are estimated from a published article, which reported a range of \$1.01 to \$3.20. This analysis did not include the potential benefits from reduced onward

transmission of tuberculosis among averted cases, potentially resulting in a conservative estimate of the return on investment. The formula used to derive estimated benefits from the return on investment (ROI) is Estimated Benefits =

Estimated Costs \times ROI + Estimated Costs. The estimated benefits are \$2.6 million and are shown in Table 31 (range: \$1.8 million to \$3.8 million).

⁵⁵ Coleman M, Marienau K, Marano N, Marks S, Cetron M, Dis TMI. Economics of United States Tuberculosis Airline Contact Investigation Policies. Travel Medicine and Infectious Disease. 2014;12:63–71.

⁵⁶ Coleman M, Marienau K, Marano N, Marks S, Cetron M, Dis TMI. Economics of United States Tuberculosis Airline Contact Investigation Policies. Travel Medicine and Infectious Disease. 2014;12:63–71.

⁵⁷ Nelson K, Marienau K, Schembri C, Redd S. Measles transmission during air travel, United States, December 1, 2008–December 31, 2011. Travel Med Infect Dis. 2013;11(2):81–9.

TABLE 31—BASELINE ESTIMATED COSTS AND BENEFITS FOR TUBERCULOSIS CONTACT INVESTIGATIONS, 2015 USD

| | Best estimate | Lower bound | Upper bound | Notes |
|--|---------------|-------------|-------------|-----------------------|
| Estimate costs for contact investigations and treatment. | \$898,260 | \$898,260 | \$898,260 | Table 30. |
| Return on investment from tuberculosis contact investigations. | 1.91 | 1.01 | 3.20 | Coleman et al. |
| Estimated benefits | 2,613,936 | 1,805,502 | 3,772,691 | = Cost × ROI + Costs. |

The provisions in the final rule should result in a small increase (assumed baseline of 10%, range: 5–15%) in the number of contacts reached by health departments and offered treatment for latent tuberculosis infection. This estimated improvement is less than that assumed for measles because tuberculosis usually involves a

much longer period of latent infection prior to active disease; thus, tuberculosis contact investigations are less time sensitive relative to measles contact investigations. The estimated costs associated with this marginal improvement to reach more contacts can be estimated by multiplying the costs of providing latent tuberculosis (\$180,000)

by this range of improvement (5%–15%) as shown in Table 32. This results in marginal increased costs associated with the final rule of \$18,000 (range: \$9,000 to \$27,000). The estimated benefits (Table 32) associated with the final rule are \$52,000 (range: \$18,000 to \$114,000).

TABLE 32—ESTIMATED COSTS AND BENEFITS FOR TUBERCULOSIS CONTACT INVESTIGATIONS ASSOCIATED WITH THIS FINAL RULE, 2015 USD

| | Best estimate | Lower bound | Upper bound | Notes |
|--|---------------|-------------|-------------|--|
| Baseline contact investigation costs | \$718,080 | \$718,080 | \$718,080 | Table 30 costs for latent tuberculosis treatment and testing. |
| Baseline latent tuberculosis treatment costs .. | \$180,180 | \$180,180 | \$180,180 | |
| Estimated improvement in health departments' abilities to contact exposed travelers. | 10% | 5% | 15% | Assumed. |
| Estimated increased cost for latent tuberculosis treatment under final rule. | \$18,018 | \$9,009 | \$27,027 | Estimated cost for improvement in contact rate as result of final rule. |
| Estimated costs under final rule | \$916,278 | \$907,269 | \$925,287 | Estimated baseline cost + increased cost as result of final rule. |
| Estimated ROI | \$1.91 | \$1.01 | \$3.20 | Table 30. |
| Estimated benefits for final rule | \$2,666,368 | \$1,823,610 | \$3,886,204 | = Cost × ROI + Costs. |
| Estimated costs associated with final rule | \$18,018 | \$9,009 | \$27,027 | Calculated from the difference in costs for the final rule—Baseline costs. |
| Estimated benefits associated with final rule | \$52,432 | \$18,108 | \$113,513 | Calculated from the difference in benefits for the final rule—Baseline benefits. |

Total Costs and Benefits for Measles and Tuberculosis Contact Investigations

The total costs for measles and tuberculosis contact investigation

activities are estimated by summing the costs and benefits of measles contact investigations (Table 29) and tuberculosis contact investigations

(Table 32). The results are summarized in Table 33.

TABLE 33—CHANGES IN MEASLES AND TUBERCULOSIS CONTACT INVESTIGATIONS COSTS AND BENEFITS RELATIVE TO BASELINE, 2015 USD

| | Best estimate | Lower bound | Upper bound |
|---------------------------|---------------|-------------|-------------|
| Final rule benefits | \$97,828 | \$26,337 | \$272,958 |
| Final rule costs | 19,968 | 10,959 | 28,977 |

Note: This table includes the sum of results in Tables 29 and 32.

Total Annual Benefits Resulting From Codification of Traveler Data Collection (71.4 and 71.5) and Change to Definition of “Ill Person” (70.1 and 71.1) Leading to Improved Contact Investigations and Health Outcomes for Measles and Tuberculosis

The total quantified benefits (Table 34) resulting from the improvement of

the quality and timeliness of traveler contact data or the improvement of illness reporting is summarized by summing the improved efficiency for HHS/CDC to provide contact data to health departments and improved efficiency for health departments to contact exposed travelers (Table 23) and the reductions associated with measles

and tuberculosis morbidity and mortality (Table 33).

TABLE 34—TOTAL ANNUAL COSTS AND BENEFITS ASSOCIATED WITH IMPROVED EFFICIENCY PUBLIC HEALTH RESPONSE ACTIVITIES, 2015 USD

| | Best estimate | Lower bound | Upper bound |
|---------------------------|---------------|-------------|-------------|
| Final rule benefits | \$110,045 | \$26,337 | \$297,393 |
| Final rule costs | 19,968 | 10,959 | 28,977 |

The benefits and costs associated with improved effectiveness of contact investigations (Table 34) can be combined with the increased costs to

airlines, vessel operators, DOT/FAA, and HHS/CDC to submit and respond to illness reports or to provide more timely and complete traveler contact data for

manifest requests (Table 19) to estimate the total annual costs and benefits of the final rule (Table 35).

TABLE 35—TOTAL ANNUAL COSTS AND BENEFITS OF THE FINAL RULE, 2015 USD

| | Best estimate | Lower bound | Upper bound |
|---------------------------|---------------|-------------|-------------|
| Final rule benefits | \$110,045 | \$26,337 | \$297,393 |
| Final rule costs | 32,622 | 10,959 | 430,839 |

Other Diseases (Besides Measles and Tuberculosis)

HHS/CDC does not have sufficient data to quantify the health impact of contact investigations for pertussis, rubella, varicella (vessels only), viral hemorrhagic fevers (including Ebola), MERS, or SARS. HHS/CDC attempts to continuously update its contact investigation protocols based on available evidence. In the past few years, HHS/CDC has stopped requesting data to conduct mumps contact investigations⁵⁸ and has modified its protocol to reduce the number of tuberculosis contacts investigated.⁵⁹

Experience from interstate flight contact investigations suggest that travelers may want to know when they have been exposed to communicable diseases during flights. The first Ebola contact investigation conducted in the United States occurred in October, 2014, and found that 60 travelers out of 164 had no contact information on the manifest that was provided by the airline. A second request was made to the airline after it was announced to the media that the airline had contacted over 800 travelers, including travelers who had flown on the same plane subsequent to the flight with the Ebola. At that time the airline was able to provide HHS/CDC more complete information for all travelers.

It is likely that the need for CDC to put out media requests for travelers to

contact the Agency created a level of fear in the general population that may not have been necessary if better contact data were available. In addition, this fear may have led to non-health costs (such as fear of airplane travel) that would have been mitigated if the Agency were able to contact all passengers without the media request. However, when HHS/CDC solicited public comment about perceived willingness to pay to be contacted in the event of an exposure to a communicable disease during, HHS/CDC only received a few public comments, all of which indicated that they had zero willingness to pay in the event of an exposure to a communicable disease.

In summary, improved alignment between regulatory text and HHS/CDC's publicly available guidance should reduce compliance costs for airlines and vessel operators while improving HHS/CDC's ability to respond to public health threats associated with international and interstate travel. To the extent that airlines and vessel operators improve responsiveness to HHS/CDC traveler data requests, HHS/CDC may become better able to respond to infectious diseases threats and (1) reduce case-loads during infectious disease outbreaks, (2) reduce public anxiety during disease outbreaks, (3) mitigate economic impacts on businesses as a consequence of reduced public anxiety, and (4) reduce the amount of personnel labor time to conduct large-scale CIs in response to a new infectious disease or one with serious public health and medical consequences like Ebola. HHS/CDC will make all reasonable efforts to work with DHS/CBP via CDC's liaison located at the National Targeting Center, as provided through internal Memorandum of Understanding, to

search and obtain data collected from their APIS and PNR data sets prior to contacting airlines or vessel operators with duplicate data requests.

Analysis of Alternatives

Traveler Contact Data Alternatives

For the less restrictive alternative, HHS/CDC assumes that the process of requesting contact data from airlines and vessel operators would be discontinued. Thus, the cost to provide such data can be modeled as a benefit to airlines and vessel operators equal to their costs under the baseline. For the more restrictive alternative, HHS/CDC assumes that suspension of entry may be implemented for travelers from countries experiencing widespread transmission of quarantinable communicable diseases. HHS/CDC notes that suspension of entry would not be considered for non-quarantinable diseases (refer to Table 4). Specifically, HHS/CDC assumes that persons traveling from affected countries are not permitted entry to the United States unless such persons spend an amount of time equivalent to the incubation period for the target disease at a location where they are not at risk of exposure and are also screened for symptoms of the disease prior to travel to the United States. During the 2014–2016 Ebola epidemic, travelers from Liberia, Sierra Leone or Guinea would not be able to enter until 21 days in another country or within the affected country but separated from others in a manner that excludes the possibility of interaction with potentially infected individuals.

On average, HHS/CDC has conducted about 2.5 contact investigations for viral hemorrhagic fevers and MERS coronavirus over the past six years. HHS/CDC assumes that if suspensions

⁵⁸ Nelson KR, Marienau KJ, Barskey AE, Schembri C. No evidence of mumps transmission during air travel, United States, November 1, 2006–October 31, 2010. *Travel Medicine and Infectious Disease*. 2012;10:165–71.

⁵⁹ Marienau KJ, Cramer EH, Coleman MS, Marano N, Cetron MS. Flight related tuberculosis contact investigations in the United States: comparative risk and economic analysis of alternate protocols. *Travel Med Infect Dis*. 2014;12(1):54–62.

of entry may be in place, some fraction of these contact investigations may not be conducted.

Thus, the cost to airlines and vessel operators to provide traveler contact data would decrease for the less

restrictive alternative resulting in estimated benefits of \$75,924. For the more restrictive scenario, the costs are relatively similar as for the final rule except for the reduction in cost associated with providing contact data

for 2.5 investigations (\$12,338 vs. \$12,654) and calculating the cost reduction of doing 2.5 fewer contact investigations each year (\$1,898) (Table 36).

TABLE 36—ESTIMATE OF THE COSTS AND BENEFITS TO AIRLINES AND VESSEL OPERATORS TO PROVIDE TRAVELER CONTACT DATA, 2015 USD

| | Baseline | Final rule | Less restrictive alternative ^a | More restrictive alternative ^b |
|---|----------|------------|---|---|
| Baseline number of contact investigations | 100 | 100 | 0 | 97.5 |
| Costs | | | | |
| Best estimate | NA | \$12,654 | \$0 | \$12,338 |
| Lower bound | NA | 0 | 0 | 0 |
| Upper bound | NA | 25,308 | 0 | 24,802 |
| Benefits | | | | |
| Best estimate | NA | \$0 | \$75,924 | \$1,898 |
| Lower bound | NA | 0 | 75,924 | 1,898 |
| Upper bound | NA | 0 | 75,924 | 1,898 |

^a The less restrictive alternative is less expensive than the status quo, because HHS/CDC does not request data from airlines and attempt to provide data to health departments to follow up with exposed travelers.

^b The more restrictive alternative also could potentially reduce costs to airlines and vessel operators because HHS/CDC would restrict travel to countries undergoing widespread transmission of quarantinable communicable diseases such as viral hemorrhagic fevers, MERS or SARS.

Illness Reporting Alternatives

HHS/CDC examines two alternatives: A less restrictive alternative in which HHS/CDC relaxes its regulatory authorities to make illness reporting compliance voluntary rather than compulsory. Under the more restrictive alternative HHS/CDC may enforce the current requirement that airlines report all persons with communicable diseases to local health departments in addition to reporting to HHS/CDC.

The current status quo for illness reporting is summarized in Tables 9 and 10. Reports can be subdivided by illnesses that fit (1) the ill person definition specified in current 42 CFR 71.1, (2) reports based on HHS/CDC's guidance for airlines and vessel operators, or (3) illness reports unrelated to current regulation or guidance. As shown in Table 9, only about 53 out of 175.4 (30%) illness reports during air travel appear to be based on symptoms included in the current definition of an ill person in existing 71.1. The remaining 70% of

reports are based on symptoms currently requested by HHS/CDC, but not required. In addition, only 67% of illness reports during air travel require HHS/CDC response and follow-up. In comparison, illness reports from vessels are much more likely to be based on the definition of ill person as defined in current 71.1 (174.6/218.6 or 80%). In addition, a much greater proportion of reports require an HHS/CDC follow-up (>95%). This may result from differences in the types of illnesses observed on vessels relative to aircraft or because of the presence of medical officers on cruise vessels, who may be better able to identify communicable diseases of public health concern during travel relative to aircraft personnel.

If illness reporting were entirely voluntary, HHS/CDC assumes the number of reports (both info-only and reports requiring response) would decrease by 50% from both airlines and vessel operators (refer to Tables 9 and 10) from the current status quo. HHS/CDC does not have any data to estimate

the magnitude of decrease in reporting. HHS/CDC believes that both HHS/CDC and DOT/FAA would continue to maintain their current infrastructure to effectively respond to public health emergencies either on aircraft or vessels. Thus, relative to the status quo, the primary impact of voluntary reporting would be reduced incremental time costs for pilots in command and masters of vessels, travelers, DOT/FAA, and HHS/CDC, especially for info-only illness reports. This 50% reduction in illness reporting would generate benefits from cost reductions for airlines and vessel operators, HHS/CDC, travelers, and DOT/FAA of approximately \$14,700 (Tables 37 and 38).

The adverse impact for the less restrictive alternative relative to the baseline would be reduced capacity for HHS/CDC to respond quickly to communicable disease threats occurring during travel. This is analyzed in a subsequent section on the health impact of regulated activities.

TABLE 37—LESS RESTRICTIVE ALTERNATIVE FOR ILLNESS REPORTING

[Effect on info-only reports, 2015 USD]

| Employee type | Change in number of info-only reports | Amount of time required per report (min) | Estimated wage rate (per hr.) | Overhead multiplier (%) | Estimated benefit (cost reduction) |
|-----------------------------------|---------------------------------------|--|-------------------------------|-------------------------|------------------------------------|
| Aircraft: | | | | | |
| Aircraft Pilots or Copilots | 60 | 2 | \$57.35 | 100 | \$229 |

TABLE 37—LESS RESTRICTIVE ALTERNATIVE FOR ILLNESS REPORTING—Continued

[Effect on info-only reports, 2015 USD]

| Employee type | Change in number of info-only reports | Amount of time required per report (min) | Estimated wage rate (per hr.) | Overhead multiplier (%) | Estimated benefit (cost reduction) |
|--|---------------------------------------|--|-------------------------------|-------------------------|------------------------------------|
| CDC employee | 60 | 60 | 39.83 | 100 | 4,780 |
| DOT/FAA employees | 60 | 26 | 70.57 | 100 | 3,670 |
| Traveler | 60 | 10 | 23.23 | 0 | 232 |
| Air total | | | | | 8,911 |
| Vessels: | | | | | |
| Captains, Mates, and Pilots of Water Vessels | 6 | 2 | 39.95 | 100 | 16 |
| CDC employee | 6 | 60 | 39.83 | 100 | 478 |
| Traveler | 6 | 10 | 23.23 | 0 | 23 |
| Maritime total | | | | | 517 |
| Total (Air + Maritime) | | | | | 9,428 |

Assume 50% reduction in reports.

TABLE 38—LESS RESTRICTIVE ALTERNATIVE FOR ILLNESS REPORTING

[Effect on reports requiring response, 2015 USD]

| Employee type | Change in number of info-only reports | Amount of time required per report (min) | Estimated wage rate (per hr.) | Overhead multiplier (%) | Estimated benefit (cost reduction) |
|---|---------------------------------------|--|-------------------------------|-------------------------|------------------------------------|
| Aircraft: | | | | | |
| Aircraft pilots or copilots | 29 | 2 | \$57.35 | 100 | \$111 |
| CDC employee | 29 | 0 | 39.83 | 100 | |
| DOT/FAA employee | 29 | 26 | 70.57 | 100 | 1,774 |
| Traveler | 29 | 60 | 23.23 | 0 | 674 |
| Total | | | | | 2,558 |
| Vessels: | | | | | |
| Captains, mates, and pilots (masters) of vessels | 104 | 2 | 39.95 | 100 | 277 |
| CDC employee | 104 | 0 | 39.83 | 100 | |
| Traveler | 104 | 60 | 23.23 | 0 | 2,416 |
| Total | | | | | 2,693 |
| Total (Air + Maritime) | | | | | 5,251 |

Notes: Assume 50% reduction in air illness reports and 15% of maritime illness reports (response, international and interstate).

Under the more restrictive alternative, HHS/CDC would require duplicate illness reporting both to HHS/CDC and to local health departments with jurisdiction upon arrival for interstate flights and voyages. This alternative is based upon the existing regulatory text under 42 CFR 70.4. HHS/CDC assumes that 50% of illness reports occur during interstate (relative to international) air travel and that 15% of maritime illness

reports occur during interstate travel. The time required for pilots in command and masters of vessels is assumed to be about 4 minutes. This duration is greater than the amount of time estimate for reporting to HHS/CDC because pilots in command and masters of vessels may have to search for contact information for local health departments and because local health departments may have less experience dealing with

illness reports than HHS/CDC. The costs to airlines and vessel operators is estimated to be \$848 per year (Table 39). Since HHS/CDC would coordinate responses to illness reports with local health departments under the status quo, there are no additional costs or benefits to requiring duplicative reports to local health departments. These costs would be added to the costs of the changes resulting from the final rule.

TABLE 39—MORE RESTRICTIVE ALTERNATIVE (ILLNESS REPORTING IN DUPLICATE TO HHS/CDC AND TO LOCAL HEALTH DEPARTMENTS), 2015 USD

| Employee type | Change in number of info-only reports | Amount of time required per report (min) | Estimated wage rate (2015 USD per hr.) | Overhead multiplier (%) | Estimated cost (\$2015 USD) |
|-----------------------------------|---------------------------------------|--|--|-------------------------|-----------------------------|
| Aircraft pilots or copilots | 88 | 4 | \$57.35 | 100 | \$673 |

TABLE 39—MORE RESTRICTIVE ALTERNATIVE (ILLNESS REPORTING IN DUPLICATE TO HHS/CDC AND TO LOCAL HEALTH DEPARTMENTS), 2015 USD—Continued

| Employee type | Change in number of info-only reports | Amount of time required per report (min) | Estimated wage rate (2015 USD per hr.) | Overhead multiplier (%) | Estimated cost (\$2015 USD) |
|--|---------------------------------------|--|--|-------------------------|-----------------------------|
| Captains, mates, and pilots (masters) of vessels | 33 | 4 | 39.83 | 100 | 175 |
| Total | | | | | 848 |

The total costs and benefits associated with the more and less restrictive illness reporting scenarios as compared to the final rule are summarized in Table 40.

TABLE 40—BEST ESTIMATE, LOWER BOUND AND UPPER BOUND OF THE CHANGES IN ANNUAL MONETIZED BENEFITS AND COSTS AS A RESULT OF THE CHANGE TO THE REPORTABLE ILLNESS DEFINITION, 2015 USD

| | Best estimate | Lower bound | Upper bound |
|--|---------------|-------------|-------------|
| Costs | | | |
| Final Rule: | | | |
| Aircraft | \$0 | \$0 | \$375,751 |
| Vessels | 0 | 0 | 802 |
| Total | 0 | 0 | 376,554 |
| Less Restrictive Alternative: ^a | | | |
| Aircraft | 0 | 0 | 0 |
| Vessels | 0 | 0 | 0 |
| Total | 0 | 0 | 0 |
| More Restrictive Alternative: | | | |
| Aircraft | 673 | 673 | 376,424 |
| Vessels | 175 | 175 | 978 |
| Total | 848 | 848 | 377,402 |
| Benefits | | | |
| Final Rule: | | | |
| Aircraft | 0 | 0 | 0 |
| Vessels | 0 | 0 | 0 |
| Total | 0 | 0 | 0 |
| Less Restrictive Alternative: ^a | | | |
| Aircraft | 11,469 | 11,469 | 11,469 |
| Vessels | 3,210 | 3,210 | 3,210 |
| Total | 14,679 | 14,679 | 14,679 |
| More Restrictive Alternative: | | | |
| Aircraft | 0 | 0 | 0 |
| Vessels | 0 | 0 | 0 |
| Total | 0 | 0 | 0 |

^a For the less restrictive scenario, the current reporting requirement is relaxed leading to a reduction in costs.

The total costs of the alternatives compared to the final rule are summarized in Table 41 and include the costs of the change to the definition of an “ill person” and the codification of the requirement for airlines to provide passenger contact data for the final rule, the less restrictive alternative, and the more restrictive alternative.

TABLE 41—TOTAL COSTS AND BENEFITS RESULTING FROM CODIFICATION OF TRAVELER DATA COLLECTION (71.4 AND 71.5) AND CHANGE TO DEFINITION OF “ILL PERSON” (70.1 AND 71.1)

| | Best estimate | Lower bound | Upper bound |
|---|---------------|-------------|-------------|
| Costs | | | |
| Final Rule: | | | |
| 71.4 and 71.5 Passenger data collection | \$12,654 | \$0 | \$25,308 |

TABLE 41—TOTAL COSTS AND BENEFITS RESULTING FROM CODIFICATION OF TRAVELER DATA COLLECTION (71.4 AND 71.5) AND CHANGE TO DEFINITION OF “ILL PERSON” (70.1 AND 71.1)—Continued

| | Best estimate | Lower bound | Upper bound |
|---|---------------|-------------|-------------|
| 70.1 and 71.1 Change in definition of an “ill person” | 0 | 0 | 376,554 |
| Total costs | 12,654 | 0 | 401,862 |
| Less Restrictive Alternative: | | | |
| 71.4 and 71.5 Passenger data collection | 0 | 0 | 0 |
| 70.1 and 71.1 Change in definition of an “ill person” | 0 | 0 | 0 |
| Total costs | 0 | 0 | 0 |
| More Restrictive Alternative: | | | |
| 71.4 and 71.5 Passenger data collection | 12,338 | 0 | 24,802 |
| 70.1 and 71.1 Change in definition of an “ill person” | 848 | 848 | 377,402 |
| Total costs | 13,186 | 848 | 402,204 |
| Benefits | | | |
| Final Rule: | | | |
| 71.4 and 71.5 Passenger data collection | 0 | 0 | 0 |
| 70.1 and 71.1 Change in definition of an “ill person” | 0 | 0 | 0 |
| Total benefits | 0 | 0 | 0 |
| Less Restrictive Alternative: | | | |
| 71.4 and 71.5 Passenger data collection | 75,924 | 75,924 | 75,924 |
| 70.1 and 71.1 Change in definition of an “ill person” | 14,679 | 14,679 | 14,679 |
| Total benefits | 90,603 | 90,603 | 90,603 |
| More Restrictive Alternative: | | | |
| 71.4 and 71.5 Passenger data collection | 1,898 | 1,898 | 1,898 |
| 70.1 and 71.1 Change in definition of an “ill person” | 0 | 0 | 0 |
| Total benefits | 1,898 | 1,898 | 1,898 |

Staff Time for Contact Investigations

For the less restrictive alternative, the change relative to baseline is equal to the current cost of performing CIs for travelers exposed on international flights (\$745,000 each for HHS/CDC and local health departments or a total of about \$1.5 million, Table 20). Under the

more restrictive alternative (*i.e.* implementing travel restrictions immediately upon evidence of widespread transmission of viral hemorrhagic fevers, SARS or MERS, the costs of these contact investigations are assumed to be avoided (potential cost reductions of about \$29,000 each to

HHS/CDC and health departments or \$58,000 in total). The benefits of the avoided contacted investigations are then added to the cost savings for the remaining contacts assuming a 0–3% improvement in HHS/CDC efficiency and a 0–2% improvement in PHD efficiency as for the final rule (Table 42).

TABLE 42—ESTIMATED BENEFITS ASSOCIATED WITH REDUCED COSTS TO CONDUCT CONTACT INVESTIGATIONS

| | HHS/CDC benefits | PHD benefits | Total |
|-------------------------------|------------------|--------------|-----------|
| Final Rule: | | | |
| Best estimate | \$7,331 | \$4,887 | \$12,218 |
| Lower bound | 0 | 0 | 0 |
| Upper bound | 14,661 | 9,774 | 24,435 |
| Less Restrictive Alternative: | | | |
| Best estimate | 745,380 | 745,380 | 1,490,760 |
| Lower bound | 745,380 | 745,380 | 1,490,760 |
| Upper bound | 745,380 | 745,380 | 1,490,760 |
| More Restrictive Alternative: | | | |
| Best estimate | 36,671 | 34,227 | 70,898 |
| Lower bound | 29,340 | 29,340 | 58,680 |
| Upper bound | 44,001 | 39,114 | 83,115 |

Measles Contact Investigation Health Outcomes—Alternatives

For this analysis, under the less restrictive alternative, HHS/CDC assumes that no contact investigations are performed for measles. As a result,

the probability of onward transmission from 3.6 to 10.1 measles patients exposed each year during travel greatly increases and is modeled based on the estimated costs of measles in the absence of intervention \$504,000 (range:

\$137,000 to \$1.3 million) (Table 28). Measles outcomes for the more restrictive alternative are the same as estimated for the final rule since there is no difference in measles efforts between the final rule and the more

restrictive alternative because measles is not a quarantinable disease. The comparative benefits relative to the

status quo baseline are shown in Table 43. For the less restrictive alternative, costs are estimated based on an increase

in measles outbreak costs relative to the baseline.

TABLE 43—ESTIMATED BENEFITS ASSOCIATED WITH AVERTED COSTS FROM MEASLES OUTBREAKS RELATIVE TO BASELINE, 2015 USD

| | Best estimate | Lower bound | Upper bound |
|---|---------------|-------------|-------------|
| Benefits | | | |
| Final Rule | \$45,396 | \$8,229 | \$159,444 |
| Less Restrictive Alternative | 0 | 0 | 0 |
| More Restrictive Alternative | 45,396 | 8,229 | 159,444 |
| Costs | | | |
| Final Rule | 1,950 | 1,950 | 1,950 |
| Less Restrictive Alternative ^a | 201,758 | 54,858 | 531,481 |
| More Restrictive Alternative | 1,950 | 1,950 | 1,950 |

^aFor the less restrictive alternative, contact investigations are not performed so the cost can be estimated based on the estimated public health benefit of contact investigations performed under the baseline (Table 29).

Tuberculosis Contact Investigations Health Outcomes—Alternatives

Under the less restrictive alternative, tuberculosis contact investigation are no longer conducted for persons exposed during travel. Relative to the baseline, there are neither costs to conduct such investigations (resulting in benefits of

about \$180,000 to forego providing treatment for latent tuberculosis treatment) or benefits associated with reduced tuberculosis morbidity and mortality. Relative to the baseline, the estimated cost of increased tuberculosis morbidity and mortality is estimated to be \$2.6 million (range: \$1.8 million to \$3.8 million). Under the more restrictive

alternative in which suspension of entry is enforced in response to quarantinable communicable disease outbreaks, there is no change relative to the final rule results because it is unlikely that a tuberculosis outbreak would cause suspension of entry. Results are summarized in Table 44.

TABLE 44—CHANGES IN TUBERCULOSIS CONTACT INVESTIGATIONS COSTS AND BENEFITS RELATIVE TO BASELINE, 2015 USD

| | Best estimate | Lower bound | Upper bound | Notes |
|------------------------------------|---------------|-------------|-------------|--|
| Benefits | | | | |
| Final Rule | \$52,432 | 18,108 | 113,513 | Table 32. Assumed to be the cost to provide LTBI treatment under the baseline (Table 32). The more restrictive alternative has the same effect on TB contact investigations as the final rule. |
| Less Restrictive Alternative | 180,180 | 180,180 | 180,180 | |
| More Restrictive Alternative | 52,432 | 18,108 | 113,513 | |
| Costs | | | | |
| Final Rule | 18,018 | 9,009 | 27,027 | Table 32. Estimated based on the benefits of avoided TB morbidity and mortality resulting from contact investigations under the baseline. The more restrictive alternative has the same effect on TB contact investigations as final rule. |
| Less Restrictive Alternative | \$2,613,936 | \$1,805,502 | \$3,772,691 | |
| More Restrictive Alternative | 18,018 | 9,009 | 27,027 | |

The total costs and benefits of changes in health outcomes associated with the more and less restrictive alternatives compared to the provisions included in the Final Rule are summarized in Table 45. The less restrictive alternative in

which contact investigations are no longer pursued shows a large increase in costs relative to the baseline and in comparison to the provisions in the final rule. In addition, there are some benefits, but not enough to offset the

costs. The more restrictive alternative does not change health outcomes for tuberculosis and measles in comparison to the final rule.

TABLE 45—CHANGES IN MEASLES AND TUBERCULOSIS CONTACT INVESTIGATIONS COSTS AND BENEFITS RELATIVE TO BASELINE, 2015 USD

| | Best estimate | Lower bound | Upper bound |
|------------------------------------|---------------|-------------|-------------|
| Benefits | | | |
| Final Rule | \$97,828 | \$26,337 | \$272,958 |
| Less Restrictive Alternative | 180,180 | 180,180 | 180,180. |
| More Restrictive Alternative | 97,828 | 26,337 | 272,958 |
| Costs | | | |
| Final Rule | 19,968 | 10,959 | 28,977 |
| Less Restrictive Alternative | 2,815,694 | 1,860,360 | 4,304,172 |
| More Restrictive Alternative | 19,968 | 10,959 | 28,977 |

Note: This table includes the sum of results in Tables 43 and 44.

The total quantified costs and benefits (Table 46) resulting from the additional data provision and timeliness of traveler contact data or the improvement of illness reporting for alternatives to the

provisions included in the final rule is summarized by summing the improved efficiency for HHS/CDC to provide contact data to health departments and improved efficiency for health

departments to contact exposed travelers (Table 42) and the reductions associated with measles and tuberculosis morbidity and mortality (Table 45).

TABLE 46—TOTAL ANNUAL COSTS AND BENEFITS ASSOCIATED WITH IMPROVED EFFICIENCY PUBLIC HEALTH RESPONSE ACTIVITIES, 2015 USD

| | Best estimate | Lower bound | Upper bound |
|------------------------------------|---------------|-------------|-------------|
| Benefits | | | |
| FR | \$110,045 | \$26,337 | \$297,393 |
| Less Restrictive Alternative | 1,670,940 | 1,670,940 | 1,670,940 |
| More Restrictive Alternative | 168,725 | 85,017 | 356,073 |
| Costs | | | |
| FR | 19,968 | 10,959 | 28,977 |
| Less Restrictive Alternative | 2,815,694 | 1,860,360 | 4,304,172 |
| More Restrictive Alternative | 19,968 | 10,959 | 28,977 |

The total annual costs and benefits for the alternatives compared to the final rule are summarized in Table 47. Although the benefits for the more restrictive alternative in which suspensions of entry would be implemented for countries experiencing outbreaks of quarantinable communicable diseases are greater than the quantified annual benefits of the

final rule, the costs are underestimated. HHS/CDC does not have sufficient data to quantify the long term costs of implementing suspensions of entry for countries experiencing outbreaks of quarantinable diseases; however, such costs would probably exceed the \$100,000 in estimated benefits associated with suspensions of entry that may result in fewer contact

investigations for quarantinable diseases such as Ebola and MERS. Refer to the appendix for some details of potential costs associated with hypothetical suspensions of entry for the countries with widespread Ebola transmission during the 2014–2016 global Ebola epidemic.

TABLE 47—TOTAL ANNUAL COSTS AND BENEFITS OF THE FINAL RULE, LESS RESTRICTIVE AND MORE RESTRICTIVE ALTERNATIVES, 2015 USD

| | Best estimate | Lower bound | Upper bound |
|------------------------------------|---------------|-------------|-------------|
| Benefits | | | |
| Final Rule | \$110,045 | \$26,337 | \$297,393 |
| Less Restrictive Alternative | 1,780,524 | 1,780,524 | 1,780,524 |
| More Restrictive Alternative | 170,623 | 86,915 | 357,971 |
| Costs | | | |
| Final Rule | 32,622 | 10,959 | 430,839 |
| Less Restrictive Alternative | 2,815,694 | 1,860,360 | 4,304,172 |
| More Restrictive Alternative | 33,154 | 11,807 | 431,181 |

Codification of Current Practice (Multiple Provisions in Final Rule)

HHS/CDC does not expect that most of the provisions included in the final rule will result in measurable changes relative to the economic baseline. The primary purpose of the provisions summarized in list below is to explain how HHS/CDC interprets its current statutory and regulatory authority under the Public Health Service Act (42 U.S.C. 264, 265) and regulations at 42 CFR parts 70 and 71. HHS/CDC is grouping the complementary provisions in part 70 and part 71 in the list below, when they align, to facilitate public review of the current provisions as well as those included in the final rule. These changes are intended to clarify the agency's standard operating procedures and policies, and due process rights for individuals. HHS/CDC believes that such clarity is an important qualitative benefit of the provisions in this final rule, but is not able to monetize this impact in a significant way.

• New Provisions: § 70.5

Requirements relating to travelers under a Federal order of isolation, quarantine, or conditional release.

○ Baseline and Current Regulatory Provision: § 70.5 Certain communicable disease; special requirements.

■ Without the final rule, HHS/CDC may issue Federal orders to restrict travel for persons infected or exposed to quarantinable communicable diseases. However, this process is less transparent and efficient than allowing travel (*i.e.* issue travel permits to allow interstate travel to persons under Federal orders for diseases not currently identified under existing 42 CFR 70.5.) Under current practice, HHS/CDC issues approximately one Federal order per year, most frequently for tuberculosis, which is a disease not included in the current 70.5.

○ Change relative to baseline as result of final rule

■ With the final rule, HHS/CDC is aligning the list of diseases for which individuals under Federal orders may be allowed to travel with the quarantinable communicable diseases specified in Executive Order. A potential future qualitative benefit would be to reduce uncertainty by the individual subject to the order, carrier operators, and cooperating health and law enforcement entities about whether HHS/CDC could issue a travel permit to an individual under a Federal order and quantifiable benefit would be the avoided cost of potential legal challenge.

○ Qualitative benefit/cost of final rule

■ Improved transparency for HHS/CDC's ability to allow individuals under

Federal orders to issue travel permits to allow individuals to travel (interstate). HHS/CDC may allow persons under Federal orders to travel interstate for whom there is greater uncertainty regarding HHS/CDC restricting their travel.

○ Monetized benefit/cost of final rule

■ Increased clarity around due process may result in fewer resources and time expended by individuals under orders and HHS/CDC in disagreements over HHS/CDC's authority to issue Federal public health orders that limit an individual's movement. This includes the potential costs of litigation and associated activities.

• New provisions: § 70.6

Apprehension and detention of persons with specific diseases; § 71.32 Persons, carriers, and things (no change to title)

○ Baseline and Current Regulatory Provision:

■ Under current 42 CFR 70.6 and § 71.32, HHS/CDC has regulatory authority to apprehend and detain individuals with quarantinable communicable diseases.

○ Change relative to baseline as result of final rule

■ As a result of these new provisions, the major change would be improved transparency of HHS/CDC's regulatory authority with regard to the issuance of Federal quarantine, isolation, or conditional release orders of individuals traveling interstate.

○ Qualitative benefit/cost of final rule

■ Improved transparency and compliance with Federal orders.

○ Monetized benefit/cost of final rule

■ Increased clarity around due process may result in fewer resources and time expended by individuals under orders, cooperating entities, and CDC in disagreements over HHS/CDC's authority to issue Federal public health orders that limit an individual's movement. This includes the potential costs of litigation and associated activities.

• New Provisions: § 70.10 Public health prevention measures to detect communicable disease; § 71.20 Public health prevention measures to detect communicable disease.

○ Baseline and Current Regulatory Provisions: No explicit regulatory provision.

■ In the absence of the final rule and under existing statutory authority provided in the Public Health Service Act and regulatory authority provided by 42 CFR 70.2 and 71.32(b), HHS/CDC could still implement public health measures at locations where individuals may gather for interstate travel or at U.S. ports of entry. However, without more

transparent regulatory authority to require such measures, travelers may be less likely to comply, either by refusing to answer risk assessment questions or providing false information. This lack of compliance may require that HHS/CDC, if it reasonably believes that the individual is infected with or has been exposed to a quarantinable communicable disease, to quarantine, isolate, or place the individual under surveillance under 42 CFR 70.6 or 71.32 and 71.33. HHS/CDC has not implemented public health measures at locations where individuals may congregate for the purposes of interstate travel in at least 50 years and cannot predict if or how often it may implement measures in the future.

○ Change relative to baseline as result of final rule

■ Improved transparency and potentially improved compliance in the event that HHS/CDC implements such measures in the future.

○ Qualitative benefit/cost of final rule

■ Improved transparency and public understanding of HHS/CDC's rationale and authority to conduct such measures and require individuals to comply.

○ Monetized benefit/cost of final rule

■ Increased clarity around due process procedures may result in fewer resources and time expended by individuals under orders and HHS/CDC in disagreements over HHS/CDC's authority to issue Federal public health orders that limit an individual's movement. This includes the potential costs of litigation and associated activities.

• New Provisions: § 70.12 Medical examinations; § 71.36 Medical Examinations

○ Baseline and Current Regulatory Provisions: 71.33 Persons: Isolation and Surveillance.

■ This is carried out under statutory authority and under the regulatory authorities in 42 CFR 70.6 and 71.32(a), 71.33, which would allow for medical examinations of individuals under Federal orders.

○ Change to baseline as result of final rule

■ With the final rule, the major change would be an alignment between the statutory language in the Public Health Service Act and improved transparency of HHS/CDC's regulatory authority.

○ Qualitative benefit/cost of final rule

■ Improved transparency and public understanding of HHS/CDC's rationale and authority to conduct such measures and require individuals to comply.

○ Monetized benefit/cost of final rule

■ Increased clarity around due process procedures may result in fewer

resources and time expended by individuals under orders, cooperating entities, and HHS/CDC in disagreements over HHS/CDC's authority to issue Federal public health orders that limit an individual's movement. This includes the potential costs of litigation and associated activities.

- New Provisions: § 70.13 Payment for Care and Treatment; § 71.30 Payment for Care and Treatment

- Baseline and Current Regulatory Provisions: No current explicit regulatory provision.

- This addition is not expected to lead to a change in HHS/CDC policy under which HHS/CDC may act as the payer of last resort for individuals subject to medical examination, quarantine, isolation, and conditional release under Federal orders. The provisions included in the final rule are similar to a Memorandum of Agreement between a number of hospitals and HHS/CDC. Under the terms of the Memorandum of Agreement, the hospital can be reimbursed for incurred medical expenses subject to HHS/CDC's discretion, availability of appropriations, and limited to what a hospital would bill Medicare. The Memorandum of Agreement also indicates that HHS/CDC should be the payer of last resort.

- HHS/CDC issued 12 isolation orders between Jan 1, 2005 and May 10, 2016, which would correspond to an average of about 1 order per year over the past 11.3 years. HHS/CDC has information on payments made for 3 of the 12 cases. In most cases, HHS/CDC makes payment directly to healthcare facilities, sometimes in lieu of payments that would be made by State or local health departments. Among the three instances for which HHS/CDC has some data on payments for treatment, care, and transportation of individuals under Federal orders:

- HHS/CDC's expected annual payments for care and treatment are estimated to be between \$0 and \$1,000,000 in any given year under the current baseline. This upper bound cost would correspond to a year in which HHS/CDC would have to incur the costs of two patients at \$500,000 per patient. This roughly corresponds to the average cost to treat an extremely drug-resistant tuberculosis case (XDR-TB). Alternatively, this could represent a situation in which HHS/CDC may have to pay a significant fraction of the total costs for one very complicated illness associated with a quarantinable communicable disease not endemic to the United States (e.g., Ebola).

- HHS/CDC has not incurred any costs for the care and treatment of any

individuals besides for those under Federal isolation orders.

- Change to baseline as result of final rule

- Improved transparency around HHS/CDC's authority for, and requirements and processes related to payment for care and treatment.

- Qualitative benefit/cost of final rule
 - Improved transparency and public knowledge of HHS/CDC's procedures and regulatory requirements.

- Monetized benefit/cost of final rule
 - None. This is a clarification of HHS/CDC's current practice. (For more details, please refer to separate RIA Appendix)

- New Provisions: § 70.14 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release; § 71.37 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release

- Baseline and Current Regulatory Provisions: No current explicit regulatory provision

- Without the final rule, HHS/CDC can under current statutory provided by the Public Health Service Act and regulatory authority under 42 CFR 70.6 and 71.32(a), 71.33 continue to issue Federal quarantine, isolation, or condition release orders. However, the issuance of federal orders is implemented through internal policies and standard operating procedures that are not as transparent to the public as detailed regulations outlining requirements.

- Change to baseline as result of final rule

- Improved transparency around HHS/CDC's authority for, and requirements and processes related to, the issuance of Federal quarantine, isolation, and conditional release orders.

- Qualitative benefit/cost of final rule
 - Improved transparency and public knowledge of HHS/CDC's procedures and regulatory requirements.

- Monetized benefit/cost of final rule
 - None. This is a clarification of HHS/CDC's current practice.

- New Provisions: § 70.15 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release; § 71.38 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release

- Baseline and Current Regulatory Provisions: No current explicit regulatory provision.

- Without the final rule, HHS/CDC can under current statutory authority provided by the Public Health Service Act and regulatory authority under 42 CFR 70.6 and 71.32(a), 71.33 continue to

issue Federal quarantine, isolation, or conditional release orders. However, the process for reassessing a Federal order is implemented through internal policy and standard operating procedures that are not as transparent to the public as detailed regulations outlining requirements.

- Change to baseline as result of final rule:

- With the final rule, individuals under Federal order may be more aware of the mandatory reassessment of a Federal quarantine, isolation, or conditional release order.

- Qualitative benefit/cost of final rule
 - Improved transparency and understanding of due process protections under a Federal public health order.

- Monetized benefit/cost of final rule
 - Increased clarity around due process protections may result in fewer resources and time expended by individuals under orders and HHS/CDC in disagreements over HHS/CDC's authority to issue Federal public health orders that limit an individual's movement. This includes the potential costs of litigation and associated activities.

- New Provisions: § 70.16 Medical review of a Federal order for quarantine, isolation, or conditional release; § 71.39 Medical review of a Federal order for quarantine, isolation, or conditional release

- Baseline and Current Regulatory Provisions: No current explicit regulatory provision.

- Without the final rule, HHS/CDC can under current statutory authority provided by the Public Health Service Act and regulatory authority under 42 CFR 70.6 and 71.32, 71.33 continue to issue Federal quarantine, isolation, or conditional release orders. However, the process for a medical review of a Federal order is outlined in internal policy and standard operating procedures that are not as transparent to the public as detailed regulations outlining requirements.

- Change to baseline as result of final rule:

- With the final rule, individuals under Federal order may become aware of their right to a medical review, and exercise that right, under this due process provision.

- Qualitative benefit/cost of final rule
 - Improved transparency and understanding of due process afforded to individuals under a Federal order

- Monetized benefit/cost of final rule
 - Increased clarity around due process protections may result in fewer resources and time expended by individuals under orders and HHS/CDC

in disagreements over HHS/CDC's authority to issue Federal public health orders that limit an individual's movement. This includes the potential costs of litigation and associated activities.

- One potential change that could have an economic effect is the requirements to appoint medical and legal representatives for individuals that qualify as "indigent". The status of "indigent" is self-reported as HHS/CDC will not require access to an individual's financial records. Those who self-identify as indigent may be required to sign an affidavit or declaration under penalty of perjury stating they meet the threshold of at least 200% of the applicable poverty guidelines. HHS/CDC notes that in practice it has never denied a request for a representative. HHS/CDC estimates the cost of providing one medical representative and one legal representative based on the average hourly wage for physicians and surgeons (\$97.33, occupation code 29–1060) and lawyers (\$65.51, occupation code 23–1011) as reported from the Bureau of Labor Statistics' May 2015 National Occupational Employment and Wage Estimates. Assuming that it takes about 40 hours of physician time and 40 hours of lawyer time per review and an overhead cost multiplier of 100%, the expected cost is about \$13,000 per review. HHS/CDC notes that public health orders are issued on average once per year. The need for HHS/CDC to pay for medical and legal representatives will depend on the income level for persons placed under federal orders, but should not exceed this \$13,000 estimate in most years and will be \$0 in many years. Without the new regulatory provision, as part of current practice, HHS/CDC would still attempt to appoint legal and medical representatives if requested for the medical review by individuals unable to afford the cost of such representation. Thus, relative to current practice, there should be minimal costs associated with this provision.

- New Provisions: § 70.17 Administrative records relating to Federal quarantine, isolation, or conditional release; § 71.29 Administrative records relating to Federal quarantine, isolation, or conditional release

- Baseline and Current Regulatory Provisions: No current explicit regulatory provision.

- Without the final rule, HHS/CDC can issue under current statutory provided by the Public Health Service Act and regulatory authority under 42 CFR 70.6 and 71.32(a), 71.33 continue to

issue Federal quarantine, isolation, or conditional release orders. However, the process for documenting the administrative record is implemented internal policy and standard operating procedures that are not as transparent to the public as a detailed regulation outlining this requirement.

- Change to baseline as result of final rule

- The requirement, with which HHS/CDC is already complying, will clarify for the public that certain documents must be retained for the administrative record.

- Qualitative benefit/cost of final rule

- Improved transparency

- Monetized benefit/cost of final rule

- Not applicable. This is a codification of an administrative activity within HHS/CDC.

- New Provisions: § 70.18 Penalties/ § 71.2 Penalties

- Baseline and Current Regulatory Provision: § 71.2 Penalties. Part 70 currently has no penalties provision.

- Without the final rule, individuals may not be aware that 18 U.S.C. 3559 and 3571 increased the maximum penalties for violations of regulations under 42 CFR part 70 and part 71. And it may not be clear to individuals that violating quarantine regulation under 42 CFR part 70 may result in criminal penalties.

- Change to baseline as result of final rule

- With the NRPM, there will be less confusion about the maximum criminal penalties for a violation of regulations under 42 CFR 70 and 71.

- Qualitative benefit/cost of final rule

- Improved transparency and alignment with current law under 18 U.S.C. 3559 and 3571.

- Monetized benefit/cost of final rule
- No individual or organization has been assessed criminal penalties for violating these regulations, so monetizing this benefit or cost is not feasible. This is simply an effort to align the domestic and foreign quarantine penalties provisions, and updates outdated regulatory language so that it reflects current statutory language concerning criminal penalties.

- New Provisions: § 71.63 Suspension of entry of animals, articles, or things from designated foreign countries and places into the United States

- Baseline and Current Regulatory Provision: § 71.32(b) has previously been used to justify the temporary embargo of imported African rodents prior to the codification of this as a requirement in existing 42 CFR 71.56.

- Without the final rule, individuals may not be aware that HHS/CDC's authority to temporarily suspend entry

of animals, articles or things from designated foreign countries and places into the United States based on existing 42 CFR 71.32(b).

- Change to baseline as result of final rule

- With the NRPM, there will be less confusion about HHS/CDC's ability to temporarily restrict importations associated with communicable disease risks.

- Qualitative benefit/cost of final rule

- Improved transparency.

- Monetized benefit/cost of final rule

- Refer to the appendix for an analysis of the temporary embargo of African rodents implemented in 2003.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), agencies are required to analyze regulatory options to minimize significant economic impact of a rule on small businesses, small governmental units, and small not-for-profit organizations. We have analyzed the costs and benefits of the final rule, as required by Executive Order 12866, and a preliminary regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. Based on the cost benefit analysis, we expect the rule to have little or no economic impact on small entities.

C. The Paperwork Reduction Act

HHS/CDC has determined that this final rule contains proposed information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). A description of these proposed provisions is given below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information. Comments are invited on the following subjects.

- Whether the proposed collection of information is necessary for the proper performance of the functions of HHS/CDC, including whether the information will have practical utility.

- The accuracy of HHS/CDC's estimate of the burden of the collection of information.

- Ways to enhance the quality, utility, and clarity of the information to be collected.

- Ways to minimize the burden of the collection of information on respondents, including by using information technology.

While HHS/CDC currently has approval to collect certain information concerning illnesses and travelers under OMB Control Numbers 0920–0134 (*Foreign Quarantine Regulations*, expiration date 05/31/2019) and 0920–0488 (*Restrictions on Interstate Travel of Persons*, expiration date 05/31/2019), CDC is requesting updates to certain information collections within these control numbers.

In another information collection request associated with this final rule, CDC is also requesting approval to require that airlines and vessels provide certain data elements to CDC, as described in proposed 71.4 and 71.5, for the purposes of contact tracing. This information is used to locate individuals, both passengers and crewmembers, who may have been exposed to a communicable disease during travel and to provide them with appropriate public health follow-up.

Written comments should be received within 30 days of the publication of this final rule. Please send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806.

Proposed Projects

(1) Foreign Quarantine Regulations (42 CFR part 71) (OMB Control No. 0920–0134)—Nonmaterial/non-substantive change—National Center for Emerging, and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

(2) Restrictions on Interstate Travel of Persons (42 CFR part 70) (OMB Control No. 0920–0488)—Nonmaterial/non-substantive change—National Center for Emerging, and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC)

(3) Airline and Vessel and Traveler Information Collection (42 CFR and 71)—New Information Collection Request—National Center for Emerging, and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Description

Section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264) authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States and interstate. Legislation and existing regulations governing foreign and

interstate quarantine activities (42 CFR parts 70 and 71) authorize quarantine officers and other personnel to inspect and undertake necessary control measures in order to protect the public health. Currently, with the exception of the CDC's Vessel Sanitation Program, inspections are performed only on those vessels and aircraft that report illness before arriving or when illness is discovered upon arrival. Other inspection agencies assist quarantine officers in public health risk assessment and management of persons, pets, and other importations of public health importance. These practices and procedures ensure protection against the introduction and spread of communicable diseases into the United States with a minimum of recordkeeping and reporting as well as a minimum of interference with trade and travel. The information collection burden is associated with these recordkeeping and reporting requirements.

At present, HHS/CDC has approval from OMB to collect certain information and impose recordkeeping requirements related to foreign quarantine responsibilities under OMB Control Number 0920–0134 (expiration 05/31/2019). The specific provisions within 42 CFR part 71 that include information collection under are as follows:

42 CFR 71.21(a), (b), and (c) Report of death and illness.

42 CFR 71.33(c) Report of persons held in isolation or surveillance.

42 CFR 71.35 Report of death or illness on carrier during stay in port.

42 CFR 71.51 Dogs and cats.

42 CFR 71.52 Turtles, terrapins, tortoises.

42. CFR 71.56 African Rodents

HHS/CDC has also used its authority under 42 CFR 71.32 to require importers to submit statements or documentation of non-infectiousness for those items that may constitute a public health risk if not rendered non-infectious.

Finally, HHS/CDC has approval from OMB to collect from importers/filers certain documents and data elements to identify and clear HHS/CDC regulated imports via the Automated Commercial Environment and the International Trade Data System using the Document Imaging System and Partner Government Agency Message Sets. These CDC Partner Government Agency Message Sets are currently limited to: CDC PGA Message Set for Importing Cats and Dogs, CDC PGA Message Set for Importing African Rodents, CDC PGA Message Set for Importing African Rodent and All Family *Viverridae* Products.

In this final rule, CDC is requesting approval from OMB for 4 non-substantive changes to OMB Control Number 0920–0134 Foreign Quarantine Regulations (42 CFR part 71):

(1) Updating the definition of “ill person,” which relates to the illness reporting requirements under 42 CFR 71.21(a), (b), and (c) for airlines and vessels arriving into the United States. CDC is updating the definition of “ill person” by implementing current practice with the anticipated effect of better facilitating identification of communicable diseases of concern and quarantinable communicable diseases aboard flights and maritime voyages to the United States, diseases such as measles, viral hemorrhagic fevers, active tuberculosis, and influenza caused by novel or re-emergent influenza viruses that are causing or have the potential to cause a pandemic. CDC is also including a provision to allow the Director to add new symptoms to the definition of ill person to respond to unknown communicable diseases that may emerge as future concerns.

The final rule updates the current definition of ill person to better focus on the signs and symptoms of communicable diseases of public health concern and quarantinable communicable diseases. The changes define an ill person in the context of the medical resources available to the operator of an airline or vessel.

CDC already requests from pilots in command of aircraft and commanders of vessels several of the symptoms included in the revised definition of ill person through publicly available guidance to airlines and vessels. Moreover, for airlines, the updated definition also better aligns with symptoms reporting guidelines published by ICAO in Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation, and the definition of “acute gastroenteritis” is used by the WHO and is currently included in reporting guidance from CDC's Vessel Sanitation Program. Therefore, CDC does not anticipate additional burden on airlines or vessel operators to respond to these information collections.

(2) CDC is requesting a change in the title of the information collection pertaining to reports of death and illness from vessels to CDC. The former title is *Radio Report of death or illness*—illness reports from ships. CDC sought a change to remove “Radio” from the title. This change reflects the fact that reports to CDC primarily via means other than radio, such as the Maritime Illness and Death Reporting System, managed by CDC's Vessel Sanitation Program. CDC

did not receive any public comments to this change, and it is therefore finalized as proposed.

(3) CDC is seeking a change in the title of a specific information collection pertaining to reports of gastro-intestinal illness to CDC. CDC is updating the definition of ill person and is replacing the term “gastro-intestinal” with “acute gastroenteritis”; therefore, the title change is requested to align with the definition.

(4) CDC is seeking a change in title of respondents from “Maritime Conveyance Operator” to “Maritime Vessel Operator” and from “Airline

Commander or Operator” to “Pilot in Command.”

Table 1 below presents estimates of annual burden (in hours) associated with each reporting and recordkeeping requirement under this OMB control number, accounting for the rule changes.

Description of Respondents. Respondents to this data collection include pilots in command of aircraft, maritime vessel operators, importers/filers, and travelers/general public. The nature of the response to HHS/CDC dictates which forms are completed and by whom. The total requested burden hours are 82,779.

There is no burden to respondents other than the time taken to complete the reports to CDC, maintain recordkeeping of illness aboard vessels and records of sickness or death in imported cats and dogs, as outlined in the table below. If a cat or dog is ill upon arrival, or dies prior to arrival, an exam is required, the initial exam fee may be between \$100 and \$200. Rabies testing on a dog that dies may be between \$50 and \$100. The expected number of ill or dead dogs arriving into the United States for which CDC may require an examination is estimated at less than 30 per year.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN 0920–0134

| Type of respondent | Regulatory provision or form name | No. of respondents | No. of responses per respondent | Average burden per response (in hours) | Total burden hours |
|--------------------------------------|---|--------------------|---------------------------------|--|--------------------|
| Maritime Vessel Operators | 42 CFR 71.21(a) Report of illness or death from ships—Maritime Vessel Illness or Death Investigation Form/Cumulative Influenza/Influenza-Like Illness (ILI) Form/Radio report or transcribed email. | 2,000 | 1 | 2/60 | 67 |
| Pilot in Command | 42 CFR 71.21 (b) Death/Illness reports from aircraft | 1,700 | 1 | 2/60 | 57 |
| Maritime Vessel Operators | 42 CFR 71.21(c) (MIDRS) Acute Gastro-Enteritis reports (24 and 4 hours before arrival). | 17,000 | 1 | 3/60 | 850 |
| Maritime Vessel Operators | 42 CFR 71.21 (c) Recordkeeping-Medical logs | 17,000 | 1 | 3/60 | 850 |
| Isolated or Quarantined individuals. | 42 CFR 71.33 Report by persons in isolation or surveillance. | 11 | 1 | 3/60 | 1 |
| Maritime Vessel Operators | 42 CFR 71.35 Report of death/illness during stay in port. | 5 | 1 | 30/60 | 3 |
| Importer | 42 CFR 71.51(c)(1), (d)—Valid Rabies Vaccination Certificates. | 245,310 | 1 | 15/60 | 61,328 |
| Importer | CDC Form 75.37 Notice To Owners And Importers Of Dogs: Requirement for Dog Confinement. | 1,400 | 1 | 10/60 | 233 |
| Importer | 42 CFR 71.51(c)(i), (ii), and (iii) exemption criteria for the importation of a dog without a rabies vaccination certificate. | 43,290 | 1 | 15/60 | 10,823 |
| Importer | 42 CFR 71.51(c)(2), (d) Application for a Permit to Import A Dog Inadequately Immunized Against Rabies. | 1,400 | 1 | 15/60 | 350 |
| Importer | 42 CFR 71.51(b) (3) Dogs/cats: Record of sickness or deaths. | 20 | 1 | 15/60 | 5 |
| Importer/Filer | 42 CFR 71.51_CDC Requested Data on Regulated Imports: Domestic Dogs and Cats (PGA Message Set). | 30,000 | 1 | 15/60 | 7,500 |
| Importer | 42 CFR 71.52(d) Turtle Importation Permits | 5 | 1 | 30/60 | 3 |
| Importers | 42 CFR 71.55, 42 CFR 71.32 Dead Bodies—Death certificates. | 5 | 1 | 1 | 5 |
| Importer | 42 CFR 71.56 (a)(2) African Rodents—Request for exemption. | 20 | 1 | 1 | 20 |
| Importer | 42 CFR 71.56(a)(iii) Appeal | 2 | 1 | 1 | 2 |
| Importer/Filer | 42 CFR 71.56 CDC Requested Data on Regulation Imports: Live African Rodents (PGA Message Set). | 60 | 1 | 15/60 | 15 |
| Importer/Filer | 42 CFR 71.32 Statements or documentation of non-infectiousness. | 2,000 | 1 | 5/60 | 167 |
| Importer/Filer | 42 CFR 71.56, 42 CFR 71.32 CDC Requested Data on Regulated Imports: Products of African Rodents; Products of all Family Viverridae (PGA Message Set). | 2,000 | 1 | 15/60 | 500 |
| Total | | | | | 82,779 |

The estimates are based on experience to date with current recordkeeping and reporting requirements of 42 CFR part 71, with additional burden included to

account for the potential for increased reports of illness during an outbreak and for reports of disease that may have

been missed by airlines or vessels and are reported to CDC after travel.

Under this final rule, CDC is also requesting a nonmaterial/non-

substantive change to Restrictions on Interstate Travel of Persons (42 CFR part 70) (OMB Control No. 0920–0488). The regulations at 42 CFR part 70 are intended to prevent the interstate spread of disease, and include a requirement that the master of vessel or person in charge of conveyance to report the occurrence on board of communicable disease. Under this regulation and control number, CDC has approval to collect the following information:

- 42 CFR 70.4 Report by the master of a vessel or person in charge of conveyance of the incidence of a communicable disease occurring while in interstate travel.

Through this final rule, CDC is adding the provision 70.11 *Report of death or illness onboard aircraft operated by airline*, which specifies that the pilot in command of an aircraft operating on behalf of an airline who conducts a commercial passenger flight in interstate traffic under a regular schedule shall report as soon as practicable to HHS/CDC the occurrence onboard of any deaths or ill persons among passengers or crew and take such measures as HHS/CDC may direct to prevent the potential spread of the communicable disease. HHS/CDC notes that it is changing the existing regulatory requirement at 42 CFR 70.4, which states that the master of a vessel or person in charge of any conveyance engaged in interstate traffic

on which a case or suspected case of communicable disease develops shall, as soon as practicable, notify the local health authority.

Under the final rule, pilots in command of an aircraft, operating on behalf of an airline, that submit the ill person or death report to HHS/CDC under new 70.11 will not be required to also submit a report to the local health authority under current 70.4. HHS/CDC will continue to share public health information with State and local health departments through electronic disease reporting networks. It is unlikely that HHS/CDC would request follow-up reports of illnesses that are reported to the local health authorities, unless there was an urgent public health need. Therefore, CDC does not anticipate any additional burden to the respondents; however, the accounting for burden in Table 2 will add 70.11 *Report of death or illness onboard aircraft operated by airline*.

As a result of this final rule, CDC does not anticipate a change in total burden. CDC is instead allocating 95% of the reports of illness or death within the proposed 70.11 *Report of death or illness onboard aircraft operated by airline*. The remains 5% will remain within 70.4 Report by the master of a vessel or person in charge of conveyance of the incidence of a communicable disease occurring while

in interstate travel, in the event that some reports are still made to State health authorities.

In addition to the requirement to report directly to HHS/CDC, HHS/CDC is updating the definition of “ill person” for the purposes of illness reports to HHS/CDC in 42 CFR part 70. HHS/CDC has, as a matter of agency guidance, communicated with airlines that the same current set of required and requested signs and symptoms of disease, as well as any death, apply to domestic as well as international flights. This guidance is similar to that of the guidelines issued by ICAO under *Note 1 to paragraph 8.15 of Annex 9 to the Convention on International Civil Aviation*. Therefore, the new proposed definition of ill person should not affect standard practice, and no change in burden is anticipated.

Table 2 below presents estimates of annual burden (in hours) associated with each reporting and recordkeeping requirement under this OMB control number, accounting for the rule changes.

Description of Respondents

Respondents to this data collection include masters of vessels or persons in charge of conveyance and pilots in command of aircraft.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN 0920–0488

| Type of respondent | Form name | No. of respondents | No. of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|---|---|--------------------|---------------------------------|--|-------------------------|
| Pilot in command | 42 CFR 70.11 Report of death or illness onboard aircraft operated by airline. | 190 | 1 | 7/60 | 22 |
| Master of vessel or person in charge of conveyance. | 42 CFR 70.4 Report by the master of a vessel or person in charge of conveyance of the incidence of a communicable disease occurring while in interstate travel. | 10 | 1 | 7/60 | 1 |
| Total | | 200 | | | 23 |

The total requested burden hours are 23. There is no burden to respondents other than the time taken to complete the reports. The estimates are based on experience to date with current recordkeeping and reporting requirements of 42 CFR part 70, and take into account the potential for additional burden from increased reports of illness during an outbreak and for reports of disease that may have been missed by respondents during travel and are reported to CDC by other means.

Finally, under this final rule HHS/CDC is requesting approval for a new information collection, Airline and Vessel and Traveler Information Collection (42 CFR part 71). This information collection request accompanies the codification of issuing orders to airlines and vessel operators for the provision to CDC of airline and vessel and traveler information (aka manifests) in the event that a quarantinable communicable disease or a communicable disease of public health concern, or a death caused by a quarantinable communicable disease or

communicable disease of public health concern, occurs during travel to the United States and public health follow-up is warranted. These proposed provisions are found in 42 CFR 71.4 for airlines and 71.5 for vessels.

The ordering of manifests from airlines and vessel operators arriving into the United States is an ongoing activity executed under CDC's broad regulatory authority found at 42 CFR 71.32 *Persons, carriers, and things*. To increase transparency with regard to CDC's authorities and manifest order process, CDC is proposing specific

regulatory provisions that outline the particular data elements CDC requires to perform contact tracing investigations. As stated in the final rule, CDC is not mandating the collection of additional data. Only that if the airlines or maritime operators have the data elements listed in 71.4 and 71.5 in their

possession, they must be provided to CDC within 24 hours.

Table 3 below presents estimates of annual burden (in hours) associated with each reporting and recordkeeping requirement under this OMB control number, accounting for the final rule changes.

Description of Respondents

Respondents to this data collection include the Airline Medical Officer or Equivalent and a Computer and Information Systems Manager.

TABLE 3—ESTIMATE OF ANNUAL BURDEN AIRLINE AND VESSEL MANIFEST ORDERS

| Type of respondent | Form name | No. of respondents | No. of responses per respondent | Average burden per response (in hours) | Total burden (in hours) |
|---|--|--------------------|---------------------------------|--|-------------------------|
| Airline Medical Officer or Equivalent/Computer and Information Systems Manager. | International TB Manifest Template | 67 | 1 | 360/60 | 402 |
| Airline Medical Officer or Equivalent/Computer and Information Systems Manager. | International Non-TB Manifest Template. | 29 | 1 | 360/60 | 174 |
| Total | | 96 | | | 576 |

The total requested burden hours included in this final rule is 576. There is no burden to respondents other than the time taken to complete the manifest information and send to CDC. The estimates are based on experience to date with current manifest order process.

D. National Environmental Policy Act (NEPA)

HHS/CDC has determined that the amendments to 42 CFR parts 70 and 71 will not have a significant impact on the human environment.

E. Executive Order 12988: Civil Justice Reform

HHS/CDC has reviewed this rule under Executive Order 12988 on Civil Justice Reform and determines that this final rule meets the standard in the Executive Order.

F. Executive Order 13132: Federalism

Under Executive Order 13132, a Federalism analysis is required if a rulemaking has Federalism implications, would limit or preempt State or local law, or impose substantial direct compliance costs on State or local governments. Under such circumstances, a Federal agency must consult with State and local officials. Federalism implications is defined as having substantial direct effects on State or local governments, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Under 42 U.S.C. 264(e), Federal public health regulations do not preempt State or local public

health regulations, except in the event of a conflict with the exercise of Federal authority. Other than to restate this statutory provision, this rulemaking does not alter the relationship between the Federal government and State/local governments as set forth in 42 U.S.C. 264. The longstanding provision on preemption in the event of a conflict with Federal authority (42 CFR 70.2) is left unchanged by this rulemaking. Additionally, there are no provisions in these regulations that impose direct compliance costs on State and local governments. Therefore, HHS/CDC believes that the rule does not warrant additional consultation under Executive Order 13132.

G. The Plain Language Act of 2010

Under 63 FR 31883 (June 10, 1998), Executive Departments and Agencies are required to use plain language in all proposed and final rules. HHS/CDC received several comments suggesting that the proposed regulation was not written in plain language and was therefore difficult to understand. Prior to publication, this final rule was reviewed by specialists in health communication and education to ensure the content and intention, as well as substance, were clear and accurate.

List of Subjects in 70.1, 70.5, 70.6, 70.10–70.18, 71.1, 71.2, 71.4, 71.5, 71.12, 71.20, 71.29, 71.30, 71.36–71.39, 71.63

Apprehension, Communicable diseases, Conditional release, CDC, Ill person, Isolation, Non-invasive, Public health emergency, Public health prevention measures, Qualifying stage,

Quarantine, Quarantinable Communicable Disease.

For the reasons discussed in the preamble, we amend 42 CFR parts 70 and 71 as follows:

PART 70—INTERSTATE QUARANTINE

■ 1. The authority citation for part 70 continues to read as follows:

Authority: Secs. 215 and 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 216, 243) section 361–369, PHS Act, as amended (42 U.S.C. 264–272); 31 U.S.C. 9701.

■ 2. Amend § 70.1 by—

■ a. Adding in alphabetical order definitions for “Airline”, “Apprehension”, and “Communicable stage”;

■ b. Revising the definition of “Conditional release”;

■ c. Adding in alphabetical order a definitions for “Contaminated environment”;

■ d. Revising the definition of “Conveyance”;

■ e. Adding in alphabetical order definitions for “Electronic or Internet-based monitoring” and “Ill person”;

■ f. Revising the definition of “Incubation period”;

■ g. Adding in alphabetical order a definition for “Indigent”;

■ h. Revising the definition of “Interstate traffic”;

■ i. Revising the definition of “Master or operator”;

■ j. Adding in alphabetical order definitions for “Medical examination”, “Medical reviewer”, “Non-invasive”, “Precommunicable stage”, “Public health emergency”, “Public health

prevention measures”, “Qualifying stage”, “Reasonably believed to be infected, as applied to an individual”, and “Representatives”.

The additions and revisions read as follows:

§ 70.1 General definitions.

Airline means any air carrier or foreign air carrier providing air transportation as that term is defined in 49 U.S.C. 40102(a)(2), (a)(5), and (a)(21).

Apprehension means the temporary taking into custody of an individual or group for purposes of determining whether Federal quarantine, isolation, or conditional release is warranted.

* * * * *

Communicable stage means the stage during which an infectious agent may be transmitted either directly or indirectly from an infected individual to another individual.

Conditional release means the temporary supervision by a public health official (or designee) of an individual or group, who may have been exposed to a quarantinable communicable disease to determine the risk of disease spread and includes public health supervision through in-person visits, telephone, or through electronic or Internet-based monitoring.

Contaminated environment means the presence of an infectious agent on a surface, including on inanimate articles, or in a substance, including food, water, or in the air.

Conveyance means an aircraft, train, road vehicle, vessel (as defined in this section) or other means of transport, including military.

* * * * *

Electronic or Internet-based monitoring means mechanisms or technologies allowing for the temporary public health supervision of an individual under conditional release and may include communication through electronic mail, SMS texts, video or audio conference, webcam technologies, integrated voice-response systems, entry of information into a Web-based forum, wearable tracking technologies, and other mechanisms or technologies as determined by the Director or supervising health authority.

Ill person means an individual who:

(1) Has a fever (a measured temperature of 100.4 °F [38 °C] or greater, or feels warm to the touch, or gives a history of feeling feverish) accompanied by one or more of the following: Skin rash, difficulty breathing, persistent cough, decreased consciousness or confusion of recent onset, new unexplained bruising or bleeding (without previous injury),

persistent diarrhea, persistent vomiting (other than air sickness), headache with stiff neck, appears obviously unwell; or

(2) Has a fever that has persisted for more than 48 hours; or

(3) Has symptoms or other indications of communicable disease, as the CDC may announce through posting of a notice in the **Federal Register**.

Incubation period means the time from the moment of exposure to an infectious agent that causes a communicable disease until signs and symptoms of the communicable disease appear in the individual or, if signs and symptoms do not appear, the latest date signs and symptoms could reasonably be expected to appear. For a quarantinable communicable disease, incubation period means the precommunicable stage.

Indigent means an individual whose annual family income is below 200% of the applicable poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2) or, if no income is earned, liquid assets totaling less than 15% of the applicable poverty guidelines.

Interstate traffic (1) Means:

(i) The movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation that is entirely within a State or possession—

(ii) From a point of origin in any State or possession to a point of destination in any other State or possession; or

(iii) Between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country.

(2) Interstate traffic does not include the following:

(i) The movement of any conveyance which is solely for the purpose of unloading persons or property transported from a foreign country, or loading persons or property for transportation to a foreign country.

(ii) The movement of any conveyance which is solely for the purpose of effecting its repair, reconstruction, rehabilitation, or storage.

* * * * *

Master or operator with respect to a vessel, means the sea crew member with responsibility for vessel operation and navigation, or a similar individual with responsibility for a conveyance. Consistent with the definition of “operate” in 14 CFR 1.1, “operator” means, with respect to aircraft, any person who uses, causes to use, or authorizes to use an aircraft, for the

purpose (except as provided in 14 CFR 91.13) of air navigation including the piloting of an aircraft, with or without the right of legal control (as owner, lessee, or otherwise).

Medical examination means the assessment of an individual by an authorized and licensed health worker to determine the individual’s health status and potential public health risk to others and may include the taking of a medical history, a physical examination, and collection of human biological samples for laboratory testing as may be needed to diagnose or confirm the presence or extent of infection with a quarantinable communicable disease.

Medical reviewer means a physician, nurse practitioner, or similar medical professional qualified in the diagnosis and treatment of infectious diseases who is appointed by the Secretary or Director to conduct medical reviews under this part and may include an HHS or CDC employee, provided that the employee differs from the CDC official who issued the Federal order for quarantine, isolation, or conditional release.

Non-invasive means procedures conducted by an authorized public health worker (*i.e.*, an individual with education and training in the field of public health) or another individual with suitable public health training and includes the visual examination of the ear, nose, and mouth; temperature assessments using an ear, oral, cutaneous, or noncontact thermometer, or thermal imaging; and other procedures not involving the puncture or incision of the skin or insertion of an instrument or foreign material into the body or a body cavity excluding the ear, nose, and mouth.

* * * * *

Precommunicable stage means the stage beginning upon an individual’s earliest opportunity for exposure to an infectious agent and ending upon the individual entering or reentering the communicable stage of the disease or, if the individual does not enter the communicable stage, the latest date at which the individual could reasonably be expected to have the potential to enter or reenter the communicable stage.

Public health emergency as used in this part means:

(1) Any communicable disease event as determined by the Director with either documented or significant potential for regional, national, or international communicable disease spread or that is highly likely to cause death or serious illness if not properly controlled; or

(2) Any communicable disease event described in a declaration by the

Secretary pursuant to 319(a) of the Public Health Service Act (42 U.S.C. 247d (a)); or

(3) Any communicable disease event the occurrence of which is notified to the World Health Organization, in accordance with Articles 6 and 7 of the International Health Regulations, as one that may constitute a Public Health Emergency of International Concern; or

(4) Any communicable disease event the occurrence of which is determined by the Director-General of the World Health Organization, in accordance with Article 12 of the International Health Regulations, to constitute a Public Health Emergency of International Concern; or

(5) Any communicable disease event for which the Director-General of the World Health Organization, in accordance with Articles 15 or 16 of the International Health Regulations, has issued temporary or standing recommendations for purposes of preventing or promptly detecting the occurrence or reoccurrence of the communicable disease.

Public health prevention measures means the assessment of an individual through non-invasive procedures and other means, such as observation, questioning, review of travel documents, records review, and other non-invasive means, to determine the individual's health status and potential public health risk to others.

Qualifying stage is statutorily defined (42 U.S.C. 264(d)(2)) to mean:

(1) The communicable stage of a quarantinable communicable disease; or

(2) The precommunicable stage of the quarantinable communicable disease, but only if the quarantinable communicable disease would be likely to cause a public health emergency if transmitted to other individuals.

* * * * *

Reasonably believed to be infected, as applied to an individual, means specific articulable facts upon which a public health officer could reasonably draw the inference that an individual has been exposed, either directly or indirectly, to the infectious agent that causes a quarantinable communicable disease, as through contact with an infected person or an infected person's bodily fluids, a contaminated environment, or through an intermediate host or vector, and that as a consequence of the exposure, the individual is or may be harboring in the body the infectious agent of that quarantinable communicable disease.

Representatives means a physician, nurse practitioner, or similar medical professional qualified in the diagnosis and treatment of infectious diseases,

and an attorney who is knowledgeable of public health practices, who are appointed by the Secretary or Director and may include HHS or CDC employees, to assist an indigent individual under Federal quarantine, isolation, or conditional release with a medical review under this part.

* * * * *

Secretary means the Secretary of Health and Human Services (HHS) or any other officer or employee of that Department to whom the authority involved has been delegated.

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■ 3. Revise § 70.5 to read as follows:

§ 70.5 Requirements relating to travelers under a Federal order of isolation, quarantine, or conditional release.

(a) The following provisions are applicable to any individual under a Federal order of isolation, quarantine, or conditional release with regard to a quarantinable communicable disease or to any individual meeting the requirements of paragraph (d), (e), or (f) of this section:

(1) Except as specified under the terms of a Federal conditional release order, no such individual shall travel in interstate traffic or from one State or U.S. territory to another without a written travel permit issued by the Director.

(2) Requests for a travel permit must state the reasons why the travel is being requested, mode of transportation, the places or individuals to be visited, the precautions, if any, to be taken to prevent the potential transmission or spread of the communicable disease, and other information as determined necessary by the Director to assess the individual's health condition and potential for communicable disease spread to others.

(3) The Director will consider all requests for a permit and, taking into consideration the risk of introduction, transmission, or spread of the communicable disease, may condition the permit upon compliance with such precautionary measures as the Director shall prescribe. The Director shall respond to a request for a permit within 5 business days.

(4) An individual to whom a permit has been issued shall retain it in his/her possession throughout the course of his/her authorized travel and comply with all conditions prescribed therein, including presentation of the permit to the operators of conveyances, as required by its terms.

(5) An individual who has had his/her request for a permit denied, or who has had a travel permit suspended or

revoked, may submit a written appeal to the Director (excluding the CDC official who denied, suspended, or revoked the permit). The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Director (excluding the CDC official who denied, suspended, or revoked the permit) within 10 calendar days of the denial, suspension, or revocation of the permit. The Director (excluding the CDC official who denied, suspended, or revoked the permit) will issue a written response to the appeal within 3 business days, which shall constitute final agency action.

(b) The operator of any conveyance operating in interstate traffic shall not:

(1) Accept for transportation any individual whom the operator knows, or reasonably should know, to be under a Federal order of isolation, quarantine, or conditional release, unless such an individual presents a permit issued by the Director or a copy of the Federal conditional release order authorizing such travel;

(2) Transport any individual whom the operator knows, or reasonably should know, to be under a Federal order of isolation, quarantine, or conditional release in violation of any of the terms or conditions prescribed in the travel permit or conditional release order issued by the Director.

(c) Whenever a conveyance operating in interstate traffic transports an individual under a Federal order or travel permit, the Director may require that the operator of the conveyance submit the conveyance to inspection, sanitary measures, and other measures, as the Director deems necessary to prevent the possible spread of communicable disease.

(d) The Director may additionally apply the provisions in paragraphs (a) through (c) of this section to individuals traveling entirely intrastate and to conveyances that transport such individuals upon the request of a State or local health authority of jurisdiction. The Director shall consider the State or local health authority's request for assistance and taking into consideration the risk of introduction, transmission, or spread of the communicable disease, grant or deny, in his/her discretion, the request for assistance.

(e) The Director may additionally apply the provisions in paragraphs (a) through (c) of this section to individuals traveling interstate or entirely intrastate and to conveyances that transport such individuals whenever the Director makes a determination under 42 CFR 70.2 that based on the existence of inadequate local control such measures are needed to prevent the spread of any

of the communicable diseases from such State or U.S. territory to any other State or U.S. territory.

(f) The Director may additionally apply the provisions in paragraphs (a) through (c) of this section to individuals under a State or local order, or written agreement, for quarantine, isolation, or conditional release and to conveyances that may transport such individuals, upon the request of a State or local health authority of jurisdiction or whenever the Director makes a determination of inadequate local control under 42 CFR 70.2. The Director shall consider the State or local health authority's request for assistance and taking into consideration the risk of introduction, transmission, or spread of the communicable disease, grant or deny, in his/her discretion, the request for assistance.

(g) The Director may exempt individuals and non-public conveyances, such as ambulances, air ambulance flights, or private vehicles, from the requirements of this section.

■ 4. Revise § 70.6 to read as follows:

§ 70.6 Apprehension and detention of persons with quarantinable communicable diseases.

(a) The Director may authorize the apprehension, medical examination, quarantine, isolation, or conditional release of any individual for the purpose of preventing the introduction, transmission, and spread of quarantinable communicable diseases, as specified by Executive Order, based upon a finding that:

(1) The individual is reasonably believed to be infected with a quarantinable communicable disease in a qualifying stage and is moving or about to move from a State into another State; or

(2) The individual is reasonably believed to be infected with a quarantinable communicable disease in a qualifying stage and constitutes a probable source of infection to other individuals who may be moving from a State into another State.

(b) The Director will arrange for adequate food and water, appropriate accommodation, appropriate medical treatment, and means of necessary communication for individuals who are apprehended or held in quarantine or isolation under this part.

■ 5. Add §§ 70.10 through 70.18 to read as follows:

Sec. * * * *

70.10 Public health prevention measures to detect communicable disease.

70.11 Report of death or illness onboard aircraft operated by an airline.

70.12 Medical examinations.

70.13 Payment for care and treatment.

70.14 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release.

70.15 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release.

70.16 Medical review of a Federal order for quarantine, isolation, or conditional release.

70.17 Administrative records relating to Federal quarantine, isolation, or conditional release.

70.18 Penalties.

§ 70.10 Public health prevention measures to detect communicable disease.

(a) The Director may conduct public health prevention measures at U.S. airports, seaports, railway stations, bus terminals, and other locations where individuals may gather to engage in interstate travel, through non-invasive procedures determined appropriate by the Director to detect the presence of communicable diseases.

(b) As part of the public health prevention measures, the Director may require individuals to provide contact information such as U.S. and foreign addresses, telephone numbers, email addresses, and other contact information, as well as information concerning their intended destination, health status, known or possible exposure history, and travel history.

§ 70.11 Report of death or illness onboard aircraft operated by an airline.

(a) The pilot in command of an aircraft operated by an airline who is conducting a commercial passenger flight in interstate traffic under a regular schedule shall report as soon as practicable to the Director the occurrence onboard of any deaths or the presence of ill persons among passengers or crew and take such measures as the Director may direct to prevent the potential spread of the communicable disease, provided that such measures do not affect the airworthiness of the aircraft or the safety of flight operations.

(b) The pilot in command of an aircraft operated by an airline who reports in accordance with paragraph (a) of this section shall be deemed to satisfy the reporting obligation under 42 CFR 70.4.

§ 70.12 Medical examinations.

(a) The Director may require an individual to undergo a medical examination as part of a Federal order for quarantine, isolation, or conditional release for a quarantinable communicable disease.

(b) The Director shall promptly arrange for the medical examination to

be conducted when one is required under this section and shall as part of the Federal order advise the individual that the medical examination shall be conducted by an authorized and licensed health worker, and with prior informed consent.

(c) As part of the medical examination, the Director may require an individual to provide information and undergo such testing as may be reasonably necessary to diagnose or confirm the presence or extent of infection with a quarantinable communicable disease.

(d) Individuals reasonably believed to be infected based on the results of a medical examination may be isolated, or if such results are inconclusive or unavailable, individuals may be quarantined or conditionally released in accordance with this part.

§ 70.13 Payment for care and treatment.

(a) The Director may authorize payment for the care and treatment of individuals subject to medical examination, quarantine, isolation, and conditional release, subject to paragraphs (b) through (h) of this section.

(b) Payment for care and treatment shall be in the CDC's sole discretion and subject to the availability of appropriations.

(c) Payment shall be secondary to the obligation of the United States or any third-party (*i.e.*, any State or local governmental entity, private insurance carrier, or employer), under any other law or contractual agreement, to pay for such care and treatment, and shall be paid by the Director only after all third-party payers have made payment in satisfaction of their obligations.

(d) Payment may include costs for providing ambulance or other medical transportation when such services are deemed necessary by the Director for the individual's care and treatment.

(e) Payment shall be limited to those amounts the hospital, medical facility, or medical transportation service would customarily bill the Medicare system using the International Classification of Diseases, Clinical Modification (ICD-CM), and relevant regulations promulgated by the Centers for Medicare and Medicaid Services in existence at the time of billing.

(f) For quarantinable communicable diseases, payment shall be limited to costs for services and items reasonable and necessary for the care and treatment of the individual or group for the time period beginning when the Director refers the individual or group to the hospital or medical facility and ends when, as determined by the Director,

the period of apprehension, quarantine, isolation, or conditional release expires.

(g) For diseases other than those described in paragraph (f) of this section, such payment shall be limited to costs for services and items reasonable and necessary for care and treatment of the individual for the time period that begins when the Director refers the individual to the hospital or medical facility and ends when the individual's condition is diagnosed, as determined by the Director, as an illness other than a quarantinable communicable disease.

(h) For ambulance or other medical transportation, payment shall be limited to the costs for such services and other items reasonable and necessary for the individual's safe medical transport.

§ 70.14 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release.

(a) A Federal order authorizing quarantine, isolation, or conditional release shall be in writing, signed by the Director, and contain the following information:

(1) The identity of the individual or group subject to the order;

(2) The location of the quarantine or isolation or, in the case of conditional release, the entity to who and means by which the individual shall report for public health supervision;

(3) An explanation of the factual basis underlying the Director's reasonable belief that the individual is in the qualifying stage of a quarantinable communicable disease;

(4) An explanation of the factual basis underlying the Director's reasonable belief that the individual is moving or about to move from one State into another or constitutes a probable source of infection to others who may be moving from one State into another;

(5) An explanation that the Federal order will be reassessed no later than 72 hours after it has been served and an explanation of the medical review of the Federal order pursuant to this part, including the right to request a medical review, present witnesses and testimony at the medical review, and to be represented at the medical review by either an advocate (*e.g.*, an attorney, family member, or physician) at the individual's own expense, or, if indigent, to have representatives appointed at the government's expense;

(6) An explanation of the criminal penalties for violating a Federal order of quarantine, isolation, or conditional release; and

(7) An explanation that if a medical examination is required as part of the Federal order that the examination will

be conducted by an authorized and licensed health worker, and with prior informed consent.

(b) A Federal order authorizing quarantine, isolation, or conditional release shall be served on the individual no later than 72 hours after the individual has been apprehended, except that the Federal order may be published or posted in a conspicuous location if the Federal order is applicable to a group of individuals and individual service would be impracticable.

(c) The Director shall arrange for translation or interpretation services of the Federal order as needed.

(d) Nothing in this section shall affect the constitutional or statutory rights of individuals to obtain judicial review of their Federal detention.

§ 70.15 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release.

(a) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall reassess the need to continue the quarantine, isolation, or conditional release of an individual no later than 72 hours after the service of the Federal order.

(b) As part of the reassessment, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall review all records considered in issuing the Federal order, including travel records, records evidencing exposure or infection with a quarantinable communicable disease, as well as any relevant new information.

(c) As part of the reassessment, and where applicable, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall consider and make a determination regarding whether less restrictive alternatives would adequately serve to protect the public health.

(d) At the conclusion of the reassessment, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall promptly issue and serve a written Federal order directing that the quarantine, isolation, or conditional release be continued, modified, or rescinded.

(e) In the event that the Director orders that the quarantine, isolation, or conditional release be continued or modified, the written Federal order shall explain the process for requesting a medical review under this part.

(f) The Director's written Federal order shall be promptly served on the

individual, except that the Federal order may be served by publication or by posting in a conspicuous location if the Federal order is applicable to a group of individuals and individual service would be impracticable.

(g) The Director shall arrange for translation or interpretation services of the Federal order as needed.

§ 70.16 Medical review of a Federal order for quarantine, isolation, or conditional release.

(a) The Director shall, as soon as practicable, arrange for a medical review upon a request by an individual under Federal quarantine, isolation, or conditional release.

(b) A request for a medical review may only occur after the Director's mandatory reassessment under section 70.15 and following the service of a Federal order continuing or modifying the quarantine, isolation, or conditional release.

(c) The medical review shall be for the purpose of ascertaining whether the Director has a reasonable belief that the individual is infected with a quarantinable communicable disease in a qualifying stage.

(d) The Director shall notify the individual in writing of the time and place of the medical review.

(e) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall designate a medical reviewer to review the medical or other evidence presented at the review, make medical or other findings of fact, and issue a recommendation concerning whether the Federal order for quarantine, isolation, or conditional release should be rescinded, continued, or modified.

(f) The individual under Federal quarantine, isolation, or conditional release may authorize an advocate (*e.g.*, an attorney, family member, or physician) at his or her own expense to submit medical or other evidence and, in the medical reviewer's discretion, be allowed to present a reasonable number of medical experts. The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall appoint representatives at government expense to assist the individual for purposes of the medical review upon a request and certification, under penalty of perjury, by that individual that he or she is indigent.

(g) Prior to the convening of the review, the individual or his/her authorized advocate or representatives shall be provided a reasonable opportunity to examine the available medical and other records involved in

the medical review that pertain to that individual.

(h) The Director shall take such measures that he/she determines to be reasonably necessary to allow an individual under Federal quarantine or isolation to communicate with any authorized advocate or representatives in such a manner as to prevent the possible spread of the quarantinable communicable disease.

(i) The medical reviewer may order a medical examination of an individual when, in the medical reviewer's professional judgment, such an examination would assist in assessing the individual's medical condition.

(j) As part of the review, and where applicable, the medical reviewer shall consider and accept into the record evidence concerning whether less restrictive alternatives would adequately serve to protect public health.

(k) The medical review shall be conducted by telephone, audio or video conference, or through other means that the medical reviewer determines in his/her discretion are practicable for allowing the individual under quarantine, isolation, or conditional release to participate in the medical review.

(l) At the conclusion of the review, the medical reviewer shall, based upon his or her review of the facts and other evidence made available during the medical review, issue a written report to the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) concerning whether, in the medical reviewer's professional judgment, the Federal quarantine, isolation, or conditional release should be rescinded, continued, or modified. The written report shall include a determination regarding whether less restrictive alternatives would adequately serve to protect public health. The written report shall be served on the individual and the individual's authorized advocate or representatives.

(m) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall, as soon as practicable, review the written report and any objections that may be submitted by the individual or the individual's authorized advocate or representatives that contest the findings and recommendation contained in the medical reviewer's written report. Upon conclusion of the review, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall promptly issue a written Federal order directing that the quarantine, isolation, or conditional

release be continued, modified, or rescinded. In the event that the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) continues or modifies the Federal quarantine, isolation, or conditional release, the Director's written order shall include a statement that the individual may request that the Director rescind the Federal quarantine, isolation, or conditional release, but based only on a showing of significant, new or changed facts or medical evidence that raise a genuine issue as to whether the individual should continue to be subject to Federal quarantine, isolation, or conditional release. The written Federal order shall be promptly served on the individual and the individual's authorized advocate or representatives, except that the Federal order may be served by publication or by posting in a conspicuous location if applicable to a group of individuals and individual service would be impracticable.

(n) The Director's written order shall not constitute final agency action until it has been served on the individual and the individual's authorized advocate or representatives, or alternatively, if applicable to a group of individuals and individual service would be impracticable, it is published or posted.

(o) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) may order the consolidation of one or more medical reviews if the number of individuals or other factors makes the holding of individual medical reviews impracticable.

(p) The Director may issue additional instructions as may be necessary or desirable governing the conduct of medical reviews.

(q) The Director shall arrange for translation or interpretation services as needed for purposes of this section.

§ 70.17 Administrative records relating to Federal quarantine, isolation, or conditional release.

(a) The administrative record of an individual under Federal quarantine, isolation, or conditional release shall, where applicable, consist of the following:

(1) The Federal order authorizing quarantine, isolation, or conditional release, including any subsequent Federal orders continuing or modifying the quarantine, isolation or conditional release;

(2) Records of any available medical, laboratory, or other epidemiologic information that are in the agency's possession and that were considered in issuing the Federal quarantine, isolation, or conditional release order,

or any subsequent Federal orders;

(3) Records submitted by the individual under quarantine, isolation, or conditional release, or by an authorized advocate or representatives, as part of a request for rescission of the Federal quarantine, isolation, or conditional release or as part of a medical review;

(4) The written findings and report of the medical reviewer, including any transcripts of the medical review and any written objections submitted by the individual under Federal quarantine, isolation, or conditional release, or by any authorized advocate or representatives;

(b) An individual subject to a Federal public health order shall upon request be served with a copy of his or her own administrative record in its entirety.

§ 70.18 Penalties.

(a) Persons in violation of this part are subject to a fine of no more than \$100,000 if the violation does not result in a death or one year in jail, or both, or a fine of no more than \$250,000 if the violation results in a death or one year in jail, or both, or as otherwise provided by law.

(b) Violations by organizations are subject to a fine of no more than \$200,000 per event if the violation does not result in a death or \$500,000 per event if the violation results in a death or as otherwise provided by law.

PART 71—FOREIGN QUARANTINE

■ 6. The authority citation for part 71 continues to read as follows:

Authority: Secs. 215 and 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 216, 243) section 361–369, PHS Act, as amended (42 U.S.C. 264–272).

■ 7. Amend § 71.1, paragraph (b), by—

■ a. Adding in alphabetical order definitions for “Airline” and “Apprehension”;

■ b. Revising the definition of “Commander”;

■ c. Adding in alphabetical order definitions for “Conditional release”, “Contaminated environment”, and “Electronic or Internet-based monitoring”;

■ d. Revising the definition of “Ill person”;

■ e. Adding in alphabetical order a definition for “Indigent”;

■ f. Revising the definition of “International voyage”;

■ g. Adding in alphabetical order definitions for “Master or operator”, “Medical examination”, “Medical reviewer”, “Non-invasive”, “Public health prevention measures”, “Representatives”, and “Secretary”.

The additions and revisions read as follows:

§ 71.1 General definitions.

* * * *

(b) * * *

Airline means any air carrier or foreign air carrier providing air transportation, as that term is defined in 49 U.S.C. 40102(a)(2), (a)(5), and (a)(21).

Apprehension means the temporary taking into custody of an individual or group for purposes of determining whether quarantine, isolation, or conditional release is warranted.

* * * *

Commander means the pilot in command of an aircraft as defined in 14 CFR 1.1.

* * * *

Conditional release means surveillance as defined under this part and includes public health supervision through in-person visits by a health official or designee, telephone, or through any electronic or internet-based means as determined by the Director.

Contaminated environment means the presence of an infectious agent on a surface, including on inanimate articles, or in a substance, including food, water, or in the air.

* * * *

Electronic or internet-based monitoring means mechanisms or technologies allowing for the temporary public health supervision of an individual under conditional release and may include communication through electronic mail, SMS texts, video or audio conference, webcam technologies, integrated voice-response systems, entry of information into a web-based forum, wearable tracking technologies, and other mechanisms or technologies as determined by the Director.

Ill person means an individual:

(i) Who if onboard an aircraft:

(A) Has a fever (a measured temperature of 100.4 °F [38 °C] or greater, or feels warm to the touch, or gives a history of feeling feverish) accompanied by one or more of the following: Skin rash, difficulty breathing, persistent cough, decreased consciousness or confusion of recent onset, new unexplained bruising or bleeding (without previous injury), persistent diarrhea, persistent vomiting (other than air sickness), headache with stiff neck, appears obviously unwell; or

(B) Has a fever that has persisted for more than 48 hours; or

(C) Has symptoms or other indications of communicable disease, as the Director may announce through posting of a notice in the **Federal Register**.

(ii) Who if onboard a vessel:

(A) Has a fever (a measured temperature of 100.4 °F [38 °C] or greater; or feels warm to the touch; or gives a history of feeling feverish) accompanied by one or more of the following: Skin rash, difficulty breathing or suspected or confirmed pneumonia, persistent cough or cough with bloody sputum, decreased consciousness or confusion of recent onset, new unexplained bruising or bleeding (without previous injury), persistent vomiting (other than sea sickness), headache with stiff neck; or

(B) Has a fever that has persisted for more than 48 hours; or

(C) Has acute gastroenteritis, which means either diarrhea, defined as three or more episodes of loose stools in a 24-hour period or what is above normal for the individual, or vomiting accompanied by one or more of the following: One or more episodes of loose stools in a 24-hour period, abdominal cramps, headache, muscle aches, or fever (temperature of 100.4 °F [38 °C] or greater); or

(D) Has symptoms or other indications of communicable disease, as the Director may announce through posting of a notice in the **Federal Register**.

Indigent means an individual whose annual family income is below 200% of the applicable poverty guidelines updated periodically in the **Federal Register** by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2) or, if no income is earned, liquid assets totaling less than 15% of the applicable poverty guidelines.

* * * *

International voyage means:

(i) In the case of a carrier, a voyage between ports or airports of more than one country, or a voyage between ports or airports of the same country if the ship or aircraft stopped in any other country on its voyage; or

(ii) In the case of a person, a voyage involving entry into a country other than the country in which that person begins his/her voyage.

* * * *

Master or operator with respect to a vessel, means the sea crew member with responsibility for vessel operation and navigation, or a similar individual with responsibility for a carrier. Consistent with the definition of “operate” in 14 CFR 1.1, “operator” means, with respect to aircraft, any person who uses, causes to use or authorizes to use aircraft, for the purpose (except as provided in 14 CFR 91.13) of air navigation including the piloting of aircraft, with or without

the right of legal control (as owner, lessee, or otherwise).

Medical examination means the assessment of an individual by an authorized and licensed health worker to determine the individual's health status and potential public health risk to others and may include the taking of a medical history, a physical examination, and collection of human biological samples for laboratory testing as may be needed to diagnose or confirm the presence or extent of infection with a quarantinable communicable disease.

Medical reviewer means a physician, nurse practitioner, or similar medical professional qualified in the diagnosis and treatment of infectious diseases who is appointed by the Secretary or Director to conduct medical reviews under this part and may include an HHS or CDC employee, provided that the employee differs from the CDC official who issued the Federal order for quarantine, isolation, or conditional release.

* * * *

Non-invasive means procedures conducted by an authorized public health worker (*i.e.*, an individual with education and training in the field of public health) or another individual with suitable public health training and includes the visual examination of the ear, nose, and mouth; temperature assessments using an ear, oral, cutaneous, or noncontact thermometer, or thermal imaging; and other procedures not involving the puncture or incision of the skin or insertion of an instrument or foreign material into the body or a body cavity excluding the ear, nose, and mouth.

* * * *

Public health prevention measures means the assessment of an individual through non-invasive procedures and other means, such as observation, questioning, review of travel documents, records review, and other non-invasive means, to determine the individual's health status and potential public health risk to others.

Representatives means a physician, nurse practitioner, or similar medical professional qualified in the diagnosis and treatment of infectious diseases, and an attorney who is knowledgeable of public health practices, who are appointed by the Secretary or Director and may include HHS or CDC employees, to assist an indigent individual under Federal quarantine, isolation, or conditional release with a medical review under this part.

* * * *

Secretary means the Secretary of Health and Human Services (HHS) or

any other officer or employee of that Department to whom the authority involved has been delegated.

* * * * *

■ 8. Revise § 71.2 to read as follows:

§ 71.2 Penalties.

(a) Persons in violation of this part are subject to a fine of no more than \$100,000 if the violation does not result in a death or one year in jail, or both, or a fine of no more than \$250,000 if the violation results in a death or one year in jail, or both, or as otherwise provided by law. (b) Violations by organizations are subject to a fine of no more than \$200,000 per event if the violation does not result in a death or \$500,000 per event if the violation results in a death or as otherwise provided by law.

■ 9. Add 71.4 to subpart A to read as follows:

§ 71.4 Requirements relating transmission of airline passenger, crew and flight information for public health purposes.

(a) Any airline with a flight arriving into the United States, including any intermediate stops between the flight's origin and final destination, shall make the data elements in paragraph (b) of this section available to the Director for passengers or crew who, as determined by the Director, may be at risk of exposure to a communicable disease, to the extent that such data are already available and maintained by the airline, within 24 hours of an order by the Director and in a format available and acceptable to both the airline and the Director.

(b) The data elements referred to in paragraph (a) of this section include:

- (1) Full name (last, first, and, if available, middle or others);
- (2) Date of birth;
- (3) Sex;
- (4) Country of residence;
- (5) If a passport is required: Passport number, passport country of issuance, and passport expiration date;
- (6) If a travel document other than a passport is required: Travel document type, travel document number, travel document country of issuance and travel document expiration date;
- (7) Address while in the United States (number and street, city, State, and zip code), except that U.S. citizens and lawful permanent residents will provide address of permanent residence in the U.S. (number and street, city, State, and zip code);
- (8) Primary contact phone number to include country code;
- (9) Secondary contact phone number to include country code;
- (10) Email address;
- (11) Airline name;

- (12) Flight number;
- (13) City of departure;
- (14) Departure date and time;
- (15) City of arrival;
- (16) Arrival date and time; and
- (17) Seat number.

(c) No later than February 18, 2019, the Secretary or Director will publish and seek comment on a report evaluating the burden of this section on affected entities and duplication of activities in relation to mandatory passenger data submissions to DHS/CBP. The report will specifically recommend actions that streamline and facilitate use and transmission of any duplicate information collected.

■ 10. Add § 71.5 to subpart A to read as follows:

§ 71.5 Requirements relating transmission of vessel passenger, crew, and voyage information for public health purposes.

(a) The operator of any vessel carrying 13 or more passengers (excluding crew) and, which is not a ferry as defined under 46 U.S.C. 2101 and U.S. Coast Guard (USCG) regulations (46 CFR 2.10–25), shall make the data elements in paragraph (b) of this section available to the Director for passengers or crew who, as determined by the Director, may be at risk of exposure to a communicable disease, to the extent that such data are already in the operator's possession, within 24 hours of an order by the Director and in a format available and acceptable to both the operator and the Director.

(b) The data elements referred to in paragraph (a) of this section include:

- (1) Full name (last, first, and, if available middle or others);
- (2) Date of birth;
- (3) Sex;
- (4) Country of residence;
- (5) If a passport is required: Passport number, passport country of issuance, and passport expiration date;
- (6) If a travel document other than a passport is required: Travel document type, travel document number, travel document country of issuance and travel document expiration date;
- (7) Address while in the United States (number and street, city, State, and zip code), except that U.S. citizens and lawful permanent residents will provide address of permanent residence in the United States (number and street, city, State, and zip code; as applicable);
- (8) Primary contact phone number to include country code;
- (9) Secondary contact phone number to include country code;
- (10) Email address;
- (11) Vessel operator;
- (12) Vessel name;
- (13) Voyage number;

- (14) Embarkation port and date;
- (15) Disembarkation port and date;
- (16) All port stops; and
- (17) Cabin number.

(c) No later than February 21, 2019, the Secretary or Director will publish and seek comment on a report evaluating the burden of this section on affected entities and duplication of activities in relation to mandatory passenger data submissions to DHS/CBP. The report will specifically recommend actions that streamline and facilitate use and transmission of any duplicate information collected.

■ 11. Add § 71.20 to subpart C to read as follows:

§ 71.20 Public health prevention measures to detect communicable disease.

(a) The Director may conduct public health prevention measures, at U.S. ports of entry or other locations, through non-invasive procedures as defined in section 71.1 to detect the potential presence of communicable diseases.

(b) As part of the public health prevention measures, the Director may require individuals to provide contact information such as U.S. and foreign addresses, telephone numbers, email addresses, and other contact information, as well as information concerning their intended destination, health status, known or possible exposure history, and travel history.

■ 12. Add §§ 71.29 and 71.30 to subpart D to read as follows:

§ 71.29 Administrative records relating to quarantine, isolation, or conditional release.

(a) The administrative record of an individual under quarantine, isolation, or conditional release shall, where applicable, consist of the following:

(1) The Federal order authorizing quarantine, isolation, or conditional release, including any subsequent Federal orders continuing or modifying the quarantine, isolation or conditional release;

(2) Records of any available medical, laboratory, or other epidemiologic information that are in the agency's possession and that were considered in issuing the Federal quarantine, isolation, or conditional release order, or any subsequent Federal orders;

(3) Records submitted by the individual under quarantine, isolation, or conditional release, or by an authorized advocate or representatives, as part of a request for rescission of the quarantine, isolation, or conditional release or as part of a medical review;

(4) The written findings and report of the medical reviewer, including any transcripts of the medical review and any written objections submitted by the

individual under Federal quarantine, isolation, or conditional release, or by an authorized advocate or representatives;

(b) An individual subject to a Federal public health order shall, upon request, be served with a copy of his or her own administrative record in its entirety.

§ 71.30 Payment for care and treatment.

(a) The Director may authorize payment for the care and treatment of individuals subject to medical examination, quarantine, isolation, and conditional release, subject to paragraphs (b) through (h) of this section.

(b) Payment for care and treatment shall be in the Director's sole discretion and subject to the availability of appropriations.

(c) Payment shall be secondary to the obligation of the United States or any third-party (including any State or local governmental entity, private insurance carrier, or employer), under any other law or contractual agreement, to pay for such care and treatment, and shall be paid by the Director only after all third-party payers have made payment in satisfaction of their obligations.

(d) Payment may include costs for providing ambulance or other medical transportation when such services are deemed necessary by the Director for the individual's care and treatment.

(e) Payment shall be limited to those amounts the hospital, medical facility, or medical transportation service would customarily bill the Medicare system using the International Classification of Diseases, Clinical Modification (ICD-CM), and relevant regulations promulgated by the Centers for Medicare and Medicaid Services in existence at the time of billing.

(f) For quarantinable communicable diseases, payment shall be limited to costs for services and items reasonable and necessary for the care and treatment of the individual for the time period beginning when the Director refers the individual to the hospital or medical facility and ends when, as determined by the Director, the period of apprehension, quarantine, isolation, or conditional release expires.

(g) For diseases other than those described in paragraph (f) of this section, such payment shall be limited to costs for services and items reasonable and necessary for care and treatment of the individual for the time period that begins when the Director refers the individual to the hospital or medical facility and ends when the individual's condition is diagnosed, as determined by the Director, as an illness

other than a quarantinable communicable disease.

(h) For ambulance or other medical transportation, payment shall be limited to the costs for such services and other items reasonable and necessary for the safe medical transport of the individual.

■ 13. Amend § 71.33 by revising paragraphs (a) and (c) to read as follows:

§ 71.33 Persons: Isolation and surveillance.

(a) The Director will arrange for adequate food and water, appropriate accommodation, appropriate medical treatment, and means of necessary communication for persons who are apprehended or held in isolation or quarantine under this subpart.

* * * * *

(c) Every person who is placed under surveillance by authority of this subpart shall, during the period of surveillance:

(1) Give information relative to his/her health and his/her intended destination and submit to surveillance, including electronic and internet-based monitoring as required by the Director or by the State or local health department having jurisdiction over the areas to be visited, and report for such medical examinations as may be required.

(2) Inform the Director prior to departing the United States or prior to traveling to any address other than that stated as the intended destination.

* * * * *

■ 14. Add §§ 71.36 through 71.39 to subpart D to read as follows:

Sec.

* * * * *

71.36 Medical examinations.

71.37 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release.

71.38 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release (surveillance).

71.39 Medical review of a Federal order for quarantine, isolation, or conditional release.

§ 71.36 Medical examinations.

(a) The Director may require that an individual arriving into the United States undergo a medical examination as part of a Federal order for quarantine, isolation, or conditional release.

(b) The Director shall promptly arrange for the medical examination to be conducted when one is required under this section and shall as part of the Federal order advise the individual that the medical examination shall be conducted by an authorized and licensed health worker, and with prior informed consent.

(c) As part of the medical examination, the Director may require

that an individual provide information and undergo such testing, as may be reasonably necessary, to diagnose or confirm the presence, absence, or extent of infection with a quarantinable communicable disease.

(d) Individuals reasonably believed to be infected, based on the results of a medical examination, may be isolated, or if such results are inconclusive or unavailable, individuals may be quarantined or conditionally released in accordance with this part.

§ 71.37 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release.

(a) A Federal order authorizing quarantine, isolation, or conditional release shall be in writing, signed by the Director, and contain the following information:

(1) The identity of the individual or group subject to the order;

(2) The location of the quarantine or isolation or, in the case of conditional release, the entity to who and means by which the individual shall report for public health supervision;

(3) An explanation of the factual basis underlying the Director's reasonable belief that the individual is exposed to or infected with a quarantinable communicable disease;

(4) An explanation that the Federal order will be reassessed no later than 72 hours after it has been served and an explanation of the medical review of the Federal order pursuant to this part, including the right to request a medical review, present witnesses and testimony at the medical review, and to be represented at the medical review by either an advocate (e.g., an attorney, family member, or physician) at the individual's own expense, or, if indigent, to have representatives appointed at the government's expense;

(5) An explanation of the criminal penalties for violating a Federal order of quarantine, isolation, or conditional release; and

(6) An explanation that if a medical examination is required as part of the Federal order that the examination will be conducted by an authorized and licensed health worker, and with prior informed consent.

(b) A Federal order authorizing quarantine, isolation, or conditional release shall be served on the individual no later than 72 hours after the individual has been apprehended, except that the Federal order may be published or posted in a conspicuous location if applicable to a group of individuals and individual service would be impracticable.

(c) The Director shall arrange for translation or interpretation services of the Federal order as needed.

(d) Nothing in these regulations shall affect the constitutional or statutory rights of individuals to obtain judicial review of their federal detention.

§ 71.38 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release (surveillance).

(a) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall reassess the need to continue the quarantine, isolation, or conditional release of an individual no later than 72 hours after the service of the Federal order.

(b) As part of the reassessment, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall review all records considered in issuing the Federal order, including travel records, records evidencing exposure or infection with a quarantinable communicable disease, as well as any relevant new information.

(c) As part of the reassessment, and where applicable, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall consider and make a determination regarding whether less restrictive alternatives would adequately serve to protect the public health.

(d) At the conclusion of the reassessment, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall promptly issue a written Federal order directing that the quarantine, isolation, or conditional release be continued, modified, or rescinded.

(e) In the event that the Director orders that the quarantine, isolation, or conditional release be continued or modified, the written Federal order shall explain the process for requesting a medical review under this part.

(f) The Director's written Federal order shall be promptly served on the individual, except that the Federal order may be served by publication or by posting in a conspicuous location if applicable to a group of individuals and individual service would be impracticable.

(g) The Director shall arrange for translation or interpretation services of the Federal order as needed.

§ 71.39 Medical review of a Federal order for quarantine, isolation, or conditional release.

(a) The Director shall, as soon as practicable, arrange for a medical review

upon a request by an individual under Federal quarantine, isolation, or conditional release.

(b) A request for a medical review may only occur after the Director's mandatory reassessment under 71.38 and following the issuance and service of a Federal order continuing or modifying the quarantine, isolation, or conditional release.

(c) The medical review shall be for the purpose of ascertaining whether the Director has a reasonable belief that the individual is infected with a quarantinable communicable disease.

(d) The Director shall notify the individual in writing of the time and place of the medical review.

(e) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall designate a medical reviewer to review the medical or other evidence presented at the review, make medical or other findings of fact, and issue a recommendation concerning whether the Federal order for quarantine, isolation, or conditional release should be rescinded, continued, or modified.

(f) The individual subject to Federal quarantine, isolation, or conditional release may authorize an advocate (e.g., an attorney, family member, or physician) at his or her own expense to submit medical or other evidence and, in the medical reviewer's discretion, be allowed to present a reasonable number of medical experts. The Director shall appoint representatives at government expense to assist the individual for purposes of the medical review upon a request and certification, under penalty of perjury, by that individual that he/she is indigent.

(g) Prior to the convening of the review, the individual or his/her authorized advocate or representatives shall be provided a reasonable opportunity to examine the available medical and other records involved in the medical review pertaining to that individual.

(h) The Director shall take such measures that he/she determines to be reasonably necessary to allow an individual under Federal quarantine or isolation to communicate with any authorized advocate or representatives in such a manner as to prevent the possible spread of the quarantinable communicable disease.

(i) The medical reviewer may order a medical examination of an individual when, in the medical reviewer's professional judgment, such an examination would assist in assessing the individual's medical condition.

(j) As part of the review, and where applicable, the medical reviewer shall

consider and accept into the record evidence concerning whether less restrictive alternatives would adequately serve to protect public health.

(k) The medical review shall be conducted by telephone, audio or video conference, or through other means that the medical reviewer determines in his/her discretion are practicable for allowing the individual under quarantine, isolation, or conditional release to participate in the medical review.

(l) At the conclusion of the review, the medical reviewer shall, based upon his or her review of the facts and other evidence made available during the medical review, issue a written report to the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) concerning whether, in the medical reviewer's professional judgment, the Federal quarantine, isolation, or conditional release should continue. The written report shall include a determination regarding whether less restrictive alternatives would adequately serve to protect public health. The written report shall be served on the individual and the individual's authorized advocate or representatives.

(m) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall, as soon as practicable, review the written report and any objections that may be submitted by the individual or the individual's advocate or representatives that contest the findings and recommendation contained in the medical reviewer's written report. Upon conclusion of the review, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall promptly issue a written Federal order directing that the quarantine, isolation, or conditional release be continued, modified, or rescinded. In the event that the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) continues or modifies the Federal quarantine, isolation, or conditional release, the Director's written order shall include a statement that the individual may request that the Director rescind the Federal quarantine, isolation, or conditional release, but based only on a showing of significant, new or changed facts or medical evidence that raise a genuine issue as to whether the individual should continue to be subject to Federal quarantine, isolation, or conditional release. The written Federal order shall be promptly served on the individual and the individual's authorized advocate or

representatives, except that the Federal order may be served by publication or by posting in a conspicuous location if applicable to a group of individual's and individual service would be impracticable.

(n) The Director's written order shall not constitute final agency action until it has been served on the individual or the individual's authorized advocate or representatives, or alternatively, if applicable to a group of individuals and individual service would be impracticable, it is published or posted.

(o) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) may order the consolidation of one or more medical reviews if the number of individuals or other factors makes the holding of individual medical reviews impracticable.

(p) The Director may issue additional instructions as may be necessary or

desirable governing the conduct of medical reviews.

(q) The Director shall arrange for translation or interpretation services as needed for purposes of this section.

■ 15. Add § 71.63 to subpart F to read as follows:

§ 71.63 Suspension of entry of animals, articles, or things from designated foreign countries and places into the United States.

(a) The Director may suspend the entry into the United States of animals, articles, or things from designated foreign countries (including political subdivisions and regions thereof) or places whenever the Director determines that such an action is necessary to protect the public health and upon a finding that:

(1) There exists in a foreign country (including one or more political subdivisions and regions thereof) or place a communicable disease the introduction, transmission, or spread of

which would threaten the public health of the United States; and

(2) The entry of imports from that country or place increases the risk that the communicable disease may be introduced, transmitted, or spread into the United States.

(b) The Director shall designate the foreign countries or places and the period of time or conditions under which the introduction of imports into the United States shall be suspended. The Secretary or Director will coordinate in advance with other Federal agencies that have overlapping authority in the regulation of entry of animals, articles, or other things, as may be necessary to implement and enforce this provision.

Dated: January 9, 2017.

Sylvia M. Burwell,
Secretary.

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Part V

Department of Agriculture

Animal and Plant Health Inspection Service

7 CFR Parts 318, 319, 330, et al.

Plant Pest Regulations; Update of Provisions; Proposed Rule

DEPARTMENT OF AGRICULTURE**Animal and Plant Health Inspection Service****7 CFR Parts 318, 319, 330, and 352****[Docket No. APHIS-2008-0076]****RIN 0579-AC98****Plant Pest Regulations; Update of Provisions****AGENCY:** Animal and Plant Health Inspection Service, USDA.**ACTION:** Proposed rule; withdrawal and reproposal.

SUMMARY: We are proposing to revise our regulations regarding the movement of plant pests. We are proposing criteria regarding the movement and environmental release of biological control organisms, and are proposing to establish regulations to allow the importation and movement in interstate commerce of certain types of plant pests without restriction by granting exceptions from permitting requirements for those pests. We are also proposing to revise our regulations regarding the movement of soil. This proposed rule replaces a previously published proposed rule, which we are withdrawing as part of this document. This proposal would clarify the factors that would be considered when assessing the risks associated with the movement of certain organisms and facilitate the movement of regulated organisms and articles in a manner that also protects U.S. agriculture.

DATES: We will consider all comments that we receive on or before March 20, 2017.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0076>.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2008-0076, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road, Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0076> or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to

help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Colin D. Stewart, Assistant Director; Pests, Pathogens, and Biocontrol Permits Branch, Plant Health Programs, PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737-1236; (301) 851-2237.

SUPPLEMENTARY INFORMATION:**Background**

Under the Plant Protection Act (7 U.S.C. 7712 *et seq.*, referred to below as the PPA or the Act), the Secretary of Agriculture has authority to carry out operations or measures to detect, control, eradicate, suppress, prevent, or retard the spread of plant pests. Section 7711(a) of the Act provides that “no person shall import, enter, export, or move in interstate commerce any plant pest, unless the importation, entry, exportation, or movement is authorized under general or specific permit and in accordance with such regulations as the Secretary may issue to prevent the introduction of plant pests into the United States or the dissemination of plant pests within the United States.” The Act gives the United States Department of Agriculture (USDA) the flexibility to respond appropriately to a wide range of needs and circumstances to protect American agriculture against plant pests. The Act defines a plant pest as “any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: (A) A protozoan; (B) A nonhuman animal; (C) A parasitic plant; (D) A bacterium; (E) A fungus; (F) A virus or viroid; (G) An infectious agent or other pathogen; (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs.”

In addition, section 412(a) of the Act provides that the Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of, among other things, any biological control organism if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States. The Act defines a biological control organism as “any enemy, antagonist, or competitor used to control a plant pest or noxious weed.”

The purpose of the regulations in “Subpart—Movement of Plant Pests” (7 CFR 330.200 through 330.212) and “Subpart—Movement of Soil, Stone, and Quarry Products” (7 CFR 330.300 through 330.301) is to prevent the

dissemination of plant pests into the United States, or interstate, by regulating the importation and interstate movement of plant pests, soil, stone, and quarry products.

These regulations were issued by the Animal and Plant Health Inspection Service (APHIS) under the authority provided by, among other statutes, the Department of Agriculture Organic Act of 1944, as amended (7 U.S.C. 147a), and the Federal Plant Pest Act, as amended (7 U.S.C. 150aa through 150jj), both of which were superseded and repealed by the PPA. Most of the provisions of the PPA regarding the importation and movement of plant pests were modeled on or directly derived from these two Acts; thus, the enactment of the PPA did not necessitate a major revision of the subpart. However, the PPA did contain provisions that clarified the authority in the earlier Acts regarding, among other things, our ability to regulate the importation and interstate movement of biological control organisms, as well as noxious weeds and associated articles.

Accordingly, on October 9, 2001 (66 FR 51340-51358, Docket No. 95-095-2), we published in the **Federal Register** a proposed rule which would have revised the plant pest regulations. Among other proposed provisions, it would have established a notification process that could be used as an alternative to the permitting system, provided for the environmental release of organisms for the biological control of weeds, and updated the text of the subpart to reflect the provisions of the PPA.

We solicited comments for 60 days ending December 10, 2001. We received 1,332 comments by that date. They were from State Departments of Agriculture, a State fish and wildlife agency, universities, plant societies, biocontrol organizations, USDA’s Forest Service and Agricultural Research Service, the U.S. Environmental Protection Agency (EPA), zoological associations, the World Trade Organization, pharmaceutical groups and biological supply companies, wildlife protection and conservation groups, trade organizations, butterfly breeders and associations, elementary schools, and private citizens.

The majority of the comments that we received were from schools and students who requested that we continue to allow the environmental release of Monarch butterflies as part of a learning curriculum. Some of these commenters also requested that we continue to allow the environmental

release of Monarch butterflies for weddings and other ceremonies.¹

We also received comments that addressed the proposed rule both generally and in regard to its specific provisions. Commenters often requested clarification regarding or suggested modification to several of the rule's provisions, but were, on the whole, generally supportive of the proposed rule. Accordingly, based on our evaluation of the comments that we received, we planned to issue a final rule.

However, the events of September 11, 2001, led to a further evaluation of our proposal to determine whether the proposed provisions had sufficient safeguards governing our permitting process. Specifically, we evaluated whether an aspect of our proposal, which would have authorized the importation of regulated organisms without prior issuance of a permit, provided that the party receiving the organisms had entered into a compliance agreement with APHIS, could serve as a potential venue for bioterrorism. We also temporarily suspended issuance of new plant pest permits.

In addition, on March 31, 2003, USDA's Office of the Inspector General (OIG) issued an audit of APHIS' permitting programs. Among other things, the audit examined APHIS' issuance of plant pest permits, and its administration of the permitting process. The audit suggested that we implement ePermits, a more thorough and technologically advanced permitting database than that used at the time, that we discontinue our practice at the time of issuing "blanket" permits to individuals or organizations to move plant pests and biological control organisms in favor of specific permits for each movement of a regulated organism, that we require more thorough documentation of an organism's intended use on each permit application, that we develop risk-based criteria for deciding whether or not to issue a permit for a particular movement, that we inspect the destinations listed on permit

applications more regularly to evaluate their suitability for the organisms held onsite, and that we establish clear protocols, with an adequate degree of APHIS oversight, regarding the disposal of organisms once a permit expires. A 2007 followup OIG audit again encouraged us to fully implement ePermits, particularly at ports of entry into the United States.

Although APHIS has not substantively revised the regulations in the subpart since the promulgation of the PPA and the release of the OIG audits, these audit reports have informed Agency decisions regarding our regulation of the movement of plant pests, biological control organisms, and associated articles.

In this proposal, we are withdrawing our 2001 proposed rule and replacing it with an alternative proposal. This proposal retains several of the provisions of the 2001 proposal. For example, the conditions under which we would consider an organism a plant pest, and thus regulated by the subpart, remain similar to those of the 2001 proposal. However, this proposal also removes or modifies other provisions of the 2001 proposal. For example, we have removed provisions that would have authorized the movement of regulated organisms through a process consisting of compliance agreements and notification of movement.

Additionally, this proposal also incorporates new provisions that were not contained in the 2001 proposed rule but that would codify procedures that we have identified as best practices since that time but not yet added to the regulations.

The most significant changes in this new proposal are:

- We are proposing to establish criteria for the movement and environmental release of both biological control organisms of noxious weeds and those of plant pests; and
- We are proposing to remove "Subpart—Movement of Soil, Stone, and Quarry Products" and would instead regulate these articles in a subpart titled "Subpart—Movement of Plant Pests, Biological Control Organisms, and Associated Articles."

The full text of the proposed regulations appears in the rule portion of this document. Our discussion of the proposed provisions follows.

Definitions

In addition to our proposed revision of "Subpart—Movement Plant Pests" and removal of "Subpart—Movement of Soil, Stone, and Quarry Products," we would also revise § 330.100, "Definitions," of "Subpart—General

Provisions," to incorporate the applicable new definitions provided by the PPA and to update or eliminate some of the definitions currently provided in that section.

From the PPA, we would add definitions for the terms *article*, *biological control organism*, *enter (entry)*, *export (exportation)*, *import (importation)*, *noxious weed*, *plant*, and *plant product*; and we would replace the current definitions of *move (moved and movement)*, *permit*, *person*, *plant pest*, and *State* with the definitions provided for those terms in the PPA. However, regarding the definition of *permit*, although the PPA definition mentions the issuance of oral permits, our proposed definition does not. For the purposes of the plant pest regulations, oral permits would not provide a reliable means of verifying that a permittee was aware of the permit conditions at the time he or she was issued the permit, and would, we believe, adversely affect APHIS' ability to ensure appropriate compliance and enforcement of our regulatory requirements.

We would also add definitions for *Animal and Plant Health Inspection Service (APHIS)*, *biocontainment facility*, *EPA*, *hand-carry*, *interstate movement*, *living*, *permittee*, *responsible individual*, *secure shipment*, *sterilization (sterile, sterilized)*, *taxon (taxa)*, *transit*, and *U.S. Customs and Border Protection (CBP)*. We will first discuss what we mean by the term *taxon (taxa)*. We will then discuss, in alphabetical order, the definitions of the other new terms that we are proposing to add to the regulations.

We would define *taxon (taxa)* as: "Any recognized grouping or rank within the biological nomenclature of organisms, such as class, order, family, genus, species, subspecies, pathovar, biotype, race, forma specialis, or cultivar." This proposed definition is based on the International Plant Protection Convention's (IPPC's) Glossary of Phytosanitary Terms,² which uses *taxon*, at various points, in reference to family, species, and subspecies.

We would define the term *Animal and Plant Health Inspection Service (APHIS)* as: "The Animal and Plant Health Inspection Service of the United States Department of Agriculture."

We would define the term *biocontainment facility* as: "A physical structure, or portion thereof,

¹ Under this proposed rule, which withdraws our 2001 proposal, we would authorize the issuance of permits for the environmental release of Monarch butterflies in accordance with current practices. Under these practices, permits issued to permittees who reside east of the Rocky Mountains would authorize the environmental release of Monarch butterflies east of the Rockies, while those issued for permittees who reside west of the Rocky Mountains would authorize the environmental release of Monarch butterflies west of the Rockies. This is because there are two distinct ecological ranges for Monarchs in the United States, with each terminating at the Rocky Mountains.

² International Standard for Phytosanitary Measures (ISPM) Number 5. To view this and other ISPMs, go to <https://www.ippc.int/en/core-activities/standards-setting/ispm/#publications>.

constructed and maintained in order to contain plant pests, biological control organisms, or associated articles.”

We would define the term *EPA* as: “The Environmental Protection Agency of the United States.”

We would define the term *hand-carry* as: “Importation of an organism that remains in one’s personal possession and in close proximity to one’s person.” Our requirements governing the movement of plant pests by baggage, currently found in § 330.212, are commonly referred to as the “hand-carry” regulations; we are proposing to revise these requirements.

We would define the term *interstate movement* as: “Movement from one State into or through any other State; or movement within the District of Columbia, Guam, the U.S. Virgin Islands, or any other territory or possession of the United States.”

We would define the term *living* as: “Viable or potentially viable.” We are including “potentially viable” within our definition of *living* because most viruses and retroviruses of plants and plant products cannot grow or reproduce outside of a host cell; however, once inserted into the cell, they are capable of both growth and self-replication, and, over time, exhibit pathogenic effects. Because of this potential for both growth and self-replication, it is generally our policy to consider such viruses living plant pests, and to require a permit for their importation, interstate movement, transit, or continued curation.

We would define the term *permittee* as: “The person to whom APHIS has issued a permit in accordance with this part and who must comply with the provisions of the permit and the regulations in this part.”

We would define the term *responsible individual* as: “The individual who a permittee designates to oversee and control the actions taken under a permit issued in accordance with this part for the movement or curation of a plant pest, biological control organism, or associated article. For the duration of the permit, the individual must be physically present during normal business hours at or near the location specified on the permit as the ultimate destination of the plant pest, biological control organism, or associated article, and must serve as a primary contact for communication with APHIS. The permittee may designate him or herself as the responsible individual. The responsible individual must be at least 18 years of age. In accordance with section 7734 of the PPA, the act, omission, or failure of any responsible

individual will also be deemed the act, omission, or failure of a permittee.”

Historically, we have only issued permits for the movement of plant pests, biological control organisms, and associated articles to individuals. However, as provided for in the definition of *permittee*, we would allow corporate entities to obtain permits under the revised regulations. This change will allow for better tracking and communication regarding a permit or permit application, and will also make it clear that the corporation as a whole is responsible for the permit. In such instances, we believe that it is of paramount importance that the permittee specifies a person whom APHIS may contact regarding the actions authorized under the permit who has first-hand knowledge of these actions. The responsible individual would fulfill this role.

We anticipate that, if this rule is finalized, we would still issue a significant number of permits to individuals, rather than corporate entities. We expect that, for the majority of such permits, the permittee would wish to designate him or herself as the responsible individual; therefore, the definition of *responsible individual* would allow for such designation.

Finally, Section 7734 of the PPA provides that a person will be held liable for the acts, omissions, and failures of an agent acting for that person, as long as the agent is acting within the scope of his or her office. Responsible individuals would be agents of the permittee pursuant to this section of the PPA.

We would define the term *secure shipment* as: “Shipment of a regulated plant pest, biological control organism, or associated article in a container or a means of conveyance of sufficient strength and integrity to prevent leakage of contents and to withstand shocks, pressure changes, and other conditions incident to ordinary handling in transportation.”

We would define the term *sterilization (sterile, sterilized)* as: “A chemical or physical process that results in the death of all living organisms on or within the article subject to the process. Examples include, but are not limited to, autoclaving and incineration.”

Note that, for the purposes of this subpart, the term sterilization does not refer to techniques that neutralize an organism by rendering it incapable of sexual reproduction. We recognize that this alternate meaning of the term “sterilization” might be more common within the regulated community, but believe that it is clear from the manner

in which we would use the term in the revised subpart that it would have a different meaning within these regulations.

We would define the term *transit* as: “Movement from and to a foreign destination through the United States.” This definition would replace a definition currently in the regulations, *through the United States*, which we define as: “From and to places outside the United States.”

We would define the term *U.S. Customs and Border Protection (CBP)* as: “U.S. Customs and Border Protection within the Department of Homeland Security.” This definition would replace the now outdated definition of *Customs* in the current regulations.

In addition, we would substantively revise the definition of *soil*. We currently define *soil* as: “The loose surface material of the earth in which plants grow, in most cases consisting of disintegrated rock with an admixture of organic material and soluble salts.” We would redefine *soil* as: “The unconsolidated material from the earth’s surface that consists of rock and mineral particles and that supports or is capable of supporting biotic communities.” This definition aligns with the current scientific understanding of soil, and would resolve ambiguities in the current definition that could be construed to suggest that soil includes consolidated or sterile matter that does not present a risk of harboring plant pests or noxious weeds. (For purposes of the regulations, it does not.) We would also remove the definition of *earth*, “the softer matter composing part of the surface of the globe, in distinction from the firm rock, and including the soil and subsoil, as well as finely divided rock and other soil formation materials down to the rock layer,” from the regulations.

We would remove the definition of *Plant Protection Act*. The Act is cited in the authority citation for part 330, and we do not believe it is necessary to define it in the regulations.

We would make nonsubstantive editorial changes to the definitions of *administrative instructions*, *Administrator*, *Department*, *Deputy Administrator*, *inspector*, *means of conveyance*, *owner*, and *Plant Protection and Quarantine Programs*.

Finally, we would retain, without modification, the existing definitions of *garbage*, *regulated garbage*, and *shelf-stable*.

Titles of the Part and Subpart

Currently, the title of part 330, “Federal Plant Pest Regulations; General; Plant Pests; Soil, Stone, and Quarry Products; Garbage,” reflects the

titles of its four subparts. As mentioned above, we are proposing to revise the second subpart, currently titled “Subpart—Movement of Plant Pests,” to clarify that it regulates the movement not only of plant pests, but also of biological control organisms and associated articles, including soil. Since we would now regulate soil within that subpart, we would remove and reserve the third subpart, “Subpart—Soil, Stone, and Quarry Products.”

For this reason, we would also update the title of the second subpart. As amended, it would now be titled “Subpart—Movement of Plant Pests, Biological Control Organisms, and Associated Articles.”

As a result of these proposed revisions, we would also revise the title of the part. It would now be titled: “Federal Plant Pest Regulations; General; Plant Pests, Biological Control Organisms, and Associated Articles; Garbage.”

Scope and General Restrictions (§ 330.200)

The proposed regulations would begin by establishing the scope of the revised subpart. Paragraph (a) would state that no person shall import, move interstate, transit, or release into the environment plant pests, biological control organisms, or associated articles, unless the importation, interstate movement, transit, or release into the environment of the plant pests, biological control organisms, or associated articles is:

- Authorized under an import, interstate movement, or continued curation permit issued in accordance with proposed § 330.201;
- Authorized in accordance with other APHIS regulations in 7 CFR chapter III;
- Explicitly granted an exception or exemption in the revised subpart from permitting requirements.
- Authorized under a general permit issued by the Administrator.

By “authorized in accordance with other APHIS regulations in 7 CFR chapter III,” we mean that certain movements of plant pests or associated articles are regulated under other APHIS regulations in title 7. For example, the transit of a plant pest through the United States would require a permit issued in accordance with § 352.5 of the plant quarantine safeguard regulations in 7 CFR part 352, and the interstate movement of regulated associated articles of domestic quarantine pests (e.g., host articles of pine shoot beetle or Asian citrus psyllid) normally require certificates or limited permits issued in accordance with their respective

subparts in the domestic quarantine notice regulations of 7 CFR part 301.

We discuss the exemptions from permitting requirements that we are proposing to grant for certain categories of biological control organisms in the discussion under the heading “*Biological control organisms* (§ 330.202),” and the exceptions from permitting requirements that we are proposing to grant for certain plant pests in the discussion under the heading “*Exceptions to permitting requirements for the importation or interstate movement of certain plant pests* (§ 330.204).”

Finally, to date, we have only issued specific permits, that is, permits issued to specific persons, for the interstate movement of plant pests. However, pursuant to section 7711 of the PPA, the Administrator may also issue general permits, that is, general authorizations, for the importation or interstate movement of plant pests.

In recent years, we have contemplated issuing a general, Web-based permit for the interstate movement of certain plant pests that we regard to be low-risk unless they are moved into certain areas of the United States, rather than specific permits for the movement of these pests. If we finalize proposed paragraph (a) of § 330.200 and decide to issue such a permit, we would announce the existence, location, and content of this general permit through a notice in the **Federal Register**.

Paragraph (b) of § 330.200 would specify the types of plant pests that we would regulate under the revised subpart. The paragraph would state that, for the purposes of the subpart, we would consider an organism to be a plant pest if the organism either directly or indirectly injures, causes damage to, or causes disease in a plant or plant product, or if the organism or part is an unknown risk to plants or plant products, but is similar to an organism known to directly or indirectly injure, cause damage to, or cause disease in a plant or plant product.

This paragraph, which is not found in the current regulations, is similar to the criteria for designating an organism a plant pest that were contained in our 2001 proposal. We have, however, made two changes to those criteria.

First, while our 2001 proposal would have designated certain organisms as plant pests if they directly or indirectly adversely affected plants, plant parts, or plant products, in this proposed rule, we would designate these organisms as plant pests if the organisms directly or indirectly injure, cause damage to, or cause disease in a plant or plant product. These latter criteria are based

on the definition of *plant pest* found in the PPA, and have been our framework in recent years for determining whether an organism is a plant pest.

We would also expand the scope of our 2001 proposal so that we may consider organisms of an unknown risk to plants or plant products to be plant pests, provided that the organisms are similar to an organism known to directly or indirectly injure, cause damage to, or cause disease in a plant or plant product.

In our 2001 proposal, we did propose that organisms of an unknown risk to plants or plant products would require a permit, but we would have designated them regulated organisms rather than plant pests. We also stated that permitting conditions for such organisms would be aimed primarily at affording us an opportunity to identify and deal with the organisms with some initial degree of regulatory oversight, in order to prevent the dissemination of plant pests into or within the United States. We thus framed permitting requirements for such organisms as a necessary stopgap measure pending positive identification of the organism and an assessment of the organism’s potential risk to plants and plant products.

However, since 2001, there have been numerous occasions when applicants have requested authorization to import organisms that cannot readily be identified to the species level for a significant portion of their lifespans, but that may be plant pests. For example, we have issued several plant pest permits for the importation of larval scarabs. Before becoming mature, all scarabs are morphologically similar to one another and exhibit similar feeding patterns, but are not plant pests. However, once mature, certain scarab species are plant pests. In order to take this potential for future effects on plants, plant parts, and plant products into consideration, in issuing a permit for any scarab grub, we have considered it to be a plant pest, and tailored permitting and containment requirements accordingly.

Paragraph (c) of § 330.200 would specify the types of biological control organisms that we would regulate under the revised subpart. Although the PPA defines a biological control organism as “any enemy, antagonist, or competitor used to control a plant pest or noxious weed,” practically speaking, we have only required permits for certain types

of biological control organisms since the PPA was promulgated.³ These are:

- Invertebrate predators and parasites (parasitoids) used to control invertebrate plant pests,
- Invertebrate competitors used to control invertebrate plant pests,
- Invertebrate herbivores used to control noxious weeds,
- Microbial pathogens used to control invertebrate plant pests,
- Microbial pathogens used to control noxious weeds, and
- Microbial parasites used to control plant pathogens.

Regarding these types of biological control organisms, we recognize that biological control organisms used to control noxious weeds are also plant pests, insofar as they injure, cause damage to, or cause disease in plants. However, since this effect is desirable and ultimately beneficial to other plants, plant parts, and plant products, it has been our policy to draft permitting conditions for the movement and environmental release of these organisms in a manner that encourages these effects, unless we have reason to believe that the organisms may also have plant pest effects on non-target plants or plant products.

As noted in the previous paragraphs, there are some types of biological control organisms for which we have not historically issued permits. However, there may be times when there would be a risk-based need to regulate the importation or interstate movement of an organism that falls within the PPA's definition of a *biological control organism*, but does not fall into any of the types of organisms listed above. For example, if a microbial parasite that has not previously been evaluated is put forth for the control of pathogenic fungi, it would not fall within the above categories, but could be an organism we would wish to regulate out of concern of the possibility of effects on non-target plants, such as fungi without phytopathogenic properties. To this end, paragraph (c) would also provide that other types of biological control organisms could be regulated under the revised subpart, as determined by APHIS. This determination would typically be on a case-by-case basis, and would be based on a permit application for movement of an organism which did not belong to any of the above types, but

for which the Administrator determined it necessary to exercise a degree of regulatory oversight in order to prevent the introduction of a plant pest into the United States or the dissemination of a plant pest within the United States.

Paragraph (d) would exempt biological control organism products that EPA has issued experimental use permits for or that EPA has registered as microbial pesticide products having outdoor uses from regulatory oversight under the revised subpart. Under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*, FIFRA), EPA regulates certain biological control organisms (eukaryotic microorganisms, prokaryotic microorganisms, and viruses) as "substances," and has established a registration process for their use as microbial pesticides. EPA issues experimental use permits (EUPs) to allow persons to release these organisms into the environment on a limited basis in order to obtain information necessary to apply to have the organisms registered as microbial pesticides. EPA also allows the transfer, sale, and/or distribution of unregistered pesticides under certain circumstances in accordance with its regulations in 40 CFR 152.30. Because registered or permitted products are already subject to extensive regulation by EPA, we have entered into a memorandum of understanding with EPA stating that we consider the products to be exempt from our regulatory oversight, and paragraph (d) would largely codify the policy in this memorandum. It would also address EPA's provision for the transfer, sale, and/or distribution of unregistered pesticides under certain circumstances, and allow for the importation and interstate movement of such unregistered pesticides without APHIS' oversight, because of EPA's oversight.

Permit Requirements (§ 330.201)

Section 330.201 would describe the types of permits that APHIS issues for plant pests, biological control organisms, and associated articles, the process for applying for a permit, and the manner in which APHIS acts on permit applications.

Paragraph (a) of § 330.201 would provide information regarding the types of permits that APHIS issues for plant pests, biological control organisms, and associated articles. It would state that we issue import permits, interstate movement permits, continued curation permits, and transit permits.

Paragraph (a)(1) would provide information regarding import permits. It would state that APHIS issues import permits to persons for secure shipment

from outside the United States into the territorial limits of the United States; that, when import permits are issued to individuals, these individuals must be 18 years of age or older and have a physical address within the United States; and that, when import permits are issued to corporate persons, these persons must maintain an address or business office in the United States with a designated individual for service of process.⁴

Paragraph (a)(2) would provide information regarding interstate movement permits. It would state that interstate movement permits are issued to persons for secure shipment from any State into or through any other State; that, when interstate movement permits are issued to individuals, these individuals must be 18 years of age or older and have a physical address within the United States; and that, when interstate movement permits are issued to corporate persons, these persons must maintain an address or business office in the United States with a designated individual for service of process.

Both import and interstate movement permits may contain conditions regarding the manner in which an organism may be moved from the destination listed on the permit. Such conditions are necessary to ensure that the organism is moved in a manner that will prevent its escape and dissemination and to ensure that the new facility to which it will be moved is capable of providing the necessary level of containment.

On a related matter, applicants for import and interstate movement permits should be aware that States and localities may have laws and regulations that restrict the movement or release of plant pests, biological control organisms, and associated articles for various reasons (for example, impact on the environment of the State or locality). We encourage applicants to consult with these authorities prior to applying for a permit.

Paragraph (a)(3) would provide information regarding continued curation permits. It would state that continued curation permits are issued in conjunction with and prior to the expiration date for an import permit or interstate movement permit, in order for the permittee to continue the actions listed on the import permit or interstate

³ It is worth noting that, prior to the PPA, we issued permits for the movement and release of invertebrate herbivores used to control noxious weeds and microbial pathogens used to control noxious weeds pursuant to authority in the Federal Plant Pest Act (FPPA). The FPPA was superseded and repealed by the PPA.

⁴ Please note that other Federal agencies have separate regulatory authority related to the importation of secure shipments of plant pests, biological control organisms, and associated articles. For example, pursuant to their general regulatory authority, DHS requires formal entry for organisms and soil that are imported via hand-carry or express courier organizations.

movement permit following the expiration of the original permit. It would also state that, when continued curation permits are issued to individuals, these individuals must be 18 years of age or older and have a physical address within the United States. It would further state that, when continued curation permits are issued to corporate persons, these persons must maintain an address or business office in the United States with a designated individual for service of process.

Paragraph (a)(4) would provide information regarding transit permits. It would state that transit permits are issued for secure shipments through the United States, and that such permits are issued in accordance with 7 CFR part 352. As we mentioned above, § 352.5 of that part contains permitting requirements for transit permits.

However, part 352 currently provides for the transit of plant pests, but does not provide for the transit of biological control organisms. Therefore, we would amend part 352 to include references to biological control organisms. (For this reason, we would also amend part 352 to add definitions for the terms *biological control organism* and *noxious weed*, and to revise the definitions for *Deputy Administrator*, *person*, *plant pest*, and *soil*. The revised definitions would be identical to the ones we are proposing for part 330.)

Currently, part 330 contains provisions for the issuance of several additional types of permits: Permits for plant pest movement associated with national defense projects, permits for means of conveyance, and courtesy permits for organisms that are not subject to APHIS regulation. However, we no longer issue a special type of permit specifically for national defense projects; if such a permit application arises, we issue the appropriate type of movement permit, and specify as a permit condition that the use of the organism is for a national defense project. Similarly, we do not issue permits specifically for means of conveyance; if we have reason to believe the means of conveyance may be an associated article, we regulate it as such and issue the appropriate movement permit.

Until 2009, we issued courtesy permits in order to facilitate the movement of organisms that were not regulated under 7 CFR part 330, but that were similar enough to a known plant pest or biological control organism that their movement might otherwise be impeded if they were not accompanied by some sort of documentation from APHIS during transit. However, courtesy permits historically generated

much confusion in the public and especially in the research community. The application form for courtesy permits was identical to the application for other types of permits, and the courtesy permit itself looked like other permits. This periodically led to the misunderstanding by some researchers that courtesy permits were required for the movement of certain organisms that were, in actuality, not subject to APHIS regulation. For these reasons, in recent years, Plant Protection and Quarantine (PPQ) has discontinued its issuance of courtesy permits for organisms that are similar to plant pests or biological control organisms, and it would not be necessary to include courtesy permits in the revised subpart.

In a related matter, § 330.207 of the current regulations states that APHIS recognizes permits issued by other Federal Agencies for the movement of regulated organisms and will issue administrative instructions or engage in correspondence with a permittee to augment the provisions of these permits through further conditions, rather than issue a duplicative permit.

We do not consider it necessary to retain those provisions in the revised subpart. First, we seldom engage in correspondence with the permittee for permits issued by another Federal agency, such as EUPs issued by EPA. Rather, if we believe that the actions authorized under the permit may place plants or plant products at risk, we discuss the matter with the issuing agency itself. Correspondingly, it is rare that we receive permit applications from applicants who have submitted a prior application to another regulatory agency. Therefore, the provisions do not reflect current Agency practices, and we believe that it is generally presupposed by the regulated community that we will recognize permits issued by other regulatory agencies for the movement of plant pests, biological control organisms, and associated articles.

Finally, we have periodically received requests from individuals to issue permits certifying organisms and associated articles that are destined for export from the United States. We note that foreign countries, rather than APHIS, set the conditions under which they will allow the importation of plant pests, biological control organisms, and associated articles from the United States. To this end, we would include a footnote stating that persons contemplating the shipment of plant pests, biological control organisms, or associated articles to places outside the United States should make arrangements directly, or through the recipient, with the country of

destination for the export of the plant pests, biological control organisms, or associated articles into that country.

That being said, for certain high-risk plant pests, interstate movement permits may place conditions on the interstate movement of the organism for export purposes. This is not included in the current regulations, but reflects recent Agency policy. Such conditions are necessary to safeguard the movement of the organism to the port of export.

Paragraph (b) of § 330.201 would provide that permit applications must be submitted by the applicant in writing or electronically through one of the methods specified at http://www.aphis.usda.gov/plant_health/permits/index.shtml, and must be submitted in advance of the action(s) proposed on the permit application. That Web page would specify that persons may apply for a permit via the Internet through APHIS' secure site for online permit applications, and would provide a link to that portal. It would also provide that a person may submit a permit application by faxing the application to APHIS, and would specify the appropriate fax number. Additionally, it would state that an application may be obtained by calling PPQ at the number provided. Finally, it would provide that a person may submit a permit application by mailing it to APHIS at the address provided. We note that because of the need for additional administrative processing, permit applications that are submitted via fax or by mail may not be reviewed as expeditiously as those submitted through APHIS' online portal. We encourage applicants to submit their applications electronically.

Paragraph (c) of § 330.201 would provide that a permit application must be complete before we will evaluate it in order to determine whether to issue the permit requested. Guidance regarding how to complete a permit application, including guidance specific to various information blocks on the application, would be available at http://www.aphis.usda.gov/plant_health/permits/index.shtml. The guidance would also specify that, in order to facilitate timely issuance of a permit, an application should be submitted at least 90 days before the actions proposed on the permit application are scheduled to take place, with additional time allotted for complex or novel applications, or applications for high-risk plant pests.

Paragraph (d) of § 330.301 would describe the actions APHIS takes on receiving a permit application. The introductory text to the paragraph

would state that APHIS reviews the information on the application to determine whether it is complete. In order to consider an application complete, APHIS may request additional information that we determine to be necessary in order to assess the risk to plants and plant products that may be posed by the actions proposed on the application. When it is determined that an application is complete, we commence review of the information provided.

Paragraph (d)(1) would describe the first part of APHIS' formal review, consultation with States, Tribes, and other individuals. We share a copy of the permit application, and the proposed permit conditions, with the appropriate State or Tribal regulatory officials, and may share them with other persons or groups to provide comment. For instance, we may share the permit application with persons or groups other than State or Tribal regulatory officials when we lack technical expertise to evaluate certain aspects of a permit application and need to solicit the opinion of individuals or groups with such expertise.

Paragraph (d)(2) would describe the second part of our review, our initial assessment of sites and facilities where the organism or article will be held or released that are listed on the permit application. Such sites and facilities may include private residences, biocontainment facilities, and field locations. Although we may not do an onsite inspection in some cases, all sites and facilities would be subject to inspection as part of the assessment. All facilities would have to be determined by APHIS to be constructed and maintained in a manner that prevents the dissemination or dispersal of plant pests, biological control organisms, or associated articles from the facility. Finally, the applicant would have to provide all information requested by APHIS regarding this assessment, and to allow all inspections requested by APHIS during normal business hours (8 a.m. to 4:30 p.m., Monday through Friday, excluding holidays). Failure to do so would constitute grounds for denial of the permit application.

Paragraphs (d)(3) and (d)(4) would describe the two possible actions we would take upon concluding review of the permit application: Issuance or denial of the requested permit. Paragraph (d)(3) would discuss permit issuance. APHIS may issue a permit to an applicant if APHIS concludes that the actions allowed under the permit would be highly unlikely to result in the introduction or dissemination of a plant pest, biological control organism, or

noxious weed within the United States in a manner that presents an unacceptable risk to plants and plant products.

We would specify that the actions allowed under the permit must be highly unlikely to result in the introduction or dissemination of a plant pest, biological control organism, or noxious weed within the United States in a manner that presents an unacceptable risk to plants and plant products because we would allow the environmental release of certain plant pests and biological control organisms under the revised subpart. The considerations that lead us to determine whether to authorize the environmental release of such organisms are discussed later in this document.

Paragraphs (d)(3)(i) through (d)(3)(iv) would describe the manner in which APHIS would issue a permit under the revised subpart. Prior to issuing the permit, APHIS would notify the applicant in writing or electronically of all proposed permit conditions. The applicant would have to agree in writing or electronically that he or she, and all his or her employees, agents, and/or officers, would comply with all permit conditions and all provisions of the regulations. If the organism or associated article will be contained in a private residence, the applicant would have to state in this agreement that he or she authorizes APHIS to conduct unscheduled assessments of the residence during normal business hours if a permit is issued.

APHIS would issue the permit after it receives and reviews the applicant's agreement. The permit would be valid for no more than 3 years. During that period, the permittee would have to abide by all permitting conditions,⁵ and use of the organism or article would have to conform to the intended use on the permit. Moreover, the use of organisms derived from a regulated parent organism during that period would have to conform to the intended use specified on the permit for the parent organism.

We would specify that the use of the organism or article under the permit must conform to the intended use on the permit, because, on occasion, laboratories have obtained a permit for the movement of a plant pest or biological control organism into biocontainment, and then used the organism for purposes that differed from

⁵ Permitting conditions may reference the regulations and policies of other Federal agencies. For example, an import permit may provide conditions that a permittee must abide by in order for customs entry of his or her shipment to occur pursuant to CBP's regulations in title 19 of the CFR.

those specified as the intended use on the permit. In such instances, APHIS was not afforded an opportunity to evaluate the uses and determine whether they present a risk to plants and plant products within the United States. There have also been instances when laboratories have claimed that subsequent generations derived from a parent organism during the time period specified on a permit are distinct organisms, and thus should not be subject to the conditions specified on the permit and may be used at the laboratory's discretion. Such unregulated use of subsequent generations or progeny could present a risk of dissemination of the pest. Hence, we would require that the use of organisms derived from a regulated parent organism must conform to the intended use specified on the permit application for the parent organism.

All activities carried out under the permit would have to cease on or before the expiration date of the permit, unless, prior to that expiration date, the permittee has submitted a new permit application and a new permit has been issued to authorize continuation of the actions.

Finally, at any point following issuance of a permit but prior to its expiration date, an inspector could conduct unscheduled assessments of the site or facility in which the organisms or associated articles are held, to determine whether they are constructed and are being maintained in a manner that prevents the dissemination of organisms or associated articles from the site or facility. As with inspections associated with our initial assessment of sites or facilities prior to permit issuance, the permittee would have to allow all such assessments that we request during normal business hours. Failure to allow such assessments would constitute grounds for revocation of the permit.

Paragraph (d)(4) would set forth the conditions under which APHIS may deny an application for a permit. Currently, in § 330.204 of the regulations, APHIS will deny a permit application when such movement would involve a danger of dissemination of the pest. Danger of plant pest dissemination may be deemed to exist when any of the following five conditions occurs:

- No acceptable safeguards adequate to prevent plant pest dissemination can be arranged.
- The destructive potential of the plant pest to plants, and parts and products thereof, should it escape despite proposed safeguards, outweighs the probable benefits to be derived from

the proposed movement and use of the pest.

- The applicant, as a previous permittee, failed to maintain the safeguards or otherwise observe the conditions prescribed in a previous permit and failed to demonstrate his ability or intent to observe them in the future.
- The movement is adverse to the conduct of an eradication, suppression, control, or regulatory program of APHIS.
- The movement is objected to in writing by an appropriate official of a State, Territory, or possession, or the District of Columbia, on the ground it will involve a danger of dissemination of the plant pest into the State, Territory or possession, or District.

Although the current regulations set out criteria that will factor into APHIS' judgment of risk and may lead us to deny a permit application, certain of the considerations have been understood by regulated entities to be absolute, and may have dissuaded persons from submitting applications for which we would have likely issued a permit. For example, for several years, there was an erroneous but widespread interpretation that the last condition afforded States and territories the right to "veto" permit applications. From this perspective, the current criteria may appear too strict.

Conversely, the current regulations do not mention circumstances that may arise during the application process that would call into question that person's ability to comply effectively with permitting conditions, such as an applicant refusing to allow APHIS to inspect a biocontainment facility listed on the application, and would thus make it unlikely that we would issue him or her a permit.

Accordingly, we are proposing to revise the conditions under which the Administrator may deny a permit application. The revised conditions would be the following:

- APHIS concludes that the actions proposed in the permit application would present an unacceptable risk to plants and plant products because of the introduction or dissemination of a plant pest, biological control organism, or noxious weed within the United States.

This condition is intended to replace the current first condition, which does not appear to allow for environmental release of a plant pest or biological control organism, and the second condition, sometimes referred to as the "balancing" condition, which can be construed to suggest that APHIS will issue a permit for a high-risk movement or use of a regulated organism, provided that the benefits potentially derived from that movement or use may be

equally great or greater. However, it is APHIS policy to base its decisions regarding permit issuance for the movement or use of plant pests, biological control organisms, and associated articles solely on an assessment of potential risk to plants and plant products associated with that movement or use.

We would retain the following two conditions drawn substantially from the current regulations:

- The actions proposed in the permit application would be adverse to the conduct of an APHIS eradication, suppression, control, or regulatory program.
- A State or Tribal executive official, or a State or Tribal plant protection official authorized to do so, objects to the movement in writing and provides specific, detailed information that there is a risk the movement will result in the dissemination of a plant pest or noxious weed into the State, APHIS evaluates the information and agrees, and APHIS determines that such plant pest or noxious weed risk cannot be adequately addressed or mitigated.

We would add the following conditions:

- The applicant does not agree to observe all of the proposed permit conditions that APHIS has determined are necessary to mitigate identified risks.
- The applicant does not provide information requested by APHIS as part of an assessment of sites or facilities, or does not allow APHIS to inspect sites or facilities associated with the actions listed on the permit application.
- APHIS determines that the applicant has not followed prior permit conditions, or has not adequately demonstrated that they can meet the requirements for the current application.

This last condition is intended to clarify the current third condition, which states that a permit application may be denied if the applicant, as a previous permittee, failed to maintain the safeguards or otherwise observe the conditions prescribed in a previous permit and failed to demonstrate his ability or intent to observe them in the future. Certain applicants have sought to interpret this current condition to suggest that actions taken under a previous permit cannot, on their own, serve as a basis for denying a future permit.

This interpretation is incorrect. In deciding to issue a permit, APHIS often relies on the previous actions of an applicant to render a judgment regarding the likelihood that the applicant can comply with the

permitting conditions. As a result, this last condition would also provide a list of factors that could lead us to a determination that the applicant cannot comply with the permit conditions:

- The applicant, or a partnership, firm, corporation, or other legal entity in which the applicant has a substantial interest, financial or otherwise, has not complied with any permit that was previously issued by APHIS.
- Issuing the permit would circumvent any order denying or revoking a previous permit issued by APHIS (for example, by issuing a permit to an immediate family member of a person with a lengthy record of non-compliance with previous permits issued.)
- The applicant has previously failed to comply with any APHIS regulation.
- The applicant has previously failed to comply with any other Federal, State, or local laws, regulations, or instructions pertaining to plant health.
- The applicant has previously failed to comply with the laws or regulations of a national plant protection organization or equivalent body, as these pertain to plant health.
- APHIS has determined that the applicant has made false or fraudulent statements or provided false or fraudulent records to APHIS.
- The applicant has been convicted or has pled *nolo contendere* to any crime involving fraud, bribery, extortion, or any other crime involving a lack of integrity.

Proposed paragraph (d)(5) would discuss withdrawal of a permit application. Any permit application could be withdrawn; however, applicants who wish to withdraw a permit application would have to provide this request in writing to APHIS. APHIS would provide written notification to the applicant as promptly as circumstances allow regarding reception of the request and withdrawal of the application.

Proposed paragraph (d)(6) of § 330.201 would discuss cancellation of a permit. Any permit that has been issued could be canceled at the request of the permittee. If a permittee wishes a permit to be canceled, he or she would have to provide the request in writing to APHIS-PPQ. Whenever a permit is canceled, APHIS would notify the permittee in writing regarding such cancellation.

Paragraph (d)(7) would discuss revocation of a permit. APHIS could revoke a permit for any of the following reasons:

- After issuing the permit, APHIS obtains information that would have

otherwise provided grounds for us to deny the permit application.

- APHIS determines that the actions undertaken under the permit have resulted in or are likely to result in the introduction into or dissemination within the United States of a plant pest or noxious weed in a manner that presents an unacceptable risk to plants or plant products.

- APHIS determines that the permittee, or any employee, agent, or officer of the permittee, has failed to comply with a provision of the permit or the regulations under which the permit was issued.⁶

Paragraph (d)(8) would discuss amendment of permits. Amendments could occur at the request of the permittee, or may be initiated by APHIS. If a permittee determines that circumstances have changed since the permit was initially issued and wishes the permit to be amended accordingly, he or she would have to contact APHIS to request the amendment and may have to provide supporting information justifying the amendment.

APHIS would review the request, and may amend the permit if only minor changes are necessary. Requests for more substantive changes could require a new permit application.

Prior to issuance of an amended permit, depending on the nature of the amendments, the permittee may have to agree in writing that he or she, and his or her employees, agents, and/or officers, would comply with the amended permit and conditions.

With regard to amendments initiated by APHIS, we could amend any permit and its conditions at any time, upon determining that the amendment is needed to address newly identified considerations concerning the risks presented by the organism or the activities being conducted under the permit. We would also be able to amend a permit at any time to ensure that the permit conditions are consistent with all of the requirements of the regulations; for example, if a subsequent rulemaking prohibits certain categories or types of organisms from being moved in certain means of conveyance, and the permit lacks these specific prohibitions.

As soon as circumstances allow, APHIS would notify the permittee of the amendment to the permit and the reason(s) for it. Depending on the nature of the amendment, the permittee may have to agree in writing or electronically that he or she, and his or her employees,

agents, and/or officers, will comply with the permit and conditions as amended before APHIS would issue the amended permit. If APHIS requests such an agreement, and the permittee does not agree in writing that he or she, and his or her employees, agents, and/or officers, will comply with the amended permit and conditions, the existing permit would be revoked.

Paragraph (d)(9) would discuss suspension of actions authorized under a permit. It would state that we may suspend authorization of actions authorized under a permit if we identify new factors that cause us to reevaluate the risk associated with those actions. In such instances, we would notify the permittee in writing of this suspension and the reasons for it. This notification would also state the actions for which we are suspending authorization. Depending on the results of our evaluation, we would subsequently contact the permittee to remove the suspension, amend the permit, or revoke the permit.

Paragraph (d)(10) would establish procedures in the event that a person whose application has been denied, whose permit has been revoked or amended, or whose authorization for actions authorized under a permit has been suspended, wishes to appeal the decision.

Biological Control Organisms (§ 330.202)

The PPA defines a biological control organism as “any enemy, antagonist, or competitor used to control a plant pest or noxious weed.”

The PPA finds that “biological control is often a desirable, low-risk means of ridding crops and other plants of plant pests, and its use should be facilitated” by APHIS and other agencies. In accordance with the PPA, APHIS authorizes the movement and environmental release of both biological control organisms through the issuance of permits.

Since the PPA was enacted, we have published several documents in the **Federal Register** that have discussed codifying our permitting processes for biological control organisms. On each occasion, individuals who support the use of biological control have requested that we consider such organisms to be distinct from plant pests, and to regulate them in a manner that facilitates, rather than restricts, their movement and environmental release. Certain of these commenters have stated that APHIS should regulate biological control organisms only when their efficacy in controlling their target plant pest or

noxious weed is not adequately established.

We regulate biological control organisms pursuant to the PPA insofar as they may pose a plant pest risk. We consider it necessary to exercise a degree of regulatory oversight regarding the movement or environmental release of such biological control organisms, even when their efficacy is well established.

It is worth noting, in that regard, that biological control organisms are usually moved for eventual environmental release. This is alluded to in the PPA’s definition of biological control organism, which specifies that an organism must be used, that is, actively employed to control a plant pest or noxious weed in order for it to be considered a biological control organism. Because biological control organisms are almost always intended for eventual release into the environment, it is not sufficient for us only to consider their use in controlling their target plant pest or noxious weed. We must also take into consideration the plant pest effects that the organism may pose to non-target plants or plant products.

If the organism is known to have non-target plant pest effects, it is consistent with APHIS’ mission to prohibit or restrict its release. To the extent that we do not know these likely non-target plant pest effects, it is also prudent for us to place regulatory controls on its movement and release until these impacts and effects are better understood.

Paragraph (a) of proposed § 330.202 would provide, as a general condition for the importation, interstate movement, and environmental release of biological control organisms that are regulated under the proposed regulations, that no such biological control organism may be imported, moved interstate, or released into the environment unless a permit has been issued in accordance with proposed § 330.201 authorizing such importation, interstate movement, or environmental release, and the organism is moved or released in accordance with this permit and the proposed regulations.

Because applications for the movement of biological control organisms often request that we authorize the release of the organism into the environment, several regulations issued pursuant to the National Environmental Policy Act of 1969, as amended (NEPA, 42 U.S.C. 4321 *et seq.*) require certain procedural actions before APHIS may issue a permit: 40 CFR parts 1500–1508, which contains the regulations of the Council

⁶ Pursuant to section 424 of the PPA, such failure, whether on the part of the permittee or on that of his or her employees, agents, or officers, may result in the assessment of civil or criminal penalties.

on Environmental Quality for implementing the procedural provisions of NEPA; 7 CFR part 1b, which contains USDA's NEPA implementing regulations; and 7 CFR part 372, which contains APHIS' implementing regulations. In accordance with these regulations under NEPA, before issuing a permit, APHIS must assess whether the actions proposed on the applications, either individually or cumulatively, are likely to have significant impacts on the human environment.

In order to make such an assessment, we often have to request additional information from applicants regarding the proposed release of the organism as part of our evaluation of the permit application. The end of paragraph (a) of § 330.202 would alert interested parties to this fact, and direct them to our portal on the Internet for further information regarding the types of information that may be requested and the manner in which this information will be evaluated.

The requirements in proposed paragraph (a) of § 330.202 would apply to the importation, interstate movement, and environmental release of most biological control organisms. However, we are aware that certain taxa of biological control organisms have become established throughout their geographical or ecological range in the continental United States, such that the additional release of pure cultures derived from field populations of a taxon of these organisms into the environment of the continental United States will present no additional plant pest risk (direct or indirect) to plants or plant products. For such organisms, we do not consider there to be a sufficient basis in risk to require permits for their interstate movement or environmental release within the continental United States.

To reflect this, paragraph (b) of § 330.202 would state that APHIS has determined that certain biological control organisms have become established throughout their geographical or ecological range in the continental United States, such that the additional release of pure cultures derived from field populations of taxa of such organisms into the environment of the continental United States will present no additional plant pest risk (direct or indirect) to plants or plant products within the United States. The paragraph would direct persons to APHIS' online portal for permit applications for a list of all such organisms.

Paragraph (b)(1) of § 330.202 would provide that pure cultures of organisms

on that list may be imported into or moved interstate within the continental United States without further restriction under the regulations, and paragraph (b)(2) of § 330.202 would provide that pure cultures of organisms on the list may be released into the environment of the continental United States without further restriction under the regulations.

We have made a draft list of such organisms available on *Regulations.gov* as a supporting document for this proposed rule (see **ADDRESSES** at the beginning of this proposed rule) and request public comment on the list. While we will consider comments received on the draft list to be distinct from those received on the proposed rule, the comments received on the draft list will inform our evaluation of the suitability of the exemptions from permitting requirements contained in proposed paragraph (b) of § 330.202.

Proposed paragraph (c) of § 330.202 would establish a petition-based process by which biological control organisms would be added to the list of organisms granted exceptions from permitting requirements for their importation or interstate movement. Any person would be able to request that APHIS add a biological control organism to the list referred to in paragraph (b) of § 330.202 by submitting a petition to APHIS. We would specify that individuals should submit the petition via email to Pests.permits@aphis.usda.gov, or through any other means listed on APHIS' Web site at http://www.aphis.usda.gov/plant_health/permits/index.shtml.

The petition would have to include the following information:

- Evidence indicating that the organism is indigenous to the continental United States throughout its geographical or ecological range, or evidence indicating that the organism has produced self-replicating populations within the continental United States for an amount of time sufficient, based on the organism's taxon, to consider that taxon established throughout its geographical or ecological range in the continental United States.

- Results from a field study where data was collected from representative habitats occupied by the biological control organism. Studies would have to include sampling for any direct or indirect impacts on target and non-target hosts of the biological control organism in these habitats. Supporting scientific literature would have to be cited.

- Any other data, including published scientific reports, that suggest that that subsequent releases of the

organism into the environment of the continental United States would present no additional plant pest risk (direct or indirect) to plants or plant products.

APHIS would review the petition to determine whether it is complete. If the petition is complete, we would conduct an evaluation of the petition to determine whether there is sufficient evidence that the organism exists throughout its geographical or ecological range in the continental United States and that subsequent releases of pure cultures of field populations the organism into the environment of the continental United States will present no additional plant pest risk (direct or indirect) to plants or plant products.

If we determine that there is sufficient evidence that that the organism exists throughout its geographical or ecological range in the continental United States and that subsequent releases of pure cultures of the organism into the environment of the continental United States will present no additional plant pest risk (direct or indirect) to plants or plant products, we would publish a notice in the **Federal Register** announcing the availability of the petition and requesting public comment on that document.

If no comments are received on the notice, or if the comments received do not lead us to reconsider our determination, we would publish a subsequent notice in the **Federal Register** describing the comments received and stating that the organism has been added to the list referred to in proposed paragraph (b) of § 330.202.

If the comments received lead us to reconsider our determination, we would publish a subsequent notice in the **Federal Register** describing the comments received and stating our reasons for determining not to add the organism to the list referred to in proposed paragraph (b).

Proposed paragraph (e) of § 330.202 would provide that any biological control organism may be removed from the list referred to in paragraph (b) of the section if information emerges that would have otherwise led us to deny the petition to add the organism to the list. Whenever an organism is removed from the list, APHIS would publish a notice in the **Federal Register** announcing that action and the basis for it.

Soil (§ 330.203)

The regulations governing the importation, interstate movement, and transit of soil and certain stone and quarry products under permit are currently found in "Subpart—Movement of Soil, Stone, and Quarry

Products,” §§ 330.300 through 330.302. We are proposing to remove and reserve that subpart and integrate the regulations for soil into the revised “Subpart—Plant Pests, Biological Control Organisms, Soil, and Associated Articles” as § 330.203. We are proposing to do so primarily in order to clarify that we regulate soil insofar as it is or may be an associated article. That is, we regulate soil insofar as it may harbor plant pests or noxious weeds: When a permit application for soil is submitted to APHIS, a soil specialist evaluates this likelihood of contamination with plant pests or noxious weeds and determines whether a permit should be issued.

As part of our revision to the soil regulations, we would also update the regulations in light of the current scientific understanding of soil and the spread of soil-borne pathogens within Canada.

Proposed paragraph (a) of § 330.203 would state that the Administrator has determined that, unless it has been sterilized, soil is an associated article, and is thus subject to the permitting requirements of § 330.201. It would also provide two conditions under which the movement of soil would not be subject to the permitting requirements of § 330.201: If the movement is regulated pursuant to other APHIS regulations in 7 CFR chapter III (e.g., § 301.86–5 requires certificates for the interstate movement of soil from an area quarantined for pale cyst nematode), or if § 330.203 states that the movement does not require such a permit. This second condition would apply to the importation of most soil from Canada, and most interstate movement of soil.

Proposed paragraphs (b)(1) through (b)(3) of § 330.203 would provide conditions governing the importation of soil. First, in a similar manner to our conditions for the importation of most biological control organisms, we would require an import permit to be issued in accordance with § 330.201 for the importation of soil, and the soil to be imported under the conditions specified on the permit. We are requiring a permit so that we can evaluate the risks associated with any particular importation of soil and assign the appropriate mitigation measures.

Currently, soil may be imported from Canada without a permit, unless the soil is from Newfoundland or the Land District of Central Saanich on Vancouver Island in the Province of British Columbia; these two areas are known to be infested with pale cyst nematodes (PCN). We are proposing to amend the regulations so that soil from any area of Canada regulated by the Canadian Food Inspection Agency

(CFIA), the national plant protection organization of Canada, for a soil-borne plant pest would require a permit. We are doing this because there have been recent detections of soil-borne plant pests of quarantine significance in Canada (such as PCN in Quebec and potato wart disease on Prince Edward’s Island) that are not reflected in the current regulations.

We would also clarify that the proposed regulations do not pertain to soil used as a growing medium for plants for planting from Canada. Plants for planting that are intended to be imported into the United States and their growing media are regulated under 7 CFR part 319, “Subpart—Plants for Planting.”

Plants for planting that can be inspected, treated, or handled to prevent them from spreading plant pests are designated in that subpart as restricted articles. Section 319.37–4 requires all restricted articles imported into the United States to be accompanied by a phytosanitary certificate of inspection, unless the section explicitly exempts the articles from this requirement. Paragraph (a)(1) of § 319.37–4 exempts greenhouse-grown plants from Canada imported in accordance with the provisions of a certification program administered by CFIA from this requirement; paragraph (c) of that section contains the provisions of CFIA’s program.

Section 319.37–8 addresses the growing media in which a restricted article may be imported. Currently, paragraph (a) of the section prohibits the use of soil as a growing medium for plants for planting from all countries other than Canada. Paragraph (b) allows a restricted article from Canada to be imported in any medium, with the restriction that articles from Newfoundland or a certain portion of the Municipality of Central Saanich in the Province of British Columbia must be accompanied by a phytosanitary certificate containing an additional declaration that the plants were grown in a manner to prevent infestation with potato cyst nematode. We are proposing to revise paragraph (b) of § 319.37–8 so that articles from any area of Canada that is regulated by CFIA for a soil-borne plant pest would have to be accompanied by a phytosanitary certificate with an additional declaration that the plants were grown in a manner to prevent infestation with that soil-borne plant pest.

Proposed paragraphs (b)(2) through (b)(4) of § 330.203 would set forth additional conditions for certain types of importations of soil. Paragraph (b)(2) would provide additional conditions for

the importation of soil via hand-carry. In addition to the requirements of proposed paragraph (b)(1), we would allow soil to be hand-carried into the United States only if the importation meets the conditions of § 330.205. That section, which is discussed later in this document, would contain our regulations governing the hand-carry of plant pests, biological control organisms, and soil.

Proposed paragraph (b)(3) would provide additional conditions for the importation of soil intended for the extraction of plant pests. Since this soil is imported precisely because it is known to contain plant pests, with very few exceptions, it is not rerouted for sterilization upon arrival in the United States. Therefore, to mitigate the risk that such soil could present a pathway for the introduction or dissemination of plant pests within the United States, we would require all such soil to be imported directly to an approved biocontainment facility.

On occasion, soil that presents a risk of harboring plant pests is imported into the United States for disposal; for example, this sometimes occurs when a natural disaster strikes an area quarantined for a soil-borne pathogen and emergency management personnel need to dispose of the resulting debris. Proposed paragraph (b)(4) would contain additional conditions for the importation of such soil. In addition to general conditions for the importation of soil, soil infested with plant pests and intended for disposal would have to be imported directly to an APHIS-approved disposal facility. Although all such facilities are subject to evaluation and approval by EPA, we would require independent APHIS approval of the facility because certain of these EPA-approved facilities are municipal landfills that may not provide adequate safeguards against plant pest dissemination.

Currently, § 330.301 restricts the importation into the United States of stone and quarry products from areas in Canada that are infested with gypsy moth. This section has at times led to confusion regarding the relationship between soil and stone and quarry products, as well as questions regarding the regulated status of articles, such as clay, that are similar to but fundamentally distinct from soil.

Proposed paragraph (b)(5) of § 330.203 would list certain articles that are not soil, and that, because of their composition or origin, present a negligible risk of serving as a medium for plant pests or noxious weeds, provided that they are free of organic material. The articles could be imported

into the United States without an import permit, unless the Administrator has issued an order stating that a particular article is an associated article. (Such orders would be maintained on PPQ's Web site, at http://www.aphis.usda.gov/plant_health/permits/organism/soil/index.shtml.) However, all such articles would be subject to inspection at the port of first arrival, subsequent reinspection at other locations, and other remedial measures deemed necessary by an inspector to remove any risk the items pose of disseminating plant pests or noxious weeds, and any other restrictions or prohibitions in 7 CFR chapter III. The articles would be:

- Consolidated material derived from any strata or substrata of the earth. Examples include clay (laterites, bentonite, china clay, attapulgite, tierrafino), talc, chalk, slate, iron ore, and gravel.
- Sediment, mud, or rock from saltwater bodies of water.
- Cosmetic mud and other commercial mud products.
- Stones, rocks, and quarry products.

These provisions do not mean that we would no longer restrict the movement of stone and quarry products from areas in Canada that are infested with gypsy moth. Instead, we would amend "Subpart—Gypsy Moth Host Material from Canada," § 319.77–1 through § 319.77–5, to incorporate those restrictions. Section 319.77–2 of that subpart contains a list of articles designated regulated articles; we would amend that section by adding a new paragraph (i) that would designate stone and quarry products as regulated articles. Section 319.77–4 contains conditions for the importation of regulated articles; we would amend the section by adding a new paragraph (d) that would provide that stone and quarry products originating in a Canadian area known to be infested with gypsy moth may be imported into the United States only if they are destined for an infested area of the United States and will not be moved through any noninfested areas of the United States, and may be moved through the United States if they are moved only through infested areas. We consider this subpart a more appropriate location for the restrictions.

Proposed paragraph (c) of § 330.203 would provide general conditions governing the interstate movement of soil. Most soil could be moved interstate without prior issuance of an interstate movement permit in accordance with § 330.201, or further restriction under the regulations. However, all soil moved interstate within the United States would still be subject to any movement

restrictions and remedial measures specified for such movement in 7 CFR part 301.

As we mentioned earlier in this document, part 301 contains our regulations that designate certain areas of the United States as quarantined areas for a particular plant pest, and that prohibit or restrict the movement in interstate commerce of certain host articles of that pest. The provisions currently in our regulations in § 330.302 mention certain sections of part 301 in which soil is considered a regulated article, such as our Japanese beetle and gypsy moth regulations, but omit others, such as our golden nematode and PCN regulations, and do not take into consideration the possibility that outbreaks of new plant pests within the United States may lead us to regulate the interstate movement of soil from areas quarantined for those or other pests.

Proposed paragraph (c)(2) would provide conditions for the interstate movement within the continental United States of soil intended for the extraction of plant pests. Again, since such soil is moved precisely because it is known to contain plant pests, it is, by definition, an associated article, and therefore would require an interstate movement permit issued in accordance with § 330.201 in order to be moved. Moreover, because of the intended use of the soil, in order to mitigate the risk of the dissemination of plant pests, the soil would have to be moved directly to an approved biocontainment facility, and in a secure manner that prevents its dissemination into the outside environment.

Proposed paragraph (c)(3) would contain additional conditions for the interstate movement within the continental United States of soil infested with plant pests and intended for disposal. We would require issuance of an interstate movement permit prior to movement, and would require that all such soil to be moved directly to an APHIS-approved disposal facility, and in a secure manner that prevents its dissemination into the outside environment.

Proposed paragraph (c)(4) would contain additional conditions for the interstate movement of soil samples from an area quarantined in accordance with 7 CFR part 301 for chemical or compositional testing or analysis. Such soil could be moved without prior issuance of an interstate movement permit in accordance with § 330.201 or further restriction under 7 CFR chapter III, provided that the soil is moved to a laboratory that has entered into and is operating under a compliance

agreement with APHIS, is abiding by all terms and conditions of the compliance agreement, and is approved by APHIS to test and/or analyze such samples.

Proposed paragraph (c)(5) would contain additional conditions for the interstate movement of soil to, from, or between Hawaii, the territories, and the continental United States. In addition to all general conditions for interstate movement of soil, soil could be moved interstate to, from, or between Hawaii, the territories, and the continental United States only if an interstate movement permit has been issued for its movement in accordance with § 330.201. This condition would apply to all soil moved to, from, or between Hawaii, the territories, and the continental United States. In addition to this provision, soil moved to, from, or between Hawaii, the territories, and the continental United States with the intent of extracting plant pests would still be subject to the conditions of proposed paragraph (c)(2) of the section, and would therefore have to be moved directly to an approved biocontainment facility. Similarly, soil infested with plant pests and intended for disposal would be subject to the conditions of proposed paragraph (c)(3) of the section, and would therefore have to be moved directly to an APHIS-approved disposal facility.

Proposed paragraph (d) would contain conditions regarding the transit of soil. Such movement would require a transit permit issued in accordance with 7 CFR part 352.

The regulations in § 330.300 currently exempt movements of soil governed by § 318.60 or § 319.69 from permitting requirements. Section 318.60 currently prohibits the movement of sand (other than clean ocean sand), soil, or earth around the roots of plants from Hawaii, Puerto Rico, or the Virgin Islands into or through any other State, Territory, or District of the United States, unless the movement is in either direction between Puerto Rico and the Virgin Islands, or the soil is intended for experimental or scientific use by USDA. We would amend § 318.60 to clarify that it pertains only to the movement of soil around the roots of plants, and that all other movement of soil from Hawaii, Puerto Rico, or the Virgin Islands, other than that soil around the roots of plants, is regulated under 7 CFR part 330. We consider this amendment necessary primarily so that we would not regulate the movement of such soil in two different subparts, and secondarily so that the section may not be used to circumvent the regulations in part 330.

"Subpart—Packing Materials," § 319.69 through § 319.69–5, contains

our regulations regarding plants and plant products used as packing materials for imported commodities. Section 319.69 prohibits the use of soil containing an appreciable mixture of vegetable matter from being used as packing material, except for soil authorized as safe for packing by other rules and regulations in the subpart. Section 319.69–1 specifies that soil containing an appreciable admixture of vegetable matter is covered by this prohibition because its decaying vegetation or plant remains carries a definite pest risk. Finally, § 319.69–5 states that the following soil may be used as packing material: Peat, peat moss, or osmunda fiber.

After reviewing this section in light of the current scientific understanding of soil, as reflected in our proposed revision to the definition of *soil* in § 330.100, we have determined that this section does not refer to soil, as it is currently understood, but to the organic decaying vegetative matter for which soil may serve as a medium, and of which peat, peat moss, and osmunda fiber are all examples. We have also determined that an instance may arise when the mitigation measures that we require in part 319 for the importation of a plant, plant part, or plant product may also address the risk associated with using organic decaying vegetative matter as a packing material for that commodity.

Therefore, we would amend the existing prohibition in § 319.69 on the use of soil as a packing material so that it instead prohibits the use of organic decaying vegetative matter as a packing material. We would remove § 319.69–1(b), which considers matter containing decaying vegetation or plant remains to be soil. We would establish an exemption for any organic decaying vegetative matter expressly authorized to be used as a packing material elsewhere in part 319. Finally, we would revise the heading of § 319.69–5 to make it clear that it does not pertain to the use of soil as a packing material, but organic decaying vegetative matter.

Exceptions to Permitting Requirements for the Importation or Interstate Movement of Certain Plant Pests (§ 330.204)

Section 7711 of the PPA provides that the Secretary of Agriculture may issue regulations to allow the importation and the movement in interstate commerce of plant pests without further restriction, if the Secretary finds that a permit for such movement is not necessary. The section further states that if the Secretary does issue such regulations, any person may petition him or her to

add a plant pest or remove a plant pest from this list of pests. Finally, the section provides that if a petition is submitted, the Secretary will act on the petition and notify the petitioner of the action he or she will take on the petition.

Section 330.204 would establish such regulations and petition process. The introductory paragraph would state that, pursuant to section 7711 of the PPA, the Administrator has determined that certain plant pests may be imported into or may move in interstate commerce within the continental United States without restriction. The list of all such plant pests would be on the PPQ Web site.

Paragraph (a) of the section would describe the three categories of plant pests that comprise the list. In order to be included on the list, a plant pest would have to:

- Be from field populations or lab cultures derived from field populations of a taxon that is established throughout its entire geographical or ecological range within the continental United States; or
- Be sufficiently attenuated so that it no longer poses a risk to plants or plant products; or
- Be commercially available and raised under the regulatory purview of other Federal agencies.

In our 2001 proposed rule, paragraph (c) of § 330.202 would have established a “no permit necessary” list for certain indigenous plant pest species that were already distributed throughout the continental United States and are known to commonly accompany plants or plant products moved in commerce. The first category aligns with the criterion for that 2001 list. We would not require permits for plant pests from a field population or lab culture derived from a field population of a taxon that is established throughout its entire geographical or ecological range within the United States because such pests are ubiquitous within the continental United States.

The second category reflects the fact that *in vitro* attenuation of plant pests such as phytopathogenic fungi, while rare, does occur. When a pest becomes attenuated, there is no longer a sufficient basis for us to presume that the pest presents a risk of directly or indirectly injuring, causing damage to, or causing disease in plants or plant products; in other words, an attenuated pest *de facto* no longer falls within the scope of the definition of *plant pest* under the PPA.

(In order to avoid confusion and the possible unregulated movement of the virulent strains of the plant pest, the list

would specify the strains of the plant pest that APHIS considers attenuated of their pathogenicity.)

The third category of plant pests is intended to avoid duplicative or conflicting regulatory oversight of certain plant pests. For example, although it is a plant pest, *Penicillium chrysogenum* is regulated by the Food and Drug Administration (FDA).

We have made a draft list of plant pests that may be imported or move in interstate commerce within the continental United States without restriction available on *Regulations.gov* as a supporting document for this proposed rule, and request public comment regarding that list. The list largely mirrors the list contained in the 2001 proposed rule, but also contains certain plant pests that belong to the second and third categories.

Paragraph (b) of § 330.204 would contain a petition process to add a plant pest to the list. Any person would be able to petition to have an additional plant pest added to the list. To submit a petition, the person would have to provide, in writing, information supporting the placement of a particular pest in one of the categories listed in paragraph (a) of § 330.204.

Information that the plant pest belongs to a taxon that is established throughout its entire geographical or ecological range within the United States would have to include scientific literature, unpublished studies, or data regarding:

- The biology of the plant pest, including characteristics that allow it to be identified, known hosts, and virulence;
- The geographical or ecological range of the plant pest within the continental United States; and
- The areas of the continental United States within which the plant pest is established.

The first category of information is intended to provide us with basic information regarding the plant pest for which unrestricted movement is sought. The second and third categories would aid our determination regarding whether the plant pest is established throughout its ecological or geographical range within the continental United States.

Information that the plant pest has been attenuated of its pathogenicity would have to include experimental data, published references, or scientific information regarding such attenuation.

Information that the plant pest is commercially available and raised under the regulatory purview of another Federal agency would have to include a citation to the relevant law, regulation,

or order under which the agency exercises such oversight. For example, *Penicillium chrysogenum* is regulated by FDA under the Kefauver-Harris drug amendments of 1962.

APHIS would review the information contained in the petition to determine whether it is complete. In order to consider the petition complete, APHIS may require additional information to determine whether the plant pest belongs to one of the categories listed in paragraph (a) of § 330.204. When it is determined that the information is complete, we would commence review of the petition.

If, after review of the petition, we determine that there is insufficient evidence that the plant pest belongs to one of the three categories listed in paragraph (a) of § 330.204—for example, the plant pest is known to exist throughout its entire geographical range in the continental United States, but population densities in certain areas are not sufficient to consider it established throughout its range—we would deny the petition, and notify the petitioner in writing regarding this denial.

Conversely, if, after review of the petition, we determine that the plant pest belongs to one of the categories in paragraph (a), we would publish a notice in the **Federal Register** that announces the availability of the petition and any supporting documentation to the public, that states that we intend to add the plant pest to the list of plant pests that may be imported into or move in interstate commerce within the continental United States without restriction, and that requests public comment.

If no comments are received on the notice, or if, based on the comments received, we determine that our conclusions regarding the petition have not been affected, we will publish in the **Federal Register** a subsequent notice stating that the plant pest has been added to the list.

Under paragraph (c) of § 330.204, any person could submit, in writing, a petition to have a plant pest removed from the list. The petition would have to contain independently verifiable information demonstrating that our initial determination that the plant pest belongs to one of the categories in paragraph (a) of the section should be changed, or that additional information is now available that would have caused us to change the initial decision.

APHIS would review the information contained in the petition to determine whether it is complete. In order to consider the petition complete, we may require additional information supporting the petitioner's claim. When

it is determined that the information is complete, we would commence review of the petition.

If, after review of the petition, we determine that there is insufficient evidence to suggest that our initial determination should be changed, we would deny the petition, and notify the petitioner in writing regarding this denial.

If, after review of the petition, we determine that there is a sufficient basis to suggest that our initial determination should be changed, we would publish a notice in the **Federal Register** that announces the availability of the petition, and that requests public comment regarding removing the plant pest from the list of plant pests that may be imported into or move in interstate commerce within the continental United States without restriction.

If no comments are received on the notice, or if the comments received do not affect our conclusions regarding the petition, we would publish in the **Federal Register** a subsequent notice stating that the plant pest has been removed from the list.

Paragraph (d) of § 330.204 would provide for APHIS-initiated changes to the list. It would provide that APHIS may propose to add a plant pest to or remove a pest from the list without a petition, if we determine that there is sufficient evidence that the plant pest belongs to one of the categories listed in paragraph (a) of the section, or if evidence emerges that leads us to reconsider our initial determination that the plant pest was or was not in one of the categories listed in paragraph (a) of the section. We would publish a notice in the **Federal Register** announcing this proposed addition or removal, making available any supporting documentation that we prepare, and requesting public comment.

If no comments are received on the notice, or if the comments received do not affect our conclusions, we will publish a subsequent notice in the **Federal Register** stating that the plant pest has been added to or removed from the list.

Hand-Carry of Plant Pests, Biological Control Organisms, and Soil (§ 330.205)

Currently, we authorize the importation of plant pests in personal baggage (referred to as “hand-carry”) under § 330.212 of the regulations. The regulations provide that the person importing the plant pest must show the permit authorizing the importation to an inspector at the port of arrival where the baggage will be inspected, that the conditions specified on the permit must be observed, that an inspector will

oversee the movement of the plant pest, that the owner of the plant pest will be responsible for all costs incidental to forwarding the plant pest prior to clearance, and that an inspector may specify and supervise the application of safeguards to prevent the dissemination of the pest until it is forwarded.

The 2003 OIG audit referenced at the beginning of this document pointed out that the hand-carry process in place at the time did not provide guidance regarding what materials may be hand-carried or who may hand-carry, and that APHIS did not track hand-carried materials to ensure that they arrive at the point of destination listed on the permit. For these reasons, the audit strongly suggested that we issue regulations to prohibit hand-carry of regulated organisms into the United States, and to explicitly state that all organisms must be imported into the United States via a bonded commercial carrier.

However, certain plant pests and biological control organisms are highly perishable, and may remain viable only if they are imported into the United States directly and without rerouting. We have also found that it is often useful, from a safeguarding perspective, to authorize hand-carry in order to have an expert regarding the organism or article exercise direct and continuous oversight of its importation.

Therefore, we would include provisions for hand-carry in this proposed rule. These provisions, which would be contained in § 330.205, would reflect current Agency processes regarding hand-carry.

The introductory text of § 330.205 would state that plant pests, biological control organisms, and soil may be hand-carried into the United States only in accordance with the provisions of the section.

Proposed paragraph (a) of § 330.205 would discuss the first such provision, authorization to hand-carry. In order to obtain such authorization, a person would have to apply for an import permit for the plant pest, biological control organism, or soil, in accordance with § 330.201, and specify hand-carry of the organism or article as the method of proposed movement.

The application would also have to specify the individual or individuals who would hand-carry the plant pest, biological control organism, or soil into the United States. If we authorize this individual or these individuals to hand-carry, this authorization could not be transferred to, nor actions under it performed by, individuals other than those identified on the permit application.

Under proposed paragraph (b) of § 330.205, the permittee would have to notify APHIS through our online portal for permit applications or by fax after the permittee has obtained an import permit but no less than 20 days prior to movement and provide the following information in order to receive a hand-carry authorization:

- A copy of the face page of the passport for the individual or individuals who will hand-carry the plant pest, biological control organism, or soil.
- A description of the means of conveyance in which the individual or individuals will travel, including flight number and airline name for air travel, or vehicle license number or other identifying number for other modes of transportation.
- Expected date and time of first arrival.
- Expected port of first arrival.
- Travel itinerary from port of first arrival to final destination.

We would require authorized identification, the description of the means of conveyance, and the expected date, time, and port of first arrival because, pursuant to the regulations in § 330.105, hand-carried organisms or soil, like all other imported articles, must be presented for inspection at the port of first arrival, and this information would help us ensure that the inspection takes place as expeditiously as possible. We would require the travel itinerary from the port of first arrival to the final destination in order to ensure that the individual does not intend to make prolonged stops en route that could result in breach of safeguarding and increase the risk of accidental dissemination of the organism or soil. The information also would help us respond promptly to accidental dissemination of the organism or soil en route to the final destination.

Under proposed paragraph (c) of § 330.205, the permittee or his or her designee would have to notify APHIS within 24 hours of arrival of the hand-carried plant pest, biological control organism, or soil at the biocontainment facility or other authorized point of destination. This notification would have to state that the plant pest, biological control organism, or soil has arrived at its destination and that the package in which it was hand-carried has remained sealed until arrival. Notification could be by fax or email, or via APHIS' permitting Web site.

Proposed paragraph (d) of § 330.205 would discuss denial, amendment, or cancellation of authorization to hand-carry. It would state that APHIS may deny a request to hand-carry, or amend

or cancel any hand-carry authorization at any time, if we deem such action necessary to prevent the introduction or dissemination of plant pests or noxious weeds within the United States.

In a similar manner, proposed paragraph (e) of § 330.205 would state that any person whose request to hand-carry has been denied, or whose hand-carry authorization has been amended or canceled, would be able to appeal the decision in writing to APHIS.

Packaging Requirements (§ 330.206)

We are proposing to revise the packaging requirements for the movement of plant pests, currently found in § 330.210. The revised requirements would be contained in proposed § 330.206.

The introductory text of the section would state that shipments in which plant pests, biological control organisms, and associated articles are imported into, moved interstate, or transited through the United States must meet the general packaging requirements of the section, as well as all specific packaging requirements on the permit itself.

Proposed paragraph (a) would contain general packaging requirements. All shipments would have to consist of an outer shipping container and at least two packages within the container. Both the container and the inner packages would have to be securely sealed to prevent the dissemination of the enclosed plant pests, biological control organisms, or associated articles.

Paragraph (a)(1) would contain general requirements for the outer shipping container. The outer shipping container would have to be rigid, impenetrable, and durable enough to remain sealed and structurally intact in the event of dropping, lateral impact with other objects, and other shocks incidental to handling.

Paragraph (a)(2) would contain requirements for inner packages. The innermost package or packages within the shipping container would have to contain all of the organisms or articles that will be moved. As a safeguard, the innermost package would have to be placed within another, larger package, for example, bagged and sealed petri samples placed within a sealed cooler. All packages within the shipping container would have to be constructed or safeguarded so that they will remain sealed and structurally intact throughout transit. The packages would also have to be able to withstand changes in pressure, temperature, and other climatic conditions incidental to shipment.

Paragraph (b) would contain general requirements for packing material. It would specify that packing material must be free of plant pests, noxious weeds, or associated articles, and must be new, or must have been sterilized or disinfected prior to reuse. Packing material would also have to be suited for the enclosed organism or article, as well as any medium in which the organism or article will be maintained, and should not be capable of harboring or being a means of the dissemination of the organism or article.

We would provide guidance regarding suitable outer shipping containers, inner packages, and packaging on the PPQ Web site.

Paragraph (c) would provide that packing materials, including media and substrates, would have to be destroyed by incineration, be decontaminated using autoclaving or another approved method, or otherwise be disposed of in a manner specified in the permit itself. It would also provide that shipping containers could not be reused, except those that have been sterilized or disinfected prior to reuse.

Proposed paragraph (d) would state that permittees who fail to meet the requirements of the section may be held responsible for all costs incident to inspection, rerouting, repackaging, subsequent movement, and any treatments.

Cost and Charges (§ 330.207)

Proposed § 330.207 would state that the inspection services of APHIS inspectors during regularly assigned hours of duty and at the usual places of duty would be furnished without cost. It would also state that APHIS would not be responsible for any costs or charges incidental to inspections or compliance with the provisions of this subpart, other than for the inspection services of the inspector.

Executive Orders 12866 and 13563 and Regulatory Flexibility Act

This proposed rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order

13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also provides an initial regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the *Regulations.gov* Web site (see **ADDRESSES** above for instructions for accessing *Regulations.gov*).

Based on the information we have, there is no reason to conclude that adoption of this proposed rule would result in any significant economic effect on a substantial number of small entities. However, we do not currently have all of the data necessary for a comprehensive analysis of the effects of this proposed rule on small entities. Therefore, we are inviting comments on potential effects. In particular, we are interested in determining the number and kind of small entities that may incur benefits or costs from the implementation of this proposed rule.

APHIS is proposing to revise its regulations regarding the importation, interstate movement, and environmental release of plant pests to incorporate provisions regarding biological control organisms (BCOs) and the movement of soils from which plant pests and BCOs are extracted. The proposed rule would revise and add definitions, streamline the permitting and compliance processes, and provide APHIS with increased flexibility in the regulation of plant pests. Parts 318, 319, and 352 of 7 CFR chapter III would also be updated to reflect the proposed changes in part 330.

A principal consequence of the proposed rule would be a streamlining of our permitting process and possible reduction in the number of permits issued under part 330, which numbered 6,538 in 2015. Approximately 33 percent of these permits (2,158) authorized the movement or environmental release of a plant pest or BCO that APHIS is proposing to exempt from permitting. While we do not expect the proposed rule would result in one-third fewer permits as one permit may list multiple BCOs or plant pests, we can say with confidence that the permitting burden would be reduced for applicants and that the permitting process could be expedited. We expect that affected entities would benefit from a 10 to 30 percent reduction in the overall time spent applying for and

receiving permits under part 330. Assuming the time required to submit an application is 1 hour and assuming an average hourly wage of \$45.50 per hour, then for the 6,538 permits issued in 2015, the time savings expected under the proposed rule would have totaled between 654 and 1,961 hours, which equates to a cost savings of between about \$29,748 and \$89,244.

The proposed rule would codify existing practices by allowing entities requesting permits to apply electronically rather than by using the mail only. Expanded use of online permit applications through APHIS' portal would result in time and cost savings as compared to applying by mail using paper applications.

Listing of exempted organisms on an APHIS-PPQ Web site, transparent procedures for petitioning for exceptions or exemptions to permitting, and provision for a notice-based process for adding and removing listed organisms would also combine to make an efficient, transparent, and user-responsive system that would facilitate the movement and environmental release of plant pests and BCOs.

Regulated entities would continue to incur time costs associated with providing information during the permitting application process, and with meeting somewhat more robust recordkeeping (maintaining records) requirements in certain instances such as with soil imports and risk based permits. The time required overall for permitting would be reduced, however, because of the newly excepted organisms.

The proposed revisions to 7 CFR part 330 would benefit entities, large and small, by increasing the efficiency of the permitting and compliance processes for plant pests, BCOs, and soils from which plant pests and BCOs are extracted, and by improving the general clarity and transparency of these regulations. The proposed rule also would facilitate the Agency's coordination with other Federal and State agencies in regulating the movement and environmental release of plant pests and BCOs. The majority of entities that would benefit from this rule are small entities, based on information obtained from the Economic Census.

National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the processes established by this proposed rule, we have prepared a draft environmental impact statement (EIS). The EIS was prepared in accordance with: (1) The

National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The draft EIS is available on *Regulations.gov* for review and comment, and may be accessed via the Internet address provided above under the heading **ADDRESSES**. Copies may also be obtained by contacting the individual listed below the section titled **FOR FURTHER INFORMATION CONTACT**.

A notice of availability regarding the draft EIS will also be published by the Environmental Protection Agency in the **Federal Register**.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), some of the reporting, recordkeeping, and third party disclosure requirements included in this proposed rule are in the process of being reinstated under Office of Management and Budget (OMB) control number 0579–0054. The new reporting requirements included in this proposed rule have been submitted as a new information collection for approval to OMB.

Please send comments on the information collection request to OMB's Office of Information and Regulatory Affairs via email to oir_submission@omb.eop.gov, Attention: Desk Officer for APHIS. Please state that your comments refer to Docket No. APHIS–2008–0076. Please send a copy of your comments to USDA, using one of the methods described under **ADDRESSES** at the beginning of this document.

Under the PPA, the Secretary of Agriculture has authority to carry out operations or measures to detect, control, eradicate, suppress, prevent, or retard the spread of plant pests. Section 7711(a) of the Act provides that “no person shall import, enter, export, or move in interstate commerce any plant pest, unless the importation, entry, exportation, or movement is authorized under general or specific permit and in accordance with such regulations as the Secretary may issue to prevent the introduction of plant pests into the United States or the dissemination of plant pests within the United States.” The Act gives USDA the flexibility to respond appropriately to a wide range of needs and circumstances to protect American agriculture against plant pests.

In addition, section 412(a) of the Act provides that the Secretary may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of, among other things, any biological control organism if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States. The Act defines a biological control organism as “any enemy, antagonist, or competitor used to control a plant pest or noxious weed.”

APHIS regulations implementing these aspects of the Plant Protection Act are contained (in part) in 7 CFR part 330.

APHIS is proposing to revise: (1) Regulations regarding the movement of plant pests; (2) criteria regarding the movement and environmental release of biological control organisms, and proposing to establish regulations to allow the importation and movement in interstate commerce of certain types of plant pests without restriction by granting exceptions from permitting requirements for those pests; and (3) regulations regarding the movement of soil. This proposal would clarify the factors that would be considered when assessing the risks associated with the movement of certain organisms and facilitate the movement of regulated organisms and articles in a manner that also protects U.S. agriculture.

This proposed rule replaces a previously published proposed rule, which APHIS is withdrawing as part of this document. This proposal would clarify the factors that would be considered when assessing the risks associated with the movement of certain organisms and facilitate the movement of regulated organisms and articles in a manner that also protects U.S. agriculture.

Implementing this rule will require respondents to complete a new petition process to remove permitting requirements for the interstate movement of certain plant pests or biological control organisms.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

- (1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;
- (2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the

validity of the methodology and assumptions used;

- (3) Enhance the quality, utility, and clarity of the information to be collected; and

- (4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; e.g., permitting electronic submission of responses).

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 160 hours per response.

Respondents: Importers and distributors of plants and plant products; importers, brokers, distributors, retailers, and exhibitors of biological control organisms and associated articles; and operators of biocontainment facilities.

Estimated Annual Number of Respondents: 6.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Annual Number of Responses: 6.

Estimated Total Annual Burden on Respondents: 960 hours (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

A copy of the information collection may be viewed on the *Regulations.gov* Web site or in our reading room. (A link to *Regulations.gov* and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this proposed rule.) Copies can also be obtained from Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2483. APHIS will respond to any information collection request-related comments in the final rule. All comments will also become a matter of public record.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2483.

Lists of Subjects

7 CFR Part 318

Cotton, Cottonseeds, Fruits, Guam, Hawaii, Plant diseases and pests, Puerto Rico, Quarantine, Transportation, Vegetables, Virgin Islands.

7 CFR Part 319

Coffee, Cotton, Fruits, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

7 CFR Part 330

Customs duties and inspection, Imports, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

7 CFR Part 352

Customs duties and inspection, Imports, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, we propose to amend 7 CFR parts 318, 319, 330, and 352 as follows:

PART 318—STATE OF HAWAII AND TERRITORIES QUARANTINE NOTICES

- 1. The authority citation for part 318 continues to read as follows:

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 7 CFR 2.22, 2.80, and 371.3.

§ 318.60 [Amended]

- 2. In § 318.60, paragraph (c) is amended by adding the words “: *And provided finally*, that the prohibitions in this paragraph do not apply to the movement of soil from Hawaii, Puerto Rico, and the Virgin Islands, other than that soil around the roots of plants; movement of soil that is not around the roots of plants is regulated under part 330 of this chapter” after the words “paragraphs (c)(1), (2), and (3) of this section”.

PART 319—FOREIGN QUARANTINE NOTICES

- 3. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

- 4. In § 319.37–8, paragraph (b)(2) is revised to read as follows:

§ 319.37–8 Growing media.

* * * * *

- (b) * * *
(2) A restricted article from an area of Canada regulated by the national plant

protection organization of Canada for a soil-borne plant pest may only be imported in an approved growing medium if the phytosanitary certificate accompanying it contains an additional declaration that the plant was grown in a manner to prevent infestation by that soil-borne plant pest.

* * * * *

■ 5. Section 319.69 is amended as follows:

■ a. By revising paragraph (a)(8); and

■ b. By removing paragraph (b)(4).

The revision to read as follows:

§ 319.69 Notice of quarantine.

(a) * * *

(8) Organic decaying vegetative matter from all countries, unless the matter is expressly authorized to be used as a packing material in this part. Exceptions to the above prohibitions may be authorized in the case of specific materials which has been so prepared, manufactured, or processed that in the judgment of the inspector no pest risk is involved in their entry.

* * * * *

§ 319.69–1 [Amended]

■ 6. Section 319.69–1 is amended by removing paragraph (b), and redesignating paragraph (c) as paragraph (b).

■ 7. Section 319.69–5 is amended by revising the section heading to read as follows:

§ 319.69–5 Types of organic decaying vegetative matter authorized for packing.

* * * * *

■ 8. Section 319.77–2 is amended as follows:

■ a. In paragraph (g), by removing the word “and”;

■ b. By revising paragraph (h); and

■ c. By adding paragraph (i).

The addition and revision to read as follows:

§ 319.77–2 Regulated articles.

* * * * *

(h) Mobile homes and their associated equipment; and

(i) Stone and quarry products.

■ 9. Section 319.77–4 is amended by adding paragraph (d) to read as follows:

§ 319.77–4 Conditions for the importation of regulated articles.

* * * * *

(d) *Stone and quarry products.* Stone and quarry products originating in a Canadian infested area may be imported into the United States only if they are destined for an infested area of the United States and will not be moved through any noninfested areas of the United States, and may be moved

through the United States if they are moved only through infested areas.

* * * * *

PART 330—FEDERAL PLANT PEST REGULATIONS; GENERAL; PLANT PESTS, BIOLOGICAL CONTROL ORGANISMS, AND ASSOCIATED ARTICLES; GARBAGE

■ 10. The authority citation for part 330 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

■ 11. The heading of part 330 is revised to read as set forth above.

■ 12. Section 330.100 is revised to read as follows:

§ 330.100 Definitions.

The following terms, when used in this part, shall be construed, respectively, to mean:

Administrative instructions.

Published documents relating to the enforcement of this part, and issued under authority thereof by the Administrator.

Administrator. The Administrator of the Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture, or any employee of APHIS to whom authority has been delegated to act in the Administrator's stead.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

Article. Any material or tangible object, including a living organism, that could harbor living plant pests or noxious weeds.

Biocontainment facility. A physical structure, or portion thereof, constructed and maintained in order to contain plant pests, biological control organisms, or associated articles.

Biological control organism. Any enemy, antagonist, or competitor used to control a plant pest or noxious weed.

Continental United States. The contiguous 48 States, Alaska, and the District of Columbia.

Department. The United States Department of Agriculture.

Deputy Administrator. The Deputy Administrator of the Plant Protection and Quarantine Programs or any employee of the Plant Protection and Quarantine Programs delegated to act in his or her stead.

Enter (entry). To move into, or the act of movement into, the commerce of the United States.

EPA. The Environmental Protection Agency of the United States.

Export (exportation). To move from, or the act of movement from, the United States to any place outside the United States.

Garbage. That material designated as “garbage” in § 330.400(b).

Hand-carry. Importation of an organism that remains in one's personal possession and in close proximity to one's person.

Import (importation). To move into, or the act of movement into, the territorial limits of the United States.

Inspector. Any individual authorized by the Administrator of APHIS or the Commissioner of CBP to enforce the regulations in this part.

Interstate movement. Movement from one State into or through any other State; or movement within the District of Columbia, Guam, the U.S. Virgin Islands, or any other territory or possession of the United States.

Living. Viable or potentially viable.

Means of conveyance. Any personal or public property used for or intended for use for the movement of any other property. This specifically includes, but is not limited to, automobiles, trucks, railway cars, aircraft, boats, freight containers, and other means of transportation.

Move (moved and movement). To carry, enter, import, mail, ship, or transport; to aid, abet, cause, or induce the carrying, entering, importing, mailing, shipping, or transporting; to offer to carry, enter, import, mail, ship, or transport; to receive to carry, enter, import, mail, ship, or transport; to release into the environment, or to allow any of those activities.

Noxious weed. Any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.

Owner. The owner, or his or her agent, having possession of a plant pest, biological control organism, associated article, or any other means of conveyance, products, or article subject to the regulations in this part.

Permit. A written authorization, including by electronic methods, by the Administrator to move plant pests, biological control organisms, or associated articles under conditions prescribed by the Administrator.

Permittee. The person to whom APHIS has issued a permit in accordance with this part and who must comply with the provisions of the permit and the regulations in this part.

Person. Any individual, partnership, corporation, association, joint venture, or other legal entity.

Plant. Any plant (including any plant part) for or capable of propagation including trees, tissue cultures, plantlet cultures, pollen, shrubs, vines, cuttings, grafts, scions, buds, bulbs, roots, and seeds.

Plant pest. Any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: A protozoan, nonhuman animal, parasitic plant, bacterium, fungus, virus or viroid, infectious agent or other pathogen, or any article similar to or allied with any of the foregoing.

Plant product. Any flower, fruit, vegetable, root, bulb, seed, or other plant part that is not included in the definition of plant; or any manufactured or processed plant or plant part.

Plant Protection and Quarantine Programs. The Plant Protection and Quarantine Programs of the Animal and Plant Inspection Health Service.

Regulated garbage. That material designated as “regulated garbage” in § 330.400(c) and § 330.400(d).

Responsible individual. The individual who a permittee designates to oversee and control the actions taken under a permit issued in accordance with this part for the movement or curation of a plant pest, biological control organism, or associated article. For the duration of the permit, the individual must be physically present during normal business hours at or near the location specified on the permit as the ultimate destination of the plant pest, biological control organism, or associated article, and must serve as a primary contact for communication with APHIS. The permittee may designate him or herself as the responsible individual. The responsible individual must be at least 18 years of age. In accordance with section 7734 of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the act, omission, or failure of any responsible individual will also be deemed the act, omission, or failure of a permittee.

Secure shipment. Shipment of a regulated plant pest, biological control organism, or associated article in a container or a means of conveyance of sufficient strength and integrity to prevent leakage of contents and to withstand shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

Shelf-stable. The condition achieved in a product, by application of heat, alone or in combination with other ingredients and/or other treatments, of being rendered free of microorganisms

capable of growing in the product at nonrefrigerated conditions (over 50 °F or 10 °C).

Soil. The unconsolidated material from the earth's surface that consists of rock and mineral particles and that supports or is capable of supporting biotic communities.

State. Any of the States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the U.S. Virgin Islands, and all other territories or possessions of the United States.

Sterilization (sterile, sterilized). A chemical or physical process that results in the death of all living organisms on or within the article subject to the process. Examples include, but are not limited to, autoclaving and incineration.

Taxon (taxa). Any recognized grouping or rank within the biological nomenclature of organisms, such as class, order, family, genus, species, subspecies, pathovar, biotype, race, forma specialis, or cultivar.

Transit. Movement from and to a foreign destination through the United States.

United States. All of the States.

U.S. Customs and Border Protection (CBP). U.S. Customs and Border Protection within the Department of Homeland Security.

■ 13. Subpart—Movement of Plant Pests, §§ 330.200 through 330.212, is revised to read as follows:

Subpart—Movement of Plant Pests, Biological Control Organisms, and Associated Articles

Sec.

- 330.200 Scope and general restrictions.
- 330.201 Permit requirements.
- 330.202 Biological control organisms.
- 330.203 Soil.
- 330.204 Exceptions to permitting requirements for the importation or interstate movement of certain plant pests.
- 330.205 Hand-carry of plant pests, biological control organisms, and soil.
- 330.206 Packaging requirements.
- 330.207 Costs and charges.

Subpart—Movement of Plant Pests, Biological Control Organisms, and Associated Articles

§ 330.200 Scope and general restrictions.

(a) No person shall import, move interstate, transit, or release into the environment plant pests, biological control organisms, or associated articles, unless the importation, interstate movement, transit, or release into the environment of the plant pests, biological control organisms, or plant pests is:

(1) Authorized under an import, interstate movement, or continued curation permit issued in accordance with § 330.201; or

(2) Authorized in accordance with other APHIS regulations in this chapter; or

(3) Explicitly granted an exception or exemption in this subpart from permitting requirements; or

(4) Authorized under a general permit issued by the Administrator.

(b) *Plant pests regulated by this subpart.* For the purposes of this subpart, APHIS will consider an organism to be a plant pest if the organism directly or indirectly injures, causes damage to, or causes disease in a plant or plant product, or if the organism is an unknown risk to plants or plant products, but is similar to an organism known to directly or indirectly injure, cause damage to, or cause disease in a plant or plant product.

(c) *Biological control organisms regulated by this subpart.* For the purposes of this subpart, biological control organisms include:

(1) Invertebrate predators and parasites (parasitoids) used to control invertebrate plant pests,

(2) Invertebrate competitors used to control invertebrate plant pests,

(3) Invertebrate herbivores used to control noxious weeds,

(4) Microbial pathogens used to control invertebrate plant pests,

(5) Microbial pathogens used to control noxious weeds,

(6) Microbial parasites used to control plant pathogens, and

(7) Any other types of biological control organisms, as determined by APHIS.

(d) *Biological control organisms not regulated by this subpart.* The preceding paragraph notwithstanding, biological control organism-containing products that are currently under an EPA outdoor experimental use permit or that are currently registered with EPA as a microbial pesticide product having outdoor uses are not regulated under this subpart. Additionally, biological control organisms that are pesticides that are not registered with EPA, but are being transferred, sold, or distributed in accordance with EPA's regulations in 40 CFR 152.30, are not regulated under this subpart for their interstate movement or importation. However, an importer desiring to import a shipment of biological control organisms subject to the Federal Insecticide Fungicide and Rodenticide Act must submit to the EPA Administrator a Notice of Arrival of Pesticides and Devices as required by CBP regulations at 19 CFR 12.112. The Administrator will provide notification

to the importer indicating the disposition to be made of shipment upon its entry into the customs territory of the United States.

§ 330.201 Permit requirements.

(a) *Types of permits.* APHIS issues import permits, interstate movement permits, continued curation permits, and transit permits for plant pests, biological control organisms, and associated articles.¹

(1) *Import permit.* Import permits are issued to persons for secure shipment from outside the United States into the territorial limits of the United States. When import permits are issued to individuals, these individuals must be 18 years of age or older and have a physical address within the United States. When import permits are issued to corporate persons, these persons must maintain an address or business office in the United States with a designated individual for service of process.

(2) *Interstate movement permit.* Interstate movement permits are issued to persons for secure shipment from any State into or through any other State. When interstate movement permits are issued to individuals, these individuals must be 18 years of age or older and have a physical address within the United States. When interstate movement permits are issued to corporate persons, these persons must maintain an address or business office in the United States with a designated individual for service of process.

(3) *Continued curation permits.* Continued curation permits are issued in conjunction with and prior to the expiration date for an import permit or interstate movement permit, in order for the permittee to continue the actions listed on the import permit or interstate movement permit. When continued curation permits are issued to individuals, these individuals must be 18 years of age or older and have a physical address within the United States. When continued curation permits are issued to corporate persons, these persons must maintain an address or business office in the United States with a designated individual for service of process.

(4) *Transit permits.* Transit permits are issued for secure shipments through the United States. Transit permits are issued in accordance with part 352 of this chapter.

(b) *Applying for a permit.* Permit applications must be submitted by the applicant in writing or electronically through one of the means listed at http://www.aphis.usda.gov/plant_health/permits/index.shtml in advance of the action(s) proposed on the permit application.

(c) *Completing a permit application.* A permit application must be complete before APHIS will evaluate it in order to determine whether to issue the permit requested. Guidance regarding how to complete a permit application, including guidance specific to the various information blocks on the application, is available at http://www.aphis.usda.gov/plant_health/permits/index.shtml.

(d) *APHIS action on permit applications.* APHIS will review the information on the application to determine whether it is complete. In order to consider an application complete, APHIS may request additional information that it determines to be necessary in order to assess the risk to plants and plant products that may be posed by the actions proposed on the application. When it is determined that an application is complete, APHIS will commence review of the information provided.

(1) *State or Tribal consultation and comment; consultation with other individuals.* APHIS will share a copy of the permit application, and the proposed permit conditions, with the appropriate State or Tribal regulatory officials, and may share the application and the proposed conditions with other persons or groups to provide comment.

(2) *Initial assessment of sites and facilities.* Prior to issuance of a permit, APHIS will assess all sites and facilities that are listed on the permit application, including private residences, biocontainment facilities, and field locations where the organism or article will be held or released. As part of this assessment, all sites and facilities are subject to inspection. All facilities must be determined by APHIS to be constructed and maintained in a manner that prevents the dissemination or dispersal of plant pests, biological control organisms, or associated articles from the facility. The applicant must provide all information requested by APHIS regarding this assessment, and must allow all inspections requested by APHIS during normal business hours (8 a.m. to 4:30 p.m., Monday through Friday, excluding holidays). Failure to do so constitutes grounds for denial of the permit application.

(3) *Issuance of a permit.* APHIS may issue a permit to an applicant if APHIS

concludes that the actions allowed under the permit will be highly unlikely to result in the introduction or dissemination of a plant pest, biological control organism, or noxious weed within the United States in a manner that presents an unacceptable risk to plants and plant products. Issuance will occur as follows:

(i) Prior to issuing the permit, APHIS will notify the applicant in writing or electronically of all proposed permit conditions. The applicant must agree in writing or electronically that he or she, and all his or her employees, agents, and/or officers, will comply with all permit conditions and all provisions of this subpart. If the organism or associated article will be contained in a private residence, the applicant must state in this agreement that he or she authorizes APHIS to conduct unscheduled assessments of the residence during normal business hours if a permit is issued.

(ii) APHIS will issue the permit after it receives and reviews the applicant's agreement. The permit will be valid for no more than 3 years. During that period, the permittee must abide by all permitting conditions, and the use of the organism or article must conform to the intended use on the permit. Moreover, the use of organisms derived from a regulated parent organism during that period must conform to the intended use specified on the permit for the parent organism.

(iii) All activities carried out under the permit must cease on or before the expiration date for the permit, unless, prior to that expiration date, the permittee has submitted a new permit application and a new permit has been issued to authorize continuation of those actions.

(iv) At any point following issuance of a permit but prior to its expiration date, an inspector may conduct unscheduled assessments of the site or facility in which the organisms or associated articles are held, to determine whether they are constructed and are being maintained in a manner that prevents the dissemination of organisms or associated articles from the site or facility. The permittee must allow all such assessments requested by APHIS during normal business hours. Failure to allow such assessments constitutes grounds for revocation of the permit.

(4) *Denial of a permit application.* APHIS may deny an application for a permit if:

(i) APHIS concludes that the actions proposed in the permit application would present an unacceptable risk to plants and plant products because of the introduction or dissemination of a plant

¹ Persons contemplating the shipment of plant pests, biological control organisms, or associated articles to places outside the United States should make arrangements directly, or through the recipient, with the country of destination for the export of the plant pests, biological control organisms, or associated articles into that country.

pest, biological control organism, or noxious weed within the United States; or

(ii) The actions proposed in the permit application would be adverse to the conduct of an APHIS eradication, suppression, control, or regulatory program; or

(iii) A State or Tribal executive official, or a State or Tribal plant protection official authorized to do so, objects to the movement in writing and provides specific, detailed information that there is a risk the movement will result in the dissemination of a plant pest or noxious weed into the State, APHIS evaluates the information and agrees, and APHIS determines that such plant pest or noxious weed risk cannot be adequately addressed or mitigated; or

(iv) The applicant does not agree to observe all of the proposed permit conditions that APHIS has determined are necessary to mitigate identified risks; or

(v) The applicant does not provide information requested by APHIS as part of an assessment of sites or facilities, or does not allow APHIS to inspect sites or facilities associated with the actions listed on the permit application; or

(vi) APHIS determines that the applicant has not followed prior permit conditions, or has not adequately demonstrated that they can meet the requirements for the current application. Factors that may contribute to such a determination include, but are not limited to:

(A) The applicant, or a partnership, firm, corporation, or other legal entity in which the applicant has a substantial interest, financial or otherwise, has not complied with any permit that was previously issued by APHIS.

(B) Issuing the permit would circumvent any order denying or revoking a previous permit issued by APHIS.

(C) The applicant has previously failed to comply with any APHIS regulation.

(D) The applicant has previously failed to comply with any other Federal, State, or local laws, regulations, or instructions pertaining to plant health.

(E) The applicant has previously failed to comply with the laws or regulations of a national plant protection organization or equivalent body, as these pertain to plant health.

(F) APHIS has determined that the applicant has made false or fraudulent statements or provided false or fraudulent records to APHIS.

(G) The applicant has been convicted or has pled *nolo contendere* to any crime involving fraud, bribery,

extortion, or any other crime involving a lack of integrity.

(5) *Withdrawal of a permit application.* Any permit application may be withdrawn at the request of the applicant. If the applicant wishes to withdraw a permit application, he or she must provide the request in writing to APHIS. APHIS will provide written notification to the applicant as promptly as circumstances allow regarding reception of the request and withdrawal of the application.

(6) *Cancellation of a permit.* Any permit that has been issued may be canceled at the request of the permittee. If a permittee wishes a permit to be canceled, he or she must provide the request in writing to APHIS-PPQ. Whenever a permit is canceled, APHIS will notify the permittee in writing regarding such cancellation.

(7) *Revocation of a permit.* APHIS may revoke a permit for any of the following reasons:

(i) After issuing the permit, APHIS obtains information that would have otherwise provided grounds for it to deny the permit application; or

(ii) APHIS determines that the actions undertaken under the permit have resulted in or are likely to result in the introduction into or dissemination within the United States of a plant pest or noxious weed in a manner that presents an unacceptable risk to plants or plant products; or

(iii) APHIS determines that the permittee, or any employee, agent, or officer of the permittee, has failed to comply with a provision of the permit or the regulations under which the permit was issued.

(8) *Amendment of permits.* (i) *Amendment at permittee's request.* If a permittee determines that circumstances have changed since the permit was initially issued and wishes the permit to be amended accordingly, he or she must request the amendment, either through APHIS' online portal for permit applications, or by contacting APHIS directly via phone or email. The permittee may have to provide supporting information justifying the amendment. APHIS will review the amendment request, and may amend the permit if only minor changes are necessary. Requests for more substantive changes may require a new permit application. Prior to issuance of an amended permit, the permittee may be required to agree in writing that he or she, and his or her employees, agents, and/or officers will comply with the amended permit and conditions.

(ii) *Amendment initiated by APHIS.* APHIS may amend any permit and its conditions at any time, upon

determining that the amendment is needed to address newly identified considerations concerning the risks presented by the organism or the activities being conducted under the permit. APHIS may also amend a permit at any time to ensure that the permit conditions are consistent with all of the requirements of this part. As soon as circumstances allow, APHIS will notify the permittee of the amendment to the permit and the reason(s) for it. Depending on the nature of the amendment, the permittee may have to agree in writing or electronically that he or she, and his or her employees, agents, and/or officers, will comply with the permit and conditions as amended before APHIS will issue the amended permit. If APHIS requests such an agreement, and the permittee does not agree in writing that he or she, and his or her employees, agents, and/or officers, will comply with the amended permit and conditions, the existing permit will be revoked.

(9) *Suspension of permitted actions.* APHIS may suspend authorization of actions authorized under a permit if it identifies new factors that cause it to reevaluate the risk associated with those actions. APHIS will notify the permittee in writing of this suspension explaining the reasons for it and stating the actions for which APHIS is suspending authorization. Depending on the results of APHIS' evaluation, APHIS will subsequently contact the permittee to remove the suspension, amend the permit, or revoke the permit.

(10) *Appeals.* Any person whose application has been denied, whose permit has been revoked or amended, or whose authorization for actions authorized under a permit has been suspended, may appeal the decision in writing to the Administrator within 10 business days after receiving the written notification of the denial, revocation, amendment, or suspension. The appeal shall state all of the facts and reasons upon which the person relies to show that the application was wrongfully denied, permit revoked or amended, or authorization for actions under a permit suspended. The Administrator shall grant or deny the appeal, stating the reasons for the decision as promptly as circumstances allow.

§ 330.202 Biological control organisms.

(a) *General conditions for importation, interstate movement, and environmental release of biological control organisms.* Except as provided in paragraph (b) of this section, no biological control organism regulated under this subpart may be imported, moved interstate, or released into the

environment unless a permit has been issued in accordance with § 330.201 authorizing such importation, interstate movement, or environmental release, and the organism is moved or released in accordance with this permit and the regulations in this subpart. The regulations in 40 CFR parts 1500–1508, 7 CFR part 1b, and 7 CFR part 372 may require APHIS to request additional information from an applicant regarding the proposed release of a biological control organism as part of its evaluation of a permit application. Further information regarding the types of information that may be requested, and the manner in which this information will be evaluated, is found at http://www.aphis.usda.gov/plant_health/permits/index.shtml.

(b) *Exceptions from permitting requirements for certain biological control organisms.* APHIS has determined that certain biological control organisms have become established throughout their geographical or ecological range in the continental United States, such that the additional release of pure cultures derived from field populations of taxa of such organisms into the environment of the continental United States will present no additional plant pest risk (direct or indirect) to plants or plant products. A list of these organisms is maintained online, at http://www.aphis.usda.gov/plant_health/permits/index.shtml.

(1) *Importation and interstate movement of listed organisms.* Pure cultures of organisms on the list may be imported into or moved interstate within the continental United States without further restriction under this subpart.

(2) *Environmental release of listed organisms.* Pure cultures of organisms on the list may be released into the environment of the continental United States without further restriction under this subpart.

(c) *Additions to the list of organisms granted exceptions from permitting requirements for their importation or interstate movement.* Any person may request that APHIS add a biological control organism to the list referred to in paragraph (b) of this section by submitting a petition to APHIS via email to pest.permits@aphis.usda.gov or through any means listed at http://www.aphis.usda.gov/plant_health/permits/index.shtml. The petition must include the following information:

(1) Evidence indicating that the organism is indigenous to the continental United States throughout its geographical or ecological range, or evidence indicating that the organism

has produced self-replicating populations within the continental United States for an amount of time sufficient, based on the organism's taxon, to consider that taxon established throughout its geographical or ecological range in the continental United States.

(2) Results from a field study where data was collected from representative habitats occupied by the biological control organism. Studies must include sampling for any direct or indirect impacts on target and non-target hosts of the biological control organism in these habitats. Supporting scientific literature must be cited.

(3) Any other data, including published scientific reports, that suggest that subsequent releases of the organism into the environment of the continental United States will present no additional plant pest risk (direct or indirect) to plants or plant products.

(d) *APHIS review of petitions.* (1) APHIS will review the petition to determine whether it is complete. If APHIS determines that the petition is complete, it will conduct an evaluation of the petition to determine whether there is sufficient evidence that the organism exists throughout its geographical or ecological range in the continental United States and that subsequent releases of pure cultures of field populations of the organism into the environment of the continental United States will present no additional plant pest risk (direct or indirect) to plants or plant products.

(2) *Notice of availability of the petition.* If APHIS determines that there is sufficient evidence that the organism exists throughout its geographical or ecological range in the continental United States and that subsequent releases of pure cultures of the organism into the environment of the continental United States will present no additional plant pest risk to plants or plant products, APHIS will publish a notice in the **Federal Register** announcing the availability of the petition and requesting public comment on that document.

(3) *Notice of determination.* (i) If no comments are received, or if the comments received do not lead APHIS to reconsider its determination, APHIS will publish in the **Federal Register** a subsequent notice describing the comments received and stating that the organism has been added to the list referred to in paragraph (b) of this section.

(ii) If the comments received lead APHIS to reconsider its determination, APHIS will publish in the **Federal Register** a subsequent notice describing

the comments received and stating its reasons for determining not to add the organism to the list referred to in paragraph (b) of this section.

(e) *Removal of organisms from the list of exempt organisms.* Any biological control organism may be removed from the list referred to in paragraph (b) of this section if information emerges that would have otherwise led APHIS to deny the petition to add the organism to the list. Whenever an organism is removed from the list, APHIS will publish a notice in the **Federal Register** announcing that action and the basis for it.

§ 330.203 Soil.

(a) The Administrator has determined that, unless it has been sterilized, soil is an associated article, and is thus subject to the permitting requirements of § 330.201, unless its movement:

(1) Is regulated pursuant to other APHIS regulations in this chapter; or

(2) Does not require such a permit under the provisions of paragraphs (b)(1) or (c)(1) of this section.

(b) *Conditions governing the importation of soil.*

(1) *Permit.* Except as provided in § 319.37–8(b)(2) of this chapter and except for soil imported from areas of Canada other than those areas of Canada regulated by the national plant protection organization of Canada for a soil-borne plant pest, soil may only be imported into the United States if an import permit has been issued for its importation in accordance with § 330.201, and the soil will be imported under the conditions specified on the permit.

(2) *Additional conditions for the importation of soil via hand-carry.* In addition to the condition of paragraph (b)(1) of this section, soil may be hand-carried into the United States only if the importation meets the conditions of § 330.205.

(3) *Additional conditions for the importation of soil intended for the extraction of plant pests.* In addition to the condition of paragraph (b)(1) of this section, soil may be imported into the United States for the extraction of plant pests if the soil will be imported directly to a biocontainment facility approved by APHIS.

(4) *Additional conditions for the importation of soil contaminated with plant pests and intended for disposal.* In addition to the condition of paragraph (b)(1) of this section, soil may be imported into the United States for the disposal of plant pests if the soil will be imported directly to an APHIS-approved disposal facility.

(5) *Exemptions.* The articles listed in this paragraph are not soil, provided that they are free of organic material. Therefore, they may be imported into the United States without an import permit issued in accordance with § 330.201, unless the Administrator has issued an order stating that a particular article is an associated article. All such articles are, however, subject to inspection at the port of first arrival, subsequent reinspection at other locations, other remedial measures deemed necessary by an inspector to remove any risk the items pose of disseminating plant pests or noxious weeds, and any other restrictions of this chapter:

(i) Consolidated material derived from any strata or substrata of the earth. Examples include clay (laterites, bentonite, china clay, attapulgite, tierrafino), talc, chalk, slate, iron ore, and gravel.

(ii) Sediment, mud, or rock from saltwater bodies of water.

(iii) Cosmetic mud and other commercial mud products.

(iv) Stones, rocks, and quarry products.

(c) *Conditions governing the interstate movement of soil.* (1) *General conditions.* Except for soil moved in accordance with paragraphs (c)(2) through (5) of this section, soil may be moved interstate within the United States without prior issuance of an interstate movement permit in accordance with § 330.201 or further restriction under this subpart. However, all soil moved interstate is subject to any movement restrictions and remedial measures specified for such movement in part 301 of this chapter.

(2) *Conditions for the interstate movement within the continental United States of soil intended for the extraction of plant pests.* Soil may be moved interstate within the continental United States with the intent of extracting plant pests, only if an interstate movement permit has been issued for its movement in accordance with § 330.201, and the soil will be moved directly to a biocontainment facility approved by APHIS in a secure manner that prevents its dissemination into the outside environment.

(3) *Conditions for the interstate movement within the continental United States of soil infested with plant pests and intended for disposal.* Soil may be moved interstate within the continental United States with the intent of disposing of plant pests, only if an interstate movement permit has been issued for its movement in accordance with § 330.201, and the soil will be moved directly to an APHIS-approved

disposal facility in a secure manner that prevents its dissemination into the outside environment.

(4) *Conditions for the interstate movement of soil samples from an area quarantined in accordance with part 301 of this chapter for chemical or compositional testing or analysis.* Soil samples may be moved for chemical or compositional testing or analysis from an area that is quarantined in accordance with part 301 of this chapter without prior issuance of an interstate movement permit in accordance with § 330.201 or further restriction under this chapter, provided that the soil is moved to a laboratory that has entered into and is operating under a compliance agreement with APHIS, is abiding by all terms and conditions of the compliance agreement, and is approved by APHIS to test and/or analyze such samples.

(5) *Additional conditions for interstate movement of soil to, from, or between Hawaii, the territories, and the continental United States.* In addition to all general conditions for interstate movement of soil, soil may be moved interstate to, from, or between Hawaii, the territories, and the continental United States only if an interstate movement permit has been issued for its movement in accordance with § 330.201. In addition, soil moved to, from, or between Hawaii, the territories, and the continental United States with the intent of extracting plant pests is subject to the conditions of paragraph (c)(2) of this section, while soil infested with plant pests and intended for disposal is subject to the conditions of paragraph (c)(3) of this section.

(d) *Conditions governing the transit of soil through the United States.* Soil may transit through the United States only if a transit permit has been issued for its movement in accordance with part 352 of this chapter.

§ 330.204 Exceptions to permitting requirements for the importation or interstate movement of certain plant pests.

Pursuant to section 7711 of the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the Administrator has determined that certain plant pests may be imported into or may move in interstate commerce within the continental United States without restriction. The list of all such plant pests is listed on the Internet at http://www.aphis.usda.gov/plant_health/permits/index.shtml.

(a) *Categories.* In order to be included on the list, a plant pest must:

(1) Be from field populations or lab cultures derived from field populations of a taxon that established throughout its entire geographical or ecological

range within the continental United States; or

(2) Be sufficiently attenuated so that it no longer poses a risk to plants or plant products; or

(3) Be commercially available and raised under the regulatory purview of other Federal agencies.

(b) *Petition process to add plant pests to the list.* (1) *Petition.* Any person may petition APHIS to have an additional plant pest added to the list of plant pests that may be imported into or move in interstate commerce within the continental United States without restriction. To submit a petition, the person must provide, in writing, information supporting the placement of a particular pest in one of the categories listed in paragraph (a) of this section.

(i) Information that the plant pest belongs to a taxon that is established throughout its entire geographical or ecological range within the United States must include scientific literature, unpublished studies, or data regarding:

(A) The biology of the plant pest, including characteristics that allow it to be identified, known hosts, and virulence;

(B) The geographical or ecological range of the plant pest within the continental United States; and

(C) The areas of the continental United States within which the plant pest is established.

(ii) Information that the plant pest has been attenuated of its pathogenicity must include experimental data, published references, or scientific information regarding such attenuation.

(iii) Information that the plant pest is commercially available and raised under the regulatory purview of another Federal agency must include a citation to the relevant law, regulation, or order under which the agency exercises such oversight.

(2) *APHIS review.* APHIS will review the information contained in the petition to determine whether it is complete. In order to consider the petition complete, APHIS may require additional information to determine whether the plant pest belongs to one of the categories listed in paragraph (a) of this section. When it is determined that the information is complete, APHIS will commence review of the petition.

(3) *Action on petitions to add pests.*

(i) If, after review of the petition, APHIS determines there is insufficient evidence that the plant pest belongs to one of the three categories listed in paragraph (a) of this section, APHIS will deny the petition, and notify the petitioner in writing regarding this denial.

(ii) If, after review of the petition, APHIS determines that the plant pest belongs to one of the categories in paragraph (a) of this section, APHIS will publish a notice in the **Federal Register** that announces the availability of the petition and any supporting documentation to the public, that states that APHIS intends to add the plant pest to the list of plant pests that may be imported into or move in interstate commerce within the continental United States without restriction, and that requests public comment. If no comments are received on the notice, or if, based on the comments received, APHIS determines that its conclusions regarding the petition have not been affected, APHIS will publish in the **Federal Register** a subsequent notice stating that the plant pest has been added to the list.

(c) *Petition process to have plant pests removed from the list.* (1) *Petition.* Any person may petition to have a plant pest removed from the list of plant pests that may be imported into or move in interstate commerce within the continental United States without restriction by writing to APHIS. The petition must contain independently verifiable information demonstrating that APHIS' initial determination that the plant pest belongs to one of the categories in paragraph (a) of the section should be changed, or that additional information is now available that would have caused us to change the initial decision.

(2) *APHIS review.* APHIS will review the information contained in the petition to determine whether it is complete. In order to consider the petition complete, APHIS may require additional information supporting the petitioner's claim. When it is determined that the information is complete, APHIS will commence review of the petition.

(3) *APHIS action on petitions to remove pests.* (i) If, after review of the petition, APHIS determines that there is insufficient evidence to suggest that its initial determination should be changed, APHIS will deny the petition, and notify the petitioner in writing regarding this denial.

(ii) If, after review of the petition, APHIS determines that there is a sufficient basis to suggest that its initial determination should be changed, APHIS will publish a notice in the **Federal Register** that announces the availability of the petition, and that requests public comment regarding removing the plant pest from the list of plant pests that may be imported into or move in interstate commerce within the continental United States without

restriction. If no comments are received on the notice, or if the comments received do not affect APHIS' conclusions regarding the petition, APHIS will publish a subsequent notice in the **Federal Register** stating that the plant pest has been removed from the list.

(d) *APHIS-initiated changes to the list.* (1) APHIS may propose to add a plant pest to or remove a pest from the list of plant pests that may be imported into or move in interstate commerce within the continental United States without restriction without a petition, if it determines that there is sufficient evidence that the plant pest belongs to one of the categories listed in paragraph (a) of the section, or if evidence emerges that leads APHIS to reconsider its initial determination that the plant pest was or was not in one of the categories listed in paragraph (a) of this section. APHIS will publish a notice in the **Federal Register** announcing this proposed addition or removal, making available any supporting documentation that it prepares, and requesting public comment.

(2) If no comments are received on the notice or if the comments received do not affect the conclusions of the notice, APHIS will publish a subsequent notice in the **Federal Register** stating that the plant pest has been added to or removed from the list.

§ 330.205 Hand-carry of plant pests, biological control organisms, and soil.

Plant pests, biological control organisms, and soil may be hand-carried into the United States only in accordance with the provisions of this section.

(a) *Authorization to hand-carry.*

(1) *Application for a permit; specification of "hand-carry" as proposed method of movement.* A person must apply for an import permit for the plant pest, biological control organism, or soil, in accordance with § 330.201, and specify hand-carry of the organism or article as the method of proposed movement.

(2) *Specification of individual who will hand-carry.* The application must also specify the individual or individuals who will hand-carry the plant pest, biological control organism, or soil into the United States. If APHIS authorizes this individual or these individuals to hand-carry, the authorization may not be transferred to, nor actions under it performed by, individuals other than those identified on the permit application.

(b) *Notification of intent to hand-carry.* After the permittee has obtained an import permit but no less than 20

days prior to movement, the permittee must notify APHIS through APHIS' online portal for permit applications or by fax and provide the following information in order to receive a hand-carry shipping authorization:

(1) A copy of the face page of the passport for the individual or individuals who will hand-carry the plant pest, biological control organism, or soil;

(2) A description of the means of conveyance in which the individual or individuals will travel, including flight number and airline name for air travel, or vehicle license number or other identifying number for other modes of transportation;

(3) Expected date and time of first arrival;

(4) Expected port of first arrival; and

(5) Travel itinerary from port of first arrival to final destination.

(c) *Notification of arrival at the facility or point of destination.* The permittee or his or her designee must notify APHIS within 24 hours of arrival of the hand-carried plant pest, biological control organism, or soil at the biocontainment facility or other authorized point of destination. This notification must state that the plant pest, biological control organism, or soil has arrived at its destination and that the package in which it was hand-carried has remained sealed until arrival. Notification must be by fax or email, or via the Internet at http://www.aphis.usda.gov/plant_health/permits/index.shtml.

(d) *Denial, amendment, or cancellation of authorization to hand-carry.* APHIS may deny a request to hand-carry, or amend or cancel any hand-carry authorization at any time, if it deems such action necessary to prevent the introduction or dissemination of plant pests or noxious weeds within the United States.

(e) *Appeal of denial, amendment, or cancellation.* Any person whose request to hand-carry has been denied, or whose authorization to hand-carry has been amended or canceled, may appeal the decision in writing to APHIS.

§ 330.206 Packaging requirements.

Shipments in which plant pests, biological control organisms, and associated articles are imported into, moved interstate, or transited through the United States must meet the general packaging requirements of this section, as well as all specific packaging requirements on the permit itself.

(a) *Packaging requirements.* All shipments must consist of an outer shipping container and at least two packages within the container. Both the

container and inner packages must be securely sealed to prevent the dissemination of the enclosed plant pests, biological control organisms, or associated articles.

(1) *Outer shipping container.* The outer shipping container must be rigid, impenetrable and durable enough to remain closed and structurally intact in the event of dropping, lateral impact with other objects, and other shocks incidental to handling.

(2) *Inner packages.* The innermost package or packages within the shipping container must contain all of the organisms or articles that will be moved. As a safeguard, the innermost package must be placed within another, larger package. All packages within the shipping container must be constructed or safeguarded so that they will remain sealed and structurally intact throughout transit. The packages must be able to withstand changes in pressure, temperature, and other climatic conditions incidental to shipment.

(b) *Packing material.* Packing material must be free of plant pests, noxious weeds, or associated articles, and must be new, or must have been sterilized or disinfected prior to reuse. Packing material must be suited for the enclosed organism or article, as well as any medium in which the organism or article will be maintained, and should not be capable of harboring or being a means of the dissemination of the organism or article.²

(c) *Requirements following receipt of the shipment at the point of destination.*

(1) Packing material, including media and substrates, must be destroyed by incineration, be decontaminated using autoclaving or another approved method, or otherwise be disposed of in a manner specified in the permit itself.

(2) Shipping containers may not be reused, except those that have been sterilized or disinfected prior to reuse.

(d) *Costs.* Permittees who fail to meet the requirements of this section may be held responsible for all costs incident to inspection, rerouting, repackaging, subsequent movement, and any treatments.

§ 330.207 Cost and charges.

The inspection services of APHIS inspectors during regularly assigned hours of duty and at the usual places of duty will be furnished without cost. APHIS will not be responsible for any costs or charges incidental to inspections or compliance with the

provisions of this subpart, other than for the inspection services of the inspector.

Subpart—Movement of Soil, Stone, and Quarry Products [Removed and Reserved]

■ 14. Subpart—Movement of Soil, Stone, and Quarry Products, §§ 330.300 through 330.302, is removed and reserved.

PART 352—PLANT QUARANTINE SAFEGUARD REGULATIONS

■ 15. The authority citation continues to read as follows:

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

■ 16. In § 352.1, paragraph (b) is amended by adding, in alphabetical order, definitions for *biological control organism* and *noxious weed*, and by revising the definitions for *Deputy Administrator*, *person*, *plant pest*, and *soil* to read as follows:

§ 352.1 Definitions.

* * * * *

(b) * * *

Biological control organism. Any enemy, antagonist, or competitor used to control a plant pest or noxious weed.

* * * * *

Deputy Administrator. The Deputy Administrator of the Plant Protection and Quarantine Programs or any employee of the Plant Protection and Quarantine Programs delegated to act in his or her stead.

* * * * *

Noxious weed. Any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.

* * * * *

Person. Any individual, partnership, corporation, association, joint venture, society, or other legal entity.

Plant pest. Any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: A protozoan, nonhuman animal, parasitic plant, bacterium, fungus, virus or viroid, infectious agent or other pathogen, or any article similar to or allied with any of the above.

* * * * *

Soil. The unconsolidated material from the earth's surface that consists of rock and mineral particles and that

supports or is capable of supporting biotic communities.

* * * * *

§ 352.2 [Amended]

■ 17. In § 352.2, paragraph (a) introductory text, the first sentence is amended by removing the words “plant pests, noxious weeds, soil,” and adding the words “plant pests, biological control organisms, noxious weeds, soil,” in their place, and by removing the words “contain plant pests or noxious weeds” and adding the words “contain plant pests, biological control organisms, or noxious weeds” in their place.

§ 352.3 [Amended]

■ 18. In § 352.3, paragraph (a) is amended by adding the words “biological control organisms,” after the words “plant pests,” each time they occur.

§ 352.5 [Amended]

■ 19. Section 352.5 is amended by adding the words “biological control organisms,” after the words “plant pests,” each time they occur.

§ 352.6 [Amended]

■ 20. Section 352.6 is amended as follows:

■ a. By removing footnote 2;

■ b. In paragraph (b), by removing the words “as specified by” and adding the words “in accordance with” in their place; and

■ c. In paragraph (c), by removing the citation “§ 330.300(b)” and adding the citation “§ 330.203” in its place.

§ 352.9 [Amended]

■ 21. Section 352.9 is amended by adding the words “biological control organisms,” after the words “plant pests,”.

§ 352.10 [Amended]

■ 22. Section 352.10 is amended as follows:

■ a. By redesignating footnote 3 as footnote 2;

■ b. By removing the words “plant pest or noxious weed dissemination” each time they occur and adding the words “plant pest, noxious weed, or biological control organism dissemination” in their place;

■ c. In paragraph (b)(1), by adding the words “biological control organisms,” after the words “Prohibited or restricted plants, plant products, plant pests,”;

■ d. In paragraph (b)(2)(i), by adding the words “or biological control organisms,” after the words “plant pests”;

² Guidance regarding suitable outer shipping containers, inner packages, and packaging is provided at http://www.aphis.usda.gov/plant_health/permits/index.shtml.

- e. In paragraph (b)(2)(ii), by adding the words “biological control organisms,” after the words “plant pests,”; and
- f. In paragraph (b)(2)(iv), by removing the words “plant pest dispersal” and adding the words “plant pest or biological control organism dispersal” in their place.

§ 352.11 [Amended]

- 23. In § 352.11, paragraph (a)(1) is amended by adding the words

“biological control organisms,” after the words “plant pests,”.

§ 352.13 [Amended]

- 24. Section 352.13 is amended by adding the words “biological control organisms,” after the words “plant pests,”.

§ 352.30 [Amended]

- 25. Section 352.30 is amended by redesignating footnotes 4 and 5 as footnotes 3 and 4, respectively.

Done in Washington, DC, this 6th day of January 2017.

David Howard,

Acting Deputy Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 2017–00532 Filed 1–18–17; 8:45 am]

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Part VI

Department of Agriculture

Animal and Plant Health Inspection Service

7 CFR Parts 340

Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms; Proposed Rule

DEPARTMENT OF AGRICULTURE**Animal and Plant Health Inspection Service****7 CFR Part 340**

[Docket No. APHIS-2015-0057]

RIN 0579-AE15

Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms**AGENCY:** Animal and Plant Health Inspection Service, USDA.**ACTION:** Proposed rule.

SUMMARY: APHIS is proposing to revise its regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms in order to update the regulations in response to advances in genetic engineering and understanding of the plant pest and noxious weed risk posed by genetically engineered (GE) organisms, thereby reducing burden for regulated entities whose organisms pose no plant pest or noxious weed risks. This would be the first comprehensive revision of the regulations since they were established in 1987.

DATES: We will consider all comments that we receive on or before May 19, 2017.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0057>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2015-0057, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0057> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Sidney Abel, Assistant Deputy Administrator, Biotechnology Regulatory Services, APHIS, 4700 River Road, Unit 147, Riverdale, MD 20737-1238; (301) 851-3896.

SUPPLEMENTARY INFORMATION:**Background***Overview of the Current Regulations*

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) administers regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests" (referred to below as the regulations). The current regulations govern the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered (GE) organisms that are considered "regulated articles."

Under the current regulations, a GE organism is considered to be a regulated article if the donor organism, recipient organism, vector, or vector agent¹ is a plant pest or if the Administrator has reason to believe the GE organism is a plant pest. A *plant pest* is defined in § 340.1 as "Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants." If a GE organism is a regulated article, in order for the organism to be imported into the United States, to be moved in interstate commerce, or to be released into the environment through a confined release (collectively referred to in the regulations as an "introduction"), a permit must be issued or the movement or environmental release must occur under a notification procedure. The organism must also be moved in a container that meets certain regulatory requirements, and the container must be marked in accordance with the regulations.

The regulations also provide a process to petition APHIS to determine that a GE organism is nonregulated. A determination of nonregulated status means that the regulated article is no longer subject to the regulations in 7 CFR part 340 and, therefore, there is no longer any authority for APHIS to require a permit or notification for the importation, interstate movement, or environmental release of the regulated

¹ These terms are defined in § 340.1 of the regulations.

article pursuant to 7 CFR part 340.

Agency Actions Following Promulgation of the Current Regulations

APHIS first issued these regulations in 1987 under the authority of the Federal Plant Pest Act of 1957 (FPPA) and the Plant Quarantine Act of 1912 (PQA), two acts that were subsumed into the Plant Protection Act (PPA, 7 U.S.C. 7701 *et seq.*) in 2000, along with other provisions. Since 1987, APHIS has amended the regulations six times, in 1988, 1990, 1993, 1994, 1997, and 2005, to institute exemptions from permitting for certain microorganisms and *Arabidopsis*, to institute the notification, petition, and extension procedures referenced above, and to exclude plants engineered to produce industrial compounds from the notification process.

Although, as discussed above, the current regulations have various functions, their primary function to date has been as a means for APHIS to authorize the importation, interstate movement, and introduction of certain GE organisms via the permit and notification procedures referred to above. Permits and notifications are collectively known as "authorizations." To date, APHIS has issued more than 18,000 authorizations for the environmental release of GE organisms in multiple sites, primarily for research and development of improved crop varieties for agriculture. Additionally, APHIS has issued more than 12,000 authorizations for the importation of GE organisms, and nearly 12,000 authorizations for the interstate movement of GE organisms. APHIS has, to date, denied slightly more than 1,500 requests for permits or notifications, many of which were denied because APHIS ultimately decided the requests lacked sufficient information on which to base an Agency decision.

For authorizations under notification, the regulations require the environmental release to meet performance-based standards set forth in the regulations. These include, among other things, that, when the regulated article is a plant and is to be used for environmental release, it must be planted in such a way that it is not inadvertently mixed with non-regulated plant material that is not part of the environmental release. In addition, the environmental release must be conducted such that the regulated article will not persist in the environment, and no offspring can be produced that could persist in the environment. This latter requirement is accomplished through various measures such as required minimum isolation distances from sexually compatible

plants, effective removal or devitalization of viable plant materials, and monitoring of release sites after completion of the tests and removal of any “volunteer” plants that are found. APHIS conducts inspections of authorized facilities or environmental release sites to evaluate compliance with the regulations.

The interstate movement, importation, or environmental release of regulated articles may be authorized under permit if developers follow the permit conditions specified by the Administrator to be necessary for each activity to prevent the dissemination and establishment of the GE organism. Such conditions include, but are not limited to, maintenance of the regulated article's identity through labeling, retention of records related to the article's specified use, segregation of the regulated article from other organisms, inspection of a site or facility where regulated articles are to undergo environmental release or will be contained after their interstate movement or importation, and the maintenance and disposal of the regulated article and all packing material, shipping containers, and any other material accompanying the regulated article to prevent the dissemination and establishment of plant pests. If a permit holder has been found out of compliance with any of the permit conditions, the permit may be canceled, and if so, further movement or environmental release of GE organisms under that permit will be prohibited.

In addition to issuing permits and authorizing notifications, APHIS has responded to petitions requesting nonregulated status under these regulations. Under this petition procedure, which is described in § 340.6, a petitioner must present detailed information and scientific data regarding the regulated article indicating why the article should not be regulated. To date, APHIS has granted 124 determinations of nonregulated status, of 159 submitted for APHIS review, and all of these determinations have been for GE plants (more information about these is posted at https://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml). Many of these plants are grown for agricultural production in the United States. APHIS determinations of nonregulated status apply to the GE plant(s) as well as their progeny, meaning the deregulated GE plant can be used in plant breeding programs and in agriculture without further oversight from APHIS.

Basis for the Proposed Rule

Advances in APHIS' Understanding of Genetically Engineered Organisms

While the current regulations have been effective in ensuring the safe importation, interstate movement, and environmental release of GE organisms developed using genetic engineering during the past 29 years, advances in genetic engineering have occurred since they were promulgated and new challenges have emerged. Additionally, APHIS has now accumulated nearly three decades of experience in evaluating GE organisms for plant pest risk. The Agency's evaluations to date have provided evidence that most genetic engineering techniques, even those that use a plant pest as a vector, vector agent, or donor, do not result in a GE organism that presents a plant pest risk. This is discussed at greater length later in this document, under the section titled “*General Restrictions and Scope (§ 340.0)*.” Additionally, genetic engineering techniques, such as genome editing and synthetic genomics, have been developed that do not employ plant pests as donor organisms, recipient organisms, vectors, or vector agents; such techniques could be used to produce GE organisms with plant pest risks without falling within the scope of *regulated article*.

Need To Evaluate GE Plants for Noxious Weed Risks

Advances in genetic engineering have also made the need to evaluate GE plants for noxious weed risk more pressing. When APHIS issued the current regulations under the authority of the FPPA and PQA, APHIS' authority to regulate noxious weeds was the Federal Noxious Weed Act of 1974 (7 U.S.C. 2801, FNWA). That act defined *noxious weed* as “Any living stage (including but not limited to, seeds and reproductive parts) of any parasitic or other plant of a kind, or subdivision of a kind, which is of foreign origin, is new to or not widely prevalent in the United States, and can directly or indirectly injure crops, other useful plants, livestock, or poultry or other interests of agriculture, including irrigation, or navigation or the fish or wildlife resources of the United States or the public health.” Because APHIS' noxious weed authority was limited at the time to plants that were of foreign origin and new to or not widely prevalent in the United States, and most GE plants at the time were modified crops that were developed in the United States and were widely prevalent, in their unmodified form, within the United States, APHIS had no basis that would allow it to

evaluate most GE plants for noxious weed risk.

In 1994, Congress amended the FNWA to allow APHIS to issue permits for the interstate movement of noxious weeds. This amendment, however, did not revise the definition of *noxious weed* in the Act.

In 2000, the PPA was issued; In addition to subsuming the FPPA and PQA, it also replaced the FNWA, and provided a new definition of noxious weed: “Any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.” The PPA also provided explicit authority to issue regulations listing noxious weeds that are prohibited or restricted from entering the United States or that are subject to restrictions on interstate movement within the United States, and provided persons with the right to petition APHIS to add or remove noxious weeds from this list.

This revised noxious weed authority led APHIS in 2010 to revise the noxious weed regulations, found in 7 CFR part 360, to reflect the provisions of the PPA. It also led APHIS to revise the manner in which APHIS evaluates plants for noxious weed risk to determine whether to list them in part 360. Under the revised approach that APHIS uses for part 360, the first two considerations in determining whether a plant is a noxious weed are: (1) Identifying what direct injury or damage (physical harm) the plant causes; and (2) identifying what indirect damage the plant may cause to interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment. APHIS then evaluates how likely the plant is to become established in areas within the United States in which it was not known to exist, in the absence of Federal regulation; for example, if it can only become established in tropical climates, Federal regulation is not necessary to prevent its establishment in temperate and subarctic climates. APHIS' final consideration is whether placing the plant under Federal regulation will affect the likelihood of introduction or dissemination of the plant. In general, APHIS lists a plant as a Federal noxious weed if APHIS determines the plant to be invasive and to have significant negative impacts, if introduced or disseminated within the United States, and if APHIS determines that Federal regulation could reduce the likelihood of such introduction or

dissemination. If APHIS determines that Federal regulation of a GE plant—pursuant to the authorities granted in the PPA—is incapable of mitigating identified noxious weed risks, the plant would not be regulated.

This approach means that there are certain plants that APHIS has determined to be weeds, but not to be Federal noxious weeds. This distinction between a weed and a Federal noxious weed warrants emphasis. “Weeds,” in the broadest sense of the term, could include any plant growing where and/or when it is unwanted; even plants that are desirable in some settings could be considered weeds in others. The plants that APHIS evaluates for inclusion on the Federal noxious weed list are, in general, a particular type of weed: An invasive, usually non-native plant that impacted natural and/or agronomic ecosystems, often with significant negative consequences. Of the problematic weeds APHIS evaluates, only a fraction² are determined to be ones for which Federal regulatory controls to prevent their introduction or dissemination are justified; these plant taxa are added to the list of Federal noxious weeds in part 360. Part 360 currently lists 111 aquatic, terrestrial, or parasitic plant taxa as Federal noxious weeds. Many weeds in the United States are not regulated as Federal noxious weeds because they have reached the extent of their ecological range and regulation (*i.e.*, controls on movement) would be costly and provide little if any benefit.

The regulations in part 360, while effective, continue to have a significant restriction that limits their applicability to GE organisms: They are predicated on a determination by APHIS that a taxon is a Federal noxious weed. This determination is easier for plants that have not been genetically engineered, because there are usually many reference points that are available and pertinent to this determination, including international experience with the weed, scientific literature regarding the plant’s biology, published studies, and other data.

For GE plants, there is usually a great deal of data and experience with the non-GE organism. In most cases these non-GE organisms are highly domesticated and cultivated widely within the United States, and there is an extensive body of scientific literature regarding their biology. However, when a GE trait is introduced into the plant, there may in certain instances be little

data or previous experience available for APHIS to rely on in evaluating the properties of the resulting GE plant. Instead, in order to determine whether the GE plant could function as a noxious weed, APHIS would have to rely on its own independent evaluation of the plant itself, based on information provided by the plant’s developers.

Historically, there has not been a significant need for such a noxious weed evaluation of GE plants. Most of the GE plants that APHIS regulated in the past, such as varieties of corn and soybeans modified with common agronomic traits, do not qualify as “noxious weeds.” This is because most GE plants to date have been agricultural crops, and most agricultural crops are not biologically weeds prior to modification. Indeed, in order to domesticate a plant for crop production, farmers often had to deliberately eliminate weedy traits, such as seed shattering, thorns, and seed dormancy, from the plant using traditional breeding techniques. Moreover, the phenotypic traits that have historically been introduced into crops through genetic engineering do not confer weediness. Because the plants have not been weeds prior to genetic engineering, and genetic engineering has not introduced weediness, evaluating the plant solely for plant pest risk has not been problematic.

Additionally, the means by which most GE plants to date have been genetically engineered has brought them under APHIS’ regulatory authority. To date, most GE plants have been engineered using a plant pest as either the donor or vector of genetic material. Because of this use of a plant pest as a donor, vector agent, or vector, the resulting GE organisms fall within the scope of *regulated articles*.

However, in recent years, there has been an increasing diversity of both agronomic and non-agronomic traits engineered in plants. There has also been an increased use of plants in genetic engineering that, in their unmodified state, are known to possess weedy traits. This is especially true of plants used in the production of biofuel. For example, switchgrass (*Panicum virgatum*), which has long been used in the production of ethanol biofuel, has growth patterns in an unmodified state that are characteristic of a weed, and, recently, has been genetically engineered for increased ethanol production. Accordingly, since such plants are somewhat weedy in their unmodified state, and genetic engineering can, in certain instances, enhance the weediness traits that are already present in a plant in its

unmodified state, there is a correspondingly higher risk that such a plant may be genetically engineered into a noxious weed.

Moreover, APHIS’ current regulatory structure, which entails evaluating such plants solely for plant pest risk, is not sufficient to properly identify all risks that these plants present to other plants and plant products. Indeed, under the current structure, such plants may entirely escape regulation. While, in the past, GE plants have almost always used a plant pest to vector genetic material, as we mentioned previously in this document, in recent years, GE techniques have arisen that do not use plant pests as donor organisms or vectors. Moreover, if plants are genetically engineered without the use of a plant pest as a vector or donor, this would require APHIS to consider the plant itself to be a plant pest in order to designate it as a regulated article. However, under the PPA’s definition of *plant pest*, a plant must be parasitic in order to be considered a plant pest. With limited exceptions, such as mistletoe, dodder, and striga, few plants are known to be parasitic. Thus, APHIS considers it both appropriate and necessary to begin to evaluate GE plants for noxious weed risk.

While APHIS discusses the nature of this proposed evaluation later in this document, it is important to delineate, in broad terms, how the Agency would consider a GE plant to be a noxious weed under the proposed regulations. For purposes of the regulations in part 340, APHIS would begin by evaluating whether the plant, in its unmodified state, has weedy characteristics, that is, a plant biologically capable of causing notable physical injury or damage. This would serve as the baseline against which to evaluate the genotype of the GE plant. In evaluating the GE plant, APHIS would assess the likelihood that the modifications made to the genome of the plant alter its ability to cause notable physical harm or injury.

For GE plants that APHIS determines to be weedy prior to genetic modification, APHIS would endeavor to determine whether the plant’s weediness has been enhanced to an extent that it has been engineered into a noxious weed. For GE plants that APHIS determines not to possess weedy traits prior to modification, APHIS would endeavor to determine whether weediness had been introduced into the organism through genetic engineering. Finally, in the event that a Federal noxious weed is genetically engineered (something that has not occurred to date), APHIS would endeavor to determine whether the GE plant is still

² Since 2011, 1700 weeds have been evaluated. Only 24 have been deemed to meet the criteria for inclusion on the list of Federal noxious weeds.

a noxious weed and warrants continued regulation.

If APHIS determines that the GE plant is a noxious weed, it would endeavor to gauge the direct or indirect injury or damage it could cause to crops, livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment. APHIS would make the results of this evaluation publicly available and share both the evaluation and the information on which it is based with the Environmental Protection Agency (EPA) and the U.S. Food and Drug Administration (FDA), as warranted.

Maintaining communication with EPA and FDA as we evaluate GE plants for noxious weed risks is consistent with APHIS' role in the Coordinated Federal Framework for Regulation of Biotechnology (Coordinated Framework).³ Since 1986, the U.S. government has regulated GE organisms consistent with the regulatory framework described in the Coordinated Framework. The Coordinated Framework, published by the Office of Science and Technology Policy, describes the comprehensive Federal regulatory policy for ensuring the safety of biotechnology research and products, and explains how Federal agencies use existing Federal statutes in a manner to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework explains the regulatory roles and authorities for the three major agencies involved in exercising oversight and/or review of GE organisms: APHIS, EPA, and FDA.

The Coordinated Framework provides as a guiding principle that, "[i]n order to ensure that limited Federal oversight resources are applied where they will accomplish the greatest net beneficial protection of public health and the environment, oversight will be exercised only where the risk posed by the introduction is unreasonable." APHIS considers this proposed rule to be entirely consistent with this principle: It will no longer consider GE organisms to be regulated articles solely because of the donor, vector, or vector agent used in genetic engineering, thereby focusing APHIS resources on those GE organisms that may present a plant pest and/or noxious weed risk. However, it is worth noting, as the Coordinated Framework itself does, that a "mosaic" of statutes have, to date,

provided Agencies with authority to exercise oversight of GE organisms. APHIS acknowledges that the Agencies functioning within the Coordinated Framework oversee different aspects of risk and that, accordingly, other Federal Agencies may continue to exercise oversight over GE crops that APHIS no longer views as plant pests or noxious weeds. To that end, APHIS acknowledges that the proposed revisions to 7 CFR part 340 could have direct or indirect impacts on the manner in which FDA and EPA exercise their roles within the Coordinated Framework. To the extent that the public health impacts are due to changes in APHIS regulatory oversight, APHIS discusses them within this document. Economic impacts, in contrast, are discussed in the economic analysis prepared for this rule, while potential environmental impacts are discussed in the draft programmatic environmental impact statement prepared for the rule.

OIG Audits and 2008 Farm Bill

Audits conducted by USDA's Office of Inspector General (OIG) are another basis for this rule. In 2005, OIG conducted an audit of APHIS' regulatory program for GE organisms. OIG found that the use of performance-based standards in APHIS' notification process allowed for a broad spectrum of methods to meet the standards, particularly regarding how the release would be contained to its test field, but Agency practices did not require responsible persons to provide written protocols detailing the exact methods that person would use to meet the standards. OIG suggested that APHIS revise the regulations to minimize the risk of inadvertent dissemination of regulated articles from a test field. Specific recommendations were to require GPS coordinates of all test field sites; to require scientific protocols or study designs from applicants prior to authorizing a field test of a GE organism; and to seek legislative authority to require applicants to provide proof of financial responsibility in the event of an unauthorized release, as APHIS considered necessary.

OIG also suggested that APHIS develop risk-based criteria for conducting inspections and exercising oversight of field tests for the release of GE organisms, and suggested that APHIS provide more explicit guidance regarding how to terminate a field test and document this termination.

In 2015, OIG issued another audit, urging APHIS to implement the recommendations from the 2005 audit that APHIS had not yet implemented.

Finally, in 2008, The Food, Conservation, and Energy Act of 2008 (Farm Bill) was promulgated. Section 10204 of the Farm Bill requires the Secretary of Agriculture to take action on each issue identified in the APHIS document entitled "Lessons Learned and Revisions under Consideration for APHIS' Biotechnology Framework,"⁴ and, where appropriate, promulgate regulations. Like the 2005 OIG audit, this APHIS document suggested the need for greater regulatory oversight of field tests of regulated articles.

On October 9, 2008, APHIS published a proposal⁴ in the **Federal Register** (73 FR 60007–60048, Docket No. APHIS–2008–0023) to amend the regulations to address advances in genetic engineering, to make explicit our evaluation of GE organisms for noxious weed potential, and to respond to the recommendations of the 2005 OIG audit and the provisions of the Farm Bill.

APHIS sought public comment on the proposal from October 9, 2008, to June 29, 2009. APHIS received more than 88,300 comments during the comment period. These were received in 5,580 submissions that included unique comments, form letters, and signatories to petitions. Many commenters expressed concerns regarding the lack of details surrounding a proposed risk-based system that would determine which organisms would fall under APHIS oversight, as well as concerns about a proposed multi-tiered permit system. Commenters also expressed concern about what they perceived to be a significant expansion of Agency regulatory authority.

Based on the breadth and nature of the comments received, APHIS published a notice in the **Federal Register** on March 4, 2015, withdrawing the proposal to allow APHIS to begin a fresh stakeholder engagement process aimed at exploring a variety of regulatory approaches.

Based on the feedback received following the withdrawal of the proposed rule, as well as to reflect provisions of The Food, Conservation, and Energy Act of 2008 (Farm Bill) and recommendations received from the 2005 and 2015 OIG audits, APHIS is proposing to update its regulations in 7 CFR part 340. APHIS is proposing to evaluate GE organisms for noxious weed potential using a different approach

⁴ <https://www.aphis.usda.gov/biotechnology/downloads/supportingdocs/LessonsLearned10-2007.pdf>.

⁴ To view the 2008 proposed rule, the subsequent withdrawal, all supporting documents, and comments APHIS received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0023>.

³ To view the framework, go to https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf.

from that of the 2008 proposed rule, and proposing a new risk analysis process to determine which organisms would require a permit. As previously proposed in 2008, APHIS is also proposing to eliminate the notification process in favor of permitting. APHIS is committed to working with stakeholders to ensure a smooth transition from the current regulatory process to the proposed regulatory process. We request comment on suggestions for ways to smooth the transition period, avoiding disruption in the market, while continuing to ensure that APHIS meets its statutory requirements.

Regulation of GE Biological Control Agents

Additionally, under the new approach, APHIS would regulate a GE organism that is intended for use as a biological control (biocontrol) agent if APHIS determines that it is a plant pest or noxious weed, with a limited exception. Biocontrol involves the reduction of plant pest and weed populations through the use of natural enemies such as parasitoids, predators, pathogens, antagonists, or competitors to suppress plant pest and weed populations.

The exception would be for GE vertebrate biocontrol agents. Although such organisms could fall within the scope of the PPA's definition of *plant pest*, particularly if they are herbivores, it is long-standing APHIS policy not to regulate vertebrates as plant pests. This policy is discussed later in this document.

Regulation of Plants That Produce Plant-Made Industrials and Pharmaceuticals

APHIS recognizes that certain plants are genetically engineered in order to produce pharmaceutical and industrial compounds, also known as plant-made pharmaceuticals and industrials (PMPIs).

When plants are genetically engineered in such a manner, the plants and the pharmaceutical and/or industrial products they produce may fall within the purview of multiple regulatory Agencies: APHIS, EPA, and/or FDA.

Under the current regulations in 7 CFR part 340, APHIS requires permits, as opposed to Notifications, for the environmental release of all GE plants that meet the definition of a regulated article and produce PMPIs. APHIS exercises oversight of all outdoor plantings of these regulated PMPI-producing plants. This oversight includes establishment of appropriate environmental release conditions, inspections, and monitoring. Products

obtained from PMPI-producing plants may be regulated by FDA (authority over pharmaceuticals) or EPA (chemical substances as defined by the Toxic Substances Control Act (TSCA)), depending on their intended use. To date, producers of PMPI-producing plants, or products derived from such plants, have not intended for such plants or plant products to be used for human or animal food. However, if such a plant or plant product is used for human or animal food, the food would be subject to applicable statutory and regulatory requirements under the Federal Food, Drug, and Cosmetic Act.

To date, PMPI-producing GE plants regulated by APHIS have been genetically engineered using a plant pest as the donor, vector, or vector agent, and thus fall under the scope of regulated article in the current regulations in 7 CFR part 340. However, under the provisions of this proposed rule, as discussed at greater length later in this document, a GE plant that is developed using a plant pest as a vector, vector agent, or donor of genetic materials would not necessarily be a regulated organism. Rather, the GE plant would be a regulated organism if it had a plant/trait combination that the Agency has not yet evaluated for plant pest and/or noxious weed risk, if it has received DNA from a taxon that contains plant pests and the DNA from the donor organism is sufficient to produce an infectious entity capable of causing plant disease or encodes a compound known to be pathogenesis-related that is expected to cause plant disease symptoms, or if it was evaluated and found to represent plant pest or noxious weed risks. Additionally, APHIS' evaluations of GE plants for plant pest or noxious weed risk would generally not require data from outdoor plantings.

Even if the plant represents a new plant/trait combination not previously reviewed, there is a likelihood that most, if not all, GE PMPI-producing plants that are currently under APHIS permits could be determined not regulated under the provisions of the proposed regulations after a regulatory status evaluation because they do not represent risks as a plant pest or noxious weed. Thus, such plants could be grown outdoors without the need for permits and without APHIS oversight.

Federal oversight of outdoor plantings of PMPI-producing plants, however, could be necessary to prevent unlawful entry into the food supply of material from such plants. Establishing growing and handling conditions to confine such plants, and inspecting to ensure such conditions are followed, may enable

corrective actions before material from the plants is inadvertently released and causes public health or economic impacts. One of the reasons APHIS' oversight of such crops has been an important part of the coordinated framework for oversight of GE plants is that companies are not necessarily required to notify FDA or EPA when the company plants PMPI-producing plants. For example, for PMPI-producing plants whose products fall under FDA authority, FDA has no regulations governing planting of such crops. For crops genetically engineered to produce pharmaceuticals, companies only have to come to FDA when they have reached the point that they are ready to begin clinical trials with the pharmaceutical derived from the plant. This could be years after they first started growing the pharmaceutical-producing plant in the field.

Under TSCA, EPA has requirements for new chemical substances, including industrial compounds produced in genetically engineered plants. However, given existing APHIS oversight, EPA does not currently have an oversight program nor regulations for genetically engineered plants with industrial compounds.

A gap in Federal oversight of PMPI producing-plants could result in the intentional or inadvertent introduction into the human or animal food supply of unevaluated pharmaceutical or industrial PMPI products, even when the principal purpose of the plants is not for human or animal food use. For example, a company could self-determine that the PMPI produced by the plant was generally recognized as safe (GRAS), and therefore conclude it had no legal obligation to keep surplus PMPI-producing plants out of the human or animal food supply, to keep such PMPI-producing plants from spreading pollen to plants grown for human and animal food purposes, or even to notify any Federal agency that they were planting such crops. In addition to potential food safety risks posed by such plants should they enter the food supply, a gap in Federal oversight could generate concerns from the general public regarding the safety and wholesomeness of the human or animal food supply, which could adversely impact agricultural interests.

APHIS has identified several options that have the potential for adequate Federal oversight of outdoor plantings of plants engineered to produce PMPIs. Under one option, a statute would be enacted, or existing statutory authority amended, to grant one or more Federal agencies explicit authority to provide oversight of outdoor plantings of all GE

PMPI-producing plants and to evaluate GE PMPI-producing plants for all possible risks, beyond plant pest and noxious weed risks. For industrial-producing plants subject to EPA's jurisdiction, a second option is for EPA to develop a program to regulate industrial-producing plants and issue regulations if warranted. Under a third option, APHIS would enter into a memorandum of understanding (MOU) and services agreement with the appropriate Federal Agencies to provide personnel and other resources to assist those Agencies in their oversight of outdoor plantings of PMPI-producing GE plants, recognizing that Federal agencies may not have authority to require notification and/or oversight of the outdoor planting of some of these plants. Under a fourth option, those Federal Agencies would supply their own personnel and resources to exercise oversight of outdoor plantings of PMPI-producing GE plants, recognizing that Federal agencies may not have authority to require notification and/or oversight of the outdoor planting of some of these plants.

APHIS recognizes that there are challenges associated with each of these options. For example, the first option would require legislation to be enacted, which is not within the purview of the Executive Branch of the Federal government. Additionally, all options could require Federal Agencies to incur the costs associated with setting up new regulatory programs. The second option would require time for EPA to stand up a genetically engineered industrial-producing plant oversight program for plants subject to EPA jurisdiction. The third option, in turn, would require policies, procedures, and guidance regarding APHIS' interaction with other Federal Agencies to be developed prior to implementation. To that end, it is important to note that APHIS does not prefer any of these options over the other, nor does the Agency consider the options listed above necessarily to be exhaustive. Rather, we put them forward to indicate that the Agency is aware of the implications of this rule with regard to PMPIs, and to request specific public comment regarding the best manner to address this issue.

Plant-Incorporated Protectant Small-Scale Field Testing

Certain plants are genetically engineered to produce plant-incorporated protectants (PIPs), meaning that they produce pesticides. PIPs fall under the regulatory oversight of EPA. However, currently only APHIS exercises regulatory oversight of PIP plantings on 10 acres or less of land.

Under the proposed rule, APHIS would only require permits for PIPs planted on 10 acres or less if they present a plant pest or noxious weed risk or have not yet been evaluated by APHIS for such risk. Under the current regulations in 7 CFR part 340, APHIS requires permits or notifications for the environmental release of all GE plants that meet the definition of a regulated article and produce PIPs. APHIS exercises oversight of all outdoor plantings of these regulated PIP-producing plants. This oversight includes establishment of appropriate environmental release conditions, inspections, and monitoring.

To date, PIP-producing GE plants regulated by APHIS have been genetically engineered using a plant pest as the donor, vector, or vector agent, and thus fall under the scope of regulated article in the current regulations in 7 CFR part 340. However, under the provisions of this proposed rule, as discussed at greater length later in this document, a GE plant that is developed using a plant pest as a vector, vector agent, or donor of genetic materials would not necessarily be a regulated organism. Rather, the GE plant would be a regulated organism if it had a plant/trait combination that the Agency has not yet evaluated for plant pest and/or noxious weed risk, or if it has received DNA from a taxon that contains plant pests and the DNA from the donor organism is sufficient to produce an infectious entity capable of causing plant disease or that encodes a compound known to be pathogenesis-related that is expected to cause plant disease symptoms. Additionally, APHIS' evaluations of GE plants for plant pest or noxious weed risk would generally not require data from outdoor plantings.

Even if the plant represents a new plant/trait combination not previously reviewed, there is a likelihood that many GE PIP-producing plants that are currently regulated under APHIS permits or notifications could be determined not regulated under the provisions of the proposed regulations after a regulatory status evaluation because they do not represent risks as a plant pest or noxious weed. Thus, such plants could be grown outdoors without the need for an APHIS permit and without undergoing APHIS oversight.

APHIS understands that this proposal would shift Federal oversight of small-scale (10 acres or less) outdoor plantings of PIPs to EPA. EPA may decide to require experimental use permits (EUP) for all, some, or none of such PIPs, and may conduct inspections of all, some, or none of those PIPs under permit. EPA would need to develop a program to

oversee small-scale testing of PIPs and issue regulations if warranted. APHIS is fully committed to coordinating with EPA in this matter in order to give EPA sufficient time to stand up such a program. APHIS understands that an MOU and services agreement may be necessary to provide personnel and other resources to assist EPA during the interim period while EPA implements its own program of oversight for the oversight of outdoor planting of PIPs 10 acres or less.

APHIS recognizes that there are challenges associated with such a transition that would also require EPA to incur the costs associated with setting up a revised regulatory program. Further, such a transition would require policies, procedures, and guidance regarding APHIS' interaction with EPA. APHIS does not consider the approach listed above necessarily to be exhaustive. Rather, APHIS puts it forward to indicate that the Agency is aware of the implications of this rule with regard to small-scale testing of PIPs and to request specific public comment regarding the best manner to address this issue.

Herbicide Resistant GE Crops and Herbicides—Synchronous Decisions With EPA

Certain plants are genetically engineered to make them resistant to herbicides. EPA registers the herbicide products used on herbicide resistant crops, but does not regulate herbicide-resistant crops themselves. APHIS has evaluated and deregulate many GE herbicide resistant plants. To date, the herbicide-resistant GE plants regulated by APHIS have been genetically engineered using a plant pest as the donor, vector, or vector agent, and thus fall under the scope of regulated article in the current regulations in 7 CFR part 340. However, under the provisions of this proposed rule, as discussed at greater length later in this document, a GE plant that is developed using a plant pest as a vector, vector agent, or donor of genetic materials would not necessarily be a regulated organism. Rather, the GE plant would be a regulated organism if it had a plant/trait combination that the Agency has not yet evaluated for plant pest and/or noxious weed risk, or if it has received DNA from a taxon that contains plant pests and the DNA from the donor organism is sufficient to produce an infectious entity capable of causing plant disease or that encodes a compound known to be pathogenesis-related that is expected to cause plant disease symptoms, or has been evaluated by APHIS in accordance with and determined to pose a risk as

a plant pest or noxious weed. Additionally, APHIS' evaluations of GE plants for plant pest or noxious weed risk would generally not require data from outdoor plantings.

Even if the plant represents a new plant/trait combination not previously reviewed, there is a likelihood that many GE herbicide-resistant plants that are currently regulated under APHIS permits or notifications could be determined not regulated under the provisions of the proposed regulations after a regulatory status evaluation because they do not represent risks as a plant pest or noxious weed. Thus, such plants could be grown outdoors without the need for permits and without APHIS oversight.

Commenters to the proposed update to the Coordinated Framework on the Regulation of Biotechnology published on September 22, 2016 (81 FR 65414–65415), expressed the need for coordination between USDA and EPA regarding the timing of deregulation/determination of nonregulated status of herbicide-resistant crops and the registration of herbicides. APHIS recognizes that the asynchronous timing of the deregulation of herbicide-resistant plants and the associated herbicide registration has led to situations where a developer could sell the herbicide-resistant plant/seed without waiting for the associated herbicide registration. In such a situation, farmers may be tempted to illegally use an unregistered herbicide on a crop.

In light of the challenges associated with the asynchronous regulatory actions on the part of APHIS and EPA, APHIS will work with EPA to explore possible solutions to better coordinate the commercial availability of seed for herbicide resistant crops concomitant with the registration of herbicides intended to be used on those crops. Furthermore, APHIS intends to limit the scope of its decisions to be on an individual/specific herbicide resistant crop basis (e.g., glyphosate resistant cotton) so that the EPA and APHIS are making decisions on the same specific herbicide resistant crop/herbicide combinations. This coordination presents challenges because once APHIS determines a GE organism does not represent a risk as a plant pest or noxious weed, APHIS cannot continue to regulate the GE organism or delay announcing the regulatory status determination. When APHIS receives a request for regulatory status determination of an herbicide resistant crop, it is likely to be three or more years before a developer is ready to undergo registration review at EPA. If

APHIS determines that the herbicide resistant plant is not a risk as a plant pest or noxious weed, APHIS does not have the authority in the PPA to require permits with regulatory controls for the movement and outdoor planting of that herbicide tolerant plant during those subsequent years. Nor is it within APHIS authority for APHIS to withhold making a regulatory status evaluation decision for several years and requiring permits for field testing during that time. The issue has not been the illegal use of pesticide during the field testing of herbicide resistant crops by developers but instead is the illegal use of pesticide by farmers on seed that has been deregulated by APHIS and is commercially available before the commercial availability of the herbicide designed for those crops. One option to address this coordination would be to enact a new statute or amend an existing statute to make it illegal to sell seeds for herbicide resistant crops before the registrations were completed for use on those crops. Another option might involve a voluntary agreement by seed developers to withhold selling seed of herbicide-resistant crops until EPA registrations are completed for the herbicide products designed for those crops. In cases where APHIS makes a decision deregulating an herbicide-resistant crop or determines under § 340.4 that an herbicide-resistant crop is unlikely to pose a risk as a plant pest and/or noxious weed and will no longer be a regulated organism and no herbicide product has been registered by EPA for use on that herbicide-resistant crop, APHIS would indicate on the APHIS Regulatory Status List Web site and Web sites associated with deregulation decisions that no herbicide product is registered by EPA for use on this herbicide-resistant crop and it is illegal to use any herbicide product on these crops unless registered by EPA for such use. Additionally, APHIS would include language in deregulation decision letters sent to the developer and **Federal Register** notices associated with § 340.4 final determinations indicating it is illegal to use herbicides on these crops until the herbicide product is registered by EPA for use on the herbicide-resistant crop. This decision letter and all other information regarding APHIS's decisions would also be made available to the public on the APHIS Web site.

APHIS does not consider the approaches listed above necessarily to be exhaustive and recognizes that one of the options listed would require legislation to be enacted, which is not within the purview of the Executive

Branch of the Federal government. However, APHIS puts them forward to indicate that the Agency is aware that asynchronous timing of the deregulation of herbicide-resistant plants and the associated herbicide registrations can lead to significant problems, and to request specific public comment regarding the best manner to address this issue.

An Overview of Our Proposed Regulatory Structure

Before discussing the specifics of these proposed revisions, APHIS wishes to provide an overview of how the Agency generally envisions the various sections of the proposed rule interacting, from the perspective of a developer of a GE organism. This overview assumes that the organism falls within the scope of our proposed definition of *GE organism*, and is a regulated organism under proposed § 340.0.

Until such time as the developer wishes to import the organism, move it interstate, or release it into the environment, no action would be required of the developer. However, if the developer believes that it possesses sufficient information to demonstrate that the organism presents no plant pest or noxious weed risk, and wished to release it into the environment, it would have to submit this information to APHIS and request that APHIS conduct an evaluation of such risk. The process for submitting such a request, as well as the possibilities for how APHIS would act on that request, is set forth in proposed § 340.4.

If APHIS evaluates the GE organism in accordance with § 340.4 and determines that it is unlikely to pose a risk as a plant pest and/or noxious weed, it would no longer be a regulated organism and may be imported, moved interstate, or released into the environment without further restriction under the proposed regulations. APHIS would maintain a list of such organisms on a Web site. If new information is obtained which indicates that a previously deregulated GE organism may present a plant pest and/or noxious weed risk, APHIS may reevaluate the GE organism and reconsider its regulatory decision.

If the organism is still a regulated organism following such an evaluation, with one, limited exception (the interstate movement of GE *Arabidopsis thaliana* under certain conditions, which APHIS discusses later in this document) the developer would need to obtain a permit for its importation, interstate movement, or environmental

release. APHIS' proposed permitting process is set forth in § 340.3.

If APHIS issues a permit to the developer for the importation, interstate movement, or release into the environment of the organism, the developer would have to comply with permitting conditions regarding such importation, interstate movement, or release into the environment. The developer would also have to comply with container and shipment requirements that pertain to the movement of regulated organisms. These requirements would also be set forth in § 340.3.

The developer would also have to retain certain records regarding permitted activities. These are set forth in proposed § 340.5. Failure to retain such records, or comply with other regulatory requirements or permitting conditions, could result in enforcement activities. These would also be set forth in § 340.5.

If, in the course of interacting with APHIS, the developer had to provide the Agency with confidential business information (CBI), the developer could denote such CBI in accordance with § 340.6.

Finally, § 340.7 would provide the developer with information regarding APHIS policy related to costs and charges incident to compliance with the regulations.

This is, again, a general overview of the proposed regulations. As such, it does not attempt to capture every nuance of the proposed regulations, nor does it apply to every scenario that may occur under those regulations.

What follows is a more in-depth discussion of the provisions of the rule.

What Constitutes a Genetically Engineered Organism Under the Proposed Regulations

While APHIS discusses most of its proposed definitions later in this document, the Agency considers it necessary, at the outset of discussion of the provisions of the proposed rule, to discuss two of its proposed definitions, for the terms *genetic engineering* and *genetically engineered (GE) organism*. This is because the proposed regulations would not apply to organisms that are created using techniques that APHIS does not consider to constitute *genetic engineering* or that fall outside the scope of *GE organism*. Such organisms, which would not be regulated by APHIS under 7 CFR part 340, would not be expected to come to APHIS for evaluation. However, if such organisms are submitted to APHIS, APHIS would evaluate them for plant pest and/or

noxious weed risk and provide guidance on their regulatory status.

By *genetic engineering*, APHIS would mean techniques that use recombinant or synthetic nucleic acids with the intent to create or alter a genome. APHIS considers synthetic nucleic acids to be nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules.

APHIS would exclude from the definition of *genetic engineering* traditional breeding techniques (including, but not limited to, marker-assisted breeding, as well as tissue culture and protoplast, cell, or embryo fusion) or chemical or radiation-based mutagenesis. APHIS would do so because the Agency has never considered such techniques to constitute genetic engineering. Accordingly, organisms created through such techniques are currently excluded from regulation under 7 CFR part 340, and would continue to be so excluded.

For the purposes of proposed 7 CFR part 340, APHIS would define *GE organism* as an organism developed using genetic engineering. Thus, if an organism is created using techniques that do not fall within the scope of *genetic engineering*, the organism itself would not fall within the scope of *GE organism*. APHIS would also exclude, from its definition of *GE organism*, certain organisms that are created using techniques that fall within the scope of *genetic engineering*, but that could otherwise have been produced using traditional breeding techniques or chemical or radiation-based mutagenesis. Such organisms are essentially identical, despite the method of creation, because while there may be small genetic differences, those differences are not phenotypically observable and these types of changes occur naturally in all organisms. APHIS would also exclude "null segregants," that is, the progeny of a GE organism where the only genetic modification was the insertion of donor nucleic acid into the recipient's genome, but the donor nucleic acid is not passed to the recipient organism's progeny and the donor nucleic acid has not altered the DNA sequence of the progeny. Specifically, for purposes of the revised regulations, an organism would not be considered a *GE organism* if:

- The genetic modification to the organism is solely a deletion of any size or a single base pair substitution which could otherwise be obtained through the

use of chemical- or radiation-based mutagenesis.⁵

- The genetic modification to the organism is solely introducing only naturally occurring nucleic acid sequences from a sexually compatible relative that could otherwise cross with the recipient organism and produce viable progeny through traditional breeding (including, but not limited to, marker-assisted breeding, as well as tissue culture and protoplast, cell, or embryo fusion).

- The organism is a "null segregant."

APHIS would exclude the first two types of organisms from the definition of *GE organism* for three reasons. First, as mentioned above, it would do so because the organisms could otherwise have been produced from practices that APHIS is proposing to exclude from the definition of *genetic engineering*. Genetic engineering is often used instead of traditional breeding practices, including chemical or radiation-based mutagenesis, in order to expedite development of an organism with a desired genotype and/or phenotype.

Examples from the realm of GE plants illustrate these practices. Chemical and radiation-based mutagenesis creates thousands of mutations in a single organism, and most of the plant breeders' subsequent efforts involve eliminating unwanted mutations by repeated crosses and selection, each of which can take months to years to complete. Conversely, using genetic engineering, single base pair substitutions, as well as deletions of differing sizes, can be precisely administered very quickly, avoiding this lengthy process of eliminating unwanted mutations. The resulting organism, however, remains identical to one that could otherwise have been developed using chemical or radiation-based mutagenesis.

Similarly, traditional breeding techniques may require many generations of crossing to introduce a naturally occurring trait. For example, it can take decades to introduce a disease-resistant trait to apples through traditional breeding techniques. However, genetic engineering can introduce the same trait in a fraction of the time while maintaining all other cultivar characteristics of the apple.

The second reason for the exclusions is that GE plants as a class, which constitute the vast preponderance of GE organisms to date, pose no greater plant pest or noxious weed risk than their

⁵ A single base pair substitution is the most common type of substitution induced by chemical mutagenesis or natural variation and, therefore, most similar to the type of genetic variation that is possible through conventional breeding.

counterparts developed through traditional breeding techniques or chemical or radiation-based mutagenesis. Moreover, it is both impracticable and unnecessary to regulate plants created through traditional breeding techniques or chemical or radiation-based mutagenesis for plant pest or noxious weed risk.

This is not to say that plants with undesirable phenotypes have never been bred through traditional breeding, or chemical or radiation-based mutagenesis never result in mutations that are undesirable. Indeed, as mentioned above, chemical and radiation-based mutagenesis tend to create thousands of mutations in an organism, most of which are undesirable.

However, traditional breeding techniques, in the form of deliberate selection and breeding of those plants with desirable phenotypes, have been used since the advent of sedentary agriculture, and nearly every domesticated crop has, at one point, been subject to traditional breeding techniques. Chemical and radiation-based mutagenesis, in turn, have been used for nearly a century in the development of thousands of commodities, including such commercial commodities as ruby red grapefruit and many commercial varieties of wheat and rice. If APHIS were to regulate organisms developed through traditional breeding techniques or chemical or radiation-based mutagenesis, that would entail the regulation, at least provisionally, of almost every commercially available human or animal food crop. This is impracticable.

Such regulations would also fail to take into consideration the usual purpose of applying traditional breeding techniques or chemical or radiation-based mutagenesis to a plant: To introduce desirable phenotypic traits into the organism or remove phenotypically undesirable traits from the organism. Additionally, it would fail to take into adequate consideration that phenotypic traits that could increase the plant pest or noxious weed risk posed by a plant tend to also adversely impact its vitality, uniformity, or commercial viability. For example, a mutation caused by chemical or radiation-based mutagenesis could render a plant more susceptible to certain viroids or pathogens and able to transfer this increased susceptibility to sexually compatible relatives, and thus increase the plant pest risk associated with the plant. However, it would also directly adversely affect the plant's vitality. For

these reasons, farmers and developers have long bred out unwanted phenotypic traits that arise as the result of traditional breeding techniques and/or chemical or radiation-based mutagenesis, and planted and/or commercialized the most phenotypically desirable plant produced using such techniques.

In this regard, it is important to note that genetic engineering is used to create this phenotypically desirable organism, rather than the other products created through traditional breeding techniques, including chemical or radiation-based mutagenesis. In 1987, the Council of the National Academy of Sciences concluded that there is no evidence of a unique risk inherent in the use of recombinant DNA techniques or the movement of genes between unrelated organisms. This means that risks associated with the introduction of recombinant DNA engineered organisms are the same as those associated with non-genetically engineered organisms and organisms modified by other methods and that the assessment of such risks should be based on the nature of the organism and the environment into which it is introduced rather than the methods by which it was produced. Furthermore, this same conclusion is a basis of the Coordinated Framework that regulation should be based on the risks of the organism and not the process used to create it. Accordingly, because the plant pest and noxious weed risk posed by the plant is equivalent, regardless of whether it was created through genetic engineering or traditional breeding (including chemical or radiation-based mutagenesis), and such risk is likely to be low because of the purpose of applying traditional breeding techniques, including chemical or radiation-based mutagenesis to a plant, APHIS is proposing to exclude GE plants that could have otherwise been developed through traditional breeding techniques, including chemical or radiation-based mutagenesis, from the definition of "genetically engineered organism" and hence from regulation under the revised 7 CFR part 340.

This same exclusion would apply to non-plant organisms. Non-plant organisms, which fall under the scope of the regulations as defined in § 340.0, are either plant pests, or organisms which have received genetic material sufficient to produce an infectious entity capable of causing plant disease or that encodes a compound known to be pathogenesis-related that is expected to cause plant disease symptoms. Organisms of the latter type would not qualify for the exclusion, as receipt of genetic material

capable of conferring the new properties could not be achieved through traditional breeding techniques, including chemical or radiation-based mutagenesis. However, it can be envisioned that plant pests might be altered in such a way that the exclusion would apply. In these cases, since the resulting plant pest would not be defined as a genetically engineered organism under 7 CFR part 340, they would be regulated, if needed, under APHIS's plant pest regulations in 7 CFR part 330. This is appropriate since these organisms are biologically analogous to non-GE plant pests with mutations. It is important to note that, to date, we have not encountered GE organisms of this type and that the GE plant pests that we do have experience with (e.g., pink bollworm expressing marker genes, citrus tristeza virus expressing antimicrobial compounds) would still be regulated under 7 CFR part 340 since this exclusion would not apply. The two APHIS program areas responsible for regulating under 7 CFR parts 330 and 340 are coordinating to ensure that together they are prepared to regulate any type of plant pest as needed.

However, APHIS has prepared a proposed rule that would remove this exception. In its place, all plant pests would require permits issued pursuant to part 330, unless the importation, interstate movement, or environmental release of the organism is explicitly authorized in other APHIS regulations in 7 CFR. Under APHIS' proposed revision to the regulations in part 340, the importation, interstate movement, or environmental release of GE organisms that could have otherwise been developed through traditional breeding techniques or chemical or radiation-based mutagenesis would not be explicitly authorized; rather, such organisms would be exempted from the regulations in part 340, with no reference to the conditions for movement or environmental release of such organisms. Accordingly, GE organisms that could have otherwise been created through traditional breeding techniques, including chemical or irradiation-based mutagenesis, and could pose a potential plant pest risk, would now be subject to 7 CFR part 330.

This touches on several important caveats with regard to the first two proposed exemptions from the definition of *genetically engineered organism*. The first is that the exemptions pertain only to 7 CFR part 340. As noted above, an organism may be exempted from regulation under 7 CFR part 340, and yet still subject to other APHIS regulations. The second

caveat is that the proposed exemptions are based on APHIS' statutory authority under the PPA. They should therefore be taken as a statement of one Agency's regulatory policy, rather than scientific findings regarding all possible risks posed by such organisms. Accordingly, for organisms that APHIS determines to present negligible plant pest or noxious weed risk, FDA and EPA may anticipate more substantial human or animal food adulterant or pesticide risks, and therefore not reduce their oversight of the same organisms.

The third caveat is that APHIS is not claiming that additions, deletions, and substitutions to an organism's genome are inherently risk-free. Indeed, as discussed later in this document, the addition into an organism's genome of a sequence that encodes an infectious entity capable of causing plant disease or encodes a compound known to be pathogenesis-related that is expected to cause plant disease symptoms introduces plant pest risk into that organism, and would be one of APHIS' criteria for regulating the organism under the proposed regulations. Rather, APHIS considers such additions, deletions, or substitutions to present an acceptable plant pest and/or noxious weed risk when they are used to create an organism that could otherwise have been created through traditional breeding techniques and/or chemical or radiation-based mutagenesis; in other words, it is the product, rather than the techniques used to derive the product, that APHIS considers to present an acceptable level of risk. The Agency considers this to be consistent with the principles set forth in the Coordinated Framework.

The third proposed exclusion is for progeny of GE organisms where the only genetic modification was the insertion of donor nucleic acid into the recipient's genome, but the inserted donor nucleic acid is not passed to the recipient organism's progeny and has not altered the DNA sequence of the recipient organism's progeny. Such progeny are often referred to as null segregants. Traits can sometimes be introduced by genetic engineering into breeding lines to simplify breeding without altering the DNA sequence of progeny; the traits can be eliminated with a simple cross and are no longer present in the final organism. An example of use of such techniques to facilitate traditional breeding would be the introduction of certain genes into trees solely to reduce the time to flowering, thereby speeding up a tree-breeding program. In this example, the progeny do not contain the early flowering gene and their DNA sequence

has not been altered by the early flowering gene. Because the DNA of the progeny is no different from the DNA of the recipient organism prior to the use of genetic engineering, APHIS does not consider the progeny to be GE organisms for purposes of the proposed regulations.

APHIS requests specific comment on its definition of genetically engineered organism, specifically the appropriateness of the proposed exemptions, and whether commenters can identify any scenarios in which they would exempt from APHIS regulation an organism that presents a plant pest and/or noxious weed risk. APHIS also requests specific comment on whether any other types of organisms should be excluded from the definition of *genetically engineered organism*. Finally, APHIS is interested in whether the terms "traditional breeding techniques" and "chemical or radiation-based mutagenesis" should be defined, and whether the exclusions themselves are sufficiently delineated.

APHIS wishes to point out that its proposed definition for *genetically engineered organism* is limited to the regulations in 7 CFR part 340 and may not reflect the definition of *genetically engineered organism* that is in use by other Federal Agencies. Differences in definitions are, in part, attributable to the differences in the agencies' statutory and regulatory authorities. Under the Coordinated Framework for the Regulation of Biotechnology, we intend to work cooperatively with other relevant agencies that may also be considering their policies or approaches related to genome editing applications within their jurisdictions.

General Restrictions and Scope (§ 340.0)

Section 340.0 would set forth general restrictions regarding the movement and environmental release of GE organisms, as well as the scope of the revised regulations in part 340.

Paragraph (a) of § 340.0 would provide that no person may move any regulated GE organisms except in accordance with part 340. Movement of regulated organisms that is not in accordance with the part could present a risk of introducing or disseminating plant pests and noxious weeds within the United States.

Paragraph (b) of § 340.0 would specify the types of GE organisms APHIS would consider to be regulated organisms under the revised regulations.

Under our proposed regulations, a GE organism would be a regulated organism if:

- Prior to genetic engineering, the GE organism belonged to any taxon listed in

accordance with § 340.2 and met the definition of *plant pest* in § 340.1. (As § 340.2 currently does, proposed § 340.2, which APHIS discusses below, would specify that certain taxa are plant pests or are known to contain plant pests. Section 340.1 would contain definitions of terms used in the proposed regulations.)

- The GE organism has received DNA from any taxon listed in accordance with § 340.2, the DNA from the donor organism is sufficient to produce an infectious entity capable of causing plant disease or encodes a compound known to be pathogenesis-related that is expected to cause plant disease symptoms, and the GE organism has not been evaluated by APHIS for plant pest risk in accordance with § 340.4.

- The GE organism is a plant that has a plant and trait combination that has not been evaluated by APHIS for plant pest and noxious weed risk in accordance with § 340.4⁵; or

- The GE organism is any of the foregoing that has been evaluated by APHIS in accordance with § 340.4 and determined to pose a risk as a plant pest or noxious weed, or is a GE organism that has otherwise been determined by the Administrator to pose a risk as a plant pest or noxious weed.

The proposed criteria differ from the current criteria in several respects. First, the current criteria consider a GE organism to be a regulated article if the donor, vector, or vector agent is a plant pest. This reflects the concern in the 1980s that if an organism was modified using genetic material taken from a plant pest, or a plant pest was used as a vector or vector agent to carry genetic material into an organism, the resulting GE organism could also be a plant pest.

Based on APHIS' experience evaluating field trial data from thousands of permits that authorize environmental release of regulated organisms, as well as more than 150 petitions for nonregulated status, this has not proven to be the case. Although a plant pest may contribute or vector genes to a GE organism, this has not been shown in APHIS' evaluation of data to cause that GE organism, particularly if it is a plant, to become a plant pest. Indeed, experience has shown that the use of genes from donor organisms which are plant pests, as well as the use of vectors which are from plant pests, has not resulted in plant pest risks of any sort in recipient organisms.

⁵ As APHIS discusses below, APHIS would maintain a list of plant and trait combinations that APHIS has evaluated for plant pest and noxious weed risk online if this rule is finalized.

Rather, the most common use of plant pest components in genetic engineering involve either the use of a disarmed version of the plant pathogenic bacterium *Agrobacterium tumefaciens* to vector genes into a plant or use of genetic material from plant pest donors which function as regulatory sequences in the plant. Use of *Agrobacterium tumefaciens* as a vector of genetic material does not leave viable bacteria behind in the recipient organism and does not cause disease. Likewise, regulatory sequences such as the 35S promoter from Cauliflower Mosaic Virus and the nopaline synthase (nos) terminator from *A. tumefaciens* are themselves unable to be expressed and do not confer plant pest traits. Rather, they facilitate the expression of other genes in the GE organism. The use of plant pests in these ways either as donors of regulatory sequences or for vectoring genetic material into a recipient organism has a long history of safe use and does not result in disease or injury to the recipient organism.

It is conceivable that a donor organism that is a plant pest could result in a GE organism that is itself a plant pest if (1) the DNA sequence that is encoded in the organism is able in itself to be expressed phenotypically or confers plant pest traits, or (2) if the inserted DNA enables the organism to produce pathogenesis-related compounds, that is, compounds that are typically produced by pathogens and involved in producing disease symptoms. Examples of such compounds would include plant degrading enzymes, plant growth regulators, phytotoxins, or compounds that can clog plant vascular systems. In either instance, APHIS would not expect phenotypic expression of plant disease unless large portions of a genome from a plant pest were introduced to a recipient organism, a practice that APHIS considers unlikely for developers to use based on their practices to date.

Likewise, based on APHIS' evaluation of field trial data to date, there is no evidence that the use of plant pests as vectors or vector agents in the production of GE organisms results in a GE organism that is itself a plant pest.

Accordingly, APHIS would regulate GE organisms that have received DNA from a taxon containing a plant pest only if the DNA from the donor organism is sufficient to produce an infectious entity or encodes a pathogenesis-related compound that is expected to cause plant disease symptoms. By "sufficient to produce an infectious entity," APHIS means that the DNA sequence that is encoded in

the organism is able in itself to be expressed phenotypically or confers traits that meets the definition of *plant pest*. In such instances, APHIS considers it appropriate and prudent to regulate the GE organism until such time as APHIS evaluates the risk it poses as a plant pest in accordance with proposed § 340.4, and thereafter to regulate it only if APHIS determine it to pose a risk as a plant pest.

Additionally, APHIS would no longer regulate a GE organism solely because its vector or vector agent is a plant pest. APHIS adopted this approach in 1987 because the use of plant pest vectors in recombinant DNA technologies was, at the time, a relatively recent development, and there was a corresponding need to exercise precaution in regulating such use until the plant pest risk associated with the practice was further evaluated. In twenty-nine years of regulating GE organisms because of the use a plant pest as a vector or vector agent, APHIS has no evidence that using genetic material from plant pests as vectors or vector agents for other genetic material results in a GE organism that is itself a plant pest. Accordingly, this proposed rule would change APHIS' approach, and GE organisms that were created using a plant pest as a vector or vector agent would no longer be regulated solely because of the use of such a vector or vector agent. Instead, the organisms would be regulated if they themselves presented a known or unevaluated plant pest risk. This is in keeping with the overarching aim of this proposed rule, which is to regulate the products of genetic engineering, rather than the methods by which those products are developed.

A second difference from the current criteria is that, for reasons discussed previously in this document, APHIS is proposing that APHIS may regulate a GE plant under 7 CFR part 340 if APHIS determines that it is a noxious weed.

Our proposed criteria would also attempt to clarify a current category of regulated articles, GE plants that are regulated because the Administrator has reason to believe they are a plant pest. When the current regulations were issued, APHIS had less experience regulating GE organisms, and there was corresponding uncertainty regarding the degree to which subjecting a plant to genetic engineering, without the use of a plant pest as a donor, vector, or vector agent, would cause the plant to become a plant pest. This category was intended to allow APHIS to consider such plants to be regulated articles, until APHIS had sufficient information to classify it either definitively as a plant pest, or to

determine that it presented no plant pest risk. The category was especially useful when a GE plant was developed using novel genetic engineering techniques.

In the 29 years since the current regulations were issued, APHIS' evaluation of petitions for nonregulated status for more than 150 GE plants has provided a basis to help the Agency delineate the plant and trait combinations that cause a GE organism to act as a plant pest from the combinations that pose no plant pest risk.

Accordingly, APHIS now considers there to be two instances in which a GE plant should be a regulated organism. The first instance is when APHIS has reached a determination that the plant and trait combination associated with the GE plant causes it to act as a plant pest or noxious weed. APHIS is making a draft list of such combinations available along with this proposed rule, as well as a list of combinations that APHIS has determined to present no plant pest or noxious weed risk,⁶ and APHIS invites public comment on these draft lists. For purposes of this proposed rule, the lists would be maintained at the following Web site: <http://www.aphis.usda.gov/biotechnology/2016-340-proposed-rule>. If the rule is finalized, APHIS would develop a different URL that would contain the lists, as well as all other information regarding this rule, and that would indicate that the rule had been finalized.

The second instance in which APHIS would consider it necessary to regulate a GE plant is when APHIS is presented with a GE plant with a novel plant and trait combination, and has not yet evaluated this plant and trait combination for its plant pest and noxious weed risk.

On a related matter, APHIS acknowledges that a novel GE organism could be developed that does not fall into any of the Agency's other categories of regulated organisms, but that APHIS determines poses a risk as a plant pest or noxious weed. APHIS's last criteria for regulated organisms would allow APHIS to regulate such an organism.

⁶ APHIS encourages stakeholders to review these lists and submit specific public comment regarding the listed plant/trait combinations. In particular, while the vast majority of listed plant/trait combinations correspond to specific organisms that have been granted nonregulated status under the current regulations, the list would not be event-specific. This means that if a crop-trait combination has nonregulated status on the list, all specific events that have that crop-trait combination would be nonregulated. Practically speaking, this means that the list would grant nonregulated status to almost all GE corn and soybean that developers have brought to APHIS to date.

Taxa That Are or Contain Plant Pests (§ 340.2)

As stated previously, § 340.2 contains a list of taxa that are considered to be plant pests. That list has not been amended since it was established in 1987.

To improve regulatory flexibility and help ensure the list remains current, APHIS is proposing to remove the list of taxa from § 340.2 and place it on the Internet at <http://www.aphis.usda.gov/biotechnology/2016-340-proposed-rule>. APHIS would advise the public of changes to the list through notices published in the **Federal Register**. These notices would request public comment.

APHIS is not proposing any changes to the listed taxa at this time, however.

Per the definition of “plant pest” in the PPA, any organism belonging to any taxon contained within any listed genus or taxon is only considered to be a plant pest if the organism “can directly or indirectly injure, or cause disease, or damage in any plants or parts thereof, or any processed, manufactured, or other products of plants.” Thus a particular unlisted species within a listed genus would be deemed a plant pest if the scientific evidence indicates that the organism is a cause of direct or indirect injury, disease, or damage to any plants, plant parts, or products of plants.

Section 7711 of the PPA generally requires permits for the importation or interstate movement of plant pests, but allows the Secretary to create “exceptions” to this general permitting requirement when the Secretary deems that a permit is not necessary. That is, these regulated activities are allowed, under certain conditions, without seeking prior authorization via permit. The current APHIS regulations refer to these PPA exceptions as “exemptions.” Paragraph (b) of current § 340.2 contains a list of exemptions from the requirement for a permit for the interstate movement of certain GE strains of the microorganisms *Escherichia coli*, *Saccharomyces cerevisiae*, and *Bacillus subtilis*, and the plant *Arabidopsis thaliana*. One of the conditions for this exemption for the listed microorganisms is that the cloned material does not include the complete infectious genome of a known plant pest.

Because, under § 340.0, APHIS must have determined that a GE microorganism is a plant pest in order for it to be a regulated organism, the GE microorganism strains mentioned above, which APHIS has evaluated and determined to present no plant pest risk, would not be regulated organisms. Thus

APHIS would not need to retain specific permitting exemptions for them in § 340.2.

APHIS would also retain the exemption from interstate movement permits for GE organism *A. thaliana* due to its historically exempted status. The exemption would be contained in § 340.3.

APHIS would propose changes to the list through publication of a **Federal Register** notice. The notice would state why APHIS has determined it necessary to add or remove a taxon from the list, and would request public comment.

APHIS would review the comments received and publish its final decision in the **Federal Register**.

The PPA also allows for a person to petition the Secretary to add or remove a plant pest from the regulations. Currently, § 340.5 contains provisions for petitioning the Administrator to amend the list of organisms in § 340.2 by either adding or deleting any genus, species, or subspecies. The list of requirements for petitioning the Administrator include formatting and submission procedures that are currently contained in § 340.5(b).

However, these procedures have not been updated since 1994. While most of the procedures are still accurate, some of them have changed. For example, the requirements do not consider the potential for electronic submission of a petition via email. They also provide an obsolete address for postal submissions. Therefore, APHIS is proposing to remove the specific requirements related to formatting and submission procedures for petitions from the regulations. The procedures would instead be located on the Internet at <http://www.aphis.usda.gov/biotechnology/2016-340-proposed-rule>. APHIS is also proposing to revise the submission procedure to allow petitions to be submitted via email, and to update the address for postal submissions.

These changes would update the submission procedure, and allow for greater flexibility in revising procedures, if, for example, the address for submissions changes in the future.

Please note that, regarding the formatting procedures, APHIS is proposing to retain a requirement that the petition not contain trade secrets or CBI. APHIS often needs CBI for permit applications, particularly for those that request the release of a GE organism into the environment, in order to determine the appropriate permitting conditions, and APHIS may need CBI as part of a regulatory status evaluation in accordance with proposed § 340.4 in order to assess the plant pest and/or noxious weed risk associated with the

organism submitted for evaluation. However, a determination that a taxon is or contains a plant pest will be based on a review of scientific literature, and thus, CBI is not germane to our determination.

Following the receipt of a petition to amend the list of organisms in § 340.2, APHIS would publish a notice announcing the availability of the petition in the **Federal Register** and solicit public comment on the petition for 60 days. Following the close of the comment period, the Administrator would announce his or her decision to either approve the petition in whole or in part or deny the petition in a subsequent **Federal Register** notice.

Finally, APHIS is proposing to add an appeals process in the event that the Administrator denies a request to amend the list of taxa that are described in § 340.2. Any person whose petition has been denied would be able to appeal the decision in writing to the Administrator within 30 days after receiving the written notification of the denial. The appeal would have to state all of the facts and reasons upon which the person relies to assert that the petition was wrongfully denied. The Administrator would then grant or deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances allow.

Notification

The current regulations in § 340.3 provide criteria for a notification procedure whereby certain GE plants may be authorized for importation, interstate movement, or environmental release in lieu of a permit. As mentioned previously in this document, rather than using customized requirements, like the permitting conditions used for the permitting procedure, the notification procedure uses performance-based standards that are described in the regulations themselves. The use of the performance-based standards that do not vary from one notification to the next facilitates rapid administrative turnaround on notifications. However, in some ways, the term “notification” has been misleading to the public, since sending a notification does not mean automatic authorization by APHIS.

Rather, currently, APHIS reviews notifications to verify that the GE plants meet the eligibility criteria and also evaluates whether the proposed importation, interstate movement, or environmental release can be done in a manner that meets the performance-based standards described in the regulation. In many ways, these APHIS evaluations for notifications are very

similar to those done for permit applications, but the notification procedure relies on applicants agreeing to meet the performance-based standards described in the regulations rather than submitting an application for APHIS review describing the specific measures they will employ for the activity (as is the case for permits). With permits, but not with notifications, APHIS can accept the proposed measures or add to them, and the result is a set of binding customized permit conditions.

Because the notification procedure uses only the performance-based standards in the regulations, it is more administratively streamlined, but the general nature of the standards has made it difficult for APHIS inspectors to determine if a notification holder is in compliance with the standards. This, in turn, can also make enforcement more difficult.

For example, under the current regulations, one of the performance-based standards for notifications relevant to controlled outdoor uses states that: "The field trial must be conducted such that (1) the regulated article will not persist in the environment, and (2) no offspring can be produced that could persist in the environment." Conversely, conditions which APHIS places on permits are more specific, and do not rely as much on subjective determinations by APHIS personnel. A specific permit condition that could be used to address just part of the performance-based standard described above might read: "After final harvest of the plants covered under this environmental release permit, the site will be monitored every 4 weeks for the emergence of volunteer seedlings for 1 year, and any emerging volunteer plants will be devitalized before they produce pollen. Records of the monitoring and management of volunteers must be maintained by the permit holder and made available to APHIS upon request."

The use of performance-based standards under the notification procedure has some benefits, such as providing the responsible person with flexibility in how the standard is met, *e.g.*, allowing for appropriate changes in protocols used during the growing season. However, there are some disadvantages in not specifically enumerating the specific measures that constitute compliance with the regulations. The permitting procedure avoids this disadvantage, because the permit conditions specify which actions need to be taken by the responsible person to be in compliance.

Because of this, APHIS has determined that it would have more

risk-appropriate oversight, better regulatory enforcement, and improved transparency if all regulated movements are authorized under the permitting procedure. Therefore, APHIS is proposing to remove current notification provisions from the regulations and require that all authorizations for movement be conducted under permit.

As mentioned earlier in this document, the use of the permitting procedure in lieu of notifications is also necessary for APHIS to address some of the recommendations arising from the OIG audits and the provisions of the 2008 Farm Bill. Both the OIG audit and the Farm Bill expressed concern with the use of performance-based standards to regulate field tests of regulated organisms, and recommended that APHIS amend the regulations to exercise greater oversight and enforcement of such field tests and to require more extensive reporting and record retention regarding such tests. These requirements can be added to a permit as permitting conditions, but do not lend themselves to performance-based standards. Some permit conditions, however, are, and have always been, performance-based. APHIS acknowledges that there is more than one way to manage risks and works with the permit applicant to find a mutually acceptable way to do so. In some instances, permit conditions may allow for the flexibility inherent in performance standards, while ensuring a specific requirement is addressed, something not possible with the notification procedure.

In short, if APHIS were to retain the notification procedure, in order to be responsive to the risk factors that may be associated with certain field trials, but not others, to make it easier to assess compliance, and to be responsive to both the OIG audits and the 2008 Farm Bill, APHIS would need to significantly revise the procedure to substantially reduce its reliance on performance-based standards. However, doing so would eliminate the primary benefit of the current notification procedure, which is that it is more administratively streamlined than the permitting procedure. Indeed, a revised procedure which took into consideration all risk factors that may be associated with specific field trials would be both complex and exhaustive. For these reasons, APHIS is proposing to do away with the notification procedure, rather than revise it.

Permits (§ 340.3)

The permitting procedure found in § 340.4 of the current regulations describes types of permits, information

required for permit applications, standard permit conditions, and administrative information (*e.g.*, time frames, appeal procedure, etc.). Permits include specific conditions that must be followed by the permit holder. Standard permit conditions, or "general conditions," are listed in the current regulations and APHIS can supplement these with additional conditions as necessary. The current regulations specify the amount of time that APHIS is allotted for review of complete permit applications: 60 days for permits for importation and interstate movement; 120 days for controlled outdoor use. The current regulations also outline requirements for protecting CBI when submitting a permit application.

APHIS proposes to reorganize the regulations to improve the clarity of the permit application and evaluation procedures. In addition, APHIS is proposing changes to the regulations to reflect certain provisions of the 2008 Farm Bill. As APHIS mentioned previously in this document, section 10204 of Title X of the Farm Bill requires the Secretary of Agriculture to take action on each issue identified in the document entitled "Lessons Learned and Revisions under Consideration for APHIS' Biotechnology Framework" and, where appropriate, promulgate regulations.

APHIS is proposing certain regulatory changes concerning permit application information requirements, permit conditions, records, and reports that address many of the considerations outlined in the "Lessons Learned and Revisions under Consideration for APHIS' Biotechnology Framework." The permitting procedure would continue to identify and obtain information relevant to evaluating the risks associated with a proposed movement, and determine and document whether, and under what conditions, the activity should be allowed.

Paragraph (a)(1) of proposed § 340.3 would provide that, except as provided in paragraph (a)(2) of the section, APHIS must have evaluated a regulated organism in accordance with § 340.4 before APHIS will issue a permit for its importation, interstate movement, or release into the environment. As mentioned previously in this document, § 340.4 would contain our process for evaluating regulated organisms for plant pest or noxious weed risk. In order to draft permitting conditions that are commensurate with the risk a GE organism poses as a plant pest or noxious weed, it is necessary for APHIS to have evaluated this risk.

If this rule is finalized, when it is fully implemented, APHIS believes that such

evaluations will take a matter of months. Additionally, such evaluations could often result in a determination that the organism poses no risk as a plant pest and/or noxious weed, and thus is not subject to the regulations. For these reasons, APHIS envisions that, if this rule is finalized, most developers would wait for APHIS to issue a final determination of regulatory status, in accordance with § 340.4, before submitting a permit application to import the regulated organism, move it interstate, or release it into the environment.

However, APHIS also envisions that there could be instances in which there would be an immediate need to import a regulated organism or move it interstate, even though APHIS has not yet evaluated the risk it poses as a plant pest and/or noxious weed. This could occur when, for example, a developer consolidates research laboratories. To allow for such instances, proposed paragraph (a)(2) of § 340.3 would provide that APHIS may issue a permit pursuant to the section for the importation or interstate movement of a regulated organism that has not been evaluated in accordance with § 340.4. For the purposes of permitting conditions, APHIS would assume that the regulated organism presents a risk as a plant pest and/or noxious weed. If the regulatory status of the organism is evaluated in accordance with § 340.4 during the duration of the permit, APHIS could amend the permit, or, if the organism is determined to pose no risk as a plant pest and/or noxious weed, terminate the permit and communicate this termination to the permittee.

While APHIS could foresee the need for the Agency to issue such permits, APHIS does wish the public to be aware of some of the issues that it has identified with doing so. First, because APHIS would not have evaluated the organism for plant pest and/or noxious weed risk, the Agency would need to presume a high degree of such risk. Accordingly, permitting conditions could be significantly more stringent for such unevaluated organisms than they would be for the same organisms, following evaluation in accordance with § 340.4. Second, unlike organisms evaluated in accordance with § 340.4 prior to permitting, determining nonregulated status for such organisms would not be a category of action that is exempt under APHIS' regulations implementing the National Environmental Policy Act (43 U.S.C. 4321 *et seq.*).

For these reasons, APHIS requests specific public comment regarding

whether paragraph (a)(2) of § 340.3 is necessary, or addresses a scenario that is unlikely to occur under the proposed regulations. APHIS also requests public comment regarding whether there are any instances in which there would be an immediate need to issue a permit for the environmental release of a regulated organism that had not yet been evaluated in accordance with § 340.4.

Paragraph (a)(3) of § 340.3 would state that, except as provided in paragraph (c) of § 340.3, a permit must be issued by APHIS for the importation, interstate movement, or release into the environment of all regulated organisms. Paragraph (c) would provide exemptions from interstate permitting requirements for *GE A. thaliana*.

Paragraph (b) of proposed § 340.3 would outline how to submit a permit application. Applicants would have to submit a permit application through a method listed at the Web address contained in the regulations; for purposes of this proposed rule, that address is <http://www.aphis.usda.gov/biotechnology/2016-340-proposed-rule>. That Web site specifies that permit applications must be submitted using APHIS' current electronic permitting system, ePermits, or the paper-based APHIS form 2000.

APHIS is proposing to list the methods for submitting a permit application on the Internet, rather than in the regulations, in order to make it easier to ensure they remain up-to-date. For example, APHIS is currently developing a new electronic permitting system to replace ePermits.

APHIS is also proposing to remove the specific requirements for what should be included in a permit application from the regulations. Instead, they would be listed on an APHIS Web site; for purposes of the proposed rule, that Web site is <http://www.aphis.usda.gov/biotechnology/2016-340-proposed-rule>.

That Web site would first list general application requirements for all permit applications, and then break out additional requirements for specific permit applications. General information requirements that all types of permit applications would have to provide include the name, title, and contact information of the responsible person and agent, if possible; the country and locality where regulated organism was collected, developed, manufactured, reared, cultivated or cultured; the intended activity (*i.e.*, importation, interstate movement, or release into the environment) for the regulated organism; and information regarding how the regulated organism

was developed using genetic engineering.

For interstate movement or importation, the permit application would also have to contain the origin and destination of the regulated organism, including information on the addresses and contact details of the sender and recipient, if different from the responsible person; the method of shipment, and means of ensuring the security of the shipment against unauthorized release of the regulated article, to be used in the importation or interstate movement; and the manner in which packaging material, shipping containers, and any other material accompanying the regulated organism will be disposed to prevent the unauthorized release of the regulated article.

Permit applications for release into the environment would have to address the spread, persistence risk, and potential harm of the regulated organism in the environment, including but not limited to a description of how the phenotype of the regulated organism differs from the phenotype of the recipient organism, particularly with respect to potential interactions with, and its likelihood of spread and/or persistence in, the environment; and the location and size of all proposed environmental release sites, including area, geographic coordinates, addresses, land use history of the site and adjacent areas, and name and contact information of a person at each environmental release site, if different from the responsible person. In the event that additional release sites are requested after the issuance of a permit, APHIS would continue the practice of evaluating and amending permits to add new release sites.

The categories of information listed above reflect the categories of information that APHIS considers necessary to be included in all permit applications, as well as additional basic information required for each permit type. APHIS has learned that there are certain areas that are not specified in the current regulations where APHIS routinely needs information from the applicant in order to ensure safety. These areas do not become apparent to applicants until they submit a permit application and APHIS subsequently follows up for additional information in order to assess the activities listed on each permit application for plant pest and/or noxious weed risk. This had led to two *de facto* lists of information requirements for permit applications: The list in the regulations themselves, and the list of information that APHIS routinely requires in order to decide

whether to grant a permit. By maintaining a single list of permit application requirements on the Internet, APHIS can ensure that the list is up-to-date and increase clarity regarding the information that the Agency needs.

The categories of information above also align with the recommendations of the 2005 and 2015 OIG audits, and the provisions of the 2008 Farm Bill. For example, the OIG recommendations have led to provisions that would enable APHIS to require geographic coordinates for the locations of environmental releases.

As mentioned previously, paragraph (c) of § 340.3 would continue to exempt *A. thaliana* from permitting requirements for interstate movement. This is based on that organism's historically exempt status, which has not resulted in the dissemination of plant pests within the United States. In the 1990 proposed rule (55 FR 28637–28638, Docket No. 90–052) in which APHIS proposed to grant such an exemption, the Agency stated its rationale for the exemption: *A. thaliana* has desirable phenotypic traits (including small size, short generation times, high seed set, and ease of growth) that lend themselves to use in scientific studies; *A. thaliana*'s small genome size, lack of repetitive DNA, and ease of genetic modification using *Agrobacterium tumefaciens* make it especially useful for molecular genetic analysis; GE *A. thaliana* often needs to be moved interstate between laboratories and other containment facilities as part of scientific studies; and safeguards exist which can adequately mitigate the plant pest risk associated with such movement. This rationale still holds true.

APHIS contemplated a Web-based list of other regulated organisms that have been granted exemptions from permitting requirements for interstate movement. However, APHIS was not able to identify any organisms that would fall within the same category as *A. thaliana*: A taxon for which certain, but not all, types of movement have been evaluated and present no plant pest risk. That said, APHIS requests public comment regarding any taxa that may be similarly situated.

Paragraph (d) of § 340.3 would contain specifics regarding APHIS' review of permit applications. APHIS would review permit applications to determine completeness. If the application is incomplete, APHIS would notify the applicant in writing, and the applicant would be provided an opportunity to revise the application. APHIS is proposing to institute a time

limit for receiving additional information in the event that a permit application is determined to be incomplete. If the applicant does not respond to a request for more information within 30 days of receipt of APHIS' request, APHIS would deem the permit application withdrawn and return it to the applicant. This time limit would help preclude the Agency from acting on a permit application when the responsible person no longer desires a permit, and would allow APHIS to focus its review of permit applications, while also affording applicants sufficient time to provide APHIS additional information in the event that they submit incomplete applications.

Once an application is complete, APHIS would review it to determine whether to approve or deny the permit application.

Paragraph (d)(2) of proposed § 340.3 would contain provisions regarding APHIS' assignment of permit conditions. If a permit application is approved, permit conditions would be assigned to each permit commensurate with the risk of the regulated organism and activity. General permit conditions, which APHIS is proposing to list in paragraph (e) of § 340.3, would be assigned to all permits. Additional or expanded permit conditions may also be assigned that are commensurate to the risk that the activities listed on the permit application present of disseminating the regulated organism, or other plant pests or noxious weeds. Examples of such additional requirements include, but are not limited to, specific requirements for reproductive, cultural, spatial, and temporal controls; monitoring; post-termination land use; site security or access restrictions; management practices such as training of personnel involved in the movement; and practices to prevent articles associated with the movement of a regulated organism from becoming contaminated with plant pests or noxious weeds.

Under paragraph (d)(3) of proposed § 340.3, all premises associated with the permit would be subject to inspection before and after permit issuance. APHIS would require that the responsible person provide APHIS inspectors access to inspect any relevant premises, facility, location, storage area, waypoint, materials, equipment, means of conveyance, and other articles related to the movement of organisms regulated under 7 CFR part 340. While this requirement is functionally the same as current inspection requirements, it clarifies what locations and articles may be subject to inspection. Failure to allow

the inspection of premises prior to the issuance of a permit would be grounds for the denial of a permit application. Failure to allow an inspection after permit issuance would be grounds for revocation of the permit.

While the current regulations provide for review of permit applications by State regulatory officials, they do not include review by Tribal officials when a permit application is submitted for the importation into, interstate movement through, or release into the environment on Tribal lands of a regulated organism. To correct this oversight, APHIS proposes to state in proposed § 340.3(d)(4) that APHIS will include relevant Tribal officials when it provides copies of permit applications to State regulatory officials.

Under the current regulations, the permitting procedure does not include a formal acknowledgement from the applicant prior to permit issuance that they are aware of and consent to the permit conditions. APHIS considers such an acknowledgement to be necessary, however, in order to verify that applicants are aware of and willing to abide by the conditions. Accordingly, APHIS is proposing to add a requirement in § 340.3(d)(5) that, prior to permit issuance, applicants must agree, in writing and in a manner prescribed by the Administrator, that they are aware of, understand, and will comply with all permit conditions. If an applicant fails to comply with this provision, their application would be denied.

The use of permits and permit conditions gives APHIS and the responsible person an understanding as to what actions must be taken for the permit holder to comply with the regulations. However, in the current regulations, APHIS also provides a list of general permitting conditions that are assigned to all permits in order to provide as much transparency and predictability as possible about permit conditions. To that end, as APHIS mentioned above, APHIS would continue to maintain general conditions that APHIS would assign to all permits issued under the regulations within the regulations themselves. Paragraph (e) of § 340.3 would contain these general conditions. APHIS would require that:

- The regulated organism must be maintained and disposed of in a manner so as to prevent the unauthorized release of the regulated organism.
- The regulated organism must be kept separate from other organisms, except as specifically allowed in the permit.

- The regulated organism must be maintained only in areas and premises specified in the permit.

- The regulated organism's identity must be maintained at all times.

- In the event of an unauthorized release, the regulated organism must undergo the application of remedial measures determined by the Administrator to be necessary to prevent the spread of regulated organism, and the responsible person must contact APHIS as described in the permit within 24 hours of discovery, and subsequently supply a statement of facts in writing no later than 5 business days after discovery.

- The duration that a permit is valid will be listed on the permit itself. During that time, the responsible person must maintain records related to permitted activities of sufficient quality and completeness to demonstrate compliance with all permit conditions and requirements under the proposed regulations. The responsible person must submit reports and notices to APHIS at the times specified in the permit and containing the information specified within the permit. Inspectors must be allowed access, during regular business hours, to the place where the regulated organism is located and to any records relating to the movement of a regulated organism. APHIS access to records includes visual inspection and reproduction (photocopying, digital reproduction, etc.) of all records required to be maintained under the proposed regulations, as requested by APHIS.

- The responsible person must notify APHIS in writing if any permitted activity associated with environmental release will not be conducted.

- Within 28 days after the initiation of any permitted activity related to environmental release, the responsible person must report to APHIS in writing the actual release site coordinates and details of the release, such as how many acres planted, how many organisms released, etc., based on permit conditions, as well as every 28 days thereafter until all releases are completed.

- A person who has been issued a permit must submit to APHIS an environmental release report within 6 months after the termination of any release into the environment. The report must include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, non-target organisms, or the environment.

Most of the conditions listed above are drawn from the conditions found in the current regulations, although APHIS

has added some additional details to clarify their meaning. For example, while the existing regulations provide that APHIS inspectors shall be allowed access to records related to the permit, they do not specify what "access to records" means. APHIS would clarify that this includes visual inspection and reproduction (photocopying, digital reproduction, etc.) of all records required to be maintained under the proposed regulations. APHIS believes that these additional details will better communicate with applicants what the general permitting conditions are, and will better support administration of the permitting program, including compliance and enforcement.

APHIS is also proposing to specify that regular reporting regarding any activities associated with environmental release of a regulated organism is a general permitting condition. As APHIS mentioned previously in this document, the 2005 and 2015 OIG audits suggested that APHIS exercise greater and more coordinated oversight over field tests of GE organisms. APHIS identified regular reporting regarding actual release site coordinates and details of the release as a key means of exercising such oversight. Adding this reporting requirement as a general permitting condition will ensure that it is communicated to all permittees.

Similarly, to respond to the recommendations of the 2005 and 2015 OIG audits, APHIS would add a requirement for Agency notification if any permitted activity associated with environmental release will not be conducted as a general permitting condition. This general condition would work in tandem with the reporting requirement mentioned above, and help APHIS resolve what could otherwise be considered inconsistencies between the permit conditions and the regular reports.

In addition, while the current general permitting conditions require a field test report following termination of a field test, in recent years, APHIS has required a more extensive report, an environmental release report, through permitting conditions. Our general permitting conditions would reflect this.

APHIS recognizes that these last three general permitting conditions pertain only to activities associated with environmental release of a regulated organism. APHIS also recognizes that it is possible that certain permit applications may not request to release the regulated organism into the environment. However, the permit issued would still contain these general conditions to communicate to the permittee APHIS' general requirements

regarding environmental release of regulated organisms. This will ensure that all permittees are aware of those requirements, and is consistent with the recommendations of the OIG audits. The conditions would also prove useful, should the responsible person subsequently request amendments to the permit to authorize environmental release.

While the general permitting conditions that are currently in the regulations contain a condition that pertains to packing material used to transport the regulated organism, APHIS would not retain this as a general permitting condition. This is because it would be covered by shipping requirements that APHIS is proposing to add to the regulations in paragraph (i) of § 340.3.

Under the current regulations, the Administrator may deny or cancel a permit if the applicant has not complied with one or more of the conditions listed on the permit. The Administrator will confirm the reasons for the cancellation or denial in writing within 10 days, and the applicant may appeal the decision in writing within 10 days after receiving the written notification of cancellation or denial. The Administrator may then grant or deny the appeal, in writing, stating the reason for the decision as promptly as circumstances allow.

APHIS is proposing to elaborate on the circumstances under which a permit application may be denied in § 340.3(f)(1). Such circumstances would include when the Administrator concludes that, based on the application or additional information, the actions proposed under the permit may result in the unauthorized release of a regulated organism, or another plant pest or noxious weed; or when the Administrator determines that the responsible person or any agent of the responsible person has failed to comply at any time with any APHIS regulation or the conditions of any permit that has previously been issued in accordance with the regulations.

The first condition pertains to instances in which APHIS cannot reach a conclusion that the risk of dissemination of regulated organisms, plant pests, or noxious weeds will be adequately mitigated if APHIS issued a permit authorizing the actions requested on the permit application. This could occur when, for example, a responsible person does not formally acknowledge that he or she understands the permitting conditions.

The second condition would pertain to instances in which prior actions taken by the applicant or his or her

agents call into question their ability to abide by permitting conditions.

While the current regulations contain procedures for denying a permit application, they do not detail measures for APHIS to revoke a permit. Therefore, APHIS proposes to establish explicit procedures for the revocation of permits. Procedures for revoking a permit would be contained in § 340.3(f)(2). These procedures would state that a permit may be revoked if, following issuance of the permit, the Administrator receives information that would otherwise have provided grounds for APHIS to deny the permit application; if the Administrator determines that actions taken under the permit have resulted in the unauthorized release of a regulated organism, or another plant pest or noxious weed; or if the Administrator determines that the responsible person or any agent of the responsible person has failed to comply at any time with any APHIS regulation or the conditions of any permit issued.

Paragraph (g) would contain the current procedures for appealing the denial of a permit application or revocation of a permit.

APHIS is also proposing to clarify in § 340.3(h) of the regulations the procedure to be used when amendment of existing permit conditions is sought by the responsible person or required by APHIS. Such amendments may include the transfer of the permit to a new responsible person. Currently, the administrative practices that APHIS uses to amend permits have not been explicit in the regulations, and these additions would provide increased transparency and efficiency.

Under the current regulations, notifications for environmental releases and interstate movement are valid for 1 year. Interstate movement permits are only valid for 1 year from the date of issuance, and a new import permit must be obtained for each imported shipment. These permits are referred to as "limited permits." The duration period for a permit issued solely for an environmental release is not currently specified.

APHIS has found that it often takes considerably longer than 1 year for activities authorized under a permit to be completed. For example, with a perennial plant such as a tree, it may take much longer than a year to gather relevant data about the plant for the purpose of determining risk.

Additionally, monitoring activities may be required for several years after a field test is complete. In other cases, multiyear research projects may require multiple shipments of regulated

organisms for analysis. APHIS is therefore proposing to eliminate the current limits in the regulations on the duration of permits for interstate movement and importation. APHIS also would continue not to specify a duration that an environmental release permit is valid in the regulations. The duration that a permit is valid would instead be specified on the permit itself, as a permitting condition. These changes should give APHIS the flexibility to issue these permits with suitable durations to meet individual circumstances.

Paragraph (i) of § 340.3 would contain shipping requirements for regulated organisms. These would specify that all shipments of regulated organisms must be secure shipments, which APHIS would define as shipments in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

Currently, § 340.8 contains container requirements for regulated organisms. These requirements are very prescriptive. While they do allow responsible persons to request variances from the requirements, this request process, by its nature, results in a case-by-case determination that other types of containers are acceptable for the transportation of regulated organisms. The current regulations also do not clearly reflect the performance-based standard that APHIS used to develop the requirements, which was that the container should be sufficient to prevent dissemination of a regulated organism during movement. Our proposed requirements would maintain this performance-based standard, while making this standard more explicit and the requirements less prescriptive, thus eliminating the need for a request process for variances.

APHIS would, however, retain a provision in the current regulations, currently a footnote to § 340.8, that specifies that all regulated organisms must be shipped in accordance with the regulations in 49 CFR part 178. Those regulations, which are administered by the Department of Transportation (DOT), provide packaging requirements for materials, including regulated organisms that DOT has designated as hazardous materials.

Paragraph (i) of § 340.3 would also specify that the container must be accompanied by a document that includes the names and contact details for the sender and the recipient. It would also specify that, following the completion of the shipment, all packing

material, shipping containers, and any other material accompanying the regulated organism would have to be treated or disposed of in such a manner so as to prevent the unauthorized dissemination and establishment of regulated organisms. As mentioned above, this latter requirement is currently a general permitting condition, but could more accurately be described as a shipping requirement.

Finally, paragraph (i) would contain container marking and identity requirements for imported GE organisms. These requirements are currently found in § 340.7.

APHIS has occasionally received inquiries from stakeholders regarding whether a permit could authorize the commercial distribution of a regulated organism. Currently, most developers of GE organisms generally have not commercialized their products until after those products were granted a determination of nonregulated status. However, APHIS does not prohibit commercializing GE organisms that have not been granted a determination of nonregulated status. APHIS currently authorizes a small number of permits for such commercial production.

Under the proposed regulations, there may be some regulated organisms that an entity wishes to commercialize or grow on a large scale, under permit. As currently occurs, APHIS would evaluate these permit applications on a case-by-case basis, to determine whether permitting conditions can be developed that adequately address the risk associated with the permitted actions.

Courtesy Permits

The current regulations in § 340.4(h) provide APHIS with the ability to issue courtesy permits in order to facilitate the movement of GE organisms that are not subject to the regulations in 7 CFR part 340 but whose movement might otherwise be hindered because of their similarity to organisms or articles that are regulated by other APHIS programs. APHIS commits significant resources to the issuance of these courtesy permits for the movement of organisms that are not subject to the provisions of part 340.

Courtesy permits have been part of the regulations since their inception in 1987, and have been useful to inform shippers and State and Federal inspectors not yet fully familiar with requirements for GE organisms that the shipments in question were not regulated. However, their continued use has led to the widespread misunderstanding by some researchers that courtesy permits are actually required for the movement of certain organisms, or that issuance of a courtesy

permit removes the requirement for applicants to follow other applicable regulations, such as the plant pest regulations found in 7 CFR part 330. This confusion partially stems from the similarities between the application form for courtesy permits and those for other types of permits, as well as between the courtesy permit itself and other permits. Therefore, in an effort to alleviate confusion and to better focus and allocate APHIS resources, APHIS is proposing to remove the regulations concerning courtesy permits. It has been common APHIS practice to facilitate the importation of non-regulated articles through the use of letters indicating that no permit is required. APHIS would continue to work with researchers and relevant government regulatory officials to facilitate the transition.

Petitions for Nonregulated Status

The current regulations in § 340.6(a) provide that any person may submit a petition to APHIS seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a petition for a determination of nonregulated status must take and the information that must be included in the petition. Those organisms which are granted nonregulated status are free of all requirements under 7 CFR part 340. This nonregulated status is different from that of certain organisms that meet the definition of regulated articles, but which are exempt from the requirement for a permit when moved interstate under the specific conditions specified in the regulations.

Published APHIS decisions made under the current regulations have used different ways to express the basic standard “unlikely to pose a plant pest risk” in determining whether to grant nonregulated status to a specific GE organism. In its determinations, APHIS has conveyed the basic standard of “unlikely to pose a plant pest risk” by concluding that the GE organism “poses no more of a plant pest risk than its non-GE counterpart,” “will not pose a plant pest risk”; or that there is “no plant pest risk,” or “no direct or indirect plant pest effects.” Regardless of the phrases used in its determination of nonregulated status to date, APHIS has applied the same basic evaluation criteria to each determination to conclude that the GE organism is unlikely to pose a plant pest risk and therefore is not subject to the part 340 regulations. Those criteria include, among other things, conclusions on the potential of the GE organism to create pest or disease problems; the potential for nontarget

effects that might affect organisms beneficial to agriculture; changes in agricultural practices that might exacerbate pest or disease problems; and potential of the GE organism to transmit the introduced trait to organisms with which it does not interbreed.

The current regulations also have a provision in § 340.6(e) to extend a determination of nonregulated status to a GE organism based on its similarity to an antecedent organism that has already been granted nonregulated status. This existing “extension procedure” was designed for APHIS to take into account the previous evaluation used to grant nonregulated status conducted by APHIS and thereby afford the potential for expedited evaluations of a petition for extension.

These provisions in the current regulations are necessary because of the manner in which *regulated article* is defined in the current regulations. As APHIS mentioned previously, the current regulations consider a GE organism to be a regulated article if the donor organism, recipient organism, vector, or vector agent is a plant pest. However, because of complexities in the science, and the changing nature of the technologies, questions can arise as to whether certain GE organisms meet the definition of *regulated article*. To address these questions, a process is necessary to allow parties to request that APHIS evaluate the GE organism for plant pest properties, and deregulate it if the Agency determines that it is not.

APHIS does not consider it necessary to retain this process in the regulations. As mentioned in our discussion of proposed § 340.0, APHIS would no longer regulate a GE organism solely because the donor organism, recipient organism, vector, or vector agent of the organism is a plant pest. Rather, for the GE organism to be regulated, APHIS would have to determine that it is a plant pest or noxious weed, or the GE organism would have to not yet be evaluated for plant pest and/or noxious weed risk. In other words, APHIS’ focal point would change from the method by which the organism is genetically engineered, to the resulting GE organism itself, and the Agency would no longer assume that the use of a plant pest within the development of the GE organism necessarily and in every instance results in a GE organism with plant pest properties.

Based on the manner in which proposed § 340.0 is structured, APHIS envisions four types of inquiries from developers of GE organisms if this rule is finalized. The first would be from developers of organisms that are uncertain of the regulatory status of

their organism, but that consider it to either be outside the scope of regulated organisms or similar to an organism that APHIS has already evaluated and assigned nonregulated status. The developers would present what they consider to be the regulatory status of the organism, as well as the information on which the developers rely to support this consideration. In such instances, APHIS would review the information⁷ and communicate to the developer whether the regulatory status that they presented to APHIS was accurate. This is substantially similar to the structure of APHIS’ current “Am I regulated?” program.⁸ That being said, because there would be some changes to that program based on the provisions of this proposed rule, if it is finalized APHIS would make guidance available to aid developers in making such inquiries of APHIS.

The second type of inquiries that APHIS would expect to receive would come from developers of GE organisms that belonged to taxa that are listed in accordance with proposed § 340.2 prior to genetic engineering, or that have received DNA from such taxa during genetic engineering. The developers would provide information regarding the development of the GE organism, and would provide information regarding why they do, or not consider, the GE organism to be a plant pest, or to have received DNA sufficient to produce an infectious entity or encode a pathogenesis-related compound that is expected to cause plant disease symptoms. Such requests would have to be made in accordance with proposed § 340.4.

The third category of inquiries would come from developers of GE plants that APHIS has not yet evaluated for plant pest and noxious weed risk and developers of other GE organisms, such as GE insects and other invertebrates,

⁷ In evaluating the similarity between two GE plants, APHIS considers whether the mechanisms of action of the introduced traits are functionally equivalent. For example, one mechanism of action for resistance in plants to the herbicide glyphosate relies on an inability of glyphosate molecules to bind and inactivate an enzyme called EPSPS, which is responsible for an essential step in a biochemical pathway for the synthesis of certain amino acids. If glyphosate cannot bind to the EPSPS enzyme, the plant is resistant to the herbicide. APHIS has granted nonregulated status to two very similar types of GE plants which differed in the donor organism for the EPSPS genes: One version of the gene was derived from corn (mEPSPS) and the other from a strain of *Agrobacterium* (CP4 EPSPS). However, in both cases the added gene encodes an EPSPS protein which does not bind to glyphosate. Accordingly, these two glyphosate resistance traits have mechanisms of action which are functionally equivalent.

⁸ See <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated>.

that were not plant pests prior to genetic engineering, but that APHIS has not yet evaluated for plant pest risk as GE organisms. These inquiries would request APHIS to evaluate the regulatory status of the GE organism. Such requests would also have to be made in accordance with proposed § 340.4.

The fourth category of inquiries would come from developers of GE organisms that APHIS has determined to be plant pests or noxious weeds, asking for a reevaluation of this determination. Such requests would have to be made in accordance with proposed § 340.4.

Regulatory Status Evaluation (§ 340.4)

Proposed § 340.4 would contain the process by which persons could request an initial evaluation or subsequent reevaluation of the regulatory status of a GE organism. The outcome of a regulatory status evaluation is a determination by the agency that a GE organism is a nonregulated organism or a regulated organism subject to permitting.

Requests for Evaluation or Reevaluation

Paragraph (a) of proposed § 340.4 would state that any person may submit a request to APHIS to have a GE organism's regulatory status evaluated, or to request the reevaluation of the regulatory status of a previously evaluated regulated organism. It would provide that the information that would have to be submitted with a regulatory status request in order for APHIS to evaluate the request is on the Internet, at <http://www.aphis.usda.gov/biotechnology/2016-340-proposed-rule>. Such information would include:

- A description of the recipient organism (including common name; genus, species, and any relevant subspecies information that would distinguish the organism; and, for microorganisms, the strain).
- The genotype of the GE organism, including a detailed description of the differences in genotype between the organism subject to the request and the non-GE organism. If genetic material is inserted into the genome, the method of transformation would also have to be described and the following provided for each gene:
 - For gene sequences, the name of the sequence, donor organism(s) or source, function of sequence, nucleic acid sequence, and publicly available sequence identification. If the genes have been modified, the nature of the modification and its purpose would have to be stated, and the request would have to identify and highlight the modifications by submitting an alignment of the modified sequence

with the unmodified sequence. If the gene is not naturally occurring, the request would have to state whether the sequence is based on that of a specific organism, and, if so, identify the organism and gene it was based on.

- For regulatory sequences, the function of each regulatory sequence as it relates to the gene sequence and the source of each regulatory sequence. Promoters (sites on DNA to which the enzyme RNA polymerase can bind to initiate the transcription of DNA into RNA) would have to be identified as constitutive, inducible, developmental, or tissue-specific. If inducible, the inducer would have to be described. If developmental, stages at which the promoter is active would have to be described. If tissue-specific, the tissues in which the promoter is active would have to be described. The strength of the promoter would also have to be described. Finally, for microorganisms, descriptions of mobile genetic elements would also have to be included.

- If the genome is edited, the following would also have to be provided: The nature of the edit(s) and the gene(s) and function(s) being modified, as well as what pathways are expected to be affected; for multiple substituted base pairs, the number of substitutions; the original unmodified sequence aligned to the modified sequence; and if the edits were created using genetic material which was integrated into the chromosome, but later eliminated through segregation, techniques used to confirm absence of the genetic material.

- A detailed description of the intended phenotype(s) of the GE organism. This would include the purpose of the new phenotype and the mechanisms of action by which the intended phenotype is conferred; any new enzymes, other gene products, or expected changes in metabolism; if applicable, the protein accession number and the enzyme commission number; and the known and potential differences from the non-GE organism that would substantiate that the GE organism is unlikely to pose a greater noxious weed risk or plant pest risk than the non-GE organism from which it was derived.

- For plants, any information that exists on known or likely changes that may affect any of the following would have to be provided: Weediness and plant pest characteristics of the plant; competitive growth ability; reproduction, spread, and persistence; stress tolerance, including a consideration of abiotic stresses such as cold and drought tolerance and biotic stresses such as herbivory (consumption

of the plant) or diseases; and any other weediness or plant pest characteristics identified of the plant or other plants with which the plant can interbreed.

- For non-plant, non-vertebrate organisms, any information that exists on known or likely differences to herbivory or virulence must be provided, including: Any observed or anticipated changes due to the genetic modification that might affect the ability of the organism to cause direct or indirect damage to plants; a description of any changes to known factors of pathogenesis and virulence factors such as polysaccharides (complex sugars consisting of multiple sugar molecules bonded together) and suppressors (genes that suppress expression of another gene); a consideration of changes that might affect geographic distributions, host range, means of dissemination, horizontal gene transfer, reproductive cycle, and persistence; and a description of any characteristics introduced to mitigate harm to plants.

- Any experimental data (including field tests) and publications that the developer believes might be relevant to APHIS's evaluation of the potential of the organism to affect plant health.

APHIS considers the categories of information specified above, which are drawn from our current conditions in § 340.7 for a petition for nonregulated status for a GE organism, to be sufficient for APHIS to evaluate a GE organism and determine its appropriate regulatory status. That being said, the Agency solicits public comment on the adequacy of the requested information in proposed 340.4(a), and whether additional or alternate requirements would be more appropriate. Specifically, APHIS is interested in instances that commenters identify in which the above information may be insufficient to reach a regulatory status determination.

To that end, APHIS wishes to highlight some of the differences between the above information and the information currently required for a request for deregulated status of a GE organism. With regard to the genotype of the GE organism, APHIS would add specific information requirements for gene sequences, regulatory sequences, and genome editing. The current regulations require the petitioner to supply a detailed description of the genotype of the GE organism, but do not specify that a description of the gene sequences, regulatory sequences, or genome editing of the organism is required. Operationally, however, APHIS considers this information to be necessary in order for the petitioner to provide a detailed description of the

genotype, and the revised regulations would reflect this operational need.

APHIS would also remove a current regulatory requirement that requires the petitioner to state the country and locality of the donor organism from which a GE organism has received genetic material in order for APHIS to evaluate the genotype of the GE organism. In the Agency's experience, this information has not proven germane to evaluating the genome of the GE organism, since it does not provide information regarding the modified genome of the GE organism, or the manner in which the genome was modified.

With regard to the phenotype of the GE organism, the proposed requirements would contain additional details that APHIS considers necessary in order to evaluate the plant pest risk of microorganisms, insects, and other invertebrates. For GE plants, it would also include information that APHIS needs in order to prepare a plant pest risk assessment and/or a weed risk assessment (WRA, discussed below).

APHIS is also proposing a significant departure from the current requirements for a petition for nonregulated status. The current requirements specify that a petition must contain field reports for all trials conducted under permit or notification procedures involving the regulated organism, including the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, non-target organisms, or the environment.

Currently, most of the field data submitted by the regulated community to meet this requirement is to demonstrate that there have not been unintended deleterious effects on plants, non-target organisms, or the environment. To date, APHIS has authorized more than 100,000 field trials—a single permit or notification may authorize multiple trials—and APHIS has not received a report of plant pest or noxious weed issues. In addition, APHIS has not received any information in such reports indicating a potential for such effects. Rather, the Agency has discovered that the expressed phenotype of the regulated organism provides the most reliable indicator of the organism's potential for deleterious effects on plants and plant products. These observations are expected and are consistent with findings of several reports of the National Research Council.⁹

Accordingly, APHIS considers information from field tests to not always be necessary for a determination of regulatory status under the proposed regulations. The approach APHIS is proposing focuses primarily on evaluating the genetics and expressed phenotype of the regulated organism, and the likelihood that, based on these genetics and phenotype, the organism will act as a plant pest or noxious weed if it is released into the environment for the uses intended by the developer.

This would not preclude a developer from providing field test information, if he or she considered such information to be pertinent to our determination. For example, if a developer wished APHIS to reevaluate the status of an organism that the Agency had previously considered to be a regulated organism, field test information demonstrating a lack of adverse effects on plants and plant products could be provided in support of that request. Nor would the provisions preclude APHIS from asking for field test information if APHIS considers it necessary in order to conclude review of a particular request. However, field test information would not be a generally applicable requirement for requests for a regulatory status determination, and would only be requested rarely, and on an as-needed basis.

Risk Analyses in Response to Regulatory Status Requests

Paragraph (b) would outline the actions the Administrator would take in response to a regulatory status request. If the request is complete, APHIS would conduct a risk analysis that includes an evidence-based, standardized approach to analyzing plant pest and/or noxious weed risks associated with the GE organism.

Currently, when APHIS receives petitions for a determination of regulated status, APHIS conducts risk assessments. Historically, these assessments have focused on evaluating the plant pest risk of the regulated organism. However, in recent years, they have also included a weediness assessment when the regulated organism is a plant.

The proposed regulations would specify that, if APHIS receives a request to evaluate the regulatory status of a GE organism, the Agency will conduct a risk analysis. The analysis would include, *inter alia*, preparation of a plant pest risk assessment, a weed risk

assessment, or both. APHIS would prepare a plant pest risk assessment (PPRA) for organisms that have received DNA from any taxon listed in accordance with § 340.2, if the DNA from the donor organisms are sufficient to produce an infectious entity capable of causing plant disease or encodes a compound known to be pathogenesis-related that is expected to cause plant disease symptoms, and the GE organisms have not been evaluated by APHIS for plant pest risk. APHIS would also prepare a PPRA for GE plants, if our initial evaluation of the plant suggested the plant may be parasitic. APHIS would also prepare a weed risk assessment for GE plants with plant and trait combinations that have not been evaluated by APHIS for noxious weed risk.

APHIS' weed risk analysis processes would use a WRA, a system developed by APHIS for the purpose of assessing noxious weed risk of GE organisms. Regulatory status decisions for GE plants would be informed based on a risk manager's evaluation and interpretation of the results of the WRA (and, for parasitic plants or plants that may otherwise fall within the scope of the definition of *plant pest*, the PPRA).

While this risk analysis would be informed by APHIS's risk assessment experience with GE organisms as well as APHIS' evaluation of other existing weed risk assessment systems that have been developed, since the WRA system for GE organisms is new, APHIS is making the WRA system publicly available along with this proposed rule. (To view the WRA system or guidance, go to <http://www.aphis.usda.gov/biotechnology/2016-340-proposed-rule>.) Similarly, APHIS will make WRAs available to the public to help make our risk management decisions as transparent as possible.

Notices of Request for Evaluation of Regulatory Status

Proposed paragraph (c) of § 340.4 would discuss our proposed notice-based process for making evaluation of regulatory status available to the public. APHIS would make both the request and the risk analysis available for public review through a notice published in the **Federal Register**. This first notice would request public comment, and would propose a regulatory status for the organism.

If no comments are received on the notice, or if the comments do not affect the conclusions of the risk analysis or the proposed regulatory status of the organism, APHIS would provide notification through the APHIS stakeholder registry at the end of the

⁹ See: NRC (National Research Council). 1989. *Field Testing Genetically Modified Organisms: Framework for Decisions*. Washington, DC: National Academy Press.

NRC (National Research Council). 2004. *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects*. Washington, DC: National Academies Press.

comment period announcing that the proposed regulatory status has been finalized.¹⁰ APHIS would subsequently publish a notice in the **Federal Register** compiling these determinations.

Alternatively, if comments lead APHIS to change its proposed regulatory status for the organism, APHIS would publish a subsequent notice in the **Federal Register** characterizing these comments and announcing the new regulatory status.

Record Retention, Compliance and Enforcement (§ 340.5)

APHIS is proposing to consolidate all record retention, compliance, and enforcement requirements in 7 CFR part 340 into a new § 340.5. APHIS is also proposing to strengthen its program in order to manage compliance with the regulations more efficiently, to augment the approaches used to prevent or remediate potential risks to plant health, and to utilize appropriate enforcement strategies. These proposed regulatory changes also reflect certain provisions of the 2008 Farm Bill and align with recommendations of the 2005 and 2015 OIG audits.

The current regulations require a responsible person to retain records demonstrating that a regulated organism that was imported or moved interstate under a permit arrived at its intended destination for 1 year, but contain no record retention requirements related to environmental release of a regulated organism. While APHIS has frequently added this record retention requirement as a permitting condition, both the 2005 and 2015 OIG audits and the 2008 Farm Bill recommended that the Agency specify the retention requirement in the regulations themselves, recommendations that are corroborated by the Agency's own experience administering the regulations.

Therefore, APHIS is proposing that all records related to permit conditions, other than those demonstrating that a regulated organism that was imported or moved interstate arrived at its intended destination, be retained for 10 years following permit expiration, unless APHIS determines otherwise and documents an alternate record retention requirement. In the event of an investigation into the possible unauthorized environmental release of a regulated organism, or the escape of a regulated organism from a containment facility, a thorough record of activities taken under the permit is necessary in order for APHIS to assess compliance

and determine whether enforcement actions are needed. When APHIS has investigated unauthorized environmental releases of regulated organisms, this has necessitated obtaining information from field trials that were conducted up to 10 years prior to the investigation. In instances in which the information was not available, this adversely impacted APHIS' ability to do an expeditious and thorough investigation.

APHIS is also proposing to extend the record retention requirement that demonstrates that a regulated organism that was imported or moved interstate arrived at its intended destination from 1 to 2 years. In the event that there is uncertainty regarding whether the organism arrived at this location, it may take APHIS more than 1 year to investigate the matter.

APHIS recognizes that, in practice, our proposed requirements would require most records associated with permitted activities to be retained 10 years, and that this is a significant duration to retain potentially a substantial number of records pertaining to permit activities. However, retaining documents for less than 10 years may impede an investigation into compliance infractions. The Agency requests specific public comment regarding whether a shorter duration is warranted for certain records pertaining to permit activities, and which activities these may be. Additionally, APHIS requests comment on any alternate means that stakeholders may identify for the Agency to obtain necessary information from developers in the event of an investigation of possible regulatory noncompliance.

The section would specify that responsible persons and their agents must comply with the proposed regulations. Failure to comply with the regulations could result in denial of a permit application or revocation of a permit, application of remedial measures in accordance with the PPA, or criminal or civil penalties.

Pursuant to sections 7714 and 7731 of the PPA, APHIS may seize, quarantine, treat, destroy, or apply other remedial measures to a regulated organism that is new to or not widely prevalent or distributed in the United States to prevent dissemination of the organism. APHIS typically issues an Emergency Action Notifications or administrative order to the owner of the regulated organism to specify these remedial measures.

If APHIS intends to issue a civil penalty, the Agency may enter into a stipulation prior to issuance of the complaint seeking the penalty. Our

regulations regarding such stipulations are located in 7 CFR 380.10.

Finally, the section would specify that for purposes of enforcing the regulations, the act, omission, or failure of any agent for a responsible person may be deemed also to be the act, omission, or failure of the responsible person.

Container and Shipment Requirements

The regulations in current §§ 340.7 and 340.8 provide detailed requirements for identifying and securely shipping containers of regulated organisms. In the revised regulations, general requirements which apply to all shipments of regulated GE organisms under permit are now listed in paragraph (i) of § 340.3. Additional supplemental conditions will be used when permits are issued to add additional case-specific measures. These supplemental conditions will be listed on the permit itself as permitting conditions. This will allow the agency to take into account the widely varying types and quantities of GE organisms to be shipped and apply highly effective yet reasonable requirements.

Confidential Business Information (§ 340.6)

As mentioned previously, in the current regulations, there are guidelines for denoting information on a permit application or petition for a determination of nonregulated status as CBI in different sections of the regulations. In the proposed regulations, APHIS is proposing to consolidate these guidelines for protecting CBI into a single section, § 340.6. This change would support the overall administration of the program by consolidating all relevant requirements, thereby making it easier for interested persons to find the necessary information.

Definitions (§ 340.1)

APHIS proposes to retain certain definitions currently found in § 340.1 of the regulations, to change other definitions, to add some new definitions, and to remove definitions that no longer appear in the regulations.

APHIS is proposing to retain the following definitions from the current regulations, without change: *Administrator*, *Animal and Plant Health Inspection Service (APHIS)*, *donor organism*, *environment*, *organism*, and *person*.

APHIS is proposing to change the definitions of the following terms from those in the current regulations:

As mentioned in the discussion of proposed § 340.0, the definition of

¹⁰ To subscribe to the APHIS stakeholder registry, go to: <https://public.govdelivery.com/accounts/USDAAPHIS/subscriber/new>.

genetic engineering would read “techniques that use recombinant or synthetic nucleic acids with the intent to create or alter a genome,” and would exclude traditional breeding techniques (including, but not limited to, marker-assisted breeding and chemical or radiation-based mutagenesis, as well as tissue culture and protoplast, cell, or embryo fusion).

This would replace the current definition for *genetic engineering*, “the genetic modification of organisms by recombinant DNA techniques.” The regulations do not define “recombinant DNA techniques,” and the current definition could also be construed to exclude the use of synthetic DNA, in-vivo DNA manipulation, and genome editing. For the purposes of this rule, APHIS is proposing to consider genome editing to be within the definition of genetic engineering. APHIS is also proposing to exclude from the definition of *genetically engineered organism* GE organisms that could have been produced via traditional breeding.

APHIS recognizes that APHIS had previously suggested this proposed rule would use the term *biotechnology*, and would define *biotechnology* in the following manner: “Laboratory-based techniques to create or modify a genome that result in a viable organism with intended altered phenotypes. Such techniques include, but are not limited to, deleting specific segments of the genome, adding segments to the genome, directed altering of the genome, creating additional genomes, or direct injection and cell fusion beyond the taxonomic family that overcomes natural physiological reproductive or recombination barriers. For the purposes of this part, this definition does not include traditional breeding, marker-assisted breeding, or chemical or radiation-based mutagenesis.”

A number of stakeholders understood the limitations associated with the current definition of *genetic engineering*, but questioned the need to abandon the term in favor of *biotechnology*. They pointed to APHIS’ long-standing use of the term *genetic engineering*, and suggested that using a different term could lead to confusion among the regulated community and the general public.

Additionally, several stakeholders expressed concern regarding the proposed definition of *biotechnology*. They pointed out to APHIS that traditional breeding often uses laboratory-based techniques, such as tissue culture and embryo rescue, to create or modify a genome, and radiation-based mutagenesis, which modifies genomes, is often conducted in

a laboratory. The stakeholders expressed concern that the definition could result in widespread confusion regarding which laboratory-based techniques to alter a genome are considered *biotechnology*, and which are not.

Stakeholders also encouraged APHIS to refer to other existing definitions used to define *biotechnology* or *genetic engineering*.

When APHIS issued the current regulations, the Agency relied on guidelines developed by the National Institutes of Health (NIH) regarding research on genetically engineered organisms to craft the definition of “genetic engineering.” Accordingly, in light of the above stakeholder concerns, APHIS revisited NIH guidelines regarding research on genetically engineered organisms. The definition that APHIS is proposing is based on NIH’s “Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules,” which are located at http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html. The section in that document that pertains to research on plants that have been genetically engineered contextually delineates the scope of genetic engineering in a manner that is equivalent to the scope of our proposed definition.

Inspector would read “Any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this part.” The current definition predates the establishment of the Department of Homeland Security, as well as the transfer of certain inspection responsibilities for imported organisms from APHIS to Customs and Border Protection.

Interstate would read “From one State into or through any other State or within the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.” This change aligns the definition of “interstate” in 7 CFR part 340 with the definition of “interstate” used in the PPA.

Move (moving, movement) would read “To carry, enter, import, mail, ship, or transport; aid, abet, cause, or induce the carrying, entering, importing, mailing, shipping, or transporting; to offer to carry, enter, import, mail, ship, or transport; to receive to carry, enter, import, mail, ship, or transport; to release into the environment; or to allow any of the above activities to occur.” This change aligns the definition of “move” in 7 CFR part 340 with the definition of “move” used in the PPA.

Permit would read “A written authorization, including by electronic methods, by the Administrator to move regulated organisms and associated articles under conditions prescribed by the Administrator.”

This change generally aligns the definition of *permit* in 7 CFR part 340 with the definition of *permit* used in the PPA. However, whereas the definition in the PPA mentions that a permit may authorize the movement of plants, plant products, and biological control organisms, plant pests, noxious weeds, and associated articles, APHIS would specify that, for purposes of part 340, it pertains to the movement of regulated organisms and associated articles. This reflects the scope of the proposed regulations.

Additionally, while the PPA allows for the issuance of oral permits, APHIS would not. Oral permits do not provide adequate documentation that a responsible person was aware of and understood permitting conditions at the time the permit was issued.

Plant would read “Any plant (including any plant part) for or capable of propagation, including a tree, a tissue culture, a plantlet culture, pollen, a shrub, a vine, a cutting, a graft, a scion, a bud, a bulb, a root, and a seed.” This change is necessary because the current definition of “plant” used in the regulations precedes the issuance of the PPA, and is broader than that definition. Therefore, APHIS would align the definition with the definition in the PPA itself.

A result of this alignment would be that APHIS would no longer consider “cellular components,” such as ribosomes, to be plants. However, cellular components are not capable of propagating to cause plant pest or noxious weed risks.

Plant pest would read “Any living stage of a protozoan, invertebrate nonhuman animal, parasitic plant, bacterium, fungus, virus or viroid, infectious agent or other pathogen, or any article similar to or allied with any of the foregoing, that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product.” This change generally aligns the definition of “plant pest” in 7 CFR part 340 with the definition of “plant pest” used in the PPA. However, while the PPA gives APHIS authority to regulate any nonhuman animal as a plant pest, it is longstanding APHIS policy not to regulate vertebrate animals as plant pests. In the absence of such a policy, all herbivores and omnivores could be considered plant pests, and thus subject to regulation, an untenable position considering that this would

require APHIS to consider livestock, such as cows, sheep, and horses, to be plant pests.

Recipient organism would read “The organism whose nucleic acid sequence will be altered through the use of genetic engineering.” In contrast, the current definition is “the organism which receives genetic material from a donor organism.” This change from the former definition is intended to be more precise by distinguishing an organism with altered traits from the same organism prior to transformation.

Release into the environment (environmental release) would read “The use of a regulated organism outside the physical constraints found in a contained facility.” This change from the former definition removes the word “regulated article,” which APHIS proposes to replace with the term “regulated organism.” This change also removes examples of types of physical confinement and replaces them with the term “contained facility,” which APHIS is proposing to define. Finally, this term clarifies that “release into the environment” and “environmental release” are synonymous terms. This can be inferred from the current regulations, but is not explicit.

Responsible person would read “The person who has control and will maintain control over a regulated organism during its movement and ensures compliance with all conditions contained in any applicable permit or exemption as well as other requirements in this part. A responsible person must be at least 18 years of age and be a legal resident of the United States.” This change would remove the term “introduction” and replace it with the term “movement.” It would also replace the term “GE organism” with the term “regulated organism” and add that a responsible person must be “at least 18 years of age.” The first two changes are to reflect the nomenclature used in the proposed regulations. The last change is necessary because individuals under the age of 18 are minors.

State would read “Any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, the Virgin Islands of the United States, or other Territories or possessions of the United States.” This change aligns the definition of “State” in 7 CFR part 340 with the definition of “State” used in the PPA.

State or Tribal regulatory official would read “State or Tribal official with responsibilities for plant health, or any other duly designated State or Tribal official, in the State or on the Tribal

lands where the importation, interstate movement, or environmental release is to take place.” The change from the former definition is the acknowledgement of Tribal authority on Tribal lands.

APHIS proposes to add definitions of the following new terms:

Agent would read “A person who is authorized to act on behalf of the responsible person to maintain control over a regulated organism during its movement and ensures compliance with all conditions contained in any applicable permit or exemption as well as other requirements in this part. Agents may be, but are not limited to, brokers, farmers, researchers, or site cooperators. An agent must be at least 18 years of age and be a legal resident of the United States.” This proposed definition would clarify that the responsible person may designate another person to act on the responsible person’s behalf, but that the person so designated must comply with all relevant regulations regarding the regulated organism as the responsible person must.

Contained facility would read “A structure for the storage and/or propagation of living organisms designed with physical barriers capable of preventing the escape of the enclosed organisms. Examples could include laboratories, growth chambers, fermenters, and containment greenhouses.” While the current regulations use the term contained facility, the term is not currently defined. APHIS proposes to add this definition to clarify what constitutes a contained facility.

Genetically engineered organism (GE organism) would read “an organism developed using genetic engineering.” As mentioned previously in this document, for purposes of the proposed regulations, APHIS would not consider an organism to be a *GE organism* if any of the following are the case:

- The genetic modification to the organism is solely a deletion of any size or a single base pair substitution which could otherwise be obtained through the use of chemical- or radiation-based mutagenesis.⁴
- The genetic modification to the organism is solely introducing only naturally occurring nucleic acid sequences from a sexually compatible relative that could otherwise cross with the recipient organism and produce viable progeny through traditional breeding (including, but not limited to, marker-assisted breeding, as well as tissue culture and protoplast, cell, or embryo fusion).

- The organism is a “null segregant,” that is, the progeny of a GE organism where the only genetic modification was the insertion of donor nucleic acid into the recipient’s genome, but the donor nucleic acid is not passed to the recipient organism’s progeny and the donor nucleic acid has not altered the DNA sequence of the progeny.

Import (importation) would read “To move into, or the act of movement into, the territorial limits of the United States.” This is the definition of “import” used in the PPA.

Interstate movement would read “To move interstate.” This proposed definition is necessary to clarify the specific type of movement referenced in the regulations.

Noxious weed would read “Any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.” This is the definition for noxious weed found in the PPA.

Nucleic acid would read “A chain or chains of nucleotides found in either DNA or RNA.” This proposed definition is necessary to clarify the term “nucleic acid,” which is used in reference to “regulatory sequences” in the proposed regulations.

Plant pest risk assessment would read “An assessment evaluating whether a GE organism is a plant pest.”

Plant product would read “Any flower, fruit, vegetable, root, bulb, seed, or other plant part that is not included in the definition of plant or any manufactured or processed plant or plant part.” This is the definition of *plant products* found in the PPA. This definition is more precise than the current definition of “product” in 7 CFR part 340, which this definition would replace. For example, the current definition of product includes “anything made by or from, or derived from an organism, living or dead.” APHIS does not plan to regulate dead organisms as APHIS has found that they do not present plant pest or noxious weed risks.

Regulated organism would read “Any GE organism that is regulated pursuant to § 340.0.” This definition would replace the definition of “regulated article.”

Regulatory sequence would read “A segment of nucleic acid molecule that is capable of increasing or decreasing the expression of specific genes within an organism.” This definition would be added to ensure clarity within the

requirements for regulatory status determinations.

Secure shipment would read “Shipment in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.” This definition would be used to clarify the container requirements in the proposed rule.

Unauthorized release would read: “The intentional or accidental release of a regulated organism in a manner not authorized by a permit issued pursuant to 7 CFR part 340.”

Weed risk assessment would read “An assessment of the characteristics of a plant as these relate to weediness.”

APHIS proposes to remove the following definitions from the regulations: *Antecedent organism*, *courtesy permit*, *expression vector*, *introduce or introduction*, *product*, *regulated article*, *Secretary*, *stably integrated*, *vector or vector agent*, and *well-characterized and contains only non-coding regulatory regions*.

These definitions would be removed because the terms would no longer be used in the regulations. APHIS proposes to eliminate the term *regulated article* partly because the use of the term “article” in current part 340 is not consistent with usage in the PPA, which uses the term article to mean “any material or tangible object that could harbor plant pests or noxious weeds”—that is, things like packing materials, shipping containers, commodities, etc.—and not a plant pest or noxious weed itself. Under the current regulation, however, *regulated article* refers exclusively to certain genetically engineered organisms. For this reason, the term “regulated article” in the current regulations is both inconsistent with the terminology of the PPA and difficult for the public to comprehend.

APHIS also proposes to remove the definition for *introduction*. APHIS currently uses the term in part 340 to denote certain kinds of activities that fall within the scope of the regulations, namely importation, interstate movement, and release into the environment. The PPA, however, does not specifically define the term *introduction*. Therefore, to avoid confusion, instead of using the term *introduction* to define the different types of regulated activities, APHIS will instead refer to these activities in the regulations as *movement* in accordance with the definition of *move* in the PPA. Additionally, as APHIS mentioned above, the regulations will specify and define the types of movements to which

the regulations would apply, namely, importation, interstate movement, and release into the environment.

Finally, based on the terms that APHIS is proposing to add or remove from the regulations, as well as the revised scope of the regulations, the Agency would revise the title of part 340 to “Movement of organisms altered or produced through genetic engineering that are noxious weeds or plant pests or that there is reason to believe are noxious weeds or plant pests.”

Costs and Charges (§ 340.7)

Section 340.7 would contain APHIS’ policy regarding costs and charges for the services of inspector, which are found in the current regulations in § 340.9. Currently, the section provides that the services of an inspector during regularly assigned hours of duty are provided free of charge, but that APHIS will not be responsible for any other costs or charges incident to inspections or compliance, apart from the services of this inspector. These provisions would be unchanged.

Technical Evaluations

APHIS recognizes that many aspects of our proposed rule hinge on a determination by APHIS regarding the plant pest or noxious weed risk posed by a particular GE organism or class of GE organisms. Often, APHIS will be able to make a determination of plant pest or noxious weed risk based on our collective experience regulating genetic engineering and review of relevant scientific literature.

However, as genetic engineering evolves and new genetic engineering techniques are developed, APHIS may lack technical expertise to fully evaluate certain GE organisms or classes of GE organisms. This is particularly likely when new or emerging genetic engineering techniques are applied to recipient organisms that have not previously been subject to genetic engineering.

In such instances, APHIS may rely on researchers or other Federal, State, Tribal, or industry experts to provide information to help APHIS determine the organism’s appropriate regulatory status. APHIS may solicit such information through a variety of means, including, but not limited to, working groups, workshops, peer review of documents (particularly risk analyses), or webinars.

National Environmental Policy Act

To provide the public with documentation of APHIS’ review and analysis of any potential environmental

impacts associated with the revision of our regulations regarding the movement of certain GE organisms, APHIS has prepared a programmatic environmental impact statement (PEIS). The PEIS was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS’ NEPA Implementing Procedures (7 CFR part 372).

The PEIS may be viewed on the Regulations.gov Web site or in our reading room. (A link to Regulations.gov and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this proposed rule.) In addition, copies may be obtained by calling or writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Executive Orders 12866 and 13563 and Regulatory Flexibility Act

This proposed rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also provides an initial regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT** or on the Regulations.gov Web site (see **ADDRESSES** above for instructions for accessing Regulations.gov).

Under the PPA, the Secretary of Agriculture is authorized to regulate the movement into and through the United States of plants, plant products, and other articles to prevent the

introduction or dissemination of plant pests and noxious weeds. As one part of its implementation of the PPA, APHIS regulates the safe introduction (environmental release, interstate movement, and importation) of certain GE organisms that might be plant pests (7 CFR part 340). APHIS is proposing to revise its regulation of GE organisms to respond to emerging trends in genetic engineering, to more efficiently use APHIS resources, and eliminate unnecessary regulatory burdens.

The proposed revisions to 7 CFR part 340 would create the framework for more focused, risk-based regulation of the GE organisms that pose plant pest and/or noxious weed risks. They would establish a regulatory status evaluation process in which risk analysis would be used to assess whether permitting of a GE organism is necessary. Shipping standards would be less prescriptive and more generally applicable, and the rule would provide for the issuance of multi-year permits. The proposed rule would also exclude certain techniques from the definition of genetic engineering and certain organisms from the definition of genetically engineered organism. These changes would improve the efficiency and clarity of the regulations.

The proposed amendments would benefit developers, producers, and consumers of certain GE organisms, public and private research entities, and the Agency. There would not be any decrease in the level of protection provided against plant pest risks, and protection against noxious weed risks would be enhanced. The risk-based process used to determine regulatory status under the proposed rule would provide cost savings to the biotech industry and allow for reallocation of APHIS resources to Biotechnology Regulatory Services (BRS) priorities.

Based on APHIS' experience evaluating field trial data from thousands of permits that authorize environmental release of regulated organisms, as well as more than 150 petitions for non-regulated status, APHIS has determined that most of the GE organisms evaluated by the Agency do not merit regulatory oversight under the PPA. There would be both direct and indirect economic benefits of not subjecting the majority of these organisms to permitting requirements.

Direct regulatory costs to biotech developers would be reduced for those organisms that are not considered to pose plant pest and/or noxious weed risk. Savings to the regulated community would result from a reduced need to collect field data, fewer reporting requirements, and lower

management costs. Petitions for non-regulated status—and the petition costs incurred—would be eliminated. There would be some new costs borne by regulated entities under the proposed rule including rule familiarization and recordkeeping. Recordkeeping cost tabulations are based on the information collection categories from the paperwork burden section of the rule, and are estimated to total about \$275,000. About 1,100 distinct entities have applied for permits or notifications under part 340. APHIS estimates that those entities would spend about 8 hours becoming familiar with the provisions of this rule at a total cost of about \$576,000.

Cost savings for these entities are expected to more than offset the new costs. APHIS estimated the cost savings for two regulatory oversight scenarios, based on a study of the costs encountered by private biotech developers as they pursue regulatory authorization of their innovations. When only USDA has regulatory oversight, compliance cost savings under the proposed rule could range from \$1.5 million to \$5.4 million for the development of a given GE trait. If EPA and/or FDA also have an oversight role in the development of a given GE trait, compliance cost savings could range from \$485,000 to \$861,000. Since 1992, between 2 and 14 petitions have been processed (granted non-regulated status or the petition withdrawn) in a given year, with an average of just under 6.

Because the rule is expected to spur innovation, we expect the number of new organisms developed annually to increase over time. In the following discussion, the annual number of new GE organisms developed under the proposed rule would range from 6 (the current annual average), to 12 (twice this average), with 10 as an intermediate number. For GE organisms that would have solely required USDA oversight, the annual savings could range from \$8.8 million to \$32.4 million (6 new organisms), from \$14.7 million to \$53.9 million (10 new organisms), and from \$17.6 million to \$64.7 million (12 new organisms). For organisms that are submitted for multi-agency evaluation, the annual savings could range from \$2.9 million to \$5.2 million (6 new organisms), from \$4.9 million to \$8.6 million (10 new organisms), and from \$5.8 million to \$10.3 million (12 new organisms).

APHIS costs of regulating GE organisms that may pose plant pest or noxious weed risks also are expected to change under the proposed rule. Fewer permits would be issued and notifications and petitions for non-

regulated status would be eliminated, but more risk assessments for regulatory determination would be performed. Current annual personnel costs of conducting GE activities (costs of activities that would be affected by the proposed rule) are estimated to total about \$5.6 million. With the proposed rule, annual costs are expected to range from \$2.5 million to \$7.8 million, depending on the volume of permits, weed risk assessments, inspections, and NEPA activities. In addition, costs to APHIS of implementing the proposed rule would include outreach activities, developing guidance documents, training, and adjusting the current permit system. APHIS estimates that the public outreach, guidance and training would cost about \$88,000. Requests for regulatory status and response letters under the proposed rule could be handled in a manner similar to the current "Am I Regulated" process outside the electronic permitting system without incurring new costs.

A quicker USDA evaluation process and related reduction to firms' regulatory uncertainty may facilitate small companies' ability to raise venture capital. Reduced regulatory requirements may also lead to greater participation by the public sector in GE research. These indirect benefits of the proposed rule may spur GE innovations, particularly in small acreage crops where genetic engineering has not been widely utilized due to the expense of regulation. While the proposed rule may help promote biotech innovations, the pace of commercialization and volume of GE products commercialized are not expected to change dramatically from current levels. Nor is control over the development process expected to be materially altered by the proposed rule. It would be in a biotech developer's own best interest to maintain the same level of supervision and control over the development process as at present to prevent undesired cross-pollination or commingling with non-GE crops.

GE crop varieties, in general, are not required to be reviewed or approved for safety by the FDA before going to market. However, the developer is responsible for ensuring product safety and developers consider voluntary consultations with FDA on food safety to be an absolute necessity for applicable GE products.¹¹ Developers also have various legal, quality control

¹¹ Genetically Engineered Crops: Past Experience and Future Prospects. Committee on Genetically Engineered Crops: Past Experience and Future Prospects; Board on Agriculture and Natural Resources; Division on Earth and Life Studies; National Academies of Sciences, Engineering, and Medicine.

and marketing motivations to maintain rigorous voluntary stewardship measures. APHIS therefore believes that developers would continue to utilize such measures for field testing even in cases where USDA would not require a permit.

Certain plants are genetically engineered in order to produce pharmaceutical or industrial compounds (plant-made pharmaceuticals or industrials), or PMPIs. Under the provisions of the proposed rule, there is a possibility that APHIS could reach a determination that a GE plant that produces PMPIs is not a regulated organism. Such a plant would not be subject to field trial oversight by USDA, and could be planted before or without an evaluation by FDA or EPA. Several options have been identified for addressing this potential gap in oversight. APHIS estimates that current PMPI inspections cost roughly \$35,000 in total annually or about \$800 each on average. Assuming that oversight continues in the same manner as APHIS oversight, a similar government expenditure could be expected under any of the PMPI oversight scenarios.

Certain plants are genetically engineered to produce PIPs. PIPs fall under the regulatory oversight of EPA. However, APHIS exercises regulatory oversight of all PIP plantings on 10 acres or less of land. Under the proposed rule, APHIS would only require permits for PIPs planted on 10 acres or less if they present a plant pest or noxious weed risk or have not yet been evaluated by APHIS for such risk. This proposal would shift Federal oversight of small-scale (10 acres or less) outdoor plantings of PIPs to EPA. EPA may decide to require EUPs for all, some, or none of such PIPs, and may conduct inspections of all, some, or none of those PIPs under

permit. EPA would need to develop a program to oversee small-scale testing of PIPs and issue regulations if warranted. APHIS is fully committed to coordinating with EPA in this matter in order to give EPA time to stand up such a program. APHIS understands that a memorandum of understanding (MOU) and services agreement may be necessary to provide personnel and other resources to assist EPA during the interim period while EPA implements its own program of oversight of outdoor planting of PIPs on 10 acres or less. APHIS recognizes that there are challenges associated with such a transition that also would require EPA to incur the costs associated with setting up a revised regulatory program. Further, it would require policies, procedures, and guidance regarding APHIS' interaction with EPA.

Farmers who adopt GE crops also may indirectly benefit from the proposed rule. The adoption of GE crops in the United States has generally reduced costs and improved profitability at the farm level. As mentioned, under the proposed rule, regulatory costs are expected to be lower, thereby potentially spurring developer innovation, especially among small companies and universities. Farmers may benefit by having access to a wider variety of traits as well as a greater number of new GE crop species, affording them a broader selection of crops to suit their particular management needs. Among the types of innovations expected are crops with greater resistance to disease and insect pests, greater tolerance of stress conditions such as drought, high temperature, low temperature, and salt, and more efficient use of fertilizer. These types of traits can lower farmer input costs (water, fertilizer, pesticide)

and increase yields during times of adverse growing conditions.

On the other hand, some farmers (e.g., growers of organic and or identity-preserved crops) could be negatively impacted by these same innovations. Some consumers choose not to purchase products derived from GE crops and instead purchase commodities such as those labeled "non-GMO" or organic. When crops intended for the non-GE or identity-preserved marketplace contain unintended GE products, the value of the non-GE or identity-preserved product is diminished. Effects of the proposed rule on the variety of GE crop species grown in the United States and their wider adoption may increase risks of cross-pollination or commingling. As more small acreage crops are modified using genetic engineering, the unintended presence of a GE organism becomes increasingly possible. Unauthorized releases of regulated GE crop plants and the entry of regulated plant material in the commercial food and feed supply can have impacts on domestic or international markets. While such releases have occurred and may occur again, such incidents are expected to be rare.

Entities potentially affected by the proposed rule fall under various categories of the North American Industry Classification System. While economic data are not available on business size for some entities, based on industry data obtained from the Economic Census and the Census of Agriculture we can assume that the majority of the businesses affected by the proposed rule would be small. APHIS welcomes public comment on the proposed rule's possible impacts.

The following table provides a summary statement of the expected direct benefits and costs of the proposed rule:

EXPECTED ANNUAL BENEFITS AND COSTS OF THE PROPOSED RULE FOR THE BIOTECHNOLOGY INDUSTRY AND FOR USDA, 2015 DOLLARS

| Entity | | | |
|---|----------------------------------|----------------------------|----------------------------|
| Biotechnology Industry | Costs (\$1,000) | | |
| Developer costs (recordkeeping and rule familiarization) ¹ . | 851 | | |
| | Cost Savings per Trait (\$1,000) | | |
| Developer Savings ² | | Proposed rule, lower bound | Proposed rule, upper bound |
| USDA sole regulatory agency | | – 1,468 | – 5,393 |
| USDA with FDA and/or EPA oversight | | – 485 | – 861 |
| APHIS Biotechnology Regulatory Services | Costs (\$1,000) | | |

**EXPECTED ANNUAL BENEFITS AND COSTS OF THE PROPOSED RULE FOR THE BIOTECHNOLOGY INDUSTRY AND FOR USDA,
2015 DOLLARS—Continued**

| Activities affected by the rule | 88 | | |
|---|--------------------|----------------------------|----------------------------|
| | Current rule | Proposed rule, lower bound | Proposed rule, upper bound |
| Costs for public outreach, training, and epermitting ³ | | | |
| Notifications | 203 | 0 | 0 |
| Petitions | 2,130 | 0 | 0 |
| Interstate movement and environmental release permits | 239 | 139 | 261 |
| Courtesy permits | 19 | 0 | 0 |
| Letters of No Permit Required | 0 | 3 | 3 |
| “Am I Regulated” Process | 7 | 0 | 0 |
| Weed risk assessments | 0 | 700 | 1,265 |
| Compliance and Inspections | 361 | 361 | 1,014 |
| NEPA/ESA | 2,648 | 1,324 | 5,297 |
| Total⁴ | 5,607 | 2,527 | 7,840 |

¹ Becoming familiar with the rule are one-time costs.

² These savings are shown on a per trait basis. If between 6 and 12 GE organisms are developed each year that would have solely required USDA oversight, annual savings could range from \$9 million to \$64.8 million. If between 6 and 12 new GE organisms per year are submitted for multi-agency evaluation, the annual savings could be from \$2.9 million to \$10.3 million.

³ Requests for regulatory status and response letters under the proposed rule could be handled in a manner similar to the current ‘Am I Regulated’ process outside the electronic permitting system without new costs.

⁴ Annual staffing costs of APHIS Biotechnology Regulatory Services total about \$19 million.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, “Consultation and Coordination with Indian Tribal Governments.” Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

The Animal and Plant Health Inspection Service has assessed the impact of this rule on Indian Tribes and

determined that this rule does have Tribal implications that require Tribal consultation under E.O. 13175. If a Tribe requests consultation, the Animal and Plant Health Inspection Service will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), some of the reporting, recordkeeping, and third party disclosure requirements included in this proposed rule have been approved under 0579–0085. The new reporting, recordkeeping, and third party disclosure requirements proposed by this rule have been submitted as a new information collection package for approval to the Office of Management and Budget (OMB). Upon approval of this new information collection, it will be merged into the existing 0579–0085.

Please send comments on the Information Collection Request (ICR) to OMB’s Office of Information and Regulatory Affairs via email to oira_submissions@omb.eop.gov, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS–2015–0057. Please send a copy of your comments to: USDA, using one of the methods described under **ADDRESSES** at the beginning of this document.

APHIS is proposing to revise its regulations governing the importation, interstate movement, and release into the environment of organisms

developed using genetic engineering. Organisms would be regulated because APHIS has determined them to present a plant pest or noxious weed risk, or has not yet evaluated them for such risk.

Persons would be able to submit a request for APHIS to evaluate the regulatory status of a GE organism. They would also be able to petition APHIS to add a genus, species, or subspecies to a list of taxa that are or contain plant pests. Finally, permits would be required for the importation, interstate movement, and environmental release of all regulated GE organisms. Responsible persons who are issued permits would be required to retain records, and would have to submit reports if they conduct field testing.

APHIS is soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help APHIS:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency’s functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological

collection techniques or other forms of information technology; e.g., permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 0.828 hours per response.

Respondents: Developers of organisms regulated under 7 CFR part 340; businesses and individuals associated with such organisms; Tribal governments.

Estimated Annual Number of Respondents: 311.

Estimated Annual Number of Responses per Respondent: 16.

Estimated Annual Number of Responses: 5035.

Estimated Total Annual Burden on Respondents: 4174 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

A copy of the information collection may be viewed on the *Regulations.gov* Web site or in our reading room. (A link to *Regulations.gov* and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this proposed rule.) Copies can also be obtained from Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2483. APHIS will respond to any ICR-related comments in the final rule. All comments will also become a matter of public record.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2483.

List of Subjects in 7 CFR Part 340

Administrative practice and procedure, Biotechnology, Genetic engineering, Imports, Packaging and containers, Plant diseases and pests, Transportation.

Accordingly, we are proposing to revise 7 CFR part 340 to read as follows:

PART 340—MOVEMENT OF ORGANISMS ALTERED OR PRODUCED THROUGH GENETIC ENGINEERING THAT ARE NOXIOUS WEEDS OR PLANT PESTS OR THAT THERE IS REASON TO BELIEVE ARE NOXIOUS WEEDS OR PLANT PESTS

Sec.

340.0 General restrictions and scope.

340.1 Definitions.

340.2 Taxa that are or contain plant pests.

340.3 Permits.

340.4 Regulatory status evaluation.

340.5 Record retention, compliance, and enforcement.

340.6 Confidential business information.

340.7 Costs and charges.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

§ 340.0 General restrictions and scope.

(a) No person may move any regulated organism except in accordance with this part.

(b) A regulated organism is any GE organism that either:

(1) Prior to genetic engineering, belonged to any taxon listed in accordance with § 340.2 and met the definition of *plant pest* in § 340.1; or

(2) Has received deoxyribonucleic acid (DNA) from any taxon listed in accordance with § 340.2, the DNA from the donor organism is sufficient to produce an infectious entity capable of causing plant disease or encodes a compound known to be pathogenesis-related that is expected to cause plant disease symptoms, and the organism has not been evaluated by APHIS for plant pest risk in accordance with § 340.4; or

(3) Is a plant that has a plant and trait combination that has not been evaluated by APHIS for plant pest and noxious weed risk in accordance with § 340.4; or

(4) Is any of the foregoing that has been evaluated by APHIS in accordance with § 340.4 and determined to pose a risk as a plant pest and/or noxious weed or is a GE organism that has otherwise been determined by the Administrator to pose a risk as a plant pest or noxious weed.¹

§ 340.1 Definitions.

Terms used in the singular form in this part shall be construed as the plural, and vice versa, as the case may demand. The following terms, when used in this part, shall be construed, respectively, to mean:

¹ The importation, interstate movement, and release into the environment of regulated organisms is subject to any other applicable restrictions of this chapter. For example, in “Subpart—Plants for Planting” (§§ 319.37–319.37–14 of this chapter), a permit is required for the importation of certain plants for planting, regardless of whether the plants for planting have been genetically engineered.

Administrator. The Administrator of the Animal and Plant Health Inspection Service (APHIS) or any other employee of APHIS to whom authority has been or may be delegated to act in the Administrator's stead.

Agent. A person who is authorized to act on behalf of the responsible person to maintain control over a regulated organism during its importation, interstate movement, or environmental release and ensures compliance with all conditions contained in any applicable permit or exemption as well as other requirements in this part. Agents may be, but are not limited to, brokers, farmers, researchers, or site cooperators. An agent must be at least 18 years of age and be a legal resident of the United States.

Animal and Plant Health Inspection Service (APHIS). An agency of the United States Department of Agriculture.

Contained facility. A structure for the storage and/or propagation of living organisms designed with physical barriers capable of preventing the escape of the enclosed organisms. Examples include laboratories, growth chambers, fermenters, and containment greenhouses.

Donor organism. The organism from which genetic material is obtained for transfer to the recipient organism.

Environment. All the land, air, and water; and all living organisms in association with land, air, and water.

Genetic engineering. Techniques that use recombinant or synthetic nucleic acids with the intent to create or alter a genome. Genetic engineering does not include traditional breeding techniques (including, but not limited to, marker-assisted breeding and chemical or radiation-based mutagenesis, as well as tissue culture and protoplast, cell, or embryo fusion).

Genetically engineered organism (GE organism). An organism developed using genetic engineering. For the purposes of this part, an organism will not be considered a genetically engineered organism if:

(1) The genetic modification to the organism is solely a deletion of any size or a single base pair substitution which could otherwise be obtained through the use of chemical- or radiation-based mutagenesis; or

(2) The genetic modification to the organism is solely introducing only naturally occurring nucleic acid sequences from a sexually compatible relative that could otherwise cross with the recipient organism and produce viable progeny through traditional breeding (including, but not limited to, marker-assisted breeding, as well as

tissue culture and protoplast, cell, or embryo fusion); or

(3) The organism is a “null segregant,” that is, the progeny of a GE organism where the only genetic modification was the insertion of donor nucleic acid into the recipient’s genome, but the donor nucleic acid is not passed to the recipient organism’s progeny and the donor nucleic acid has not altered the DNA sequence of the progeny.

Import (importation). To move into, or the act of movement into, the territorial limits of the United States.

Inspector. Any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this part.

Interstate. From one State into or through any other State or within the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

Interstate movement. To move interstate.

Move (moving, movement). To carry, enter, import, mail, ship, or transport; aid, abet, cause, or induce the carrying, entering, importing, mailing, shipping, or transporting; to offer to carry, enter, import, mail, ship, or transport; to receive to carry, enter, import, mail, ship, or transport; to release into the environment; or to allow any of the above activities to occur.

Noxious weed. Any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.

Nucleic acid. A chain or chains of nucleotides found in either DNA or ribonucleic acid.

Organism. Any active, infective, or dormant stage of life form of an entity characterized as living, including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, mycoplasma-like organisms, as well as entities such as viroids, viruses, or any entity characterized as living, related to the foregoing.

Permit. A written authorization, including by electronic methods, by the Administrator to move regulated organisms and associated articles under conditions prescribed by the Administrator.

Person. Any individual, partnership, corporation, company, society, association, or other organized group.

Plant. Any plant (including any plant part) for or capable of propagation, including a tree, a tissue culture, a plantlet culture, pollen, a shrub, a vine, a cutting, a graft, a scion, a bud, a bulb, a root, and a seed.

Plant pest. Any living stage of a protozoan, invertebrate nonhuman animal, parasitic plant, bacterium, fungus, virus or viroid, infectious agent or other pathogen, or any article similar to or allied with any of the foregoing, that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product.

Plant pest risk assessment. An assessment evaluating whether a GE organism is a plant pest.

Plant product. Any flower, fruit, vegetable, root, bulb, seed, or other plant part that is not included in the definition of plant or any manufactured or processed plant or plant part.

Recipient organism. The organism whose nucleic acid sequence will be altered through the use of genetic engineering.

Regulated organism. Any GE organism that is regulated pursuant to § 340.0.

Regulatory sequence. A segment of nucleic acid molecule that is capable of increasing or decreasing the expression of specific genes within an organism.

Release into the environment (environmental release). The use of a regulated organism outside the physical constraints found in a contained facility.

Responsible person. The person who has control and will maintain control over a regulated organism during its movement and ensures compliance with all conditions contained in any applicable permit or exemption as well as other requirements in this part. A responsible person must be at least 18 years of age and be a legal resident of the United States.

Secure shipment. Shipment in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

State. Any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, the Virgin Islands of the United States, or other Territories or possessions of the United States.

State or Tribal regulatory official. State or Tribal official with responsibilities for plant health, or any other duly designated State or tribal official, in the State or on the Tribal lands where the movement is to take place.

Unauthorized release. The intentional or accidental release of a regulated organism in a manner that is not authorized by a permit issued pursuant to this part.

Weed risk assessment. An assessment of the characteristics of a plant as these relate to weediness.

§ 340.2 Taxa that are or contain plant pests.

(a) Taxa that are or contain plant pests are listed on the APHIS Web site at <http://www.aphis.usda.gov/biotechnology/2016-340-proposed-rule>. Within any taxonomic group included on the list, the lowest unit of classification actually listed is the taxon or group which may contain organisms that are regulated. Organisms belonging to all lower taxa contained within the group listed are included as organisms that may be or may contain plant pests, and are regulated if they meet the definition of a plant pest in § 340.1.

(b) **APHIS-initiated changes to listed taxa.** APHIS may propose to add or remove a taxon from the list referred to in paragraph (a) of this section through a notice published in the **Federal Register**. The notice will state why APHIS has determined it necessary to add or remove the taxon, and will request public comment. If no comments are received on the notice, or the comments received do not affect APHIS’ determination, APHIS will publish a subsequent notice in the **Federal Register** stating that the taxon has been added or removed from the list referred to in paragraph (a) of this section.

(c) **Petitions to amend the list of taxa.** Any person may submit to the Administrator a petition to amend the list of taxa referred to in paragraph (a) of this section by adding or removing any taxon. The petitioner may supplement, amend, or withdraw a petition in writing without prior approval of the Administrator and without prejudice to resubmission at any time until the Administrator rules on the request. A petition to amend the list of taxa must be submitted in accordance with the procedures and format provided on the APHIS Web site at <http://www.aphis.usda.gov/biotechnology/2016-340-proposed-rule>.

(d) **Administrative action on a petition.** (1) A petition to amend the list of taxa that meets the requirements of paragraph (b) of this section as well as the date of the petition will be acknowledged by APHIS. If a request does not meet the requirements of paragraph (b) of this section, the requester will be sent a notice indicating how the request is deficient.

(2) APHIS will publish in the **Federal Register**, for 60 days public comment, a notice announcing the availability of a petition to amend the list of organisms. Following the close of the comment period, APHIS will review the comments received and publish its final decision in the **Federal Register**.

(e) *Appeal of denial.* Any person whose petition has been denied may appeal the decision in writing to the Administrator within 30 days after receiving the written notification of the denial. The appeal must state all of the facts and reasons upon which the person relies to assert that the petition was wrongfully denied. The Administrator will grant or deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances allow.

§ 340.3 Permits.

(a)(1) Except as provided in paragraph (a)(2) of this section, APHIS must have evaluated a regulated organism in accordance with § 340.4 before it will issue permits for importation, interstate movement, or release into the environment of the organism pursuant to this section.

(2) APHIS may issue a permit pursuant to this section for the importation or interstate movement of a regulated organism that has not been evaluated in accordance with § 340.4, at the request of an applicant. For the purposes of permitting conditions, APHIS will assume the regulated organism presents a risk as a plant pest and/or noxious weed. If the regulatory status of the organism is evaluated in accordance with § 340.4 during the duration of the permit, APHIS may amend or terminate the permit accordingly.

(3) Except as provided in paragraph (c) of this section, a permit must be issued by APHIS for the importation, interstate movement, or release into the environment of all regulated organisms.

(b) A responsible person must apply for and obtain a permit through a method listed at <http://www.aphis.usda.gov/biotechnology/2016-340-proposed-rule>. The application must also contain all the categories of information listed at that Web site for the type of permit being requested.

(c) A permit for interstate movement is not required for genetically engineered *Arabidopsis thaliana*, provided that it is moved as a secure shipment, the cloned genetic material is stably integrated into the plant genome, and the cloned material does not include the complete infectious genome of a plant pest.

(d) *Administrative actions.* (1) APHIS will review the application to determine if it is complete. APHIS will notify the applicant in writing if the application is incomplete, and the applicant will be provided the opportunity to revise the application. If the applicant does not respond to the request for additional information within 30 days of receipt of APHIS's request, APHIS will deem the application withdrawn. Once an application is complete, APHIS will review it to determine whether to approve or deny the application.

(2) *APHIS assignment of permit conditions.* If a permit application is approved, the Administrator will assign permit conditions to each permit commensurate with the risk of the regulated organism and activity. General conditions assigned to all permits are located in paragraph (e) of this section. The Administrator may assign additional or expanded permit conditions commensurate with the risk that the activities listed on the permit application present of disseminating the regulated organism, or other plant pests or noxious weeds.

(3) *Inspections.* All premises associated with the permit are subject to inspection before and after permit issuance. The responsible person must provide APHIS inspectors access to inspect any relevant premises, facility, release location, storage area, waypoint, materials, equipment, means of conveyance, and other articles related to the proposed movement of organisms regulated under this part. Failure to allow the inspection of a premises prior to the issuance of a permit will be grounds for the denial of a permit application. Failure to allow the inspection of a premises following permit issuance will be grounds for revocation of the permit.

(4) *State or Tribal review and comment.* The Administrator will submit for notice and review a copy of the permit application and any permit conditions to the appropriate State or Tribal regulatory official. Comments received from the State or Tribal regulatory official may be considered by the Administrator prior to permit issuance.

(5) *Agreement with permit conditions.* Prior to issuance of a permit, the responsible person must agree in writing, in a manner prescribed by the Administrator, that the responsible person and all agents of the responsible person are aware of, understand, and will comply with the permit conditions. Failure to comply with this provision will be grounds for the denial of a permit.

(e) *General permit conditions.* The following conditions will be assigned to all permits issued under this section. A responsible person, and his/her agents, must ensure compliance with these conditions, as well as any additional or expanded conditions listed on the permit:

(1) The regulated organism must be maintained and disposed of in a manner so as to prevent the unauthorized release of the regulated organism.

(2) The regulated organism must be kept separate from other organisms, except as specifically allowed in the permit.

(3) The regulated organism must be maintained only in areas and premises specified in the permit.

(4) The regulated organism's identity must be maintained at all times.

(5) In the event of an unauthorized release:

(i) The regulated organism must undergo the application of remedial measures determined by the Administrator to be necessary to prevent the spread of regulated organism;

(ii) The responsible person must contact APHIS as described in the permit within 24 hours of discovery, and subsequently supply a statement of facts in writing no later than 5 business days after discovery.

(6) The duration that the permit is valid will be listed on the permit itself. During such time, the responsible person must maintain records related to permitted activities of sufficient quality and completeness to demonstrate compliance with all permit conditions and requirements under this part. The responsible person must submit reports and notices to APHIS at the times specified in the permit and containing the information specified within the permit. Inspectors must be allowed access, during regular business hours, to the place where the regulated organism is located and to any records relating to the movement of a regulated organism. APHIS' access to records includes visual inspection and reproduction (photocopying, digital reproduction, etc.) of all records required to be maintained under this part, as requested by APHIS.

(7) The responsible person must notify APHIS in writing if any permitted activity associated with environmental release will not be conducted.

(8) Within 28 days after the initiation of any permitted activity related to environmental release, the responsible person must report to APHIS in writing the actual release site coordinates and details of the release, such as how many acres planted, how many organisms released, etc., based on permit

conditions, as well as every 28 days thereafter until all releases are completed.

(9) A person who has been issued a permit must submit to APHIS an environmental release report within 6 months after the termination of any release into the environment. The report must include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

(f) *Denial or revocation of a permit.* Permit applications may be denied, or permits revoked, in accordance with this paragraph.

(1) *Denial.* The Administrator may deny, either orally or in writing, any application for a permit. If the denial is oral, the Administrator will communicate the denial and the reasons for it in writing as promptly as circumstances allow. The Administrator may deny a permit application if:

(i) The Administrator concludes that, based on the application or on additional information, the actions proposed under the permit may result in the unauthorized release of the regulated organism, or another plant pest or noxious weed; or

(ii) The Administrator determines that the responsible person or any agent of the responsible person has failed to comply at any time with any provision of this part or any other part of the regulations, or any permit that has previously been issued in accordance with this part.

(2) *Revocation.* The Administrator may revoke, either orally or in writing, any permit which has been issued. If the revocation is oral, the Administrator will communicate the revocation and the reasons for it in writing as promptly as circumstances allow. The Administrator may revoke a permit if:

(i) Following issuance of the permit, the Administrator receives information that would otherwise have provided grounds for APHIS to deny the permit application;

(ii) The Administrator determines that actions taken under the permit have resulted in the unauthorized release of the regulated organism, or another plant pest or noxious weed; or

(iii) The Administrator determines that the responsible person or any agent of the responsible person has failed to comply at any time with any provision of this part or any other part of the regulations. This includes failure to comply with the conditions of any permit issued.

(g) *Appeal of denial or revocation of permit.* Any person whose permit application has been denied or whose

permit has been or revoked may appeal the decision in writing to the Administrator. Any appeal must occur within 10 days after receiving the written notification of the denial or revocation. The appeal must state all of the facts and reasons upon which the person relies to assert that the permit was wrongfully denied or revoked. The Administrator will grant or deny the appeal, in writing, stating the reasons for the decision as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict. Rules of practice concerning such a hearing will be adopted by the Administrator.

(h) *Amendment of permits.*

(1) *Amendment at responsible person's request.* If a responsible person determines that circumstances have changed since the permit was initially issued and wishes the permit to be amended accordingly, he or she must request the amendment by contacting APHIS directly. The responsible person may have to provide supporting information justifying the amendment. APHIS will review the amendment request, and may amend the permit if only minor changes are necessary. Requests for more substantive changes may require a new permit application. Prior to issuance of an amended permit, the responsible person may be required to agree in writing that he or she, and his or her agents, will comply with the amended permit and conditions.

(2) *Amendment initiated by APHIS.* APHIS may amend any permit and its conditions at any time, upon determining that the amendment is needed to address newly identified considerations concerning the risks presented by the organism or the activities being conducted under the permit. APHIS may also amend a permit at any time to ensure that the permit conditions are consistent with all of the requirements of this part. As soon as circumstances allow, APHIS will notify the responsible person of the amendment to the permit and the reason(s) for it. Depending on the nature of the amendment, the responsible person may have to agree in writing or electronically that he or she, and his or her agents, will comply with the permit and conditions as amended before APHIS will issue the amended permit. If APHIS requests such an agreement, and the responsible person does not so agree, the existing permit will be revoked.

(i) *Shipping under a permit.* All shipments of regulated organisms must be secure shipments. Regulated organisms must also be shipped in

accordance with the regulations in 49 CFR part 178. The container must be accompanied by a document that includes the names and contact details for the sender and recipient. Following the completion of the shipment, all packing material, shipping containers, and any other material accompanying the regulated organism must be treated or disposed of in such a manner so as to prevent the unauthorized dissemination and establishment of regulated organisms. Additionally, for any regulated organism to be imported into the United States, the outmost container must bear the nature and quantity of the contents; the country and locality where collected, developed, manufactured, reared, cultivated, or cultured; the name and address of the shipper, owner, or person shipping or forwarding the organism; the name, address, and telephone number of the consignee; the identifying shipper's mark and number; and the number of written permit authorizing the importation. For regulated organisms imported by mail, the container must also be addressed to a plant inspection station listed in § 319.37-14 of this chapter. All imported containers of regulated organisms must be accompanied by an invoice or packing list indicating the contents of the shipment.

§ 340.4 Regulatory status evaluation.

(a) Any person may submit a request to APHIS to have a GE organism's regulatory status evaluated, or to request the reevaluation of the regulatory status of a previously evaluated regulated organism. Information needed for such a request is found on the Internet, at <http://www.aphis.usda.gov/biotechnology/2016-340-proposed-rule>.

(b) *Administrative action.* (1) Upon receiving or initiating a regulatory status request, APHIS will evaluate the request for completeness, and may contact the person submitting the request for additional information.

(2) If the request is complete, APHIS will conduct an analysis of plant pest and/or weed risks of the GE organism.

(c)(1) APHIS will make both the request and the risk analysis available for public review through a notice published in the **Federal Register**. The notice will request public comment, and will propose a regulatory status for the organism.

(2) If no comments are received on the notice, or if the comments do not affect the conclusions of the risk analysis or the proposed regulatory status of the organism, APHIS will provide notification through the APHIS stakeholder registry at the end of the

comment period announcing that the proposed regulatory status has been finalized. APHIS will subsequently publish a notice in the **Federal Register** compiling these determinations.

(3) If comments lead APHIS to change its proposed regulatory status for the organism, APHIS will publish a subsequent notice in the **Federal Register** characterizing these comments and announcing the new regulatory status.

§ 340.5 Record retention, compliance, and enforcement.

(a) *Record retention.* Responsible persons or their agents are required to establish and keep the following records and reports:

(1) All records and reports required as a condition of a permit;

(2) Addresses and any other information needed to identify all contained facilities where the regulated organism was stored or utilized, and all locations where the regulated organism was used in an environmental release;

(3) A record identifying which APHIS permit, if any, authorized the permitted activity; and

(4) Copies of contracts between the responsible person and all agents that conduct activities subject to this part for the responsible person, and copies and documents relating to agreements made without a written contract.

(b) *Record retention.* Records indicating that a regulated organism that was imported or moved interstate

reached its intended destination must be retained for at least 2 years. All other records must be retained for 10 years following permit expiration, unless determined otherwise by the Administrator and documented in the supplemental permit conditions or other regulatory requirements.

(c) *Compliance and enforcement.* (1) Responsible persons and their agents must comply with all of the requirements of this part. Failure to comply with any of the requirements of this part may result in any or all of the following:

(i) Denial of a permit application or revocation of a permit;

(ii) Application of remedial measures in accordance the Plant Protection Act, 7 U.S.C. 7701 *et seq.*; and/or

(iii) Criminal and/or civil penalties.

(2) Prior to the issuance of a complaint seeking a civil penalty, the Administrator may enter into a stipulation, in accordance with § 380.10 of this chapter.

(d) *Liability for acts of an agent.* For purposes of enforcing this part, the act, omission, or failure of any agent for a responsible person may be deemed also to be the act, omission, or failure of the responsible person.

§ 340.6 Confidential business information.

Persons submitting confidential business information in any document submitted to APHIS under this part should do so in the following manner. If there are portions of a document

deemed to contain confidential business information, those portions must be identified, and each page containing such information must be marked "CBI Copy." A second copy of each such document must be submitted with all such CBI deleted and marked on each page where the CBI was deleted: "CBI Deleted." In addition, any person submitting CBI must justify how each piece of information requested to be treated as CBI is a trade secret or is commercial or financial information and is privileged or confidential.

§ 340.7 Costs and charges.

The services of the inspector related to carrying out this part and provided during regularly assigned hours of duty and at the usual places of duty will be furnished without cost.² The U.S. Department of Agriculture will not be responsible for any costs or charges incident to inspections or compliance with the provisions of this part, other than for the services of the inspector.

Done in Washington, DC, this 10th day of January 2017.

Ben Thomas,

Deputy Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 2017-00858 Filed 1-18-17; 8:45 am]

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² The Department's provisions relating to overtime charges for an inspector's services are set forth in part 354 of this chapter.



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Part VII

Department of Agriculture

Agricultural Marketing Service

7 CFR Part 205

National Organic Program (NOP); Organic Livestock and Poultry Practices;
Final Rule

DEPARTMENT OF AGRICULTURE**Agricultural Marketing Service****7 CFR Part 205**

[Document Number AMS–NOP–15–0012;
NOP–15–06FR]

RIN 0581–AD44

**National Organic Program (NOP);
Organic Livestock and Poultry
Practices**

AGENCY: Agricultural Marketing Service,
USDA.

ACTION: Final rule.

SUMMARY: The United States Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) is amending the organic livestock and poultry production requirements by adding new provisions for livestock handling and transport for slaughter and avian living conditions; and expanding and clarifying existing requirements covering livestock care and production practices and mammalian living conditions.

DATES: *Effective Date:* This rule becomes effective March 20, 2017.

Implementation Dates: This rule will be fully implemented March 20, 2018. There are two exceptions:

(1) Organic egg operations that are certified before March 20, 2020 need to implement the outdoor access requirements by March 21, 2022. Organic egg operations that become certified after March 20, 2020 need to comply with the outdoor access requirements in order to obtain certification.

(2) Organic broiler operations must fully implement the indoor space requirements by March 20, 2020.

FOR FURTHER INFORMATION CONTACT: Paul Lewis, Ph.D., Director of Standards Division, Telephone: (202) 720–3252; Fax: (202) 260–9151.

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List of Subjects in 7 CFR Part 205

I. Executive Summary

A. Purpose of the Final Rule

This final rule creates greater consistency in organic livestock and poultry practice standards. Based on recommendations from the Office of Inspector General and the National Organic Standards Board, AMS determined that the current USDA organic regulations (7 CFR part 205) covering livestock care and production practices and living conditions needed additional specificity and clarity to better ensure consistent compliance by

certified organic operations and to provide for more effective administration of the National Organic Program (NOP) by AMS. One purpose of the Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6501–6522) is to assure consumers that organically produced products meet a consistent and uniform standard (7 U.S.C. 6501).

B. Summary of Provisions

Specifically, this final rule:

1. Clarifies how producers and handlers participating in the NOP must treat livestock and poultry to ensure their wellbeing.

2. Clarifies when and how certain physical alterations may be performed on organic livestock and poultry in order to minimize stress. Additionally, some forms of physical alterations are prohibited.

3. Sets maximum indoor and outdoor stocking densities for organic chickens, which vary depending on the type of production and stage of life.

4. Defines outdoor space and requires that outdoor spaces for organic poultry include soil and vegetation.

5. Adds new requirements for transporting organic livestock and poultry to sale or slaughter.

6. Clarifies the application of USDA Food Safety and Inspection Service (FSIS) requirements regarding the handling of livestock and poultry in connection with slaughter to certified organic livestock and poultry establishments and provides for the enforcement of USDA organic regulations based on FSIS inspection findings.

7. AMS has only established indoor space requirements for chickens in this final rule. AMS may propose space requirements for other avian species in the future. Other avian species must meet all other indoor requirements including exit doors, ammonia levels, and lighting.

C. Costs and Benefits

AMS estimates the following costs and benefits for this final rule.

| Assumed conditions | Affected population | Costs, millions ^a | Benefits, millions | Transfers, millions |
|---|--|------------------------------|--------------------|---------------------|
| All producers remain in organic market; Organic layer and broiler populations continue historical growth rates after rule. | Organic layer and organic broiler production at full implementation of rule, i.e., 2022 for layers; 2020 for broilers. | \$28.7–\$31.0 | \$16.3–\$49.5 | N/A |
| 50% of organic layer production in year 6 (2022), moves to the cage-free market. Organic layer and broiler populations continue historical growth rates after rule. | Organic layer and organic broiler production at full implementation of rule, i.e., 2022 for layers; 2020 for broilers. | \$11.7–\$12.0 | \$4.5–\$13.8 | \$79.5–\$86.3 |

| Assumed conditions | Affected population | Costs, millions ^a | Benefits, millions | Transfers, millions |
|--|--|------------------------------|--------------------|---------------------|
| 50% of current organic layer production moves to the cage-free market in year 6 (2022). There are no new entrants after publication of this rule that cannot comply. | Current organic layer production; organic broiler production at full implementation of rule in 2020. | \$8.2 | \$4.1–\$12.4 | \$45.6–\$49.5 |

Other impacts: Estimated paperwork burden: \$3.9 million

^a All values in the costs, benefits and transfer columns of this table are annualized and discounted at 3% and 7% rates.

II. General Information

A. Does this action apply to me?

You may be affected by this action if you are engaged in the meat, egg, poultry, dairy, or animal fiber industries. Affected entities may include, but are not limited to:

- Individuals or business entities that are considering organic certification for a new or existing livestock farm or slaughter facility.
- Existing livestock farms and slaughter facilities that are currently certified organic under the USDA organic regulations.
- Certifying agents accredited by USDA to certify organic livestock operations and organic livestock handling operations.

This listing is not intended to be exhaustive, but identifies key entities likely to be affected by this action. Other types of entities could also be affected. To determine whether you or your business may be affected by this action, you should carefully examine the regulatory text. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

III Background

This final rule addresses care and production practices, transport, slaughter, and living conditions for organic livestock and poultry.¹ The provisions in this rule on outdoor access for organic poultry have a significant history of AMS actions that are based on National Organic Standards Board (the NOSB) recommendations. Outdoor access is a prominent issue in this final rule. Poultry practices for outdoor access currently vary, especially practices implemented for layer operations. Some organic poultry operations provide large, open-air

outdoor areas, while other operations provide minimal outdoor space or use screened and covered enclosures commonly called “porches” to meet outdoor access requirements. In a 2010 audit, the USDA Office of Inspector General identified inconsistencies in how accredited certifying agents (or “certifiers”) consider porches under outdoor access while implementing certification of organic poultry operations. AMS initially responded to this audit finding by publishing draft guidance on outdoor access for organic poultry. However, after receiving public comment on the draft guidance, AMS determined that rulemaking was necessary to reduce the variation in outdoor access practices for organic poultry; therefore, AMS did not finalize the draft guidance. To assist with this rulemaking, the NOSB developed a series of recommendations to further clarify organic livestock and poultry care and production practices, transport, slaughter, and living conditions, including outdoor access for poultry. The NOSB deliberations on these recommendations revealed that there is considerable support for these recommendations within the organic community and consumers have specific expectations for organic livestock care, which includes outdoor access for poultry.

On April 13, 2016 AMS issued a proposed rule to amend organic livestock and poultry practices. Background on current organic livestock standards, NOSB recommendations contributing toward the development of the proposed rule, AMS policy, and related issues are described in preamble of that action.²

IV. Comments Received

In response to AMS’s request for comments on the proposed rule, a total of 6,675 written comments were received. Approximately 78 percent of the submitted comments—or 5,182 comments—consisted of form letters. There were 1,493 individual comments on the proposed rule. Comments were

received from producers, producer associations, handlers, certifying agents, consumers and consumer groups, animal welfare organizations, veterinarians, state government agencies, foreign government agencies, and trade associations or organizations. AMS analysis and response to comments is described in the following preamble sections of the final rule.

A. Regulatory Authority of the Final Rule

(Comment) Several comments argued that USDA does not have sufficient regulatory authority under OFPA to publish final rules for livestock living conditions and animal welfare as described in the proposed rule. They argued that the livestock section of OFPA only provides authority to prepare regulations regarding feeds and animal health care issues.

(Response) AMS affirms that USDA has the authority to conduct this rulemaking; this action falls within our purview to implement the Organic Foods Production Act. AMS is issuing these regulations to strengthen the USDA organic livestock production regulations with clear provisions to fulfill one purpose of OFPA: to assure consumers that organically-produced products meet a consistent and uniform standard (7 U.S.C. 6501). In accordance with OFPA, this action will clarify USDA statutory and regulatory mandates and establish consistent, transparent, and enforceable requirements. Two provisions within OFPA convey the intent for the USDA to develop more specific standards for organic livestock production; that purpose was also explained in the accompanying Senate Committee report.³ Section 6509(d)(2) authorizes

¹ As defined in § 205.2, the term “livestock” includes any cattle, sheep, goats, swine, poultry, or equine animals used for food or in the production of food, fiber, feed, or other agricultural-based consumer products. In this final rule, the terms “livestock” and “livestock and poultry” are used throughout the preamble. Unless otherwise specified, the term “livestock” refers to both mammalian livestock and avian livestock.

² <https://www.federalregister.gov/documents/2016/04/13/2016-08023/national-organic-program-organic-livestock-and-poultry-practices>.

³ The Senate report that accompanied the OFPA legislation set the expectation for greater specificity in the future for organic livestock standards as the industry matured: “More detailed standards are enumerated for crop production than for livestock production. This reflects the extent of knowledge and consensus on appropriate organic crop production methods and materials. With additional research and as more producers enter into organic livestock production, the Committee expects that USDA, with the assistance of the National Organic Standards Board will elaborate on livestock

the NOSB to recommend standards in addition to the OFPA provisions for livestock health care to ensure that livestock is organically produced. Further, section 6509(g) directs the Secretary to develop detailed regulations through notice and comment rulemaking to implement livestock production standards. AMS has already exercised this authority to implement additional regulations regarding feed and living conditions for organic livestock (see *Access to Pasture*, 75 FR 7154 (February 17, 2010)). Therefore, the statute contemplated that the assurance of organic integrity for livestock products would require more specific guidelines and provided the authority for that future regulatory activity.

This rule would continue the process initiated with the *Access to Pasture* rulemaking to establish clear and comprehensive requirements for all organic livestock, consistent with recommendations provided by USDA's Office of Inspector General and nine separate recommendations from the NOSB. Further, it will align regulatory language and intent to enable producers and consumers to readily discern the required practices for organic poultry production and to differentiate the products in the marketplace.

B. Regulatory Clarity of the Final Rule

(Comment) The proposed rule sought comments on the clarity of the proposed requirements by posing the following specific question: "Can farmers, handlers, and certifying agents readily determine how to comply with the proposed regulations?"

Though they did not directly answer the question posed in the proposed rule, a few comments nevertheless commented more generally on the clarity of the proposed rule. Speaking specifically of the revisions to mammalian living conditions, one comment indicated that the proposed rule was needed as a means to strengthen vague organic livestock standards. This comment did, however, highlight areas that continue to be unclear, claiming inconsistencies in the interpretation of standards upon implementation of the rule. Another commenter provided general support for the proposed rule, as rulemaking clarity will lead to consistent compliance by certified operations while addressing consumer expectations and demand. In

contrast, one comment stated that that rule is confusing specifically addressing mammals and avian species. Another comment stated that only organic certifiers with limited livestock experience will find the current the organic regulations clear and concise in contrast to the more seasoned organic inspector community. This commenter further stated that those experienced in the organic industry realize the challenge to promulgate universal standards. The comment also asserted that creating new standards will make it difficult for certifiers to be effective in their work.

(Response) Where appropriate, AMS has amended sections of the final rule to clarify the requirements based on comments, with the goal of making the requirements readily understandable for organic stakeholders.

C. Consumer Education and Outreach

(Comment) A few comments stated that USDA should do more to inform consumers about what organic means and doesn't mean, and that educating consumers about the existing standards would be better than changing the regulations.

(Response) AMS agrees that consumer education is important to ensure that organic consumers understand the limitations of the existing organic regulations. However, numerous comments and the NOSB have requested that AMS clarify the current regulatory text and add sufficient detail in support of consistent enforcement of the USDA organic regulations that affect the welfare of organic livestock and poultry. Therefore, AMS has opted to proceed with this rulemaking. AMS received a number of comments which addressed how the variability in outdoor access practices among organic producers threatens consumer confidence in the organic label. This is discussed more fully in the Executive Orders 12866 and 13563 section—see *Impact of Consumer Confusion*.

D. International Trade Agreements

(Comment) A number of comments asked how the final rule would impact existing organic trade agreements, such as equivalency agreements and recognition agreements. For example, some comments highlighted where specific standards in the proposed rule differ from existing standards in specific countries. It was also asked whether existing equivalency agreements would require renegotiation as a result of a final rule.

(Response) When the USDA organic regulations are amended, the USDA notifies the trading partner in

accordance with the terms established in the international organic equivalency arrangement. In addition, the proposed regulations are shared with the World Trade Obligations (WTO) pursuant to the WTO Agreement on Technical Barriers to Trade. Under the current organic equivalency arrangements, the USDA notifies the trading partner in advance of any final USDA organic regulation that may affect the terms of the existing equivalency determination. The foreign country reviews the information, and may initiate discussion to determine whether a renegotiation of the equivalence arrangement is needed. With recognition arrangements, the certification bodies in the foreign country are accredited by the recognized foreign government authority to certify operations under the USDA organic regulations. As a result, the USDA notifies the foreign government of the final USDA organic regulation, and the foreign government authority informs its accredited certification bodies of the final regulation. AMS will provide training and technical assistance during the implementation period to assist foreign governments and accredited certification bodies.

E. Meat and Poultry Imports

(Comment) USDA received comments regarding meat and poultry imports and how AMS will regulate livestock slaughter by certified operations in foreign countries. One comment provided country-specific recommendations regarding cattle to stipulate that while cattle are in Australia, "they must abide by the standards and guidelines prescribed in the Australian Animal Welfare Standards for the Land Transport of Livestock (The Standards)." Additionally, a comment indicated that U.S. certifiers are currently unequipped to verify compliance with these other rules/laws for producers outside of the U.S.

(Response) Products certified under the USDA organic regulations must first comply with the requirements of the Food and Drug Administration (FDA) and Food Safety and Inspection Service (FSIS). In other countries, FSIS has memorandums of understanding that recognize other countries' processes for safe and humane livestock handling and slaughter. Generally, USDA organic requirements go beyond minimum regulatory requirements for humane handling and slaughter. For NOP requirements, certifiers must ensure inspectors are qualified to evaluate compliance of applicants for organic certification. Certifiers are not responsible for verifying compliance

criteria." Senate Committee on Agriculture, Forestry and Nutrition, *Report of the Committee on Agriculture, Forestry and Nutrition to Accompany S. 2830 Together with Additional and Minority Views*, 101st Congress, S. REP. NO. 101-357, at 289 (1990).

with regulations other than those for organic certification. AMS did not amend the proposed rule based on these comments.

V. Related Documents

Documents related to this final rule include the Organic Foods Production Act of 1990, as amended, (7 U.S.C. 6501–6522) and its implementing regulations (7 CFR part 205). The NOSB deliberated and made the recommendations described in this proposal at public meetings announced in the following **Federal Register** Notices: 67 FR 19375 (April 19, 2002); 74 FR 46411 (September 9, 2009); 75 FR 57194 (September 20, 2010); and 76 FR 62336 (October 7, 2011). NOSB meetings are open to the public and allow for public participation.

AMS published a series of past proposed rules that addressed, in part, the organic livestock requirements at: 62 FR 65850 (December 16, 1997); 65 FR 13512 (March 13, 2000); 71 FR 24820 (April 27, 2006); and 73 FR 63584 (October 24, 2008). Past final rules relevant to this topic were published at: 65 FR 80548 (December 21, 2000); 71 FR 32803 (June 7, 2006); and 75 FR 7154 (February 17, 2010). AMS published the most recent proposed rule at 81 FR 21956 (April 13, 2016).

VI. Definitions (§ 205.2)

A. Description of Regulations

1. Summary of the Final Rule

This final rule adds sixteen new terms to § 205.2: beak trimming, caponization, cattle wattling, de-beaking, de-snooding, dubbing, indoors or indoor space, mulesing, non-ambulatory, outdoors or outdoor space, perch, pullet, ritual slaughter, soil, toe clipping, and vegetation. Six of these terms—caponization, cattle wattling, de-snooding, dubbing, mulesing, and soil—remain unchanged from the proposed rule. The definitions of seven additional terms were revised in response to comments: beak trimming, de-beaking, indoors or indoor space, outdoors or outdoor space, perch, pullets, and toe clipping. The term roost, which was included in the proposed rule, has been removed from the final rule in response to comments. Three terms that were not included in the proposed rule, non-ambulatory, ritual slaughter, and vegetation, have been added to the final rule.

Physical Alterations

The final rule prohibits several physical alterations on organic livestock. Eight terms related to these physical alterations are defined in the

final rule so that certifying agents and producers may ensure that they do not inadvertently perform a prohibited physical alteration which may be known by a different name locally.

Indoors or Indoor Space

The final rule defines “indoors or indoor space” as the space inside of an enclosed building or housing structure that has a solid, slatted, or perforated floor. The term “indoors” from the proposed rule was modified to include “or indoor space” because both of these terms are used interchangeably throughout the rule. While all organic livestock must be provided with species-appropriate shelter, structures providing indoor space are not required. If indoor spaces are provided to organic livestock, then species-specific requirements for the indoor space must be met. Indoor spaces are differentiated from outdoor spaces based upon the structure being enclosed so that livestock may be confined within the footprint of the building.

Indoor space is enclosed so that livestock may be confined within the building or housing structure; outdoor space is the area outside of the enclosed building or enclosed housing structure, but includes roofed areas that are not enclosed. One of the key considerations distinguishing indoor space from outdoor space is how the livestock are managed in that space. How livestock are managed may determine whether space is considered indoors, outdoors, or neither indoors nor outdoors. As an example, a screened in and roofed porch to which the (enclosed) birds always have access, including during temporary confinement events, would be considered indoor space. That same porch would be considered neither indoors nor outdoors if the birds did not have continuous access to the space during temporary confinement events. If the screens were removed from that porch so that the birds could freely access other outdoor space, then the porch would be considered outdoor space (see “Outdoors or outdoor space,” below). These distinctions provide flexibility for producers to work with their certifying agents when developing their organic system plans (OSPs), yet still aligns with the position that enclosed porches are not considered to be outdoor space.

The final rule defines four types of avian indoor space. These indoor housing types are defined because each housing type has a differing indoor space requirement. AMS continues to include an indoor space requirement at § 205.241(b)(8)(v) for housing that does

not fit within one of the types defined in § 205.2.

The final rule further clarifies the requirements for avian species indoor space requirements by defining the term “perch” as a rod or branch type structure or flat space above the floor of the house that accommodates roosting, allowing birds to utilize vertical space in the house.

Outdoors or Outdoor Space

The final rule defines “outdoors or outdoor space” to clarify the meaning of outdoor areas for mammalian and avian species. The term “outdoors” from the proposed rule was modified to include “or outdoor space” because these two terms are used interchangeably throughout the rule. “Outdoors or outdoor space” is defined as any area outside of an enclosed building or enclosed housing structure, but including roofed areas that are not enclosed. In this definition, “outdoors or outdoor space” includes all of the non-enclosed space encompassing soil-based areas such as pastures, pens, or sacrifice lots; hardened surface areas such as feedlots, walkways, or loafing sheds; and areas providing outdoor shelter such as windbreaks and shade structures.

The outdoor space has species-specific requirements. For example, this rule sets the requirement that 50 percent of the outdoor space for avian species must be soil-based and that the soil be maximally covered with vegetation. Vegetative cover must be maintained in a manner that does not provide harborage for rodents and other pests. For avian species, the definition of outdoors has been revised to include pasture pens, which are floorless pens that are moved regularly and provide direct access to soil and vegetation. These pens may consist of solid roofing over all or part of the pen to provide shelter for the birds. For further discussion see “Pasture Pens vs. Other Mobile Housing” in section IX. Avian Living Conditions.

To assist with the mitigation of biosecurity and predation risks, fencing, netting, or other materials are permitted over all or part of the outdoor areas to prevent predators and other wild birds from entering the outdoor area. Many producers also use portable or permanent shade structures throughout their pastures. Structures for shade are also permitted in the outdoor space. For example, the area within a standalone, roofed shade structure could be included as outdoor space area. Areas under the eaves or the awning of a building, with a roof attached to the outer wall of the indoor space structure,

can also be considered outdoors. While these areas may have solid roofs overhead, they can offer the same quality of outdoor space as uncovered outdoor areas, including natural ventilation/open air, direct sunlight, soil, vegetation, and open access to uncovered areas beyond.

The final rule defines “soil” as the outermost layer of the earth comprised of minerals, water, air, organic matter, fungi, and bacteria, in which plants may grow roots. Soil is defined to distinguish these areas from impervious areas such as concrete or pavement. Soil may consist of bare ground but is generally covered with vegetation. As described in the mammalian and avian living condition sections, maximum vegetative cover should be maintained on the soil as appropriate for the species, season, geography, and climate. Designated sacrifice areas or dry lots are permitted. Outdoor areas must be maintained in a manner that maintains or improves natural resources, including soil and water quality. Temporary confinement may be provided to protect soil and water quality.

Non-Ambulatory

The final rule adds the term “non-ambulatory” and references the definition in 9 CFR 309.2(b). FSIS defines non-ambulatory as “livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.” Any non-ambulatory livestock on organic farms must be medically treated, even if the treatment causes the livestock to lose organic status or be humanely euthanized.

Pullets

AMS modified the definition of pullets, which is used by the AMS Livestock, Poultry, and Seed Program, to include species other than chickens. This final rule defines “pullets” as female chickens or other avian species being raised for egg production that have not yet started to lay eggs. Once avian females begin laying eggs, AMS refers to them as layers. The term “pullets” does not describe young broilers used for meat production.

Stocking Density

The final rule defines “stocking density” as the weight of animals on a given area or unit of land. This term is used to describe the indoor and outdoor space requirements for organic livestock. For example, the final rule establishes maximum stocking densities

for avian species, and the producer must ensure that the area provided is large enough to not exceed the established maximum stocking density when all birds in the flock are on the given area (*i.e.*, indoors) or unit of land.

Ritual Slaughter

The final rule adds the term “ritual slaughter” and references the definition in the Humane Methods of Slaughter Act (7 U.S.C. 1902(b)). This Act defines ritual slaughter as “slaughtering in accordance with the ritual requirements of the Jewish faith or any other religious faith that prescribes a method of slaughter whereby the animal suffers loss of consciousness by anemia of the brain caused by the simultaneous and instantaneous severance of the carotid arteries with a sharp instrument and handling in connection with such slaughtering.”

Organic livestock and handling operations may use ritual slaughter to convert their livestock to meat or poultry without loss of organic status.

Vegetation

The final rule adds the term “vegetation” and defines it as living plant matter that is anchored in the soil by roots and provides ground cover. This term applies to the requirement for vegetation in outdoor areas, which is central to protecting soil and water quality as well as providing for livestock to exhibit their natural behaviors. The roots of vegetation provide stability and structure to soil. Vegetation helps water soak into the soil rather than running off, which can cause erosion. Livestock also have natural behaviors of grazing, rooting, nesting, etc., which require vegetation.

B. Discussion of Comments Received

1. Definition of Beak Trimming

(Comment) The term beak trimming was included in the proposed rule and was defined as the removal of the curved tip of the beak. Many comments expressed that the definition for this term was vague and that the difference between beak trimming and de-beaking was unclear. Comments also shared that it is common within the industry to use the terms beak trimming and de-beaking interchangeably and that a more quantitative measure should be included if the intent of the rule is to control the amount of beak trimmed. One comment requested additional clarification with regards to trimming the bottom of the beak. Some comments suggested revisions to the definition to provide clarity, including the American Veterinary Medical Association (AVMA)

which recommended the following definition: “Beak trimming (formerly de-beaking) is the removal of approximately one-quarter to one-third of the upper beak, or both upper and lower beak, of a bird in order to control injurious pecking and cannibalism.” Four comments suggested that the proposed definition be revised to specify the anatomical name of the portion of the beak that is removed in beak trimming. Other comments stated that the definition should specify the age at which beak trimming can be performed.

(Response) AMS agrees with the majority of comments which expressed that the definition of beak trimming should be clarified. We have replaced the definition from the proposed rule with a definition similar to the one provided by AMVA which specifies that beak trimming is “the removal of approximately one-quarter to one-third of the upper beak, or both upper and lower beak”. For the purposes of these regulations, AMS modified the AVMA definition to replace the word “approximately” with “not more than” in order to ensure that beak trimming is clearly distinguished from de-beaking. We believe that this definition adequately addresses the comments received and is both accurate and clear without being overly prescriptive. AMS does not believe that it is necessary to refer to anatomical names for portions of the beak in this definition since these terms are not used in the regulatory text. Other comments in response to the age at which beak trimming can be done are addressed in the avian living conditions section of the final rule.

2. Definition of De-Beaking

(Comment) The term de-beaking was included in the proposed rule and was defined as “the removal of more than the beak tip.” The comments received regarding the term beak trimming also addressed de-beaking, expressing that the proposed definition was vague and that the distinction between beak trimming and de-beaking was not clear. One comment requested that the definition of de-beaking be removed entirely as the industry has taken steps to eliminate this practice.

(Response) In response to comments, AMS amended the definition of de-beaking in the final rule to make it more specific. AMS believes that it is important to define de-beaking in order to differentiate it from beak trimming. Comments did not provide a suggested definition for the term, and as a result AMS decided to define de-beaking as anything that goes beyond what is defined in this rule as beak trimming.

Thus, the amended definition of de-beaking clarifies that it is the removal of more than one-third of the upper beak, or more than one-third of both the upper and lower beaks of a bird.

3. Definition of Caponization

(Comment) AMS received two comments stating that the definition for “caponization” should not be included in the final rule. Comments stated that it is unnecessary for AMS to define “caponization” because it is beyond the purview of the AMS.

(Response) This final rule prohibits caponization, as defined, based upon a recommendation from the NOSB. Thus, it is within AMS’s purview. AMS believes that, because caponization is prohibited, it is necessary to clearly define what it is so that certifying agents and producers can ensure that they do not inadvertently perform this physical alteration.

4. Definition of Indoors

(Comment) AMS received a range of comments on the proposed definition of indoors. A number of comments suggested that the term “indoors” be replaced by the term “indoors for avian species” since the definition of the term is specifically related to avian living spaces. Other comments recommended changing the term “pasture housing” to “mobile housing.” These comments pointed out that there are fixed housing systems that offer pasture to birds. They also noted that the term “pasture-raised” is defined by other third-party animal welfare standards, and those standards allow fixed housing to be used in combination with a spoke-and-wheel pasture rotation for pasture-raised poultry. Thus, they felt that the term “mobile housing” is more accurate based on the type of housing that AMS intended to describe in the proposed definition.

Two comments recommended that the reference to 70% perforated flooring be removed from the description of pasture housing since this requirement is restrictive when considering that different types of pasture housing (or mobile housing) vary in design. These comments suggested that the definition instead focus on the mobility of the housing and its frequent movement.

Various comments expressed that more clarity is needed in the definition of “indoors” in order to define exactly what counts as indoors and outdoors for the various types of pasture-based systems used. These comments recommended that definitions for “moveable pasture pen” and “day range system” be added in order to provide additional clarity and to better represent

the actual types of pasture housing used in pastured-poultry operations. Commenters used “Salatin” style housing, “Prairie Schooners,” and simple hoop structures as examples of moveable pasture pens. The comments described these systems as providing direct access to soil and vegetation; having walls and roofs made of mesh, plastic, wood, and other materials; and having mobility. Birds in these systems are on pasture 24 hours per day, while roofing on all or part of the structure provides shade and protection. These commenters argued that these systems are unique, provide access to the soil and vegetation, and allow birds to exhibit natural behavior, and should be specifically permitted and addressed in the requirements.

(Response) AMS agrees that the proposed definition for indoors focuses specifically on describing what qualifies as indoor areas for avian species. Rather than creating a new term, “indoors for avian species,” AMS determined that it would be best to define indoors more broadly, and provide a separate sub-category of terms that define what is indoors specifically for avian species. Having a broadly applicable definition of indoors helps to clearly distinguish it from the meaning of outdoors. Further defining indoor areas for avian species within the definition of indoors allows AMS to provide more specificity where it is needed. As a result, AMS revised the basic definition of indoors to define it as the space inside of an enclosed building or housing structure with solid, slatted, or perforated flooring.

AMS also agrees with comment that stated that the term “mobile housing” is more appropriate to describe pasture housing that is regularly moved to provide birds with access to new pasture. In various situations, the term “pasture housing” may be applied to stationary housing that provides access to pasture, and this could cause confusion for producers, certifying agents, and inspectors. In response to comments, AMS replaced the term “pasture housing” with “mobile housing” in the final rule.

Additionally, AMS removed the reference to 70% perforated flooring from the definition of mobile housing. AMS agrees with comments that defining mobile housing without specifying what its flooring is made of is more applicable given the diversity of structures used in mobile housing systems.

AMS made several revisions in the final rule in response to comments requesting more clarity around the definitions of indoors and outdoors as they apply to pasture-based systems.

AMS agrees with comments that the proposed definitions for these terms did not adequately consider pastured poultry systems where birds are contained within a lightweight, floorless enclosure such as a pen that provides the birds in the pen with direct contact to soil and vegetation. As such, these systems did not clearly fall under either definition that AMS proposed for indoors or outdoors. AMS has clarified that pasture pens are outdoors or outdoor space by revising the definition in section 205.2. For further discussion of this topic, see section IX. Avian Living Conditions, “Pasture Pens vs. Other Mobile Housing.”

Organic livestock must be provided with outdoor space as the default living space, along with shelter. Organic producers may choose to provide indoor covered, enclosed and floored space as shelter if needed for the health and wellbeing of the birds, but it is not required. In addition to revising the broad definition of indoors, AMS responded to these comments by providing a separate definition of pasture pens under the definition of outdoors at section 205.2. The definition of outdoors, similar to the definition of indoors, defines pasture pens in a sub-category of terms describing outdoors for avian species.

Nest Box Areas and Other Indoors Comments

(Comment) A small number of comments stated that it was unclear from the proposed rule whether accessible nest box areas could be included in indoor space calculations. These comments suggested adding “and accessible nest boxes” to the first sentence of the definition for indoors. Some comments requested that the definition of indoors clarify that the term includes porches and lean-to type structures attached to the building or housing structure. One comment questioned the reference to feed and water on each level in the description of aviary housing. This comment noted that it is not necessary to include this specific requirement in case producers prefer to keep food and water on the main level of housing to encourage birds to move around and go outdoors. One comment suggested a new definition for “indoors” as: “The flat space or platform areas which are under a solid roof and contained within a solid wall.” Another comment that the definition for indoors specify that it may not contain prohibited materials.

(Response) AMS did not add “accessible nest boxes” to the definition of indoors as some comments requested. Most third-party animal welfare

standards consider nest boxes to be distinct from usable floor areas of the house where birds can move around freely. These third-party standards use indoor space calculation methods that do not include nest boxes. AMS believes that aligning with other third-party animal welfare standards by excluding nest boxes from indoor space calculations is the most sensible approach. Since many organic egg producers participate in other third-party verified animal welfare programs, this approach avoids creating separate requirements for producers which could be confusing and burdensome.⁴ In addition, AMS' approach aligns with the NOSB's 2011 recommendation stating that nest boxes cannot be included in the calculation of indoor space.⁵ Therefore, AMS did not change the definition of "indoors" to include nest boxes. AMS also clarified in § 205.241(b)(7) that nest boxes cannot be included in indoor space calculations.

AMS determined that a specific reference to porches and enclosed lean-to type structures is not necessary in the definition of "indoors." AMS believes that the definition adequately covers these types of structures and that including them in a broader list of housing categories would be confusing. However, AMS does provide clarification in the regulatory text under Avian Living Conditions (§ 205.241) that these structures can be counted as indoor space provided that they are fully accessible to birds at all times, including during temporary confinement.

AMS removed "feed and water on each level" from the definition of aviary housing in the definition of "indoors or indoor space" at § 205.2. Not all avian housing is designed this way, and this revision allows producers to work with their certifying agents to determine the best location for food and water depending on their housing system.

5. Definition of Outdoors

Soil/Vegetation Requirement

(Comment) Many comments stated that the definition of outdoors should include a requirement for vegetation instead of soil. These comments expressed concern about soil and water quality in the absence of vegetation in outdoor areas used by livestock. Many also felt that vegetation is important for animal health and natural behaviors. Other comments requested that the 50 percent soil requirement in the definition of outdoors should be removed. These comments felt that this reference contradicted the use of feeding pads and feeding yards, which are specifically allowed under the rule. They also expressed concern that including a requirement specifically for 50 percent soil in the definition of outdoors could negatively impact soil and water quality during winter or dry months.

Various comments questioned the statement in the proposed definition indicating that areas with solid walls or a solid roof attached to the outer wall of an indoor living space cannot be considered outdoors. Comments questioned how these areas (such as eaves or awnings) are different from an outdoor space that has a solid roof and no walls and is not connected to the structure providing the indoor space. They reasoned that these areas provide the same quality of outdoor space and are important for providing shade and protection. Other comments stated that allowing areas under the eaves of buildings and awnings to be counted as outdoors would simplify outdoor space calculations.

Some comments stated that porches should be included in the definition of outdoors. They cited the need to calculate porches as outdoor space due to producer costs, biosecurity concerns, mortality rates, and environmental concerns.

(Response) AMS agrees with comments that it is important that outdoor areas for livestock include vegetation to protect soil and water quality and promote animal health and natural behaviors. AMS is also in agreement with comments that requested that the reference to soil be removed from the definition of outdoors. In response to these comments, AMS in conjunction with Natural Resource Conservation Service, determined that requirements for soil and vegetation in outdoor access areas should be included in the sections of the final rule that address mammalian and poultry living conditions rather than in the definition of outdoors.

Including a requirement for vegetation in the definition for outdoors may make it difficult for some producers to meet outdoor access requirements during certain times of the year (*i.e.* winter months, dry seasons), in certain regions, or for certain species.

AMS agrees that outdoor areas that are partially covered, such as areas under the eaves or the awning of a building, can be considered outdoors. These areas can offer the same qualities of outdoor space (such as natural ventilation, soil, vegetation, and open access to uncovered outdoor areas) as independent shade structures. In response to comments, AMS revised the definition of outdoors to remove the statement that disqualifies areas where there is a solid wall or roof attached to the indoor living space. This revision is intended specifically to accommodate for features of an avian housing structure that may provide cover but are in areas that are truly outdoors. In these areas, birds have access to soil and vegetation, natural ventilation, and open access to uncovered outdoor areas beyond. AMS considers these areas as distinct from porches specifically because they are not fully enclosed.

For further discussion about porches see "Porches" in the Discussion of Comments Received, section IX. Avian Living Conditions.

6. Definition of Perch and Roost

(Comment) AMS received a number of comments about the proposed definitions of the terms "perch" and "roost." Comments stated that the terms in the proposed rule were confusing and are used interchangeably within the proposed rule and within the industry. Some comments suggested replacing the word roost with the word slats, to refer to raised slats positioned over a manure pit. Other comments stated that the reference to manure pit(s) should be removed from the definition of roost entirely, as not all roosts are located over one.

(Response) AMS recognizes that using both terms "perch" and "roost" could be confusing, as the terms can be used interchangeably by producers and industry. AMS determined that it is only necessary to include the term "perch" in the final rule. As defined, this term is intended to refer to various features in poultry housing, such as rods, branch type structures, and flat roost slats that accommodate roosting and are elevated to allow birds to stay off the floor of the house. Perches may be over a manure pit but this is not a requirement. AMS also removed "roost" from the definitions section and regulatory text section based on

⁴ United Egg Producers: <http://www.unitedegg.org/information/pdf/UEP-Animal-Welfare-Guidelines2016.pdf>.

Humane Farm Animal Care: <http://certifiedhumane.org/wp-content/uploads/2014/01/Std14.Layers.6A.pdf>.

Global Animal Partnership: <http://gapstaging.blob.core.windows.net/standards/DRAFT%205-Step%20Animal%20Welfare%20Rating%20Pilot%20Standards%20for%20Laying%20Hens.pdf>.

American Humane Certified: http://www.humaneheartland.org/index.php?option=com_content&view=article&id=3&Itemid=106&jsmallfib=1&dir=JSROOT/Animal+Welfare+Full+Standards+%2B+Supplements.

⁵ NOSB, 2011. Formal Recommendation by the NOSB to the NOP, Animal Welfare and Stocking Rates. Available at: <http://www.ams.usda.gov/rules-regulations/organic/nosb/recommendations>.

comment feedback that the term was not necessary.

7. Definition of Soil

(Comment) A small number of comments expressed confusion over the proposed definition of soil and asked whether soil, as defined, is required to be bare since the definition did not include a reference to vegetation. One of these comments suggested revising the definition to add “which may be bare or vegetated” in order to provide clarification. Another comment requested that the definition of soil be revised to describe it as being vegetated, citing soil and water quality concerns. Other comments expressed concern about conflicts with other definitions of soil currently in use. One of these comments suggested replacing the proposed definition of “soil” with a more technical definition from the Natural Resources Conservation Service (NRCS), while another comment suggested using the term “certified ground.” A separate commenter thought that the impact of the proposed rule was limited without an adequate definition of soil that clearly states the quality, depth, and presence of vegetation.

(Response) After considering the comments received, we have retained the definition of soil from the proposed rule because we believe that it is an accurate and a commonly understood description of the term. AMS believes that a more complex or overly technical definition of soil is unnecessary and could contribute to confusion. However, AMS recognizes that the intent of some comments was to avoid circumstances in which animals on bare soil could create soil or water quality problems, and the Agency agrees that avoiding such an outcome is paramount. The final rule provides additional clarification in the avian and mammalian living conditions sections regarding the various requirements for soil and vegetation in outdoor areas to differentiate between the needs and management of avian and mammalian species.

8. Definition of Stocking Density

(Comment) AMS received various comments identifying that the reference to “unit of land” in the definition for stocking density is limiting, since it applies to both outdoor and indoor space. Comments suggested that the definition refer to “area of space” instead of to “unit of land.” One comment suggested that AMS also remove the phrase “at any one time” from the definition of stocking density. The comment stated that this phrase could be interpreted to allow space

requirements to be calculated by applying the stocking density to a percentage of animals that might be in an area at a point in time, rather than applying the stocking density to the total flock.

(Response) In the final rule, AMS has removed the phrase “at any one time” from the definition to reduce the chance of confusion over the intended meaning and application of the term. AMS has also revised the term to include “given area” in response to comments that the term is used for both indoor and outdoor areas.

For further discussion about space calculations, please see AMS’s response to comments in Avian Living Conditions.

9. Definition of Toe Clipping

(Comment) AMS received various comments questioning whether toe clipping is the same as toe trimming. Toe clipping was a new term defined and used in the proposed rule. Toe trimming, a similar term, was also used in various places throughout the proposed rule and brought forth questions about interchangeability between the terms.

A number of comments also pointed out that toe clipping can be performed on both male and female birds. These comments said that the definition of the term would be more accurate if the specific reference to a male bird was removed.

(Response) AMS recognizes that the proposed rule defined toe clipping and used the term toe trimming in the proposed rule. AMS also recognizes that toe clipping can be done on both male and female birds. In response to comments, the final rule defines toe clipping as the removal of the nail and distal joint of the back two toes of a bird without reference to the sex of the bird. Additionally, the term “toe clipping” is used consistently throughout the final rule and “toe trimming” has been removed.

10. Miscellaneous Comments

Scratch Area

Two comments asked for clarification about of the definition and composition of a scratch area. AMS has removed the term “scratch area” from the regulatory text. Since the term “scratch area” is not included in the regulatory text, AMS sees no need to define the term.

Enrichment/Suitable Enrichment

A small number of comments asked AMS to define the term enrichment or the phrase suitable enrichment. AMS has not defined the term, as we have removed the requirement for suitable

enrichment in the final rule. For further discussion, see AMS’s response to comments in the section on FDA regulations and food safety.

Willful Acts of Abuse

One comment requested that the rule provide a definition of “willful acts of abuse.” The comment noted that this definition was included in the NOSB’s 2011 recommendation on transport and slaughter. Since the term “willful acts of abuse” is not included in the regulatory text, AMS sees no need to define the term.

Litter

One comment requested that AMS include a definition of litter in the rule. This comment stated that it is unclear if litter is intended to mean bedding or if it can consist solely of dehydrated manure. AMS determined that the term “litter” is commonly used by avian producers to describe substrates used to absorb moisture and dilute manure, as well as to provide birds the opportunity to express natural behaviors such as foraging and dust bathing. AMS did not provide a definition for litter in the final rule. Instead, litter is described in more detail in the avian living section of the rule.

Dubbing

Four comments stated that the definition of dubbing does not include the removal of the wattles. AMS reviewed the uses of the term dubbing and found some references that included the removal of wattles and others that only referred to combs. Other sources refer to the practices separately as “wattle trimming” and “comb trimming.” AMS retained the definition of dubbing in the final rule to include the removal of both combs and wattles.

Swine Aggression

One comment requested that the final rule define “swine aggression” to prevent unnecessary confinement of pigs. This commenter stated that without a definition for the term, the provision of the rule allowing for individual housing for swine in cases where aggression is documented could be used for unnecessary confinement of pigs. AMS determined that it would be challenging to develop a definition for “swine aggression” that would be applicable across stages of production, and the diverse realities that exist on each farm. Instead, producers should work with their certifying agents to describe the types of aggression that would warrant individual housing on their operation as they develop an OSP.

VII. Livestock Health Care Practices (§ 205.238)

A. Description of Regulations.

1. Summary of the Final Rule

AMS amended current provisions and added new provisions to the organic livestock care and production practice standards. The amendment to § 205.238(a)(2) specifies that the sufficiency of the feed ration be demonstrated by appropriate body condition of the livestock. Livestock producers are required to monitor their animals to ensure body condition is being maintained. In addition, certifying agents need to verify the nutritional adequacy of the animals' diet by assessing the body condition of organic livestock during inspection. Suitable body condition varies between species, between breeds, and between production types; for example, a suitable condition for dairy cattle may be considered too thin in beef cattle. AMS plans to publish guidance to assist certifying agents, inspectors, and producers in assessing body condition for different species.

AMS revised § 205.238(a)(5) to clarify the conditions under which physical alterations may be performed on livestock. Physical alterations may only be performed for an animal's welfare, identification, or safety. Alterations must be done at a reasonably young age with minimal pain or stress to the animal, and may only be performed by a person who can competently perform the procedure. Competency in performing physical alterations may be demonstrated by appropriate training or experience of the person.

A 2009 NOSB recommendation allowed teeth clipping and tail docking in piglets, but this revision was retracted in the 2011 NOSB recommendation. In this final rule, AMS added § 205.238(a)(5)(i), which restricts needle teeth clipping and tail docking in pigs. These two types of physical alterations may not be performed on a routine basis, but may be performed as needed to improve animal welfare, as listed below.

Needle teeth clipping and tail docking in pigs may only be performed in response to documented animal welfare reasons after alternative steps to prevent harm fail. Teeth clipping, if performed, is limited to the top third of each needle tooth. For example, an organic swine producer who clipped needle teeth or performed tail docking would need to document excessive needle teeth scarring on the underline of a sow or piglets, or document tail biting on piglets in the litter. Swine producers

would also need to document that alternative methods to prevent scarring had failed. Such alternative methods may include, but are not limited to, cross-fostering prior to teat fidelity across litters to minimize weight variation, providing sufficient enrichment materials, and providing vegetation for rooting.

AMS is finalizing § 205.238(a)(5)(ii) to list the physical alterations that are prohibited in an organic operation. Based on the 2011 NOSB recommendations, the following physical alterations to avian species are prohibited: De-beaking, de-snooding, caponization, dubbing, toe clipping of chickens, toe clipping of turkeys unless with infra-red at hatchery, and beak clipping after 10 days of age. In addition, the following physical alterations to mammalian species are prohibited: Tail docking of cattle, wattling of cattle, face branding of cattle, tail docking of sheep shorter than the distal end of the caudal fold, and mulesing of sheep.

AMS added a new § 205.238(a)(7) which specifies that surgical procedures on livestock to treat an illness must be done in a manner that minimizes pain, stress, and suffering. The NOSB recommended that all surgical procedures for livestock be done with the use of anesthetics, analgesics, and sedatives. USDA organic regulations require that all surgical procedures for treatment of disease be undertaken in a manner that employs best management practices in order to minimize pain, stress, and suffering, and only with the use of anesthetics, analgesics, and sedatives as listed in §§ 205.603(a) and 205.603(b).

AMS added a new § 205.238(a)(8) that requires organic producers to actively monitor and document lameness within the herd or flock. Lameness can be an issue in various livestock species, including broilers, sheep, and dairy cattle. The requirement for producers to create a plan for monitoring and recording instances of lameness in the organic system plan enables organic livestock producers to identify and address potential problems among animals before they become widespread. In addition, documentation of lameness will provide an auditable trail for certifying agents to verify that livestock producers are monitoring these potential causes of animal suffering.

AMS revised § 205.238(b) to state that synthetic medications allowed under § 205.603 may be administered to alleviate pain or suffering. In addition, synthetic medications allowed under § 205.603 may be administered when preventative practices and veterinary

biologics are inadequate to prevent sickness.

AMS amended § 205.238(c)(1) to clarify that milk from an animal treated with an allowed substance in § 205.603, which has a withholding time, may not be sold, labeled, or represented as organic during that holding time. However, organic animals or breeder stock may continue to provide milk for organic calves on the same operation during the withholding time. This is consistent with the 2010 NOSB recommendation that a calf nursing a cow treated topically with lidocaine or other approved synthetic with a withdrawal time would not lose organic status. For example, if an organic beef cow was nursing her organic calf and the cow became injured, her calf could continue to nurse the cow even during the seven-day withholding period if lidocaine was used to minimize pain and stress during her treatment. In this scenario, the calf would not lose organic status.

AMS revised § 205.238(c)(2) to clarify that other veterinary biologics, in addition to vaccines, are exempt from the prohibition on administering animal drugs in the absence of illness. The USDA Center for Veterinary Biologics (CVB) regulates vaccines and all other veterinary biologics. While vaccines are commonly referred to as veterinary biologics, the CVB also categorizes bacterins and toxoids as biologics. This change is consistent with the definition for biologics in § 205.2 and supports § 205.238(a)(6), which identifies the use of vaccines and other veterinary biologics as a required practice to improve animal health.

AMS revised § 205.238(c)(3) to clarify that organic livestock producers are prohibited from administering synthetic or nonsynthetic hormones to promote growth, or for production and reproductive purposes. However, hormones listed in § 205.603 (e.g., oxytocin) may continue to be used to treat illnesses. Stakeholders have noted that the USDA organic regulations do not mention the use of hormones to stimulate production or for reproductive purposes. This addition clarifies that all hormones—unless used to treat an illness—are prohibited in organic production.

AMS added a new § 205.238(c)(8) to prohibit organic livestock producers from withholding treatment designed to minimize pain and suffering for injured, diseased, or sick animals. Injured, diseased, or sick animals may be treated with any allowed natural substance or synthetic medication that appears on the National List. However, if no appropriate medication is allowed for

organic production, organic livestock producers are required to administer treatment even if the animals subsequently lose their organic status. Furthermore, as recommended by the American Veterinary Medical Association, some forms of euthanasia may be an acceptable practice for minimizing pain and suffering.

AMS added a new § 205.238(c)(9) that requires livestock producers to identify and record treatment of sick and injured animals in animal health records. Early identification can lead to more effective prevention or treatment, which will enhance the overall health of the livestock on that operation.

AMS added a new § 205.238(c)(10) that prohibits the practice of forced molting in poultry. Section 205.238(a)(2) of this final rule requires a nutritionally sufficient feed ration for livestock. Forced molting, a practice in which feed is severely restricted for a period of time in order to rejuvenate egg production, runs counter to this provision. The new 205.238(c)(10) was added to be consistent with the NOSB recommendation.

AMS added a new § 205.238(d) that requires organic livestock operations to minimize internal parasite problems in livestock. The plan to minimize internal parasites must include preventative measures such as pasture management, fecal monitoring, and emergency measures in the event of a parasite outbreak. Livestock producers must also work with their certifying agents to approve a parasite control plan.

In certain cases, livestock may suffer from an illness or injury from which recovery is unlikely. AMS added a new § 205.238(e) to address euthanasia based on the 2011 NOSB recommendations. Section 205.238(e)(1) requires livestock producers to maintain written plans for euthanizing sick or injured livestock. Section 205.238(e)(2) prohibits the following methods of euthanasia: Suffocation, manual blows to the head by blunt instrument or manual blunt force trauma, and use of equipment that crushes the neck (*e.g.*, killing pliers or Burdizzo clamps). In the event of an emergency situation where a local, State, or Federal government agency requires the use of a non-organic method of euthanasia, organic livestock operations will not lose organic certification or face other penalties for the use of non-organic methods of euthanasia. The NOSB recommended listing the allowable methods of euthanasia, however, given that new humane euthanasia methods may emerge, AMS does not intend to discourage producer adoption of these techniques. Therefore, AMS allows

organic livestock producers to use any method of euthanasia except for those prohibited in section 205.238(e)(2). The list of prohibited methods could be amended to include other techniques, if needed, through future rulemaking. AMS added a new § 205.238(e)(3) which states that after the euthanasia procedure, livestock must be examined to ensure that they are dead.

B. Discussion of Comments Received

1. Selection of Breeds

(Comment) AMS received one comment requesting that we prohibit selective breeding of livestock and poultry for characteristics that may compromise their health and natural behaviors. The comment stated that some chicken breeds that are bred for increased white meat may have difficulty walking due to the size of their breasts relative to the strength/size of their legs.

(Response) Animal breeding is frequently conducted on non-certified operations, outside the scope of organic certification. Day-old birds are often selected and purchased by organic producers before the animals are brought into organic management. Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites is a requirement under § 205.238(a). Some species or types of livestock or poultry may not be suitable for organic production. Under existing regulations, certifying agents should verify that producers have selected breeds that are suitable for their site-specific conditions and that are resistant to prevalent diseases and parasites.

2. Provision of Feed Ration Resulting in Appropriate Body Condition

(Comment) One comment stated that the language proposed at § 205.238(a)(2) “. . . resulting in appropriate body condition” should be the sole indicator of the sufficiency of feed rations. Other comments, while expressing support for the inclusion of this additional language, argued that “appropriate body condition” is difficult to quantify. One comment requested that body condition standards be specified in the final rule. Other comments requested that body condition assessment guidance accompany the final rule.

(Response) Livestock body condition may vary greatly depending on the livestock breed, age, season of the year, or stage of production. The primary requirement under this section is to require livestock to receive a feed ration that is sufficient to meet nutritional

requirements. This would generally be verified by comparing the net energy and other nutrient requirements for the animal with the diet provided. AMS has added “. . . resulting in appropriate body condition” as a secondary assessment factor within the regulations for inspectors to use to gauge the nutritional status of an individual animal or group of animals. Because qualified organic inspectors should have sufficient livestock experience to evaluate the nutritional condition of livestock as part of their qualifications to inspect an organic livestock operation, we agree that guidance on how to assess appropriate body condition by species would be helpful for training purposes. AMS will provide such guidance after publication of the final rule.

3. Physical Alterations—General, Surgeries, and Pain Management

AMS received a number of comments requesting specific changes in words and phrases regarding the first part of § 205.238(a)(5): Physical alterations may be performed to benefit the welfare or hygiene of the animals, for identification purposes or safety. Physical alterations must be performed on livestock at a reasonably young age, with minimal stress and pain and by a competent person. These specific comments will be addressed one by one in the following discussion of comments.

(Comment) AMS received many comments proposing that the word “hygiene” be removed from § 205.238(a)(5). Comments believed that a broad interpretation of hygiene could create conflict among regulatory provisions, resulting in a loophole where farmers could seek to justify physical alterations even when prohibited under proposed § 205.238(a)(5)(ii). For example, hygiene is the main reason the tails of cows are docked on dairy farms, and thus hygiene should not be a justification for physical alterations.

(Response) AMS agrees that the term hygiene could be used to justify physical alterations otherwise prohibited, and has removed hygiene from this section of the final rule.

(Comment) AMS received comments that “reasonably young age” in § 205.238(a)(5) was too vague. These comments requested that we provide target ages for all physical alterations for all livestock.

(Response) The appropriate age of animals for performing alterations may depend on several factors, such as the nature of the physical alteration, temperature, season, species breed, and

health and condition of the animal. Certifying agents will need to work with producers on a case-by-case basis to assess the specific issues, needs, and justifications related to physical alterations on their operation by species and breed for inclusion in their organic system plans within the parameters provided in the final rule. Identifying target ages on every species for every possible physical alteration would be overly prescriptive and would unnecessarily impede operators in the humane management of their livestock. Therefore, AMS has not made changes in the final rule based on this comment.

(Comment) AMS received comments that “by a competent person” is too subjective to evaluate and should be removed from § 205.238(a)(5). Comments requested further that “competent person” be replaced with “licensed veterinarian.”

(Response) While AMS did not define a “competent person,” AMS will rely on certifying agents to assess the requisite expertise of the individual. Most routine physical alterations, such as dehorning, castration, and beak clipping are not conducted by licensed veterinarians. Livestock operators perform these operations, often on a daily basis. Requiring all physical alterations to be conducted by a licensed veterinarian would result in significant expense and inconvenience to an organic livestock operator. The proposed rule requires that physical alterations be conducted by a “competent person.” This would generally be understood to be someone who has the education, training, and experience necessary to conduct physical operations quickly and easily, with minimal stress and pain for the animal. Certifying agents will assess the competence of personnel conducting physical operations and determine if they have the necessary competencies based on the complexity of the alteration to be performed. AMS has not made any changes in the final rule based on this comment.

(Comment) For § 205.238(a)(5), AMS received many comments that the phrase “minimal stress and pain” was not an explicit enough description of how physical alterations must be performed on livestock. These comments requested that the use of synthetic pain medications allowed on § 205.603 be mandatory. Similar comments were made regarding the language at § 205.238(a)(7). Again, comments requested that USDA organic regulations mandate the use of synthetic pain medication rather than simply allow them.

(Response) AMS agrees that, in many situations, pain medications may be the

best way to minimize stress and pain. While certified operations are permitted to use pain medications to treat or prevent pain caused by performing allowed physical alterations, pain medications may not be necessary for some allowed physical alterations. Therefore, AMS has not made any changes based on these comments.

(Comment) AMS received one comment requesting that we add “where effective non-physical methods are not available” to § 205.238(a)(5).

(Response) Under this final rule, physical alterations may be performed to benefit the welfare of the animals, for identification purposes, or for safety purposes. This comment suggests an additional broad requirement that a producer would need to provide justifications for routine, allowed physical alterations, which were not recommended by the NOSB and were not presented for public comment in the proposed rule. Therefore, AMS has not made any changes based on this comment.

4. Physical Alterations—Swine

(Comment) Many comments requested a complete prohibition of needle teeth clipping and tail docking in swine. Some comments supported the principle that needle teeth clipping and tail docking in pigs should not be routinely used, but could be permitted with documentation that alternative methods to prevent harm failed, as proposed in § 205.238(a)(5)(i). One comment supported the provisions regarding tail docking and needle teeth clipping in swine but requested clarification as to whether proof was required at the operation level or on a by litter basis. This comment felt that requiring proof to be provided at a by litter basis seemed excessive and potentially harmful to the welfare of the sows in that operation.

(Response) AMS does not agree with a complete prohibition of needle teeth clipping and tail docking in swine due to possible animal welfare impacts. AMS is retaining this provision based on consideration of recommendations by the NOSB. AMS will allow certifying agents to determine whether the specific need for physical alterations are sufficiently justified by producers on an operation, litter, or individual animal basis in their organic system plans.

5. Physical Alterations—Specific Prohibitions

(Comment) AMS received several comments regarding both the proposed language at § 205.238(a)(5)(ii) and the specific physical alterations proposed as prohibited for livestock and poultry.

Many comments were supportive of the physical alterations proposed as prohibited, with some comments offering refinements or requesting clarification. Many comments requested that additional practices be prohibited, and other comments argued that some of the practices that were proposed as prohibited should be allowed.

AMS received comments that the opening sentence of § 205.238(a)(5)(ii), “The following practices must not be performed on a certified operation,” creates a loophole in which practices can be performed during the one-year transition of a dairy animal.

(Response) AMS has clarified the regulatory text in the final rule to state: “The following practices are prohibited . . .” The discussion of comments on the specific physical alterations proposed as prohibited is divided into avian and mammalian sections.

Avian Physical Alteration Prohibitions

(Comment) AMS received comments identifying that we used the terms “toe clipping” and “toe trimming” interchangeably and inconsistently in reference to altering the toes of male turkeys in the proposed rule. These comments also said that the proposed rule incorrectly defined this physical alteration practice as applying only to the toes of male turkeys, rather than all turkeys, in § 205.2 and § 205.238(a)(5)(ii) of the rule text. Another comment stated that toe trimming, toe cutting, and de-clawing are all essentially the same toe treatment. AMS also received a separate comment requesting that we prohibit toe clipping in turkeys, or only permit the use of infra-red, rather than a hot blade or electric cauterization.

(Response) The definition of “toe clipping” is addressed in this final rule in the Discussion of Comments Received for § 205.2. To be consistent with the changes made to the definition of “toe clipping” in § 205.2, the rule text at § 205.238(a)(5)(ii) “. . . toe clipping of male turkeys unless with infra-red at hatchery . . .” has been changed to “. . . toe clipping of turkeys unless with infra-red at hatchery . . .” AMS received an NOSB recommendation advising the complete prohibition of toe clipping for chickens. Turkeys or other poultry were not included in this prohibition of toe clipping. Methods of both toe clipping and beak clipping are addressed together in a separate discussion following the below discussion of comments regarding beak clipping.

(Comment) AMS received various comments on beak trimming. Many

comments requested that all beak trimming be prohibited, one requested that we only allow infra-red beak treatments, and another comment asked if re-trimming of beaks would be allowed. One comment suggested that AMS limit beak trimming to no more than the thickness of a dime. Some comments were opposed to the prohibition on de-beaking.

(Response) AMS is not completely prohibiting beak trimming in poultry in the final rule due to animal welfare and economic impacts to poultry producers. This physical alteration is allowed at up to 10 days of age. Re-trimming of beaks is allowed at up to 10 days of age, but is not permitted after 10 days of age. In addition, beak trimming cannot be limited to a specific measurement because of the wide variability in beaks of bird species and breeds. Therefore, AMS is retaining the definition of beak trimming in § 205.2 as the removal of the curved tip of the beak as recommended by the NOSB. AMS is also retaining de-beaking as defined in § 205.2, and de-beaking remains prohibited in § 205.238(a)(5)(ii) of the final rule as recommended by the NOSB. AMS received many requests about the methods of beak trimming, toe clipping, and toe cutting, which are addressed immediately below.

Methods of Beak Trimming, Toe Clipping, and Toe Cutting

(Comment) A few comments inquired about various methods of beak clipping, toe trimming, and toe clipping, including the use of traditional mechanical devices, such as knives or scissors, and more modern methods, such as electric cauterization (also called a cautery knife), the hot blade, and infra-red. Some comments stated that the use of infra-red is less invasive and painful, causes less tissue damage, and results in fewer chronic pain issues compared with other methods of poultry beak trimming, toe trimming, and toe clipping. One comment stated that all forms of beak trimming, toe trimming, and toe clipping are inhumane. Other comments asked for guidance on methods of beak trimming.

(Response) Following a review of recent poultry periodicals and literature, AMS notes that infra-red is the newest technology being used for beak trimming, toe clipping, and toe cutting. Articles report that infra-red appears to be more humane and is gradually being adopted over electric cauterization and the hot blade.⁶ The final rule does not

require all beak trimming and toe clipping to use only the infra-red method since AMS did not include this restriction in the proposed rule and AMS does not know the availability, cost, or impact of only allowing infra-red technology in organic production systems. AMS may request that NOSB provide additional advice and recommendations on methods of poultry beak trimming, toe clipping, and toe cutting if conditions warrant in the future.

(Comment) AMS received two comments requesting that the final rule exclude wattles from the definition of dubbing in § 205.2. They also asked that we remove the prohibition of dubbing in § 205.238(a)(5)(ii). One comment reported that dubbing is used in research to mitigate comb injuries, and is not currently used by the layer industry. This comment stated that with the push for outdoor access in regions where cold weather is a certainty, dubbing may be needed to stop frostbite and other comb injuries that could occur when birds are outdoors.

(Response) AMS disagrees with the comment and is retaining the definition of dubbing that includes both wattles and combs in § 205.2 along with the prohibition of dubbing in § 205.238(a)(5)(ii) of the final rule. Dubbing is the practice of cutting off the comb, wattle and earlobes of chickens. The practice of dubbing, sometimes carried out by poultry operators without anaesthetic, is a cause of pain and distress. Blood circulating from the comb to the wattles helps the bird to regulate its body temperature during hot weather. Removing either wattle or comb provides no benefit to the bird.

Mammalian Physical Alteration Prohibitions

(Comment) AMS received various comments regarding prohibiting the use of some physical alterations of livestock and mandating pain-relieving medications for other physical alterations. Many comments requested that the final rule prohibit or restrict de-horning, yet allow disbudding of cattle. Some comments supported the allowance of dehorning or disbudding, but only if performed by a licensed veterinarian and with pain relief mandated. One comment noted that while caponization was prohibited in poultry, castration of cattle, sheep, pigs, or other animals was not mentioned. This comment requested that castrations be performed by licensed veterinarians with pain relief mandated. Another

comment proposed that castration be prohibited after two months of age.

(Response) Dehorning and castration of livestock are important practices for animal welfare and farm management. For example, dehorned livestock are easier and less dangerous to handle and transport; can present a lower risk of interference from dominant animals at feeding time; and can pose a reduced risk of injury to udders, flanks, and eyes of other animals. Castration is also an important practice from a safe handling and product quality perspective. Castrated male cattle (steers) are less aggressive, are easier to handle, and yield better marbled, more tender beef. Therefore, AMS is not prohibiting these practices in the final rule.

While best management practices suggest that dehorning and castration should be done at the earliest age practical to minimize pain and suffering,⁷ this suggestion is vague and, as such, would be difficult to enforce. Further, requiring alterations to be performed before a specific age may unnecessarily exclude some animals from further management as organic if alterations were delayed for reasons beyond a certified operation's control. Therefore, AMS did not make these changes in the final rule.

While the final rule does not mandate the use of allowed synthetics to manage pain, it does not prohibit the use of pain medications when performing allowed physical alterations. The final rule allows operations to work with their certifying agents to agree on a physical alteration process that uses medications, as needed, to meet the regulatory requirement to perform alterations while minimizing pain and stress.

(Comment) AMS received one comment seeking to prohibit all branding, and not just face branding. This same comment offered that there are many alternative animal identification methods such as ear tags, ear notches, back tags, neck chains, tail tags, freeze brands, tattoos, paint marks, leg bands, and electronic identification methods (e.g., electronic ear tags, microchips, electronic collars). Another comment stated that our prohibition of face branding would place operations at odds in states with regulations that require face branding of steers from Mexico. Nevada was provided as the example.⁸

⁷ American Veterinary Medical Association, *Castration and Dehorning of Cattle*. <https://www.avma.org/KB/Policies/Pages/Castration-and-Dehorning-of-Cattle.aspx>.

⁸ Nevada State regulations, Chapter 571—Diseased Animals; NAC 571.040 Cattle and bison.

⁶ American Veterinary Medical Association, *Literature Review on the Welfare Implications of Beak Trimming*, February 2010. https://www.avma.org/KB/Resources/LiteratureReviews/Documents/beak_trimming_bgnd.pdf.

(Response) In its recommendation on animal welfare, the NOSB recommended a prohibition specific to face branding. Therefore, the scope of the proposed rule submitted for public comment was limited to that aspect. AMS did not make changes based on this comment. In the future, if the NOSB recommends a prohibition on all branding, we will consider that aspect for proposed rulemaking, with opportunity for public comment.

With consideration to the comment regarding state requirements for face branding of imported cattle, AMS has considered this comment and has amended the final rule to provide an exception for these state requirements. We have amended paragraph 205.238(a)(5)(ii) to prohibit face branding, except as required by state or federal law.

6. Monitoring and Recordkeeping Regarding Lameness and Treatment

(Comment) AMS received various comments on the proposed new section § 205.238(a)(8) that requires organic producers to actively monitor lameness within the herd or flock, to document cases and causes of lameness, and to describe how they were managed or treated. One comment from the dairy industry remarked that we do not provide a definition or a consistent system for identifying and assessing the degree and severity of lameness, and as a result, producer observations and recordkeeping will not be universal or consistent. For example, some operations may appear to have more cases because they are addressing a potentially worsening condition at an earlier stage, while less observant and less aggressively managed operations may not be as effective at identifying lameness. This comment described a private industry example of a system that offers consistency with a 5-point locomotion scoring (LS) scale in which an animal with a normal walk and no sign of lameness scores as one (1) with the scale progressing to a score of five (5) as a 'severely lame' cow.⁹

A few comments suggested that we develop thresholds to assist producers with developing plans to reduce the incidence of lameness. As an example, one comment suggested that if greater than 10% of a herd or flock for more than two years experienced lameness, the producer must implement a plan to reduce the incidence of lameness. Another comment suggested we collect

data to establish the average percentage of lameness by species and then require producers to stay below that percentage.

Some comments expressed opposition to this proposed requirement. One comment reported that certifying agents are not trained or qualified to "identify a particular disease or ailment" and that this requirement would violate the certifying agents' prohibition on consulting. Other comments stated that USDA organic regulations already require livestock producers to maintain treatment records for sick and injured animals per the requirements of § 205.103, and that adding this additional record-keeping requirement was too prescriptive and would do little to "lead to effective prevention or treatment."

(Response) AMS included this new requirement in response to an NOSB recommendation, and it will be retained in the final rule. AMS agrees that a species-based system for scoring lameness will follow the final rule as guidance. AMS agrees with comments that establishing a percentage of herd or flock lameness threshold connected to species averages could be valuable, and we will consider requesting that the NOSB provide additional advice and recommendations on herd or flock lameness thresholds.

7. Ammonia Levels in Poultry Houses

(Comment) AMS received comments that it was redundant to include ammonia requirements in both § 205.238 and § 205.241, and comments recommended we keep the requirement in only one section. Other comments suggested we make the requirement in § 205.238 apply to all types of livestock production rather than limit the requirement to poultry production.

(Response) AMS agrees it is not necessary to include both sections as proposed. In the final rule, we have retained the requirement in § 205.241 and removed the requirement in § 205.238.

With regard to ammonia levels in other types of operations, the NOSB recommendations and subsequent proposed rule focused primarily on the ammonia levels in poultry houses. While AMS recognizes that ammonia levels may be relevant for other types of livestock production, we have not broadened the requirement to cover other types of operations in this final rule. AMS may consider future rulemaking to establish ammonia-level action thresholds if recommended by the NOSB and supported by public comment and available evidence.

The remaining discussion of comments regarding ammonia can be

found in the discussion of comments in Avian Living Conditions at § 205.241.

8. Use of Milk From Animals Undergoing Treatments

(Comment) AMS received comments on the use of milk from animals undergoing treatment with allowed medications on the National List in § 205.603. Some of these comments asked if milk from cows treated with synthetic parasiticides could be provided to a cow's calf or other young calves in the same operation. One comment requested that the USDA organic regulations include nonsynthetic substances not prohibited on § 205.604 but require an FDA withholding period for milk when these substances are administered. A few comments did not want the milk from treated animals fed to any calf.

In addition, another comment requested the removal of the word "edible" from § 205.238(c)(1). This comment argued that including this word could allow the sale of fiber products as organic from animals that have been treated with antibiotics or other prohibited substances.

(Response) AMS concurs with the comments on allowing milk from animals treated with synthetic substances that are included on the National List in § 205.603 to be fed to a treated cow's calf or to other calves in the same operation. AMS also agrees with the comment indicating that the word "edible" may provide a loophole in the regulations that would allow the sale of fiber products as organic from animals that have been treated with antibiotics or other prohibited substances. The word "edible" has been removed from this regulation in the final rule.

AMS does not agree with comments on restricting the sale of milk from animals treated with nonsynthetic substances that are not included on the National List in § 205.604 but have an FDA-required withholding period. AMS is not aware of any nonsynthetic substance that is categorized as a drug with a required withholding period. The USDA organic regulations, in § 205.105(b), prohibit the use of nonsynthetic substances that are on the National List in § 205.604. Currently, under USDA organic regulations, if a nonsynthetic substance is not listed in § 205.604, it may be used in organic livestock production, provided its use complies with all regulation requirements that supersede the USDA organic regulations. Since USDA organic regulations require prohibited nonsynthetic substances to be listed in § 205.604, AMS cannot include a

2. (e) (1) <http://www.leg.state.nv.us/NAC/NAC-571.html#NAC571Sec002>.

⁹ Zinpro Performance Minerals, Locomotion Scoring of Dairy Cattle, www.zinpro.com/lameness/dairy/locomotion-scoring.

prohibition of nonsynthetic substances not listed in § 205.604 under § 205.238(c)(1).

Accordingly, § 205.238(c)(1) in the final rule prohibits an operation to “sell, label, or represent as organic any animal or product derived from any animal treated with antibiotics, any substance that contains a synthetic substance not allowed under § 205.603, or any substance that contains a nonsynthetic substance prohibited in § 205.604.” Milk from animals undergoing treatment with synthetic substances allowed under § 205.603 cannot be sold as organic but may be fed to a treated animal’s calf or to calves on the same operation. Milk from animals undergoing treatment with prohibited substances cannot be sold as organic or fed to organic livestock.

9. Administering Synthetic Medications for Disease

(Comment) AMS received comments on the rule revisions proposed for § 205.238(b). Some of these comments argued that the addition of § 205.238(b)(3), regarding regulation requirements for the use of parasiticides, created confusion. Other comments addressed concerns for physical alterations and surgical procedures and requested that AMS mandate, rather than simply allow, the use of pain medications to relieve pain. One comment requested that AMS add the term “injury” to the conditions for which administering synthetic medications is allowed in organic livestock production under § 205.603.

A few comments addressed the prohibition on administering animal drugs in the absence of illness since the scope of the phrase “animal drug” as defined by the FDA includes preventative procedures or products. These comments argued that the USDA organic regulations prohibit producers from utilizing drugs that are designed to keep animals healthy and prevent illness. One comment asked if antibiotics could be used to treat pain.

(Response) AMS agrees with the comments that stated that the amendment to § 205.238(b), as proposed, is confusing and should be clarified. In the final rule, § 205.238(b)(3) has been deleted and the requirements for this provision have been incorporated under § 205.238(b). Producers may administer medications that are allowed under § 205.603 to alleviate pain or suffering and when preventive practices and veterinary biologics are inadequate to prevent sickness. This amendment to § 205.238(b) includes allowing the administration of synthetic medications

when animals are injured or undergo surgery. The requirements for the use of parasiticides under § 205.238(b) is not changed in the final rule; parasiticides allowed under § 205.603 may be used on: (1) breeder stock, when used prior to the last one-third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and (2) dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic. AMS does not agree with comments that addressed the prohibition on administering animal drugs, including antibiotics, in the absence of illness to keep animals healthy and prevent illness. Under the USDA organic regulations, a livestock producer must establish and maintain preventive health care practices as prescribed in § 205.238(a). This requirement has been included within the USDA organic regulations since these regulations were published on December 21, 2000. This final rule has not changed this requirement. When preventive practices have been inadequate to prevent illness, a producer may administer synthetic medications that are listed in § 205.603. The USDA organic regulations do allow synthetic medications listed in § 205.603 to be used during surgery for the animal’s welfare.

(Comment) One comment stated that it is inconsistent and confusing to allow other veterinary biologics, in addition to vaccines, to be exempt from the prohibition on administering animal drugs in the absence of illness. This comment argued that many vaccines contain compounded drugs, which may include prohibited chemicals such as hormones or anti-inflammatories.

(Response) AMS disagrees with this comment. The final rule does not add any new substances to the National List of Allowed and Prohibited Substances. Currently, vaccines are the only synthetic biologic substance on the National List. All other synthetic biologics are prohibited. Additionally, the USDA organic regulations require synthetic animal drugs that are allowed for use in organic livestock production to be manufactured with excipients (non-active drug ingredients) according to regulation requirements described under § 205.603(f).

(Comment) AMS received comments indicating that the requirements for use of synthetic medications allowed in § 205.238(c)(2) should be the same as the requirements for use of synthetic medications allowed in § 205.238(b)(3). These comments argued that the language in these regulation sections

should be consistent because they both address circumstances in which synthetic medications can and cannot be administered.

(Response) AMS agrees with these comments and has amended the final rule by inserting changes into § 205.238(b) to clarify when synthetic medications can be administered in organic livestock production. AMS also revised § 205.238(c)(2) to be consistent with paragraph (b) in this section and to describe the exceptions under which the use of synthetic medications are permitted.

10. Prohibitions on the Use of Hormones

(Comment) AMS received comments asking if the new regulations in § 205.238(c)(3), which prohibit the administration of hormones for growth promotion, production, or reproduction, include oxytocin, which may be used in postparturition therapeutic applications. Comments expressed concern that the addition of the terms “production” and “reproduction” may cause confusion with the allowed use of oxytocin as a medical treatment in aiding cows after calving.

(Response) AMS agrees with comments about the potential for confusion when producers or certifying agents interpret the terms “production” and “reproduction” in applications of oxytocin for therapeutic use following calving. In the final rule, AMS amended § 205.238(c)(3) to provide clarification on the allowed use of oxytocin by adding the condition, “except as provided in § 205.603.” The inclusion of this condition clarifies the allowed use of oxytocin in organic livestock production for therapeutic applications.

11. Prohibition on Withholding Treatment To Minimize Pain and Suffering

(Comment) AMS received comments on § 205.238(c)(7) recommending that the USDA organic regulations require livestock producers to have a written marketing plan for diverted animals that have been treated with antibiotics or other prohibited substances. These comments added that such marketing plans might encourage medical treatment of illness or injury. A comment from a certifying agent proposed that § 205.238(c)(7) be amended to state that operations cannot: “Withhold medical treatment designed to minimize pain and suffering from an ill or injured animal in an effort to preserve its organic status. All appropriate medications must be used to restore an animal to health when methods acceptable to organic production fail. Livestock and products

from livestock treated with a prohibited substance must be clearly identified and shall not be sold, labeled, or represented as organically produced.”

(Response) AMS disagrees with these comments and did not add the requirement for a written marketing plan for diverted animals to § 205.238(c)(7). Under OFPA, AMS does not have the authority to require this type of marketing plan. AMS recognizes that a written marketing plan for diverted animals treated with prohibited substances would be a beneficial component of an organic system plan for producers and certifying agents. Certifying agents can encourage producers to include a component for marketing diverted animals in their organic system plan, however this is not required under USDA organic regulations. Organic livestock producers should clearly identify and separate any animal that has been treated with a prohibited substance. Products from livestock treated with a prohibited substance must be clearly identified and shall not be sold, labeled, or represented as organic. In addition, AMS has determined that § 205.238(c)(7), as described in the proposed rule, requires producers to apply all appropriate medications to restore an animal to health when methods acceptable to organic production fail. The amendment proposed by the certifying agent requiring producers to use all appropriate medications to restore an animal to health when methods acceptable to organic production fail is adequately addressed within § 205.238(c)(7).

12. Prohibition on Forced Molting

(Comment) AMS received comments indicating that § 205.238(c)(10), which prohibits the “practice of forced molting or withdrawal of feed to induce molting,” is too general. Some comments proposed details and definitions about humane methods of molting to better manage the natural molting behaviors of a flock. A certifying agent suggested that AMS add the following language: “. . . or other interventions” to § 205.238(c)(10). This comment indicated that including this phrase would clarify that the USDA organic regulations prohibit all forms of induced or forced molting. An additional comment suggested that forced molting be defined as the starvation of laying hens to make them enter the next laying cycle.

(Response) AMS disagrees with comments proposing that additional language is needed to indicate that all procedures of forced molting are prohibited under § 205.238(c)(10). This

regulation specifies that organic producers must not practice forced molting or withdrawal of feed to induce molting. Forced molting practices, including but not limited to the starvation of laying hens, not allowing birds to exercise full range of motion, or the disposal of male chicks or live unhatched eggs by suffocation, are prohibited under § 205.238(c)(10). Because the regulation under § 205.238(c)(10) already includes the prohibition of forced molting or the withdrawal of feed to induce molting, AMS does not agree that additional language is needed to clarify this regulation.

13. Comprehensive Parasite Management Plan

(Comment) AMS received a number of comments in support of the requirement that producers have a comprehensive parasite management plan as required in § 205.238(d). A certifying agent commented in support of the internal parasite management plan, but argued that requiring producers to create a separate plan would be redundant and burdensome to producers. One comment stressed that a parasite management plan should be developed in conjunction with a comprehensive pest management plan.

(Response) AMS agrees with comments in support of a comprehensive pest management plan in livestock and poultry operations that also addresses management of all vectors of internal parasites, illness, and disease. Livestock producers should describe their comprehensive parasite management plan within their overall organic system plan. Under § 205.238(d), livestock producers would describe their parasite management plan as an integral component of comprehensive plans for mammalian living condition practices in § 205.239, or avian living condition practices in § 205.241.

AMS disagrees with comments indicating that a comprehensive plan to minimize internal parasites requires livestock producers to create a separate plan from their organic system plan, which would be redundant and burdensome. The USDA organic regulations do not require producers to create a separate plan, outside of their organic system plan, for comprehensive parasite management.

14. Humane Euthanasia Plan and Prohibited Methods

(Comment) AMS received comments that were in support of the new regulations on humane and prohibited methods of euthanasia described under

§ 205.238(e). Some comments also sought more details and clarification on methods of euthanasia. The USDA organic regulations specify only three euthanasia methods as prohibited in § 205.238(e)(2) and provide no other parameters for selecting an appropriate euthanasia method. In their comment on the proposed rule, the American Veterinary Medical Association (AVMA) indicated that organic livestock operations culling livestock should implement euthanasia methods according to the most recent edition of the AVMA Guidelines for the Euthanasia of Animals. AVMA argued that the guidelines are widely accepted scientific and ethical standard for euthanasia. Other comments included a request that the USDA organic regulations prohibit the practice of euthanizing piglets by manual blunt force trauma. Another comment asked that we reconsider the banning of Burdizzo devices for emergency euthanasia if other methods are not available. This comment indicated that properly used Burdizzo devices are effective as an emergency euthanasia device for larger animals. One comment requested that we clarify whether poultry operations who cull flocks using onsite euthanasia must adhere to the euthanasia requirements, and requested that we consider developing guidance on culling poultry flocks.

(Response) This final rule specifies, under § 205.238(e)(2), that the following methods of euthanasia are not permitted for use in organic livestock production: suffocation, manual blow to the head by blunt instrument or manual blunt force trauma, and use of equipment that crushes the neck, including killing pliers or Burdizzo clamps. Blow(s) to the head by blunt instrument as prohibited at § 205.238(e)(2) does apply to piglets. AMS disagrees with the comment to allow Burdizzo clamps and retains the prohibition of these clamps under § 205.238(e)(2). AMS agrees with the AVMA comment on euthanasia methods. The final rule, in § 205.238(c)(8), references the AVMA guidelines on euthanasia.

15. Out of Scope Comments

Disposal of Male Chicks or Live Unhatched Eggs by Suffocation

(Comment) One comment asked if we could prohibit the common practice of the disposal of male chicks or live unhatched eggs by suffocation.

(Response) Under the USDA organic regulations, poultry or edible poultry products must be sourced from poultry that has been under continuous organic management beginning no later than the

second day of life. Male chicks or live unhatched eggs that are under continuous organic management can only be euthanized by methods described in § 205.238(e).

VIII. Mammalian Living Conditions (§ 205.39)

A. Description of Regulations

1. Summary of the Final Rule

AMS separated mammalian living conditions from avian living conditions due to the different physiology and husbandry practices for birds and mammals. As a result, AMS revised the title of § 205.239 from “Livestock Living Conditions” to “Mammalian Livestock Living Conditions.” By creating clear requirements for mammalian livestock and avian livestock, animal wellbeing can be enhanced and consumers can be assured of the integrity of the USDA organic seal. Information regarding avian living conditions are addressed in new § 205.241.

The final rule revised § 205.239(a)(1) to remove the requirement that all ruminant livestock must be able to feed simultaneously. One method of feeding livestock, including ruminants, is the use of a self-feeder or a creep-feeder. With creep-feeding and self-feeding, feed is accessible to all animals at all times though they may not feed at the exact same time. Self-feeding and creep-feeding provide organic ruminant producers with more flexibility and options to manage their farm and livestock in farm-specific methods.

AMS is maintaining the current § 205.239(a)(3), which requires the use of appropriate, clean, dry bedding. If roughages are used as bedding, they must be organically produced and handled by certified operations, with the exception of transitioning dairy producers.

AMS revised § 205.239(a)(4)(i) to specify that shelter must be designed to accommodate natural behaviors over every 24-hour period. Shelter must have sufficient space for the animals to lie down, stand up, and fully stretch their limbs and allow livestock to express their normal patterns of behavior over a 24-hour period. AMS recognizes that there are times when animals will be constrained for livestock handling or management purposes. An animal may be limited in its freedom of movement during parts of the day for a variety of reasons, including milking, feeding, or other handling purposes. Animals may be constrained for limited amounts of time to ensure hygiene and wellbeing of the animals. Stalls for organic dairy cattle are often designed to limit the animals from turning to the sides. This

stall design directs manure and urine into a collection system to prevent mastitis and maintain low somatic cell counts in the milk. Mammalian livestock may be housed for part of the day in stalls as described in the organic system plan as long as they have complete freedom of movement during significant parts of the day for grazing, loafing, and exhibiting natural social behavior. This allowance does not permit the use of gestation crates or other confinement systems in which swine would be housed individually in stalls for months at a time. However, if livestock are temporarily confined indoors as permitted in § 205.239(b), livestock must be able to move around, turn around, and stretch their limbs indoors for part of the day. Operations will need to fully describe the use of any stalls, methods used in stall management, and how livestock are able to express their normal patterns of behavior.

AMS added § 205.239(a)(4)(iv) to set requirements for an indoor space for bedding and resting that is sufficiently large and comfortable to keep the animals clean, dry, and free of lesions, with the exception of animals raised on pasture or range. Because livestock on pasture or range may not have access to traditional barns or bedded areas, AMS recognizes that while livestock do need to be provided with shelter (defined in § 205.2), livestock do not need to be provided with indoor space. These types of operations may use windbreaks or other methods to provide shelter for the livestock. Additionally, not all man-made shelters are designed to hold bedding; for example, a shelter designed to provide shade may be portable and thus incompatible with holding bedding. Operations need to describe in their OSP how they will provide shelter to their livestock in a manner suitable for the species, stage of production, and environment.

AMS added new requirements in § 205.239(a)(7) concerning the individual housing of dairy young stock. Section 205.239(a)(7) allows for the individual housing of animals until the weaning process is complete but no longer than six months, as long as the animals have sufficient room to turn around, lie down, stretch out while lying down, get up, rest, and groom themselves. In addition, the individual housing of young stock needs to be designed so that animals can see, smell, and hear other animals.

AMS added three new provisions in § 205.239(a)(8) to require the group housing of swine, with three listed exceptions: § 205.239(a)(8)(i) allows for sows to be individually housed at

farrowing and during the suckling period; § 205.239(a)(8)(ii) allows for boars to be individually housed to reduce the likelihood of fights and injuries; and § 205.239(a)(8)(iii) allows for swine to be individually housed after multiple documented instances of aggression or to allow an individual pig to recover from a documented illness.

AMS added two new provisions in §§ 205.239(a)(9) and (10) concerning swine housing. Section 205.239(a)(9) prohibits the use of flat decks or piglet cages. This provision prohibits the stacking of piglets in flat decks in multiple layers. In addition, § 205.239(a)(10) requires that both indoor and outdoor areas for swine have some space that permits rooting. Rooting is a natural behavior that must be accommodated by organic swine producers and could be done in soil, deep packed straw, or other materials. Organic swine producers must also demonstrate how swine will be allowed to root during temporary confinement periods.

AMS added a new provision in § 205.239(a)(11) to further clarify the use of barns or other structures with stalls. If indoor shelter is provided by a structure with stalls, then there must be a sufficient number of stalls that allow for the natural behavior of the animals. In no case may a cage be considered a stall. One exception is provided for this provision: In the case of group-housed swine, more animals than feeding stalls may be allowed as long as all animals are fed routinely every day. AMS is aware of some enhanced swine welfare systems, in which animals are robotically fed once they enter an individual feeding stall; once finished, the animal may leave the stall and another animal may enter for its specific quantity of feed. AMS does not intend to prohibit such systems, which enhance the wellbeing of organic animals. AMS also added specific allowances for a variety of cattle barns, including tie stall barns, stanchion barns, and free stall barns. While these barns can all be suitable for organic certification systems, the specific procedures used by producers with these barns may be incompatible with organic production. If a producer provides too few stalls in a free stall barn or leaves an animal tied up for 24 hours per day in a tie stall barn, these methods would not be permitted under USDA organic regulations.

AMS added a new requirement for outdoor access in § 205.239(a)(12). Organic livestock are required to have unencumbered access to the outdoors year-round, unless temporary confinement is justified under a specific

reason described in the regulations (e.g., nighttime confinement for protection from predators). When the outdoor space includes soil, then maximal vegetative cover must be maintained as appropriate for the season, climate, geography, species of livestock, and stage of production. Ruminants must have access to graze during the growing season. Swine are not required to have access to the soil or vegetation; however, if a swine producer chooses to allow swine to have access to the soil as a rooting material, then the producer must maintain as much vegetative cover as possible given the natural behavior of swine to root, the season, and local environmental conditions.

AMS revised § 205.239(b)(7) to clarify the exemption for temporary confinement for the purpose of breeding livestock. Livestock may only be confined for the time required for natural or artificial breeding. A group of livestock may be confined before the procedures and while the various individuals are bred; afterward, the group shall be returned to living spaces that allow outdoor access. Livestock may not be confined indoors to observe estrus or until they are determined to be pregnant. Section 205.239(c)(1) describes the time when ruminants may be denied access to pasture, but not access to the outdoors, before and after a breeding attempt.

AMS revised § 205.239(b)(8) to clarify the temporary confinement exception for youth livestock projects. Because many youth livestock projects include the sale of market animals, organic animals that were under continuous organic management may be sold as organic animals at youth fairs, even if the sales facility is not certified organic. Thus, the revised provision includes an exemption to the § 205.239(b)(6) requirement that a livestock sales facility be certified as an organic operation. As an example, if a youth exhibition and sale is held at a livestock sales facility that is not certified organic, the youth may sell the organic animal as an organic animal, provided all other requirements for the organic management of livestock are met. During the youth event, the livestock may be temporarily confined indoors. Otherwise, non-certified sales facilities, such as auction barns or fairgrounds, may not sell or represent livestock as organic. AMS provided this exception to encourage the next generation of organic farmers.

AMS revised § 205.239(d) to reflect the similar proposed changes in § 205.239(a)(1). AMS removed the phrase requiring that all ruminants be able to feed simultaneously. This

change would allow the use of self-feeding and creep-feeding so that the ruminants would have access to feed continuously over a 24-hour period.

B. Discussion of Comments Received

1. Opposition To Changes in the Mammalian Living Conditions Section/Make No Changes for Ruminants

(Comment) A number of comments were opposed any changes to the mammalian living conditions section. Some comments indicated that current organic regulations were sufficient and no more were needed. Other comments noted that the sections pertaining to ruminants were sufficient and that no changes needed to be made to them.

(Response) AMS revised the mammalian living conditions sections to clarify a number of provisions for mammals, including ruminants. These changes were recommended by the NOSB through an open public comment process. In addition, livestock living conditions have always been a part of the USDA organic regulations. AMS received many questions from certifying agents and organic producers concerning livestock living conditions that needed clarification in the regulatory text. Due to the NOSB recommendations and the need to clarify livestock living condition requirements, AMS believes that the changes are needed.

2. Outdoor Area Requirements

Many comments were opposed to requiring soil as part of the outdoor access requirement for all mammals. These comments provided many reasons for excluding soil from the outdoor requirement, including environmental, soil quality, animal health, and disease transmission concerns. Commenters opposed soil for dairy animals during the non-growing season and for swine at any time, though some commenters supported soil for swine. Comments opposing soil as a requirement of outdoor access came from producers, certifying agents, trade associations, and others.

Environmental Concerns

(Comment) Comments showed concern that dairy cattle during the non-growing season or during times when the cattle could be temporarily confined during the grazing season would cause environmental damage to the soil and surrounding waters if dairy cattle were required to be on the soil. Comments cited a variety of conditions (e.g., during winter when the ground may become very muddy). Cattle walking and standing on the soil would destroy any

vegetation and cause the soil to wash away during subsequent rain events. Comments cited that USDA NRCS provided funding to build hardened outdoor spaces for dairy cattle to use so as to prevent damage to soil and prevent nutrients in the soil being washed into streams and rivers. These comments already noted that in the pasture rule response to comments, AMS recognized that sacrifice areas (soil-based areas that are designed for livestock to be held in during wet or winter conditions) are not possible in all regions and thus cannot be required.

Some comments were also concerned about the environmental damage that swine could do if the outdoor area included access to soil. Natural behavior of swine includes rooting of the soil, which destroys the vegetation and root structure of the vegetation. If swine are left too long on the land, the land loses vegetation and runoff could occur.

Other comments called for minimum outdoor space allowance for swine in order to protect the soil. These comments noted that if there was sufficient space, a minimum vegetative cover could be maintained, which would minimize or prevent any environmental damage the swine may cause. These comments suggested that the NOSB evaluate how much space is required for swine outdoors and then pass a recommendation that AMS could act upon. Other comments suggested that AMS use a space allowance that the NOSB livestock subcommittee had discussed but which had never been passed by the full board.

(Response) USDA organic regulations prohibit organic producers from reducing soil and water quality. The regulations also provide for temporary confinement of livestock to protect soil and water quality. AMS agrees with comments that livestock should be kept off of soil-covered areas during times of the year when livestock could damage soil and vegetation. In response to comments and consultation with NRCS regarding best practices, AMS removed "soil" as part of the outdoor requirements but requires that ruminants have access to pasture during the grazing season. However, outside of the grazing season, soil based outdoor areas are not required. Operations must provide year-round outdoor access, using either hardened surfaces or soil based areas unless the livestock are temporarily confined indoors.

AMS also agrees with some comments that thought the NOSB should reevaluate swine living conditions and determine minimum outdoor space requirements. AMS recognizes that if swine are placed in too small of an area

with soil, environmental problems may occur. AMS is including this topic area in the list of issues that the NOSB may address in a future recommendation.

Health Concerns

(Comment) Some comments expressed concern regarding health implications for swine if soil access was required as part of the outdoor space requirements. These comments noted that a number of diseases that had been eradicated in domestic swine, such as pseudorabies, were still present in feral swine. With outdoor space that requires soil access, domestic swine are more likely to come in contact with feral swine and contract one of these diseases. In the event that these diseases are detected in the domestic swine herd, there would be trade implications as countries may close their markets to U.S. pork.

These comments also discussed health concerns related to consumer safety. Trichinosis, a parasite in pork, has essentially been eradicated in the domestic swine herd. Comments expressed concerns that with outdoor access, swine could become infected with this parasite and could then infect consumers of this pork with this painful condition.

(Response) AMS also agrees with some comments that thought the NOSB should reevaluate swine living conditions and determine minimum outdoor space requirements. Therefore, the final rule requires year-round outdoor access for swine but does not require access to soil-covered areas. AMS recognizes that if swine are placed in too small of an area with soil, environmental problems may occur. AMS is including this topic area in the list of issues that the NOSB may address in a future recommendation. As part of the review process, the NOSB can take into consideration the presence of diseases in the soil or in feral hog populations, which if transmitted to domestic swine, may cause loss of foreign markets to organic and conventional pork producers.

3. Indoor Housing Requirements

Comments expressed concern with several topics regarding indoor housing for mammalian species, including stalls, space for natural behaviors, space for young dairy animals, swine confinement, the requirement that all mammals have access to indoors, and the use of bedding.

(Comment) Comments noted opposition to the proposed requirement that livestock be able to lie down in full lateral recumbence, turn around, and fully stretch their limbs. These

comments stated that most dairy producers use a type of stall housing—whether free stall, tie stall, or stanchion barns—that would not provide the indoor space for a dairy cow to lie down in full lateral recumbence. Most comments wanted organic dairy producers to have the flexibility to use their existing barns and structures as part of an organic system plan approved by their certifying agent. These comments explained that cattle rarely lie down in that manner and usually only do so to sun themselves in a pasture. Many comments preferred the current language for natural maintenance, comfort behaviors, and an opportunity to exercise.

(Comment) Comments also showed concern with the proposed requirements for dairy young stock. Comments agreed with the description of the housing for dairy young stock, but these comments differed on the timing of when dairy young stock must be group-housed. Some comments wanted the dairy young stock to be group-housed by eight weeks of age while others wanted group housing to occur at six months of age. Those preferring a lower age for group housing cited EU organic standards, which include lower age requirements. The comments preferring six months of age discussed how weaning—the removal of milk from the diet of a young animal—is not a good stopping point as calves may retain the suckling impulse. Comments described how a calf can ruin the udder of a heifer by suckling on her in response to the suckling impulse, and these comments tended to prefer six months as the cutoff for group housing, which coincides with when dairy young stock must be provided with pasture or outdoor access if outside the growing season.

(Comment) Comments also addressed indoor housing for swine. Many comments were opposed to the use of farrowing crates or stalls and called for AMS to specifically prohibit their use. These comments wanted to ensure that swine had the opportunity to turn around, lie down, and move around, even during the farrowing period. Other comments were concerned that producers would individually house swine after documented cases of aggression. These comments requested that AMS define aggression so producers did not individually house swine unnecessarily. Comments were split on the requirement for bedding or rooting materials during the farrowing period. Some wanted to require rooting and nesting materials specifically during that time frame while others wanted to remove the requirement for bedding or rooting materials during the

farrowing period to reduce disease and maintain cleanliness of the hogs.

(Comment) Comments were split on the issue of a cleanliness standard. Some comments supported such a standard if appropriate guidance was issued. Other comments opposed a cleanliness standard based on the rationale that during certain stages of production—such as ruminants on early spring pastures or swine with access to the soil during rainy periods—animals will be healthy yet also be dirty with manure or mud. Comments that opposed this standard preferred the requirement for clean, dry bedding to be provided. One comment was concerned about the requirement for a shelter that can hold bedding. This comment noted that many cattle are raised in pasture or range conditions that would not include access to the indoors, though may include shade and windbreaks for animal wellbeing.

(Response) AMS agrees with the comments that indicated that indoor space requirements to allow for full lateral recumbence and turning around without touching the enclosure may negatively affect many current producers without enhancing animal well-being. To clarify this issue, AMS revised the standard to specifically state that over a 24-hour period, mammalian livestock must have the opportunity to move, turn around, and exhibit natural behaviors.

AMS also stated that tie stalls, free stalls, stanchion barns, compost pack, and bed pack barns are all suitable facilities for cattle and can be used as part of an Organic System Plan. As part of the OSP, mammalian livestock producers must describe how livestock, over a 24-hour period of time, will be able to turn around, move, lie down, and exhibit natural behaviors. AMS recognizes that certain stall facilities designed for animal comfort and cleanliness purposefully minimize the ability of the animal to turn around. Livestock cannot be confined to these stalls all day, even if the animal may be temporarily confined indoors. As an example, if during the winter, livestock are temporarily confined indoors in a tie stall barn due to a snow storm, the livestock must have the opportunity to move around, turn around, and exhibit natural behaviors.

AMS has declined to clarify individual housing in response to swine aggression. The threshold for aggression to allow for individual housing may differ depending on the facilities, the operation, the producer, and the breeds of swine involved. Swine producers must describe their response to aggression in their OSP, which must be

approved by their certifying agent. AMS chooses to provide flexibility to organic swine producers to work with their certifying agents to develop a plan for when swine may be individually housed due to aggression.

AMS has chosen to keep the requirement for rooting materials but has removed the requirement that rooting must be available in exercise areas. Rooting is a natural behavior for swine and must be provided by organic swine producers. However, AMS agreed with the comments that requested that bedding and rooting material not be required during the farrowing period when swine may be individually housed. Swine producers may choose to use bedding and rooting material during the farrowing period, but it is not required.

AMS is clarifying that the USDA organic regulations for livestock require outdoor space as the default living space. Indoor space may be provided as a type of shelter, but it does not have to be provided to organic livestock. If indoor space is provided, then the structure must include space for appropriate bedding. However, in range or pasture conditions where no indoor space is required, the requirements for the indoor space do not apply, and bedding does not need to be provided. This does not allow producers to deny livestock access to the indoors if required by law or if it is necessary for the welfare of the animals. However, AMS recognizes that in many production systems, beef cattle, sheep, and some dairy animals may be routinely raised outdoors without indoor spaces. Shade and shelter must be provided based on what is appropriate for the animal species, season, and environmental condition.

IX. Avian Living Conditions (§ 205.241)

A. Description of Regulations

1. Summary of the Final Rule

The new § 205.241, entitled “Avian living conditions,” includes requirements for all organic avian (“bird” or “poultry”) species, including but not limited to, chickens, turkeys, geese, quail, pheasant, and any other species that are raised for organic eggs, organic meat, or other organic agricultural products.

New § 205.241(a) establishes general requirements for organic poultry production. These general principles are further clarified in §§ 205.241(b), (c), and (d). Section 205.241(a) requires organic poultry operations to establish and maintain living conditions that accommodate the wellbeing and natural behaviors of the birds. These living

conditions include: Year-round access to the outdoors, soil, shade, shelter, exercise areas, fresh air, direct sunlight, clean water for drinking, materials for dust bathing, and adequate space to escape aggressive behaviors. The living conditions provided should be appropriate to the species, its stage of life, the climate, and the environment. These requirements, based upon a 2009 NOSB recommendation,¹⁰ are largely identical to previously established livestock requirements at § 205.239(a)(1), although AMS has added requirements for materials for dust bathing and for adequate outdoor space to escape aggressive behaviors.

New § 205.241(b) specifies the indoor space requirements for avian species. While shelter must always be provided to birds, indoor space is not a requirement. If indoor space is provided to the birds, then the indoor space requirement must be followed. New § 205.241(b)(1) requires that indoor space be sufficiently spacious to allow all birds to move freely, stretch their wings, stand normally, and engage in natural behaviors. Cages or environments that limit free movement within the indoor space are prohibited. In addition, the indoor space must allow birds to engage in natural behaviors such as dust bathing, scratching, and perching. The requirements are adopted from a 2009 NOSB recommendation and modify previously established requirements for organic livestock at § 205.239(a)(4) that required, “shelter designed to allow for . . . natural maintenance, comfort behaviors, and opportunity to exercise”.

Section 205.241(b)(2) requires producers to monitor ammonia levels at least monthly and implement practices to maintain ammonia levels below 10 ppm. When ammonia levels exceed 10 ppm, producers must implement additional practices and additional monitoring to reduce ammonia levels below 10 ppm. Ammonia levels above 25 ppm are not in compliance with organic avian living conditions. Ammonia is a natural breakdown product of manure from livestock and is harmful to birds when inhaled, especially at concentrations above 25 ppm. In most cases, high levels of ammonia indicate that litter is damp or litter management practices require modification.

New § 205.241(b)(3) clarifies the lighting requirements for organic layers and fully feathered birds. Organic producers may use artificial light for up

to 16 hours per day (24-hour period). The 16-hour period must be calculated as a single continuous time period. Artificial light must be lowered gradually to encourage hens to move to perches or otherwise settle for the night. Producers must design indoor spaces with access to natural light so that, on sunny days, inspectors can read and write when the lights are turned off. This requirement sets forth a performance-based standard that facilitates inspection, provides for enough lighting to accommodate natural avian behavior, and allows flexibility to operations in determining how to design their facilities for compliance.

Section 205.241(b)(4) describes the required exit areas, or doors, on shelters so that the birds can easily access both indoor and outdoor areas. Access and utilization of outdoor areas is a core principle of organic production systems. Organic avian systems must be designed so birds have ready access to outdoor areas and so birds are able to return indoors to roost in the evening. Producers must provide exit doors and door sizes to enable all birds to access outdoor and indoor areas. Door size and appropriate placement must provide meaningful outdoor access to the birds. Exit doors must be designed and managed in a manner that prevents movement of wild birds, rodents, and other animals into the poultry house.

New § 205.241(b)(5) requires perches for chicken layers at a rate of six inches per bird for all housing, with the exception of aviary housing. Perch space may include the alighting rail in front of nest boxes. Perches are not required for broilers, meat birds, or layers of non-*Gallus gallus* species. Aviary housing must provide six inches of perch space for 55 percent of the flock (*i.e.*, 3.3 inches of perch for each bird in flock). Perch requirements for aviary housing have been adjusted, as birds in aviary housing are also able to escape aggressive behavior by moving between tiers in the house. These requirements are adopted from 2009 and 2011 NOSB recommendations.

New § 205.241(b)(6) specifies indoor requirements to allow for certain natural behaviors. Indoor space must include areas that allow for scratching and dust bathing. Litter (*i.e.*, bedding), such as wood shavings or straw, must be provided indoors. Manure excreted by birds in a poultry house alone, without additional litter, would not be sufficient to meet this requirement. This section also requires that litter be maintained in a dry manner. Wet litter can lead to a variety of problems for birds, including excess ammonia, lameness, and pest problems. Litter may be topped off

¹⁰ <https://www.ams.usda.gov/sites/default/files/media/NOP%20Final%20Sunset%20Rec%20Animal%20Welfare.pdf>.

when needed to maintain sufficient dryness. The requirements are adopted from 2009 and 2011 NOSB recommendations.

Section 205.241(b)(7) includes specific flooring requirements for indoor avian housing with slatted/mesh floors. These houses must provide at least 30 percent solid flooring to allow birds indoors to engage in natural behaviors, including scratching and dust bathing, without crowding. The requirement is adopted from a 2009 NOSB recommendation.

New §§ 205.241(b)(8), 205.241(b)(9), and 205.241(b)(10) list the required minimum indoor space requirements for different types of housing. These are minimum standards, and organic producers may choose to provide more indoor space than required. The indoor space requirements apply to chickens (*Gallus gallus*), with layer requirements at § 205.241(b)(8), pullet requirements at § 205.241(b)(9), and broiler requirements at § 205.241(b)(10). Indoor space requirements for layers vary by the type of housing provided. The types of housing are further defined in § 205.2 and include: Mobile housing, aviary housing, slatted/mesh floor housing, and floor litter housing. For housing that does not fit into any of these defined types, the indoor space requirement is no more than 2.25 pounds of hen per square foot. Pasture pens that are moved regularly and provide direct access to soil and vegetation are not considered indoors (see definition of “outdoors” in § 205.2). These requirements are adapted from 2009 and 2011 NOSB recommendations, and made in consideration of third-party animal welfare standards.

AMS has established indoor space requirements for common types of poultry housing. Less indoor space is required per bird in houses that provide more access to vertical space in the house, as birds have more room to move around (e.g., aviary and slatted/mesh floor housing). Housing where birds have more limited access to vertical space (e.g., floor litter housing) must provide more indoor space per bird. AMS has also allowed for higher stocking densities in mobile housing, as birds managed in these systems spend more time outdoors, and mobile housing must be relatively small and light, as it is moved frequently.

AMS has only established indoor space requirements for chickens in this final rule. AMS may propose space requirements for other avian species in the future. Other avian species must meet all other indoor requirements including exit doors, ammonia levels, and lighting.

AMS is using pounds of bird per square foot to establish space requirements. In other words, the minimum space that must be provided depends on the average weight of birds at that time. All weight references in §§ 205.241(b) and (c) refer to the weight of live birds and not the weight of processed birds, for example. By stating the requirement in pounds per square foot, the application of the space requirement is more consistent between breeds, where the average weight per bird can vary significantly. This unit of measurement (pounds per square foot) was recommended by the NOSB in 2011 for pullets and broilers, and AMS is extending this same unit of measurement to layers. Under this final rule, larger breeds (i.e., heavier on a per bird basis) must be provided with more indoor space than smaller birds, on a per bird basis. For example, Rhode Island Red birds are heavier than White Leghorns or ISA Browns, and thus cannot be stocked as densely, in terms of number of birds per unit area.

For example, a layer in a floor litter housing system that is 32 weeks of age and weighs 4.3 pounds must be provided with 1.43 square feet per bird (equivalent to 3.0 pounds of bird for each one square foot); however, at 80 weeks of age and a weight of 4.5 pounds, each bird must be provided with 1.5 square feet per bird (3.0 pounds of bird for each one square foot). In other words, for each 10,000 square feet, a producer could stock 6,993 birds at 32 weeks of age (bird weight of 4.3 pounds) but only 6,667 birds at 80 weeks of age (bird weight of 4.5 pounds). Although older and heavier birds require more space, natural mortalities over time may result in compliance with the space requirements over a production cycle. To calculate the weight of birds, an average weight may be established for the flock by taking weights of a representative sample of the flock. The requirement is not specific to each individual bird in a flock. AMS understands that many producers already monitor and track bird weight closely during the production cycle to monitor bird development and health and calculate feed requirements. However, if weight is not monitored by a producer, the producer will need to establish the weight of birds based on objective criteria to determine the space required indoors and outdoors. Certifiers may also weigh birds at inspections to verify compliance with the requirements.

New § 205.241(b)(11) specifies how the area of the indoor space is calculated. Indoor space must be calculated to ensure that birds are

provided with adequate indoor space to meet the space requirements at §§ 205.241(b)(8) through (10). The total size of the indoor space is calculated by including all flat areas in a house, excluding nest boxes. Elevated round perches, for example, are not flat areas and could not be included as indoor space. These requirements match various third-party animal welfare standards, which consider nest boxes to be distinct from useable floor areas of the house where birds can move around freely. They also align with the 2009 and 2011 NOSB recommendations.

New § 205.241(b)(12) clarifies that indoor space may include enclosed porches and lean-to type structures (e.g. screened in, roofed) provided that the birds always have access to the space, including during temporary confinement events. The same porch must not be counted as indoor space if the birds do not have continued access to the space during temporary confinement events. This ensures that enclosed porches that are not fully accessible to birds are not counted in indoor space calculations.

Section 205.241(c) establishes the requirements for outdoor areas for organic avian species, including the amount of outdoor space that must be provided to organic avian species. The requirements of section 205.241(c) are adopted or adapted from previously established requirements at section 205.239, 2009 and 2011 NOSB recommendations, and third-party animal welfare organization standards. Section 205.241(c)(1) requires that the outdoor space be designed to promote and encourage outdoor access for all birds. Producers are required to provide access to the outdoors at an early age. This section requires door spacing to be designed to promote and encourage outdoor access and requires outdoor access to be provided on a daily basis (further described at § 205.241(b)(4)). Outdoor access may only be temporarily restricted in accordance with § 205.241(d).

Section 205.241(c)(2) requires outdoor areas for poultry to have a minimum of 50 percent soil and that the soil portion of the outdoor area include maximal vegetative cover. Vegetative cover must be maintained in a manner that does not provide harborage for rodents and other pests. For example, a producer may mow vegetation to ensure that tall vegetation does not provide harborage for pests. A maximum of 50 percent of the outdoor area may be gravel, concrete, or surfaces other than soil or soil with vegetative cover. Maximal vegetation is required, as vegetation protects soil and water quality and

allows birds to engage in natural behaviors, including foraging, pecking, and scratching. The amount of vegetation present will depend on the season, climate, geography, species, and the stage of production.

Section 205.241(c)(3) clarifies how producers may provide shade to meet the general requirements of § 205.241(a). Shade may be provided in outdoor areas by trees, shade structures, or other appropriate objects. This section addresses shade in outdoor areas; it does not permit structures that do not meet the definition of “outdoors” (§ 205.2) to be included in calculations of outdoor space.

New §§ 205.241(c)(4) through (6) specify minimum outdoor space requirements for chickens (*Gallus gallus*). AMS has only established outdoor stocking densities for chickens in this final rule. AMS may propose space requirements for other species in the future.

Organic layer producers must provide at least one square foot of outdoor space for every 2.25 pounds of bird in the flock. For example, if birds average 4.5 pounds, a producer must provide 2.0 square feet of outdoor space for each bird in the flock. Organic pullet producers must provide at least one square foot of outdoor space for every 3.0 pounds of bird in the flock. Organic broiler producers must provide at least one square foot of outdoor space for every 5.0 pounds of bird in the flock. Outdoor space must be provided for all birds in the flock (*i.e.*, a producer must assume that all birds are outdoors at once to calculate the outdoor space that must be provided). All weight references in §§ 205.241(b) and (c) refer to the weight of live birds and not the weight of processed birds.

New § 205.241(c)(7) clarifies that porches and lean-to type structures that are not enclosed (*e.g.* with a roof, but with screens removed) and allow birds to freely access other outdoor areas can be counted as outdoor space. This ensures that enclosed porches are not counted as outdoor space, while providing flexibility for producers to use modified porches as outdoor space when they are open to larger outdoor areas that the birds can access.

New § 205.241(d) describes the conditions under which organic avian livestock producers may temporarily confine birds indoors (“temporary” and “temporarily” further defined at § 205.2). Producers must record confinement, and should do so in a manner that will demonstrate compliance with the regulations (also see § 205.103). Records could include the reason for the confinement, the

duration of the confinement, and the flocks that were confined. Records should be sufficient for a certifier to determine if birds were confined in compliance with this section. The requirements of section 205.241(d) are adopted or adapted from previously established requirements for organic livestock at section 205.239(b), 2009 and 2011 NOSB recommendations, and third-party animal welfare organization standards.

New § 205.241(d)(1) provides an allowance for temporary confinement in response to inclement weather, which is defined at § 205.2. In addition, this provision allows birds to be confined indoors when the temperature does not exceed 40 °F. It also allows birds to be denied outdoor access or be brought inside when the daytime temperature exceeds 90 °F. In this case, producers have to provide outdoor access during parts of the day when temperatures are between 40–90 °F, unless other forms of inclement weather occur. Weather may still qualify as inclement weather (§ 205.2) within the 40–90 °F temperature range. For example, excessive precipitation and very violent weather can occur when temperatures are within 40 °F and 90 °F. Likewise, weather may meet the definition of inclement weather within the range of 40 °F and 90 °F if the relative humidity is very high and the air temperature is nearing 90 °F, or under extremely windy conditions. As inclement weather is defined, in part, as weather that can cause physical harm to a species, a producer would still be in compliance with § 205.241(d)(1) if birds were confined at temperatures that did not exceed 90 °F, if the weather could cause physical harm.

Section 205.241(d)(2) provides an allowance for temporary confinement indoors due to a bird’s stage of life. In this section, AMS has established specific requirements for confining chicken broilers and chicken pullets due to their stage of life (“stage of life” previously defined at § 205.2). Additionally, the section includes a general provision for confining other avian species until fully feathered. Chicken broilers may be confined through 4 weeks of age and chicken pullets may be temporarily confined indoors through 16 weeks of age. The NOSB recommended 16 weeks of age as the age after which outdoor access is required to provide adequate time for pullets to complete their vaccination program before exposure to pathogens outdoors. Any confinement beyond the time when birds are fully feathered must be in accordance with § 205.241(d).

New § 205.241(d)(3) provides an allowance for temporary indoor confinement under conditions in which the health, safety, or well-being of the birds could be jeopardized. Temporary confinement must be recorded, and to confine birds under this provision, a producer must have sufficient justification to demonstrate that an animal’s health, safety, or well-being could be jeopardized by access to the outdoors. Certifiers will verify compliance with this requirement. Producers and certifiers should consult with animal health officials, as appropriate, to determine when confinement of birds is warranted to protect the health, safety, or well-being of the birds. Animal health officials are also encouraged to reach out to certifiers and to AMS to discuss specific health concerns. AMS will continue to engage animal health officials, including State Departments of Agriculture and State Veterinarians, about risks to bird health and provide appropriate guidance to certifiers or producers, as necessary.

New § 205.241(d)(4) provides an allowance for indoor confinement to prevent risk to soil or water quality. This provision allows for confinement of birds when the outdoor area is being managed to reestablish vegetation. As outdoor areas must be maximally vegetated, producers may need to occasionally confine birds to meet the vegetation requirement at § 205.241(c)(2).

Section § 205.241(d)(5) provides an allowance for indoor confinement for preventive health care procedures and for the treatment of illness or injury. Neither life stages nor egg laying are considered an illness for confinement purposes. For example, this provision allows producers to briefly confine a flock to administer a vaccine or to confine an individual animal that requires medical treatment.

New § 205.241(d)(6) provides an allowance for indoor confinement for sorting, shipping, and poultry sales. Birds must be managed organically during the entire time of confinement. For example, any feed provided during confinement must be organic. Confinement must be no longer than necessary to sort the birds or to catch the birds, place them in shipping containers, and conduct the sale.

New § 205.241(d)(7) provides an allowance for indoor confinement to train pullets to lay eggs in nest boxes, with a maximum period of five weeks allowed for confinement. The training period must not be any longer than required to establish the proper behavior. As soon as the behavior is established, birds must be provided

with access to the outdoors, except when confined in accordance with other provisions under § 205.241(d).

Section 205.241(d)(8) provides an allowance for indoor confinement for youth exhibitions, such as with 4-H or the National FFA Organization. This provision also includes an exemption to the requirement that a livestock sales facility be certified as an organic operation. As an example, if a youth exhibition and sale is held at a livestock sales facility that is not certified organic, a youth may sell birds there as organic, provided all other requirements for organic management are met. During the youth event, the livestock may be temporarily confined indoors. Otherwise, non-certified sales facilities, such as auction barns, may not sell or represent livestock as organic. AMS is adding these provisions at § 205.241(d)(8) to encourage the next generation of organic producers.

New § 205.241(e) requires organic poultry producers to manage manure in a manner that does not contribute to contamination of crops, soil, or water quality by plant nutrients, heavy metals, or pathogenic organisms. Organic poultry producers must manage the outdoor space in a manner that does not put soil or water quality at risk. In addition, organic poultry producers must comply with all other governmental agency requirements for environmental quality. The requirements of this section are adapted from previously established requirements for organic livestock at section 205.239(e).

B. Discussion of Comments Received

1. Ammonia Levels

(Comment) AMS received several comments noting that it was redundant to include ammonia requirements in both § 205.238 and § 205.241, and recommending that we keep the requirement in only one section. Other comments suggested we make the requirement in § 205.238 apply to all types of livestock production rather than limit the requirement to poultry production.

(Response) AMS agrees it is not necessary to include both sections as proposed. In the final rule, we have retained the requirement in § 205.241(b)(2) and removed the requirement in § 205.238. AMS recognizes that ammonia levels may be relevant for other types of livestock production, but we have not broadened the requirement in the final rule. AMS may seek the NOSB's recommendation on this topic at a later date.

(Comment) We received comments that it was not clear if AMS was establishing a maximum ammonia limit of 10 ppm or 25 ppm. These comments noted that the consequences of exceeding 25 ppm were not clearly different than the consequences for exceeding 10 ppm. Other comments stated that birds could be continuously exposed to ammonia levels in excess of 10 ppm but below 25 ppm without any consequences, limiting the benefits to animal welfare from this requirement.

(Response) The final rule is modified to clarify that producers must implement practices to maintain ammonia levels below 10 ppm. The 10 ppm level is established so that organic birds live in an indoor environment without excessive ammonia levels, which can be harmful to bird health. If required monthly monitoring indicates ammonia levels are above 10 ppm, then the producer must conduct additional monitoring and implement additional practices to bring ammonia levels to below 10 ppm.

The rule also establishes a maximum ammonia level of 25 ppm. Ammonia levels above 25 ppm would be a violation of the organic requirements and lead to appropriate compliance actions, including potential loss of organic certification. The ammonia levels described in the final rule are consistent with the NOSB's recommendation and the thresholds established by a number of animal welfare standards.

(Comment) We received some comments that a maximum ammonia level of 25 ppm was too high and that AMS should revise the upper limit to 20 ppm to better protect animal health.

(Response) AMS has not revised the requirement in the final rule because the 25 ppm level limit was established based on NOSB's recommendation. This limit is also consistent with various third-party animal welfare standards. Furthermore, AMS notes that a producer is required to implement additional practices to reduce ammonia levels when levels exceed 10 ppm. With this 10 ppm action level, AMS does not think it is necessary to reduce the upper limit to be below 25 ppm.

(Comment) We received comments related to the monitoring and measurement of ammonia levels. One comment argued that measurement of ammonia with an objective tool such as test strips or meters should not be required and that the rule should allow for subjective measures (e.g., a smell test). Another comment noted that the human nose cannot reliably or accurately detect levels of ammonia and recommended AMS clarify that

subjective measurement is not sufficient to determine ammonia levels. We also received comments that monthly testing may not be adequate to verify compliance with the limits proposed.

(Response) In the final rule, AMS has not specified how ammonia levels are to be measured. Producers and certifiers may use a number of methods to measure ammonia levels, including test strips, continuous monitoring devices, or handheld meters. Given the minimal cost of the simplest methods to test ammonia levels and that action is required by producers at a relatively low level (above 10 ppm), producers must use a non-subjective method to measure ammonia levels.

AMS agrees that monthly monitoring may not be sufficient when ammonia levels exceed 10 ppm. AMS has revised the final rule at § 205.241(b)(2) to specify that additional monitoring is required when ammonia levels exceed 10 ppm. The additional requirement is included to ensure that the additional practices implemented by the producer lower ammonia levels below 10 ppm. A producer may return to monthly ammonia monitoring when ammonia levels fall below 10 ppm.

2. Lighting

(Comment) AMS received many form letter comments stating that the regulations should require 8 hours of continuous darkness each day for all birds. The comments appear to prefer this to the language proposed at § 205.241(b)(3) that states, "artificial light may be used to prolong the day length up to 16 hours." Comments suggested the rule as proposed would not ensure a period of darkness.

(Response) AMS has revised the final rule to state, "artificial light may be used to prolong the day length, to provide up to 16 hours of continuous light." AMS has included the word "continuous" to ensure that layers and mature birds are not subjected to multiple periods of light and dark over the course of a 24-hour day. In most locations, except for locations in extreme latitudes during summer months, this requirement ensures that birds are provided with an 8-hour period of continuous darkness per day, as requested by comments. Producers located in extreme latitudes are not required by the final rule to provide 8 hours of total darkness.

(Comment) Several comments requested clarification about whether the time period for dimming artificial light is to be included in the 16-hour time period described in § 205.241(b)(3).

(Response) Artificial light may be used to provide up to 16 hours of

continuous light. The rule does not allow for additional use of artificial light outside of this continuous 16-hour time period. If artificial lights are dimmed, the time that artificial lights are on (dim or not) must be included within the allowed 16-hour time period.

(Comment) Several comments noted that the method for evaluating the level of natural light in a poultry house (§ 205.241(b)(3)) was overly subjective, including a comment that different inspectors may require different light levels to read and write. Comments suggested that the requirement could be difficult to enforce or that differences between inspectors could lead to inconsistent enforcement of the requirement. Several comments requested we set a specific light requirement that could be verified with a light meter.

(Response) AMS considered alternatives to the requirement as proposed, including a requirement to measure light quantitatively. This alternative would have required producers and organic inspectors to use light meters to monitor and verify the amount of light in a poultry house. While a specific minimum light level could be established, AMS does not believe it is necessary to meet the objective of providing natural light and would impose an additional cost on producers or certifiers. AMS decided that a qualitative assessment of natural light by inspectors, as specified in the proposed rule, is adequate to ensure poultry houses include sufficient natural light. The final rule, therefore, is unchanged.

(Comment) AMS received some comments that the requirement to dim artificial light intensity gradually was not necessary and could require producers to install new equipment. One comment suggested we do not require that lights be dimmed but only recommend it, by changing the wording from, “must be lowered gradually,” to “should be lowered gradually.” Other comments stated that continuous dim lighting be prohibited.

(Response) To protect bird welfare by ensuring that birds are provided with a period of time to move to perches or settle for the night, AMS has retained the requirement that artificial light be lowered gradually at night. AMS notes that producers may turn off artificial light before the end of the natural day to allow natural light in the house to lower gradually. In this case, the total length of the day, including any use of artificial light, would not exceed 16 hours for layers and mature birds except for operations located in extreme latitudes, where natural day lengths

may exceed 16 hours per day. The requirement at § 205.241(b)(3) applies only to layers and fully feathered birds.

(Comment) We received one comment that stated that AMS should require windows on poultry houses to be evenly distributed to allow for natural light throughout the house.

(Response) The final rule requires that natural light be provided in housing for layers and mature birds, such that natural light indoors is sufficient for an inspector to read and write when all lights are turned off. As this requirement applies to indoor space and could be applied to any location indoors, AMS has not included additional requirements in the final rule for windows and skylights to be distributed evenly in a house. Housing where natural light is sufficient (*i.e.*, to read and write) in only a few localized places within the house would not meet the requirement. Natural light must be sufficient for an inspector to read and write throughout the house when all artificial lights are off in the house.

(Comment) Several comments asked why AMS only discussed “layers and mature birds” in the section on use of artificial light. Comments requested clarification on the use of artificial light for production of meat birds (*e.g.*, broilers, turkeys) and for immature layers (*e.g.*, pullets). Comments stated that continuous light has negative effects on all birds and that AMS should not limit the requirement to layers and mature birds only. Similarly, several comments noted that it was unclear if the requirements for natural light indoors applied only to layers and mature birds, or if the natural light requirement applied to all poultry houses.

(Response) AMS has clarified that layers and fully feathered birds, including fully feathered broilers and fully feathered turkeys, are subject to the artificial light requirement (§ 205.241(b)(3)).

3. Exit Areas

(Comment) Comments suggested AMS simplify the final rule by describing all requirements about exit areas (*i.e.*, doors) in a single section. As proposed, AMS described requirements for exit areas in §§ 205.241(b)(5) and 205.241(c)(2).

(Response) AMS agrees with these comments. In the final rule, all requirements for exit areas appear at § 205.241(b)(5). All requirements proposed at § 205.241(c)(2) have been moved to § 205.241(b)(5).

(Comment) AMS received several comments to eliminate the requirement that all birds within the house be able

go through the exit areas within one hour. Comments stated the one-hour requirement would not be easy to verify. Other comments stated that verifying compliance by forcing birds outdoors would cause birds stress. Some comments suggested that AMS establish more specific requirements for exit areas, such as a minimum width, height, and number of doors per house. Comments argued that this would allow producers to design facilities that would absolutely meet the regulations and would allow certifiers to more easily verify compliance with specific requirements.

(Response) In the final rule, AMS has removed the requirement, as proposed, that exit areas be designed so that all birds within the house can go through the exit areas within one hour. AMS removed the one hour requirement, as it is not feasible for certifying agents to verify compliance with this requirement or take enforcement actions. AMS considered specifying the number and dimensions of exit doors, but decided that setting a clear performance standard for ready access to the outdoors is preferable to specific number and size requirements. In the final rule, AMS is establishing a clear performance standard so organic poultry producers will have the flexibility to design exit doors that provide ready access to the outdoors for birds, based on the design of the poultry house and the outdoor space. In any case, exit areas must: (1) Be sized to allow all birds to exit and enter the house, (2) be distributed to ensure birds have ready access to the outdoors, and (3) be designed and managed in a manner that prevents movement of wild birds, rodents, and other animals into the poultry house. Appropriate distribution ensures that all birds are close enough to a door to be able to readily gain access to the outdoors.

(Comment) AMS received comments on the distribution of exit areas on poultry houses. Some comments recommended AMS specify that exit areas must be provided on every side of the poultry house, while others suggested AMS clarify that exit areas are only required on sides of the house adjacent to the outdoor area. Other comments recommended that AMS specify a maximum distance between a bird inside and the nearest exit area.

(Response) To clarify the requirement, AMS has revised the phrase, “distributed around the building.” The final rule requires, “Poultry houses must have sufficient exit areas that are appropriately distributed to ensure that all birds have ready access to the outdoors . . .” This requirement is

reinforced at § 205.241(c)(1) which requires, “door spacing must be designed to promote and encourage outside access for all birds on a daily basis.” For some producers, it may be necessary to provide exit areas on all sides of a house to provide “ready access to the outdoors” and to “promote and encourage outside access,” as required under § 205.241(c)(1). However, other producers may be able to provide exit areas to meet the requirements without providing exit areas on every side of a house. The appropriate size, design, and distribution of exit areas on a building will be different for different types of buildings. Exit areas will need to be managed and maintained in a manner that complies with the FDA Egg Safety Rule (74 FR 33030, July 9, 2009).

4. Perches and Roosts

(Comment) AMS received many comments related to how the requirement for perches applies to broilers. Additionally, AMS received several comments about the perch requirement for turkeys, as well as comments about how the requirement will be determined for different species or breeds. We also received comments that noted that some types of poultry, including meat type chickens, will use perches when young but then stop using perches as their weight increases, preferring to spend time on flat surfaces at that time. Other comments noted that meat type chickens can sustain leg injuries moving between perches or roosts and the ground, especially if perches or roosts are too high off the ground.

(Response) In the final rule, AMS has not included a requirement for perch space for broilers or turkeys. The final rule specifies that six inches of perch space per bird is required for layers of species *Gallus gallus*. AMS may undertake further work on this topic, with the assistance of the NOSB, as appropriate.

(Comment) Some comments stated that the requirement of six inches of perch space per bird is excessive and that, at this rate, some perch space would be unused by birds. Other comments stated that all birds in a flock may not perch simultaneously and therefore six inches per bird is not necessary.

(Response) AMS recognizes that all birds in a house may not perch simultaneously. However, we have kept a requirement for six inches per layer in the final requirement. This requirement recognizes that each layer likely requires more than six inches per layer

but that not all layers will be perching at the same time.

(Comment) We received many comments that AMS’s terms “perch” and “roost” are confusing, as the terms can be used interchangeably by producers and industry. Other comments stated that the definition of “roost” in § 205.2 was too narrowly stated, as roosts are not always found over manure pits. One comment stated that the proposed requirement at § 205.241(b)(6) was too narrowly stated, as roosts in poultry houses can be flat, round, or oval. The comment suggested that AMS revise the requirement to simply state that roosts must allow birds to grip with their feet. Another comment suggested AMS change the term “roost” to “slats” in § 205.2 and maintain the same definition.

(Response) AMS recognizes that using both terms “perch” and “roost” could be confusing, as the terms can be used interchangeably by producers and industry. In the final rule, AMS has removed the term “roost” but retained the term “perch” in § 205.2. As defined, this term is intended to refer to various features in poultry housing, such as rods, branch type structures, and flat roost slats that accommodate roosting and are elevated to allow birds to stay off the floor of the house. Perches may be over a manure pit but this is not a requirement.

(Comment) AMS received a comment that questioned why the perch requirement is different for multi-tiered facilities than for other facilities.

(Response) We have included a perch requirement in multi-tiered facilities that is different from single-level facilities because multi-tiered facilities are designed to allow birds to utilize vertical space. Since birds in these facilities may move between levels to escape aggressive behaviors and engage in natural behaviors, less perch space per bird provides the same benefit.

5. Indoor Space Requirements

(Comment) AMS received many comments that AMS did not require enough indoor space. These comments argued that the requirements are similar to current space allowances used in the organic poultry industry and the rule would therefore not improve consumer confidence in the organic seal. Many comments recommended birds be provided with at least 1.5 square feet per bird, regardless of size. Other comments noted the requirements proposed by AMS fell short of the 2.0 square feet of indoor space recommended by the NOSB. Some comments stated AMS should not include different indoor space

requirements for different types of production or housing systems (e.g., pasture housing, aviary housing, slatted/mesh floor housing, floor litter housing). These comments suggested a single requirement for all housing systems.

(Response) In this final rule, AMS has included indoor space requirements that are based on pounds per square feet rather than square feet per layer. These requirements are equivalent to (for a 4.5 pound layer): 1.5 square feet per bird for floor litter housing; 1.2 square feet per bird for slatted/mesh floor housing; and 1 square foot per bird for mobile and aviary housing. The requirements were developed by considering the NOSB’s recommendations, commonly-used third-party animal welfare standards, and current practices of certified organic producers. They were designed to balance the need for clear guidance that could be applied across different breeds and types of bird, the goal of safeguarding the value of the organic seal, and the cost of diverging significantly from common practice among organic operations certified to third-party animal welfare standards. AMS also determined that the indoor space requirements differ based on housing design. Less indoor space is required per bird in houses that provide more access to vertical space in the house, as birds have more room to move around (e.g., aviary and slatted/mesh floor housing). Housing where birds have more limited access to vertical space (e.g., floor litter housing) must provide more indoor space per bird. We have also allowed for higher stocking densities in mobile housing, as birds managed in these systems spend more time outdoors, and mobile housing must be relatively small and light because it is moved frequently.

(Comment) We received numerous comments that the indoor space requirement for turkeys was too large and did not align with current practices of organic turkey producers, including a comment that AMS did not take into account that houses are designed to ensure all turkeys have easy access to feed and water.

(Response) AMS proposed a maximum indoor stocking rate for turkeys of 5.0 pounds per square foot. AMS established the proposed space requirements for turkeys based on a preliminary recommendation included in a “Proposed Discussion Document” by the NOSB, which was presented at the NOSB’s spring 2012 meeting.¹¹ The

¹¹ U.S. Department of Agriculture, Agricultural Marketing Service. “NOSB Meetings.” <https://www.ams.usda.gov/rules-regulations/organic/nosb/meetings>.

NOSB never issued a final recommendation to AMS on space requirements for turkeys. In the final rule, AMS has removed the specific space requirements for turkeys and other avian species in light of: (1) Numerous comments from turkey producers that the proposed stocking density requirements would have a major impact due to current industry practices; (2) the absence of an NOSB recommendation; and (3) information that the proposed requirements were more stringent than other third-party animal welfare standards. AMS intends to address space requirements for turkeys in future rulemaking. Producers of organic turkey and other avian species are still subject to all other requirements of the final rule, including all other indoor space requirements at § 205.241(b), outdoor space requirements at § 205.241(c), and the general requirements at § 205.241(a). This includes the requirement at § 205.241(b)(1) that, “Poultry housing must be sufficiently spacious to allow all birds to move freely, stretch their wings, stand normally, and engage in natural behaviors.” Certifiers should verify that producers are in compliance with these requirements. For example, producers that do not provide birds with outdoor access are not in compliance with the regulations, unless birds are temporarily confined in compliance with § 205.241(d).

6. Outdoor Space Requirements

(Comment) AMS received many comments that the outdoor space required for birds was not large enough. Comments noted that additional outdoor space would be required to ensure vegetation would not be removed entirely from the outdoor area. Some comments stated the size of the outdoor area was insufficient to prevent buildup of manure, which could lead to contamination of nearby surface water and of the soil in the outdoor area. Additionally, some comments stated that more outdoor area was required to ensure birds could be rotated around the outdoor areas since rotation serves important functions, including vegetation regrowth, parasite and disease reduction, and nutrient management. Further, AMS also received comments claiming that this rule would not protect small farmers and was more advantageous to larger producers. These comments remarked that the indoor and outdoor stocking density requirements for layers are weak which threatens consumer confidence in the organic label and continues the economic disadvantage for farmers using more stringent practices.

(Response) AMS recognizes that a larger outdoor area requirement than proposed could have benefits as described by comments. AMS, however, retained the proposed outdoor space requirement in the final rule. The requirement aligns with the recommendation by the NOSB and is established to meet consumer expectations while recognizing the land constraints that were raised by many other commenters (see below). AMS emphasizes that the regulations established here do not limit producers from providing a larger outdoor area for birds.

(Comment) Some comments stated the outdoor space required for poultry was too large. Specifically, some comments from producers noted that all birds in a house do not go outdoors at any one time and requested that AMS reduce the outdoor area requirement to recognize this observation. Several comments noted that producers may not have the amount of land required for outdoor space, or that the land available may not be near the barns, and that these producers would be forced to cease organic production.

(Response) AMS recognizes that an entire flock may not occupy the outdoor area at the same time, as a percentage of the flock may choose to remain inside, even when presented with the opportunity to go outdoors. However, AMS has not revised the outdoor space requirements in the final rule. The outdoor space requirements in the final rule ensure birds have adequate space outdoors if all birds in the flock do go outdoors. When all birds do not use the outdoor area simultaneously, the birds that are outdoors will effectively have more space per bird. This space requirement aligns with the recommendation by the NOSB. NOSB recommendations were guided by public comment that highlighted consumer expectations, or that sought to preserve the value of the organic seal to consumers. For further discussion of land availability and costs to producers, see discussion of comments below in section titled “Assumption about Two Barn Footprints”.

(Comment) AMS received comments that stated the outdoor area required for turkeys was too large. Comments from some organic producers said they would need to increase the size of the outdoor area by 80 percent to meet the proposed requirement.

(Response) AMS proposed a maximum outdoor stocking rate for turkeys of 5 pounds per square foot based on a preliminary recommendation included in a “Proposed Discussion Document” by the NOSB, which was

presented at their spring 2012 meeting.¹² In the absence of a final NOSB recommendation on space requirements for turkeys and in light of the numerous comments AMS received on the topic, AMS has removed the specific space requirements for turkeys in the final rule. AMS intends to address space requirements for turkeys in future rulemaking, once we have received additional input from the NOSB. Producers of organic turkey are still subject to all other requirements of the final rule, including all other outdoor space requirements at § 205.241(c), indoor space requirements at § 205.241(b), and the general requirements at § 205.241(a). Certifiers should verify that producers are in compliance with these requirements. For example, producers that do not provide turkeys with outdoor access are not in compliance with the regulations, unless birds are temporarily confined in compliance with § 205.241(d).

(Comment) AMS received several comments that the general requirement for “adequate space to escape from predators and aggressive behaviors” proposed in § 205.241(a) should be revised. These comments stated that space outdoors does not necessarily help poultry escape from predators and recommended that AMS remove the language “escape from predators.”

(Response) In the final rule, AMS has revised the wording in this section to remove the requirement for adequate space to escape predators. This should not be interpreted to mean that AMS does not recognize the importance of birds having a place to escape from predators, but simply that outdoor space may not meet this goal. The section continues to require “adequate outdoor space to escape aggressive behaviors . . .” (§ 205.241(a)), as outdoor space may allow birds to escape from the aggressive behaviors of other birds in the flock.

(Comment) Some comments requested that we clarify calculations for birds kept in mobile housing units that provide direct contact with the ground. Comments asked whether birds in these production systems also require additional outdoor space.

(Response) See “Pasture pens vs. other mobile housing” comment and response.

7. Space Calculations—General

(Comment) AMS received many comments requesting that we describe

¹² U.S. Department of Agriculture, Agricultural Marketing Service. “NOSB Meetings.” <https://www.ams.usda.gov/rules-regulations/organic/nosb/meetings>.

the requirements for indoor and outdoor space using square feet per bird instead of setting a maximum pounds of bird per square foot, as AMS proposed. Comments stated that using square feet per bird would be more intuitive or easier to use when verifying compliance with the regulations.

(Response) AMS understands that it is simpler to think about space requirements on a per bird basis rather than as a number of pounds per square feet. However, AMS has not revised the description of the space requirements in the final rule, as pounds per square foot most fairly addresses differences between species and breeds. From comments received, AMS identified approximately half a dozen layer breeds commonly used for organic production, not including heritage breeds used by some organic producers. Each breed has slightly different characteristics, including the average weight per bird. By retaining the space requirements expressed as maximum pounds per square foot, AMS believes the requirement will be most equitable across species and breeds.

(Comment) Many comments discussed whether a porch could be calculated as either indoor or outdoor space. Some comments questioned when a porch could be included in calculations as either indoor or outdoor space (*i.e.*, whether access to the porch must be available at all times). Other comments opposed allowing porches as either indoor or outdoor space, stating that counting porches as indoor space would be a loophole that would result in less indoor space.

(Response) AMS disagrees with comments that space within a porch should never be allowed to count as space for birds. If a porch is always available to birds when inside, the porch space could be utilized by birds and the space should have the same benefits as other indoor space. However, if a porch is not accessible to birds at all times, it may not be included as indoor space. Space in porches may not be included in the calculation for indoor space if birds cannot access the porch for any reason, for example, if doors are closed due to inclement weather or threat of diseases. When calculating the space available to birds outdoors, only space that is outside an enclosed building or housing structure (see definition of “outdoors” at § 205.2), may be included as part of the outdoor area. However, in response to comments, AMS has added § 205.241(c)(7) to clarify that unenclosed porches and lean-to type structures (*e.g.* with roof, but with screens removed) that allow birds to access the rest of the outdoor area can

be included in the calculation of outdoor space.

(Comment) Several comments requested that AMS clarify what was meant by “at any time” when referring to indoor and outdoor space requirements in §§ 205.241(b) and (c). Some comments thought that this section could be interpreted to mean that space requirements apply only to the birds in the outdoor area at a specific moment rather than to all birds in the flock. Comments noted that different interpretations of the phrase could influence the amount of space provided, as all birds in a house may not be outdoors at the same time.

(Response) In the final rule, AMS has revised the wording in §§ 205.241(b) and (c) to remove the phrase “at any time” and to clarify that space must be provided at the established rates for all birds in the flock. In § 205.241(c), we specified that outdoor space must be provided for all birds in the flock. We have not specified that indoor space is to be calculated for every bird in the flock, as all birds in a flock are regularly indoors at the same time and the method of calculating is clear.

(Comment) Some comments requested clarification about when birds should be weighed to calculate the indoor and outdoor space requirements. Other comments asked if the rule requires that birds be weighed to determine space requirements.

(Response) AMS notes that the space requirements are not linked to any specific age. At any time in a production cycle, producers must meet the requirements. For example, a layer in a floor litter housing system that is 32 weeks of age and weighs 4.3 pounds must be provided with 1.43 square feet per bird (equivalent to 3.0 pounds of bird for each one square foot); however, at 80-weeks of age and a weight of 4.5 pounds, each bird must be provided with 1.5 square feet per bird (3.0 pounds of bird for each one square foot). In other words, for each 10,000 square feet, a producer could stock 6,993 birds at 32 weeks of age (bird weight of 4.3 pounds) but only 6,667 birds at 80 weeks of age (bird weight of 4.5 pounds). Although older and heavier birds require more space, natural mortalities over time may result in compliance with the space requirements over a production cycle. To calculate the weight of birds, an average weight may be established for the flock by taking weights of a representative sample of the flock. The requirement is not specific to each individual bird in a flock. AMS understands that many producers already monitor and track bird weight closely during the production cycle to

monitor bird development and health and calculate feed requirements. However, if weight is not monitored by a producer, the producer and/or certifier will need to establish the weight of birds based on objective criteria to determine the space required indoors and outdoors.

8. Space Calculations—Indoors

(Comment) Some comments requested clarification about whether the area occupied by nest boxes in poultry houses could be included in the calculation of the available indoor space.

(Response) In the final rule, AMS has clarified in § 205.241(b)(11) how indoor space is to be calculated and that nest boxes may not be included in the calculation of indoor space. This clarification aligns with the NOSB’s December 2011 recommendation on indoor space, as well as with the methods for calculating indoor space used by animal welfare groups and third-party production standards. The total size of the indoor space is calculated by including all flat areas in a house, excluding nest boxes. Elevated round perches, for example, are not flat areas and could not be included as indoor space.

(Comment) We received some comments that asked what types of housing would be subject to the indoor requirement of 2.25 pounds of hen per square foot. Another comment stated that AMS could hinder innovation by implementing a stricter requirement (*i.e.*, more indoor space per bird) than for other types of housing defined in § 205.2.

(Response) AMS is not aware of housing that does not fit within one of our housing definitions included in § 205.2, and disagrees that the requirement would disadvantage any type or size production system. In the final rule, AMS continues to include an indoor space requirement at § 205.241(b)(8)(v) for housing that does not fit within one of the types defined in § 205.2 as “indoors” or “outdoors.” AMS also notes that requirements for new housing types could be included in the requirements at a later date, at the recommendation of the NOSB, as appropriate. If housing does not fit within one of the types described in § 205.2 and included at §§ 205.241(b)(8)(i) to (iv), producers must provide an indoor stocking density of no more than 2.25 pounds of hen per square foot.

9. Space Calculations—Outdoors

(Comment) Some comments requested that AMS clarify how to calculate the

outdoor stocking density. Comments asked whether producers could rotate birds around the outdoor area when this would result in a higher stocking density, as long as the stocking density as calculated over the entire outdoor area met the requirement.

(Response) The outdoor area requirement is to be calculated as the outdoor area available to all birds in the flock at any given time. For example, if a producer rotates birds between two outdoor areas, each area must be large enough to meet the stocking density requirement. Performing the calculation in this way ensures that birds are provided with the outdoor space required at all times. AMS has not revised the final rule in response to this comment.

(Comment) AMS received several comments about how the area of the outdoor space is to be calculated. Comments stated that AMS's intent to prohibit porches as outdoors was clear but that the proposed prohibition for including outdoor areas under a solid roof if attached to the structure was either confusing or overly restrictive. Some comments stated that large overhangs or other covered areas can actually encourage birds to go outdoors, as these areas provide a degree of safety for birds (*i.e.*, safety from aerial predators). Other comments mentioned that producers may create shade structures by leaning lumber against the side of building. Comments requested that AMS clarify that these areas are outdoors and can be included in outdoor space calculations.

(Response) AMS recognizes that overhangs, eaves, or other covered areas may encourage use of outdoor areas by providing overhead protection. In the final rule, AMS has removed the requirement as proposed at § 205.241(c)(6).

Additionally, AMS has revised the definition of "outdoors" to, "Any area in the open air, outside a building or housing structure." AMS also revised the definition of "indoors" to, "the space inside of an enclosed building or housing structure." Any outdoor space that meets the definition may be included in outdoor space calculations. AMS has also added § 205.241(c)(7), which clarifies that porches and lean-to type structures that are not enclosed, but allow free access to other outdoor areas can be counted in outdoor space calculations. These changes do not affect the decision that an enclosed porch cannot be counted as outdoor space. See AMS's response to comments on Definitions for further discussion.

(Comment) Some comments requested that AMS clarify whether producers

must have outdoor areas if they only raise pullets and the pullets are sold or moved to another location prior to 16 weeks of age.

(Response) Section 205.241(d) includes requirements for temporarily confining birds from the outdoors. When birds are temporarily confined from the outdoors in compliance with the requirements at § 205.241(d), outdoor space is not required. To establish if confinement from the outdoors is in compliance with the requirements, a producer must, as required by § 205.201, "develop an organic . . . system plan that is agreed to by the producer . . . and an accredited certifying agent." Beyond 16 weeks of age, all layer producers must have land available for outdoor access at the maximum stocking rate of 2.25 pounds per square foot, unless birds are temporarily confined in accordance with § 205.241(d). Producers may not confine birds in an indefinite manner to avoid or bypass outdoor space requirements.

10. Porches

(Comment) AMS received many comments that stated that porches should be considered as outdoor space in organic poultry production. Comments received in favor of porches as outdoor space argued that they allow producers to better protect bird health by reducing contact between organic birds and other animals that can carry disease (*e.g.*, wild birds, rodents, insects, cats, other animals); reducing contact between organic birds and pathogens in soil (*e.g.*, parasites, bacteria, viruses); and limiting predation. Additionally, many comments argued that production costs and, in turn, retail costs would increase if porches were prohibited. Some of the comments in favor of porches as outdoor space noted that porches also provide conditions similar to the outdoors (*e.g.*, sunlight, fresh air), and others stated that porches do in fact meet consumer expectations, as demonstrated by demand for organic eggs, many of which are produced in porch-based systems. Some comments in favor of porches recommended they be considered outdoor space for currently certified organic producers indefinitely. Another comment recommended that AMS allow porches as outdoor space but require enrichments on the porch to encourage birds to use porches.

AMS also received many comments that were opposed to any use of porches as outdoor space in organic production, including many comments stating they were unaware that currently, operations

that provide porches as the only outdoor space for birds are allowed to be certified organic. Generally, these comments expressed that birds should be outside as much as possible on soil or on pasture with sunshine, fresh air, and adequate space in order to maximize opportunities for birds to exhibit natural behavior as recognized by animal welfare experts, consume a diverse diet, and meet consumer expectations for birds raised organically. Many stated that shoppers pay more for organic food and that animals should be raised in a manner that is more in line with consumer expectations, including access to soil and vegetated areas.

(Response) In the final rule, AMS has retained a requirement for outdoor access, and AMS has defined the outdoors (§ 205.2) to clarify that birds must be in the open air, outside an enclosed building or housing structure, to be considered outdoors. AMS disagrees with comments that argued that consumers are satisfied with the use of porches, or that demand for organic eggs is evidence of their satisfaction. AMS received a vast number of comments that indicate that consumers are unaware that porches have been used for outdoor access in organic production. The comments received indicate that there is a gap between how consumers think birds are raised on organic farms and the actual practices of some—but not all—organic producers. One of the key objectives in implementing this final rule is to assure consumers that the practices used to produce organic products meet a consistent standard, including outdoor access for poultry. This objective is guided by the NOSB recommendations and public and expert comment received during those deliberations that indicated a risk to the integrity and value of the organic seal from the gap between consumer expectation and current industry practice.

For further discussion of porches, including comments and cost impacts, see section XII, "Porches as Outdoor Areas."

11. Biosecurity

(Comment) A number of comments stated that the proposed rule would compromise biosecurity measures and increase exposure of birds to disease and infection by requiring access to the outdoors. Comments stated that there would be increased exposure of organic birds to wild birds and the feces of wild birds, which could harbor and transmit diseases. Additionally, comments noted the requirements would expose organic birds to more contact with soil, other animals (*e.g.*, rodents, cats), or insects

(e.g., flies, ticks, mites, lice) that can harbor and transmit disease to domestic poultry. Comments stated that increased exposure to disease vectors, including viruses, parasites, and bacteria, would increase bird morbidity and mortality, negatively affect production, put other farms at risk, or force producers to decide between protecting bird health and maintaining organic certification. Comments noted that soil cannot be disinfected in the same way a house can be disinfected, which could lead to an increase in disease and mortality over time. Many comments stated that rearing birds in the controlled environment of a poultry house is best for bird health.

However, several comments also noted that confinement of poultry to the indoors is not a guarantee that birds will be protected from disease. A comment noted that in the 2015 outbreak of highly pathogenic avian influenza (HPAI) in the United States, the affected poultry farms were non-organic operations that permanently confine birds from the outdoors. Commenters urged AMS to consider that outdoor access is only one component of a comprehensive biosecurity plan and that factors other than outdoor access have been implicated in confirmed cases of HPAI (e.g., cross-contamination due to persons or equipment moving between poultry houses or between farms).

(Response) In the final rule, AMS has retained the requirement for outdoor access for organic birds, but the Agency engaged in extensive deliberations to align these requirements with the best practices of federal agencies focused on biosecurity and food safety. Outdoor space requirements have also been retained for layers, pullets, and broilers of species *Gallus gallus*. AMS recognizes that certain conditions may require the temporary confinement of birds to protect bird health and prevent disease and has preserved the ability of producers to take these precautionary measures, in consultation with their certifiers. AMS believes that outdoor access should be provided when conditions do not jeopardize bird health, safety, or well-being and that outdoor access requirements can be factored into comprehensive biosecurity plans. Finally this rule does not obviate the necessity to comply with all other applicable laws and regulations, including animal health regulations of APHIS.

The final rule continues to allow producers to temporarily confine birds because of conditions under which the health, safety, or well-being of the animal could be jeopardized. This

provision has been included to protect animal health. AMS also recognizes that specific disease risks may require temporary confinement to protect bird health, in the absence of a documented occurrence of disease. In response to comments, AMS has removed a provision from this section that would have required a documented occurrence of disease in the region or migratory pathway to temporarily confine animals. By revising the requirement, AMS is providing producers with additional options to address disease risks. This provision to temporarily confine birds must be part of an Organic System Plan approved by the producer's accredited certifying agent. Additional requests for temporary confinement, outside of the approved Organic System Plan, must be approved by the certifying agent. AMS encourages state departments of agriculture to coordinate with NOP and certifiers on occasions where temporary confinement may be necessary to protect animal health. See AMS's discussion of comments on "Temporary confinement—disease" for further discussion of confining animals under this provision.

12. Pasture Pens vs. Other Mobile Housing

(Comment) Several comments requested that AMS clarify how the regulations apply to poultry producers that use certain types of mobile pasture-based systems. The comments described these systems as providing direct access to soil and vegetation; having walls and roofs made of mesh, plastic, wood, and other materials; and having mobility. Birds in these systems are on pasture, however, roofing on all or part of the structure provides shade and protection. These comments argued that these systems should meet the definition of outdoors because they provide access to soil and vegetation and allow for natural behaviors (scratching, pecking, foraging, etc.).

(Response) For further discussion, see AMS's response to comments in the Definitions section. AMS made several revisions in the final rule in response to comments requesting more clarity around the definitions of indoors and outdoors as they apply to pasture-based systems. We revised the definition of outdoors in § 205.2 to clarify that pasture pens are outdoors. Additionally, we use the term "mobile housing" in § 205.241(b)(8)(1) of the final rule to distinguish pasture pens from mobile housing. Mobile housing provides indoor space while pasture pens are considered outdoors.

Birds raised in pasture pen systems must be provided with space to meet

outdoor space requirements at §§ 205.241(c)(4) through (6); specifically, space for chickens must be provided at a rate of no less than one square foot for every 2.25 pounds of layer, 3.0 pounds of pullet, or 5.0 pounds of broiler in the flock. Species other than chickens must be provided with outdoor space to meet the requirements of §§ 205.241(c)(1) through (3). AMS has determined that this type of production, which provides animals with constant access to pasture, also meets consumer expectations of organically produced birds, and expects that the outdoor space requirement ensures birds in these systems have sufficient space to express natural behaviors and meet the requirements of § 205.241(a).

13. FDA Regulations and Food Safety

(Comment) AMS received numerous comments stating that the proposed rule would compromise egg producers' efforts to prevent *Salmonella enterica* serotype Enteritidis (SE) from contaminating eggs, as required by FDA regulations (21 CFR part 118). FDA requirements include: preventing stray poultry, wild birds, cats, and other animals from entering poultry houses; using appropriate methods to control rodents and flies (when monitoring indicates unacceptable activity); and removing vegetation and debris outside a poultry house that may provide harborage for pests (21 CFR 118.4). Comments stated the AMS requirements for outdoor access and for enrichments in outdoor areas would conflict with current FDA requirements to prevent SE.

(Response) AMS engaged in extensive deliberations to reduce the likelihood that requirements under this rule would jeopardize or impact practices that poultry producers have implemented to meet FDA requirements to prevent SE (21 CFR part 118) published on July 9, 2009 (74 FR 33030). Under the FDA requirements, producers must have and implement a written SE prevention plan and take measures to prevent introduction or transfer of SE into or among poultry houses (21 CFR 118.4). Under FDA regulations, the minimum requirements to prevent SE include, but are not limited to: preventing stray poultry, wild birds, cats, and other animals from entering poultry houses; and removing debris within a poultry house and vegetation and debris outside a poultry house that may provide harborage for pests. Enrichments in the outdoor area could provide harborage for rodents, and thus, could conflict with FDA requirements at 21 CFR 118.4(c)(3).

In the final rule, AMS has removed the proposed requirement, “outdoor areas must have suitable enrichment to entice birds to go outside.” This requirement has been removed in the final rule to remove conflict with FDA rules to prevent SE contamination. Section 205.241(c)(1) requires that “outside access and door spacing must be designed to promote and encourage outside access for all birds on a daily basis. Producers must provide access to the outdoors at an early age to encourage (*i.e.*, train) birds to go outdoors.”

Additionally, AMS has amended the rule at § 205.241(c)(2) to require at least half of the outdoor area to be soil with vegetative cover, which encourages birds to come outdoors and accommodates natural behaviors. Organic producers must ensure that vegetation does not provide harborage to pests, as required under FDA requirements (21 CFR 118.4(c)(3)). For example, vegetation in outdoor areas must be kept at a short enough height to ensure it does not harbor pests. FDA draft guidance¹³ recommends that vegetation should be maintained to less than 6 inches in height.

(Comment) Comments also stated that doors, as required by AMS, would directly conflict with the FDA requirement to prevent stray poultry, wild birds, cats, and other animals into poultry houses. Comments stated that any door to allow organic birds to move between the indoors and outdoors would inevitably lead to the movement of other animals between the outdoors and indoors, and that failure to prevent this movement would conflict with the FDA requirements.

(Response) The FDA SE rule includes required measures to prevent SE contamination, including biosecurity and pest control measures (21 CFR part 118). Under this final rule, organic producers must provide access to the outdoors (§§ 205.241(a), 205.241(c)(1)). To also comply with FDA requirements, organic producers need to take measures to prevent wild animals and pests from moving freely between the outdoors and indoors. For example, producers could: use visual deterrents to discourage wild birds in or around housing; set traps for pests outdoors and indoors; use perimeter fences to keep stray or wild animals out of outdoor areas; reduce

access to feed indoors by managing spilled feed; or design exit areas on housing to prevent wild birds from entering the house.

(Comment) Several comments noted that soil can be contaminated with persistent synthetic chemicals, including dioxins, and specifically, polychlorinated dibenzo-*p*-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), and polychlorinated biphenyls (PCBs). The comments noted that the requirement for birds to be outdoors on soil would result in elevated levels of these substances in organic eggs—through ingestion of soil or vegetation by birds—and subsequently pose health risks to humans that ingest organic eggs. Comments noted that dioxins are widespread and persistent in the environment, and comments cited studies that found that eggs from free range hens contain higher levels of dioxins. Additionally, comments noted risks of bioaccumulation into eggs of heavy metals such as lead and mercury, as well as DDT, when birds are outdoors on soil.

(Response) No provision under this rule allows for the sale of eggs that contain substances—including dioxins, heavy metals, and PCBs—in excess of levels established by the FDA or other agencies. This rule does not change the requirement that producers, regardless of whether or not they are organic, must comply with FDA requirements. Additionally, organic regulations at § 205.671 address unavoidable residual environmental contamination (further defined at § 205.2) and do not allow for the sale of contaminated agricultural products as organic. For more information on action levels published by the FDA, see FDA’s Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed.¹⁴

14. Vegetation in Outdoor Areas

(Comment) AMS received many comments stating that vegetation should be required in outdoor areas for birds. Comments noted that vegetation is important for birds to engage in the natural behavior of foraging and that denuded soil increases health risks for flocks. Additionally, comments noted that vegetated soil benefits soil and water quality compared to bare soil by reducing water runoff, preventing erosion, and taking up nutrients. Most comments recommended the outdoor area be covered with at least 50 percent vegetation, while some comments recommended AMS require up to 90 or

100 percent vegetative cover in outdoor areas.

(Response) AMS agrees that vegetation in outdoor areas has benefits that warrant this requirement. We have revised the final rule at § 205.241(c)(2) as follows: “at least 50 percent of outdoor space must be soil. Outdoor space with soil must include maximal vegetative cover appropriate for the season, climate, geography, species of livestock, and stage of production . . .” This requirement recognizes the important function and role of vegetation in the outdoor space, including its benefits to soil health and to birds by allowing for the expression of natural behaviors. Vegetation in outdoor areas must be maintained to ensure it does not provide harborage for rodents and other pests. For example, vegetation in outdoor areas must be kept at a short enough height to ensure it does not harbor pests. FDA draft guidance recommends that vegetation should be maintained to less than 6 inches in height.¹⁵

Additionally, AMS has included at § 205.241(d)(4) an allowance to temporarily confine birds for “risk to soil or water quality, including to establish vegetation by reseeding the outdoor space.” Birds may not be confined any longer than required to seed the area and allow for the vegetation to establish itself. This allowance for temporary confinement was included by AMS to acknowledge that some producers may need to reseed outdoor areas to meet the vegetation requirement included in § 205.241(c)(2) and that birds may need to be kept off the area to allow seeds to germinate and establish. The minimum outdoor space requirements do not apply when birds are temporarily confined under this provision, and a producer may still allow birds outdoors. For example, if 50 percent of the outdoor area is covered by gravel, birds may be allowed into this portion of the outdoor area. Providing a smaller outdoor area when confining animals to reseed the outdoor area and establish vegetation would be in compliance with the provision at § 205.241(d)(4).

(Comment) AMS received a number of comments that contact with gravel or pavement does not allow chickens to exhibit their natural instinctive behaviors. Many comments requested we reduce the amount of outdoor area that can be anything but soil (including soil with vegetative cover) from 50 percent to 25 percent or less.

¹³ U.S. FDA, Draft Guidance for Industry: Questions and Answers Regarding the Final Rule, Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation (Layers with Outdoor Access). Available at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm360028.htm>.

¹⁴ <http://www.fda.gov/food/guidanceregulation/ucm077969.htm>.

¹⁵ <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm360028.htm>.

(Response) AMS has retained the requirement as proposed that outdoor areas be at least 50 percent soil, but we have also revised the requirement to add a requirement for maximal vegetative cover in the outdoor soil area. We think this revision communicates the importance of contact with the ground yet still provides an allowance for producers to use other surfaces as necessary. For example, gravel surfaces may be necessary to ensure adequate drainage adjacent to a house. A producer could still provide a surface or materials in this outdoor area that would accommodate the natural behavior of birds, including scratching and dust bathing.

(Comment) AMS received many comments about whether vegetation would be permitted in outdoor areas, since the proposed rule stated at section 205.241(c)(8), “At least 50 percent of outdoor access space *must be soil*”. Comments stated that bare soil could lead to degradation of soil and the runoff from bare soil could contaminate nearby water resources.

(Response) AMS understands from comments received that there was confusion about whether outdoor areas could be vegetated or if AMS would require outdoor areas to be cleared of vegetation. In the final rule, AMS has revised the outdoor space requirement to clarify that outdoor soil areas must be covered with vegetation given site-specific conditions.

(Comment) AMS received a few comments about whether land used for outdoor access for poultry must be certified organic and meet the same requirements as land used in the production of organic crops or pasture. One comment recommended that producers not be allowed to remove the top soil from the outdoor area and replace it with another fill material to forego the land transition period requirement (*i.e.*, a three-year period without prohibited synthetic substances).

(Response) AMS agrees that land used to provide outdoor access to poultry must be certified as part of an organic system plan. The USDA organic regulations require that organic agricultural products fed to livestock be organically produced. Additionally, the regulations require that crops be produced from land to which no prohibited substances, including synthetic chemicals, have been applied during the three years immediately preceding the harvest of the agricultural product. As birds may consume vegetation from land used to provide outdoor access, this land must meet the same requirements as used to produce

any other organic crop. The implementation period for this final rule takes into account the possibility that producers may need to transition land to meet outdoor space requirements.

15. Enrichments and Bird Training

(Comment) AMS received many comments that the requirement for “suitable enrichment” in outdoor areas was too subjective. Some comments recommended AMS remove this part of the requirement, while other comments recommended AMS specify the number and types of enrichments required. Many other comments noted that enrichments outdoors would attract other animals and violate FDA requirements for shell egg producers to prevent SE contamination of eggs. Some comments requested AMS clarify how the requirement for suitable enrichment outdoors applies to broiler production.

(Response) In response to comments, AMS has removed the requirement that outdoor areas must have suitable enrichment to entice birds to go outside in the final rule. See AMS’s response to comments about FDA regulations in the section above on FDA regulations and food safety. AMS has, however, amended the rule at § 205.241(c)(2) to require at least half of the outdoor area to be soil with vegetative cover, which provides an environment that encourages birds to come outdoors. Additionally, we have retained the requirement in the final rule that outside access and door spacing be designed to promote and encourage outside access for all birds on a daily basis. Producers must still meet the general requirements of § 205.241(a) and provide living conditions that accommodate the health and natural behavior of birds, including: year-round access to outdoors; shade; shelter; exercise areas; fresh air; direct sunlight; clean water for drinking; materials for dust bathing; and adequate outdoor space to escape aggressive behaviors.

(Comment) Several comments noted that suitable enrichments should be required indoors for broilers. A comment stated that perches are of questionable benefit to broiler-type birds and that a general requirement for indoor enrichment for broilers would be beneficial. A comment recommended that beneficial indoor features might include straw bales, string, deep litter, and dust baths.

(Response) In the final rule, AMS has not included a perch or indoor enrichment requirement for broilers. AMS may undertake further work on this topic, with the assistance of the NOSB, as appropriate. However, broiler producers must meet the requirement at

§ 205.241(b)(1), which requires that birds be able to engage in natural behaviors indoors. Producers should work with their certifier to determine if birds are able to engage in natural behaviors indoors.

(Comment) Several comments noted the benefits of covered areas in the outdoor space for birds and recommended AMS require these features in outdoor areas. Comments noted that birds will be encouraged to go outdoors if they can seek and find safety from overhead predators under trees, roofs, or other structures.

(Response) AMS agrees that protection from predators could be important to encourage birds to use outdoor areas. Furthermore, overhead protection could reduce mortality by reducing predation. However, in the final rule, AMS has not included a specific requirement to provide covered areas outdoors. Producers are required to promote and encourage outside access in the final rule (§ 205.241(c)(1)), and overhead protection may be used to meet this requirement. However, AMS has not specified exactly how producers must promote and encourage outside access. We believe this flexibility is important to allow producers to implement practices that are best suited to their operations, while still establishing a clear standard for producers to promote and encourage outdoor access and while protecting birds from disease and predation.

16. Temporary Confinement—Weather

(Comment) AMS received many comments about temporary confinement for air temperatures that are under 40 °F or above 90 °F. One comment stated that allowing birds to go outdoors at 40 °F would cool down the barn quickly and create moisture issues. Other comments noted that additional fuel would be required to maintain indoor temperatures if doors were opened during cool weather and that birds would require more feed to compensate for the energy required to maintain their body temperature. Comments on the upper limit proposed by AMS noted that cooling systems in poultry houses would not work as designed with doors open, and that birds would be subjected to additional stress that could result in higher incidence of illness or death. Some alternate recommendations for the temperature range were 55–90, 50–90, 60–90, and 50–85 °F. Meanwhile, some comments supported removing any lower or upper limits and instead defining inclement weather. Additionally, several comments requested AMS clarify if producers are required to provide birds with access to

the outdoors if the temperature is only within the range of 40 °F and 90 °F for a short period of time in the day.

Comments stated that such a requirement could be impractical for producers that may not be available to open doors at any time on a given day.

(Response) Organic regulations already include a definition of the term “inclement weather” at § 205.2. In the proposed rule, AMS did not suggest changes to this definition, but we did propose to include a specific temperature range, outside of which producers could temporarily confine birds. The temperature range was proposed to ensure consistent practices between producers for temporarily confining birds due to weather. However, as noted by comments, temperature alone is not necessarily an indicator of inclement weather. For example, humidity can amplify the effect of high temperatures. Information from one poultry breeding company indicates birds experience extreme heat stress at a temperature of 82 °F when the relative humidity exceeds 75 percent. However, at 20% relative humidity, birds experience a similar degree of heat stress once the temperature reaches 100 °F.¹⁶

The final rule allows for temporary confinement of birds for, “inclement weather, including when air temperatures are under 40 °F or above 90 °F.” AMS notes that weather may still qualify as inclement weather (§ 205.2) even within this temperature range. For example, excessive precipitation and very violent weather can occur when temperatures are within 40 °F and 90 °F. Likewise, weather may meet the definition of inclement weather within the range of 40 °F and 90 °F if the relative humidity is very high and the air temperature is nearing 90 °F, or under extremely windy conditions. As inclement weather is defined as weather than can cause physical harm to a species, a producer would still be in compliance with § 205.241(d)(1) if birds were confined at temperatures that did not exceed 90 °F but when the weather could cause physical harm.

17. Temporary Confinement—Stage of Life

(Comment) AMS received comments that layers should be required to go outdoors before 16 weeks of age. Other comments noted that pullets can be moved from dedicated pullet rearing facilities to dedicated layer houses when pullets are older than 16 weeks;

these comments also requested additional time to allow for confinement until pullets are moved to layer houses. One comment cited that the allowance for 16 weeks of temporary confinement conflicts with AMS’s proposed requirement at § 205.241(c) that producers, “provide access to the outdoors at an early age to encourage (*i.e.*, train) birds to go outdoors.” Comments noted at least one study that found birds used outdoor areas more when allowed outdoor access earlier in life. Some comments noted that layers are fully feathered around 8 weeks of age and should therefore be provided with access to the outdoors at 8 weeks of age.

(Response) The final rule allows producers to temporarily confine layers for up to 16 weeks of age. AMS agrees that 16 weeks of confinement from the outdoors is not always required. In fact, many organic producers already provide outdoor access for layers prior to 16 weeks of age. AMS also recognizes, however, that many layer operations use vaccination programs to protect bird health and prevent disease, and in many cases, birds receive vaccines during the first 16 weeks of life. Requiring outdoor access before this age could compromise bird health. Birds that are over 16 weeks of age may not be confined under the provision at § 205.241(d)(2)(ii). Any confinement of birds beyond 16 weeks of age must be done only in accordance with other provisions at § 205.241(d). In any case, producers must describe their practices for confining birds in their Organic System Plan, and certifiers must approve these plans.

(Comment) AMS received several comments that turkeys are not ready to go outdoors by four weeks of age, as proposed by AMS, because full feather plumage is not complete until approximately seven weeks of age. The comments requested turkeys be addressed specifically in the regulations, as turkeys have different requirements than chickens or other bird species.

(Response) AMS recognizes that turkeys may require a longer period of time than chickens for feather development. In response to comments, AMS has revised the final rule at § 205.241(d)(2)(iii) to allow temporary confinement of turkeys and other species until fully feathered. The requirement for chickens (*Gallus gallus*) remains unchanged from the proposed rule and allows temporary confinement for the first 4 weeks of life for broilers and the first 16 weeks of life for pullets.

18. Temporary Confinement—Disease

(Comment) AMS received many comments about temporary confinement for bird health, safety, or well-being at § 205.241(d)(3). Specifically, comments showed concern that the requirement for a documented disease in the region or relevant migratory pathway would compromise a producer’s ability to proactively confine animals to prevent exposure of a flock to disease. One comment suggested that AMS allow birds to be kept inside when there is a reasonable expectation of disease that can rapidly spread through poultry. Another comment suggested that detection of a disease, rather than occurrence of a disease, should be sufficient grounds to confine birds. Other comments urged AMS to allow confinement when recommended by a State or Federal animal health official. Additionally, comments stated that the terms “region,” “migratory pathway,” and “documented occurrence” were not clear and could lead to varying interpretations, including extended periods of confinement for birds in the absence of real risk. One comment suggested that AMS remove references to “region” and “migratory pathway” and allow confinement only in the case of a current local occurrence of a disease.

(Response) The organic livestock and poultry standards allow temporary confinement of poultry for “conditions under which the health, safety, or well-being of the animal could be jeopardized.” In the case of risks posed by highly contagious and rapidly spreading disease, AMS recognizes that it is complicated to precisely assess disease threats, and AMS recognizes that various animal health experts, including State and Federal officials, serve important roles in monitoring disease threats and communicating those threats to producers. In response to comments, AMS has revised the final rule to provide additional flexibility for confining animals to prevent the spread of disease and protect bird health. To temporarily confine birds under this provision, producers must be able to demonstrate that the birds’ health, safety, or well-being are jeopardized by access to the outdoors. Plans to temporarily confine birds must be part of the producer’s organic system plan approved by the certifying agent. Producers must keep records of confinement and records to justify confinement (see §§ 205.103 and 205.241(d)).

¹⁶ http://www.hyline.com/userdocs/pages/TB_HEAT_ENG.pdf.

19. Temporary Confinement—Nest Box Training

(Comment) AMS received several comments that the allowed period (2 weeks) for confining birds for nest box training (*i.e.*, to train birds to lay eggs in designated nest areas) was inadequately short. Comments stated that additional time was required to ensure birds would lay eggs in nest boxes. Comments stated that more time than proposed would reduce the number of eggs laid outside of nest boxes and the time required to collect these eggs. Comments also noted that eggs laid outside of nest boxes could be more at risk of *Salmonella* contamination through direct contact with manure and dirt. Some comments suggested that AMS modify the requirement to allow as much time as required for birds to reach a certain percentage of the total expected egg production. For example, a comment suggested we allow birds to be confined for nest box training until at least 80 percent of the expected daily egg production could be documented. Other comments recommended increasing the allowed time period to three or four weeks, while others recommended a period of six to eight weeks for nest box training.

(Response) AMS recognizes that nest box training is important, as it reduces eggs laid outside of nests; simplifies management; and reduces contact between eggs and manure, dirt, and other substances. AMS understands that different species and breeds may require different amounts of time for nest box training. In response to comments, AMS has revised the final rule to align with the NOSB's recommendation. Birds may be confined to train birds to use nests, but the period must not exceed five weeks.

20. Temporary Confinement—Other

(Comment) One comment recommended AMS add the word “temporarily” to the last sentence of § 205.241(d) to be clear that confinement cannot be permanent or lasting (see definition of “temporary and temporarily” in § 205.2).

(Response) AMS agrees with the comment, and we have revised § 205.241(d) to clarify, “Operations may temporarily confine birds” for reasons at § 205.241(d).

(Comment) AMS received several comments that the proposed requirement “each instance of confinement must be recorded” was unnecessary. Comments cited the existing requirement for recordkeeping and did not think it was practical or reasonable to require producers to

record every single instance of confinement, such as every time birds were put inside at night. Some comments noted that producers have written standard operating procedures that describe when birds are confined and this would serve as a sufficient record of confinement.

(Response) AMS agrees that the value of requiring producers to record each instance of confinement may be limited, especially when the confinement is routine, such as confinement of birds inside a poultry house at night for the birds' safety. However, AMS thinks it is also important that certifiers be able to readily assess a producer's compliance with the regulations. By requiring producers to record each instance of confinement, certifiers can easily identify instances of confinement, including the reason for confinement. These records can then be reviewed with third-party information to verify the reason for confinement. For example, a certifier can check weather information for the area to confirm there was inclement weather on the dates when animals were confined or confirm the occurrence of a disease in the region for that time. Meanwhile, AMS has been promoting recordkeeping requirements for organic producers (*i.e.* Sound and Sensible¹⁷ initiative), aimed at making organic certification more accessible, attainable, and affordable while maintaining high standards, ensuring compliance, and protecting organic integrity. AMS agrees that the proposed requirement at § 205.241(d) to record each instance of confinement may not result in records that would help certifiers ensure compliance. In the final rule, AMS has revised § 205.241(d) to clarify that confinement must be recorded. Producers do not need to record each instance of confinement if the producer has described the reasons for routine temporary confinement (*i.e.*, a standard operating procedure) in their Organic System Plan. For example, a producer may describe that birds are confined nightly, or that pullets are confined until 8 weeks of age, in their OSP instead of recording these instances of confinement on a daily basis. AMS notes that producers must also comply with § 205.103, including § 205.103(b)(4) which requires records be sufficient to demonstrate compliance with the regulations. If a certifier determines that the description of practices in the producer's standard operation procedure, for example, are not sufficient to demonstrate when birds are actually confined, the certifier may

require as a corrective measure that the producer modify their standard operation procedure or keep records that will be sufficient to demonstrate animals are provided with outdoor access in compliance with the regulations.

(Comment) AMS received a comment that producers should be required to provide additional indoor space if poultry are confined for more than one week. The comment suggested that AMS require indoor space equivalent to the total combined indoor and outdoor space that is otherwise required when birds are not temporarily confined.

(Response) AMS recognizes that the total space per bird is reduced when birds are temporarily confined. However, producers are not able to predict events that require temporary confinement, such as disease outbreaks. If it were necessary to confine animals for more than one week, a producer may need to cull perhaps half of the entire flock in order to meet the requirement proposed by the commenter. In cases where birds could not be sold as organic, the financial loss to producers would be great, or a producer could be forced to destroy a large portion of the flock. AMS does not think this is warranted for circumstances that are beyond a producer's control.

(Comment) AMS received a comment that the period for temporary confinement for youth projects following the conclusion of a fair or demonstration should be extended from 24 hours to one week, to ensure that birds are healthy and will not pass any sickness or disease acquired at these events to other birds.

(Response) The final rule maintains an allowance to confine birds up to 24 hours after the birds have arrived home at the conclusion of a youth event. However, AMS notes that birds may be temporarily confined for a longer period of time in accordance with § 205.241(d)(3), which allows for temporary confinement because of conditions under which the health, safety, or well-being of animals could be jeopardized. Producers must describe their practices in their organic system plan and work with their certifier to ensure that temporary confinement practices meet the requirements.

21. Soil and Water Quality

(Comment) AMS received comments that increased outdoor access could contaminate water systems, as a result of birds being outside on soil. Comments stated that water runoff from outdoor areas containing manure would need to be managed to comply with U.S. Environmental Protection Agency

¹⁷ <https://www.ams.usda.gov/report-presentation/sound-sensible>.

(EPA), state, or local requirements. Comments stated that compliance could require landscape modifications, such as installation of berms or drainage systems around poultry barns. These modifications could be expensive and burdensome, as they can require federal and state permits.

(Response) An overarching requirement of organic production is that soil and water quality be maintained or improved (7 CFR 205.200). To minimize potential impacts to soil or water quality from livestock with outdoor access, AMS has included a requirement in the final rule for vegetation in outdoor areas (§ 205.241(c)(2)). Vegetation acts to hold soil, reduce water runoff, and take up nutrients deposited in animal feces. Clean Water Act National Pollutant Discharge Elimination System (NPDES) permit requirements for concentrated animal feeding operations do not encompass outdoor areas that have vegetation in the normal growing season. (See 40 CFR 122.23(1)(ii)). Therefore, AMS does not expect this rule would adversely alter an organic operation's status or costs of compliance with respect to EPA regulations for concentrated animal feeding operations, nor does it expect the rule to subject operations to additional requirements. This rule does not affect NPDES compliance requirements for other aspects of the poultry growing areas. Other federal, state, or local regulatory requirements may apply to the facilities as well.

(Comment) AMS received comments that requiring birds to be outside on soil would lead to contamination of soil due to excess nutrients from manure. Comments requested that AMS not require outdoor access.

(Response) AMS recognizes concerns about impacts to soil quality, and the final rule includes provisions to protect soil quality. However, AMS disagrees with comments that soil quality should be addressed by removing the requirement for outside access altogether. In the final rule, § 205.241(e) requires producers to manage manure in a manner that does not contribute to contamination of crops, soil, or water. Section 205.241(d)(4) allows for temporary confinement of birds because of risk to soil quality. Each producer will need to manage soil quality as appropriate to their climate, soil type, and size of outdoor area. AMS notes that managing soil in outdoor areas may also include feed management, as excess nutrients provided in feed are excreted by birds. Producers may attain resources and assistance with feed management and manure management by contacting

the USDA's Natural Resources Conservation Service (NRCS).¹⁸

22. Other Comments—Avian Living Conditions

(Comment) AMS received several recommendations to include requirements for slow-growing poultry breeds or for breeds that are suited to free-range conditions. Some comments recommended that AMS set a minimum age at slaughter or a maximum daily growth rate requirement to ensure sustainable weight gain and animal health.

(Response) AMS has not included a requirement for slow-growing breeds or minimum age requirements for slaughter in the final rule. AMS agrees that this topic may deserve further attention and input from stakeholders, and we may ask the NOSB to explore this topic.

(Comment) AMS received comments that current organic regulations require access to the outdoors and that these new rules are not necessary for AMS to require outside access or for AMS to prohibit porches as outside access. The comments cited existing regulations at § 205.239(a)(1), which include a requirement that producers establish and maintain “year-round access for all animals to the outdoors . . . Continuous total confinement of any animal indoors is prohibited.”

(Response) AMS acknowledges that current organic regulations require outdoor access for poultry, but we disagree with the argument that current regulations could achieve the same results as the regulations revised by this final rule. As recommended by the NOSB, AMS is implementing this final rule to establish specific regulations for the care of livestock, as authorized under OFPA (7 U.S.C. 6509(d)(2)).

(Comment) Some comments stated that the requirements in § 205.241(b)(1) and § 205.241(b)(11) were duplicative and that the sections should be combined in a single requirement to streamline the requirements.

(Response) AMS agrees with these comments and has moved the text from § 205.241(b)(11) as proposed to § 205.241(b)(1). We have removed the originally proposed text at § 205.241(b)(1) in the final rule.

(Comment) A comment suggested moving the requirement on litter at § 205.241(b)(4)(iii) to clarify that the requirement applies to all types of poultry houses and not just houses with slatted or mesh floors.

(Response) AMS agrees with the comment that the requirement, “litter

must be provided and maintained in a dry condition,” proposed at § 205.241(b)(4)(iii) is more appropriately placed as a standalone requirement. In the final rule, this requirement has been moved to § 205.241(b)(6).

(Comment) A comment noted that proposed § 205.241(b)(4)(i), which allows, “mesh or slatted flooring under drinking areas to provide drainage,” was unnecessary and did not actually impose a requirement since the section only states this type of flooring “may” be used.

(Response) AMS agrees that the allowance for mesh or slatted flooring under drinking areas is not necessary, as nothing else in the requirements prohibits use of mesh or slatted flooring under drinking areas. We have included a separate requirement to maintain litter in a dry condition. In the final rule, AMS has removed § 205.241(b)(4)(i) as proposed. Additionally, AMS has removed § 205.241(b)(4) of the proposed rule, and moved the requirement proposed at § 205.241(b)(4)(ii) to § 205.241(b)(7). The requirements on scratch areas, dust baths, and litter now appear at §§ 205.241(b)(6) and (7).

(Comment) Some comments asked for clarification on the meaning of the term “litter” as used in the avian living section. Comments stated that it was not clear if producers are required to add litter material for birds or if dehydrated manure would suffice without any additional litter. Another comment recommended AMS use the term “bedding” in place of litter, as this term is used elsewhere in the regulations.

(Response) AMS has used the term “litter” in § 205.241, as this term is commonly used by avian producers. The term has not been further defined in § 205.2. Litter includes substrates used to absorb moisture and dilute manure. Litter also provides birds with the opportunity to dust bathe and to express foraging and scratching behaviors. Common types of litter include wood shavings or chips, straw, rice hulls, and sand. The final rule at § 205.241(b)(6) requires that litter be provided and maintained in a dry condition. AMS has not specified the amount of litter that must be provided. However, the rule does require that litter be provided. An absence of litter would not be in compliance with this requirement. Litter should be provided in amounts required to absorb moisture, dilute manure, and to allow birds to express natural behaviors such as dust bathing, foraging, and scratching.

(Comment) Some comments stated AMS's requirements were not based on scientific evidence and appeared to be made by AMS arbitrarily, including the

¹⁸ <http://offices.sc.egov.usda.gov/locator/app>.

specific indoor and outdoor space requirements for birds.

(Response) The provision on indoor and outdoor space requirements in this rule are based on nine separate NOSB recommendations submitted to the Secretary. In developing these recommendations at their public meetings, the NOSB considered technical information and public comments, including comments from organic livestock producers, animal welfare experts and the scientific community. AMS is establishing these requirements, in consideration of the NOSB's recommendations, to assure consumers that organically produced products meet a consistent standard.

X. Transport (§ 205.242(a))

A. Description of the Final Rule

1. Summary of the Final Rule

New § 205.242(a)(1) requires that animals are clearly identified during transport. AMS's approach requires that animals are clearly identified but provides flexibility on how the identity is maintained during transport.

New § 205.242(a)(2) sets minimum fitness requirements for livestock to be transported. Section 205.242(a)(2)(i) requires that calves have a dry navel cord and the ability to stand and walk without assistance, if they are to be transported. This provision would apply to transport to buyers, auction facilities, or slaughter facilities. Beef cattle and dairy cattle producers may transport calves on the farm before the navel is dried and the calves can walk. Section 205.242(a)(2)(ii) prohibits transport of non-ambulatory animals to buyers, auction facilities, or slaughter facilities. These animals may either be given medical treatments and cared for until their health conditions improve, so that they are able to walk, or they may be euthanized.

New §§ 205.242(a)(3) and (4) set minimum standards for the trailer, truck, or shipping container used for transporting organic livestock. The mode of transportation is required to provide seasonal-appropriate ventilation to protect animals against cold or heat stress. This provision requires that air flow be adjusted depending on the season and temperature. In addition, bedding is required to be provided on trailer floors as needed to keep livestock clean, dry, and comfortable. If roughage is used as bedding, the bedding needs to be organically produced and handled. Bedding is not required for poultry crates.

Section 205.242(a)(5) requires that all livestock be provided with organic feed and clean water if transport time

exceeds 12 hours. The 12-hour time period includes all times during which the animals are on the trailer, truck, or shipping container, even if these modes of transportation are not moving. In cases such as poultry slaughter in which requirements do not allow feed 24 hours before slaughter, producers and slaughter facilities need to ensure that transport time does not exceed 12 hours. After 12 hours of transport, the birds would need to be fed, which may prolong the time to slaughter. The certified operation must present records—which verify that transport times meet the 12 hour requirement—to the certifying agent during inspections or upon request.

New § 205.242(a)(6) requires that operations that transport livestock to sales or slaughter have emergency plans in place that adequately address problems reasonably possible during transport. Such emergency plans could include how to provide feed and water if transport time exceeds 12 hours, what to do if livestock escape during transport, or how to euthanize an animal injured during transport. Shipping and/or receiving operations need to include these plans in their OSPs.

B. Discussion of Comments Received

1. General Transport, Transport to Slaughter, and Identification of Organic Livestock

(Comment) One comment asked AMS to clarify whether § 205.242(a)(1), which regulates transportation of organic livestock, applies to transport in general or only transportation to slaughter. Other comments expressed concern over the requirement that organic livestock must be transported in designated pens. The comments noted that while identification of organic livestock during transport is essential, requiring designated pens would be burdensome. In practice, identification is generally done through ear tags or other methods, and that requiring designated pens is burdensome.

(Response) Section 205.242(a)(1) applies to transport of organic livestock to buyers, auction, and slaughter facilities. AMS agrees that requiring identification of pens during transport for organic livestock may not be necessary to maintain an audit trail and organic integrity. AMS has amended the language in § 205.242(a)(1) to remove the requirement for designating and identifying organic pens during transport, changing the text to read: Certified organic livestock must be clearly identified as organic, and the identity must be traceable during

transport to buyers, auction, and slaughter facilities.

2. Fit for Transport

(Comment) Several comments pointed out that the term 'sick' in § 205.242(a)(2)(ii) should be defined to reduce the possibility that animals are withheld from slaughter due to a minor ailment that does not impact the quality of slaughter products. The comments suggested that the language, "sick, injured, weak, disabled, blind, and lame" in this section be replaced with "non-ambulatory," which is consistent with humane slaughter practices and readily verified. Several comments also requested that § 205.242(a)(2) be changed to specify that livestock must be ambulatory to be fit for transport to buyers, auctions, or slaughter facilities.

(Response) AMS agrees that animals should not be withheld from slaughter due to a minor ailment that does not impact the quality of slaughter products and has made the suggested change in § 205.242(a)(2)(ii). In the final rule, the terms "Sick, injured, weak, disabled, blind, and lame," have been replaced with "non-ambulatory." As defined in defined at 9 CFR 309.2(b), non-ambulatory is a condition recognized within the industry and provides a more standardized criterion to evaluate.¹⁹ AMS points out that the definition at 9 CFR 309.2(b) lists examples of conditions that may make livestock non-ambulatory. However, some of these animals may still be able to ambulate. Every situation is case-specific and needs to be evaluated by the certified operator.

3. Transport of Calves

(Comment) Two comments were concerned with the requirement in the proposed rule that calves must not be transported to auction or slaughter facilities until their navel cords are dried and they have the ability to stand and walk on their own. Both comments suggested changes to the rule to allow for more flexibility around when calves could be transported. One comment requested changes to the rule to allow calves with a dry, clean, and disinfected navel cord to be transported, and the other suggested that the rule be revised to set a minimum age for calf transport

¹⁹ 9 CFR 309.2(b): All seriously crippled animals and non-ambulatory disabled livestock shall be identified as U.S. Suspects and disposed of as provided in § 311.1 of this subchapter unless they are required to be classed as condemned under § 309.3. Non-ambulatory disabled livestock are livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions.

instead of specific navel characteristics. AMS also received comments from organizations that represent hundreds of organic dairy operations. These organizations supported the proposed requirement in § 205.242(a)(2)(i).

(Response) AMS reviewed and considered comments from all organizations that reviewed and analyzed the proposed rule. Based on the widespread support of this subsection, AMS did not feel that a change to the regulation was warranted.

4. Bedding

(Comment) Several comments expressed opposition to the use of bedding for transport of livestock over long distances because of the risk of animal injury due to certain types of bedding or the need to discourage laying down in trailers where crowding may be an issue. One comment asked for clarification on whether rubber mats would be an acceptable form of bedding during transport. Several comments from stakeholders recommended that bedding also be a requirement for poultry crates, stating that poultry should also be kept clean, dry, and comfortable during transport.

(Response) Section 205.242(a)(4) includes the phrase “as needed,” which allows for the discretion of the certified operation and their certifier when determining if the use of bedding is appropriate based on risk of injury to the livestock and other welfare concerns. AMS believes that this language describes the requirements with sufficient clarity, while not being overly prescriptive. Certified operations should describe in their organic system plan how they will determine whether or not bedding is necessary during transport. Certifying agents should assess this information when reviewing the certified operators’ organic system plan for compliance. In some cases, bedding may not be required because of other animal welfare considerations. Regarding the acceptability of rubber mats during transport, there is nothing in the proposed rule that prohibits the use of rubber mats. The bedding exemption for poultry crates is consistent with the 2011 NOSB recommendation, and AMS is not making changes to require bedding for these livestock. However, a minor change has been made to § 205.242(a)(4) to clarify that bedding is not required for poultry crates.

(Comment) One certifying agent addressed a position AMS made in the preamble to the proposed rule regarding the use of nonorganic bedding in transport, which would render animals nonorganic. While the commenter does

not feel that the use of nonorganic bedding should be allowed, they suggested that if it were used unintentionally, the stated sanction is impractical and harsh since bedding in trailers and temporary pens would be in contact with animals for only a short period of time.

(Response) Certifiers are responsible for taking appropriate enforcement actions depending on the nature of the violation. AMS agrees that stating specific sanctions for non-compliant practices is not appropriate. Compliance procedures under the USDA organic regulations are specified under 7 CFR 205.660–668.

5. Transport Exceeding 12 Hours

(Comment) Opposing comments were received on the topic of transport exceeding 12 hours. Several comments indicated that 12 hours was too long for livestock to go without feed and water because animals may have been without feed and water prior to loading for transport. These comments stated that it is cruel not to provide feed and water either continuously or at least every 6 to 8 hours. Conversely, several comments stated that livestock are rarely trucked for longer than 12 hours but that, if they are, they can go without feed and water for longer than 12 hours. One comment stated that if livestock are to be trucked for longer than 12 hours to slaughter or auction, it is likely that the transportation load will be larger and may not be exclusively organic. This comment stated that if the 12-hour rule is to be implemented, it will decrease the availability of transport for organic livestock and increase transport cost, especially for small- to mid-size operations. It was recommended that AMS rely on the federally mandated Twenty Eight Hour Law and remove the requirement for access to feed and water after 12 hours of transport. Another comment stated that the 12-hour requirement may be a hardship to the industry and is not important to birds in transit or waiting for slaughter. The comment stated that birds in strange cages or transport racks are not concerned about food. Several comments requested clarification on whether the 12-hour time period included lairage at the slaughter facility.

(Response) The 12-hour time period was recommended by the NOSB in their 2011 NOSB recommendation on *Animal Handling and Transport to Slaughter*. AMS has determined that the NOSB recommendation, which states that water and organic feed must be available if transport time exceeds 12 hours, is practical and humane. AMS’s decision on transport time also aligns

with several animal welfare organization positions. With regard to transporting poultry, one animal welfare organization has a 10-hour limit for broilers, and another has no specific time limit for broilers but recommends that animals are taken without delay to their destination. With regard to whether this time frame includes lairage at the slaughter facility, once livestock arrive at the slaughter facility, they must be handled in compliance with § 205.242(b)(1) for mammalian species or § 205.242(c)(1) for avian species.

6. Twenty-Eight Hour Law

(Comment) Several comments received stated that the Twenty-Eight Hour Law provides minimal protection for animals, excludes poultry, and is under-enforced by APHIS. Some comments stated that the law is out of date and inhumane, and they recommended that the proposed rule be amended to limit transport of organically raised animals (including poultry) without food, water, and rest to no more than eight hours. These comments further recommended that the USDA develop a specific inspection program to adequately ensure compliance with these transportation standards. One comment recommended that the Twenty-Eight Hour Law and the requirement regarding noncompliance records also apply to poultry. Even though this regulation currently excludes poultry, this comment noted that the NOP definition of livestock includes poultry and that the consumer expectation of meat carrying the organic label is that all livestock is subject to the same requirements. Another comment requested that the final rule provide a transport limit for poultry since it is not covered under any federal regulation.

Certifying agents and other industry groups commented that § 205.242(a)(5)(i) does not clearly specify the regulation for which the noncompliance records and subsequent corrective actions must be provided. They suggested that this section, specifically § 205.242(a)(5)(ii), directly reference the Federal Twenty-Eight Hour Law (4 U.S.C. 80502) and the regulations at 9 CFR 89.1–89.5. In addition, one comment suggested that a “Memorandum of Interview (MOI)” be added for incidents related to the transport of poultry; noncompliance records are currently not issued for incidents involving poultry since the transport and slaughter of birds are not covered by any federal regulation.

(Response) The intention of §§ 205.242(a)(5)(i) and 205.242(a)(5)(ii) in the proposed rule was to clarify the authority of the NOP, certifying agents,

and State organic programs to initiate compliance action if certified operations, or the transport operation that has been contracted by the certified operation to transport organic livestock, are found to have violated the Twenty-Eight Hour Law (49 U.S.C. 80502) and its regulations at 9 CFR 89.1–89.5. However, after consultation with APHIS, AMS has decided to remove reference to the Twenty-Eight Hour Law in the final rule. This is based upon the fact that common carriers are already subject to this law under APHIS. In addition, § 205.242(a)(5) provides that animals may not be transported for more than 12 consecutive hours without feeding and watering. This requirement is more stringent than the Twenty-Eight Hour Law. The USDA Animal and Plant Health Inspection Service (APHIS) can already take enforcement action based on the Twenty-Eight Hour Law and has standards for in-transit feed, water, and rest stations. Animals should be transported to the final destination in a manner that is not detrimental to the welfare of the animals. The role of Accredited Certifying Agents is to review transport times to verify that certified operations are in compliance with the 12 hour requirement and that the transport is not detrimental to the animal's welfare.

Accordingly, after consultation with APHIS, AMS has decided to remove reference to the Twenty-Eight Hour Law in the final rule. The final rule has been amended accordingly.

7. Responsibility and Organic Integrity During Transport and/or at Auction Facilities

(Comment) Several comments expressed concern over whose responsibility it is to maintain organic integrity/compliance with standards during transport. Some comments asserted that non-certified truckers would be responsible for compliance with bedding and feed requirements. One comment suggested adding language to the final rule to clarify that if animals are off-loaded during transport, the location must be certified if the animal is to retain organic status. One comment asked whether it is possible for organic livestock to maintain their organic status when they are kept at non-certified auction facilities while they are marketed and sold. The same comment asked whether the length of time the animal is at the facility or away from the original operation of origin and out of oversight of organic certification inspections impacts the organic status of the animal. One comment indicated that the proposed rule implies that the

responsibility for compliance of transportation would fall back solely on the producer and that often it is the purchaser of the livestock (a broker or slaughter company for example) that would be paying for the transportation. This comment states that the entity who pays is the one with the most leverage to set requirements for transportation and obtain records that will verify practices. There is concern that the new requirements cannot be verified adequately without direct observation. The commenter suggested that § 205.242(a)(5)(ii) and 205.242(a)(6) be changed to specify that the operation responsible for documenting that transportation adequately meets the requirements is the certified operation that arranged the transport.

(Response) The criteria for who is responsible for maintaining organic integrity and who has to be certified are provided in NOP 5031: Certification Requirements for Handling Unpackaged Organic Products Guidance and the NOP Instruction 4009: Who Needs to be Certified? Both documents can be found on the AMS Web site: <https://www.ams.usda.gov/>. An operation that handles bulk, unpackaged organic products (such as cattle, milk, or grain) must be certified organic. If animals are off-loaded, the site or facility must be certified organic. Operations that are only transporting livestock, and whose handling practices are supervised and approved by the certified operation and their certifying agent, are not required to be certified. In this case, organic compliance is the responsibility of the certified operator who is responsible for the transportation and is verified by their certifier. AMS has changed §§ 205.242(a)(5)(i) and 205.242(a)(6) to specify that the certified operation responsible for overseeing the transport of organic livestock is responsible for keeping verification records that demonstrate organic compliance during transport.

XI. Slaughter (§ 205.242(b) and (c))

A. Description of Regulations

1. Summary of the Final Rule

Slaughter and the Handling of Livestock in Connection With Slaughter

The requirements with regard to slaughter and handling of livestock in connection with slaughter are governed by separate authority applicable to both certified organic and non-organic livestock products. The final rule reiterates that compliance with these regulations, as determined by FSIS, is required for certified organic livestock operations.

New § 205.242(b) regarding mammalian slaughter clarifies the authority of the NOP, certifying agents, and State organic programs to review records related to humane handling and slaughter issued by the controlling national, federal, or state authority, and records of any required corrective actions if certified operations are found to have violated FSIS regulations governing the humane handling of mammalian livestock in connection with slaughter (note that AMS has separated mammalian from avian slaughter requirements due to the differences in how mammalian and avian livestock are handled and slaughtered). This new section, titled “Mammalian Slaughter,” governs mammals defined as “livestock” or “exotic animals” under the FSIS regulations. Under the FSIS regulations, “livestock” are cattle, sheep, swine, goat, horse, mule, or other equine. “Exotic animals” include antelope, bison, buffalo, cattalo, deer, elk, reindeer, and water buffalo. These regulations govern the handling and slaughter of the majority of mammalian animals used for food in the United States and apply to all operations that slaughter these animals.

New § 205.242(b)(1) requires certified organic slaughter facilities to be in full compliance with the Humane Methods of Slaughter Act (HMSA) of 1978 (7 U.S.C. 1901 *et seq.*) and its implementing FSIS regulations, as determined by FSIS. The HMSA requires that humane methods be used for handling and slaughtering livestock and defines humane methods of slaughter. In the HMSA, Congress found “that the use of humane methods in the slaughter of livestock prevents needless suffering; results in safer and better working conditions for persons engaged in the slaughtering industry; brings about improvement of products and economies in slaughtering operations; and produces other benefits for producers, processors, and consumers which tend to expedite an orderly flow of livestock and livestock products in interstate and foreign commerce.” The HMSA is referenced in the FMIA at 21 U.S.C. 603 and is implemented by FSIS humane handling and slaughter regulations found at 9 CFR part 309 and 9 CFR part 313. The FMIA provides that, for the purposes of preventing inhumane slaughter of livestock, the Secretary of Agriculture will assign inspectors to examine and inspect the methods by which livestock are slaughtered and handled in connection with slaughter in slaughtering

establishments subject to inspection (21 U.S.C. 603(b)).

All establishments that slaughter livestock, which include any certified organic operations that slaughter livestock, must meet the humane handling and slaughter requirements the entire time they hold livestock in connection with slaughter. FSIS provides for continuous inspection in livestock slaughter establishments, and inspection program personnel verify compliance with the humane handling regulations during each shift that animals are slaughtered, or when animals are on site, even during a processing-only shift. The regulations at 9 CFR part 313 govern the maintenance of pens, driveways, and ramps; the handling of livestock, focusing on their movement from pens to slaughter; and the use of different stunning and slaughter methods. Notably, FSIS inspection program personnel verify compliance with the regulations at 9 CFR part 313 through the monitoring of many of the same parameters proposed by the NOSB in 2011, including prod use, slips and falls, stunning effectiveness, and incidents of egregious inhumane handling.²⁰ The regulations at 9 CFR part 309 govern ante-mortem inspection and ensure that only healthy ambulatory animals are slaughtered and that non-ambulatory are euthanized and disposed of promptly. FSIS has a range of enforcement actions available regarding violations of the humane slaughter requirements for livestock, including noncompliance records, regulatory control actions, and suspensions of inspection.

Further, FSIS encourages livestock slaughter establishments to use a systematic approach to humane handling and slaughter to best ensure that they meet the requirements of the HMSA, FMIA, and implementing regulations.²¹ With a systematic approach, establishments focus on treating livestock in such a manner as to minimize excitement, discomfort, and accidental injury the entire time they hold livestock in connection with slaughter. Establishments may develop written animal handling plans and share them with FSIS inspection program personnel.

AMS added a new § 205.242(b)(2) for those certified organic facilities that slaughter exotic animals and voluntarily request FSIS inspection. FSIS also

provides, upon request, voluntary inspection of certain exotic animal species on a fee-for-service basis under the authority of the Agricultural Marketing Act of 1946. FSIS regulates the humane handling of the slaughter of exotic animals under the regulations at 9 CFR part 352.10, which require that exotic animals be slaughtered and handled in connection with slaughter in accordance with the requirements for livestock at 9 CFR part 309 and 9 CFR part 313. Violation of these regulations can result in a denial of service by FSIS.

New § 205.242(b)(3) requires that all certified organic slaughter facilities provide any FSIS noncompliance records or corrective action records relating to humane handling and slaughter to certifying agents during inspections or upon request. Not all violations of FSIS regulations result in a suspension of FSIS inspection services. In some cases, FSIS will issue a noncompliance record and the slaughter facility must perform corrective actions to bring the slaughter facility back into compliance. These records must be provided to certifying agents during inspection or upon request to verify that the slaughter facility is in full compliance and has taken all corrective actions. In addition, AMS recognizes that in the U.S. some slaughter facilities are regulated by the State for intra-state meat sales. In foreign countries, foreign governments may be the appropriate regulatory authority for humane slaughter inspections. In all cases, the relevant humane slaughter noncompliance records and corrective action records must be provided to certifying agents during the inspections or upon request.

Slaughter and the Handling of Poultry in Connection With Slaughter

AMS added a new § 205.242(c) regarding avian slaughter facilities. Section 202.242(c)(1) clarifies the authority of the NOP, certifying agents, and State organic programs to review noncompliance records related to the use of good manufacturing practices in connection with slaughter issued by the controlling national, federal, or state authority and records of subsequent corrective action if certified operations are found to have violated the Poultry Products Inspection Act (PPIA) requirements regarding poultry slaughter, violated the FSIS regulations regarding the slaughter of poultry, or failed to use good commercial practices in the slaughter of poultry, as determined by FSIS. Under the PPIA and the FSIS regulations, poultry are defined as chickens, turkeys, ducks, geese, guineas, ratites, and squabs.

These species constitute the majority of avian species slaughtered for human food in the U.S. However, the organic standards for avian slaughter apply to all species biologically considered avian or birds. The NOSB did not directly address avian slaughter requirements. However, AMS added avian slaughter requirements for consistency with the new mammalian slaughter requirements and to provide consistent slaughter requirements for certified organic operations.

While the HMSA does not apply to poultry, under the PPIA at 21 U.S.C. 453(g)(5) a poultry product is considered adulterated if it is in whole, or in part, the product of any poultry which has died by other means than slaughter. FSIS regulations, in turn, require that poultry be slaughtered in accordance with good commercial practices in a manner that will result in thorough bleeding of the poultry carcass and will ensure that breathing has stopped before scalding (9 CFR 381.65 (b)). Compliance with FSIS Directives 6100.3 and 6910.1, as determined by FSIS is required under the final rule.

In a 2005 **Federal Register** Notice, FSIS reminded all poultry slaughter establishments that live poultry:

... must be handled in a manner that is consistent with good commercial practices, which means they should be treated humanely. Although there is no specific federal humane handling and slaughter statute for poultry, under the PPIA, poultry products are more likely to be adulterated if, among other circumstances, they are produced from birds that have not been treated humanely, because such birds are more likely to be bruised or to die other than by slaughter.²²

Also in this Notice, FSIS suggested that poultry slaughter establishments consider a systematic approach to handling poultry in connection with slaughter. FSIS defined a systematic approach as one in which establishments focus on treating poultry in such a manner as to minimize excitement, discomfort, and accidental injury the entire time that live poultry is held in connection with slaughter. Although the adoption of such an approach is voluntary, it would likely better ensure that poultry carcasses are unadulterated.

FSIS inspection program personnel verify that poultry slaughter is conducted in accordance with good commercial practices in the pre-scald area of slaughter establishments, where they observe whether establishment employees are mistreating birds or

²⁰ FSIS Directive 6900.2, Revision 2, *Humane Handling and the Slaughter of Livestock*, August 15, 2011.

²¹ *Humane Handling and Slaughter Requirements and the Merits of a Systematic Approach to Meet Such Requirements*, FSIS, 69 FR 54625, September 9, 2004.

²² *Treatment of Live Poultry before Slaughter*, FSIS, 70 FR 56624, September 28, 2005.

handling them in a way that will cause death or injury, prevent thorough bleeding, or result in excessive bruising. Examples of noncompliant mistreatment could include breaking the legs of birds to hold the birds in the shackle, birds suffering or dying from heat exhaustion, and breathing birds entering the scalders.²³ Also, in 2015, FSIS issued specific instructions to inspection program personnel for recording noncompliance with the requirement for the use of good commercial practices in poultry slaughter.²⁴

New § 205.242(c)(2) requires that all certified organic slaughter facilities provide, during the annual organic inspection, any FSIS noncompliance records and corrective action records related to the use of good manufacturing practices in the handling and slaughter of poultry in order to determine that slaughter facilities have addressed any outstanding FSIS noncompliances and are in good standing with FSIS. Not all violations of FSIS regulations result in a suspension of inspection services. In some cases, FSIS will issue a noncompliance record and the slaughter facility must perform corrective actions to bring the slaughter facility back into compliance. These records must be provided to the certifying agent at inspection or upon request to verify that the slaughter facility is operating in compliance with FSIS regulations and is addressing/has addressed all corrective actions. In addition, AMS recognizes that some poultry slaughter facilities in the U.S. are regulated by the State for intra-state poultry sales. In foreign countries, foreign governments may be the appropriate regulatory authority for poultry slaughter inspections. In all cases, the relevant noncompliance records and corrective action records must be provided to the certifying agent during inspections or upon request.

Unlike the requirements for livestock slaughter inspection, exemptions from poultry slaughter inspection exist for some poultry that is going to be sold to the public. AMS added handling and slaughter standards for such poultry that is either exempt from or not covered by the inspection requirement of the PPIA. Section 205.242(c)(3) would prohibit hanging, carrying, or shackling any lame birds by their legs. Birds with broken legs or injured feet may suffer needlessly if carried or hung by their legs. Such birds must either be

euthanized or made insensible before being shackled.

New § 205.242(c)(3)(i) through (iii) require poultry slaughter operations that are either exempt or not covered by the requirements of the PPIA to meet the standards that non-exempt slaughter operations must meet. AMS included a requirement that no lame birds be hung on shackles by their feet. AMS also included a requirement that all birds that were hung or shackled on a chain or automated slaughter system be stunned prior to exsanguination. This requirement does not apply to small-scale producers who do not shackle the birds or use an automated system but who instead place the birds in killing cones before exsanguinating them without stunning. This requirement would not apply to ritual slaughter establishments (e.g., Kosher or Halal slaughter facilities), who are required to meet all the humane handling regulatory requirements except stunning prior to shackling, hoisting, throwing, cutting, or casting. New § 205.242(c)(3)(iii) requires that all birds be irreversibly insensible prior to being placed in the scalding tank.

B. Discussion of Comments Received

1. Special Animal Welfare Requirements for Certified Organic Slaughter Facilities

(Comment) Several comments stated that the organic standards should require that only organic animals are handled at a certified organic slaughter facility and that the organic standards should go above and beyond the FSIS requirements for humane slaughter. For example, comments recommended that there should be more severe sanctions if noncompliances related to animal welfare are repeated, that the NOP should train slaughter facility staff on the USDA organic regulations, that the organic standards should be as explicit as NOSB recommendations on slaughter, and that the standards include a recommended hierarchy identifying the most humane methods of slaughter for each species. Comments also requested that the organic requirements include more detailed language regarding humane and prohibited forms of euthanasia of non-ambulatory animals upon arrival at the slaughter facility. Several comments recommended adding to 205.242(b)(1): 9 CFR part 309 regarding ante-mortem inspection to ensure that only healthy ambulatory animals are slaughtered and that non-ambulatory animals are euthanized and disposed of promptly. This regulation has recently been updated to include veal calves.

(Response) The USDA organic regulations provide for enforcement options that are implemented by the certifying agent when there are repeated violations of humane handling and slaughter regulations. AMS is not ranking allowed methods of slaughter for preference based on humane considerations as that would be challenging to enforce. AMS agrees with the suggestion to add reference to 9 CFR part 309 in the final rule in §§ 205.242(b)(1) and 205.242(b)(2), which cover the requirements for the humane and prompt euthanizing and disposing of non-ambulatory animals at the slaughter facility. Additionally, AMS has determined that the FSIS regulations are sufficient for protecting animal welfare because they include many of the provisions recommended by the NOSB for livestock slaughter. Adding requirements beyond the FSIS regulations may be overly prescriptive for organic production. AMS will provide trainings on this regulation, which will be available to all interested parties, including certifying agents, organic producers, and handlers who would like further clarification on these requirements.

2. Inspectors Not Trained in FSIS Requirements

(Comment) Several comments expressed concern over the requirement for organic inspectors to verify the mitigation of noncompliances found during FSIS inspections. The comments stated that inspectors do not have the expertise to determine if corrective actions to FSIS noncompliances are sufficient. Comments stated that verifying FSIS regulatory requirements is beyond the scope of organic certification and that this would place an unnecessary burden on inspectors and certifying agents. Other comments stated that FSIS personnel are specifically trained in identifying and responding to the PPIA and good commercial practice regulations, whereas certifying agents are not. They expressed concern that the new requirements for transporting livestock and poultry to sale or slaughter are redundant and unnecessary since FSIS already has regulations in place for slaughter. They assert that the duty of identifying and responding to noncompliance events remains exclusively under the oversight of trained FSIS personnel in order to protect the welfare of poultry during slaughter. In addition, several certifying agents were concerned that cross-references to external statutes may render the organic standards obsolete and in need of future revision should

²³ FSIS Directive 6100.3, Revision 1, *Ante-Mortem and Post-Mortem Poultry Inspection*, April 30, 2009.

²⁴ FSIS Notice 07–15, *Instructions for Writing Poultry Good Commercial Practices Noncompliance Records and Memorandum of Interview Letters for Poultry Mistreatment*, January 21, 2015.

the external statutes significantly change. Comments cited the USDA organic standards cross-referencing of the EPA's List 4 of Inerts as an example. Comments recommended that AMS determine the specific elements of the cited laws they wish to incorporate into the standards and include generic language that reflect those requirements. Several comments recommended that there be trained inspectors dedicated exclusively to observing compliance (ideally daily or at least on a weekly rotating basis) with animal welfare conditions on site at all organic slaughter facilities, with particular attention at the point of slaughter.

(Response) Through this final rule, AMS has established requirements that govern mammalian and avian species that are slaughtered by organic operations. Because these requirements are consistent with existing federal regulations for livestock slaughter, AMS expects that the organic producers and handlers will comply with these requirements. FSIS standards apply to organic and non-organic livestock, and FSIS is already carrying out inspections to this regulation. The role of the organic certifier/inspector is to verify whether FSIS has issued noncompliance records and if so, to verify that the certified operation has resolved or is working to resolve any FSIS noncompliances and is in good standing with FSIS. If not, the organic certifier is required to take appropriate enforcement action of organic rules under the USDA organic regulations. For example, if FSIS noncompliances have not been resolved, the certifying agent may issue a noncompliance to the certified facility to request verification that FSIS noncompliances have been resolved with FSIS as a condition for ongoing organic certification. Otherwise, this regulation would not change the current scope of the organic inspection of certified slaughter facilities. Organic inspectors are not required to know how to inspect slaughter facilities according to FSIS regulatory requirements and are not required to determine if corrective actions mitigate FSIS noncompliances.

However, as with any inspection, inspectors need to be highly qualified in the type of operation they are inspecting. AMS conducts annual trainings for certifying agents and will ensure that FSIS issues are also covered during those trainings. AMS will provide guidance to certifiers (agents) and inspectors on issues that may need further clarification once this rule is in effect. Regarding cross-referencing other federal regulations, AMS has determined that this does not pose a

significant risk as stated in the comments. The FSIS regulation may be amended over time, but it is less likely to become obsolete. Furthermore, AMS will ensure updates and trainings are provided when FSIS regulations or procedures change.

3. Vocalization Thresholds

(Comment) One comment suggested that specific vocalization thresholds be included in the regulation, as provided in the 2011 NOSB recommendation and the Certified Humane Slaughter Standards. Vocalizations of livestock in slaughter facilities can be associated with animal distress and welfare problems in the plant. The NOSB recommended that: (1) No more than 3% of cattle vocalize as they move through the restrainer, stunning box, and stunning area; (2) no more than 5% of hogs squeal in the restrainer due to human provocation; (3) no more than 5% of livestock vocalize when a head holder is used during stunning or slaughter; and (4) no more than 1% of hogs vocalize due to hot wanding. Vocalization scoring, as suggested by the NOSB recommendation, could be used as an objective method for detecting welfare problems during slaughter since cattle and hogs will vocalize during handling if stressed, injured, or scared but they will not vocalize if calm. The percentages provided in the NOSB recommendation would indicate well-managed slaughter plants; skilled, careful handlers; adequate equipment design and condition, and calm animals.

(Response) Facilities that meet the FSIS humane handling and slaughter requirements will ensure that animal distress during handling/slaughter is minimized, achieving the same impact as using vocalization threshold scoring. FSIS inspection program personnel verify compliance with the regulations at 9 CFR part 313 through the monitoring of many of the parameters recommended by the NOSB in 2011, including prod use, slips and falls, stunning effectiveness, and incidents of egregious inhumane handling. AMS did not feel that a change to the rule to include vocalization thresholds was warranted.

4. International Animal Welfare Requirements

(Comment) Several comments asked how an established final rule would impact existing organic trade agreements, such as equivalency agreements and recognition agreements. For example, some comments highlighted specific provisions in the proposed rule that differ from

established regulations in some foreign countries. Some of the comments questioned whether existing equivalency agreements would require renegotiation when the final rule becomes effective.

(Response) When the USDA organic regulations are amended, the USDA follows a set of steps with respect to international trade agreements. Under equivalency arrangements, the USDA notifies the foreign country of any amended USDA organic regulation that may affect the terms of the existing equivalency determination. The foreign country reviews the information and may initiate discussion to determine whether renegotiation is needed. With recognition agreements, the certification bodies in the foreign country are accredited by the recognized foreign government authority to certify operations under the USDA organic regulations. As a result, the USDA notifies the foreign government of the amended USDA organic regulation, and the foreign government authority informs its accredited certification bodies of the amended regulation.

(Comment) Comments were received regarding meat and poultry imports and how AMS will regulate livestock slaughter by certified organic operations in foreign countries. One comment provided country-specific recommendations regarding cattle transport and slaughter requirements. This comment recommended a modification of the new rules to stipulate that while cattle are in other countries that must adhere to state and/or federal animal welfare standards, these countries must abide by the standards and guidelines prescribed in their domestic animal welfare standards for the transport and slaughter of livestock. Additionally, one comment indicated that U.S. certifiers are currently unequipped to verify compliance with these other rules/laws for producers outside of the U.S.

(Response) Many facilities in other countries are already producing meat and poultry for the U.S. market that complies with FSIS export program requirements, regardless of whether the facility is certified organic. Certifying agents operating in countries outside of the U.S. are accredited by the USDA and will need to incorporate this final rule into their NOP certification programs. Foreign certifying agents will need to verify that livestock are being transported and handled according to the requirements of the final rule as well as FSIS equivalent programs. Noncompliance records related to these equivalent programs will be reviewed during annual organic certification

assessments and verified through annual organic inspections or upon request by the certifier. When noncompliances are observed by the appropriate authority under the FSIS equivalency program, the certifying agent will implement the necessary enforcement actions under the organic program, as applicable.

5. Humane Methods of Slaughter Act

(Comments) Some comments received expressed concern that the proposed rule § 205.242(b)(1) contains no reference to the Humane Methods of Slaughter Act (HMSA). Instead, it refers to the Federal Meat Inspection Act (which itself references the HMSA) and parenthetically to the FSIS regulations at 9 CFR part 313. Comments recommended that this omission be corrected to include a direct reference to the HMSA by name and citation and to clarify that the HMSA provides minimum standards. The same comments recommended that provisions from the National Organic Standards Board (NOSB) recommendations on transport and slaughter be added.

(Response) The final rule requires certified organic slaughter facilities to be in full compliance with the Humane Methods of Slaughter Act (HMSA) of 1978 (7 U.S.C. 1901 *et seq.*) and its implementing FSIS regulations, as determined by FSIS. The HMSA requires that humane methods be used for handling and slaughtering livestock and defines humane methods of slaughter. The HMSA is referenced in the FMIA at 21 U.S.C. 603 and is implemented by FSIS humane handling and slaughter regulations found at 9 CFR part 313. The FMIA provides that, for the purposes of preventing inhumane slaughter of livestock, FSIS assigns inspectors to examine and inspect the methods by which livestock are slaughtered and handled in connection with slaughter in slaughtering establishments subject to inspection (21 U.S.C. 603(b)). The final rule references the FSIS regulation 9 CFR part 313 because the regulation clearly conveys how operators must comply with the HMSA Act.

6. Avian Slaughter

(Comment) Several comments expressed concern that the proposed rule addresses avian slaughter, which is not covered by the Humane Methods of Slaughter Act (HMSA) and therefore is not currently governed by clearly defined humane standards. Other comments received state that the requirements of § 205.242(c)(3) for organic poultry slaughter operations

exempt from or not covered by the requirements of the PPIA—which provide that no lame birds may be shackled, hung, or carried by their legs; that birds must be stunned prior to exsanguination; and that all birds must be irreversibly insensible prior to scalding—should apply to *all* organic poultry slaughter, and that it is not clear from the language of the proposed rule that these same requirements apply to slaughter plants exempt from or not covered by the PPIA. Comments also stated that FSIS has not codified the contents of the “good manufacturing practices” Directives 6100.3 and 6910.1. These comments argued that the avian slaughter section, as proposed, creates a discrepancy in which slaughter plants covered by the PPIA would implement less stringent requirements than those proposed for exempt/non-covered plants under § 205.242(c)(3). Several comments provided additional conditions for humane avian slaughter that should be incorporated into the final rule.

(Response) Section 205.242(c)(1) clarifies the authority of the NOP, certifying agents, and State organic programs to initiate compliance action if certified operations are found to have violated the Poultry Products Inspection Act (PPIA) requirements regarding poultry slaughter, as well as the FSIS regulations regarding the slaughter of poultry and the use of good commercial practices in the slaughter of poultry. The NOSB did not directly address avian slaughter requirements. However, AMS is implementing avian slaughter requirements for consistency with the mammalian slaughter requirements and to better ensure the welfare of all animals slaughtered by certified operations. While the HMSA does not apply to poultry, under the PPIA at 21 U.S.C. 453(g)(5), a poultry product is considered adulterated if it is in whole, or in part, the product of any poultry which has died otherwise than by slaughter. FSIS regulations require that poultry be slaughtered in accordance with good commercial practices, in a manner that will result in thorough bleeding of the poultry carcass and that will ensure that breathing has stopped before scalding (9 CFR 381.65 (b)). In a 2005 **Federal Register** Notice, FSIS reminded all poultry slaughter establishments that live poultry: “. . . must be handled in a manner that is consistent with good commercial practices, which means they should be treated humanely.” Also in this Notice, FSIS suggested that poultry slaughter establishments consider a systematic approach to handling poultry in

connection with slaughter. FSIS defined a systematic approach as one in which establishments focus on treating poultry in such a manner as to minimize excitement, discomfort, and accidental injury the entire time that live poultry is held in connection with slaughter. FSIS inspection program personnel verify that poultry slaughter is conducted in accordance with good commercial practices in the pre-scald area of slaughter establishments, where they observe whether employees are mistreating birds or handling them in a way that will cause death or injury, prevent thorough bleeding, or result in excessive bruising. AMS agrees with the suggestion to include reference to the FSIS Directives 6100.3 and 6910.1 in 205.242(c)(1) and has made this change in the final rule.

(Comment) Some comments expressed concern that learning and enforcing FSIS rules could present an undue/unreasonable burden for certifiers and producers, especially for on-farm poultry processing. They request information on how a processor can prove they are in compliance with FSIS requirements and on how an operation slaughtering poultry on-farm under exemption can prove compliance with FSIS requirements.

(Response) A certified organic operation must meet the requirements of the USDA organic regulation. Operations must be compliant with all regulations that impact products they produce. Certifying agents are not assessing compliance with other regulations but only verifying compliance through review and inspection of a certified operation's noncompliance records issued by the regulatory authority. This final rule recognizes that some operations are exempt from poultry slaughter inspection and proposed handling and slaughter standards for such poultry that is either exempt from or not covered by the inspection requirement of the PPIA. Section 205.242(c)(3) prohibits hanging, carrying, or shackling any lame birds by their legs. Birds with broken legs or injured feet may suffer needlessly if carried or hung by their legs. Such birds must either be euthanized or made insensible before being shackled.

In addition, the final rule includes §§ 205.242(c)(3)(i) through (iii) to require poultry slaughter operations that are either exempt or not covered by the requirements of the PPIA to meet animal welfare standards that non-exempt slaughter operations must meet. This final rule requires that no lame birds be hung on shackles by their feet and that all birds that were hung or shackled on a chain or automated slaughter system

be stunned prior to exsanguination. This requirement would not apply to small-scale producers who do not shackle the birds or use an automated system but who instead place the birds in killing cones before exsanguinating them without stunning. This requirement would also not apply to ritual slaughter establishments (e.g., Kosher or Halal slaughter facilities), who are required to meet all the humane handling regulatory requirements except stunning prior to shackling, hoisting, throwing, cutting, or casting. Additionally, § 205.242(c)(3)(iii) requires that all birds be irreversibly insensible prior to being placed in the scalding tank.

7. Religious Slaughter and Avian Slaughter by Exempt Operations

(Comment) Several comments expressed concern that the rule may require that Kosher or Halal slaughter facilities use a stunning step prior to exsanguination. These comments indicated that the rule is not clear on whether the stunning requirement is mandatory for operations that are exempt from or not covered by the requirements of the Poultry Products Inspection Act. While this requirement is directed at processors operating under state inspection who do not fall under the USDA FSIS inspection requirements, designated religious slaughter facilities are exempt from certain aspects of the Poultry Products Inspection Act, necessitating additional clarity. One comment recommended that slaughter not be limited to stunning prior to exsanguination and include other methods, such as the hand slaughter of birds in killing cones by way of exsanguination. The comment suggested that this should apply to both small/exempt and large/non-exempt producers.

(Response) Sections 205.242(c)(3)(i) through (iii) of the final rule requires that poultry slaughter operations that are either exempt or not covered by the requirements of the PPIA meet animal welfare standards that non-exempt slaughter operations must meet. Except as described below, the final rule requires that all birds that are hung or shackled on a chain or automated slaughter system be stunned prior to exsanguination. This requirement would not apply to handling operations, including small-scale exempt producers, that do not shackle the birds or use an automated system but that instead place the birds in killing cones, or use other methods, before exsanguinating the birds without stunning. This requirement would also not apply to ritual slaughter establishments (e.g., Kosher or Halal slaughter facilities),

who are required to meet all the humane handling regulatory requirements except stunning prior to shackling, hoisting, throwing, cutting, or casting. Non-exempt operations must meet the requirements of PPIA.

8. Records

(Comment) Several comments were received that suggested amending the term “noncompliant records” to “noncompliance records” in all relevant sections of 202.242 as this is the typical title of enforcement documents issued by the USDA Food Safety and Inspection Service (FSIS), as well as state departments of agriculture.

(Response) AMS agrees that reference to “noncompliant records” should be “noncompliance records” and has made the necessary changes to all relevant sections of the final rule.

9. Scope of Inspection

(Comment) One comment stated that, while the proposed rule proposes that sick, injured, weak, disabled, blind, and lame animals must not be transported for sale or slaughter, an organic producer can withdraw livestock from certification. Once this certification is withdrawn, certification agencies have limited authority to document a noncompliance. The comment requested clarification regarding the enforcement of this scenario.

(Response) Only animals certified organic and identified/traceable as such during transport are subject to the requirements of this rule.

10. OIE Terrestrial Animal Health Code

(Comment) One comment proposed that the organic animal welfare rule should be more consistent with the OIE Terrestrial Animal Health Code as it applies to transport and slaughter of organic livestock.

(Response) The NOSB reviewed many regulatory references when developing its organic transport and slaughter recommendations. AMS considered OIE Terrestrial Animal Health Code but is not making changes based on the OIE Terrestrial Animal Health Code at this time. However, AMS may provide these standards to the NOSB for their consideration in the future.

XII. Executive Orders 12866 and 13563—Executive Summary

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives, and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety

effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This rulemaking has been designated as an “economically significant regulatory action” under section 3(f) of Executive Order 12866, and, therefore, has been reviewed by the Office of Management and Budget (OMB).

AMS is conducting this rulemaking to maintain consumer confidence in the USDA organic seal. This action is necessary to augment the USDA organic livestock production regulations with clear provisions to fulfill one purpose of the Organic Foods Production Act (OFPA) (7 U.S.C. 6501–6522): To assure consumers that organically-produced products meet a consistent and uniform standard. OFPA mandates that detailed livestock regulations be developed through notice and comment rulemaking and intends for the involvement of the National Organic Standards Board (NOSB) in that process (7 U.S.C. 6508(g)). In 2010, AMS published a final rule (75 FR 7154, February 17, 2010) clarifying the pasture and grazing requirements for organic ruminant livestock, which partially addressed OFPA’s objective for more detailed livestock standards. This rule extends that level of detail and clarity to all organic livestock and poultry, and would ensure that organic standards cover their entire lifecycle, consistent with recommendations provided by USDA’s Office of Inspector General and nine separate recommendations from the NOSB.

This rule adds requirements for the production, transport, and slaughter of organic livestock and poultry. The provisions for outdoor access and space for organic poultry production are the focal areas of this rule. Currently, organic poultry are required to have outdoor access, but this varies widely in practice. Some organic poultry operations provide large, open-air outdoor areas, while other operations provide minimal outdoor space or use screened and covered enclosures commonly called “porches” to meet outdoor access requirements. This variability perpetuates an uneven playing field among producers and sows consumer confusion about the meaning of the USDA organic label. This final rule will resolve the current ambiguity about outdoor access for poultry and address the wide disparities in production practices among the organic poultry sector. Greater clarity about the significance of the USDA organic seal in the marketplace will help to maintain

consumer confidence in the organic label, which drives the \$43 billion in sales of organic products, and support a fair, viable market for producers who chose to pursue organic certification.

The economic impact analysis describes the potential impacts for organic egg and broiler producers, because these types of operations will face additional production costs as a result of this rule, and the potential benefits of greater clarity in the requirements for organic poultry. The following provisions will require producers to incur costs to provide:

- Additional indoor space for broilers;

- Additional outdoor space for layers;

To project costs, AMS assessed current, or baseline, conditions and considered how producers might respond to the above requirements. Based on public comment, NOSB deliberations and surveys of organic poultry producers, we determined that the indoor stocking density requirements for broilers and the outdoor access/stocking density requirements for layers drive the costs of this rule. For organic layers, the key factor affecting compliance is the availability of land to accommodate all birds at the required stocking density. We considered two potential scenarios of how producers would respond: (1) All affected organic egg producers make operational changes to comply with the rule and maintain current levels of production; or, (2), 50 percent of organic egg operations move to the cage-free market because they choose to leave the organic market. Based on public comment, AMS assumed that organic broiler producers would build new facilities to maintain their current production level and remain in the organic market. In this analysis, AMS accounts for costs that accrue to legacy producers and new entrants; the full compliance costs recur annually and are included in the total. Legacy producers are producers who decided to go into the organic business with no knowledge of the costs that would be imposed by this rulemaking. Costs do not accrue

until this rule is fully implemented, *i.e.*, three years after publication for broiler producers and five years after publication for layer producers.

In summary, AMS estimates that production costs will range between \$8.2 million to \$31 million annually. This range spans three producer response scenarios, which are summarized in the table below.

- We estimate that the annualized costs for organic broiler and egg producers are \$28.7 to \$31 million (over 15 years), if all certified organic egg production in 2022 complies with this rule and all certified organic broiler production in 2020 complies with this rule. The timeframe corresponds to the end of the implementation period for the outdoor access requirements for layers and indoor space requirements for broilers. In this scenario, the potential reduced feed efficiency and increased mortality from greater outdoor access are the key variables that impact costs for layers.

- We estimate the annualized costs for organic broiler and organic egg production is \$11.7 to \$12.0 million if 50 percent of organic egg production in 2022 transitions to the cage-free egg market. Under the latter scenario, the shift would also result in foregone profits of nearly \$80 to \$86 million (annualized) for production that moves from organic to cage-free egg production. (Because foregone revenues are not a direct cost of compliance with the rule, they are totaled separately from estimated compliance costs). In this scenario, the difference in price between organic and cage-free eggs accounts for the transfer impact.

- We estimate the annualized costs for organic broiler and organic egg production is \$8.2 million if 50 percent of organic egg production in 2022 transitions to the cage-free egg market and producers who cannot comply with the rule do not enter organic production during the implementation timeframe.

- In the above scenarios, we estimate the annualized costs for organic broiler production account for \$3.5 million to \$4.0 million of the above totals. This

reflects costs to build additional housing for more space per bird to meet the indoor stocking density requirement.

This rule will have broad, important benefits for the organic sector as a whole which are difficult to quantify. Clear and consistent standards, which more closely align to consumer expectations, are essential to sustaining demand and supporting the growth of the \$43 billion U.S. organic market. Clear parameters for production practices will ensure fair competition among producers by facilitating equitable certification and enforcement decisions.

To monetize the benefits of this rule, AMS used research that has measured consumers' willingness to pay for outdoor access between \$0.21 and \$0.49 per dozen eggs. Based on this, AMS estimates that the annualized benefits would range between \$4.1 million to \$49.5 million annually. The range in benefits accounts for several producer response scenarios, which correspond to those described above for the cost estimates.

In the Regulatory Flexibility Analysis, we report that large poultry operations would have significantly higher compliance costs than small operations on average. Larger organic layer operations, in particular, will have demand greater land areas for outdoor access.

AMS estimates that business revenues for small organic layer operations are \$736 million, or about \$1.03 million per firm. For small egg producers, business revenues would need to be less than \$867,000 to \$967,000 per firm for the rule to cost more than 3% of revenue. The estimated business revenue is calculated from the projected organic egg production from small producers using AMS Market News data on the U.S. organic layer population, estimated lay rate of 308 eggs/hen/year and the wholesale price for organic eggs \$2.83/dozen (AMS Market News).

A summary of the estimated costs and benefits associated with this rule is provided in Table A.

TABLE A—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF FINAL RULE

| Assumed conditions | Affected population | Costs, millions ^a | Benefits, millions | Transfers, millions |
|---|--|------------------------------|--------------------|---------------------|
| All producers remain in organic market; Organic layer and broiler populations continue historical growth rates after rule. | Organic layer and organic broiler production at full implementation of rule, <i>i.e.</i> , 2022 for layers; 2020 for broilers. | \$28.7–\$31.0 | \$16.3–\$49.5 | N/A |
| 50% of organic layer production in year 6 (2022), moves to the cage-free market. Organic layer and broiler populations continue historical growth rates after rule. | Organic layer and organic broiler production at full implementation of rule, <i>i.e.</i> , 2022 for layers; 2020 for broilers. | \$11.7–\$12.0 | \$4.5–\$13.8 | \$79.5–\$86.3 |

TABLE A—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF FINAL RULE—Continued

| Assumed conditions | Affected population | Costs, millions ^a | Benefits, millions | Transfers, millions |
|--|--|------------------------------|--------------------|---------------------|
| 50% of current organic layer production moves to the cage-free market in year 6 (2022). There are no new entrants after publication of this rule that cannot comply. | Current organic layer production; organic broiler production at full implementation of rule in 2020. | \$8.2 | \$4.1–\$12.4 | \$45.6–\$49.5 |

Other impacts: Estimated paperwork burden: \$3.9 million.

^a All values in the costs, benefits and transfers columns of this table are annualized and discounted at 3% and 7% rates.

XIII. Retrospective Analysis

Within 3–5 years of full implementation, the Administrator shall conduct and make publicly available a retrospective analysis of the impacts of this rulemaking. This analysis will include a retrospective evaluation of the benefits, costs and transfers of the rule, along with a comparison of these impacts to the prospective estimates contained in this final regulatory impact analysis. The retrospective analysis should include consideration of factors such as: The impacts on exit and entry of affected entities; market shares of affected entities, as well as market competition and concentration; the impacts on the number of producers participating in the organic program; impacts on organic egg production volume, impacts on secondary (e.g., feed/grain) markets; impacts on supply and price of eggs; and impacts on consumer understanding. An opportunity for public comment on this analysis will be provided.

XIV. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This final rule cannot be applied retroactively.

States and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in section 6514(b) of the OFPA. States are also preempted under sections 6503 and 6507 of the OFPA from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 6507(b)(2) of the OFPA, a State organic certification program may contain additional

requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) Further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to section 6519(f) of the OFPA, this final rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601–624), the Poultry Products Inspection Act (21 U.S.C. 451–471), or the Egg Products Inspection Act (21 U.S.C. 1031–1056), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301–399), nor the authority of the Administrator of the EPA under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136–136(y)).

Section 6520 of the OFPA provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

XV. Executive Order 13175

This final rule has been reviewed in accordance with the requirements of Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments." Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that

have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

AMS assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a Tribe requests consultation, AMS will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

XVI. Paperwork Reduction Act

A. Summary

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (PRA), AMS is requesting OMB approval for a new information collection totaling 131,683 hours for the reporting and recordkeeping requirements contained in this final rule. OMB previously approved information collection requirements associated with the NOP and assigned OMB control number 0581–0191. AMS intends to merge this new information collection, upon OMB approval, into the approved 0581–0191 collection. Below, AMS has described and estimated the annual burden, *i.e.*, the amount of time and cost of labor, for entities to prepare and maintain information to participate in this voluntary labeling program. The OFPA, as amended, provides authority for this action.

Title: National Organic Program: Organic Livestock and Poultry Practices.
OMB Control Number: 0581–0293.

Expiration Date of Approval: 3 years from OMB date of approval.

Type of Request: New collection.

Abstract: Information collection and recordkeeping is necessary to implement reporting and recordkeeping necessitated by amendments to

§§ 205.238, 205.239, 205.241, 205.242 and 205.290 for additional animal welfare standards for organic livestock production under the USDA organic regulations. OFPA authorizes the further development of livestock production standards (7 U.S.C. 6513(c)). This action is necessary to address multiple recommendations provided to USDA by the NOSB to add specificity about animal welfare practices with the purpose of ensuring consumers that conditions and practices for livestock products labeled as organic encourage and accommodate natural behaviors and utilize preventive health care slaughter practices.

All certified organic operations must develop and maintain an organic system plan for certification (§ 205.201). The OSP must include a description of practices and procedures to be performed and maintained, including the frequency with which they will be performed; under this final rule, organic livestock operations are subject to additional reporting requirements. The amendments to §§ 205.238, 205.239, 205.241, 205.242, and 205.290 require livestock operations to provide specific documentation as part of an organic system plan to include conditions on livestock living conditions to permit natural behavior, including minimum space requirements, outdoor access, and utilization of preventive health care practices (e.g. physical alterations, euthanasia).

The PRA also requires AMS to measure the recordkeeping burden. Under the USDA organic regulations each producer is required to maintain and make available upon request, for 5 years, such records as are necessary to verify compliance (§ 205.103). Certifying agents are required to maintain records for 5 to 10 years, depending on the type of record (§ 205.510(b)), and make these records available for inspection upon request (§ 205.501(a)(9)). The new information that livestock operations must provide for certification will assist certifying agents and inspectors in the efficient and comprehensive evaluation of these operations and will impose an additional recordkeeping burden for livestock operations. Certifying agents currently involved in livestock certification are required to observe the same recordkeeping requirements to maintain accreditation, therefore AMS expects that this final rule does not significantly increase the recordkeeping burden on certifying agents.

Reporting and recordkeeping are essential to the integrity of the organic certification system. A clear paper trail is a critical tool for verifying that practices meet the mandate of OFPA

and the USDA organic regulations. The information collected supports the AMS mission, program objectives, and management needs by enabling us to assess the efficiency and effectiveness of the NOP. The information also affects decisions because it is the basis for evaluating compliance with OFPA and USDA organic regulations, administering the NOP, establishing the cost of the program, and facilitating management decisions and planning. It also supports administrative and regulatory actions to address noncompliance with OFPA and USDA organic regulations.

This information collection is only used by the certifying agent and authorized representatives of USDA, including AMS and NOP staff. Certifying agents, including any affiliated organic inspectors, and USDA are the primary users of the information.

Respondents

AMS identified three types of entities (respondents) that will need to submit and maintain information in order to participate in organic livestock certification. For each type of respondent, we describe the general paperwork submission and recordkeeping activities and estimate: (i) the number of respondents; (ii) the hours they spend, annually, completing the paperwork requirements of this labeling program; and, (iii) the costs of those activities.

1. *Certifying agents.* Certifying agents are State, private, or foreign entities accredited by USDA to certify domestic and foreign livestock producers and handlers as organic in accordance with OFPA and USDA organic regulations. Certifying agents determine if a producer or handler meets organic requirements, using detailed information from the operation about its specific practices and on-site inspection reports from organic inspectors. Currently, there are 79 certifying agents accredited under NOP; many of which certify operations based in the U.S. and abroad. AMS assumes all currently accredited certifying agents evaluate livestock operations for compliance with the USDA organic regulations and will therefore be subject to the amendments at §§ 205.238, 205.239, 205.241, 205.242, and 205.290.

Each entity seeking to continue USDA accreditation for livestock will need to submit information documenting its business practices including certification, enforcement and recordkeeping procedures and personnel qualifications (§ 205.504). AMS will review that information during its next scheduled on-site

assessment to determine whether to continue accreditation for the scope of livestock. Certifying agents will need to annually update the above information and provide results of personnel performance evaluations and the internal review of its certification activities (§ 205.510).

AMS projects that the additional components of organic system plans for livestock may entail longer review times than those for other types of production systems. AMS estimates the annual collection cost per certifying agent will be \$3,053.27. This estimate is based on an estimated 91.8 labor hours per year at \$33.26 per hour for a total salary component of \$3,053.27 per year. This value is assumed to be an underestimate as the certifying agent bears a portion of the burden of the inspector and certifying agents employ varying numbers of inspectors. The source of the hourly rate is the May 2015 National Occupational Employment and Wage Estimates, United States, published annually by the Bureau of Labor Statistics. The rate is the mean hourly wage for compliance officers (occupation code 13–1041). This classification was selected as an occupation with similar duties and responsibilities to that of a certifying agent.²⁵

2. *Organic inspectors.* Inspectors conduct on-site inspections of certified operations and operations applying for certification and report the findings to the certifying agent. Inspectors may be the agents themselves, employees of the agents, or individual contractors. The USDA organic regulations call for certified operations to be inspected annually; a certifying agent may call for additional inspections on an as needed basis (§ 205.403(a)). Any individual who applies to conduct inspections of livestock operations will need to submit information documenting their qualifications to the certifying agent (§ 205.504(a)(3)). Inspectors will need to provide an inspection report to the certifying agent for each operation inspected (§ 205.403(e)). AMS projects that on average, inspectors will spend 3 hours longer than their current timeframe (10 hours) to complete an inspection report for livestock operations. This estimate is due to the additional components of the organic system plan that will need to be

²⁵ Compliance officers examine, evaluate, and investigate eligibility for or conformity with laws and regulations governing contract compliance of licenses and permits, and perform other compliance and enforcement inspection and analysis activities not classified elsewhere. Bureau of Labor Statistics, Occupational Employment and Wages, May 2015, 13–1041 Compliance Officers.

inspected. Inspectors do not have recordkeeping obligations; certifying agents maintain records of inspection reports.

According to the International Organic Inspectors Association (IOIA), there are approximately 250 inspectors currently inspecting crop, livestock, handling, and/or wild crop operations that are certified or have applied for certification. AMS assumes that approximately half (125) of these inspectors inspect livestock operations.

AMS estimates the annual collection cost per inspector to be \$6,760. This estimate is based on an estimated 321 additional labor hours per year at \$21.06 per hour for a total salary component of \$6,760 per year. The source of the hourly rate is the May 2015 National Occupational Employment and Wage Estimates, United States, published annually by the Bureau of Labor Statistics. The rate is the mean hourly wage for agricultural inspectors (occupation code 45–2011).²⁶

3. *Producers and handlers.* Domestic and foreign livestock producers and handlers will submit the following information to certifying agents: An application for certification, detailed descriptions of specific practices, annual updates to continue certification, and changes in their practices. Handlers include those who produce or transport livestock and may include bulk distributors, food and feed manufacturers, processors, or packers. Some handlers may be part of a retail operation that processes organic products in a location other than the premises of the retail outlet.

In order to obtain and maintain certification, livestock producers and handlers will need to develop and maintain an organic system plan. This is a requirement for all organic operations and the USDA organic regulations describe what information must be included in an organic system plan (§ 205.201). This final rule describes the additional information (§§ 205.238, 205.239, 205.241, 205.242, and 205.290) that will need to be included in a livestock operation's organic system plan in order to assess compliance. Certified operations are required to keep records about their organic production and/or handling for five years (§ 205.103(b)(3)).

AMS used the Organic Integrity Database to estimate the number of

livestock operations that would be affected by this action.²⁷ According to that source, AMS estimates that 4,844 currently certified foreign and domestic livestock operations will be subject to the amendments at §§ 205.238, 205.239, 205.240, 205.241, 205.242, and 205.290. To estimate the number of livestock operations that will apply for and become certified on an annual basis, AMS assumed that this would be proportional to the estimated annual increase in certified operations (350). Therefore, AMS estimates that there will be 69 new certified organic livestock operations annually.

AMS estimates the annual collection and recordkeeping costs per organic livestock producer to be \$559.45. This estimate is based on an estimated 16.65 labor hours per year at \$33.60 per hour for a total salary component of \$559.45 per year. AMS estimates that as producers adapt to the requirements introduced by the amendments at §§ 205.238, 205.239, 205.241, 205.242, and 205.290, the number of labor hours per year for currently certified operators will decrease. The source of the hourly rate is the May 2015 National Occupational Employment and Wage Estimates, United States, published annually by the Bureau of Labor Statistics. The rate is the mean hourly wage for farmers, ranchers and other agricultural managers (occupation code 11–9013).²⁸ Administrative costs for reporting and recordkeeping will vary among certified operators. Factors affecting costs include the type and size of operation, and the type of systems maintained.

Reporting Burden

Estimate of Burden: Public reporting burden for the collection of information is estimated to be 20.3 hours per year.

Respondents: Certifying agents, inspectors, and certified livestock operations.

Estimated Number of Respondents: 5,117.

Estimated Number of Responses: 42,522.

Estimated Total Annual Burden on Respondents: 104,124 hours.

Total Cost: \$2,992,895.

Recordkeeping Burden

²⁷ NOP 2016 List of certified USDA organic operations. Available at the USDA National Organic Program Organic Integrity Database, <http://apps.ams.usda.gov/nop/>.

²⁸ Farmers, Ranchers, and Other Agricultural Managers plan, direct, or coordinate the management or operation of farms, ranches, greenhouses, aquacultural operations, nurseries, timber tracts, or other agricultural establishments. Excludes "First-Line Supervisors of Farming, Fishing, and Forestry Workers" (45–1011).

Estimate of Burden: Public recordkeeping burden is estimated to be an annual total of 5.18 hours per respondent.

Respondents: Livestock operations (including exempt operations).

Estimated Number of Respondents: 5,396.

Estimated Total Annual Burden on Respondents: 27,954 hours.

Total Cost: \$939,240.

Grand Total of Reporting, Training & Recordkeeping Costs: \$3,932,134

Comments: For the proposed rule, AMS invited comments from all interested parties concerning the information collection and recordkeeping required as a result of the proposed amendments to 7 CFR part 205. Comments were invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

B. Discussion of Comments Received

AMS received a total of 6,675 written comments on the proposed rule, which addressed the proposed requirements for organic livestock production practices. AMS received 12 comments that addressed the information collection and recordkeeping burden estimates; two of these comments were duplicative. AMS did not make changes based on comments for several reasons. AMS received eight comments specifically objecting to the recordkeeping requirements, relative to the population of respondents. AMS expects that this is because this rule refers to specific, narrow documentation requirements that are already within the scope of the general recordkeeping requirements for organic producers and the components of an organic system plan. Specifically, such records fully disclose all activities in sufficient detail to be readily understood and audited and be sufficient to demonstrate compliance with the USDA organic regulations (7 CFR 205.103); and that an organic system plan must contain a description of practices and procedures to be performed, and monitoring

²⁶ Agricultural Inspectors inspect agricultural commodities, processing equipment, and facilities, and fish and logging operations, to ensure compliance with regulations and laws governing health, quality, and safety. Bureau of Labor Statistics, Occupational Employment and Wages, May 2015, 45–2011 Agricultural Inspectors.

practices to ensure the plan implemented (7 CFR 205.201). AMS believes, and some comments support this conclusion, that many organic producers already maintain the records that are specified in this rule as part of their organic system plans. In addition, AMS understands that numerous organic livestock producers also participate in third-party animal welfare certification programs and would likely maintain records concerning animal health/condition to participate in those programs. The comments to the questions posed in the proposed rule concerning reporting and recordkeeping requirements and AMS's responses are described below.

1. Whether the Proposed Collection of Information Is Necessary for the Proper Performance of the Functions of the Agency, Including Whether the Information Will Have Practical Utility

(Comment) While stating their support for more specific standards regarding the care of poultry and livestock in organic operations, four out of the ten comments expressed concerns about the specific records that would be required to document how animal illness and injury would be prevented and treated. In particular, these comments stated that body condition scoring and monitoring the causes and treatments of lameness as well as having a parasite management strategy and a written plan for the use of euthanasia was too prescriptive. One comment indicated that providing written justification for the use of teeth trimming and tail docking in pigs on a per litter basis would be burdensome while another comment was concerned about needing to document every instance of indoor confinement of poultry.

One comment indicated that quantifiable measures in the 2012 pasture rule had not necessarily increased consistency in interpretation or implementation by certifying agents or producers. This comment also noted that the prescriptive requirements and quantifiable measures in this new regulation would burden producers and certifying agents. The comment contends that this recordkeeping burden would lessen time for producers to perfect solutions on their operation and increase certifying agent and inspector focus on paper trail rather than assessing the livestock system as a whole.

(Response) Recordkeeping is a core principle of the organic program and an important tool for producers to demonstrate, and certifying agents to verify, compliance with the regulations.

We believe that the requirements which specify specific documentation are minimal and are essential for verifying the rule is being implemented successfully.

2. The Accuracy of the Agency's Estimate of the Burden of the Proposed Collection of Information Including the Validity of the Methodology and Assumptions Used

(Comment) Two of the ten comments questioned the validity of the \$3000.94 estimate of their annual costs, stating that it underestimated the direct labor hours that will be necessary to implement the new requirements. These comments spoke to the need for new forms, extensive training for personnel and certified operations, and processing additional compliance-related correspondence after the rule takes effect.

One comment estimated that each livestock file would require an additional 1-hour review which would amount to about 900 direct labor hours annually for this entity; this estimate is higher than the proposed rule estimate of 91.8 hours as an average for all certifying agents. Consequently, the comment stated that the additional annual labor costs would be \$27,000 at \$30 per hour. Alternatively, this comment expects most of their livestock operation inspections to require only one additional hour to inspect rather than the AMS estimate of three hours of additional inspection time per operation in the proposed rule. Whether the inspection takes one or three hours to verify these new requirements, the comments acknowledged that it is the client operations that will ultimately absorb the increased costs of inspections, and they will need time to prepare.

One comment from a certifying agent included a survey of its certified operations to determine if the records described in the proposed rule are necessary to enforce compliance with the standards. Overall, their clients (74.5 percent) reported that additional records are not needed with the largest group (40.1 percent) responding that they already keep more records than would be needed to enforce compliance. While a smaller proportion (25 percent) of their clients said that the records are needed to enforce compliance, the largest portion of that group of responders (21.8 percent) feel more records will be needed. The certifying agent also asked their clients to estimate how much additional time would be spent maintaining records with 89.3 percent stating somewhere between 1–40 hours annually. A much smaller

portion expected to spend more than 40 hours per year maintaining records. In conclusion, the certifying agent acknowledged the difficulties with accurately estimating the labor hours that will be needed to establish and maintain the records, and affirmed that some requirements will be met through the current records already kept.

(Response) The estimates of total recordkeeping and reporting burden are average per-operation estimates based on the number of operations and animals across the whole industry. A certifying agent with a large number of livestock and poultry operation clients will have larger annual respective costs.

Describing the illness and injury prevention and treatment strategies in writing with useful monitoring and recordkeeping systems unique to the needs, species, and breeds of each operation in an organic system plan will require an initial investment of labor that may need to be absorbed. In actuality, these prevention strategies and monitoring systems should already be in place at least informally.

Based on one certifying agent's query, 75 percent of their client operations are already keeping the necessary records. The majority of the operations that reported the need for more recordkeeping reported that they see them as necessary, and one hour per week (greater than 40 hours annually) was the most direct labor hours reported by a small percentage of the certified operations queried. The query did not ask certified operations whether or not they perceived the necessary records as a burden. These recordkeeping systems should become routine over time and help operations become more efficient, thus reducing their management burden. The regulation provides marketplace assurance through verification.

3. Ways To Enhance the Quality, Utility, and Clarity of the Information To Be Collected

(Comment) One certifying agent affirmed that assessing the condition of the animals as well as the dietary rations provided is needed. This comment noted that a broad, integrated approach that observed the overall wellness of the animals was more appropriate. Indicators of poor health could be flagged without requiring the systemized use of body condition scoring.

A Land Grant College that works with smaller scale farmers through their extension services expressed general concern that some small farmers may no longer choose to be certified organic due to the costs and burdens of

recordkeeping. The organization perceived a duplication in reporting requirements being imposed on organic livestock operations. The comment also noted that the recordkeeping required to document food safety, labor, and environmental compliance has been increasing exponentially in recent decades as well, and is exacerbating the recordkeeping burden of farmers of all scales.

(Response) We agree that a broad integrated approach which observes the overall wellness of the animals, flags indicators of poor health, and scores body condition is important. Using a consistent recordkeeping system within an operation is more important than all operations using the same system, although it may be more efficient for inspectors if all certifying agents voluntarily select the same system.

AMS is not seeking to collect and compare data from one operation to another, or from one certifying agent to another. Body condition scoring is considered a low-cost, hands-on, internally consistent method to assess and monitor the condition of individual animals, herds, or flocks. Using a body scoring system is more accurate and efficient than relying on memory about animals' respective conditions, and helps producers identify the need for treatment or intervention. In addition, certifying agents should make every effort to be sure their recordkeeping requirements are not duplicative and coordinate with the requirements of other standards, where possible, that are outside of the direct scope of AMS.

4. Ways To Minimize the Burden of the Collection of Information on Those Who Are To Respond, Including the Use of Appropriate Automated, Electronic, Mechanical, or Other Technological Collection Techniques or Other Forms of Information Technology

(Comment) Three commenters requested that AMS provide monitoring form templates, training, and other resources in producer-friendly language and format, especially for body condition scoring. One certifying agent requested that we provide the tables that show the original rule language side-by-side with the final rule changes as a separate document for use in outreach materials and training.

A Land Grant College offered that they were likely to prepare new tools and templates to assist organic farmers with monitoring and recording lameness in individual animals. This comment also noted that new records would be needed to document when animals are restricted from outdoor access due to

temperature fluctuations within the ranges specified in the rule.

(Response) AMS is considering developing tools to assist producers and certifying agents, especially for body condition scoring. These optional resources will be available on the NOP Web-site. AMS also plans to offer four regional trainings for producers and certifying agents—most likely in Pennsylvania, Iowa, California, and Texas. Other agricultural extension services and agents, the Natural Resources Conservation Service, and other Federal, state, and nonprofit organizations have tools and resources for monitoring animal health and living conditions that can be adapted.

XVII. Civil Rights Impact Analysis

AMS has reviewed this final rule in accordance with the Department Regulation 4300–4, Civil Rights Impact Analysis (CRIA), to address any major civil rights impacts the rule might have on minorities, women, and persons with disabilities. After a careful review of the rule's intent and provisions, AMS determined that this rule would only impact the organic practices of organic producers and that this rule has no potential for affecting producers in protected groups differently than the general population of producers. This rulemaking was initiated to clarify a regulatory requirement and enable consistent implementation and enforcement.

Protected individuals have the same opportunity to participate in the NOP as non-protected individuals. The USDA organic regulations prohibit discrimination by certifying agents. Specifically, § 205.501(d) of the current regulations for accreditation of certifying agents provides that “No private or governmental entity accredited as a certifying agent under this subpart shall exclude from participation in or deny the benefits of the NOP to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status.” Section 205.501(a)(2) requires “certifying agents to demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart” including the prohibition on discrimination. The granting of accreditation to certifying agents under § 205.506 requires the review of information submitted by the certifying agent and an on-site review of the certifying agent's client operation. Further, if certification is denied, § 205.405(d) requires that the certifying agent notify the applicant of their right

to file an appeal to the AMS Administrator in accordance with § 205.681.

These regulations provide protections against discrimination, thereby permitting all producers, regardless of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status, who voluntarily choose to adhere to the rule and qualify, to be certified as meeting NOP requirements by an accredited certifying agent. This action in no way changes any of these protections against discrimination.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205 is amended as follows:

PART 205—NATIONAL ORGANIC PROGRAM

■ 1. The authority citation for part 205 continues to read as follows:

Authority: 7 U.S.C. 6501–6522.

■ 2. Section 205.2 is amended by adding definitions for “Beak trimming”, “Caponization”, “Cattle wattle”, “De-beaking”, “De-snooding”, “Dubbing”, “Indoors or indoor space”, “Mulesing”, “Non-ambulatory”, “Outdoors or outdoor space”, “Perch”, “Pullets”, “Religious slaughter”, “Soil”, “Stocking density”, “Toe clipping”, and “Vegetation” in alphabetical order to read as follows:

§ 205.2 Terms defined.

* * * * *

Beak trimming. The removal of not more than one-quarter to one-third of the upper beak or the removal of one-quarter to one-third of both the upper and lower beaks of a bird in order to control injurious pecking and cannibalism.

* * * * *

Caponization. Castration of chickens, turkeys, pheasants, and other avian species.

Cattle wattle. The surgical separation of two layers of the skin from the connective tissue for along a 2 to 4 inch path on the dewlap, neck, or shoulders used for ownership identification.

* * * * *

De-beaking. The removal of more than one-third of the upper beak or removal

of more than one-third of both the upper and lower beaks of a bird.

De-snooding. The removal of the turkey snood (a fleshy protuberance on the forehead of male turkeys).

* * * * *

Dubbing. The removal of poultry combs and wattles.

* * * * *

Indoors or indoor space. The space inside of an enclosed building or housing structure available to livestock. Indoor space for avian species includes, but is not limited to:

(1) *Mobile housing.* A mobile structure for avian species with solid or perforated flooring that is moved regularly during the grazing season.

(2) *Aviary housing.* A fixed structure for avian species that has multiple tiers or levels.

(3) *Slatted/mesh floor housing.* A fixed structure for avian species that has both: (1) A slatted floor where perches, feed, and water are provided over a pit or belt for manure collection; and

(ii) Litter covering the remaining solid floor.

(4) *Floor litter housing.* A fixed structure for avian species that has absorbent litter covering the entire floor.

* * * * *

Mulesing. The removal of skin from the buttocks of sheep, approximately 2 to 4 inches wide and running away from the anus to the hock to prevent fly strike.

* * * * *

Non-ambulatory. As defined in 9 CFR 309.2(b).

* * * * *

Outdoors or outdoor space. Any area outside an enclosed building or enclosed housing structure, including roofed areas that are not enclosed. Outdoor space for avian species includes, but is not limited to:

(1) *Pasture pens.* Floorless pens, with full or partial roofing, that are moved regularly and provide direct access to soil and vegetation.

(2) *[Reserved]*

* * * * *

Perch. A rod or branch type structure above the floor of the house that accommodates roosting, allowing birds to utilize vertical space in the house

* * * * *

Pullets. Female chickens being raised for egg production that have not yet started to lay eggs.

* * * * *

Ritual slaughter. Slaughtering in accordance with the ritual requirements of the Jewish faith or any other religious faith that prescribes a method of slaughter whereby the animal suffers

loss of consciousness by anemia of the brain caused by the simultaneous and instantaneous severance of the carotid arteries with a sharp instrument and handling in connection with such slaughtering.

* * * * *

Soil. The outermost layer of the earth comprised of minerals, water, air, organic matter, fungi, and bacteria in which plants may grow roots.

* * * * *

Stocking density. The weight of animals on a given area or unit of land.

* * * * *

Toe clipping. The removal of the nail and distal joint of the back two toes of a bird.

* * * * *

Vegetation. Living plant matter that is anchored in the soil by roots and provides ground cover.

* * * * *

■ 3. Section 205.238 is revised to read as follows:

§ 205.238 Livestock care and production practices standard.

(a) The producer must establish and maintain preventive health care practices, including:

(1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites.

(2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, proteins and/or amino acids, fatty acids, energy sources, and fiber (ruminants), resulting in appropriate body condition.

(3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites.

(4) Provision of conditions which allow for exercise, freedom of movement, and reduction of stress appropriate to the species.

(5) Physical alterations may be performed to benefit the welfare of the animals, for identification purposes, or for safety purposes. Physical alterations must be performed on livestock at a reasonably young age, with minimal stress and pain and by a competent person.

(i) The following practice may not be routinely used and must be used only with documentation that alternative methods to prevent harm failed: Needle teeth clipping (no more than top one-third of the tooth) in pigs and tail docking in pigs.

(ii) The following practices are prohibited: De-beaking, de-snooding, caponization, dubbing, toe clipping of

chickens, toe clipping of turkeys unless with infra-red at hatchery, beak trimming after 10 days of age, tail docking of cattle, wattling of cattle, face branding of cattle, tail docking of sheep shorter than the distal end of the caudal fold, and mulesing of sheep.

(6) Administration of vaccines and other veterinary biologics.

(7) All surgical procedures necessary to treat an illness shall be undertaken in a manner that employs best management practices in order to minimize pain, stress, and suffering, with the use of appropriate and allowed anesthetics, analgesics, and sedatives.

(8) Monitoring of lameness and keeping records of the percent of the herd or flock suffering from lameness and the causes. Certified operations may monitor lameness in a manner prescribed by the NOP.

(b) Producers may administer medications that are allowed under 205.603 to alleviate pain or suffering, and when preventive practices and veterinary biologics are inadequate to prevent sickness. Parasiticides allowed under § 205.603 may be used on:

(1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and

(2) Dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.

(c) An organic livestock operation must not:

(1) Sell, label, or represent as organic any animal or product derived from any animal treated with antibiotics, any substance that contains a synthetic substance not allowed under § 205.603, or any substance that contains a nonsynthetic substance prohibited in § 205.604. Milk from animals undergoing treatment with synthetic substances allowed under § 205.603 cannot be sold as organic but may be fed to calves on the same operation. Milk from animals undergoing treatment with prohibited substances cannot be sold as organic or fed to organic livestock.

(2) Administer synthetic medications unless:

(i) In the presence of illness or to alleviate pain and suffering, and

(ii) That such medications are allowed under § 205.603.

(3) Administer hormones for growth promotion, production, or reproduction, except as provided in § 205.603.

(4) Administer synthetic parasiticides on a routine basis.

(5) Administer synthetic parasiticides to slaughter stock.

(6) Administer animal drugs in violation of the Federal Food, Drug, and Cosmetic Act; or

(7) Withhold medical treatment from a sick animal in an effort to preserve its organic status. All appropriate medications must be used to restore an animal to health when methods acceptable to organic production fail. Livestock treated with a prohibited substance must be clearly identified and neither the animal nor its products shall be sold, labeled, or represented as organically produced.

(8) Withhold individual treatment designed to minimize pain and suffering for injured, diseased, or sick animals, which may include forms of euthanasia as recommended by the American Veterinary Medical Association.

(9) Neglect to identify and record treatment of sick and injured animals in animal health records.

(10) Practice forced molting or withdrawal of feed to induce molting.

(d) Organic livestock operations must have comprehensive plans to minimize internal parasite problems in livestock. The plan will include preventive measures such as pasture management, fecal monitoring, and emergency measures in the event of a parasite outbreak. Parasite control plans shall be approved by the certifying agent.

(e) *Euthanasia*. (1) Organic livestock operations must have written plans for prompt, humane euthanasia for sick or injured livestock.

(2) The following methods of euthanasia are not permitted: suffocation; manual blow to the head by blunt instrument or manual blunt force trauma; and the use of equipment that crushes the neck, including killing pliers or Burdizzo clamps.

(3) Following a euthanasia procedure, livestock must be carefully examined to ensure that they are dead.

■ 4. Section 205.239 is revised to read as follows:

§ 205.239 Mammalian livestock living conditions.

(a) The producer of an organic livestock operation must establish and maintain year-round livestock living conditions which accommodate the wellbeing and natural behavior of animals, including:

(1) Year-round access for all animals to the outdoors, shade, shelter, exercise areas, fresh air, clean water for drinking, and direct sunlight, suitable to the species, its stage of life, the climate, and the environment: Except, that, animals may be temporarily denied access to the outdoors in accordance with paragraphs (b) and (c) of this section. Yards, feeding pads, and feedlots may be used to

provide ruminants with access to the outdoors during the non-grazing season and supplemental feeding during the grazing season. Yards, feeding pads, and feedlots shall be large enough to allow all ruminant livestock occupying the yard, feeding pad, or feedlot to feed without competition for food. Continuous total confinement of any animal indoors is prohibited. Continuous total confinement of ruminants in yards, feeding pads, and feedlots is prohibited.

(2) For all ruminants, management on pasture and daily grazing throughout the grazing season(s) to meet the requirements of § 205.237, except as provided for in paragraphs (b), (c), and (d) of this section.

(3) Appropriate clean, dry bedding. When roughages are used as bedding, they shall have been organically produced in accordance with this part by an operation certified under this part, except as provided in § 205.236(a)(2)(i), and, if applicable, organically handled by operations certified to the NOP.

(4) Shelter designed to allow for:

(i) Over a 24-hour period, sufficient space and freedom to lie down, turn around, stand up, fully stretch their limbs, and express normal patterns of behavior;

(ii) Temperature level, ventilation, and air circulation suitable to the species;

(iii) Reduction of potential for livestock injury; and

(iv) If indoor housing is provided, areas for bedding and resting that are sufficiently large, solidly built, and comfortable so that animals are kept clean, dry, and free of lesions.

(5) The use of yards, feeding pads, feedlots and laneways that shall be well-drained, kept in good condition (including frequent removal of wastes), and managed to prevent runoff of wastes and contaminated waters to adjoining or nearby surface water and across property boundaries.

(6) Housing, pens, runs, equipment, and utensils shall be properly cleaned and disinfected as needed to prevent cross-infection and build-up of disease-carrying organisms.

(7) Dairy young stock may be housed in individual pens until completion of the weaning process but no later than 6 months of age, provided that they have enough room to turn around, lie down, stretch out when lying down, get up, rest, and groom themselves; individual animal pens shall be designed and located so that each animal can see, smell, and hear other calves.

(8) Swine must be housed in a group, except:

(i) Sows may be housed individually at farrowing and during the suckling period;

(ii) Boars; and

(iii) Swine with documented instance of aggression or recovery from an illness.

(9) Piglets shall not be kept on flat decks or in piglet cages.

(10) For swine, rooting materials must be provided, except during the farrowing and suckling period.

(11) In confined housing with stalls for mammalian livestock, enough stalls must be present to provide for the natural behaviors of the animals. A cage must not be called a stall. For group-housed swine, the number of individual feeding stalls may be less than the number of animals, as long as all animals are fed routinely over a 24-hour period. For group-housed cattle, bedded packs, compost packs, tie-stalls, free-stalls, and stanchion barns are all acceptable housing as part of an overall organic system plan.

(12) Outdoor space must be provided year-round. When the outdoor space includes soil, maximal vegetative cover must be maintained as appropriate for the season, climate, geography, species of livestock, and stage of production.

(b) The producer of an organic livestock operation may provide temporary confinement or shelter for an animal because of:

(1) Inclement weather;

(2) The animal's stage of life, however, lactation is not a stage of life that would exempt ruminants from any of the mandates set forth in this part;

(3) Conditions under which the health, safety, or well-being of the animal could be jeopardized;

(4) Risk to soil or water quality;

(5) Preventive healthcare procedures or for the treatment of illness or injury (neither the various life stages nor lactation is an illness or injury);

(6) Sorting or shipping animals and livestock sales, provided that the animals shall be maintained under continuous organic management, including organic feed, throughout the extent of their allowed confinement;

(7) Breeding: Except, that, animals shall not be confined any longer than necessary to perform the natural or artificial insemination. Animals may not be confined to observe estrus; and

(8) 4-H, National FFA Organization, and other youth projects, for no more than one week prior to a fair or other demonstration, through the event, and up to 24 hours after the animals have arrived home at the conclusion of the event. These animals must have been maintained under continuous organic management, including organic feed,

during the extent of their allowed confinement for the event. Notwithstanding the requirements in paragraph (b)(6) of this section, facilities where 4–H, National FFA Organization, and other youth events are held are not required to be certified organic for the participating animals to be sold as organic, provided all other organic management practices are followed.

(c) The producer of an organic livestock operation may, in addition to the times permitted under paragraph (b) of this section, temporarily deny a ruminant animal pasture or outdoor access under the following conditions:

(1) One week at the end of a lactation for dry off (for denial of access to pasture only), three weeks prior to parturition (birthing), parturition, and up to one week after parturition;

(2) In the case of newborn dairy cattle for up to six months, after which they must be on pasture during the grazing season and may no longer be individually housed: Except, That, an animal shall not be confined or tethered in a way that prevents the animal from lying down, standing up, fully extending its limbs, and moving about freely;

(3) In the case of fiber bearing animals, for short periods for shearing; and

(4) In the case of dairy animals, for short periods daily for milking. Milking must be scheduled in a manner to ensure sufficient grazing time to provide each animal with an average of at least 30 percent DMI from grazing throughout the grazing season. Milking frequencies or duration practices cannot be used to deny dairy animals pasture.

(d) Ruminant slaughter stock, typically grain finished, shall be maintained on pasture for each day that the finishing period corresponds with the grazing season for the geographical location. Yards, feeding pads, or feedlots may be used to provide finish feeding rations. During the finishing period, ruminant slaughter stock shall be exempt from the minimum 30 percent DMI requirement from grazing. Yards, feeding pads, or feedlots used to provide finish feeding rations shall be large enough to allow all ruminant slaughter stock occupying the yard, feeding pad, or feed lot to feed without crowding and without competition for food. The finishing period shall not exceed one-fifth (1/5) of the animal's total life or 120 days, whichever is shorter.

(e) The producer of an organic livestock operation must manage manure in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, heavy

metals, or pathogenic organisms and optimizes recycling of nutrients and must manage pastures and other outdoor access areas in a manner that does not put soil or water quality at risk.

■ 5. Section 205.241 is added to read as follows:

§ 205.241 Avian living conditions.

(a) The producer of an organic poultry operation must establish and maintain year-round poultry living conditions that accommodate the health and natural behavior of poultry, including: Year-round access to outdoors; shade; shelter; exercise areas; fresh air; direct sunlight; clean water for drinking; materials for dust bathing; and adequate outdoor space to escape aggressive behaviors suitable to the species, its stage of life, the climate, and environment. Poultry may be temporarily denied access to the outdoors in accordance with paragraph (d) of this section.

(b) Indoor space requirements—

(1) Poultry housing must be sufficiently spacious to allow all birds to move freely, stretch their wings, stand normally, and engage in natural behaviors.

(2) Producers must monitor ammonia levels at least monthly and implement practices to maintain ammonia levels below 10 ppm. When ammonia levels exceed 10 ppm, producers must implement additional practices and additional monitoring to reduce ammonia levels below 10 ppm. Ammonia levels must not exceed 25 ppm.

(3) For layers and fully feathered birds, artificial light may be used to prolong the day length, to provide up to 16 hours of continuous light. Artificial light intensity must be lowered gradually to encourage hens to move to perches or settle for the night. Natural light must be sufficient indoors on sunny days so that an inspector can read and write when all lights are turned off.

(4) Exit areas—poultry houses must have sufficient exit areas that are appropriately distributed to ensure that all birds have ready access to the outdoors.

(5) Perches—for layers (*Gallus gallus*), six inches of perch space must be provided per bird. Perch space may include the alighting rail in front of the nest boxes. All layers must be able to perch at the same time except for aviary housing, in which 55 percent of layers must be able to perch at the same time.

(6) All birds must have access to areas in the house that allow for scratching and dust bathing. Litter must be provided and maintained in a dry condition.

(7) Houses with slatted/mesh floors must have 30 percent minimum of solid floor area available with sufficient litter available for dust baths so that birds may freely dust bathe without crowding.

(8) For layers (*Gallus gallus*), indoor stocking density must not exceed (live bird weight):

(i) Mobile housing: 4.5 pounds per square foot.

(ii) Aviary housing: 4.5 pounds per square foot.

(iii) Slatted/mesh floor housing: 3.75 pounds per square foot.

(iv) Floor litter housing: 3.0 pounds per square foot.

(v) Other housing: 2.25 pounds per square foot.

(9) For pullets (*Gallus gallus*), indoor stocking density must not exceed 3.0 pounds of bird per square foot.

(10) For broilers (*Gallus gallus*), indoor stocking density must not exceed 5.0 pounds of bird per square foot.

(11) Indoor space includes flat areas available to birds, excluding nest boxes.

(12) Indoor space may include enclosed porches and lean-to type structures (e.g. screened in, roofed) as long as the birds always have access to the space, including during temporary confinement events. If birds do not have continuous access to the porch during temporary confinement events, this space must not be considered indoors.

(c) Outdoor space requirements—

(1) Access to outdoor space and door spacing must be designed to promote and encourage outside access for all birds on a daily basis. Producers must provide access to the outdoors at an early age to encourage (i.e., train) birds to go outdoors. Birds may be temporarily denied access to the outdoors in accordance with § 205.241(d).

(2) At least 50 percent of outdoor space must be soil. Outdoor space with soil must include maximal vegetative cover appropriate for the season, climate, geography, species of livestock, and stage of production. Vegetative cover must be maintained in a manner that does not provide harborage for rodents and other pests.

(3) Shade may be provided by structures, trees, or other objects in the outdoor area.

(4) For layers (*Gallus gallus*), outdoor space must be provided at a rate of no less than one square foot for every 2.25 pounds of bird in the flock.

(5) For pullets (*Gallus gallus*), outdoor space must be provided at a rate of no less than one square foot for every 3.0 pounds of bird in the flock.

(6) For broilers (*Gallus gallus*), outdoor space must be provided at a rate of no less than one square foot for every 5.0 pounds of bird in the flock.

(7) Outdoor space may include porches and lean-to type structures that are not enclosed (e.g. with roof, but with screens removed) and allow birds to freely access other outdoor space.

(d) The producer of an organic poultry operation may temporarily confine birds. Confinement must be recorded. Operations may temporarily confine birds when one of the following circumstances exists:

(1) Inclement weather, including when air temperatures are under 40 degrees F or above 90 degrees F.

(2) The animal's stage of life, including:

(i) The first 4 weeks of life for broilers (*Gallus gallus*);

(ii) The first 16 weeks of life for pullets (*Gallus gallus*); and

(iii) Until fully feathered for bird species other than *Gallus gallus*.

(3) Conditions under which the health, safety, or well-being of the animal could be jeopardized.

(4) Risk to soil or water quality, including to establish vegetation by reseeding the outdoor space.

(5) Preventive healthcare procedures or for the treatment of illness or injury (neither various life stages nor egg laying is an illness or injury).

(6) Sorting or shipping birds and poultry sales, provided that the birds are maintained under continuous organic management, throughout the extent of their allowed confinement.

(7) For nest box training, provided that birds shall not be confined any longer than required to establish the proper behavior. Confinement must not exceed five weeks.

(8) For 4–H, National FFA Organization, and other youth projects, provided that temporary confinement for no more than one week prior to a fair or other demonstration, through the event, and up to 24 hours after the birds have arrived home at the conclusion of the event. During temporary confinement, birds must be under continuous organic management, including organic feed, for the duration of confinement. Notwithstanding the requirements in paragraph (d)(6) of this section, facilities where 4–H, National FFA Organization, and other youth events are held are not required to be certified organic for the participating birds to be sold as organic, provided all other organic management practices are followed.

(e) The producer of an organic poultry operation must manage manure in a manner that does not contribute to contamination of crops, soil, or water by

plant nutrients, heavy metals, or pathogenic organisms. The producer must also optimize recycling of nutrients and must manage outdoor access in a manner that does not put soil or water quality at risk.

■ 6. Section 205.242 is added to read as follows:

§ 205.242 Transport and slaughter.

(a) *Transportation.* (1) Certified organic livestock must be clearly identified as organic, and this identity must be traceable for the duration of transport.

(2) All livestock must be fit for transport to buyers, auction or slaughter facilities.

(i) Calves must have a dry navel cord and be able to stand and walk without human assistance.

(ii) Non-ambulatory animals must not be transported for sale or slaughter. Such animals may be medically treated or euthanized.

(3) Adequate and season-appropriate ventilation is required for all livestock trailers, shipping containers, and any other mode of transportation used to protect animals against cold and heat stresses.

(4) Bedding must be provided on trailer floors and in holding pens as needed to keep livestock clean, dry, and comfortable during transport and prior to slaughter. Bedding is not required in poultry crates. When roughages are used for bedding, they must be certified organic.

(5) Arrangements for water and organic feed must be made if transport time, including all time on the mode of transportation, exceeds 12 hours.

(i) The producer or handler of an organic livestock operation, who is responsible for overseeing the transport of organic livestock, must provide records to certifying agents during inspections or upon request that demonstrate that transport times for organic livestock are not detrimental to the welfare of the animals and meet the requirements of paragraph (a)(5) of this section.

(6) Organic producers and handlers, who are responsible for overseeing the transport of organic livestock, must have emergency plans in place that adequately address possible animal welfare problems that might occur during transport.

(b) *Mammalian slaughter.* (1) Producers and handlers who slaughter organic livestock must be in compliance, as determined by FSIS, with the Federal Meat Inspection Act

(21 U.S.C. 603(b) and 21 U.S.C. 610(b)), the regulations at 9 CFR part 313 regarding humane handling and slaughter of livestock, and the regulations of 9 CFR part 309 regarding ante-mortem inspection.

(2) Producers and handlers who slaughter organic exotic animals must be in compliance with the Agricultural Marketing Act of 1946 (7 U.S.C. 1621, *et seq.*), the regulations at 9 CFR parts 313 and 352 regarding the humane handling and slaughter of exotic animals, and the regulations of 9 CFR part 309 regarding ante-mortem inspection.

(3) Producers and handlers who slaughter organic livestock or exotic animals must provide all noncompliance records related to humane handling and slaughter issued by the controlling national, federal, or state authority and all records of subsequent corrective actions to certifying agents during inspections or upon request.

(c) *Avian slaughter.* (1) Producers and handlers who slaughter organic poultry must be in compliance, as determined by FSIS, with the Poultry Products Inspection Act requirements (21 U.S.C. 453(g)(5)); the regulations at paragraph (v) of the definition of “*Adulterated*” in 9 CFR 381.1(b), and 9 CFR 381.90, and 381.65(b)); and FSIS Directives 6100.3 and 6910.1.

(2) Producers and handlers who slaughter organic poultry must provide all noncompliance records related to the use of good manufacturing practices in connection with slaughter issued by the controlling national, federal, or state authority and all records of subsequent corrective actions to the certifying agent at inspection or upon request.

(3) Producers and handlers who slaughter organic poultry, but are exempt from or not covered by the requirements of the Poultry Products Inspection Act, must ensure that:

(i) No lame birds may be shackled, hung, or carried by their legs;

(ii) All birds shackled on a chain or automated system must be stunned prior to exsanguination, with the exception of ritual slaughter; and

(iii) All birds must be irreversibly insensible prior to being placed in the scalding tank.

Dated: January 11, 2017.

Elanor Starmer,
Administrator, Agricultural Marketing Service.

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Part VIII

Department of Housing and Urban Development

24 CFR Parts 30 and 206

Federal Housing Administration: Strengthening the Home Equity Conversion
Mortgage Program; Final Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**24 CFR Parts 30 and 206**

[Docket No. FR-5353-F-03]

RIN 2502-AI79

Federal Housing Administration: Strengthening the Home Equity Conversion Mortgage Program

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Final rule.

SUMMARY: This final rule codifies several significant changes to FHA's Home Equity Conversion Mortgage program that were previously issued under the authority granted to HUD in the Housing and Economic Recovery Act of 2008 and the Reverse Mortgage Stabilization Act of 2013, and makes additional regulatory changes. The HECM program is FHA's reverse mortgage program that enables seniors who have equity in their homes to withdraw a portion of the accumulated equity. The intent of the Home Equity Conversion Mortgage program is to ease the financial burden on elderly homeowners facing increased health, housing, and subsistence costs at a time of reduced income. FHA's mission is to serve underserved markets, which must be balanced with HUD's inherent, as well as, statutory obligation under the National Housing Act to protect the FHA insurance funds. This rulemaking strengthens the FHA Home Equity Conversion Mortgage program and codifies changes that reduce risk to the Mutual Mortgage Insurance Fund and increase the sustainability of this important program for seniors. This final rule follows publication of a May 19, 2016, proposed rule and takes into consideration the public comments received on the proposed rule.

DATES: *Effective Date:* September 19, 2017.

FOR FURTHER INFORMATION CONTACT:

Karin Hill, Senior Policy Advisor, Office of Single Family Housing, Department of Housing and Urban Development, 451 7th Street SW., Room 9282, Washington, DC 20410-8000; telephone number 202-402-3084 (this is not a toll-free number). Persons with hearing or speech challenges may access this number through TTY by calling the toll-free Federal Relay Service at 800-877-8339.

SUPPLEMENTARY INFORMATION**I. Executive Summary***A. Purpose of Regulatory Action*

Since the 2008 housing and economic recession, the HECM portfolio has experienced major borrower demographic and behavioral changes that have caused additional risk to the Mutual Mortgage Insurance Fund (MMIF). Some of the changes include shifting from a predominantly adjustable interest rate mortgage with borrowers receiving payments over time using the line of credit, modified term, or modified tenure payment options to a fixed interest rate mortgage with borrowers drawing large amounts of HECM proceeds at the time of closing; younger borrowers with higher amounts of property indebtedness; and increasing property charge defaults. While program changes made prior to and during 2013, such as consolidating the HECM Standard and HECM Saver products, did improve the stability of the HECM program, the HECM portfolio has continued to experience volatility. The economic value of the HECM portfolio has fluctuated from a negative \$1.2 billion reported in FHA's Fiscal Year (FY) 2014 submission to Congress, to a positive \$6.8 billion in FY 2015, to a negative \$7.7 billion in FY 2016. Even under an improved housing market, the positive impacts of program changes on the HECM portfolio overall will be gradual and initially difficult to model for purposes of the actuarial study, as they will be evidenced only in future cohorts of activity. As a result, it is critical to remain vigilant in monitoring program performance and policy to ensure the soundness of the MMIF.

Recognizing the need to stabilize the HECM program and ensure it remains a sustainable program, Congress passed and the President signed into law, the Reverse Mortgage Stabilization Act of 2013 (RMSA) (Pub. L. 113-29). The RMSA gave FHA the tools to make, through mortgagee letter,¹ changes to the HECM program that are necessary to improve the fiscal safety and soundness of the program. Under this authority, FHA implemented a number of changes to the HECM program, including the Financial Assessment and Property Charge Funding Requirements; deferring the due and payable status for Eligible Non-Borrowing Spouses; limiting disbursements during the first 12 months of the HECM; and eliminating future draws on fixed interest rate HECMs.

¹ Mortgagee letters issued under the authority granted to HUD in RMSA will be identified throughout this rule as RMSA mortgagee letters.

On May 19, 2016 (81 FR 31770), HUD published a proposed rule to codify these policies, with amendments as discussed in the preamble to the proposed rule. In addition, FHA proposed to implement a number of new policies. Also, so that all regulatory requirements are codified in the HECM regulations, HUD also proposed to codify HECM program changes made by mortgagee letter² under the Housing and Economic Recovery Act of 2008 (HERA) (Pub. L. 110-289), which implemented the HECM for Purchase program and established new origination fee limits, and amends the initial and monthly mortgage insurance premium (MIP) limits to correspond with statutory changes. This final rule follows publication of the May 19, 2016, proposed rule and takes into consideration the public comments received on the proposed rule.

B. Summary of Major Provisions of This Final Rule

In this rule, FHA codifies existing policy which has been implemented by mortgagee letters under various statutory authorities; implements statutory changes; issues new origination and servicing policies; and clarifies existing regulatory language. The main policy provisions are discussed below. All policies which have been implemented by mortgagee letters will remain in effect until the effective date of this final rule.

Implementing Statutory Changes and Codifying Existing Policies Implemented Under Statutory Authority

Financial Assessment and Property Charge Funding Requirements. RMSA Mortgagee Letter 2014-21 required mortgagees to perform a Financial Assessment of the prospective borrower prior to loan approval, which considers the prospective borrower's credit history, cash flow and residual income, extenuating circumstances, and compensating factors. Based on the results of the Financial Assessment, the mortgagee may require a Life Expectancy Set Aside (LESA) for the payment of certain property charges. For fixed interest rate HECMs, if a LESA is required, it may only be a Fully-Funded LESA. For adjustable interest rate HECMs, if a LESA is required, the mortgagee may require either a Partially- or Fully-Funded LESA. Proceeds from a Partially-Funded LESA will be disbursed to the borrower semi-annually to be used to assist in the payment of

² Mortgagee letters issued under the authority granted to HUD in HERA will be identified throughout this rule as HERA mortgagee letters.

property charges; for Fully-Funded LESAs, mortgagees disburse funds directly to the tax authority or insurance company for the payment of certain property charges when they are due. If the mortgagee does not require a Fully-Funded LESA, a borrower with an adjustable or fixed interest rate HECM, may elect to have a Fully-Funded LESA.

Deferring the Due and Payable Status for Eligible Non-Borrowing Spouses. RMSA Mortgagee Letter 2014–07, as amended by RMSA Mortgagee Letter 2015–02, established a Deferral Period, during which the due and payable status of a HECM is deferred after the death of the last surviving borrower for an Eligible Non-Borrowing Spouse, provided eligibility and all other FHA requirements are, and continue to be, satisfied. In addition, the new policy required the principal limit to be based on the age of the youngest borrower or Eligible Non-Borrowing Spouse, instead of only the youngest borrower. The new policy also provided for a 30-day period for the Eligible Non-Borrowing Spouse to cure a default and to reinstate a Deferral Period.

Limiting Disbursements During the First 12 Months of the HECM. Through RMSA Mortgagee Letter 2014–21, FHA limited initial disbursements for HECMs. For fixed and adjustable interest rate HECMs, the funds advanced to the borrower at closing and during the First 12-Month Disbursement Period could not exceed the greater of 60 percent of the principal limit; or Mandatory Obligations plus an additional 10 percent of the principal limit.

While FHA does not intend to change the current limits of 60 percent and 10 percent at this time, this rule provides flexibility for this limit to be changed in the future to respond to market changes or other factors. Specifically, this rule revises the regulations such that the 60 percent cap will never be modified to be less than 50 percent, and the additional percentage will never be modified to be less than 10 percent absent future rulemaking.

Eliminating Future Draws on Fixed Interest Rate HECMs. Ginnie Mae issued an All Participants Memorandum, APM 14–04, announcing that fixed interest rate HECM loans with future draws would be ineligible for securitization on or after June 1, 2014. As a result of APM 14–04, in RMSA Mortgagee Letter 2014–11, FHA limited the insurability of fixed interest rate mortgages under the HECM program to mortgages with the Single Lump Sum payment option, which does not allow for future draws after closing.

HECM for Purchase Program. HECM for Purchase program requirements were

originally located in HERA Mortgagee Letter 2009–11. This rule codifies the HECM for Purchase program requirements, with an important change to the existing prohibition on interested party contributions. The rule permits the seller to pay fees required to be paid by the seller under state or local law and fees that are customarily paid by a seller in the locality of the subject property and to purchase the Home Warranty policy. The rule also allows the Commissioner to define the types and parameters of other allowable interested party contributions through **Federal Register** notice for comment.

Allowable Loan Origination Fees and Charges. FHA implemented the loan origination fee limits imposed by HERA through HERA Mortgagee Letter 2008–34. In this rule, FHA clarifies that such loan origination fee limits include expenses incurred in originating, processing and closing the HECM.

Amount of MIP. This rule amends the allowable initial and monthly MIP charges to reflect that HECMs are now obligations of the MMIF instead of the General Insurance Fund and to reflect statutory amendments to the National Housing Act providing FHA with a wider range of acceptable MIP charges. FHA is not changing actual MIP charges, which may be set outside of the rulemaking process by mortgagee letter or other similar administrative issuance.

Seasoning Requirements. HUD implemented seasoning requirements for existing non-HECM liens through Mortgagee Letter 2014–21. Under the mortgagee letter, borrowers could only pay off existing non-HECM liens using HECM proceeds if the liens had been in place longer than 12 months or resulted in less than \$500 cash to the borrower. This rule adopts these seasoning requirements for existing non-HECM liens but amends them to: (1) Impose the 12-month requirement beginning at the date of the HECM closing rather than the HECM loan application; and (2) allow the pay-off, at closing, of Home Equity Lines of Credit (HELOCs) that do not meet seasoning requirements from borrower funds, the HECM funds, or a combination of HECM funds and borrower funds, as long as the draw from HECM funds does not exceed the draw limits during the first 12 months of the HECM.

New Origination and Servicing Policies

Disclosure of Available HECM Program Options. This rule requires that mortgagees inform potential HECM borrowers of all of the HECM products, features, and options that FHA insures, in a manner acceptable to the Commissioner, irrespective of the

particular HECM products offered by the mortgagee.

Interest Rate Lock-In. This rule amends the definition of “expected average mortgage interest rate,” to provide that the mortgagee, with the agreement of the borrower, may lock in the expected average mortgage interest rate prior to the date of loan closing or establish the expected average mortgage interest rate on the date of loan closing.

Appraisal Requirements. This rule requires the mortgagee to have the property appraised no later than 30 days after receipt of the request by an applicable party in connection with a pending property sale; the property must be appraised within 30 days of a foreclosure sale. The rule also allows the Commissioner to approve the use of other appraisers when the mortgagee is required to appraise the property.

Limiting Reimbursement of Property Charge Advances. This rule limits insurance claim reimbursement to a mortgagee to two-thirds of the total payments for: (a) Taxes, ground rents, and water rates; (b) special assessments, which are noted on the application for insurance or which become liens after the insurance of the mortgage; and (c) hazard insurance premiums on the mortgaged property not in excess of a reasonable rate.

Acquisition and Sale of Property. This rule replaces the requirement that the property be sold for at least 95 percent of the appraised value with a more flexible provision which allows the Commissioner to lower this amount as necessary to adapt to market conditions and other factors. This rule also requires that the closing costs from the sale be no more than the greater of 11 percent of the sales price, or a fixed dollar amount as determined by the Commissioner through **Federal Register** notice.

Cash for Keys. This rule provides an incentive for parties with legal authority to dispose of a property that serves as the security for a HECM to complete a deed in lieu of foreclosure more quickly. The rule also applies the Cash for Keys incentive when a bona fide tenant vacates the property prior to an eviction being initiated by the mortgagee in the case of a foreclosure. This rule grants the Commissioner the flexibility to increase the minimum amount of time a mortgagee shall grant the borrower or bona fide tenant to vacate the property and the authority to establish the amount of the financial incentive.

Pay-Off of Debt Not Secured by the Property. This rule allows HECM proceeds to be used to pay off debt that is not secured by the property, as defined by the Commissioner through

Federal Register notice, as a mandatory obligation.

Property Charge Payments. This rule allows the Commissioner, through **Federal Register** notice, to establish an incentive for the borrower voluntarily electing a Life Expectancy Set Aside. Additionally, the final rule authorizes the Commissioner, through **Federal Register** notice, to expand the borrower's options for electing to have the mortgagee make property charge payments.

C. Costs and Benefits of This Rule³

This rule codifies the following program changes that have reduced risks to both FHA and to borrowers: Implementation of limits on fixed-rate full draw loans (full draw loans expose FHA to high risk of insurance loss, and such loans are often not sustainable solutions for borrowers since they do not provide the borrower with future access to HECM proceeds); a Financial Assessment to enable mortgagees to determine if the HECM enables borrowers to comply with the mortgage requirements and that the HECM is a sustainable solution for borrowers; protection to Eligible Non-Borrowing Spouses from foreclosure after the death of the last borrower; removal of incentives for borrowers to obtain higher principal limits by using only the age of the older spouse through quitclaiming the younger spouse from the title; and a Life Expectancy Set Aside which will reduce the incidence of borrower defaults due to non-

compliance with the mortgage obligation for the borrower to make timely payment of property taxes, and hazard and flood insurance payments. The new changes to the HECM program are expected to reduce foreclosures arising from these defaults, which will benefit FHA, borrowers, and communities where properties are located; give FHA more flexibility to accept short sales on properties where market conditions warrant; and provide homeowners with the ability to purchase a more suitable home without incurring the costs of two loan closings. Together, these changes may initially reduce HECM origination volume, although the potential demand for HECM is expected to remain high.

The social benefits that may be realized by this rule also include reducing resolution costs and borrower distress in cases where loans are no longer sustainable; improved sustainability of the MMIF, which would enhance the choice and wellbeing of future borrowers; and increased protections for borrowers, including those afforded non-borrowing spouses and those from improving the ultimate sustainability of HECM loans related to financial assessment changes.

The policies discussed in this rule may reduce FHA HECM insurance endorsements by \$1.9 billion per year, thereby reducing choices for potential HECM borrowers to access home equity and imposing an equivalent cost on them; reduce foreclosures due to tax and

insurance default by up to 6,000 cases (totaling about \$1.5 billion in loan amount) per year, along with reduction in ancillary costs of foreclosures to neighborhoods and local governments; and reduce loan origination costs for 2,000 "HECM for Purchase" borrowers, saving them \$12 million per year representing transfers from mortgagees to borrowers.

Other costs from the rule would include reduced borrowers' choice and the well-being of those borrowers who may not meet the eligibility requirements, or who no longer have access to as much upfront cash. The table below and the bullet points that follow display the benefits, costs, and transfers of this rule.

Absent the changes in the HECM program made by mortgagee letters issued by HUD under the authority of RMSA, the ongoing operation of the HECM program would have required a credit subsidy appropriation under the Federal Credit Reform Act of approximately \$684 million. The fact that this appropriation was not required represents a transfer from potential HECM borrowers to taxpayers. This transfer was effected by the regulatory mortgagee letters, and not this final rule which merely codifies these existing policies in the Code of Federal Regulations. This transfer amount is reported in this analysis to inform the public, but had no bearing on whether these provisions would be included in the final rule.

| Benefits | Costs | Transfers |
|--|---|--|
| 4,400 fewer foreclosures per year from tax and insurance default. • \$1.1 billion aggregate unpaid principal balance. • Reduction in ancillary costs of foreclosures to neighborhoods, borrowers, and local governments. Reduced loan origination costs for 2,000 "HECM for Purchase" borrowers per year. • Total benefit of \$12 million per year. • Frees resources for other purposes. | Reduce FHA HECM insurance endorsements by \$1.9 billion per year, thereby reducing choices for potential HECM borrowers to access home equity. No additional costs | Mortgagee letters issued under authority granted by the Reverse Mortgage Stabilization Act and codified by this rule reduced credit subsidy appropriations required under the Federal Credit Reform Act for the HECM program from \$684 million to \$0. This is a transfer from potential HECM borrowers to taxpayers. No additional transfers. |

Other benefits include the following:

- Improving the financial condition of the FHA MMIF due to:

- Fewer foreclosures and lower loss rates;
- Financial incentives of a Cash for Keys program for short sales and REO properties;

- Persistently lower insured loan balances over time, due to limits on initial disbursement; and
- More flexibility for FHA to accept short sales on properties where market conditions warrant.
- Improving overall HECM program viability and in turn improving suitability and attractiveness for potential borrowers

- Reduces risks to both FHA and to borrowers associated with fixed-rate full draw loans (full draw loans expose FHA to high risk of insurance loss, and such loans are often not suitable for borrowers);

- Helps borrowers and their housing counselors determine if a HECM is a sustainable option for them through the use of a Financial Assessment;

³ Any changes made in this section from what was presented in the proposed rule only indicate

policy changes that were made based on public comments or reconsideration of the issues.

- Provides protection to Eligible Non-Borrowing Spouses from foreclosure, and removes incentives for borrowers to obtain higher principal limits than they would otherwise be eligible for by using only the age of the older spouse; and
- Reduces the incidence of borrower defaults due to non-compliance with the mortgage obligation.

II. Background

A. Program Description

The HECM program, authorized by section 255 of the National Housing Act (NHA) (12 U.S.C. 1715z–20), is FHA's reverse mortgage insurance program. The regulations for this program are codified in 24 CFR part 206. The HECM program enables FHA-approved mortgagees to extend insured mortgage financing to eligible borrowers, 62 years of age or older, who want to convert the equity in their homes into liquid assets. The withdrawal of equity may take a variety of forms, as authorized by the NHA and selected by the borrower. The home, which serves as security for the mortgage, must be, and continue to be, the borrower's principal residence during the life of the borrower. For adjustable interest rate HECMs, equity payments to the borrower may be in the form of monthly disbursements for life or a fixed term of years, disbursements from a line of credit advance or a combination of monthly disbursements and a line of credit. For fixed interest rate HECMs, equity payments to the borrower must be in the form of a single lump sum disbursement at closing.

The maximum amount of equity in the home that is available to a borrower under a HECM loan is the "principal limit" that is calculated for that loan. The borrower retains ownership of the property and may sell the home at any time keeping any residual sale proceeds in excess of the outstanding loan balance. Until the mortgage is repaid, and regardless of whether or not additional disbursements under the mortgage are permissible, interest on the mortgage, mortgage insurance premiums, and servicing charges, where applicable, continue to accrue.

B. HUD's May 19, 2016, Proposed Rule

On May 19, 2016, HUD published its proposed rule to implement the HERA and RMSA mortgagee letters described above in addition to other regulatory changes. HUD proposed to strengthen the HECM program by consolidating the requirements of these HERA and RMSA mortgagee letters into the regulations and introducing new requirements that would reduce risk to the Mutual Mortgage Insurance Fund and increase

the sustainability of the HECM program for seniors. Interested readers should refer to the preamble of the May 19, 2016, proposed rule for details regarding the proposed regulatory changes to the HECM program.

C. Solicitation of Comment on Required Assignment

On August 11, 2016, at 81 FR 53095, HUD published in the **Federal Register** a supplemental notice of proposed rulemaking to solicit comment in response to a proposal raised by one of the public commenters on the proposed rule. The document opened the public comment period solely to address this proposal regarding the mortgagee's option to file a claim when the loan balance reaches 98 percent of the maximum claim amount.

The current regulations at § 206.107(a) provide the mortgagee an option, before the mortgage is submitted for insurance endorsement, to select either: (1) The assignment option, which allows the mortgagee to assign the HECM to the Secretary if the mortgage balance is equal to or greater than 98 percent of the maximum claim amount; or (2) the shared premium option, which allows the mortgagee to retain a portion of the monthly MIP but does not allow the mortgagee to assign the mortgage unless the mortgagee fails to make payments and the Secretary demands assignment. Under the assignment option, the mortgagee may only assign the mortgage to the Secretary if the following requirements are satisfied: (1) The mortgagee is current in making the required payments to the mortgagor; (2) the mortgagee is current in making the required MIP payments to the Secretary; (3) the mortgage is not due and payable; and (4) the mortgage is a first lien of record and title to the property securing the mortgage is good and marketable.

The public commenter suggested that, under the assignment option, HUD should instead require that the mortgagee assign the HECM loan to FHA if the outstanding loan balance is equal to or greater than 98 percent of the maximum claim amount. The commenter stated that, in some cases, a mortgagee may decline to file a claim in this scenario if the property value has risen rapidly and the loan has an above-market rate. The commenter concluded that lenders in this way have a "put option" and "can choose to keep the best loans and make claims for the worst ones".

HUD is deferring its final determination as to whether to adopt the commenter's proposal at this time, and after HUD fully reviews and takes into consideration the comments

received, HUD will issue, or choose not to issue, its final determination of this proposal through a subsequent final rule.

III. Overview of Final Rule—Key Changes Made at Final Rule Stage

In the May 19, 2016, proposed rule, HUD explicitly solicited public comment on numerous proposed policy changes, including specific questions on the maximum closing costs allowed on the sale of a property, including utilities as property charges, property inspections, non-borrowing spouse communication, and the benefits and costs of the rule. HUD received 241 public comments, including 83 unique comments, on the proposed rule. HUD appreciates all the questions raised, and suggestions and recommendations made by the public commenters. After review and consideration of the public comments and upon further consideration of issues by HUD, the following highlights key clarifications and changes made by HUD at the final rule stage.

The final rule:

- Amends the provision limiting the number of mortgages by allowing borrowers to provide legal documentation evidencing the release of the borrower's financial obligation to satisfy the existing HECM rather than requiring the borrower to demonstrate a final divorce decree. (See § 206.34.)

- Amends the seasoning requirements for existing non-HECM liens to: (1) Impose the 12-month requirement beginning at the date of the HECM closing rather than the HECM loan application; and (2) allow the pay-off at closing of Home Equity Lines of Credit (HELOCs) that do not meet the seasoning requirements from borrower funds, the HECM funds, or a combination of HECM funds and borrower funds, as long as the draw from HECM funds does not exceed the draw limits during the first 12 months of the HECM. (See § 206.36.)

- Includes required pay-off of debt not secured by the property, as defined by the Commissioner through **Federal Register** notice, as a mandatory obligation. (See § 206.25(b) and § 206.25(c).)

- Clarifies that the mortgagees are required to request borrowers to designate, at the borrower's discretion, an alternative individual for the purpose of communicating with the mortgagee if the mortgagee has not been able to reach the borrower directly. (See § 206.40(c).)

- Retains the current policy requirement that the mortgagor must provide the mortgagee with a physical copy of the housing counseling

certificate, and removes the requirement that the HECM counselor upload the certificate to an electronic database. (See § 206.41(c).)

- Clarifies that the mortgagee shall provide any disclosures required by law when asking the borrower about any costs or other obligations that the borrower has incurred to obtain the mortgage. (See § 206.43(a).)

- Allows fees customarily paid by the seller in the subject property locality to be included as an interested party contribution. (See § 206.44(c).)

- Clarifies the requirement for maintaining flood insurance coverage. (See § 206.45(c).)

- Grants the FHA Commissioner the authority, where a HECM is due and payable, to increase the maximum closing costs allowable for selling the property above 11% of the sales price by establishing a fixed dollar amount as determined through **Federal Register** notice. (See § 206.125(a)(2)(ii).)

- Allows the FHA Commissioner to approve the use of qualified appraisers acceptable to and identified by the Commissioner when the mortgagee is required to appraise the property. (See § 206.125(b).)

- Authorizes the FHA Commissioner to expand availability of the Cash for Keys incentive, in an amount to be determined by the Commissioner, on REO properties with bona fide tenants. (See § 206.125(g)(4).)

- For the Cash for Keys incentive, authorizes the Commissioner to increase the minimum amount of time a mortgagee shall grant the borrower or bona fide tenant to vacate the property. (See § 206.125(f)(1)(ii) and § 206.125(g)(4).)

- Amends the limitation on reimbursements for advances made by the mortgagee for property charges to cover two-thirds of the overall advances made by the mortgagee rather than the full value of the first two years of such advances. (See § 206.129(d)(3).)

- Removes the ability for the borrower to elect that the mortgagee pay ground rents through the borrower's voluntary election to have the mortgagee pay property charges. (See § 206.205(b)(2) & § 206.205(d).)

- Authorizes the Commissioner to establish an incentive for voluntarily electing a Life Expectancy Set Aside through **Federal Register** notice. (See § 206.205(b)(2)(ii).)

- Authorizes the Commissioner to expand the borrower's options for property charge payment by the mortgagee through **Federal Register** notice. (See § 206.205(d).)

Deferred Final Determination

Additionally, in order to fully consider the comments received on these issues, HUD will defer making its final determination of the policies listed below from the proposed rule and afterwards, HUD will issue its final determination on these issues in a final rule.

- The change to the cap on interest rate adjustments for annually adjustable interest rate products and the imposition of a five percent cap on interest rate adjustments for monthly adjustable interest rate products;

- The establishment of extenuating circumstances exceptions for exceeding the Initial Disbursement Limit or Borrower's Advance during the First 12-Month Disbursement Period;

- Post-closing property inspections;
- The requirement to undergo counseling before signing a HECM for Purchase contract and/or making an earnest money deposit; and

- The definition of property charges to include utilities.

IV. Public Comments and HUD's Response to Public Comments

A. The Public Comments Generally

HUD received 241 public comments, including duplicate mass mailings, resulting in 83 unique public submissions covering a wide range of issues. Comments came from a wide variety of entities, including lenders, servicers, interest groups, real estate agents, and academics. In general, the public commenters expressed support for codifying policy implemented via Mortgage Letter under statutory authority, updating CFR part 206 and a number of the proposed regulatory changes. Many commenters also raised questions or offered suggestion for changes at the final rule stage. This section of the preamble discusses the significant issues raised by the commenters and provides HUD's responses to the comments received. All public comments can be viewed at <https://www.regulations.gov/docket?D=HUD-2016-0052>.

B. Specific Public Comments

1. Definitions

Comment: The definition of "borrower" should be consistent with the definition used in the Mortgagee Optional Election Assignment guidance (Mortgagee Letter 2015-15) to mean the "original borrower under a note and mortgage." The commenter encouraged the use of consistent definitions throughout HECM program guidance.

HUD Response: With the recent changes to the HECM program,

particularly the protections and benefits for non-borrowing spouses, it was necessary for HUD to revise the definitions of "borrower" and "mortgagor" in order to resolve title issues involving quit claiming practices of non-borrowing spouses or other non-borrowing owners. The definition of "borrower," as provided in 206.3, "means a mortgagor who is an original borrower under the HECM Loan Agreement and Note. The term does not include successors or assigns of a borrower."

Comment: HUD should clarify that the new proposed definition of "mortgagee" does not conflict with the rule change regarding sales to other FHA-approved entities, as proposed in § 206.101(d)(2). The commenter stated that "mortgagee" is defined as the original lender under a mortgage and its successors and assigns, as approved by the Commissioner, but that HUD also proposed to include a non-FHA-approved entity as a possible successor or assign, in some limited cases.

HUD Response: These requirements are not new additions to the HECM program. They were previously listed in the regulations at 24 CFR part 203 and incorporated into the HECM program by reference. This rule simply moves the regulations into part 206 in order to reduce the number of cross-references. HUD intends to retain these regulatory requirements.

2. State Statutes of Limitations

Comment: HUD should state that when a HECM loan is assigned to HUD, any state statute of limitations on collecting or foreclosing upon the loan does not apply to HUD. The commenter also suggested that HUD state that any such state law is preempted by HUD HECM regulations and program guidelines.

HUD Response: HUD appreciates the recommendation and will take it under consideration for future rulemaking and policy guidance. However, FHA reminds mortgagees that the model loan document provided must be adapted by the lenders to local and state requirements that preserve first lien status.

3. Program Complex/Disclosures

Comment: The HECM program is incredibly complex and could be improved by the use of plain language educational materials and software.

HUD Response: HUD agrees that the program is complex. The HECM program is unique and was designed to reduce the effects of economic hardships that senior homeowners may experience. Over the years, changing

borrower and industry practices have required HUD to respond with appropriate policymaking to manage risk to the MMIF and support sustainability of the program. HUD supports consumer education and awareness through its HECM counseling requirement. HUD understands the need to provide plain language educational materials and appreciates suggested content. However, prospective borrowers must understand the terms and conditions of the mortgage as defined in the legal documents.

Comment: The program changes are overly restrictive and protective of senior borrowers. The commenter stated that seniors are not necessarily uneducated and have had many years of experience. The commenter also stated that the current disclosure and guideline requirements are sufficient.

HUD Response: HUD's mission is to serve underserved markets, which must be balanced with HUD's inherent, as well as, statutory obligation under the NHA to protect the MMIF. Knowing that many seniors are educated and resourceful, HUD must take every precaution to ensure seniors who need a reverse mortgage are equipped with the information necessary to make an informed decision of whether the HECM is a sustainable solution that enhances their financial position.

Comment: The changes in this rule are less about protecting seniors and more about controlling the marketplace, lenders, and seniors, and that the same policies do not apply to forward mortgages.

HUD Response: Despite the varying opinions concerning the recent changes to the HECM program, HUD's mission is to serve underserved markets, which must be balanced with HUD's inherent, as well as statutory, obligation under the NHA to protect the MMIF. Governance of the marketplace is beyond HUD's purview and the reverse mortgage industry must examine its practices to determine what is acceptable and beneficial for the survival of this program. The requirements of the HECM program are unique and it is important to note that the program has a very different risk profile than Forward Mortgages. Where feasible, HUD strives to adopt forward mortgage requirements that can be applied to the HECM Program.

Comment: HUD should expand the disclosure requirement to allow for new and improved methods with which to inform potential HECM borrowers. One commenter proposed that HUD host a technology roundtable to discuss and evaluate a new consumer-friendly marketing campaign. Another

commenter stated that HUD should elaborate on the disclosure requirement and further define the extent to which lenders must disclose all products, features, and options that HUD will insure. Commenters stated that the description of these products should include overall access to equity, costs, and the amount of funds available during the first 12 months.

HUD Response: Mortgagees are required to explain in clear, consistent language all requirements and features of the HECM program. Mortgagees have the flexibility to identify and use methods that will ensure borrowers are properly informed of all features and products that are available.

Comment: HUD should discourage product-steering by lenders.

HUD Response: HUD believes its requirement that mortgagees must disclose all products, whether they are offered by the mortgagee or not, will discourage product-steering.

Comment: HUD should promulgate suitability rules to ensure that lenders only recommend reverse mortgage loans that are suitable for borrowers' needs.

HUD Response: Housing counseling and the Financial Assessment are prudent practices for evaluating whether the HECM is a sustainable solution. Both practices promote the participation of homeowners who are well-informed and financially well-positioned for a HECM loan.

Comment: Disclosing too many options may be confusing to borrowers.

HUD Response: HUD disagrees and believes that the full disclosure of all products is necessary to insure borrowers are aware of all options and to avoid potential steering.

4. Interest Rate Lock-In

Comment: HUD should eliminate the credit line growth feature of adjustable-rate HECM loans. The commenter stated that the growth is determined by interest rate, lender margin, and mortgage insurance premiums, and borrowers have access to increasing amounts of funds even if home prices fall, which leads to greater risk for the MMIF.

HUD Response: The HECM program was designed to allow the line growth feature to insure borrowers had access to equity. Other program features balance risk such as principal limit factors, MIP, controls over large cash draws upfront, and no future draws on fixed rate product.

Comment: HUD should clarify that rate locks are optional.

HUD Response: The rate lock is optional. HUD notes that the proposed rule, in its definition "expected average

mortgage interest rate," indicates that mortgagees, with the agreement of the borrower, may lock in the expected average mortgage interest rate and the mortgagee's margin prior to the date of loan closing or on the date of loan closing. HUD retains this option in this final rule.

Comment: HUD should maintain the current policy regarding the timing of when the mortgagee may lock in the rate that determines the principal limit, which is the application date.

HUD Response: HUD appreciates the feedback but believes the borrower should have the flexibility of setting the expected average mortgage interest rate and mortgagee's margin, if applicable, any time prior to closing or at closing.

Comment: HUD should continue to permit the "float down" option whereby the principal limit may be recalculated at closing if the expected interest rate has declined and is lower than at application date.

HUD Response: HUD will continue to permit the "float down" option, per ML 2006-22.

Comment: HUD should allow the borrower to keep the rate lock they have chosen or the expected rate based on the index in effect at closing, whichever is most beneficial to the borrower.

HUD Response: HUD will continue to permit the "float down" option, per ML 2006-22.

Comment: HUD should elaborate on the interest rate lock-in timeframes and further clarify the terms used.

HUD Response: The guidance found in ML 2006-22 provides useful background for interest rate lock-in timeframes.

5. Shared Premium/Shared Appreciation

Comment: Shared appreciation should not be utilized in the HECM market. One commenter stated that the terms of a shared appreciation reverse mortgage are heavily weighted towards benefiting the mortgagee and not the borrower. Another commenter stated that there should be a prohibition against shared appreciation schemes, due to the harm done to the borrower.

HUD Response: The National Housing Act provides for a shared appreciation option, and HUD will retain the shared appreciation option in the regulations to allow for future potential product design.

Comment: The shared appreciation option has not been utilized, but may be useful in the future. One commenter stated that shared appreciation could be an example of a product that seems unnecessary but eventually becomes popular due to changing market

conditions. The commenter stated that “low balance” HECM options or the HECM Saver product could be other examples of such products. Commenters stated that these items could allow for important product design and innovation in the future. Some commenters suggested that this could give an opportunity for further review and study on how such features may be used to design new products and features. Some commenters also stated that the product could be used in the future to reduce risk to the MMIF. One commenter stated that these options have the potential for creating competitive loan products in the marketplace.

HUD Response: HUD will retain the shared appreciation option in the regulations for future potential product design.

Comment: More information is needed on the shared premium and shared appreciation options. The commenter also stated that the 2009 PLF tables do not include the shared premium basis points as in previous versions, and that there is little explanation of how the shared premium and shared appreciation options are administered or audited by HUD, or whether these loans are eligible for securitization.

HUD Response: We do not currently administer these options.

6. Deferral of Due & Payable Status

Comment: Eligible Non-Borrowing Spouses should continue to enjoy the benefits of any monthly distributions or the availability of any line of credit funds once the last borrower dies. The commenter stated that the eligible NBS should still have access to these benefits since the amount available to the borrower is determined by the age of the NBS.

HUD Response: The NBS is not a borrower and as such is not a party to the Loan Agreement. The Loan Agreement is a contract solely between the borrower and the mortgagee, not the NBS. Upon the last surviving borrower's death, the terms of the Loan Agreement provide that no further funds can be made available to a person who is not a party to the Agreement.

Comment: Ninety days is insufficient for a grieving spouse to take practical measures to secure her or his right to the property. One commenter stated that the probate process alone can take longer than ninety days for reasons outside of the surviving spouse's control. Commenters suggested that the time frame should be extended to 180 days. Another commenter suggested 120 days would be sufficient. One commenter

also suggested that HUD may require that a probate action be opened within a reasonable time after the borrower's death.

HUD Response: HUD appreciates the recommendation. HUD would like to remind the public that a NBS does not have to obtain legal title in order to be eligible for a deferral period. A NBS must establish a legal right to remain in the property, which may be accomplished through means other than obtaining legal title to the property. While HUD understands and appreciates that concerns raised about the time required to obtain legal title, as it is not the requirement and the NBS has other means in which to establish a legal right to remain, HUD will not adopt this recommendation at this time.

Comment: Thirty days after a deferral period ceases is not a sufficient time frame to cure a default. The commenter stated that most spouses will need more time to obtain documentation or evidence from a taxing authority to provide timely payment and to successfully navigate the servicer's protocols.

HUD Response: Non-borrowing spouses are provided the same timeframes and opportunity during a deferral period to cure a default as a borrower is provided during his or her lifetime and HUD believes this timeframe to be sufficient. Additionally, borrowers and non-borrowing spouses can cure a default up until the foreclosure sale occurs.

Comment: HUD should expand the definition of events that are able to trigger the deferral period under § 206.55. The commenter recommended that the definition should be expanded to cover all events that are outside the control of the borrower, such as significant health or life events. Another commenter stated that due and payable status should also be deferred when a borrower is no longer residing in the home serving as collateral property but there is an Eligible NBS present and occupying the home.

HUD Response: HUD understands the issue raised by the commenter but is unable to adopt this suggestion to expand events that would be eligible for a deferral period. The other events that would give rise to a due and payable status result from a borrower failing to comply with his or her obligations of the mortgage. As such, HUD cannot provide for a deferral where there is a breach of a contractual duty.

Additionally, by providing a deferral period for a NBS where the borrowing spouse has died, the requirements of this provision in the NHA are satisfied.

7. Initial Disbursement Limit/Borrower's Advance

Comment: HUD should allow any funds disbursed as a monthly tenure payment to the borrower to exceed the Initial Disbursement Limit (IDL) during the first 12 months. One commenter stated that applying the Initial Disbursement Limit to monthly tenure payments causes confusion by requiring the payments to be reduced so that they remain less than the IDL during the first 12 months, and then recast at the end of the first year to recapture the amount reduced during that time period.

HUD Response: HUD appreciates the recommendation and will take it under consideration for future rulemaking or policy guidance.

Comment: HUD should clarify what constitutes fees and charges for real estate purchase contracts, warranties, inspections, surveys, and engineer certifications.

HUD Response: HUD appreciates the recommendation and will take it under consideration for future policy guidance.

Comment: HUD should only require the borrower to report whether the amount drawn during the First 12-Month Disbursement Period will exceed the 60 percent limit. Commenters stated that reporting the exact percentage would be confusing and unnecessary.

HUD Response: HUD has amended the language in this final rule to remove the word “exact” from § 206.25(a) to avoid any confusion. HUD will continue to require the borrower to indicate what percentage, up to 10% of the principal limit, she or he chooses to receive during the first year. The additional amount that the borrower plans to use during the First 12-Month Disbursement Period is needed for the initial MIP calculations.

Comment: HUD should not further amend the limits on the initial disbursements during the first 12 months.

HUD Response: HUD appreciates the concern raised. However, the flexibility in the regulation will enable HUD to react to market conditions, for the viability of the HECM program, and to protect the fiscal soundness of the MMIF. The flexibility in place at § 206.25(a) allows the Commissioner to raise or lower the maximum initial draw but cannot go lower than 50% and the additional percentage cannot be less than 10%.

Comment: HUD should be careful not to set limits at a point in which it eliminates access to the program for many potential borrowers. The commenter referenced examples of

seniors who were convinced to withdraw the maximum amount at closing and immediately invest in financial products.

HUD Response: The flexibility in place at § 206.25(a) only allows the Commissioner to raise or lower the maximum initial draw but cannot go lower than 50% and the additional percentage cannot be less than 10%. This limitation was specifically designed to reduce initial draws and is presently set at the amount of Mandatory Obligations or 60% plus an additional 10% of the Principal Limit. In addition, the MIP Structure also provides a lower upfront rate of 0.50% for draws of 60% or less and 2.50% for draws in excess of 60%. Mortgagee Letter 2014–10 provides specific guidance regarding the borrower's right to determine the amount of the initial disbursement and requires mortgagees to inform them of these rights.

8. Allowable Charges and Fees

Comment: HUD should clarify in the preamble to the final rule that the origination fee limit does not include and does not apply to third party closing costs or fees. Another commenter stated that including more fees without increasing the allowable origination fee is reducing funds for a company to operate even though the costs of operating a business and the cost of living is increasing.

HUD Response: HUD is not seeking to include additional borrower charges in the loan origination fee. The amendments to § 206.31 in this final rule clarify the loan origination fee includes expenses incurred in originating, processing, and closing the HECM. Third party closing costs or fees such as an appraisal fee, MIP, transfer fees, etc., are the responsibility of the borrower. The practice of the lender using the loan origination fee to cover the full amount or a portion of those fees and charges to reduce the borrower's out-of-pocket expenses may continue.

Comment: HUD should clarify the ability of mortgagees to charge other fees, which should also be included as allowable Mandatory Obligations. Commenters stated the following should fall under this category: Tax history verifications, credit report fees, 4506T tax verifications, and other verifications such as verification of employment, income, bank statements, and assets. Another commenter requested that HUD allow mortgagees to incur and pass along to HECM borrowers a document delivery or technology fee that allows for the delivery of loan documents and disclosures as well as any required

document review fee such as those mandated by state law. Another commenter requested additional clarification on the allowance of closing charges and fees.

HUD Response: Section 206.25 was amended by the proposed rule to include credit report fees as mandatory obligations. The final rule retains this language. HUD issued ML 2016–10 to permit a Third Party Property Tax Verification Fee to verify the borrower's property tax payment history and the annual amount of property taxes due for a specific property. HUD will use its administrative authority to clarify its policy concerning the handling of reasonable and customary fees and charges that are required to do business as an FHA-approved lender.

Comment: HUD should consider adding regulations to limit broker compensation, particularly as to adjustable rate line of credit reverse mortgages where the Truth in Lending Act regulations do not apply. The commenter provided an example of a mortgage broker receiving a yield spread premium of 15 percent of the loan amount in exchange for acceptance of a higher-than-market interest rate, without the borrower's understanding of the situation.

HUD Response: HUD does not have regulatory authority to issue these requirements. Loan originator compensation is regulated by the CFPB under the Truth in Lending Act and its implementing Regulation Z (12 CFR part 1026). The provisions apply to closed-end consumer credit transactions secured by a dwelling, including reverse mortgages that are not home equity lines of credit under 12 CFR 1026.40. See 12 CFR 1026.36.

Comment: HUD should consider addressing the allowance of Appraisal Management Company fees and document preparation fees as part of the allowable loan origination fees and charges.

HUD Response: HUD appreciates the recommendation and will take it under consideration for future policy guidance.

Comment: A second HECM should be allowed in the case of a divorce. Commenters stated that the divorced co-borrower must show a divorce decree and/or a copy of the deed indicating the former spouse is responsible for the prior marital home.

HUD Response: HUD is adopting in this final rule the proposed rule change that allows for a new HECM when the existing HECM is satisfied prior to or at the closing of the new HECM, or the borrower provides legal documentation, acceptable to the Commissioner,

evidencing release of financial obligation to satisfy the existing HECM, which may include a divorce.

Comment: A second HECM should be allowed when the individual is no longer on title to the property with the existing HECM and a new primary residence has been established. The commenter stated that the proposed rule solved for married individuals only and not other situations such as domestic partners or relatives.

HUD Response: HUD is adopting in this final rule the proposed rule change that allows for a new HECM when the existing HECM is satisfied prior to or at the closing of the new HECM, or the borrower provides legal documentation, acceptable to the Commissioner, evidencing release of financial obligation to satisfy the existing HECM. This requirement is applicable to all borrowers and not just married individuals.

10. Title of Property Which Is Security for the HECM

Comment: HUD should allow the NBS to go on title without having to refinance or qualify for another loan. The commenter stated that there are many examples of spouses not qualifying under the new regulations and as a result, they have to stay off title, which causes other legal issues not pertaining to the mortgage on the property.

HUD Response: The new definitions for "mortgagor" and "borrower" in § 206.3 of this final rule address the commenter's concern.

Comment: Allowing non-borrowing spouses to remain on the title could open the door to claims by other non-borrowing owners. Commenters expressed concerns over whether other co-owners could demand the sale of the property or demand to receive their share of the home title. One commenter asked if HUD could limit the ability to remain on title to eligible NBSs only or perhaps only to owners who also reside in the home. Another commenter suggested that HUD should limit the ability of a non-borrower to remain on title to spouses, or alternatively, grant a life estate right to the borrower so that the borrower could keep the home.

HUD Response: While HUD understands the potential issues that could arise from shared legal ownership of a property, HUD has determined it is not in a place to dictate to a homeowner or homeowners how to best structure legal ownership to a property. Further, even should HUD be inclined to limit those individuals on title at origination, there is nothing that would prevent the borrower from subsequently adding additional individuals to title. These

individuals whether added before or after origination would have certain legal rights as would any other legal owner of a property. Ultimately, how a homeowner or homeowners elect to hold title is within their control.

Comment: HUD should clarify when a certification must be signed by all non-borrowing spouses and non-borrowing owners to consent to the borrower obtaining a HECM. The commenter recommended that the certification be required at the time of closing or funding.

HUD Response: HUD will take these comments under consideration when implementing related policy through guidance.

Comment: HUD should clarify that HECM servicers may encourage borrowers on currently outstanding HECMs to add NBSs and heirs to the title when preparing for end-of-life arrangements.

HUD Response: HUD has determined it is not appropriate to dictate to a homeowner or homeowners how to best structure legal ownership to a property.

12. Seasoning Requirements for Existing Non-HECM Liens

Comment: An unintended consequence of the rule is that it disallows a HECM even when the non-HECM lien would not result in exceeding the 60 percent of the initial disbursement limit. Some commenters suggested that the policy should be changed so that liens seasoned for less than one year can be paid off at closing if the PLU is 60 percent or less.

HUD Response: HUD has considered this proposal and is incorporating a change to the final rule for HELOCs. The final rule allows borrowers to pay off unseasoned HELOCs using their own funds, HECM funds, or a combination of HECM funds and non-HECM funds. The final rule allows the use of HECM funds to pay off unseasoned HELOCs if the IDL or Borrower's Advance remains at or under the percentage set by the Commissioner in § 206.25(a).

Comment: The seasoning requirement should be eliminated altogether. The commenter stated that many seniors take out a home equity line of credit without realizing a reverse mortgage would be a better option. The commenter explained that if an emergency makes it difficult for this senior to make monthly payments on the HELOC, it would put the borrower in an even worse financial situation if the borrower could not apply for a HECM for twelve months. Another commenter stated that this requirement only hurts the seniors who have to wait up to twelve months to get their HECM

loan. One commenter asked what is wrong with allowing debts to be paid off at closing. Some commenters stated that it is not reasonable to expect a homeowner to possibly know that an ordinary consumer transaction such as opening a home equity line of credit will close the door to a HECM. One commenter suggested two alternatives: (1) Reduce the seasoning requirement to draws made in the last 60 to 90 days; or (2) make the effective date the date of closing rather than the date of application.

HUD Response: This final rule retains an amended seasoning requirement that imposes the 12-month requirement beginning at the date of the HECM closing rather than the HECM loan application, and at closing, allows the pay-off of HELOCs that do not meet seasoning requirements from borrower funds, HECM funds, or a combination of a borrower's own funds and HECM funds if the IDL or Borrower's Advance remains under the percentage set by the Commissioner in § 206.25(a).

Comment: The seasoning requirement should be rewritten to exclude construction and rehab loans, as long as the borrower can show that all loan proceeds were paid to contractors. One commenter stated that in many cases, these loans are required to bring the property into compliance for a HECM.

HUD Response: Existing policy does not consider funds paid to third parties for construction and rehab to be "cash to the borrower". As long as documentation is provided to show that loan proceeds in excess of \$500 were paid to a contractor, the seasoning requirement in § 206.36 is considered satisfied.

Comment: HUD should clarify the current interpretation by wholesale lenders concerning such loan proceeds passing through the bank account of the borrower.

HUD Response: If documentation is provided to show that the loan proceeds in excess of \$500 were paid to a third party, funds that were received by the borrower and paid through the borrower's bank account satisfies the seasoning requirement in § 206.36.

Comment: Rather than allowing the Commissioner to impose additional seasoning requirements through notice and comment, the seasoning requirements under Mortgage Letter 2014-21 should remain the same and be incorporated into the regulations.

HUD Response: As stated in the proposed rule and retained in the final rule in § 206.36, the seasoning requirements that may be established by the Commissioner will not prohibit the payoff of non-HECM liens if the liens

have been in place for longer than 12 months or have resulted in cash to the borrower in an amount of \$500 or less.

Comment: HUD should allow for greater flexibility for paying off existing mortgages by imposing a 1.75 percent upfront MIP cap rather than a 2.5 percent cap or by increasing the percentage allowable from 42 percent to 52 percent with a 60 percent cap on distributions.

HUD Response: HUD will take these comments under consideration when implementing future policy guidance.

11. Financial Assessment

Comment: The introduction of non-property related expenses is outside the scope of the financial assessment. One commenter stated that a senior will pay the property taxes when given a choice between paying the property taxes or paying off a credit card.

HUD Response: It is critical to evaluate the willingness (credit history) and financial capacity of the borrower in order to determine whether the HECM loan is a sustainable solution for the borrower in order to reduce defaults and manage risk to the MMIF.

Comment: Proof of on-time property taxes and insurance payments should not be required. The commenter stated that those who have a history of less-than-stellar credit, even if they pass the Financial Assessment, should be considered for a LESA.

HUD Response: Current regulations in § 206.205 require that if the borrower does not meet the Financial Assessment requirements that a Fully- or Partially-Funded LESA is required. And all HECM borrowers have the option to voluntarily request a LESA for payment of taxes and insurance or voluntarily request the mortgagee to pay taxes and insurance out of the HECM proceeds if a LESA is not required.

Comment: Willingness is the primary cause of tax and insurance defaults.

HUD Response: HUD rejects this comment and recognizes the majority of its borrowers demonstrate a willingness to pay their property charges in a timely manner. HUD's guidance, as provided in the revised HECM Financial Assessment and Property Charge Guide attached to Mortgage Letter 2016-10, includes instructions for reviewing and evaluating the applicant's credit history, including tax and insurance payment history, and extenuating circumstances of prospective borrowers to determine whether the HECM loan is a sustainable solution and whether a LESA must be required.

Comment: Borrowers with a certain minimum credit score should be exempt from the income assessment.

HUD Response: HUD is receptive to adding FICO Scores to the Financial Assessment process; however, at this time, sufficient performance data is not available to support the implementation of FICO score criteria for HECMs. HUD is now collecting FICO information on HECM borrowers and will, over time, evaluate how that may be incorporated in the Financial Assessment process.

Comment: Additional compensating factors should be taken into consideration at the discretion of the direct endorsement underwriter, just as in traditional mortgages.

HUD Response: HUD does not allow additional compensating factors to be taken into consideration of the direct endorsement underwriter on forward mortgages and does not intend to adopt this recommendation for the HECM program.

Comment: HUD should audit recent financial assessments to determine how much documentation is unnecessary. One commenter stated that many guideline requirements are beyond risk management and ambiguous, and suggested that HUD could establish quarterly meetings with industry underwriters and sales leaders for a path toward closing good loans with limited documentation.

HUD Response: HUD continues to closely monitor performance of the HECM portfolio and will update guidance on the Financial Assessment as needed.

Comment: HUD should wait to implement further changes to the financial assessment, since the impact of the changes that took effect in April 2015 are not yet fully understood.

HUD Response: The proposed rule does not include any changes to the Financial Assessment requirements. HUD continues to closely monitor the performance of the HECM portfolio and will update guidance on the Financial Assessment as needed.

Comment: HUD should allow seniors to pay off revolving debt at closing from proceeds in order to qualify under the financial assessment rules, particularly since this can be done with forward mortgages.

HUD Response: In this final rule, HUD has included use of HECM proceeds to be used to pay-off unsecured debt, as defined by the Commissioner through **Federal Register** notice, as a mandatory obligation.

Comment: The financial assessment guidelines are overly restricting access to the HECM program. One commenter stated that a LESA eliminates some concern regarding residual income, since a person with a full LESA is covered with regards to tax and

insurance. Another commenter stated that the Financial Assessment guidelines apply HUD practices designed for younger, employment-aged consumers and should be more closely correlated to the actual situation of aging homeowners over time. The commenter suggested that the rule should recognize the evolving nature of the Financial Assessment protocol and require further review to expand the population of low-risk senior homeowners who are eligible to participate in the HECM program. Another commenter stated that even borrowers with excellent credit are forced to go through many underwriting conditions that would not be required for an FHA forward mortgage. Another commenter stated that the process of obtaining a HECM has become unnecessarily documentation-intensive and rigid with respect to the specific documentation format.

HUD Response: As stated in § 206.37(b)(1), the financial capacity of the borrower must be evaluated to determine whether the HECM is a sustainable solution for the borrower. HUD has always required full documentation for borrowers on all its mortgage programs, except for streamlined refinances. Providing specific documentation requirements ensures consistency and these requirements may vary from forward mortgages because of the different profile of the programs and the borrowers. However, a significant amount of the required financial assessment documentation reflects standard documentation criteria for real estate secured loans. The need to require additional cash flow and projected financial documentation on HECMs reflects the unique structure of this type of mortgage and borrower. HUD appreciates the recommendation and will take it under consideration for future policy guidance.

Comment: The requirement to use the prior year's tax bill amount multiplied by 1.04 or an amount set by the Commissioner through notice is unnecessary as the LESA formula already has a 1.2 times multiplier to the annual taxes and insurance.

HUD Response: When the mortgagee requires the payment of taxes and flood and hazard insurance at closing, or the borrower requests that their property charges are paid at closing, and a new tax bill has not been issued or is unavailable, the 1.04 multiplier is used to calculate the projected amount of taxes and insurance to be disbursed during the first 12 months. The 1.2 multiplier is used for the LESA and takes into account expected increases in

property taxes and hazard and flood insurance over the life expectancy of the youngest mortgagor.

Comment: HUD should clarify that Financial Assessment underwriting should not include utility payments in the expenses of HECM borrowers.

HUD Response: Utility payments, using the residual income formula in the Financial Assessment Guide, is a requirement and HUD does not intend to change this policy at this time.

13. Disclosure, Verification, & Certifications

Comment: HUD should clarify, in guidance if not in the regulations, that borrowers will not be required to grant the agent specified power of attorney with the ability to access HECM funds. Some commenters stated that some borrowers will not know someone trustworthy enough for that purpose. Another commenter suggested that HUD should restrict this person's role to that of a "trusted contact" person. One commenter stated that HUD should clarify that the designation of an additional contact is optional on the part of HECM borrowers.

HUD Response: It was not HUD's intent to have all borrowers designate an agent with the authority to make financial decisions or withdraw funds. It is HUD's intent that HECM borrowers be requested to designate a point of contact that mortgagees would be required to use in the event a problem arises or in the event of the borrower's death or incapacitation. Accordingly, HUD has revised § 206.40(c) to clarify that the contact person is not acting as an agent and that the mortgagee will be required to request the designation, but that the borrower is not required to designate such a contact person.

Comment: HUD should require borrowers to provide a trusted contact at the time of loan origination, who would be notified in the event HUD could not establish contact with the borrower. The commenter stated that a failure to respond by the borrower would result in a notification sent to the trusted contact.

HUD Response: HUD has revised § 206.40(c) to clarify that the contact person will not be an "agent" and that the mortgagee will only request that the borrower designate such a contact person that mortgagees would be required to use if they cannot reach the borrower directly in the event a problem arises or in the event of the borrower's death or incapacitation.

Comment: The servicer should verify the agent's information annually when the borrower's certification of residency is obtained, to ensure that the information is up-to-date.

HUD Response: In § 206.211(a), the proposed rule includes the borrower designation of alternate individual as part of the annual certification.

Comment: The requirement to collect an alternative point of contact for notifications from the mortgagee should be required at the time of loan origination and updated annually.

HUD Response: HUD has revised § 206.40(c) to clarify the mortgagee shall request but not require the borrower to designate an alternative individual at origination. In section 206.211(a), the proposed rule includes the borrower designation of alternate individual as part of the annual certification.

Comment: HUD should make certain revisions to the Eligible Non-Borrowing Spouse Certification. The commenter stated that the certification should affirm that the NBS does not have, and is not aware of, any claims against the mortgagee. The commenter also stated that the certification should affirm that the NBS agrees to execute documentation reasonably requested in order to toll the running of any applicable statute of limitation after the borrower passes away but the NBS remains in the property during a deferral period. The commenter finally stated that similar changes should be made to the certifications issued under FHA Info, prior to the issuance of Mortgagee Letter 2016–05 for HECMs subject to the Mortgagee Letter and the MOE Assignment election.

HUD Response: HUD will take these comments under consideration when implementing related policy through guidance. Additionally, FHA reminds mortgagees that the model loan document provided must be adapted by the lenders to local and state requirements that preserve first lien status.

Comment: HUD should allow mortgagees to amend the HECM loan documents to revise the recitals in the security instrument to make clear that the non-borrowing spouse is not a borrower. The commenter also stated that the repair rider and other riders should be indicated as secured items in the initial recitals of the HECM mortgages.

HUD Response: HUD will take these comments under consideration when implementing related policy through guidance. Additionally, FHA reminds mortgagees that the model loan document provided must be adapted by the lenders to local and state requirements that preserve first lien status.

Comment: HUD should add a seventh Qualifying Attribute that the non-borrowing spouse must agree to execute

certain documentation in order to toll the running of any applicable statute of limitation during a deferral period.

HUD Response: HUD will take these comments under consideration when implementing related policy through future rulemaking or policy guidance. Additionally, FHA reminds mortgagees that the model loan document provided must be adapted by the lenders to local and state requirements that preserve first lien status.

Comment: HUD should consider defining the due and payable date as the later of when the Eligible NBS no longer meets all of the Qualifying Attributes or when the borrower dies, in those cases where there is an Eligible NBS present. The commenter stated that this language could be used by mortgagees in states that do not allow the tolling of a statute of limitations.

HUD Response: HUD will take these comments under consideration for future rulemaking. Additionally, HUD reminds mortgagees that the model loan document provided must be adapted to local and state requirements that preserve first lien status.

14. Monetary Investment for HECM for Purchase

Comment: Like most other loan products, there should only be a restriction to payment of those items that are reasonable and customary. Many commenters stated that seller contribution rules for the HECM for Purchase program should be the same as those in the FHA forward market. Some commenters stated that further restrictions result in the senior borrowers having more of a cost burden than similar borrowers using FHA's forward mortgage program as well as conventional and VA mortgage borrowers. One commenter stated that HECM buyers are currently unnecessarily burdened with paying for transfer tax, owner's title insurance, and some escrow fees, whereas forward mortgage buyers have these expenses paid by a third party. Another commenter stated that these restrictions cause seniors to pay more than what they would if they chose a forward mortgage, especially with new construction. One commenter stated that not allowing for customary transaction charges normally paid by the seller can create confusing market irregularities when a HECM is used to purchase a new home. The commenter also stated that some HECM rules are in direct conflict with state law.

HUD Response: In addition to allowing seller payment of fees required by State or Local tax laws and a Home Warranty Policy, the final rule has been

revised to allow fees customarily paid by a seller in the subject property locality to be a permissible interested party contribution. The final rule also retains the proposed rule language to grant flexibility to the Commissioner to consider additional permissible interested party contributions through notice for comment, and will take these comments under consideration in possibly issuing such a future notice.

Comment: The amount of closing costs that other parties can pay should be expanded to further support the use of the HECM for Purchase program. Some commenters stated that it does not make sense to prevent other parties from helping to cover other borrower costs, when these practices are perfectly acceptable for all other types of mortgage transactions. Some commenters stated that HUD should allow lenders credit for buyer closing costs up to 3 percent. Other commenters suggested that the rule be changed to allow the seller to pay 3 to 6 percent of closing costs, similar to the forward side. Another commenter stated that the lender should be able to pay closing costs without limitation, other than the counseling fee. Commenters stated that the practice of prohibiting sellers from paying customary fees or closing costs is unfair to reverse mortgage borrowers. Another commenter stated that if HUD allows the same closing costs to be paid by the seller as are allowed in a traditional FHA loan, HECM for Purchase loans will skyrocket in popularity and greatly benefit the senior real estate market. One commenter stated that even a 2 percent allowable concession would put the consumer into a better cost structure. Another commenter recommended that HUD exclude lender closing cost credits, adjustments, and discounts from the definition of "interested party" contributions.

HUD Response: In addition to allowing seller payment of fees required by State or Local tax laws and Home Warranty Policy, the final rule has been revised to allow fees customarily paid by a seller in the subject property locality to be a permissible interested party contribution. The final rule also retains the proposed rule language to grant flexibility to the Commissioner to consider additional permissible interested party contributions through notice for comment, and will take these comments under consideration in possibly issuing such a future notice.

Comment: HUD should specify what it means by "typical" and "required by state law."

HUD Response: HUD appreciates the recommendation and will take it under

consideration for future policy guidance.

Comment: HUD should allow the seller to pay for the buyer's closing costs and thereby increase the popularity of HECM for Purchase loans. The commenter stated that many borrowers would use a HECM for Purchase loan that they do not intend to live in for the long-term, which would be a great loan for the MMIF.

HUD Response: In addition to the allowing seller payment of fees required by State or Local tax laws and Home Warranty Policy, the final rule was revised to allow fees and charges customarily paid by a seller in the subject property locality to be included as a permissible interested party contribution. HUD will continue to explore responsible lending practices and protections for the benefit for this protected class.

Comment: Continuing the ban on closing costs is a good idea for new construction but not for resales.

HUD Response: HUD appreciates the recommendation and will take it under consideration for future policy guidance.

Comment: HUD should find a way to relieve all closing costs if the borrower agrees to dedicate at least part of the funds toward life and/or annuity products which have prematurity distribution clauses.

HUD Response: Section 255(o) of the National Housing Act prohibits prospective borrowers from being required to purchase additional products, such as annuities as a requirement or condition of HECM eligibility. Currently, closing costs associated with a HECM are limited to certain items such as, but not limited to, MIP, mortgagee's title insurance, hazard and/or flood insurance, loan origination fees, the discharge of all liens against the property which serves as collateral for the HECM, and other reasonable and customary amounts, but not more than the amount actually paid by the mortgagee.

Comment: HUD should clarify that lender-paid broker fees that are disclosed as a "credit" on the HUD-1 for RESPA purposes are not lender credits for purposes of the HECM for Purchase program. The commenter stated HUD should clarify that although lender-paid mortgage broker fees are reflected as a "credit" on line 802 of the HUD-1, such fees paid by lenders to mortgage brokers are not a credit for purposes of the HECM for Purchase program.

HUD Response: HUD appreciates the recommendation and will take it under

consideration for future policy guidance.

15. Eligible Properties

Comment: HUD should require the Certificate of Occupancy as a closing condition rather than for purposes of an application. Another commenter stated that HUD should remove the requirement for a certificate of occupancy to be issued prior to application. The commenter stated that the rule as proposed would restrict consumer access to the HECM for Purchase program. One commenter stated that the builder may not be able to afford to complete the home, and then have the buyer apply for the HECM and wait another 3–6 weeks to close.

HUD Response: The timing for taking the initial loan application will be addressed in future policy guidance rather than this final rule.

Comment: Requiring the certificate of occupancy to be completed on new construction before the HECM can be originated is very burdensome for seniors. Some commenters suggested that the HECM regulations should follow standard FHA rules for forward mortgages wherein the case number and application may ensue upon 90 percent of property completion with the Certificate of Occupancy obtained prior to closing. The commenter, and others, stated that this would enable seniors to compete for new construction homes in 55-and-over communities and energy efficient properties. Another commenter suggested that HUD should allow for an order of a case number and appraisal any time after the home is 50 percent complete. Another commenter stated that newly-built senior housing that is more accommodative to aging independently is a major national demographic trend.

HUD Response: HUD appreciates the comments concerning the timing for collecting habitability documentation and will take it under consideration for future policy guidance.

Comment: As an alternative, HUD should allow for a "temporary" or "conditional" Certificate of Occupancy to be accepted at application. The commenter suggested that the conditional or temporary issues to be addressed would be sod, landscaping, or perhaps an unfinished driveway.

HUD Response: HUD appreciates the recommendation and will take it under consideration for future policy guidance.

Comment: HUD should clarify that the leasehold period is based on the life of the borrower rather than the life of the mortgagor.

HUD Response: The NHA requires that the leasehold period must be under a lease for not less than 99 years that is renewable, or under a lease that has a term that ends no earlier than the minimum number of years, as specified by the Secretary, beyond the actuarial life expectancy of the mortgagor or comortgagor, whichever is the later date. The leasehold period cannot be based on the life of the borrower as the NHA requires that it be based on the life of the mortgagor.

Comment: The proposal to add a new flood insurance mandate "to the extent required by the Commissioner" is vague and unnecessary. One commenter stated that the proposed rule does not contain any description of the criteria the Commissioner would use to make the determination as to whether flood insurance was required. The commenter also stated that federal law and the flood insurance program were already designed to protect mortgagees and the federal government from the risk of property loss due to floods. Another commenter stated that HUD should make it clear that flood insurance is not required unless required under the National Flood Act because the property is in a flood zone.

HUD Response: These requirements are not new additions to the HECM program. They were previously listed in the regulations at 24 CFR part 203 and incorporated into the HECM program by reference. This rule simply moves the regulations into part 206 in order to reduce the number of cross-references. HUD intends to retain these regulatory requirements.

Comment: Section 206.45(c)(1)(ii) should be deleted or paragraph (1) should be edited by adding a paragraph break after the first comma of § 206.45(c)(1)(ii). The commenter stated that, without a paragraph break, it is unclear whether the phrase "if flood insurance under the National Flood Insurance Program (NFIP) is available" applies only to paragraph (ii) or paragraph (i) as well.

HUD Response: The final rule has been revised to clarify the flood insurance requirements.

Comment: HUD should remove its inclusion of collateral "subsequently erected" as it relates to hazard insurance requirements because risk can be effectively mitigated through insurance requirements for the collateral used to secure the loan at the time of origination. One commenter stated that the ability for the servicers to monitor collateral that has been subsequently erected by the borrower is impractical and would require periodic inspections of the property at an added

cost to the borrower. Another commenter requested that the requirement be to protect the collateralized value at the time of origination.

HUD Response: These requirements are not new additions to the HECM program. They were previously listed in the regulations at 24 CFR part 203 and incorporated into the HECM program by reference. This rule simply moves the regulations into part 206 in order to reduce the number of cross-references. HUD intends to retain these regulatory requirements.

16. Repair Work

Comment: HUD should clarify that repair administration fees need not be listed on the HUD Settlement Statement at closing.

HUD Response: The HUD-1 Settlement Statement is under the purview of the CFPB and is a statement of actual charges and adjustments paid by the borrower and the seller, if applicable, to be given to the parties in connection with the settlement.

Comment: HUD should permit the mortgagees to establish a set-aside range between 150 and 200 percent of the estimated cost of repairs. The commenter stated that when an appraiser makes repair estimates, it would be more beneficial to have up to 200 percent of the estimated cost set aside, whereas if a qualified contractor makes the repair estimates, 150 percent should suffice.

HUD Response: HUD currently requires the repair set aside to be established in an amount equal to 150% of the estimated cost of repairs when such required repairs do not exceed 15% of the MCA. The 150% limit provides a sufficient range of flexibility; however, borrowers are also permitted to add additional funds to the Repair Set Aside, but the funds cannot be drawn until the repairs are completed.

17. "Spot Approval" Exception for Condominiums

Comment: The "spot approval" exception should be reinstated for expired approvals. One commenter stated that in some cases, the "spot approval" exception is the only way in which some elderly homeowners can stay in their condominium unit when the property management does not get the entire project FHA approved. One commenter stated that without access to FHA, seniors who live in a non-certified condominium project are cut off from a major potential source of needed cash to pay bills and support their retirement years. The commenter asked whether there is still an opportunity to

reconsider maintaining the spot approval exception and whether there are alternatives to the spot approval. Another commenter suggested that if the spot approval process is not reinstated, the approval process for condominiums needs to be completely revamped because in some markets, it is impossible to get a condominium FHA approved. One commenter stated that many condominium developments do not fully understand FHA approval and that homeowners are afraid to speak up to say that a HECM would improve their financial circumstances so that they would be able to continue to stay in the development. Another commenter asked whether spot approvals could be allowed for HECMs only, as the previous spot approval process was poorly handled and abused frequently. The commenter stated that condominiums provide an attractive, low-maintenance option for seniors. Another commenter requested that HUD re-visit, update, and remedy the spot approval process for single-family FHA-insured loans, including HECMs.

HUD Response: HECMs are subject to existing HUD Condominium eligibility and approval processes as published in ML 2016-15, ML 2016-13, ML 2015-27, and ML 2012-18. This final rule updates the existing HECM regulations regarding spot loans to comply with condominium guidelines that were implemented under HERA via the mortgagee letters referenced above. HUD appreciates the recommendation and will take it under consideration for future rulemaking and policy guidance.

18. Eligible HECM for Purchase Sales

Comment: Ninety days after acquisition is too long to require the seller to wait in order to re-sell the property. One commenter stated that 75 days is plenty of time to fix up a house, get an offer, and close, and that a seller could sell to conventional and VA loan customers earlier.

HUD Response: This requirement does not represent a change in the regulations. This rule simply restates the requirements of part 203 that were previously incorporated into part 206 through cross-references.

19. MIP

Comment: The MIP is too high. One commenter stated that the elevated upfront MIP will often alienate a senior due to cost and suggested, alternatively, that the upfront MIP could be added to the balance similar to the FHA forward mortgage process. Another commenter suggested that the refund of MIP be permitted on a sliding scale or prorated

basis during the first few years of the loan.

HUD Response: It has been HUD's longstanding practice to allow borrowers to finance the initial MIP charge. In response to the sliding scale or proration suggestion, once a mortgage is insured, HUD's longstanding policy has been to require termination of the mortgage without refunding initial MIP. This practice will continue. The limited circumstances for warranting a refund of initial MIP are outlined in paragraph 7-13 of HUD Handbook 4235.1.

Comment: HUD should change the upfront MIP structure for all HECMs. Several comments proposed a tiered MIP structure tied to the percent of Principal Limit disbursed during the first 12 months of the HECM. One commenter suggested a .01 percent upfront MIP for initial draws up to 25 percent, a half-percent upfront MIP for initial draws between 26 and 50 percent, two and half percent upfront MIP for initial draws between 51 and 75 percent, and a three and a half percent upfront MIP for initial draws between 76 and 100 percent. Another commenter suggested that any initial draw under 50 percent would be charged a half-percent upfront MIP; an initial draw between 50 and 60 percent would be charged a one percent upfront MIP; an initial draw between 60 and 70 percent would be charged one and a half percent upfront MIP; etc.

HUD Response: HUD will take these comments under consideration when implementing related policy through guidance.

Comment: The initial MIP should be refundable for a HECM terminated in the first twelve months due to the death of the borrower(s).

HUD Response: Once a mortgage is insured, HUD's longstanding policy has been to require termination of the mortgage without refunding initial MIP.

Comment: HUD should review the legislative history and authority regarding HUD's ability to increase the MIP and re-consider proposing this change at another time.

HUD Response: This final rule updates the existing HECM regulations to include statutory MIP requirements that were implemented under Public Law 111-229 on August 11, 2010, that amended subparagraph (B) of section 203(c)(2) of the National Housing Act (12 U.S.C. 1709(c)(2)(B)).

Comment: The consumer should only be credited with 100 percent of the initial MIP if they are too short to close; otherwise, a fixed amount or percentage should be credited. The commenter stated that lenders that normally credit 100 percent have the servicing rights so

they will recoup this credit on the back end, but some other loan officers cannot offer the same deal and are disadvantaged.

HUD Response: HUD requires the payment of initial MIP as a condition of endorsement. HUD is responsible for oversight and management of the HECM portfolio, not competitive pricing. HUD encourages and supports a borrower's decision to look for the best financing option that will meet their individual short- and long-term needs.

Comment: HUD should refrain from changing the time period of 10 days to remit payment of initial MIP to the Commissioner. The commenter stated that there are occasional cases in which the commenter is unaware of an error with the MIP payment, and 5 days would not be sufficient time to resolve the issue and remit payment before incurring a late charge.

HUD Response: FHA is not changing the 15-day requirement to remit initial MIP to the Secretary. However, the final rule retains the requirement to assess a late charge when MIP is remitted more than 5 days after the payment date as described in § 206.111(a).

20. Insurance of Mortgage

Comment: HUD should use the principal limit on the deed instead of 150 percent of the maximum claim amount. The commenter explained that using a deeded amount of 150 percent of the maximum claim amount causes reverse mortgage borrowers in certain states to pay approximately 260 percent of the tax they should owe. The commenter stated that these states charge an intangible tax or deed/mortgage tax on the deeded amount of the loan.

HUD Response: HUD appreciates the recommendation and will take it under consideration for future policy guidance.

21. Commissioner Authorized to Make Payments

Comment: If the regulations permit the Commissioner to require or not require a subordinate mortgage through notice, HUD should clarify how this change will affect the claims process.

HUD Response: The proposed rule provides flexibility for the Commissioner to consider future policy changes. HUD appreciates the recommendation and will take it under consideration for future policy guidance.

22. Acquisition and Sale of Property

Comment: Acquiring appraisals in the currently strong real estate market typically takes 45–60 days, so the

proposed 30-day time frame is not realistic. One commenter asked what happens when the appraisal is not performed within 30 days of application if the delay is a result of borrower action or inaction. Another commenter stated that the longer appraisal turnaround time can be attributed to the market, weather, review of title prior to appraisal, borrower illness, borrower-created delays, or the rural location of a property.

HUD Response: HUD's longstanding policy has been to use 30 days as the appraisal timeframe. However, should there be any issues due to market conditions making appraisers unavailable, the mortgagee as always may request an extension, which HUD, in its discretion, may grant.

Comment: HUD should revise the proposed language to state that a servicing mortgagee must have a valid appraisal in place at the time of the foreclosure sale date based on HUD's current definition of a valid appraisal.

HUD Response: HUD will issue guidance subsequent to the publication of the final rule in which it will clarify the use of a valid appraisal for establishing the bid amount at a foreclosure sale.

Comment: HUD should provide additional clarity regarding the effective date for the correction involving the appraisal date following the borrower's death instead of the foreclosure sale. The commenter stated that HUD and participating lenders may have disbursed excessive funds as a result of multiple appraisal orders and subsequent curtailments due to the previous drafting error. Some commenters suggested that this drafting error correction should be retroactive in order to protect servicing mortgagees for missing the timeline.

HUD Response: This final rule does not and cannot amend insurance contracts for HECM loans.

Comment: HUD should differentiate the type of "value" requested in reference to the term, "appraised value." The commenter highly recommended, in the case of a foreclosure sale, for the appraisal to include an estimate of the property's market value and liquidation value.

HUD Response: HUD intends to retain its longstanding practice of requiring the "as is" appraised value.

Comment: HUD should clarify that appraisals for pending property sales should be ordered from a HUD-rostered appraiser within 30 days according to the uniform standards, while in cases of foreclosure, appraisals should be received within 30 days prior to the expected foreclosure sale.

HUD Response: Section 206.125(b) of the final rule was revised to provide the Commissioner with the flexibility to have the property appraised by an appraiser on the FHA Roster or other qualified individual. HUD will publish guidance subsequent to the publication of the final rule in which it can clarify the use of a valid appraisal for establishing the bid amount at a foreclosure sale.

Comment: Picky appraisal conditions are infuriating appraisers to the point that they are refusing to accept the orders.

HUD Response: HUD appreciates the comment and will take it under consideration for future policy guidance.

Comment: HUD should tighten appraiser eligibility standards. The commenter suggested that HUD consider a requirement for FHA appraisers to demonstrate verifiable education on FHA appraisal requirements, as authorized by the Housing and Economic Recovery Act of 2008.

HUD Response: Regulations of appraiser requirements are outside the scope of this proposed rule, but HUD appreciates the comment and will take it under consideration.

Comment: There is currently a significant undersupply of appraisers. One commenter suggested that the requirements to become an appraiser should be revised. Another commenter stated that the undersupply is causing borrowers to pay above-market rates and that the wait times are beginning to increase beyond one month in certain areas. The commenter suggested that some funds should be placed into attracting talent into the appraiser pool.

HUD Response: Regulations of appraiser requirements are outside the scope of this proposed rule, but HUD appreciates the comment and will take it under consideration.

Comment: For the Cash for Keys program, the amount should be consistent with Mortgagee Letter 2016–03, up to a maximum of \$3,000.

HUD Response: HUD will take these comments under consideration when implementing related policy through guidance.

Comment: HUD should allow for the Cash for Keys option in lieu of evictions and not merely deed-in-lieu transactions.

HUD Response: HUD has adopted this change in the final rule and will make Cash for Keys available after foreclosure to bona fide tenants only. A bona fide tenant means a tenant of the property who is not a mortgagor, borrower, a spouse or child of a mortgagor or

borrower, or any other member of a mortgagor's or borrower's family. The incentive to have the borrower or person with legal right to dispose of the property provide a deed-in-lieu would be negated if they were aware that they could force the mortgagee to foreclose, allowing them to remain in the property longer and still be paid a Cash for Keys incentive.

Comment: Cash for Keys should not only be available during the first six months following the due date. The commenter stated that there may be circumstances in which a property cannot be transferred within this time frame, but a deed-in-lieu of foreclosure would still be an attractive option for both parties.

HUD Response: Deeds in lieu are offered as a means to save the time it takes to foreclose, particularly in states with long foreclosure timeframes and to limit the expenses HUD reimburses in eventual claims. As indicated in the preamble to the proposed rule, 9 months allows a borrower or other party with the legal right to dispose of the property 6 full months to sell the property and then 3 additional months for the mortgagee to obtain a title search and get the deed signed, provided that title is clear. Allowing a deed in lieu to occur after that time does not represent the time or cost savings intended by a deed in lieu.

Comment: Nine months is not sufficient time to allow the borrower to attempt to sell the property under the time frame for a deed-in-lieu of foreclosure following the time at which the HECM becomes due and payable. The commenters stated that deed-in-lieu of foreclosure transactions should be allowed up until the foreclosure sale date. The commenters also stated that probate proceedings can make it difficult for the heirs to sell the property within nine months.

HUD Response: Deeds in lieu are offered as a means to save the time it takes to foreclose, particularly in states with long foreclosure timeframes and to limit the expenses HUD reimburses in eventual claims. As indicated in the preamble to the proposed rule, 9 months allows a borrower or other party with the legal right to dispose of the property 6 full months to sell the property and then 3 additional months for the mortgagee to obtain a title search and get the deed signed, provided that title is clear. Allowing a deed in lieu to occur at any time up until the foreclosure sale date does not represent the time or cost savings intended by a deed in lieu.

Comment: Sixty days is not sufficient for notice to be provided to HUD regarding the mortgage becoming due

and payable. One commenter stated that death cannot always be discovered within this timeframe, which results in servicers facing significant curtailment risk due to their inability to provide such timely notice. The commenter suggested as an alternative to require mortgagees to report notice of the passing of the last surviving borrower within ten days of receiving notification of the borrower's death following reasonable diligence in monitoring the loan portfolio. Another commenter recommended notification within 60 days of the servicer discovering and confirming the title was conveyed and that no HECM borrower remains on title. One commenter recommended that the required timeline should begin when the servicer knew or reasonably should have known of the death.

HUD Response: The timeframes in the proposed rule for the due date did not change, with the exception of adding the end of a deferral period. However, the final rule codifies in § 206.125 the guidance issued in ML 2015–10, and HUD believes these are acceptable timeframes.

Comment: The proposal to base the foreclosure on the due date conflicts with ML 2015–10 and should remain as is.

HUD Response: HUD believes the initiation of foreclosure is more appropriately aligned with the due date, i.e., the date of notice to HUD that the borrower has died or conveyed title to the property or the date HUD grants due and payable permission. Basing the foreclosure initiation date on when notice is made to the borrower poses increased risk to the MMIF because it allows mortgagees to delay the process unnecessarily by simply withholding the required notice and thereby increasing eventual claim expenses.

23. Payment of Claim

Comment: As in Mortgagee Letter 2016–03, HUD should require servicers to exercise reasonable diligence in prosecuting the foreclosure proceedings to completion and in acquiring title to and possession of the property pending varying state procedures. The commenter stated that the process associated with the foreclosure of a property with HECM financing can be lengthy and that the two-year reimbursement period would put both the MMIF and servicer at risk.

HUD Response: HUD has taken public comments into consideration and has replaced the two-year reimbursement period in § 206.129(d)(3) with a limit of two-thirds of total advances for the allowable expenses outlined in this section.

Comment: HUD should remove the proposed two-year limitation on insurance claim reimbursements for property charge advances. One commenter stated that if this limitation were applied to existing HECMs, the number of HECM foreclosures would increase as servicers called the loans due and payable as the two-year limit was reached. The commenter also stated that this result would conflict with HUD guidance allowing the deferral of due and payable status for low-balance arrearages and “At Risk” borrowers. Another commenter stated that the process can be delayed by factors outside of a servicer's control, such as a tax and insurance default and a repayment plan, new tax and insurance disbursements, and default/foreclosure timelines.

HUD Response: HUD has taken public comments into consideration and has replaced the two-year reimbursement period in § 206.129(d)(3) with a limit of two-thirds of total advances for the allowable expenses outlined in this section.

Comment: Regarding the regulations addressing the amount of payment when the borrower sells the property, HUD should include provisions for loans assigned prior to the effective date of the rule that are or are not in due and payable status. The commenter stated that for such loans that are due and payable, the claim amount should be based on the outstanding loan balance as of the due date and should include the allowance for items to capture the costs of title, foreclosure costs, and costs associated with the acquisition of the property.

HUD Response: The language in the final rule has been revised to clearly define what is reimbursable where the borrower sells the property, pre and post due and payable, based on the effective date of the final rule.

Question 1: Should the HECM program provide for the pro rata curtailment of debenture interest and reduction of expenses incurred as a result of the mortgagee's delay in filing the mortgage insurance claim, and if so, how should such a policy be structured to ensure feasible implementation?

Comment: Debenture interest should be curtailed on a pro rata basis, but curtailing expenses could create an incorrect incentive on the part of servicers to refrain from expending such amounts, which would perhaps impact recoveries and place the MMIF at risk.

HUD Response: The regulations do not remove the requirement for mortgagees to protect the lien interest or to preserve and protect the property.

HUD is exploring options to ensure mortgagees meet required timeframes. There is great risk to the FHA MMIF when mortgagees fail to timely prosecute foreclosures or take other required actions.

Comment: Debenture interest should be paid from the date of notification to HUD. The commenter stated that servicers must demonstrate reasonable diligence in monitoring for death but should not be penalized for issues related to reporting bureaus.

HUD Response: HUD believes without this time frame; mortgagees will have little incentive to move the HECM to termination in a timely manner. In addition, HUD believes mortgagees have resources to identify the borrower's death, but because there may be an expense related to such resources, the mortgagees prefer not to subscribe to them. HUD contends that 60 days is sufficient time to identify a borrower's death through available resources, and move the HECM toward its logical conclusion.

Comment: The debenture interest rate should continue to be based on the endorsement date rather than the date on which the default on the mortgage occurred.

HUD Response: HUD did not propose changing the date upon which the debenture interest rate is based. It only proposed to restate the requirements of part 203 that are applicable to the HECM program instead of cross-referencing to part 203, which includes the debenture interest calculations.

24. First Lien Status

Comment: As a result of this rule change, lenders and servicers in super lien states will do a more thorough job of monitoring HOA payments to ensure that the liens do not occur in the first place. The commenter stated that this rule change would allow homeowner associations to receive the funds they are owed sooner.

HUD Response: HUD appreciates the comment.

Comment: The proposed rule change on the lien priority for homeowners' associations and condominiums disregards the laws of 21 states and the District of Columbia. Commenters noted that allowing homeowners' association and condominium "super liens" to take precedence over HECM liens would probably render such properties unloanable. Some commenters stated that the proposed changes would effectively eliminate a condominium or house purchase in those states by anyone planning to finance with a HECM for Purchase. One commenter stated that condominiums provide a maintenance-

free lifestyle that is especially popular with the HECM customer base. Another commenter estimated that there would be about a sixteen percent loss of volume as a result of this rule change. One commenter stated that this change may cause further restrictions to financing options for senior homeowners living in low maintenance condominiums. Commenters stated that the rule change exposes community association homeowners and residents, including senior citizens, to risk of higher housing costs and unjust financial burdens. One commenter stated that these state association lien priority laws intend to prevent the unjust enrichment of lenders at the expense of community association homeowners that occurred during the Great Recession. Another commenter stated that the proposed rule may disqualify more than 4 million senior citizens living in condominiums. One commenter stated that removing the HECM option for homeowners and potential homeowners in these markets would have dire consequences on the senior population, the economic stability in those markets, and a negative impact on the MMIF due to the reduction of HECM loans. Another commenter stated that the difficulty surrounding assignment of loans in such markets could result in an inadvertent curtailment or cessation of HECM mortgage origination and servicing. One commenter stated that seniors move into condominiums without considering a HECM, and then find out later that this is not an option.

HUD Response: HUD has removed the language referring to homeowners' association liens and condo association liens for the final rule. However, HUD reminds mortgagees that in order for a HECM to be eligible for loan assignment, the mortgage must be a valid, legally enforceable first lien and title to the property securing the mortgage must be good and marketable. In the event that HUD discovers later that good and marketable title is lacking due to a lien, HUD may require repurchase.

Comment: HUD should prohibit HOA liens of record at the time of assignment, and not afterwards. The commenter stated that servicing mortgagees have no way to determine whether HOA dues are past due, and a lien from past due HOA dues may only be reflected on a title report ordered as part of or prior to an assignment.

HUD Response: HUD has removed the language referring to homeowners' association liens and condo association liens in this final rule. However, HUD reminds mortgagees that in order for a

HECM to be eligible for loan assignment, the mortgage must be a valid, legally enforceable first lien and title to the property securing the mortgage must be good and marketable. In the event that HUD discovers later that good and marketable title is lacking due to a lien, HUD may require repurchase.

Comment: The non-payment of HOA/COA fees is already a condition of default for HECMs. The commenter encouraged HUD to share data regarding the extent of HOA defaults to help advocates better understand the scope of this issue.

HUD Response: HUD has removed the language referring to homeowners' association liens and condo association liens in this final rule. However, HUD reminds mortgagees that in order for a HECM to be eligible for loan assignment, the mortgage must be a valid, legally enforceable first lien and title to the property securing the mortgage must be good and marketable. In the event that HUD discovers later that good and marketable title is lacking due to a lien, HUD may require repurchase.

Comment: Instead of threatening seniors' ability to take advantage of the HECM program in certain states, HUD should focus on ensuring compliance from the lending community with program rules and guidelines concerning foreclosure, property preservation, and title conveyance. The commenter stated that the proposed rule threatens pro-homeowner, pro-consumer state statutes by excluding senior citizens from the HECM program in these states.

HUD Response: HUD has removed the language referring to homeowners' association liens and condo association liens in this final rule. However, HUD reminds mortgagees that in order for a HECM to be eligible for loan assignment, the mortgage must be a valid, legally enforceable first lien and title to the property securing the mortgage must be good and marketable. In the event that HUD discovers later that good and marketable title is lacking due to a lien, HUD may require repurchase.

Comment: HUD's proposal will likely have a disproportionate, negative impact on female HECM borrowers residing in condominiums in association lien priority jurisdictions.

HUD Response: HUD has removed the language referring to homeowners' association liens and condo association liens in this final rule. However, HUD reminds mortgagees that in order for a HECM to be eligible for loan assignment, the mortgage must be a

valid, legally enforceable first lien and title to the property securing the mortgage must be good and marketable. In the event that HUD discovers later that good and marketable title is lacking due to a lien, HUD may require repurchase.

Comment: HUD does not justify this rule change by indicating any losses HUD may have suffered insuring reverse mortgages due to state law association lien priority.

HUD Response: HUD has removed the language referring to homeowners' association liens and condo association liens in this final rule. However, HUD reminds mortgagees that in order for a HECM to be eligible for loan assignment, the mortgage must be a valid, legally enforceable first lien and title to the property securing the mortgage must be good and marketable. In the event that HUD discovers later that good and marketable title is lacking due to a lien, HUD may require repurchase.

Comment: HUD should include in the LESA any association assessments in states that recognize association lien priority. One commenter suggested requiring a set-aside for 6 months' worth of fees for borrowers in those markets that have super lien laws. Another commenter stated that HUD should explore whether HOA dues should be included as part of the required set-aside, as well as what the impact would be on low-income households.

HUD Response: HUD has removed the language referring to homeowners' association liens and condo association liens in this final rule. However, HUD reminds mortgagees that in order for a HECM to be eligible for loan assignment, the mortgage must be a valid, legally enforceable first lien and title to the property securing the mortgage must be good and marketable. In the event that HUD discovers later that good and marketable title is lacking due to a lien, HUD may require repurchase.

Comment: The different treatment of utility charges and condominium or HOA fees results in irrational discrimination against owners in such associations. The commenter stated that if a nonpayment of utilities would result in a lien, then HUD will reimburse the lender for advancing the payment as a property charge. However, the commenter stated, if the utilities are centrally metered and paid for by a condominium association or HOA and reimbursed through assessments, then HUD would not have to reimburse the lender for advancing payments.

HUD Response: HUD has removed the language referring to homeowners'

association liens and condo association liens in this final rule. However, HUD reminds mortgagees that in order for a HECM to be eligible for loan assignment, the mortgage must be a valid, legally enforceable first lien and title to the property securing the mortgage must be good and marketable. In the event that HUD discovers later that good and marketable title is lacking due to a lien, HUD may require repurchase.

Comment: HUD should clarify its position and procedures under circumstances where state laws limit a mortgage's first lien status.

HUD Response: HUD has removed the language referring to homeowners' association liens and condo association liens in this final rule. However, HUD reminds mortgagees that in order for a HECM to be eligible for loan assignment, the mortgage must be a valid, legally enforceable first lien and title to the property securing the mortgage must be good and marketable. In the event that HUD discovers later that good and marketable title is lacking due to a lien, HUD may require repurchase.

Comment: HOA dues should be considered property charges and treated like taxes and insurances with regard to default and repayment plans in the super lien states in which delinquent HOA dues may become a superior lien to the HECM. Commenters stated that the consumer should be allowed to repay any advances made on these liens, just like any other property charge. One commenter stated that this would protect HUD's lien position and the MMIF, and provide loss mitigation options to HECM borrowers.

HUD Response: HUD has removed the language referring to homeowners' association liens and condo association liens in this final rule. However, HUD reminds mortgagees that in order for a HECM to be eligible for loan assignment, the mortgage must be a valid, legally enforceable first lien and title to the property securing the mortgage must be good and marketable. In the event that HUD discovers later that good and marketable title is lacking due to a lien, HUD may require repurchase.

Comment: HUD should expressly prohibit the extinguishment of HECM mortgage lien interests by HOA super liens. Commenters stated that HUD has successfully relied on the Constitution's Supremacy Clause to bar HOA foreclosure sales from extinguishing first liens deeds of trust in Nevada when they are insured through HUD.

HUD Response: HUD has removed the language referring to homeowners'

association liens and condo association liens in this final rule. However, HUD reminds mortgagees that in order for a HECM to be eligible for loan assignment, the mortgage must be a valid, legally enforceable first lien and title to the property securing the mortgage must be good and marketable. In the event that HUD discovers later that good and marketable title is lacking due to a lien, HUD may require repurchase.

Comment: HUD should clarify that this requirement would not apply to existing HECM loans where HUD has issued a commitment to insure.

HUD Response: HUD has removed the language referring to homeowners' association liens and condo association liens in this final rule. However, HUD reminds mortgagees that in order for a HECM to be eligible for loan assignment, the mortgage must be a valid, legally enforceable first lien and title to the property securing the mortgage must be good and marketable. In the event that HUD discovers later that good and marketable title is lacking due to a lien, HUD may require repurchase.

25. Effect of Noncompliance With Regulations

Comment: The proposed new section 206.137 would violate the basic precept in the National Housing Act that mortgage insurance on an FHA loan is incontestable in the hands of the holder. The commenter stated that this provision would cause a problem with loans being pooled or sold in the secondary market, as almost all HECM loans are.

HUD Response: Section 206.137 does not represent a change in the regulations. This rule incorporates this provision from 24 CFR part 203 into part 206, whereas it had previously been incorporated by cross-reference.

26. Final Payment

Comment: HUD needs to process all past due HECM supplemental claims and streamline the process for paying such claims in the future within a time period less than that proposed in new section § 206.144.

HUD Response: Section 206.144 does not represent a change in the regulations. This rule incorporates this provision from 24 CFR part 203 into part 206, whereas it had previously been incorporated by cross-reference.

27. Providing Information

Comment: HUD should expand its requirement to provide the borrower with a single statement at the end of each month to include additional

documentation that will help to modernize the HECM program. The commenter suggested that the borrower be provided with visual charts and diagrams depicting the loan status, analysis tools for borrowers to explore changing the disbursement plan, online banking methods to review account statement data, and account statement formats that comply with the Plain Writing Act. Another commenter stated that specific contact information for HECM experts with the mortgagee or servicer should be included on the monthly statement.

HUD Response: HUD does not intend to prescribe a burdensome process for providing monthly statements. However, HUD does not restrict mortgagees from offering any additional information through the monthly statement. Additionally, servicers' monthly statements already include a phone number for borrowers to contact a HECM representative.

Comment: Mortgagees should be required to provide borrowers with a dedicated phone number they can call and speak to employees on a team specifically trained to address inquiries concerning HECM mortgages.

HUD Response: The final rule, as did the proposed rule, states that the borrower may speak to the employee or employees specifically designated by the mortgagee or its servicer to address inquiries concerning mortgages insured under this part. Since the part in question is 24 CFR part 206, which deals solely with the HECM program, the language in the rule already addresses the commenter's concern.

Comment: HUD should retain the requirement that the mortgagee provide a single point of contact for HECM loan inquiries. The commenter stated that as seniors can be targets for fraud or elder abuse, providing a consistent point of contact can provide borrowers with a level of comfort when dealing with their reverse mortgage company.

HUD Response: With the growth of the HECM portfolio, the staffing turnover within the mortgage industry, and the challenges a borrower can face if their single point of contact is away from the office when needed, it is no longer feasible for borrowers to be provided the name of a single person with whom they may speak. HUD feels that having a group of mortgagee staff specializing in HECMs available to borrowers gives borrowers more opportunity to speak to someone who can assist them. HUD is adamant, however, that borrowers must be able to reach a live person when calling a mortgagee and not have to rely on voice mail and a return call.

28. Life Expectancy Set-Asides

Comment: HUD should allow the life expectancy set-aside to be re-evaluated after closing in order to use the correct property tax amount for that year rather than the previous year's amount.

HUD Response: Currently, HUD requires the servicing mortgagee to disburse payments based on the actual property tax and insurance amounts for that year.

Comment: Lenders should have the ability to change the first-year set-aside to \$0, as pre-closing charges are being paid from the loan proceeds.

HUD Response: Currently, HUD permits the mortgagee to require, or when requested by the borrower, to disburse funds for payment of taxes and insurance at closing, when such property charges are coming due within 30–45 days following closing. Payment of taxes and insurance by the Mortgagee usually requires multiple disbursements by the lender over the initial disbursement period depending on due dates for tax and insurance payments, thus, it is not feasible to omit the first year of Life Expectancy Set Aside payments.

Comment: The borrower's election to have the servicer pay taxes and insurance by drawing from a line of credit or withholding funds from monthly tenure payments should not be irreversible and should be available to borrowers at any time during the HECM. One commenter stated that few borrowers would elect this option without such flexibility.

HUD Response: HUD appreciates the recommendation and has added language that provides the Commissioner with the authority to issue a **Federal Register** Notice to expand the property charge payment options at a future date.

Comment: HUD should eliminate the lifetime and partial LESA and implement a three-year tax and insurance reserve set-aside. The commenter stated that LESAs can amount to hundreds of thousands of dollars or even exceed the entire amount of the potential HECM, particularly in higher property tax areas.

HUD Response: HUD explored various options to address its property charge default risk, including shorter periods. After careful consideration and review, the LESA provided the most security for allowing the borrower to age in place and comply with the terms and conditions of the mortgage.

Comment: Partially-funded LESAs should be paid directly to the tax authority or insurance company. The commenter stated that disbursement to

the borrower introduces additional risk that property charges will not be paid.

HUD Response: HUD explored various options to address its property charge default risk, including identifying prospective borrowers who have shown a willingness to pay their financial obligations but fall short of having the means to make the payment. The Partially-Funded LESA fills the gap for allowing the borrower to be responsible for such payments. Additionally, tax payments cannot be paid on a partial basis and would be operationally infeasible.

Comment: Thirty days is an insufficient time frame for a borrower to respond to the mortgagee's notification of a missed property charge payment. The commenter stated that thirty days is a short time to respond to the mortgagee's request regarding the non-payment, especially when there is a delay in the mortgagee's processing or mailing of the initial notice. The commenter suggested that the time period be extended to 90 days.

HUD Response: This provision simply codifies what has been implemented through ML 2015–10. HUD believes the timeframe is sufficient for a borrower to have contacted the mortgagee to express their willingness to repay the funds due.

Comment: HUD should provide a time frame or guidance concerning how the mortgagee is to determine the borrower is unwilling or unable to repay the mortgagee for funds advanced to pay property charges outside of a LESA.

HUD Response: ML 2015–11 provides the availability of loss mitigation options for a mortgagee to work with the borrower.

29. Allowable Charges and Fees After Endorsement

Comment: What is the goal of allowing a servicing charge to be included in the mortgage Note rate?

HUD Response: The option for allowing a servicing charge which is included in the mortgage Note Rate provides flexibility for the lender to cover servicing costs in a manner that is consistent with mortgage industry practices if a Servicing Fee Set Aside is not established. In addition, allowing the servicing charge to be included in the Note Rate provides the borrower access to more funds from which to draw against since such funds are not being withheld in the Servicing Fee Set Aside.

Question 1: What is an appropriate servicing fee range (minimum and maximum dollar amounts) for the flat monthly servicing fee, and what factors support the upper and lower bounds of that range?

Comment: HUD should not allow this charge. The commenter stated that the charge would infuriate and confuse the borrower, as well as complicating the loan and contributing to the headline that reverse mortgages are too expensive.

HUD Response: Servicing fee charges are an allowable fee that has been a part of the HECM program since inception. Servicing fees provide compensation to servicers for servicing the HECM loan.

Comment: HUD should increase the dollar amounts for allowable servicing fees based on the Consumer Price Index from the last servicing fee adjustment in 1998. The commenter stated that reverse mortgage borrowers usually require more time spent on servicing-related issues as compared to forward mortgage borrowers. The commenter also justified a raise in servicing fees based on the increase in servicing policy requirements implemented since 1998.

HUD Response: HUD will take these comments under consideration when implementing related policy through guidance.

Comment: There is no reason for the annual adjustable and fixed rate loans to have a different dollar amount servicing fee than the monthly adjustable HECMs. The commenter stated that all of these products have the same servicing requirements. *HUD Response:* Adjustable rate loans require additional support for future draws and payment plan changes.

Question 2: What is an appropriate servicing fee range, in basis points, that could be included in the Note rate, and what factors support the upper and lower bounds of that range?

Comment: There is no reason to separate the servicing fee from the lender margin. The commenter stated that on a fixed rate loan, the lender always has the option of charging a higher interest rate to cover increased servicing costs, and on an adjustable rate loan, the margin can be increased to cover rising servicing costs.

HUD Response: The Note rate includes the lender's margin and may also include a servicing fee as stated in § 206.207(b).

Comment: The basis range is acceptable as currently prescribed and adjustments to this range should be made by the Government National Mortgage Association (GNMA).

HUD Response: The current prescribed range is in accordance with GNMA servicing parameters.

30. Housing Counseling
Comment: HUD should include continuing education requirements so that counselors keep up-to-date on the ongoing changes in the HECM program. The commenter noted that some clients have indicated counselors have discouraged them from using a HECM and that the counselors seem unaware of the usefulness of a HECM ARM as a financial planning tool.

HUD Response: All counseling sessions are required to cover all the potential risk for a HECM, including property charges, ineligible NBS, etc. The rule would not change those existing counseling requirements in these areas. One of the primary purposes of HECM counseling is to provide education on all aspects of HECMs from an objective third party. The current HECM counselor roster rule requires that counselors take continuing education every 2 years and retake the HECM counselor test every 3 years. This ensures that counselors stay current with program requirements.

Comment: Counseling should be mandatory for all seniors considering FHA loans. The commenter stated that it is unconscionable for seniors to receive a forward 20–30-year loan and not receive counseling on the option of a HECM loan. *HUD Response:* Counseling by a counselor on the HECM roster is statutorily required. Given the unique nature of a HECM loan, the requirement for counseling is a critical consumer protection for an “at risk” population.

Comment: Borrowers are not very well-prepared for the multiple downside risks inherent in reverse mortgages. One commenter stated that many borrowers are told by unscrupulous loan brokers that there are no further obligations to fulfill once they receive the HECM, and that current counseling is ineffective at correcting those misrepresentations. The commenter suggested that HUD study this counseling problem and adjust counseling requirements accordingly. Another commenter stated that the counselors should have training and additional responsibility to inform the borrower whether a reverse mortgage is right for the borrower. Alternatively, the commenter stated, the counselor should be required to inform the borrower that they should seek financial or legal advice to understand the suitability and consequences of the HECM.

HUD Response: HUD disagrees with these comments. HUD believes HECM Roster Counselors are qualified and fully capable, based on their training

and continuing education, to thoroughly educate clients on reverse mortgages. Furthermore, HECM Roster Counselors must follow a strict protocol when providing counseling to potential HECM Borrowers. The protocol, found in Appendix 2 of HUD Handbook 7610.1, Rev.5, requires HECM Counselors to educate clients on the financial implications of obtaining a HECM, the effect of obtaining a HECM or other reverse mortgage product on public benefits and on borrower and non-borrower spouse post-closing obligations for items, including, but not limited to, repairs, payment of taxes and insurance and loan re-payment when the loan becomes due and payable.

HUD believes that the proper role of a HECM Counselor is to educate clients on the features of reverse mortgages and on the appropriateness of a reverse mortgage or other financial options to meet the client's needs. HUD further believes that it is not the role of the HECM Counselor to advise the client whether to proceed with a reverse mortgage, or which reverse mortgage product to use, but to provide guidance and resources to enable the client to make an informed decision. HUD disagrees that HECM Counselors should be required to inform clients that they should seek financial or legal advice to understand the suitability and consequences of the HECM. As with forward mortgages, it is the consumers' decision whether or not to seek financial or legal advice before entering into a loan transaction.

Comment: Counselors should not explicitly tell borrowers to shop for loans or that they can get certain terms such as a zero origination fee. One commenter stated that the role of the counselor should be strictly limited to providing counseling on how the program works and not to give the borrower advice.

HUD Response: A thorough HECM counseling session includes a presentation of all the alternatives to a HECM. Counselors may recommend that the borrower shop around for better priced products as part of such a session, but are not permitted to direct a client to any specific lender or provide lender price comparisons.

Comment: HUD should clarify to what “electronic database” the counselor needs to upload the counseling certificate. One commenter asked whether an electronically uploaded certificate would waive the requirement for an original borrower signature on the counseling certificate. Another commenter asked for clarification on this point. The commenter also stated that HUD should give seniors and

mortgagees the option to receive a hard copy of the counseling certificate.

HUD Response: Upon further consideration to require HECM counselors to upload the certificate to an “electronic database,” HUD is no longer pursuing this option as it would impose a financial burden upon borrowers to send a signed and dated copy of the certificate back to the counselor and difficult for the counselor to manage the process.

Comment: *Non-borrowing spouses should not have an additional counseling component.* The commenter stated that such a requirement would cause an unnecessary increase of fees as well as delay time to begin the HECM financing process. The commenter also stated that HUD would need to address the problem of educating all HECM counselors and updating the information they provide to borrowers and non-borrowing spouses.

HUD Response: Non-borrowing spouses have been required to receive counseling since 2009. HECM counselors make every effort to counsel both borrowers and non-borrowing spouses jointly unless extenuating circumstances exist that prevent this. This is part of the guidance to counselors in the HECM protocol. HECM counselors are also encouraged to include family members in a counseling session. The clients have the ultimate decision as to who to include in these sessions, and this may include legal counsel, financial advisors, etc.

Comment: *HUD should clarify that mortgagees may denote on the HECM mandated counseling disclosure that the borrower is required to undergo face-to-face counseling or be counseled by a counselor or counseling agency that is “domiciled” within a particular state.* The commenter also suggested that HUD indicate which counseling agencies can provide such face-to-face counseling or is domiciled within a state. The commenter stated that several states have face-to-face counseling requirements or requirements that the senior be counseled by a counselor or counseling agency that is “domiciled” in a particular state.

HUD Response: HUD will consider this recommendation as part of the current HECM counseling protocol revisions.

Comment: *HUD should require information about suitability to be provided to prospective borrowers prior to the counseling session.* One commenter suggested that HUD refer to California Civil Code Section 1923.5 as a guide for providing the potential borrower such information.

HUD Response: HUD will consider these suggestions as part of the current HECM counseling protocol revisions.

Comment: *Counseling should be in-person or face-to-face electronically and should be digitally recorded and broken up into two sessions.* The commenter also suggested that the counseling should include all members of the household in a discussion on inter-family loans and provide clear information on where to turn for help if the borrower later has problems with the reverse mortgage.

HUD Response: HUD will consider these suggestions as part of the current HECM counseling protocol revisions.

Comment: *HUD should not restrict financial professionals from helping borrowers seek professional money management advice.* The commenter stated that HUD should not ask the homeowner if they plan to use the HECM proceeds to purchase life or annuity products. The commenter also stated that almost all HECM lenders are trying to tie the product more closely with the financial and estate planning communities.

HUD Response: The language in the rule is consistent with the statutory requirement in § 255(d)(11) of the NHA.

31. Maximum Closing Costs Allowed on Sale of Property

Question 1: Is 11 percent a reasonable cap? HUD chose this percentage based on the policy for sale of its REO inventory, which allows for payment of 6 percent sales commission and 5 percent for other closing costs, but is interested in comments to indicate whether the amount should be higher or lower, and why the commenter believes the adjustment is appropriate.

Comment: *The maximum closing costs allowed should be based on a sliding scale so that the expenses are limited to the greater of \$15,000 or 11 percent of the sales price of the property.* The commenter stated that strictly limiting such charges to 11 percent for properties that sell for small dollar amounts may not even cover the actual expenses incurred by the mortgagee.

HUD Response: The final rule now states that closing costs shall not exceed the greater of: (a) 11 percent of the sales price; or (b) a fixed dollar amount as determined by the Commissioner. The amount as determined by the Commissioner will be issued through **Federal Register** notice.

Comment: *The schedule of allowable costs under the 11 percent cap should include lien payoff, cleaning, and repairs.* The commenter stated that the

economics of a HECM short sale often lead to property maintenance issues. The commenter also stated that allowable closing costs need to be clearly communicated to servicers.

HUD Response: Due to the non-recourse nature of HECM loans, short sales represent a risk to the FHA MMIF through claims. Furthermore, short sales do not allow the borrower or seller to retain any funds and the sales price is based on the “as is” appraised value. Therefore, it is not necessary for the borrower to make extensive repairs.

Comment: *This amount is unworkable for lower balance home values, unless there is a tiered approach.* One commenter stated that this limitation can result in a shortage of closing costs when selling lower value homes because many of the costs are fixed and unrelated to the sale price of the property.

HUD Response: The final rule states that closing costs shall not exceed the greater of: (a) 11 percent of the sales price; or (b) a fixed dollar amount as determined by the Commissioner. The amount as determined by the Commissioner will be issued through **Federal Register** notice.

Question 2: Should HUD implement a tiered approach to the maximum percent of closing costs in relation to sales price? For example, should a property selling for under \$100,000 be allowed a higher percentage of closing costs than a property selling for over \$100,000?

Comment: *HUD should adopt a tiered approach to take into account that 11 percent may not be sufficient for lower balance home values.* One commenter stated that a greater percentage should be assigned to lower sales prices.

HUD Response: The final rule now states that closing costs shall not exceed the greater of: (a) 11 percent of the sales price; or (b) a fixed dollar amount as determined by the Commissioner. The amount as determined by the Commissioner will be issued through **Federal Register** notice.

Question 3: Should HUD implement a tiered approach to the maximum dollar amount of closing costs in relation to the sales prices? For example, should a property selling for under \$100,000 be allowed a different dollar amount than a property selling for over \$100,000?

Comment: *HUD should set a minimum dollar amount for lower balance home values.*

HUD Response: The final rule now states that closing costs shall not exceed the greater of: (a) 11 percent of the sales price; or (b) a fixed dollar amount as

determined by the Commissioner. The amount as determined by the Commissioner will be issued through **Federal Register** notice.

Comment: A fixed closing costs dollar amount limitation in line with customary costs would be more appropriate if closing costs are to be capped. The commenter volunteered to work with HUD to establish customary costs based on the commenter's data and experience.

HUD Response: The final rule now states that closing costs shall not exceed the greater of: (a) 11 percent of the sales price; or (b) a fixed dollar amount as determined by the Commissioner. The amount as determined by the Commissioner will be issued through **Federal Register** notice.

32. Non-Borrowing Spouse Communication

Question 1: What difficulties have Non-Borrowing Spouses, heirs, and successors in interest had in obtaining information about HECMs and understanding and exercising their rights?

Comment: HUD should create a written guide for the heirs that is to be delivered by the servicer with the initial letter of repayment. The commenter opined that it would be very beneficial for all parties, including FHA's MMIF, if a standard guide was created to outline the steps the heirs should be taking, and that it would result in faster repayment, more participation in the Cash for Keys initiative, and fewer foreclosures. The commenter suggested alternatively that the guide could be created by a group chosen by NRMLA.

HUD Response: HUD will take this suggestion under consideration for future policy guidance.

Comment: Many servicers are not properly communicating about how someone can qualify as an Eligible Non-Borrowing Spouse. Commenters stated that servicers provide conflicting and inaccurate information, reject paperwork for unexplained reasons, and lose paperwork. One commenter suggested that HUD develop a standardized letter to contact non-borrowing spouses or heirs that is written in simple, clear language.

HUD Response: HUD expects mortgagees to comply with the regulatory requirements of § 206.125(a)(2), which specifies the information required to be provided to the borrower's estate or heirs. HUD does not intend to develop a standardized letter.

Comment: Heirs have had great difficulty getting information from the

servicer about options and steps required at the time of loan repayment.

HUD Response: HUD has clarified in the final rule that mortgagees must request that HECM borrowers designate a point of contact that mortgagees would be required to use in the event a problem arises or in the event of the borrower's death or incapacitation. Accordingly, HUD has revised § 206.40(c) to clarify that the contact person is not acting as an agent and that the mortgagee will be required to request the designation, but that the borrower is not required to designate such a contact person.

Question 2: What adjustments could HUD make to this rule to address the identified difficulties and facilitate communication with Non-Borrowing Spouses, heirs, and successors in interest?

Comment: HUD should encourage servicers to request that borrowers designate family members or others who are authorized to speak with them about a loan on behalf of a borrower or following the death of a borrower.

HUD Response: HUD has clarified in the final rule that mortgagees must request that HECM borrowers designate a point of contact that mortgagees would be required to use in the event a problem arises or in the event of the borrower's death or incapacitation. Accordingly, HUD has revised § 206.40(c) to clarify that the contact person is not acting as an agent and that the mortgagee will be required to request the designation, but that the borrower is not required to designate such a contact person. The mortgagee shall communicate with an alternate individual if one has been designated by the borrower.

Comment: HUD should produce and require collateral material regarding what happens when the loan is due and payable. The commenter stated that the material should be available to the non-borrowing spouse and the borrower's heirs, and should be available on HUD's Web site.

HUD Response: HUD will take this suggestion under consideration for future policy guidance.

Comment: HUD should create a template certification packet for all servicers to use for surviving non-borrowing spouse situations.

HUD Response: HUD certification language requirements for NBS are contained in ML 14-07 and ML 15-02.

Comment: HUD should require servicers to provide at least the loan balance and standard information about options for repayment to anyone who can prove an heir interest in the

property, or who is an executor of the estate. The commenter stated that the borrower should also be encouraged to designate who should have access to detailed information about the account.

HUD Response: HUD has clarified in the final rule that mortgagees must request that HECM borrowers designate an alternate individual that mortgagees would be required to use in the event a problem arises or in the event of the borrower's death or incapacitation. Accordingly, HUD has revised § 206.40(c) to clarify that the alternate individual is not acting as an agent and that the mortgagee will be required to request the designation, but that the borrower is not required to designate such an individual. If the borrower has designated an alternate individual, mortgagees would be required to contact the designated individual if they cannot reach the borrower directly in the event a problem arises or in the event of the borrower's death or incapacitation. HUD currently has procedures for communicating with the borrower's estate upon the death of the last borrower.

33. Benefits & Costs

Comment: The estimated \$1.9 billion cut in endorsements is very conservative if the changes to the HECM program are made as proposed. The commenter stated that the impact on endorsement volume of the financial assessment is not yet fully understood. The commenter also stated that the post-closing inspection requirement and including utilities as a property charge will drive away many of the affluent borrowers that are more common after the establishment of the financial assessment. The commenter also pointed to the super lien issue as a change that could cause an immediate drop in endorsement volume of \$1.9 billion on its own.

HUD Response: FHA appreciates your comments and will defer implementing this policy to allow further research and analysis to be conducted.

Comment: The RIA fails to quantify how disqualification of otherwise eligible HECM borrowers residing in community associations in association lien priority jurisdictions balances HUD's duty to protect taxpayers and ensure access to credit. The commenter stated that HUD did not demonstrate it considered less damaging but effective policy alternatives than their proposal on first lien status in the 22 jurisdictions with association lien priority statutes from the HECM program.

HUD Response: HUD appreciates your comments and will defer implementing

this policy to allow further research and analysis to be conducted.

34. Mortgagee Letter 2015–11

Comment: HUD should add an additional factor under the critical circumstances for the “at risk” loss mitigation option: a diagnosis of Alzheimer’s or other dementia of family member receiving care at the residence.

Comment: HUD should extend the repayment period for property charge advances and extend the foreclosure time frames for “at risk” homeowners.

HUD Response: These two comments reference a mortgagee letter outside the scope of this proposed rule. The proposed rule states, and the final rule continues to state, at § 206.205(e)(2)(ii) that “the mortgagee may provide any permissible loss mitigation made available by the Commissioner through notice.” Specific discretionary loss mitigation options are provided through mortgagee letters, not the regulations, and HUD will consider these comments in the development of such future policy guidance.

35. Other Comments & Suggestions

Comment: The limit on HECMs should be raised from \$625,000. One commenter stated that, due to the strong housing recovery, many housing markets have average appraised values well over \$625,000, and this limit unduly discriminates against seniors, so the cap should be raised to \$1 million. Another commenter suggested that the cap should be raised to \$1.5 million, or at the least, should be indexed to inflation.

HUD Response: HUD is unable to adopt this suggestion because HECM mortgage limits must comply with current statutory requirements. The private sector has the ability to develop a market for larger reverse mortgages.

Comment: There should be a new program using a fixed 5.06 percent that will pay off all current liens on the property up to 80 percent of the appraisal value regardless of the age of the youngest borrower. The current loan programs do not properly cover upside-down borrowers.

HUD Response: HUD continues to evaluate and monitor risks to the program and the MMIF. The current principal limit factors have been set to ensure the HECM program remains financially sound and viable for current and future senior borrowers.

Comment: HUD should work towards reducing costs and improving the image of its HECM program. One commenter stated that HUD should start a public relations campaign to highlight the features and benefits of the program,

just as it does for forward loans. The commenter also suggested that HUD respond to all the false and misleading comments made about the HECM program. Another commenter stated that HUD needs to improve consumer awareness by confirming safeguards and offering free education.

HUD Response: In addition to the required counseling for prospective HECM borrowers, HUD provides various online resources for prospective borrowers, HECM counselors, and HECM lenders.

Comment: HUD should explain why bridge loans are allowed with forward loans but not with reverse mortgages.

HUD Response: HUD does not have restrictions on the use of bridge loans for the HECM program. However, § 206.32 states that in order for a mortgage to be eligible for a HECM, a borrower must establish to the satisfaction of the mortgagee that after the initial payment of loan proceeds under § 206.25(a), there will be no outstanding or unpaid obligations incurred by the borrower in connection with the mortgage transaction, except for mortgage servicing charges permitted under § 206.27(b) and any future Repair Set Aside established pursuant to § 206.19(f)(1).

Comment: HUD should clarify what constitutes “sufficient inquiry” for the purposes under § 206.43. The commenter also asked for clarification that the mortgagee does not violate HUD regulations if the mortgagee does not make disbursements directly to the estate planning firm if it is determined that the borrower may have engaged such an estate planning firm.

HUD Response: HUD will clarify the meaning of “sufficient inquiry” through guidance.

Comment: The IRS should make a positive ruling to allow the carry-forward status of the accrued interest and MIP against retirement income.

HUD Response: The rulings of the IRS are outside of the scope of this rule and HUD’s authority in general.

Comment: HUD should emphasize the value of placing the property in a living trust with a durable power of attorney.

The commenter stated that many borrowers may become incapacitated, resulting in default, and that the servicer would be unable to discuss home retention or workout options without anyone having legal authority.

HUD Response: Trusts are currently eligible under the HECM program, but the homeowner has the responsibility for identifying the proper legal measures that can be taken to oversee their personal affairs if the homeowner becomes incapacitated.

Comment: HUD should examine the Property Assessed Clean Energy (PACE) program to determine if there is potential for default so that immediate notification can be sent to the borrowers warning them not to attach these liens to their properties. The commenter stated that PACE liens appear to be superior to HECMs and that property taxes may double or triple after the placement of the liens.

HUD Response: This recommendation is outside the scope of this rule. HUD’s recent guidance on the PACE program (ML 2016–11) states that properties with PACE obligations are not eligible for an FHA-insured HECM loan.

Comment: For all regulations and mortgagee letters, HUD should create accompanying template documents which all lenders and servicers are required to use. The commenter stated that such consistent and clear guidance would make it easier for HUD to have oversight, regulatory control, and enforcement capability.

HUD Response: HUD does not provide templates for every regulation and mortgagee letter because various state laws govern specific information that must be provided and because minor changes would require HUD to reissue multiple templates. Instead, HUD prescribes what information must be communicated and allows servicers to apply their business practices in creating the letters.

Comment: HUD should create or task a unit such as the National Servicing Center to help individual consumers understand their rights and options, provide immediate response to consumers with urgent issues such as foreclosure, and act as liaison between consumer and servicer when necessary.

HUD Response: This comment falls outside the scope of the proposed rule, but HUD believes that the National Servicing Center already provides many of these services to HECM borrowers.

Comment: HUD should put a moratorium on all tax and insurance defaults until HUD has a structure and system in place to review and enforce consumer protections to ensure defaults are compliant with consumer protection regulations and valid.

HUD Response: This is outside the scope of the proposed rule.

Comment: HUD should not allow changes by the servicer to the HECM contract.

HUD Response: This is outside the scope of the proposed rule.

Comment: Force-placed insurance premiums should not be a default trigger.

HUD Response: Regulations at § 206.27(b) require the borrower to pay

property charges, including insurance. A borrower's failure to obtain insurance causes the mortgagee to force-place insurance. A default occurs where there are no HECM funds to pay for insurance and a borrower fails to reimburse the mortgagee for the funds advanced to pay these charges.

Comment: There is concern over state law developments that purport to impose duties or limitations upon HECM servicers. The commenter stated that these state laws are viewed as inconsistent with HECM regulations and guidelines, conflicting with generally accepted servicing principles, and having the potential effect of harming consumers and property values.

HUD Response: HUD provides requirements that mortgagees must comply with to file for claim benefits. It is the mortgagee's responsibility to comply with both federal and state requirements in order to obtain claim benefits.

V. Findings and Certifications

Paperwork Reduction Act

The information collection requirements contained in this proposed have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and assigned OMB Collection Numbers 2502–0524 and 2502–0611. In accordance with the Paperwork Reduction Act, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a currently valid OMB control number.

Regulatory Planning and Review—Executive Orders 12866 and 13563

Under Executive Order 12866 (Regulatory Planning and Review), a determination must be made whether a regulatory action is significant and, therefore, subject to review by OMB in accordance with the requirements of the order. This rule was determined to be a “significant regulatory action,” as defined in section 3(f) of Executive Order 12866.

Executive Order 13563 (Improving Regulations and Regulatory Review) directs executive agencies to analyze regulations that are outmoded, ineffective, insufficient, or excessively burdensome and to modify, streamline, expand, or repeal them in accordance with what has been learned. Executive Order 13563 also directs that, where relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law, agencies are to identify and consider regulatory

approaches that reduce burdens and maintain flexibility and freedom of choice for the public. This rule reduces burdens on mortgagees by codifying in one place all the regulatory policy related to the HECM program. Prior to this rule, mortgagees had to deduce the current program requirements by determining which HECM regulations in 24 CFR part 206 were superseded by HERA and RMSA mortgagee letters.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Many of the policies discussed in this rule, such as the requirement that mortgagees perform a Financial Assessment of prospective HECM borrowers, the requirements of the HECM for Purchase program, the introduction of the Single Lump Sum payment option, and the limitation on disbursements during the First 12-Month Disbursement Period, have already been implemented by mortgagees large and small. The codification of these policies will not impact large or small mortgagees, other than easing burden by providing them with one location to find all HECM regulatory requirements.

The new policy changes in this rule would address important concerns with the HECM program, including the risk the program has, in the past, posed to the MMIF, as well as the continued availability of this program for seniors. Some of the new policy proposals are expected to relieve burdens on all mortgagees, large and small. For example, the amendment to the definition of “expected average mortgage interest rate”, providing the mortgagee with the ability to lock in the expected average mortgage interest rate prior to the date of loan closing, will align the provision with current industry policy. Removing the duplicative appraisal requirement and creating a Cash for Keys incentive structure will both relieve burden on mortgagees. Other policies contained in the rule may result in mortgagees incurring additional costs. However, as detailed in the regulatory impact analysis for the rule, these costs are not estimated to rise to the level of having a significant impact on a substantial number of small entities. Moreover, HUD has attempted to mitigate the economic impacts of these provisions. One example is the requirement that all

mortgagees disclose all available HECM program options. To minimize the effect of this provision on all mortgagees, FHA intends to create disclosure documents listing all available options for mortgagees to provide to prospective borrowers. Another example is the limitation on insurance claim reimbursement for the mortgagee's payment of certain property charges. Rather than limiting this reimbursement based on the timing of the property charges, requiring mortgagees to track when each property charge occurred, HUD is limiting the reimbursement to two-thirds of all property charges, consistent with how mortgagees are reimbursed for foreclosure costs.

FHA believes that these policies are reasonable and provide mitigating features so that the FHA-approved mortgagees, large and small, will not be adversely affected by these policies.

Accordingly, the undersigned certifies that this rule would not have a significant economic impact on a substantial number of small entities.

Environmental Impact

A Finding of No Significant Impact (FONSI) with respect to the environment has been made at the proposed rule state in accordance with HUD regulations in 24 CFR part 50, which implemented section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)). The FONSI remains applicable to this final rule and is available for public inspection during regular business hours in the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. Due to security measures at the HUD Headquarters building, please schedule an appointment to review the FONSI by calling the Regulations Division at (202) 708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at (800) 877–8339.

Executive Order 13132, Federalism

Executive Order 13132 (entitled “Federalism”) prohibits, to the extent practicable and permitted by law, an agency from promulgating a regulation that has federalism implications and either imposes substantial direct compliance costs on state and local governments and is not required by statute, or preempts state law, unless the relevant requirements of section 6 of the executive order are met. This rule does not have federalism implications and does not impose substantial direct

compliance costs on state and local governments or preempt state law within the meaning of the executive order.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance number for Home Equity Conversion Mortgages is 14.183.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments, and on the private sector. This rule would not impose any federal mandates on any state, local, or tribal governments, or on the private sector, within the meaning of the UMRA.

List of Subjects

24 CFR Part 30

Administrative practice and procedure, Grant programs—housing and community development, Loan programs—housing and community development, Mortgage insurance, Penalties.

24 CFR Part 206

Aged condominiums, Loan programs, Housing and community development, Mortgage insurance, Reporting and recordkeeping requirements.

Accordingly, for the reasons stated in the preamble, HUD amends 24 CFR parts 30 and 206 to read as follows:

PART 30—CIVIL MONEY PENALTIES: CERTAIN PROHIBITED CONDUCT

■ 1. The authority citation for part 30 continues to read as follows:

Authority: 12 U.S.C. 1701q–1; 1703, 1723i, 1735f–14, and 1735f–15; 15 U.S.C. 1717a; 28 U.S.C. 2461 note; 42 U.S.C. 1437z–1 and 3535(d).

■ 2. Revise paragraphs (a)(8) and (a)(10) of § 30.35 to read as follows:

§ 30.35 Mortgagees and lenders.

(a) * * *

(8) Fails to timely submit documents that are complete and accurate in connection with a conveyance of a property or a claim for insurance benefits, in accordance with §§ 203.365, 203.366, or 203.368, or a claim for insurance benefits in accordance with § 206.127 of this title;

* * * * *

(10) Fails to service FHA insured mortgages, in accordance with the requirements of 24 CFR parts 201, 203, 206, and 235;

* * * * *

■ 3. Revise part 206 to read as follows:

PART 206—HOME EQUITY CONVERSION MORTGAGE INSURANCE

Subpart A—General

Sec.

- 206.1 Purpose.
- 206.3 Definitions.
- 206.7 Effect of amendments.
- 206.8 Preemption.

Subpart B—Eligibility; Endorsement

- 206.9 Eligible mortgagees.
- 206.13 Disclosure of available HECM program options.
- 206.15 Insurance.
- Eligible Mortgagees
- 206.17 Eligible mortgages: general.
- 206.19 Payment options.
- 206.21 Interest rate.
- 206.23 Shared appreciation.
- 206.25 Calculation of disbursements.
- 206.26 Change in payment option.
- 206.27 Mortgage provisions.
- 206.31 Allowable charges and fees.
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Eligible Borrowers

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Authority: Authority: 12 U.S.C. 1715b, 1715z–20; 42 U.S.C. 3535(d).

Subpart A—General

§ 206.1 Purpose.

The purposes of the Home Equity Conversion Mortgage (HECM) Insurance

program are set out in section 255(a) of the National Housing Act, Public Law 73–479, 48 Stat. 1246 (12 U.S.C. 1715z–20) (“NHA”).

§ 206.3 Definitions.

As used in this part, the following terms shall have the meaning indicated.

Bona fide tenant means a tenant of the property who is not a mortgagor, borrower, a spouse or child of a mortgagor or borrower, or any other member of a mortgagor’s or borrower’s family.

Borrower means a mortgagor who is an original borrower under the HECM Loan Agreement and Note. The term does not include successors or assigns of a borrower.

Borrower’s Advance means the funds advanced to the borrower at the closing of a fixed interest rate HECM in accordance with § 206.25.

CMT Index means the U.S. Constant Maturity Treasury Index.

Commissioner means the Federal Housing Commissioner or the Commissioner’s authorized representative.

Contract of insurance means the agreement evidenced by the issuance of a Mortgage Insurance Certificate or by the endorsement of the Commissioner upon the credit instrument given in connection with an insured mortgage, incorporating by reference the regulations in subpart C of this part and the applicable provisions of the National Housing Act.

Day means calendar day, except where the term *business day* is used.

Deferral Period means the period of time following the death of the last surviving borrower during which the due and payable status of a HECM is deferred for an Eligible Non-Borrowing Spouse provided that the Qualifying Attributes and all other FHA requirements continue to be satisfied.

Eligible Non-Borrowing Spouse means a Non-Borrowing Spouse who meets all Qualifying Attributes for a Deferral Period.

Estate planning service firm means an individual or entity that is not a mortgagee approved under part 202 of this chapter or a participating agency approved under subpart B of 24 CFR part 214 and that charges a fee that is:

(1) Contingent on the prospective borrower obtaining a mortgage loan under this part, except the origination fee authorized by § 206.31 or a fee specifically authorized by the Commissioner; or

(2) For information that borrowers and Eligible and Ineligible Non-Borrowing Spouses, if applicable, must receive under § 206.41, except a fee by:

(i) A participating agency approved under subpart B of 24 CFR part 214; or
(ii) An individual or company, such as an attorney or accountant, in the *bona fide* business of generally providing tax or other legal or financial advice; or

(3) For other services that the provider of the services represents are, in whole or in part, for the purpose of improving a prospective borrower’s access to mortgages covered by this part, except where the fee is for services specifically authorized by the Commissioner.

Expected average mortgage interest rate means the interest rate used to calculate the principal limit established at closing. For fixed interest rate HECMs, the expected average mortgage interest rate is the same as the fixed mortgage (Note) interest rate and is set simultaneously with the fixed interest rate. For adjustable interest rate HECMs, it is either the sum of the mortgagee’s margin plus the weekly average yield for U.S. Treasury securities adjusted to a constant maturity of 10 years, or it is the sum of the mortgagee’s margin plus the 10-year LIBOR swap rate, depending on which interest rate index is chosen by the borrower. The margin is determined by the mortgagee and is defined as the amount that is added to the index value to compute the expected average mortgage interest rate. The index type (CMT or LIBOR) used to calculate the expected average mortgage interest rate must be the same index type used to calculate mortgage interest rate adjustments—commingling of index types is not allowed. The mortgagee’s margin is the same margin used to determine the initial interest rate and the periodic adjustments to the interest rate. Mortgagees, with the agreement of the borrower, may simultaneously lock in the expected average mortgage interest rate and the mortgagee’s margin prior to the date of loan closing or simultaneously establish the expected average mortgage interest rate and the mortgagee’s margin on the date of loan closing.

First 12-Month Disbursement Period means the period beginning on the day of loan closing and ending on the day before the loan closing anniversary date. When the day before the anniversary date of loan closing falls on a Federally-observed holiday, Saturday, or Sunday, the end period will be on the next business day after the Federally-observed holiday, Saturday or Sunday.

HECM means a Home Equity Conversion Mortgage.

HECM counselor means an independent third party who is currently active on FHA’s HECM Counselor Roster and who is not, either

directly or indirectly, associated with or compensated by, a party involved in originating, servicing, or funding the HECM, or the sale of annuities, investments, long-term care insurance, or any other type of financial or insurance product who provides statutorily required counseling to prospective borrowers who may be eligible for or interested in obtaining an FHA-insured HECM. This counseling assists elderly prospective borrowers who seek to convert equity in their homes into income that can be used to pay for home improvements, medical costs, living expenses, or other expenses.

Ineligible Non-Borrowing Spouse means a Non-Borrowing Spouse who does not meet all Qualifying Attributes for a Deferral Period.

Initial Disbursement Limit means the maximum amount of funds that can be advanced to a borrower of an adjustable interest rate HECM allowed at loan closing and during the First 12-Month Disbursement Period in accordance with § 206.25.

Insured mortgage means a mortgage which has been insured as evidenced by the issuance of a Mortgage Insurance Certificate.

LIBOR means the London Interbank Offered Rate.

Loan documents mean the credit instrument, or Note, secured by the lien, and the loan agreement.

Mandatory Obligations are fees and charges incurred in connection with the origination of the HECM that are requirements for loan approval and which will be paid at closing or during the First 12-Month Disbursement Period in accordance with § 206.25.

Maximum claim amount means the lesser of the appraised value of the property, as determined by the appraisal used in underwriting the loan; the sales price of the property being purchased for the sole purpose of being the principal residence; or the national mortgage limit for a one-family residence under subsections 255(g) or (m) of the National Housing Act (as adjusted where applicable under section 214 of the National Housing Act) as of the date of loan closing. The initial mortgage insurance premium must not be taken into account in the calculation of the maximum claim amount. Closing costs must not be taken into account in determining appraised value.

MIP means the mortgage insurance premium paid by the mortgagee to the Commissioner in consideration of the contract of insurance.

Mortgage means a first lien on real estate under the laws of the jurisdiction where the real estate is located. If the

dwelling unit is in a condominium, the term *mortgage* means a first lien covering a fee interest or eligible leasehold interest in a one-family unit in a condominium project, together with an undivided interest in the common areas and facilities serving the project, and such restricted common areas and facilities as may be designated. The term refers to a security instrument creating a lien, whether called a *mortgage*, *deed of trust*, *security deed*, or another term used in a particular jurisdiction.

Mortgagee means original lender under a mortgage and its successors and assigns, as are approved by the Commissioner.

Mortgagor means each original mortgagor under a HECM mortgage and his heirs, executors, administrators, and assigns.

Non-Borrowing Spouse means the spouse, as defined by the law of the state in which the spouse and borrower reside or the state of celebration, of the HECM borrower at the time of closing and who is also not a borrower.

Participating agency means all housing counseling and intermediary organizations participating in HUD's Housing Counseling program, including HUD-approved agencies, and affiliates and branches of HUD-approved intermediaries, HUD-approved multi-state organizations (MSOs), and state housing finance agencies.

Principal limit means the maximum amount calculated, taking into account the age of the youngest borrower or Eligible Non-Borrowing Spouse, the expected average mortgage interest rate, and the maximum claim amount. The principal limit is calculated for the first month that a mortgage could be outstanding using factors provided by the Commissioner. It increases each month thereafter at a rate equal to one-twelfth of the mortgage interest rate in effect at that time, plus one-twelfth of the annual mortgage insurance rate. For an adjustable interest rate HECM, the principal limit increase may be made available to the borrower each month thereafter except that the availability during the First 12-Month Disbursement Period may be restricted. Although the principal limit of a fixed interest rate HECM will continue to increase at the rate provided by the Commissioner, no further funds may be made available for the borrower to draw against after closing. The principal limit may decrease because of insurance or condemnation proceeds applied to the outstanding loan balance under § 206.209(b).

Principal residence means the dwelling where the borrower and, if applicable, Non-Borrowing Spouse,

maintain their permanent place of abode, and typically spend the majority of the calendar year. A person may have only one principal residence at any one time. The property shall be considered to be the principal residence of any borrower who is temporarily in a health care institution provided the borrower's residency in a health care institution does not exceed twelve consecutive months. The property shall be considered to be the principal residence of any Non-Borrowing Spouse, who is temporarily in a health care institution, as long as the property is the principal residence of his or her borrower spouse, who physically resides in the property. During a Deferral Period, the property shall continue to be considered to be the principal residence of any Non-Borrowing Spouse, who is temporarily in a health care institution, provided he or she qualified as an Eligible Non-Borrowing Spouse and physically occupied the property immediately prior to entering the health care institution and his or her residency in a health care institution does not exceed twelve consecutive months.

Property charges means, unless otherwise specified, obligations of the borrower that include property taxes, hazard insurance premiums, any applicable flood insurance premiums, ground rents, condominium fees, planned unit development fees, homeowners' association fees, and any other special assessments that may be levied by municipalities or state law.

Qualifying Attributes means the requirements which must be met by a Non-Borrowing Spouse in order to be an Eligible Non-Borrowing Spouse.

§ 206.7 Effect of amendments.

The regulations in this part may be amended by the Commissioner at any time and from time to time, in whole or in part, but amendments to subparts B and C of this part will not adversely affect the interests of a mortgagee on any mortgage to be insured for which either the Direct Endorsement mortgagee or Lender Insurance mortgagee has approved the borrower and all terms and conditions of the mortgage, or the Commissioner has made a commitment to insure. Such amendments will not adversely affect the interests of a borrower in the case of a default by a mortgagee where the Commissioner makes payments to the borrower.

§ 206.8 Preemption.

(a) *Lien priority.* The full amount secured by the mortgage shall have the same priority over any other liens on the property as if the full amount had been disbursed on the date the initial

disbursement was made, regardless of the actual date of any disbursement. The amount secured by the mortgage shall include all direct payments by the mortgagee to the borrower and all other loan advances permitted by the mortgage for any purpose, including loan advances for interest, property charges, mortgage insurance premiums, required repairs, servicing charges, counseling charges, and costs of collection, regardless of when the payments or loan advances were made. The priority provided by this section shall apply notwithstanding any State constitution, law, or regulation.

(b) *Second mortgage.* If the Commissioner holds a second mortgage, it shall have a priority subordinate only to the first mortgage (and any senior liens permitted by paragraph (a) of this section).

Subpart B—Eligibility; Endorsement

§ 206.9 Eligible mortgagees.

(a) *Statutory requirements.* See sections (b)(2), (c), and 255(d)(1) of the NHA.

(b) *HUD approved mortgagees.* Any mortgagee authorized under paragraph (a) of this section and approved under part 202 of this chapter, except an investing mortgagee approved under § 202.9 of this chapter, is eligible to apply for insurance. A mortgagee approved under §§ 202.6, 202.7, 202.9 or 202.10 of this chapter may purchase, hold and sell mortgages insured under this part without additional approval.

§ 206.13 Disclosure of available HECM program options.

At the time of initial contact, the mortgagee shall inform the prospective HECM borrower, in a manner acceptable to the Commissioner, of all products, features, and options of the HECM program that FHA will insure under this part, including: fixed interest rate mortgages with the Single Lump Sum payment option; adjustable interest rate mortgages with tenure, term, and line of credit disbursement options, or a combination of these; any other FHA insurable disbursement options; and initial mortgage insurance premium options, and how those affect the availability of other mortgage and disbursement options.

§ 206.15 Insurance.

Mortgages originated under this part must be endorsed through the Direct Endorsement program under § 203.5 of this chapter, except that any references to § 203.255 in § 203.5 shall mean § 206.115. The mortgagee shall submit the information as described in § 206.115(b) for the Direct Endorsement

program; the certificate of housing counseling as described in § 206.41; a copy of the title insurance commitment satisfactory to the Commissioner (or other acceptable title evidence if the Commissioner has determined not to require title insurance under § 206.45(a)); the mortgagee's election of either the assignment or shared premium option under § 206.107; and any other documentation required by the Commissioner. If the mortgagee has complied with the requirements of §§ 203.3 and 203.5, except that any reference to § 203.255 in these sections shall mean § 206.115 for purposes of this section, and other requirements of this part, and the mortgage is determined to be eligible, the Commissioner will endorse the mortgage for insurance by issuing a Mortgage Insurance Certificate.

Eligible Mortgages

§ 206.17 Eligible mortgages: general.

(a) [Reserved]

(b) *Interest rate and payment options.* A HECM shall provide for either fixed or adjustable interest rates in accordance with § 206.21.

(1) Fixed interest rate mortgages shall use the Single Lump Sum payment option (§ 206.19(e)).

(2) Adjustable interest rate mortgages shall initially provide for the term (§ 206.19(a)), the tenure (§ 206.19(b)), the line of credit (§ 206.19(c)), or a modified term or modified tenure (§ 206.19(d)) payment option, subject to a later change in accordance with § 206.26.

(c) *Shared appreciation.* A mortgage may provide for shared appreciation in accordance with § 206.23.

§ 206.19 Payment options.

(a) *Term payment option.* Under the term payment option, equal monthly payments are made by the mortgagee to the borrower for a fixed term of months chosen by the borrower in accordance with this section and § 206.25(e), unless the mortgage is prepaid in full or becomes due and payable earlier under § 206.27(c).

(b) *Tenure payment option.* Under the tenure payment option, equal monthly payments are made by the mortgagee to the borrower in accordance with this section and with § 206.25(f), unless the mortgage is prepaid in full or becomes due and payable under § 206.27(c).

(c) *Line of credit payment option.* Under the line of credit payment option, payments are made by the mortgagee to the borrower at times and in amounts determined by the borrower as long as the amounts do not exceed the payment amounts permitted by § 206.25.

(d) *Modified term or modified tenure payment option.* Under the modified term or modified tenure payment options, equal monthly payments are made by the mortgagee and the mortgagee shall set aside a portion of the principal limit to be drawn down as a line of credit as long as the amounts do not exceed the payment amounts permitted by § 206.25.

(e) *Single Lump Sum payment option.* Under the Single Lump Sum payment option, the Borrower's Advance will be made by the mortgagee to the borrower in an amount that does not exceed the payment amount permitted in § 206.25. The Single Lump Sum payment option will be available only for fixed interest rate HECMs. Set asides requiring disbursements after close may be offered in accordance with paragraphs (f)(1) through (3) of this section.

(f) *Principal limit set asides—(1) Repair Set Aside.* When repairs required by § 206.47 will be completed after closing, the mortgagee shall set aside a portion of the principal limit equal to 150 percent of the Commissioner's estimated cost of repairs, plus the repair administration fee.

(2) *Property Charge Set Aside—(i) Life Expectancy Set Aside (LESA).* When required by § 206.205(b)(1) or selected by the borrower under § 206.205(b)(2)(i)(B), the mortgagee shall set aside a portion of the principal limit, consistent with the requirements of § 206.205, for payment of the following property charges: property taxes including special assessments levied by municipalities or state law, and flood and hazard insurance premiums.

(ii) *Borrower elects to have mortgagee pay property charges—(A) First year property charges.* When required by § 206.205(d), the mortgagee shall set aside a portion of the principal limit for payment of the following property charges that must be paid during the First 12-Month Disbursement Period: property taxes including special assessments levied by municipalities or state law, and flood and hazard insurance premiums. The mortgagee's estimate of withholding amount shall be based on the best information available as to probable payments which will be required to be made for property charges in the coming year. The mortgagee may not require the withholding of amounts in excess of the current estimated total annual requirement, unless expressly requested by the borrower. Each month's withholding for property charges shall equal one-twelfth of the annual amounts as reasonably estimated by the mortgagee.

(B) *Property charges for subsequent years.* For subsequent year property

charges, the mortgagee's estimate of withholding amount shall be based on the best information available as to probable payments which will be required to be made for property charges in the coming year. If actual disbursements during the preceding year are used as the basis, the resulting estimate may deviate from those disbursements by as much as ten percent. The mortgagee may not require the withholding of amounts in excess of the current estimated total annual requirement, unless expressly requested by the borrower. Each month's withholding for property charges shall equal one-twelfth of the annual amounts as reasonably estimated by the mortgagee.

(3) *Servicing Fee Set Aside.* When servicing charges will be made as permitted by § 206.207(b), the mortgagee shall set aside a portion of the principal limit sufficient to cover charges through a period equal to the payment term which would be used to calculate tenure payments under § 206.25(f).

(g) *Interest accrual and repayment.* The interest charged on the outstanding loan balance shall begin to accrue from the funding date and shall be added to the outstanding loan balance monthly as provided in the mortgage. Under all payment options, repayment of the outstanding loan balance is deferred until the mortgage becomes due and payable under § 206.27(c).

(h) *Disbursement limits.* (1) For all HECMs, no disbursements shall be made under any of the payment options, notwithstanding anything to the contrary in this section or in § 206.25, in an amount which shall cause the outstanding loan balance after the payment to exceed any maximum mortgage amount stated in the security instruments or to otherwise exceed the amount secured by a first lien.

(2) For adjustable interest rate HECMs:

(i) No disbursements shall be made under any of the payment options during the First 12-Month Disbursement Period in excess of the Initial Disbursement Limit.

(ii) If the borrower makes a partial prepayment of the outstanding loan balance during the First 12-Month Disbursement Period, the mortgagee shall apply the funds from the partial prepayment in accordance with the Note.

(3) For fixed interest rate HECMs, if the borrower makes a partial prepayment of the outstanding loan balance any time after loan closing and before the contract of insurance is terminated, the mortgagee shall apply the funds from the partial prepayment

in accordance with the Note. Any increase in the available principal limit by the amount applied towards the outstanding loan balance shall not be available for the borrower to draw against.

§ 206.21 Interest rate.

(a) *Fixed interest rate.* A fixed interest rate is agreed upon by the borrower and mortgagee.

(b) *Adjustable interest rate.* An initial expected average mortgage interest rate, which defines the mortgagee's margin, is agreed upon by the borrower and mortgagee as of the date of loan closing, or as of the date of rate lock-in, if the expected average mortgage interest rate was locked in prior to closing. The interest rate shall be adjusted in one of two ways depending on the option selected by the borrower, in accordance with paragraphs (b)(1) and (b)(2) of this section. Whenever an interest rate is adjusted, the new interest rate applies to the entire loan balance. The difference between the initial interest rate and the index figure applicable when the firm commitment is issued shall equal the margin used to determine interest rate adjustments. If the expected average mortgage interest rate is locked in prior to closing, the difference between the expected average mortgage interest rate and the value of the appropriate index at the time of rate lock-in shall equal the margin used to determine interest rate adjustments.

(1) *Annual adjustable interest rate HECMs.* A mortgagee offering an annual adjustable interest rate shall offer a mortgage with an interest rate cap structure that limits the periodic interest rate increases and decreases as follows:

(i) *Types of mortgages insurable.* The types of adjustable interest rate mortgages that are insurable are those for which the interest rate may be adjusted annually by the mortgagee, beginning after one year from the date of the closing.

(ii) *Interest rate index.* Changes in the interest rate charged on an adjustable interest rate mortgage must correspond either to changes in the one-year LIBOR or to changes in the weekly average yield on U.S. Treasury securities, adjusted to a constant maturity of one year. Except as otherwise provided in this section, each change in the mortgage interest rate must correspond to the upward and downward change in the index.

(iii) *Frequency of interest rate changes.* (A) The interest rate adjustments must occur annually, calculated from the date of the closing, except that the first adjustment shall be

no sooner than 12 months or later than 18 months.

(B) To set the new interest rate, the mortgagee will determine the change between the initial (*i.e.*, base) index figure and the current index figure, or will add a specific margin to the current index figure. The initial index figure shall be the most recent figure available before the date of mortgage loan origination. The current index figure shall be the most recent index figure available 30 days before the date of each interest rate adjustment.

(iv) *Magnitude of changes.* The adjustable interest rate mortgage initial contract interest rate shall be agreed upon by the mortgagee and the borrower. The first adjustment to the contract interest rate shall take place in accordance with the schedule set forth under paragraph (b)(1)(iii) of this section. Thereafter, for all annual adjustable interest rate mortgages, the adjustment shall be made annually and shall occur on the anniversary date of the first adjustment, subject to the following conditions and limitations:

(A) For all annual adjustable interest rate HECMs, no single adjustment to the interest rate shall result in a change in either direction of more than two percentage points from the interest rate in effect for the period immediately preceding that adjustment. Index changes in excess of two percentage points may not be carried over for inclusion in an adjustment for a subsequent year. Adjustments in the effective rate of interest over the entire term of the mortgage may not result in a change in either direction of more than five percentage points from the initial contract interest rate.

(B) At each adjustment date for annual adjustable interest rate HECMs, changes in the index interest rate, whether increases or decreases, must be translated into the adjusted mortgage interest rate, except that the mortgage may provide for minimum interest rate change limitations and for minimum increments of interest rate changes.

(2) *Monthly adjustable interest rate HECMs.* If a mortgage meeting the requirements of paragraph (b)(1) of this section is offered, the mortgagee may also offer a mortgage which provides for monthly adjustments to the interest rate such that changes in the interest rate charged on an adjustable interest rate mortgage correspond either to changes in the one-year LIBOR or to changes in the weekly average yield on U.S. Treasury securities, adjusted to a constant maturity of one year (except as otherwise provided in this section, each change in the mortgage interest rate must correspond to the upward and

downward change in the index), or to the one-month CMT index or one-month LIBOR index, and which sets a maximum interest rate that can be charged.

(c) *Pre-loan disclosure.* (1) At the time the mortgagee provides the borrower with a loan application, a mortgagee shall provide a borrower with a written explanation of all adjustable interest rate features of a mortgage. The explanation must include the following items:

(i) The circumstances under which the rate may increase;

(ii) Any limitations on the increase; and

(iii) The effect of an increase.

(2) Compliance with pre-loan disclosure provisions of 12 CFR part 1026 (Truth in Lending) shall constitute full compliance with paragraph (c)(1) of this section.

(d) *Post-loan disclosure.* At least 25 days before any adjustment to the interest rate may occur, the mortgagee must advise the borrower of the following:

(1) The current index amount;

(2) The date of publication of the index; and

(3) The new interest rate.

§ 206.23 Shared appreciation.

(a) *Additional interest based on net appreciated value.* Any mortgage for which the mortgagee has chosen the shared premium option (§ 206.107) may provide for shared appreciation. At the time the mortgage becomes due and payable or is paid in full, whichever occurs first, the borrower shall pay an additional amount of interest equal to a percentage of any net appreciated value of the property during the life of the mortgage. The percentage of net appreciated value to be paid to the mortgagee, referred to as the appreciation margin, shall be no more than twenty-five percent, subject to an effective interest rate cap of no more than twenty percent.

(b) *Computation of mortgage share.* The mortgagee's share of net appreciated value is computed as follows:

(1) If the outstanding loan balance at the time the mortgagee's share of net appreciated value becomes payable is less than the appraised value of the property at the time of loan origination, the mortgagee's share is calculated by subtracting the appraised value at the time of loan origination from the adjusted sales proceeds (*i.e.*, sales proceeds less transfer costs and capital improvement costs incurred by the borrower, but excluding any liens) and multiplying by the appreciation margin.

(2) If the outstanding loan balance is greater than the appraised value at the time of loan origination but less than the adjusted proceeds, the mortgagee's share is calculated by subtracting the outstanding loan balance from the adjusted sales proceeds and multiplying by the appreciation margin.

(3) If the outstanding loan balance is greater than the adjusted sales proceeds, the net appreciated value is zero.

(4) If there has been no sale or transfer involving satisfaction of the mortgage at the time the mortgagee's share of net appreciated value becomes payable, *sales proceeds* for purposes of this section shall be the appraised value as determined in accordance with procedures approved by the Commissioner.

(c) *Effective interest rate.* To determine the effective interest rate, the amount of interest which accrued in the twelve months prior to the sale of the property or the prepayment is added to the mortgagee's share of the net appreciated value. The sum of the mortgagee's share of the net appreciated value and the interest, when divided by the sum of the outstanding loan balance at the beginning of the twelve-month period prior to sale or prepayment plus the payments to or on behalf of the borrower (but not including interest) in the twelve months prior to the sale or prepayment, shall not exceed an effective interest rate of twenty percent.

(d) *Disclosure.* At the time the mortgagee provides the borrower with a loan application for a mortgage with shared appreciation, the mortgagee shall disclose to the borrower the principal limit, payments and interest rate which are applicable to a comparable mortgage offered by the mortgagee without shared appreciation.

§ 206.25 Calculation of disbursements.

(a) *Initial disbursements—(1) Initial Disbursement Limit—Adjustable Interest Rate HECMs:* for term, tenure, line of credit, modified term, and modified tenure payment options:

(i) The mortgagee is responsible for determining the maximum Initial Disbursement Limit.

(ii) The maximum disbursement allowed at closing and during the First 12-Month Disbursement Period is the lesser of:

(A) The greater of an amount established by the Commissioner through notice which shall not be less than 50 percent of the principal limit; or the sum of Mandatory Obligations and a percentage of the principal limit established by the Commissioner through notice which shall not be less than 10 percent; or

(B) The principal limit less the sum of the funds in the LESA for payment beyond the First 12-Month Disbursement Period and the Servicing Fee Set Aside.

(iii) The amount in the First 12-Month Disbursement Period or at any point in time may not exceed the principal limit.

(iv) Mortgagees shall monitor and track all disbursements that occur at loan closing and during the First 12-Month Disbursement Period; the total amount of disbursements shall not exceed the maximum Initial Disbursement Limit.

(v) The borrower shall notify the mortgagee at loan closing of the amount of the additional percentage of the principal limit beyond Mandatory Obligations that the borrower will draw or that will remain available to be drawn during the First 12-Month Disbursement Period. The borrower may not increase or decrease this election after closing.

(2) *Borrower's Advance—Fixed Interest Rate HECMs:* for the Single Lump Sum payment option:

(i) The mortgagee is responsible for determining the maximum Borrower's Advance.

(ii) The disbursement shall only be taken at the time of closing and the maximum disbursement shall not exceed the lesser of:

(A) The greater of an amount established by the Commissioner through notice which shall not be less than 50 percent of the principal limit; or the sum of Mandatory Obligations and a percentage of the principal limit established by the Commissioner through notice which shall not be less than 10 percent; or

(B) The principal limit less the sum of the funds in the LESA for payment beyond the First 12-Month Disbursement Period and the Servicing Fee Set Aside.

(iii) The borrower shall notify the mortgagee at loan closing of the amount of the additional percentage of the principal limit beyond Mandatory Obligations that the borrower will draw. The borrower may not increase or decrease this election after closing.

(b) Mandatory Obligations for traditional and refinance transactions include:

(1) Initial MIP under § 206.105(a);
(2) Loan origination fee;
(3) HECM counseling fee;
(4) Reasonable and customary amounts, but not more than the amount actually paid by the mortgagee for any of the following items:

(i) Recording fees and recording taxes, or other charges incident to the recordation of the insured mortgage;

(ii) Credit report;

(iii) Survey, if required by the mortgagee or the borrower;

(iv) Title examination;

(v) Mortgagee's title insurance;

(vi) Fees paid to an appraiser for the initial appraisal of the property; and

(vii) Flood certifications.

(5) Repair Set Asides;

(6) Repair administration fee;

(7) Delinquent Federal debt;

(8) Amounts required to discharge any existing liens on the property;

(9) Customary fees and charges for warranties, inspections, surveys, and engineer certifications;

(10) Funds to pay contractors who performed repairs as a condition of closing, in accordance with standard FHA requirements for repairs required by the appraiser;

(11) Property tax and flood and hazard insurance payments required by the mortgagee to be paid at loan closing;

(12) Property charges not included in paragraph (b)(11) of this section and which are scheduled for payment during the First 12-Month Disbursement Period, as follows:

(i) *Adjustable Interest Rate HECMs.*

(A) The total amount of property charge payments scheduled for payment from the borrower authorized option under § 206.205(d) during the First 12-Month Disbursement Period;

(B) The total amount of semi-annual disbursements scheduled to be made during the First 12-Month Disbursement Period to the borrower from a Partially-Funded LESA; or

(C) The total amount of property charges scheduled for payment during the First 12-Month Disbursement Period from a Fully-Funded LESA.

(D) Mortgagees shall use the actual insurance premium and actual tax amount; if a new tax bill has not been issued, the mortgagee must use the prior year's amount multiplied by 1.04 or an amount set by the Commissioner through notice.

(ii) *Fixed Interest Rate HECMs.* (A) The total amount of property charges scheduled for payment during the First 12-Month Disbursement Period from a Fully-Funded LESA.

(B) Mortgagees shall use the actual insurance premium and actual tax amount; if a new tax bill has not been issued, the mortgagee must use the prior year's amount multiplied by 1.04 or an amount set by the Commissioner through notice;

(13) Required pay-off of debt not secured by the property, as defined by the Commissioner through **Federal Register** notice; and

(14) Other charges as authorized by the Commissioner through notice.

(c) Mandatory Obligations for HECM for Purchase transactions include:

- (1) Initial MIP under § 206.105(a);
- (2) Loan origination fee;
- (3) HECM counseling fee;
- (4) Reasonable and customary

amounts, but not more than the amount actually paid by the mortgagee for any of the following items:

- (i) Recording fees and recording taxes, or other charges incident to the recordation of the insured mortgage;
 - (ii) Credit report;
 - (iii) Survey, if required by the mortgagee or the borrower;
 - (iv) Title examination;
 - (v) Mortgagee's title insurance;
 - (vi) Fees paid to an appraiser for the initial appraisal of the property; and
 - (vii) Flood certifications.
- (5) Delinquent Federal debt;
- (6) Fees and charges for real estate purchase contracts, warranties, inspections, surveys, and engineer certifications;

(7) The amount of the principal that is advanced towards the purchase price of the subject property;

(8) Property tax and flood and hazard insurance payments required by the mortgagee to be paid at loan closing;

(9) Property charges not included in paragraph (c)(8) of this section and which are scheduled for payment during the First 12-Month Disbursement Period, as follows:

(i) *Adjustable Interest Rate HECMs.*

(A) The total amount of property charge payments scheduled for payment from the borrower authorized option under § 206.205(d) during the First 12-Month Disbursement Period;

(B) The total amount of semi-annual disbursements scheduled to be made during the First 12-Month Disbursement Period to the borrower from a Partially-Funded LESA; or

(C) The total amount of property charges scheduled for payment during the First 12-Month Disbursement Period from a Fully-Funded LESA.

(D) Mortgagees shall use the actual insurance premium and actual tax amount; if a new tax bill has not been issued, the mortgagee must use the prior year's amount multiplied by 1.04 or an amount set by the Commissioner through notice.

(ii) *Fixed Interest Rate HECMs.* (A) The total amount of property charges scheduled for payment during the First 12-Month Disbursement Period from a Fully-Funded LESA.

(B) Mortgagees shall use the actual insurance premium and actual tax amount; if a new tax bill has not been issued, the mortgagee must use the prior year's amount multiplied by 1.04 or an amount set by the Commissioner through notice;

(10) Required pay-off of debt not secured by the property, as defined by the Commissioner through **Federal Register** notice; and

(11) Other charges as authorized by the Commissioner through notice.

(d) *Timing of disbursements.*

Mortgage proceeds may not be disbursed until after the expiration of the 3-day rescission period under 12 CFR part 1026, if applicable.

(e) *Monthly disbursements—term option.* (1) Using factors provided by the Commissioner, the mortgagee shall calculate the monthly disbursement so that the sum of paragraphs (e)(1)(i) or (e)(1)(ii) of this section added to paragraphs (e)(1)(iii), (e)(1)(iv), and (e)(1)(v) of this section shall be equal to the principal limit at the end of the payment term.

(i) An initial disbursement under paragraph (a) of this section plus any initial servicing charge set aside under § 206.19(f)(3); or

(ii) The outstanding loan balance at the time of a change in payment option in accordance with § 206.26, plus any remaining servicing charge set aside under § 206.19(f)(3); and

(iii) The amount of the principal limit set aside in accordance with § 206.19(f) which is not included in the amount set aside in paragraphs (e)(1)(i) or (e)(1)(ii) of this section;

(iv) All MIP or monthly charges due to the Commissioner in lieu of mortgage insurance premiums due through the payment term; and

(v) All interest through the remainder of the payment term. The expected average mortgage interest rate shall be used for this purpose.

(2) The mortgagee shall make all monthly disbursements through the payment term even if the outstanding loan balance exceeds the principal limit because the actual average mortgage interest rate exceeds the expected average mortgage interest rate unless the HECM becomes due and payable under § 206.27(c). In the event of a deferral of due and payable status in accordance with § 206.27(c)(3), disbursements shall cease immediately upon the death of the borrower and no further disbursements are permissible.

(3) Mortgagees shall ensure that term monthly disbursements made to the borrower during the First 12-Month Disbursement Period do not exceed the Initial Disbursement Limit. If the sum of disbursements made during the First 12-Month Disbursement Period would exceed the Initial Disbursement Limit for that time period, the mortgagee shall decrease the monthly disbursements during the First 12-Month Disbursement Period to conform with the Initial

Disbursement Limit; upon conclusion of the First 12-Month Disbursement Period, the borrower may request a payment plan recalculation.

(4) If the borrower makes a partial prepayment of the outstanding loan balance during the First 12-Month Disbursement Period, the mortgagee shall apply the funds from the partial prepayment in accordance with the Note.

(5) If the mortgagee receives repayment from insurance or condemnation proceeds after restoration or repair of the damaged property, the available principal limit and outstanding loan balance shall be reduced by the amount of such payments.

(f) *Monthly disbursements—tenure option.* (1) Monthly disbursements under the tenure payment option shall be calculated as if the number of months in the payment term equals 100 minus the lesser of the age of the youngest borrower or 95, multiplied by 12, but payments shall continue until the mortgage becomes due and payable under § 206.27(c), except that in the event that payments would exceed any maximum mortgage amount stated in the security instrument or would otherwise exceed the amount secured by the first lien, in accordance with § 206.19(h) payments will cease immediately; payments may be reinstated only in the event a new Note and mortgage are executed in accordance with § 206.27(b)(10); and in the event of a deferral of due and payable status in accordance with § 206.27(c)(3) payments will cease immediately upon the death of the borrower.

(2) Mortgagees shall ensure that tenure monthly disbursements made to the borrower during the First 12-Month Disbursement Period do not exceed the Initial Disbursement Limit. If the sum of disbursements made during the First 12-Month Disbursement Period would exceed the Initial Disbursement Limit for that time period, the mortgagee shall decrease the monthly disbursements during the First 12-Month Disbursement Period to conform with the maximum Initial Disbursement Limit; upon conclusion of the First 12-Month Disbursement Period, the borrower may request a payment plan recalculation.

(3) If the borrower makes a partial prepayment of the outstanding loan balance during the First 12-Month Disbursement Period, the mortgagee shall apply the funds from the partial prepayment in accordance with the Note.

(4) If the mortgagee receives repayment from insurance or

condemnation proceeds after restoration or repair of the damaged property, the available principal limit and outstanding loan balance shall be reduced by the amount of such payments.

(g) *Line of credit separately or with monthly disbursements.* If the borrower has a line of credit, separately or combined with the term or tenure payment option, the principal limit is divided into an amount set aside for servicing charges under § 206.19(f)(3), an amount equal to the line of credit (including any portion of the principal limit set aside for repairs or property charges under § 206.19(f)(1) or (2)), and the remaining amount of the principal limit (if any). The line of credit amount increases at the same rate as the total principal limit increases under § 206.3. The sum of disbursements made during the First 12-Month Disbursement Period shall not exceed the Initial Disbursement Limit. If a requested disbursement would exceed the Initial Disbursement Limit, the mortgagee may make a partial disbursement to the borrower for the amount that will not exceed the limit. Upon the conclusion of the First 12-Month Disbursement Period, the borrower may request subsequent disbursements up to the available principal limit.

(h) *Single Lump Sum payment option.* (1) Under the Single Lump Sum payment option, the Borrower's Advance shall be made by the mortgagee to the borrower in an amount that does not exceed the maximum allowable Borrower's Advance under paragraph (a)(2) of this section.

(2) If the borrower makes a partial prepayment of the outstanding loan balance any time after loan closing and before the contract of insurance is terminated, the mortgagee shall apply the funds from the partial prepayment in accordance with the Note.

(i) *Payment of MIP and interest.* At the end of each month, including the first month, interest accrued during that month shall be added to the outstanding loan balance. Where the first month is a partial month, a prorated amount of interest shall be added. Monthly MIP, which will accrue from the closing date, shall be added to the outstanding loan balance beginning with the first day of the second month after closing when paid to the Commissioner.

(j) *Mortgagee late charge.* The mortgagee shall pay a late charge to the borrower for any late disbursement. If the mortgagee does not mail or electronically transfer a scheduled monthly disbursement to the borrower on the first business day of the month or make a line of credit disbursement

within 5 business days of the date the mortgagee received the request, the late charge shall be 10 percent of the entire amount that should have been paid to the borrower for that month or as a result of that request. In no event shall the total late charge exceed five hundred dollars. For each additional day that the borrower does not receive payment, the mortgagee shall pay interest at the mortgage interest rate on the late payment. Any late charge and interest shall be paid from the mortgagee's funds and shall not be added to the outstanding loan balance.

(k) *No minimum payments.* A mortgagee shall not require, as a condition of providing a loan secured by a mortgage insured under this part, that the monthly payments under the term or tenure payment option or draws under the line of credit payment option exceed a minimum amount established by the mortgagee.

§ 206.26 Change in payment option.

(a) *General.* The payment option may be changed as provided in this section.

(b) *Borrower request for payment plan change—(1) Adjustable Interest Rate HECMs.* (i) During the First 12-Month Disbursement Period, no payment plan change shall cause disbursements to exceed the Initial Disbursement Limit.

(ii) After the First 12-Month Disbursement Period, as long as the outstanding loan balance is less than the principal limit, a borrower may request a recalculation of the current payment option, a change from any payment option to another available payment option or a disbursement of any amount (not to exceed the difference between the principal limit and the sum of the outstanding loan balance and any set asides for repairs, servicing charges or property charges). A mortgagee will continue to bear interest at an adjustable interest rate as agreed between the mortgagee and the borrower at loan origination. The mortgagee shall recalculate any future monthly payments in accordance with § 206.25.

(iii) *Fee for change in payment.* The mortgagee may charge a fee, not to exceed an amount determined by the Commissioner, whenever there is a payment plan change or whenever payments are recalculated.

(iv) *Limitations.* The Commissioner may, through notice, establish limitations on the frequency of payment plan changes, a minimum notice period that a borrower must provide in order to make a request under paragraph (b)(1)(ii) of this section, or other limitations on payment plan change requests by the borrower.

(2) Fixed Interest Rate HECMs.

Borrowers may not request a change in payment option.

(c) *Change due to initial repairs.* When initial repairs after closing under § 206.47 are required using a Repair Set Aside, mortgagees shall comply with the following:

(1) Adjustable Interest Rate HECMs.

(i) If repairs after closing under § 206.47 are completed without using all of the funds set aside for repairs, the mortgagee shall transfer the remaining amount to a line of credit, modified term, or modified tenure payment option and inform the borrower of the sum available to be drawn.

(ii) If repairs after closing under § 206.47 cannot be completed with the funds set aside for repairs, the mortgagee may advance additional funds to complete repairs from an existing line of credit. If a line of credit is not sufficient to make the advance or if no line of credit exists, future monthly disbursements shall be recalculated for use as a line of credit in accordance with § 206.25.

(iii) If repairs are not completed when required by the mortgage, the mortgagee shall stop monthly payments and the mortgage shall convert to the line of credit payment option. Until the repairs are completed, the mortgagee shall make no line of credit disbursements except as needed to pay for repairs required by the mortgage.

(2) *Fixed Interest Rate HECMs.* No unused set aside funds shall be made available to the borrower, except that a borrower may be reimbursed for the cost of repair materials (not including labor), in accordance with § 206.47, under conditions established by the Commissioner.

§ 206.27 Mortgage provisions.

(a) *Form.* The mortgage shall be in a form meeting the requirements of the Commissioner.

(b) *Provisions.* The terms of the mortgage shall contain an explanation of how payments will be made to the borrower, how interest will be charged, and when the mortgage will be due and payable. The mortgage shall include a provision deferring the due and payable status that occurs because of the death of the last surviving borrower for an Eligible Non-Borrowing Spouse. It shall also contain provisions designed to ensure compliance with this part and provisions on the following additional matters:

(1) Disbursements by the mortgagee under the term or tenure payment options shall be mailed to the borrower or electronically transferred to an account of the borrower on the first

business day of each month beginning with the first month after closing. Disbursements under the line of credit payment option shall be mailed to the borrower or electronically transferred to an account of the borrower within five business days after the mortgagee has received a written request for disbursement by the borrower. In accordance with § 206.55, in no event may disbursements continue during a Deferral Period.

(2) The borrower shall insure all improvements on the property that serves as collateral for the HECM whether in existence at the time of origination or subsequently erected, against any hazards, casualties, and contingencies, including but not limited to fire and flood, for which the mortgagee requires insurance. Such insurance shall be maintained in the amount and for the period of time that is necessary to protect the mortgagee's investment. Whether or not the mortgagee imposes a flood insurance requirement, the borrower shall at a minimum insure all improvements on the property, whether in existence at the time of origination or subsequently erected, against loss by floods to the extent required by the Commissioner. If the mortgagee imposes insurance requirements, all insurance shall be carried with companies acceptable to the mortgagee, and the insurance policies and any renewals shall be held by the mortgagee and shall include loss payable clauses in favor of and in a form acceptable to the mortgagee.

(3) The borrower shall not participate in a real estate tax deferral program or permit any liens to be recorded against the property, unless such liens are subordinate to the insured mortgage and, if applicable, any second mortgage held by the Commissioner.

(4) A mortgage may be prepaid in full or in part in accordance with § 206.209.

(5) The borrower must keep the property in good repair.

(6) The borrower must provide for the payment of property charges in accordance with § 206.205.

(7) The payment of monthly MIP may be added to the outstanding principal balance.

(8) The borrower shall have no personal liability for payment of the outstanding loan balance. The mortgagee shall enforce the debt only through sale of the property. The mortgagee shall not be permitted to obtain a deficiency judgment against the borrower if the mortgage is foreclosed.

(9) If the mortgage is assigned to the Commissioner under § 206.121(b), the borrower shall not be liable for any difference between the insurance

benefits paid to the mortgagee and the outstanding loan balance including accrued interest, owed by the borrower at the time of the assignment.

(10) If State law limits the first lien status of the mortgage as originally executed and recorded to a maximum amount of debt or a maximum number of years, the borrower shall agree to execute any additional documents required by the mortgagee and approved by the Commissioner to extend the first lien status to an additional amount of debt and an additional number of years and to cause any other liens to be removed or subordinated.

(c) *Date the mortgage comes due and payable.* (1) The mortgage shall state that the outstanding loan balance will be due and payable in full if a borrower dies and the property is not the principal residence of at least one surviving borrower, except that the due and payable status shall be deferred in accordance with paragraph (c)(3) of this section if the requirements of the Deferral Period are met; or if a borrower conveys all of his or her title in the property and no other borrower retains title to the property. For purposes of the preceding sentence, a borrower retains title in the property if the borrower continues to hold title to any part of the property in fee simple, as a leasehold interest as set forth in § 206.45(a), or as a life estate.

(2) The mortgage shall state that the outstanding loan balance shall be due and payable in full, upon approval of the Commissioner, if any of the following occur:

(i) The property ceases to be the principal residence of a borrower for reasons other than death and the property is not the principal residence of at least one other borrower;

(ii) For a period of longer than 12 consecutive months, a borrower fails to occupy the property because of physical or mental illness and the property is not the principal residence of at least one other borrower;

(iii) The borrower does not provide for the payment of property charges in accordance with § 206.205; or

(iv) An obligation of the borrower under the mortgage is not performed.

(3) *Deferral of due and payable status.* The mortgage documents shall contain a provision deferring due and payable status, called the Deferral Period, for an Eligible Non-Borrowing Spouse until the death of the last Eligible Non-Borrowing Spouse or the requirements of the Deferral Period in § 206.55 cease to be met and have not been cured as provided for in § 206.57.

(d) *Second mortgage to Commissioner.* Unless otherwise

provided by the Commissioner, a second mortgage to secure any payments by the Commissioner as provided in § 206.121(c) must be given to the Commissioner before a Mortgage Insurance Certificate is issued for the mortgage. If the Commissioner does not require a second mortgage to be given to the Commissioner prior to the issuance of a Mortgage Insurance Certificate, the Commissioner may require a second mortgage to be given to the Commissioner at a later day in order to secure payments by the Commissioner as provided in § 206.121(c).

§ 206.31 Allowable charges and fees.

(a) *Fees at closing.* The mortgagee may collect, either in cash at the time of closing or through an initial payment under the mortgage, the following charges and fees incurred in connection with the origination, processing, and closing of the mortgage loan:

(1) *Loan Origination Fee.* Mortgagees may charge a loan origination fee and may use such fee to pay for services performed by a sponsored third-party originator. The loan origination fee limit shall be the greater of \$2,500 or two percent of the maximum claim amount of \$200,000, plus one percent of any portion of the maximum claim amount that is greater than \$200,000. Mortgagees may accept a lower origination fee. Mortgagees may pay fees for services performed by a sponsored third-party originator and these fees may be included as part of the loan origination fee. The total amount of the loan origination fee may not exceed \$6,000, except that the Commissioner may through notice adjust the maximum limit in accordance with the annual percentage increase in the Consumer Price Index of the Bureau of Labor Statistics of the Department of Labor in increments of \$500 only when the percentage increase in such index, when applied to the maximum origination fee, produces dollar increases that exceed \$500. The loan origination fee may be fully financed with the mortgage.

(2) *Reasonable and customary amounts.* Reasonable and customary amounts, but not more than the amount actually paid by the mortgagee, for any of the following items:

(i) Recording fees and recording taxes, or other charges incident to the recordation of the insured mortgage;

(ii) Credit report;

(iii) Survey, if required by the mortgagee or the borrower;

(iv) Title examination;

(v) Mortgagee's title insurance;

(vi) Fees paid to an appraiser for the initial appraisal of the property;

(vii) Flood certifications; and

(viii) Such other charges as may be authorized by the Commissioner.

(b) *Repair administration fee.* If the property requires repairs after closing in order to meet FHA requirements, the mortgagee may collect a fee for each occurrence as compensation for administrative duties relating to repair work pursuant to § 206.47(c) and (d), not to exceed the greater of one and one-half percent of the amount advanced for the repairs or fifty dollars. The mortgagee shall collect the repair fee by adding it to the outstanding loan balance.

§ 206.32 No outstanding unpaid obligations.

In order for a mortgage to be eligible under this part, a borrower must establish to the satisfaction of the mortgagee that after the initial payment of loan proceeds under § 206.25(a), there will be no outstanding or unpaid obligations incurred by the borrower in connection with the mortgage transaction, except for mortgage servicing charges permitted under § 206.207(b) and any future Repair Set Aside established pursuant to § 206.19(f)(1); and the initial disbursement will not be used for any payment to or on behalf of an estate planning service firm.

Eligible Borrowers

§ 206.33 Age of borrower.

The youngest borrower shall be 62 years of age or older at the time of loan closing.

§ 206.34 Limitation on number of mortgages.

(a) Once a borrower has obtained an insured mortgage under this part, the borrower is eligible to obtain future insured HECM loan financing if the existing HECM is satisfied prior to or at the closing of the new HECM, or the borrower provides legal documentation, in a manner acceptable to the Commissioner, evidencing release of the borrower's financial obligation to satisfy the existing HECM.

(b) Current HECM borrowers that plan to sell their existing residence and use the HECM for Purchase program to obtain a new principal residence must pay off the existing FHA-insured mortgage before the HECM for Purchase mortgage can be insured.

§ 206.35 Title of property which is security for HECM.

(a) A mortgagor is not required to be a borrower; however, any borrower is required to be on title to the property which serves as collateral for the HECM,

and is therefore, by definition, also a mortgagor.

(b) The mortgagor shall hold title to the entire property which is the security for the mortgage. If there are multiple mortgagors, all the mortgagors must collectively hold title to the entire property which is the security for the mortgage. If one or more mortgagors hold a life estate in the property, for purposes of this section only, the term "mortgagor" shall include each holder of a future interest in the property (remainder or reversion) who has executed the mortgage.

(c) If Non-Borrowing Spouses and non-borrowing owners of the property will continue to hold title to the property which serves as collateral for the HECM, such Non-Borrowing Spouses and non-borrowing owners must sign the mortgage as mortgagors, evidencing their commitment of the property as security for the mortgage.

(d) All Non-Borrowing Spouses and non-borrowing owners shall sign a certification that:

- (1) Consents to their spouse or other borrowing owner obtaining the HECM;
- (2) Acknowledges the terms and conditions of the mortgage; and
- (3) Acknowledges that the property will serve as collateral for the HECM as evidenced by mortgage lien(s).

§ 206.36 Seasoning requirements for existing non-HECM liens.

(a) The Commissioner may establish, through notice, seasoning requirements for existing non-HECM liens. Such seasoning requirements shall not prohibit the payoff of existing non-HECM liens using HECM proceeds if the liens have been in place for longer than 12 months prior to the HECM closing or if the liens have resulted in cash to the borrower in an amount of \$500 or less, whether at closing or through cumulative draws prior to the date of the HECM closing.

(b) Mortgagees must provide documentation satisfactory to the Commissioner as established by notice that the seasoning requirement was met.

(c) *Home Equity Lines of Credit.* The borrower may pay off, at closing, a Home Equity Line of Credit (HELOC) that does not meet seasoning requirements from borrower funds, the HECM funds, or a combination of HECM funds and borrower funds, as long as the draw from HECM funds does not exceed the percentage approved by the Commissioner under the authority of § 206.25(a).

§ 206.37 Credit standing.

(a) Each borrower shall have a general credit standing satisfactory to the Commissioner.

(b) *Required Financial Assessment—*
(1) *Requirement for Financial Assessment prior to loan approval.* Prior to loan approval, the mortgagee shall assess the financial capacity of the borrower to comply with the terms of the mortgage and evaluate whether the HECM is a sustainable solution for the borrower, in accordance with instructions established by the Commissioner through notice. The Financial Assessment shall consider the borrower's credit history, cash flow and residual income, extenuating circumstances, and compensating factors.

(i) *Credit history.* In accordance with FHA guidelines in existence at the time of FHA Case Number assignment, mortgagees shall conduct an in-depth credit history analysis to determine if the borrower has demonstrated the willingness to meet his or her financial obligations.

(ii) *Cash flow and residual income analysis.* In accordance with FHA guidelines in existence at the time of FHA Case Number assignment, mortgagees shall conduct a cash flow and residual income analysis to determine the capacity of the borrower to meet his or her documented financial obligations with his or her documented income.

(iii) *Extenuating circumstances.* Where the borrower's credit history does not meet the criteria set by the mortgagee based on FHA guidelines in existence at the time of FHA Case Number assignment, mortgagees shall consider and document, as part of the Financial Assessment, extenuating circumstances that led to the credit issues.

(iv) *Compensating factors.* The mortgagee shall document and identify in the Financial Assessment any considered compensating factors.

(2) *Completion and approval of Financial Assessment.* The Financial Assessment shall be completed and approved by a DE Underwriter registered in HUD's system of record by the underwriting mortgagee.

(3) *Nondiscrimination.* (i) The Financial Assessment shall be conducted in a uniform manner that shall not discriminate because of race, color, religion, sex, national origin, familial status, disability, marital status, actual or perceived sexual orientation, gender identity, source of income of the borrower, location of the property, or because the applicant has in good faith exercised any right under the Consumer Credit Protection Act (15 U.S.C. 1601 *et seq.*).

(ii) The Financial Assessment shall be conducted in compliance with all

applicable laws and regulations, including but not limited to, the following:

- (A) Fair Housing Act (42 U.S.C. 3601 *et seq.*);
- (B) Fair Credit Reporting Act (15 U.S.C. 1681 *et seq.*);
- (C) Equal Credit Opportunity Act (15 U.S.C. 1691 *et seq.*); and
- (D) Regulation B (12 CFR part 1002).

§ 206.39 Principal residence.

(a) The property must be the principal residence of each borrower, and if applicable, Eligible Non-Borrowing Spouse, at closing.

(b) *HECM for Purchase.* For HECM for Purchase transactions, each borrower, and if applicable, Eligible Non-Borrowing Spouse, must occupy the property within 60 days from the date of closing.

§ 206.40 Disclosure, verification and certifications.

(a) *Disclosure and certification of Social Security and Employer Identification Numbers—(1) Borrower.* The borrower must meet the requirements for the disclosure and verification of Social Security and Employer Identification Numbers, as provided by part 200, subpart U, of this chapter.

(2) *Eligible Non-Borrowing Spouse.* The Eligible Non-Borrowing Spouse shall comply with the requirements for disclosure and verification of Social Security and Employer Identification Numbers by borrowers in paragraph (a)(1) of this section.

(b) *Certifications.* Each borrower and each Non-Borrowing Spouse shall provide all required certifications to HUD and the mortgagee, as required by the Commissioner.

(c) *Designation of alternate individual.* At the time of origination, the mortgagee shall request that the borrower designate an alternate individual for the purpose of communicating with the mortgagee if the mortgagee has not been able to reach the borrower. The designation of the alternate individual is at the discretion of the borrower. If the mortgagee is unable to make contact or communicate with the borrower for any reason, including death or incapacitation, the mortgagee shall communicate with the alternate individual, if one has been designated by the borrower.

§ 206.41 Counseling.

(a) *List provided.* At the time of the initial contact with the prospective borrower, the mortgagee shall give the borrower a list of the names, addresses, and telephone numbers of HECM

counselors and their employing agencies, which have been approved by the Commissioner, in accordance with subpart E of this part, as qualified and able to provide the information described in paragraph (b) of this section. The borrower, any Eligible or Ineligible Non-Borrowing Spouse, and any non-borrowing owner must receive counseling.

(b) *Information to be provided.* (1) A HECM counselor must discuss with the borrower:

(i) The information required by section 255(f) of the NHA;

(ii) Whether the borrower has signed a contract or agreement with an estate planning service firm that requires, or purports to require, the borrower to pay a fee on or after closing that may exceed amounts permitted by the Commissioner or this part;

(iii) If such a contract has been signed under paragraph (b)(1)(ii) of this section, the extent to which services under the contract may not be needed or may be available at nominal or no cost from other sources, including the mortgagee; and

(iv) Any other requirements determined by the Commissioner.

(2) If the HECM borrower has an Eligible Non-Borrowing Spouse, in addition to meeting the requirements of paragraph (b)(1) of this section, a HECM counselor shall discuss with the borrower and Eligible Non-Borrowing Spouse:

(i) The requirement that the Eligible Non-Borrowing Spouse must obtain ownership of the property or other legal right to remain in the property for life, upon the death of the last surviving borrower;

(ii) A failure to obtain ownership or other legal right to remain in the property for life will result in the HECM becoming due and payable and the Eligible Non-Borrowing Spouse will not receive the benefit of the Deferral Period;

(iii) The requirement that the property must be the principal residence of the Eligible Non-Borrowing Spouse prior to and after the death of the borrowing spouse;

(iv) The requirement that the Eligible Non-Borrowing Spouse fulfills all obligations of the mortgage, including the payment of property charges and upkeep of the property; and

(v) Any other requirements determined by the Commissioner.

(3) If the HECM borrower has an Ineligible Non-Borrowing Spouse, in addition to meeting the requirements of paragraph (b)(1) of this section, a HECM counselor shall discuss with the

borrower and Ineligible Non-Borrowing Spouse:

(i) The Deferral Period will not be applicable;

(ii) The HECM will become due and payable upon the death of the last surviving borrower; and

(iii) Any other requirements determined by the Commissioner.

(c) *Certificate.* The HECM counselor will provide the borrower with a certificate stating that the borrower, Non-Borrowing Spouse, and non-borrowing owner, as applicable, has received counseling. The borrower shall provide the mortgagee with a physical copy of the certificate.

§ 206.43 Information to borrower.

(a) *Disclosure of costs of obtaining mortgage.* The mortgagee shall ensure that the borrower has received full disclosure of all costs of obtaining the mortgage. The mortgagee shall ask the borrower about any costs or other obligations that the borrower has incurred to obtain the mortgage, as defined by the Commissioner, in addition to providing any disclosures required by law. The mortgagee shall clearly state to the borrower which charges are required to obtain the mortgage and which are not required to obtain the mortgage.

(b) *Lump sum disbursement.* (1) If the borrower requests that at least 25 percent of the principal limit amount (after deducting amounts excluded in the following sentence) be disbursed at closing to the borrower (or as otherwise permitted by § 206.25), the mortgagee must make sufficient inquiry at closing to confirm that the borrower will not use any part of the amount disbursed for payments to or on behalf of an estate planning service firm, with an explanation of § 206.32 as necessary or appropriate.

(2) This paragraph does not apply to any part of the principal limit used for the following:

(i) Initial MIP under § 206.105(a) or fees and charges allowed under § 206.31(a) paid by the mortgagee from mortgage proceeds instead of by the borrower in cash; and

(ii) Amounts set aside in accordance with § 206.19(f) for repairs under § 206.47, for property charges under § 206.205, or for servicing charges under § 206.207(b).

§ 206.44 Monetary investment for HECM for Purchase program.

(a) *Monetary investment.* At closing, HECM for Purchase borrowers shall provide a monetary investment that will be applied to satisfy the difference between the principal limit and the sale

price for the property, plus any HECM loan-related fees that are not financed into the loan, minus the amount of the earnest deposit.

(b) *Funding sources.* To satisfy the required monetary investment, borrowers may use:

- (1) Cash on hand;
- (2) Cash from the sale or liquidation of the borrower's assets;
- (3) HECM mortgage proceeds; or
- (4) Other approved funding sources as determined by the Commissioner through notice.

(c) *Interested party contributions.* (1) The following interested party contributions are permissible:

- (i) Fees required to be paid by a seller under state or local law;
- (ii) Fees customarily paid by a seller in the subject property locality; and
- (iii) The purchase of the Home Warranty policy by the seller.

(2) The Commissioner may define additional permissible interested party contributions and impose requirements for permissible interested party contributions through a notice in the **Federal Register**.

Eligible Properties

§ 206.45 Eligible properties.

(a) *Title.* A mortgage must be on real estate held in fee simple; or on a leasehold that is under a lease with a duration lasting until the later of: 99 years, if such lease is renewable; or the actuarial life expectancy of the mortgagor plus a number of years specified by the Commissioner, which shall not be more than 99 years. The mortgagee shall obtain a title insurance policy satisfactory to the Commissioner. If the Commissioner determines that title insurance for reverse mortgages is not available for reasonable rates in a state, then the Commissioner may specify other acceptable forms of title evidence in lieu of title insurance.

(b) *Type of property.* The property shall include a dwelling designed principally as a residence for one family or such additional families as the Commissioner shall determine. A condominium unit designed for one-family occupancy shall also be an eligible property.

(c) *Borrower and mortgagee requirement for maintaining flood insurance coverage.* (1) During such time as the mortgage is insured, the borrower and mortgagee shall be obligated, by a special condition to be included in the mortgage commitment, to obtain and to maintain National Flood Insurance Program (NFIP) flood insurance coverage on the property improvements (dwelling and related

structures/equipment essential to the value of the property and subject to flood damage) if NFIP flood insurance is available with respect to the property improvements that:

(i) Are located in an area designated by the Federal Emergency Management Agency (FEMA) as a floodplain area having special flood hazards; or

(ii) Are otherwise determined by the Commissioner to be subject to a flood hazard.

(2) No mortgage may be insured that covers property improvements located in an area that has been identified by FEMA as an area having special flood hazards, unless the community in which the area is situated is participating in the NFIP and such insurance is obtained by the borrower. Such requirement for flood insurance shall be effective one year after the date of notification by FEMA to the chief executive officer of a flood prone community that such community has been identified as having special flood hazards.

(3) The flood insurance must be maintained during such time as the mortgage is insured in an amount at least equal to the lowest of the following:

- (i) 100 percent replacement cost of the insurable value of the improvements, which consists of the development or project cost less estimated land cost; or
- (ii) The maximum amount of the NFIP insurance available with respect to the particular type of the property; or
- (iii) The outstanding principal balance of the loan.

(d) *Lead-based paint poisoning prevention.* If the appraiser of a dwelling constructed prior to 1978 finds defective paint surfaces, 24 CFR 200.810(d) shall apply unless the borrower certifies that no child who is less than six years of age resides or is expected to reside in the dwelling, except that any reference to "mortgagor" in 24 CFR 200.810(d) shall mean "borrower" for purposes of this paragraph.

(e) *Restrictions on conveyance.* The property must be freely marketable. Conveyance of the property may only be restricted as permitted under 24 CFR 203.41 or 24 CFR 234.66 and this part, except that a right of first refusal to purchase a unit in a condominium project is permitted if the right is held by the condominium association for the project.

(f) *Location of property.* The mortgaged property shall be located within the United States, Puerto Rico, Guam, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, and American Samoa. The

mortgaged property, if otherwise acceptable to the Commissioner, may be located in any location where the housing standards meet the requirements of the Commissioner.

(g) *HECM for Purchase.* (1) A HECM for Purchase transaction is where title to the property is transferred to the HECM borrower and, at the time of closing, the HECM first and second liens, if applicable, will be the only liens against the property.

(2) Properties are eligible for FHA insurance under the HECM for Purchase program when construction is completed and the property is habitable, as evidenced by the issuance of a Certificate of Occupancy or its equivalent, by the local jurisdiction.

§ 206.47 Property standards; repair work.

(a) *Need for repairs.* Properties must meet the applicable property requirements of the Commissioner in order to be eligible. Properties that do not meet the property requirements must be repaired in order to ensure that the repaired property will serve as adequate security for the insured mortgage.

(b) *Assurance that repairs are made.* The mortgage may be closed before the repair work is completed if the Commissioner estimates that the cost of the remaining repair work will not exceed 15 percent of the maximum claim amount and the mortgage contains provisions approved by the Commissioner concerning payment for the repairs.

(c) *Reimbursement to contractor.* When repair work is completed after closing by a contractor, the mortgagee shall cause one or more inspections of the property to be made by an inspector or other qualified individual acceptable to the Commissioner in order to ensure that the repair work is satisfactory, and prior to the release of funds from the Repair Set Aside. The mortgagee shall hold back a portion of the contract price attributable to the work done before each interim release of funds, and the total of the hold backs will be released after the final inspection and approval of the release by the mortgagee. The mortgagee shall ensure that all mechanics' and materialmen's liens are released of record.

(d) *Reimbursement to borrower.* The mortgagee shall not reimburse the borrower for any labor the borrower performed. The mortgagee may reimburse the borrower for the actual cost of repair materials from the Repair Set Aside, provided that the mortgagee causes one or more inspections of the property by an inspector or other qualified individual acceptable to the

Commissioner and meets all reimbursement requirements established by the Commissioner.

(e) *HECM for Purchase*. For HECM for Purchase transactions, where major property deficiencies threaten the health and safety of the homeowner or jeopardize the soundness and security of the property, all repairs must be completed by the seller prior to closing. Appraisers shall complete the appraisal report as "Subject To" the completion of the repairs.

§ 206.51 Eligibility of mortgages involving a dwelling unit in a condominium.

If the mortgage involves a dwelling unit in a condominium, the project in which the unit is located shall have been committed to a plan of condominium ownership by deed, or other recorded instrument, that is acceptable to the Commissioner.

§ 206.52 Eligible sale of property—HECM for Purchase.

(a) *Sale by owner of record—(1) Owner of record requirement*. To be eligible for a mortgage insured by FHA, the property must be purchased from the owner of record and the transaction may not involve any sale or assignment of the sales contract.

(2) *Supporting documentation*. The mortgagee shall obtain documentation verifying that the seller is the owner of record and must submit this documentation to FHA as part of the application for mortgage insurance, in accordance with §§ 206.15 and 206.115(b)(9).

(b) *Time restrictions on re-sales—(1) General*. The eligibility of a property for a mortgage insured by FHA is dependent on the time that has elapsed between the date the seller acquired the property (based upon the date of settlement) and the date of execution of the sales contract that will result in the FHA mortgage insurance (the re-sale date). The mortgagee shall obtain documentation verifying compliance with the time restrictions described in this paragraph and must submit this documentation to FHA as part of the application for mortgage insurance, in accordance with § 206.115(b).

(2) *Re-sales occurring 90 days or less following acquisition*. If the re-sale date is 90 days or less following the date of acquisition by the seller, the property is not eligible for a mortgage to be insured by FHA.

(3) *Re-sales occurring between 91 days and 180 days following acquisition*. (i) If the re-sale date is between 91 days and 180 days following acquisition by the seller, the property is

generally eligible for a mortgage insured by FHA.

(ii) However, FHA will require that the mortgagee obtain additional documentation if the re-sale price is 100 percent over the purchase price. Such documentation must include an appraisal from another appraiser. The mortgagee may also document its loan file to support the increased value by establishing that the increased value results from the rehabilitation of the property.

(iii) FHA may revise the level at which additional documentation is required under paragraph (b)(3) of this section at 50 to 150 percent over the original purchase price. FHA will revise this level by **Federal Register** notice with a 30 day delayed effective date.

(4) *Authority to address property flipping for re-sales occurring between 91 days and 12 months following acquisition*. (i) If the re-sale date is more than 90 days after the date of acquisition by the seller, but before the end of the twelfth month after the date of acquisition, the property is eligible for a mortgage to be insured by FHA.

(ii) However, FHA may require that the mortgagee provide additional documentation to support the re-sale value of the property if the re-sale price is 5 percent or greater than the lowest sales price of the property during the preceding 12 months (as evidenced by the contract of sale). At FHA's discretion, such documentation must include, but is not limited to, an appraisal from another appraiser. FHA may exclude re-sales of less than a specific dollar amount from the additional value documentation requirements.

(iii) If the additional value documentation supports a value of the property that is more than 5 percent lower than the value supported by the first appraisal, the lower value will be used to calculate the maximum claim amount. Otherwise, the value supported by the first appraisal will be used to calculate the maximum claim amount.

(iv) FHA will announce its determination to require additional value documentation through issuance of a **Federal Register** notice. The requirement for additional value documentation may be established either on a nationwide or regional basis. Further, the **Federal Register** notice will specify the percentage increase in the re-sale price that will trigger the need for additional documentation, and will specify the acceptable types of documentation. The **Federal Register** notice may also exclude re-sales of less than a specific dollar amount from the additional value documentation

requirements. Any such **Federal Register** notice, and any subsequent revisions, will be issued at least thirty days before taking effect.

(v) The level at which additional documentation is required under paragraph (b)(4) of this section shall supersede that under paragraph (b)(3) of this section.

(5) *Re-sales occurring more than 12 months following acquisition*. If the re-sale date is more than 12 months following the date of acquisition by the seller, the property is eligible for a mortgage insured by FHA.

(c) *Exceptions to the time restrictions on sales*. The time restrictions on sales described in paragraph (b) of this section do not apply to:

(1) Sales by HUD of Real Estate-Owned (REO) properties under 24 CFR part 291 and of single family assets in revitalization areas pursuant to section 204 of the NHA (12 U.S.C. 1710);

(2) Sales by another agency of the United States Government of REO single family properties pursuant to programs operated by these agencies;

(3) Sales of properties by nonprofit organizations approved to purchase HUD REO single family properties at a discount with resale restrictions;

(4) Sales of properties that were acquired by the sellers by inheritance;

(5) Sales of properties purchased by an employer or relocation agency in connection with the relocation of an employee;

(6) Sales of properties by state- and federally-chartered financial institutions and government-sponsored enterprises (GSEs);

(7) Sales of properties by local and state government agencies; and

(8) Only upon announcement by FHA through issuance of a notice, sales of properties located in areas designated by the President as federal disaster areas. The notice will specify how long the exception will be in effect.

(d) *Sanctions and indemnification*. Failure of a mortgagee to comply with the requirements of this section may result in HUD requesting indemnification of the mortgage loan, or seeking other appropriate remedies under 24 CFR part 25.

Refinancing of Existing Home Equity Conversion Mortgages

§ 206.53 Refinancing a HECM loan.

(a) *General*. Except as otherwise provided in this section, all requirements applicable to the insurance of HECMs under this part apply to the insurance of refinanced HECMs. FHA may, upon application by a mortgagee, insure any mortgage given

to refinance an existing HECM insured under this part, including loans assigned to the Commissioner as described in § 206.107(a)(1) and § 206.121(b).

(b) *Definition of “total cost of the refinancing”.* For purposes of paragraphs (d) and (e) of this section, the term “total cost of the refinancing” means the sum of the allowable charges and fees permitted under § 206.31 and the initial MIP described in § 206.105(a) and paragraph (c) of this section.

(c) *Initial MIP limit.* (1) The initial MIP paid by the mortgagee pursuant to § 206.105(a) shall not exceed the difference between: three percent of the increase in the maximum claim amount for the new HECM, minus the amount of the initial MIP already charged and paid by the borrower for the existing HECM that is being refinanced. No refunds will be given if the initial MIP paid on the existing HECM exceeds the initial MIP due on the new HECM.

(2) The HECM refinance authority is only applicable when the property that serves as collateral for the FHA-insured mortgage remains the same.

(3) Existing HECM borrowers refinancing an existing HECM are eligible for a MIP reduction under the conditions of this section, but existing HECM borrowers who participate in a HECM for Purchase transaction are ineligible for a reduction in the initial MIP.

(d) *Anti-churning disclosure—(1) Contents of anti-churning disclosure.* In addition to providing the required disclosures under § 206.43, the mortgagee shall provide to the borrower its best estimate of:

(i) The total cost of the refinancing to the borrower; and

(ii) The increase in the borrower's principal limit as measured by the estimated initial principal limit on the mortgage to be insured less the current principal limit on the HECM that is being refinanced under this section.

(2) *Timing of anti-churning disclosure.* The mortgagee shall provide the anti-churning disclosure concurrently with the disclosures required under § 206.43.

(e) *Waiver of counseling requirement.* The borrower and any Non-Borrowing Spouse may elect not to receive counseling under § 206.41, but only if:

(1) The original HECM was assigned a Case Number on or after August 4, 2014, and the borrower and Non-Borrowing Spouse, if applicable, received counseling required under § 206.41; or where the original HECM was assigned a Case Number prior to August 4, 2014, and there is no applicable Non-Borrowing Spouse.

(2) The borrower has received the anti-churning disclosure required under paragraph (d) of this section.

(3) The increase in the borrower's principal limit (as provided in the anti-churning disclosure) exceeds the total cost of the refinancing by an amount established by the Commissioner through **Federal Register** notice. FHA may periodically update this amount through publication of a notice in the **Federal Register**. Publication of any such revised amount will occur at least 30 days before the revision becomes effective.

(4) The time between the date of the closing on the original HECM and the date of the application for refinancing under this section does not exceed five years (even if less than five years have passed since a previous refinancing under this section).

Deferral of Due and Payable Status

§ 206.55 Deferral of due and payable status for Eligible Non-Borrowing Spouses.

(a) *Deferral Period.* If the last surviving borrower predeceases an Eligible Non-Borrowing Spouse, and if the requirements of paragraph (d) of this section are satisfied, the due and payable status will be deferred for as long as the Eligible Non-Borrowing Spouse continues to meet the Qualifying Attributes in paragraph (c) of this section and the requirements of paragraphs (d) and (e) of this section.

(b) *End of Deferral Period.* (1) If a Deferral Period ceases or becomes unavailable because a Non-Borrowing Spouse no longer satisfies the Qualifying Attributes and has become an Ineligible Non-Borrowing Spouse, a mortgagee may not provide an opportunity to cure the default, and the HECM will become immediately due and payable as a result of the death of the last surviving borrower.

(2) If a Deferral Period ceases but the Eligible Non-Borrowing Spouse continues to meet the Qualifying Attributes, the mortgagee must provide an Eligible Non-Borrowing Spouse with 30 days to cure the default, in accordance with § 206.57.

(c) *Qualifying Attributes.* (1) In order to qualify as an Eligible Non-Borrowing Spouse, the Non-Borrowing Spouse must:

(i) Have been the spouse of a HECM borrower at the time of loan closing and remained the spouse of such HECM borrower for the duration of the HECM borrower's lifetime;

(ii) Have been properly disclosed to the mortgagee at origination and specifically named as an Eligible Non-Borrowing Spouse in the HECM mortgage and loan documents;

(iii) Have occupied, and continue to occupy, the property securing the HECM as his or her principal residence; and

(iv) Meet any other requirements as the Commissioner may prescribe by **Federal Register** notice for comment.

(2) A Non-Borrowing Spouse who meets the Qualifying Attributes in paragraph (c)(1) of this section at origination is an Eligible Non-Borrowing Spouse and may not elect to be ineligible for the Deferral Period. A Non-Borrowing Spouse that is ineligible for the Deferral Period at the time of loan origination because he or she failed to satisfy the Qualifying Attributes requirements in paragraph (c)(1) of this section is not subsequently eligible for a Deferral Period when the borrowing spouse dies or moves out of the home.

(3) An Eligible Non-Borrowing Spouse shall become an Ineligible Non-Borrowing Spouse should any of the Qualifying Attributes requirements in paragraph (c)(1) of this section cease to be met.

(d) *Additional requirements for Deferral Period.* An Eligible Non-Borrowing Spouse must satisfy and continue to satisfy the following requirements:

(1) Within 90 days from the death of the last surviving HECM borrower, establish legal ownership or other ongoing legal right to remain for life in the property securing the HECM;

(2) After the death of the last surviving borrower, ensure all other obligations of the HECM borrower(s) contained in the loan documents continue to be satisfied; and

(3) After the death of the last surviving borrower, ensure that the HECM does not become eligible to be called due and payable for any other reason.

(e) *Unaffected terms of HECM.* All applicable terms and conditions of the mortgage and loan documents, and all FHA requirements, continue to apply and must be satisfied.

(f) Nothing in this section may be construed as interrupting or interfering with the ability of the borrower's estate or heir(s) to dispose of the property if they are otherwise legally entitled to do so.

§ 206.57 Cure provision enabling reinstatement of Deferral Period.

(a) When the mortgagee is required by § 206.55(b)(2) to provide an Eligible Non-Borrowing Spouse with 30 days to cure the default, this section shall apply.

(b) If the default is cured within the 30-day timeframe, the Deferral Period shall be reinstated, unless:

(1) The mortgagee has reinstated the Deferral Period within the past two years immediately preceding the current notification to the Eligible Non-Borrowing Spouse that the mortgage is due and payable;

(2) The reinstatement of the Deferral Period will preclude foreclosure if the mortgage becomes due and payable at a later date; or

(3) The reinstatement of the Deferral Period will adversely affect the priority of the mortgage lien.

(c) If the default is not cured within the 30-day timeframe, the mortgagee shall proceed in accordance with the established timeframes to initiate foreclosure and reasonable diligence in prosecuting foreclosure.

(d) Even after a foreclosure proceeding has been initiated, the mortgagee shall permit an Eligible Non-Borrowing Spouse to cure the condition which resulted in the Deferral Period ceasing, consistent with § 206.55(b)(2), and to reinstate the mortgage and Deferral Period, and the mortgage insurance shall continue in effect. The mortgagee may require the Eligible Non-Borrowing Spouse to pay any costs that the mortgagee incurred to reinstate the mortgage, including foreclosure costs and reasonable attorney's fees. Such costs may not be added to the outstanding loan balance and shall be paid from some other source of funds. The mortgagee shall reinstate the Deferral Period unless:

(1) The mortgagee has reinstated the Deferral Period within the past two years immediately preceding the latest notification to the Eligible Non-Borrowing Spouse that the mortgage is due and payable;

(2) The reinstatement of the Deferral Period will preclude foreclosure if the mortgage becomes due and payable at a later date; or

(3) The reinstatement of the Deferral Period will adversely affect the priority of the mortgage lien.

§ 206.59 Obligations of mortgagee.

(a) *Certifications and disclosures at closing.* At closing, the mortgagee shall obtain the appropriate certification from each borrower identified as married as well as from each identified Non-Borrowing Spouse. When a HECM borrower has identified an Ineligible Non-Borrowing Spouse, the mortgagee shall also disclose the amount of mortgage proceeds that would have been available under the HECM if he or she were an Eligible Non-Borrowing Spouse.

(b) *Divorce.* In the event of a divorce between the HECM borrower and Eligible Non-Borrowing Spouse, a

mortgagee shall obtain a copy of the final divorce decree and shall not require the now Ineligible Non-Borrowing Spouse to fulfill any further requirements.

(c) *Death of borrower.* Within 30 days of being notified of the death of the borrower, the mortgagee shall:

(1) Obtain all certifications, as required by the Commissioner, from the Eligible Non-Borrowing Spouse, and continue to obtain the required certifications no less than annually thereafter for the duration of the Deferral Period; and

(2) Notify any Eligible Non-Borrowing Spouse that the due and payable status of the loan is in a Deferral Period only for the amount of time that such Eligible Non-Borrowing Spouse continues to meet all requirements established by the Commissioner.

(d) *Non-compliance with requirements.* If the Eligible Non-Borrowing Spouse ceases to meet any requirements established by the Commissioner, the mortgagee shall notify the Eligible Non-Borrowing Spouse within 30 days that the Deferral Period has ended and the HECM is immediately due and payable, unless the Deferral Period is reinstated in accordance with § 206.57. The mortgagee shall obtain documentation validating the reason for the cessation of the Deferral Period and, if applicable, the reason for reinstatement of the Deferral Period.

§ 206.61 HECM proceeds during a Deferral Period.

(a) The HECM is not assumable. HECM proceeds may not be disbursed to any party during a Deferral Period, except as determined by the Commissioner through notice.

(b) If a Repair Set Aside was established as a condition of the HECM, funds may be disbursed from the Repair Set Aside during a Deferral Period for the sole purpose of paying the cost of those repairs that were specifically identified prior to origination as necessary to the insurance of the HECM. Repairs under this paragraph shall only be paid for using funds from the Repair Set Aside if the repairs are satisfactorily completed during the time period established in the Repair Rider or such additional time as provided by the Commissioner. Unused funds remaining beyond the established time period shall not be disbursed.

Subpart C—Contract Rights and Obligations

Sale, Assignment and Pledge

§ 206.101 Sale, assignment and pledge of insured mortgages.

(a) *Sale of interests in insured mortgages.* No mortgagee may sell or otherwise dispose of any mortgage insured under this part, or group of mortgages insured under this part, or any partial interest in such mortgage or mortgages by means of any agreement, arrangement or device except pursuant to this subpart.

(b) *Sale of insured mortgage to approved mortgagee.* A mortgage insured under this part may be sold to another approved mortgagee. The seller shall notify the Commissioner of the sale within 15 calendar days, on a form prescribed by the Commissioner and acknowledged by the buyer.

(c) *Effect of sale of insured mortgage.* When a mortgage insured under this part is sold to another approved mortgagee, the buyer shall thereupon succeed to all the rights and become bound by all the obligations of the seller under the contract of insurance and the seller shall be released from its obligations under the contract, provided that the seller shall not be relieved of its obligation to pay mortgage insurance premiums until the notice required by § 206.101(b) is received by the Commissioner.

(d) *Assignments, pledges and transfers by approved mortgagee.* (1) An assignment, pledge, or transfer of a mortgage or group of mortgages insured under this part, not constituting a final sale, may be made by an approved mortgagee to another approved mortgagee provided the following requirements are met:

(i) The assignor, pledgor or transferor shall remain the mortgagee of record.

(ii) The Commissioner shall have no obligation to recognize or deal with any party other than the mortgagee of record with respect to the rights, benefits and obligations of the mortgagee under the contract of insurance.

(2) An assignment or transfer of an insured mortgage or group of insured mortgages may be made by an approved mortgagee to other than an approved mortgagee provided the requirements under paragraphs (d)(1)(i) and (d)(1)(ii) of this section are met and the following additional requirements are met:

(i) The assignee or transferee shall be a corporation, trust or organization (including but not limited to any pension trust or profit-sharing plan) which certifies to the approved mortgagee that:

(A) It has assets of \$100,000 or more; and

(B) It has lawful authority to hold an insured mortgage or group of insured mortgages.

(ii) The assignment or transfer shall be made pursuant to an agreement under which the transferor or assignor is obligated to take one of the following alternate courses of action within 1 year from the date of the assignment or within such additional period of time as may be approved by the Commissioner:

(A) The transferor or assignor shall repurchase and accept a reassignment of such mortgage or group of mortgages.

(B) The transferor or assignor shall obtain a sale and transfer of such mortgage or group of mortgages to an approved mortgagee.

(3) Notice to or approval of the Commissioner is not required in connection with assignments, pledges or transfers pursuant to this section.

(e) *Declaration of trust.* A sale of a beneficial interest in a group of mortgages insured under this part, where the interest to be acquired is related to all of the mortgages as an entirety, rather than an interest in a specific mortgage, shall be made only pursuant to a declaration of trust, which has been approved by the Commissioner prior to any such sale.

(f) *Transfers of partial interests.* A partial interest in a mortgage insured under this part may be transferred under a participation agreement without obtaining the approval of the Commissioner, if the following conditions are met:

(1) *Principal mortgagee.* The insured mortgage shall be held by an approved mortgagee which, for the purposes of this section, shall be referred to as the *principal mortgagee*.

(2) *Interest of principal mortgagee.* The principal mortgagee shall retain and hold for its own account a financial interest in the insured mortgage.

(3) *Qualification for holding partial interest.* A partial interest in an insured mortgage shall be issued to and held only by:

(i) A mortgagee approved by the Commissioner; or

(ii) A corporation, trust or organization (including, but not limited to any pension fund, pension trust, or profit-sharing plan) which certifies to the principal mortgagee that:

(A) It has assets of \$100,000 or more; and

(B) It has lawful authority to acquire a partial interest in an insured mortgage.

(4) *Participation agreement provisions.* The participation agreement shall include provisions that:

(i) The principal mortgagee shall retain title to the mortgage and remain

the mortgagee of record under the contract of mortgage insurance.

(ii) The Commissioner shall have no obligation to recognize or deal with anyone other than the principal mortgagee with respect to the rights, benefits and obligations of the mortgagee under the contract of insurance.

(iii) The mortgage and loan documents shall remain in the custody of the principal mortgagee.

(iv) The responsibility for servicing the insured mortgages shall remain with the principal mortgagee.

§ 206.102 Insurance Funds.

Loans endorsed for insurance under this part, prior to October 1, 2008, shall be obligations of the General Insurance Fund. Loans endorsed for insurance under this part, on or after October 1, 2008, shall be obligations of the MMIF.

Mortgage Insurance Premiums

§ 206.103 Payment of MIP.

(a) The payment of any MIP due under this subpart shall be made to the Commissioner by the mortgagee in cash until an event described in paragraph (b) or (c) of this section occurs.

(b) *Payment of the mortgage.* The MIP shall no longer be remitted if the mortgage is paid in full.

(c) *Acquisition of title.* (1) If the mortgagee or a party other than the mortgagee acquires title at a foreclosure sale, or the mortgagee acquires title by a deed in lieu of foreclosure, and the mortgagee notifies the Commissioner that a claim for the payment of the insurance benefits will not be presented, the MIP shall no longer be remitted.

(2) If the mortgagee or a party other than the mortgagee acquires title at a foreclosure sale or the mortgagee acquires title by a deed in lieu of foreclosure, or where the property is sold in accordance with § 206.125(c), and a claim for the payment of the insurance benefits will be presented, the MIP shall no longer be remitted as of the date of the foreclosure sale, the date the deed in lieu of foreclosure is recorded, or the date in which the sale in accordance with § 206.125(c) is completed, as applicable.

§ 206.105 Amount of MIP.

(a) *Initial MIP.* The mortgagee shall pay to the Commissioner an initial MIP that does not exceed three percent of the maximum claim amount.

(b) *Monthly MIP.* The Commissioner may establish and collect a monthly MIP, which will accrue daily from the closing date, at a rate not to exceed 1.50 percent of the remaining insured principal balance, or up to 1.55 percent

for any mortgage involving an original principal obligation that is greater than 95 percent of appraised value of the property. A mortgagee may only add the monthly MIP to the loan balance when paid to the Commissioner.

(c) *Calculation of the initial MIP.* The mortgagee shall calculate the initial MIP based on the amount of funds the borrower has elected to be made available during the First 12-Month Disbursement Period, except that the calculation shall not include any funds set aside in the Servicing Fee Set Aside, if applicable. The initial MIP calculation shall be determined based on the sum of the following amounts:

(1) For adjustable interest rate HECMs, the amount of Mandatory Obligations, the amount disbursed to the borrower at loan closing, and the amount of the available Initial Disbursement Limit not taken by the borrower at loan closing that the borrower selects to remain available during the First 12-Month Disbursement Period.

(2) For fixed interest rate HECMs, the amount of Mandatory Obligations and the amount disbursed to the borrower at loan closing.

(d) *Adjustments to initial or monthly MIP.* The Commissioner may adjust the amount of any initial or monthly MIP through notice. Such notice shall establish the effective date of any premium adjustment therein.

§ 206.107 Mortgagee election of assignment or shared premium option.

(a) *Election of option.* Before the mortgage is submitted for insurance endorsement, the mortgagee shall elect either the assignment option or the shared premium option.

(1) Under the assignment option, the mortgagee shall have the option of assigning the mortgage to the Commissioner if the outstanding loan balance is equal to or greater than 98 percent of the maximum claim amount, regardless of the deferral status, or the borrower has requested a payment which exceeds the difference between the maximum claim amount and the outstanding loan balance and:

(i) The mortgagee is current in making the required payments under the mortgage to the borrower;

(ii) The mortgagee is current in its payment of the MIP (and late charges and interest on the MIP, if any) to the Commissioner;

(iii) The mortgage is not due and payable under § 206.27(c)(1), or, if due and payable under § 206.27(c)(1), its due and payable status has been deferred pursuant to a Deferral Period;

(iv) An event described in § 206.27(c)(2) has not occurred, or the Commissioner has been so informed but has denied approval for the mortgage to be due and payable. At the mortgagee's option, the mortgagee may forgo assignment of the mortgage and file a claim under any of the circumstances described in § 206.123(a)(3)–(5); and

(v) The mortgage is a first lien of record and title to the property securing the mortgage is good and marketable. The provisions of § 206.136 pertaining to mortgagee certifications also apply.

(2) Under the shared premium option, the mortgagee may not assign a mortgage to the Commissioner unless the mortgagee fails to make payments and the Commissioner demands assignment (§ 206.123(a)(2)), but the mortgagee shall only be required to remit a reduced monthly MIP to the Commissioner. The mortgagee shall collect from the borrower the full amount of the monthly MIP provided in § 206.105(b) but shall retain a portion of the monthly MIP paid by the borrower as compensation for the default risk assumed by the mortgagee. The portion of the MIP to be retained by a mortgagee shall be determined by the Commissioner as calculated in § 206.109. For a particular mortgage, the applicable portion shall be determined as of the date of the commitment. The mortgagee retains the right to file a claim under any of the circumstances described in § 206.123(a)(2)–(5).

(b) *No election for shared appreciation.* Shared appreciation mortgages shall be insured by the Commissioner only under the shared premium option.

§ 206.109 Amount of mortgagee share of premium.

Using the factors provided by the Commissioner, the amount of the mortgagee share of the premium shall be determined for each mortgage based upon the age of the youngest borrower or Eligible Non-Borrowing Spouse and the expected average mortgage interest rate.

§ 206.111 Due date of MIP.

(a) *Initial MIP.* The mortgagee shall pay the initial MIP to the Commissioner within fifteen days of closing and as a condition to the endorsement of the mortgage for insurance.

(b) *Monthly MIP.* Each monthly MIP shall be due to the Commissioner on the first business day of each month except the month in which the mortgage is closed.

§ 206.113 Late charge and interest.

(a) *Late charge.* Initial MIP remitted to the Commissioner more than 5 days

after the payment date in § 206.111(a) and monthly MIP remitted to the Commissioner more than 5 days after the payment date in § 206.111(b) shall include a late charge of four percent of the amount owed.

(b) *Interest.* In addition to any late charge provided in paragraph (a) of this section, the mortgagee shall pay interest on any initial MIP remitted to the Commissioner more than 20 days after closing, and interest on any monthly MIP remitted to the Commissioner more than 5 days after the payment date prescribed in § 206.111(b). Such interest rate shall be paid at a rate set in conformity with the Treasury Financial Manual.

(c) *Paid by mortgagee.* Any late charge and interest owed may not be added to the outstanding loan balance and must be paid by the mortgagee.

§ 206.115 Insurance of mortgage.

(a) *Mortgages with firm commitments.* For applications for insurance involving mortgages not eligible to be originated under the Direct Endorsement program under § 203.5 (any reference to § 203.255 in § 203.5 shall mean § 206.115 for purposes of this section), the Commissioner will endorse the mortgage for insurance by issuing a Mortgage Insurance Certificate.

(b) *Endorsement with Direct Endorsement processing.* For applications for insurance involving mortgages originated under the Direct Endorsement program under § 203.5 (any reference to § 203.255 in § 203.5 shall mean § 206.115 for purposes of this section), the mortgagee shall submit to the Commissioner, within 60 days after the date of closing of the loan or such additional time as permitted by the Commissioner, properly completed documentation and certifications as listed in this paragraph (b):

(1) Property appraisal upon a form meeting the requirements of the Commissioner (including, if required, any additional documentation supporting the appraised value of the property under § 206.52), and a HUD conditional commitment, or a Lender's Notice of Value issued by the Lender Appraisal Processing Program (LAPP) approved lender when the appraisal was originally completed for use in a VA application, but only if the appraiser was also on the FHA roster as of the effective date of the appraisal, and all accompanying documents required by the Commissioner;

(2) An application for insurance of the mortgage in a form prescribed by the Commissioner;

(3) A certified copy of the mortgage and loan documents executed upon

forms which meet the requirements of the Commissioner;

(4) An underwriter certification, on a form prescribed by the Commissioner, stating that the underwriter has personally reviewed the appraisal report and credit application (including the analysis performed on the worksheets) and that the proposed mortgage complies with FHA underwriting requirements, and incorporates each of the underwriter certification items that apply to the mortgage submitted for endorsement, as set forth in the applicable handbook or similar publication that is distributed to all Direct Endorsement mortgagees, except that if FHA makes the TOTAL Mortgage Scorecard available to HECM mortgagees by setting out requirements applicable for the use of the TOTAL Mortgage Scorecard in a **Federal**

Register notice for comment, mortgagees may follow such procedures and meet such requirements in lieu of providing the underwriter certification;

(5) Where applicable, a certificate under oath and contract regarding use of the dwelling for transient or hotel purposes;

(6) Where an individual water or sewer system is being used, an approval letter from the local health authority indicating approval of the system in accordance with § 200.926d(f);

(7) A mortgage certification on a form prescribed by the Commissioner, stating that the authorized representative of the mortgagee who is making the certification has personally reviewed the mortgage documents and the application for insurance endorsement, and certifying that the mortgage complies with the requirements of paragraph (b) of this section. The certification shall incorporate each of the mortgagee certification items that apply to the mortgage loan submitted for endorsement, as set forth in the applicable handbook or similar publication that is distributed to all Direct Endorsement mortgagees;

(8) Documents required by § 206.15;

(9) Documentation providing that the seller is the owner of record in accordance with § 206.52(a) and the time restriction requirements of § 206.52(b) are met;

(10) For HECM for Purchase transactions, a Certificate of Occupancy, or its equivalent, if required for new construction; and

(11) Such other documents as the Commissioner may require.

(c) *Pre-endorsement review for Direct Endorsement.* (1) Upon submission by an approved mortgagee of the documents required by paragraph (b) of this section, the Commissioner will

review the documents and determine that:

(i) The mortgage is executed on a form which meets the requirements of the Commissioner;

(ii) The mortgage maturity meets the requirements of the applicable program;

(iii) The stated mortgage amount does not exceed 150 percent of the maximum claim amount;

(iv) All documents required by paragraph (b) of this section are submitted;

(v) All necessary certifications are made in accordance with paragraph (b) of this section;

(vi) There is no mortgage insurance premium, late charge or interest due to the Commissioner; and

(vii) The mortgage was not in default when submitted for insurance or, if submitted for insurance more than 60 days after closing, the mortgagee certifies that the borrower is current in paying all property charges or is otherwise in compliance with all the terms and conditions of the mortgage documents.

(2) The Commissioner is authorized to determine if there is any information indicating that any certification or required document is false, misleading, or constitutes fraud or misrepresentation on the part of any party, or that the mortgage fails to meet a statutory or regulatory requirement. If, following this review, the mortgage is determined to be eligible, the Commissioner will endorse the mortgage for insurance by issuance of a Mortgage Insurance Certificate. If the mortgage is determined to be ineligible, the Commissioner will inform the mortgagee in writing of this determination, and include the reasons for the determination and any corrective actions that may be taken.

(d) *Submission by mortgagee other than originating mortgagee.* If the originating mortgagee assigns the mortgage to another approved mortgagee before pre-endorsement review under paragraph (c) of this section, the assignee may submit the required documents for pre-endorsement review in the name of the originating mortgagee. All certifications must be executed by the originating mortgagee (or its underwriter, if appropriate). The purchasing mortgagee may pay any required mortgage insurance premium, late charge and interest.

(e) *Post-Endorsement review for Direct Endorsement.* Following endorsement for insurance, the Commissioner may review all documents required by paragraph (b) of this section. If, following this review, the Commissioner determines that the mortgage does not

satisfy the requirements of the Direct Endorsement program, the Commissioner may place the mortgagee on Direct Endorsement probation, or terminate the authority of the mortgagee to participate in the Direct Endorsement program pursuant to § 206.15, or refer the matter to the Mortgagee Review Board for action pursuant to part 25 of this title.

(f) *Creation of the contract.* The mortgage shall be an insured mortgage from the date of the issuance of a Mortgage Insurance Certificate, from the date of the endorsement of the credit instrument, or from the date of FHA's electronic acknowledgement to the mortgagee that the mortgage is insured, as applicable. The Commissioner and the mortgagee are thereafter bound by the regulations in this subpart with the same force and to the same extent as if a separate contract had been executed relating to the insured mortgage, including the provisions of the regulations in this subpart and of the National Housing Act.

§ 206.116 Refunds.

No amount of the initial MIP shall be refundable except as authorized by the Commissioner.

HUD Responsibility to Borrowers

§ 206.117 General.

The Commissioner is required by statute to take any action necessary to provide a borrower with funds to which the borrower is entitled under the mortgage and which the borrower does not receive because of the default of the mortgagee. The Commissioner may hold a second mortgage to secure repayment by the borrower under § 206.27(d). Where the Commissioner does not hold a second mortgage, but makes a payment to the borrower, and such payment is not reimbursed by the mortgagee, the Commissioner shall accept assignment of the first mortgage.

§ 206.119 [Reserved]

§ 206.121 Commissioner authorized to make payments.

(a) *Investigation.* The Commissioner will investigate all complaints by a borrower concerning late payments. If the Commissioner determines that the mortgagee is unable or unwilling to make all payments required under the mortgage, including late charges, the Commissioner shall pay such payments and late charges to the borrower.

(b) *Reimbursement or assignment.* The Commissioner may demand that within 30 days from the demand, the mortgagee reimburse the Commissioner, with interest from the date of payment

by the Commissioner, or assign the insured mortgage to the Commissioner. Interest shall be paid at a rate set in conformity with the Treasury Financial Manual. If the mortgagee complies with the reimbursement demand, then the contract of insurance shall not be affected. If the mortgagee complies by assigning the mortgage for record within 30 days of the demand, then the Commissioner shall pay an insurance claim as provided in § 206.129(e)(3) and assume all responsibilities of the mortgagee under the first mortgage. If the mortgagee fails to comply with the demand within 30 days, the contract of insurance will terminate as provided in § 206.133(c).

(c) *Second mortgage.* If the contract of insurance is terminated as provided in § 206.133(c), all payments to the borrower by the Commissioner will be secured by the second mortgage, unless otherwise provided by the Commissioner. Payments will be due and payable in the same manner as under the insured first mortgage. The liability of the borrower under the first mortgage shall be limited to payments actually made by the mortgagee to or on behalf of the borrower (including prior recoupment of the MIP remitted by the mortgagee and billed to the borrower), and shall exclude accrued interest, whether or not it has been included in the outstanding loan balance, and shared appreciation, if any. Interest will stop accruing on the first mortgage when the Commissioner begins to make payments under the second mortgage. The first mortgage will not be due and payable until the second mortgage is due and payable.

Claim Procedure

§ 206.123 Claim procedures in general.

(a) *Claims.* Mortgagees may submit claims for the payment of the mortgage insurance benefits if:

(1) The conditions of § 206.107(a)(1) pertaining to the optional assignment of the mortgage by the mortgagee have been met and the mortgagee assigns the mortgage to the Commissioner;

(2) The mortgagee is unable or unwilling to make the payments under the mortgage and assigns the mortgage to the Commissioner pursuant to the Commissioner's demand, as provided in § 206.121(b);

(3) The borrower or other permissible party sells the property for less than the outstanding loan balance and the mortgagee releases the mortgage of record to facilitate the sale, as provided in § 206.125(c);

(4) The mortgagee acquires title to the property by foreclosure or a deed in lieu

of foreclosure and sells the property as provided in § 206.125(g) for an amount which does not satisfy the outstanding loan balance or fails to sell the property as provided in § 206.127(a)(2); or

(5) The mortgagee forecloses and a bidder other than the mortgagee purchases the property for an amount that is not sufficient to satisfy the outstanding loan balance, as provided in § 206.125(e).

(b) [Reserved]

§ 206.125 Acquisition and sale of the property.

(a) *Initial action by the mortgagee.* (1) The mortgagee shall notify the Commissioner within 60 days of the mortgage becoming due and payable when the conditions stated in the mortgage, as required by § 206.27(c)(1) have occurred or when the Deferral Period ends. The mortgagee shall notify the Commissioner within 30 days when one of the conditions stated in the mortgage, as required by § 206.27(c)(2), has occurred.

(2) After notifying and receiving approval of the Commissioner when needed, the mortgagee shall notify the borrower, Eligible Non-Borrowing Spouse, borrower's estate, and borrower's heir(s), as applicable, within 30 days of the later of notifying the Commissioner or receiving approval, if needed, that the mortgage is due and payable. The mortgagee shall give the applicable party 30 days from the date of notice to engage in the following actions:

(i) Pay the outstanding loan balance, including any accrued interest, MIP, and mortgagee advances in full;

(ii) Sell the property for an amount not to be less than the amount determined by the Commissioner through notice, which shall not exceed 95 percent of the appraised value as determined under § 206.125(b), with the net proceeds of the sale to be applied towards the outstanding loan balance. Closing costs shall not exceed the greater of: 11 percent of the sales price; or a fixed dollar amount as determined by the Commissioner through **Federal Register** notice. For the purposes of this section, *sell* includes the transfer of title by operation of law;

(iii) Provide the mortgagee with a deed in lieu of foreclosure;

(iv) Correct the condition which resulted in the mortgage coming due and payable for reasons other than the death of the last surviving borrower;

(v) For an Eligible Non-Borrowing Spouse, correct the condition which resulted in an end to the Deferral Period in accordance with § 206.57; or

(vi) Such other actions as permitted by the Commissioner through notice.

(3) For a borrower, even after a foreclosure proceeding is begun, the mortgagee shall permit the borrower to correct the condition which resulted in the mortgage coming due and payable and to reinstate the mortgage, and the mortgage insurance shall continue in effect. The mortgagee may require the borrower to pay any costs that the mortgagee incurred to reinstate the borrower, including foreclosure costs and reasonable attorney's fees. Such costs shall be paid by adding them to the outstanding loan balance. The mortgagee may refuse reinstatement by the borrower if:

(i) The mortgagee has accepted reinstatement of the mortgage within the past two years immediately preceding the current notification to the borrower that the mortgage is due and payable;

(ii) Reinstatement will preclude foreclosure if the mortgage becomes due and payable at a later date; or

(iii) Reinstatement will adversely affect the priority of the mortgage lien.

(4) For an Eligible Non-Borrowing Spouse, even after a foreclosure proceeding is begun, the mortgagee shall permit the Eligible Non-Borrowing Spouse to cure the condition which resulted in the Deferral Period ceasing, in accordance with § 206.57(d).

(b) *Appraisal.* The mortgagee shall have the property appraised by an appraiser on the FHA roster, or other appraiser acceptable to, and identified by, the Commissioner through **Federal Register** notice, no later than 30 days after receipt of the request by an applicable party in connection with a potential property sale. The property shall be appraised before a foreclosure sale and have an effective appraisal date that is no more than 30 days before such sale. The appraisal shall be at the requesting party's expense unless the mortgage is due and payable. If the mortgage is due and payable, the appraisal shall be at the mortgagee's expense but the mortgagee shall have a right to be reimbursed out of the proceeds of any sale by the borrower or other permissible party. The Commissioner may, through **Federal Register** notice, identify other acceptable types of valuation for establishing the value of HECMs for the purpose of sale.

(c) *Sale by borrower or other permissible party.* Where the HECM is not due and payable, the borrower or an authorized representative of the borrower may sell the property for at least the lesser of the outstanding loan balance or the appraised value. Where the HECM is due and payable at the

time the contract for sale is executed, the borrower or other party with legal right to dispose of the property may sell the property in accordance with the amount established by § 206.125(a)(2)(ii). The mortgagee shall satisfy the mortgage of record (and the Commissioner will satisfy any second mortgage required by the Commissioner under § 206.27(d) of record) in order to facilitate the sale, provided that there are no junior liens (except the mortgage to secure payments by the Commissioner if required under § 206.27(d)) and all the net proceeds from the sale are paid to the mortgagee.

(d) *Initiation of foreclosure.* (1) The mortgagee shall commence foreclosure of the mortgage within six months of the due date defined in § 206.129(d)(1), or within such additional time as may be approved by the Commissioner.

(2) If the laws of the State, city, or municipality or other political subdivision in which the mortgaged property is located or if Federal bankruptcy law does not permit the commencement of the foreclosure in accordance with § 206.125(d)(1), the mortgagee shall commence foreclosure within six months after the expiration of the time during which such foreclosure is prohibited by such laws.

(3) The mortgagee shall give written notice to the Commissioner within 30 days after the initiation of foreclosure proceedings, and shall exercise reasonable diligence in prosecuting the foreclosure proceedings to completion and in acquiring title to and possession of the property. A time frame that is determined by the Commissioner to constitute "reasonable diligence" for each State is made available to mortgagees.

(4) The mortgagee shall bid at the foreclosure sale an amount at least equal to the lesser of the sum of the outstanding loan balance and any and all other incurred expenses, or the current appraised value of the property. Such a bid by any party other than the mortgagee, for the full loan balance and all associated expenses, will result in a full payoff of the loan and no claim for insurance benefits being presented to FHA.

(e) *Other bidders at foreclosure sale.* If a party other than the mortgagee is the successful bidder at the foreclosure sale, the net proceeds of the sale shall be applied to the outstanding loan balance.

(f) *Deed in lieu of foreclosure.* (1)(i) In order to avoid delays and additional expense as a result of instituting and completing a foreclosure action, the mortgagee shall accept a deed in lieu of foreclosure from the borrower or other party with legal right to dispose of the

property provided it is filed for recording within 9 months of the due date and the mortgagee is able to obtain good and marketable title.

(ii) *Cash for Keys*. The Commissioner may provide a financial incentive, in an amount to be determined by the Commissioner, to be paid by the mortgagee and reimbursed through any subsequent claim where a borrower or other party with a legal right to do so deeds the property within 6 months of the due date.

(2) In exchange for the executed and delivered deed, the mortgagee shall cancel the credit instrument and deliver it to the borrower and satisfy the mortgage of record. If applicable, the mortgagee shall request that the Commissioner cancel the credit instrument and deliver it to the borrower and satisfy the mortgage of record.

(g) *Sale of the acquired property*. (1) Upon acquisition of the property by foreclosure or deed in lieu of foreclosure, the mortgagee shall take possession of, preserve, and repair the property and shall make diligent efforts to sell the property within six months from the date the mortgagee acquired the property, or such additional time as provided by the Commissioner. The mortgagee shall sell the property for an amount not less than the appraised value (as provided under paragraph (b) of this section) unless the mortgagee does not file an application for insurance benefits or written permission is obtained from the Commissioner authorizing a sale at a lower price.

(2) Repairs shall not exceed those required by local law, or the requirements of the Commissioner or the Secretary of Veterans Affairs if the sale of the property is financed with a mortgage insured by the Commissioner or guaranteed, insured, or taken by the Secretary of Veterans Affairs. No other repairs shall be made without the specific advance approval of the Commissioner.

(3) The mortgagee shall not enter into a contract for the preservation, repair, or sale of the property with any officer, employee, or owner of ten percent or more interest in the mortgagee or with any other person or organization having an identity of interest with the mortgagee or with any relative of such officer, employee, owner, or person.

(4) The Commissioner may provide financial incentive, in an amount to be determined by the Commissioner, to be paid by the mortgagee and reimbursed through a subsequent claim when a bona fide tenant vacates the property prior to an eviction being initiated by the mortgagee.

§ 206.127 Application for insurance benefits.

(a) *Mortgagee acquires title*. (1) The mortgagee shall apply for the payment of the insurance benefits within 30 days after the sale of the property by the mortgagee or within such additional time as approved by the Commissioner. Application shall be made by notifying the Commissioner of the sale of the property, the sale price, and income and expenses incurred in connection with the acquisition, repair, and sale of the property.

(2) If the property will not be sold within six months from the foreclosure sale date where the mortgagee is the successful bidder, the mortgagee shall apply for the insurance benefit not later than 30 days after the end of the six-month period, substituting the appraised value, using a valid appraisal, for the sale price. The mortgagee may add the cost of the appraisal to the claim amount.

(b) *Party other than the mortgagee acquires title*. The mortgagee shall apply for the payment of the insurance benefits within 30 days after a party other than the mortgagee acquires title to the property. Application shall be made by notifying the Commissioner of the sale of the property and the sale price. Transferring a portfolio that includes REO properties to another entity does not constitute a "sale" under this section.

(c) *Mortgagee assigns the mortgage*. The mortgagee shall file its claim for the payment of insurance benefits within 15 days after the date the assignment of the mortgage to the Commissioner is filed for recording. The application for the payment of the insurance benefits shall include the items listed in § 206.135(a) and the certification required under § 206.136.

(d) *Contract of insurance not terminated*. Mortgagees may only file an application for insurance benefits provided the contract of insurance has not terminated.

§ 206.129 Payment of claim.

(a) *General*. If the claim for the payment of the insurance benefits is acceptable to the Commissioner, payment shall be made in cash in the amount determined under this section.

(b) *Limit on claim amount*. (1) For HECMs assigned Case Numbers prior to September 19, 2017, in no case may the claim paid under this subpart exceed the maximum claim amount. The interest allowance provided in paragraphs (d)(3)(x), (e)(2), and (f)(2)(i) of this section shall not be included in determining the limit on the claim amount.

(2) For HECMs assigned Case Numbers on or after September 19, 2017, in no case may the claim paid under this subpart exceed the maximum claim amount, as defined in § 206.3. The interest allowance provided in paragraphs (d)(3)(x), (e)(2) and (f)(2)(ii) of this section shall be made in cash in the amount determined under this section and shall be included in determining the limit on the claim amount.

(c) *Shared appreciation mortgages*. The terms *loan balance* and *accrued interest* as used in this section do not include interest attributable to the mortgagee's share of the appreciated value of the property.

(d) *Amount of payment—mortgagee acquires title or is unsuccessful bidder*. This paragraph describes the amount of payment if the mortgagee acquires title by purchase, foreclosure, or deed in lieu of foreclosure, or when a party other than the mortgagee is the successful bidder at the foreclosure sale.

(1) *Due and payable date* means the date when the mortgagee notifies or should have notified the Commissioner that the mortgage is due and payable under the conditions stated in the mortgage, as required by § 206.27(c)(1) or the date that the Deferral Period, as provided for in the mortgage by § 206.27(c)(3), ends; or the date the Commissioner approved a due and payable request as provided for in the mortgage by § 206.27(c)(2).

(2) The amount of the claim shall be computed by:

(i) Totaling the outstanding loan balance and any accrued interest and servicing fees which have not been added to the outstanding loan balance as of the due and payable date, and allowances for items set forth in paragraph (d)(3) of this section; and

(ii) Subtracting from that total the amount for which the property was sold (or the appraised value determined under § 206.127(a)(2)) and the items set forth in paragraph (d)(4) of this section.

(3) The claim shall include items listed in paragraphs (d)(3)(i) through (xiv) of this section. For HECMs with Case Numbers assigned on or after September 19, 2017, the inclusion of items listed in paragraphs (d)(3)(i), (ii), and (iii) of this section shall be limited to two-thirds of advances made by the mortgagee on such expenses.

(i) Taxes, ground rents, water rates, and utility charges that are liens prior to the mortgage;

(ii) Special assessments, which are noted on the application for insurance or which become liens after the insurance of the mortgage;

(iii) Hazard and flood insurance premiums on the mortgaged property not in excess of a *reasonable rate*;

(A) For purposes of this section, *reasonable rate* means a rate that is not in excess of the rate or advisory rate set by the principal State-licensed rating organization for essential property insurance in the voluntary market, or if coverage is available under a FAIR Plan, the FAIR Plan rate;

(B) If a State has neither a FAIR Plan nor a State-licensed rating organization for essential property insurance in the voluntary market, the mortgagee must provide to the Home Ownership Center (HOC) having jurisdiction, information concerning the lowest rates available from an insurer for the types of coverage involved, with a request for a determination of whether the rate is reasonable. FHA will determine the rate to be reasonable if it approximates the rate assessed for comparable insurance coverage applicable to similarly situated properties in a State that offers a FAIR Plan or maintains a State-licensed rating organization;

(iv) Taxes imposed upon any deeds or other instruments by which said property was acquired by the mortgagee pursuant to § 206.125;

(v) Reasonable payments made by the mortgagee, with the approval of the Commissioner, for the purpose of protecting, operating, or preserving the property, or removing debris from the property;

(vi) Reasonable costs for performing property inspections required by § 206.140 and to determine if the property is vacant or abandoned are considered to be costs of protecting, operating or preserving the property;

(vii) Charges for the administration, operation, maintenance, or repair of community-owned property or the maintenance or repair of the mortgaged property, paid by the mortgagee for the purpose of discharging an obligation arising out of a covenant filed for record prior to the issuance of the mortgage; and charges for the repair or maintenance of the mortgaged property required by, and in an amount approved by, the Commissioner under § 206.142;

(viii) Reasonable costs of the title search ordered by the mortgagee, in accordance with procedures prescribed by FHA, to determine if the criteria for approval of the mortgagee's acceptance of a deed in lieu of foreclosure or to determine clear title to complete a pre-foreclosure sale;

(ix) Foreclosure costs or costs of acquiring the property in accordance with such conditions as the Commissioner shall prescribe;

(x) An amount equal to the interest allowance which would have been earned, from the due and payable date to the date when payment of the claim is made, if the claim had been paid in debentures, except that when the mortgagee fails to meet any one of the applicable requirements of §§ 206.125 and 206.127 of this subpart within the specified time, and in a manner satisfactory to the Commissioner (or within such further time as the Commissioner may approve in writing), the interest allowance in such cash payment shall be computed only to the date on which the particular required action should have been taken or to which it was extended.

(A) *Debenture interest rate.* The debenture interest rate provided for in § 206.146 shall be used.

(B) *Maturity of debentures.* Debentures shall mature 20 years from the date of issue.

(C) *Registration of debentures.* Debentures shall be registered as to principal and interest.

(D) *Form and amounts of debentures.* Debentures issued under this part shall be in such form and amounts; and shall be subject to such terms and conditions; and shall include such provisions for redemption, if any, as may be prescribed by the Commissioner, with the approval of the Secretary of the Treasury; and may be in book entry or certificated registered form, or such other form as the Commissioner by regulation may prescribe.

(E) *Redemption of debentures.* Debentures shall, at the option of the Commissioner and with the approval of the Secretary of the Treasury, be redeemable at par plus accrued interest on any semiannual interest payment date on three months' notice of redemption given in such manner as the Commissioner shall prescribe. The debenture interest on the debentures called for redemption shall cease on the semiannual interest payment date designated in the call notice. The Commissioner may include with the notice of redemption an offer to purchase the debentures at par plus accrued interest at any time during the period between the notice of redemption and the redemption date. If the debentures are purchased by the Commissioner after such call and prior to the named redemption date, the debenture interest shall cease on the date of purchase.

(F) *Issue date of debentures.* The issue date of debentures is determined by the due and payable date as defined in paragraph (d)(1) of this section.

(G) *Cash adjustment.* Any difference of less than \$50 between the amount of

debentures to be issued to the mortgagee and the total amount of the mortgagee's claim, as approved by the Commissioner, may be adjusted by the issuance of a check in payment thereof;

(xi) Any amount of incentive paid by the mortgagee in accordance with § 206.125(f)(1)(ii) or § 206.125(g)(4);

(xii) Costs of any appraisal under §§ 206.125 or 206.127, provided that the property was appraised after the mortgage became due and payable and that the mortgagee is not otherwise reimbursed for such costs;

(xiii) Reasonable payments made by the mortgagee for:

(A) Preservation and maintenance of the property;

(B) Repairs necessary to meet the objectives of the property standards required for mortgages insured by the Commissioner, those required by local law, and such additional repairs as may be specifically approved in advance by the Commissioner; and

(C) Expenses in connection with the sale of the property including a sales commission at the rate customarily paid in the community and, if the sale to the buyer involves a mortgage insured by the Commissioner or guaranteed by the Secretary of Veterans Affairs, a discount at a rate not to exceed the maximum allowable by the Commissioner, as of the date of execution of the discounted loan. Closing costs shall not exceed the greater of: 11 percent of the sales price; or a fixed dollar amount as determined by the Commissioner through **Federal Register** notice; and

(xiv) A certification that the property is undamaged in accordance with § 206.143.

(4) There shall be deducted from the amount computed in paragraph (d)(2)(i) of this section:

(i) The items listed in § 206.145; and

(ii) Any adjustment for damage or neglect to the property pursuant to §§ 206.140, 206.141, and 206.142.

(e) *Amount of payment—assigned mortgages.* This paragraph describes the amount of payment if the mortgagee assigns a mortgage to the Commissioner under § 206.107(a)(1) or § 206.121(b).

(1) When a mortgagee assigns a mortgage which is eligible for assignment under § 206.107(a)(1), the amount of payment shall be computed by subtracting from the outstanding loan balance on the date of assignment all cash retained by the mortgagee, including amounts held or deposited for the account of the borrower or to which it is entitled under the mortgage transaction that have not been applied in reduction of the principal mortgage indebtedness, and any adjustments for damage or neglect to the property

pursuant to §§ 206.140, 206.141 and 206.142.

(2) The claim shall also include:

(i) Reimbursement for such costs and attorney's fees as the Commissioner finds were properly incurred in connection with the assignment of the mortgage to the Commissioner; and

(ii) An amount equivalent to the interest allowance which will have been earned from the date the mortgage was assigned to the Commissioner to the date the claim is paid, if the claim had been paid in debentures, except that if the mortgagee fails to meet any of the requirements of § 206.127(c), or § 206.131 if applicable, within the specified time and in a manner satisfactory to the Commissioner (or within such further time as the Commissioner may approve in writing), the interest allowance in the payment of the claim shall be computed only to the date on which the particular required action should have been taken or to which it was extended. The provisions of paragraphs (d)(3)(x)(A)-(G) of this section pertaining to debentures are applicable except that the issue date of the debentures shall be the date the mortgage was assigned to the Commissioner.

(3) When a mortgagee assigns a mortgage under § 206.121(b) after demand by the Commissioner, the mortgagee will not receive the entire claim payment as contained in paragraphs (e)(1) and (2) of this section. The amount of the claim shall be computed by totaling the payments made by the mortgagee to the borrower or for the benefit of the borrower, and subtracting from the total the cash retained by the mortgagee, including amounts held or deposited for the account of the borrower or to which it is entitled under the mortgage transaction that have not been applied in reduction of the principal mortgage indebtedness, and any adjustments for damage or neglect to the property pursuant to §§ 206.141 and 206.142. The claim shall also be reduced by an amount determined by the Commissioner to reimburse the Commissioner for administrative expenses incurred in assuming the mortgagee's responsibility under the mortgage, which may include expenses for staff time. If more than one mortgage is assigned to the Commissioner, the administrative expenses incurred for all the mortgages assigned shall be allocated among the mortgages as determined by the Commissioner. The claim shall not include accrued interest whether or not it has been included in the loan balance.

(f) *Amount of payment-borrower sells the property.* This paragraph describes the amount of payment if the property is sold in accordance with § 206.125(c) to one other than the mortgagee for less than the outstanding loan balance, and the mortgagee releases the mortgage to facilitate the sale.

(1)(i) *For HECMs assigned Case Numbers prior to September 19, 2017,* the amount of the claim shall be computed by totaling the outstanding loan balance and any accrued interest and servicing fees which have not been added to the outstanding loan balance on the date the deed is recorded, and an allowance for items set forth in paragraphs (d)(3)(i)–(vii) and (d)(3)(xii) of this section, and subtracting from the total the amount for which the property was sold.

(ii) *For HECMs assigned Case Numbers on or after September 19, 2017, the following provisions apply:*

(A) *When the loan is not in due and payable status.* The amount of the claim shall be computed by totaling the outstanding loan balance and any accrued interest and servicing fees which have not been added to the outstanding loan balance on the date the deed is recorded, and an allowance for items set forth in paragraph (d)(3)(xiii)(C) of this section, and subtracting from the total the amount for which the property was sold.

(B) *When the loan is in due and payable status.* The amount of the claim shall be computed by totaling the outstanding loan balance and any accrued interest and servicing fees which have not been added to the outstanding loan balance as of the due date, the items set forth in paragraph (d)(3) of this section, and subtracting from the total the amount for which the property was sold.

(2)(i) *For HECMs assigned Case Numbers prior to September 19, 2017,* the claim shall also include an amount equivalent to the interest allowance which would have been earned from the date the deed is recorded to the date when payment of the claim is made, if the claim had been paid in debentures, and in a manner satisfactory to the Commissioner; the interest allowance in such cash payment shall be computed only to the date on which the particular action should have been taken or to which it was extended. The provisions of paragraphs (d)(3)(x)(A)-(G) of this section pertaining to debentures apply except that the issue date of the debentures is the date the deed is recorded instead of the due date.

(ii) *For HECMs assigned Case Numbers on or after September 19, 2017, the following provisions apply:*

(A) *When the loan is not in due and payable status.* The claim shall also include an amount equivalent to the interest allowance which would have been earned from the date the deed is recorded to the date when payment of the claim is made, if the claim had been paid in debentures, and in a manner satisfactory to the Commissioner; the interest allowance in such cash payment shall be computed only to the date on which the particular action should have been taken or to which it was extended. The provisions of paragraphs (d)(3)(x)(A)-(G) of this section pertaining to debentures apply except that the issue date of the debentures shall be the date the deed is recorded.

(B) *When the loan is in due and payable status.* The claim shall also include an amount equivalent to the interest allowance which would have been earned from the due and payable date to the date when payment of the claim is made, if the claim had been paid in debentures, except that when the mortgagee fails to meet any of the applicable requirements of §§ 206.125 and 206.127 within the specified time determined by the due and payable date, as defined in paragraph (d)(1) of this section (or within such further time as the Commissioner may approve in writing), and in a manner satisfactory to the Commissioner; the interest allowance in such cash payment shall be computed only to the date on which the particular action should have been taken or to which it was extended. The provisions of paragraphs (d)(3)(x)(A)-(G) of this section pertaining to debentures apply.

Condominiums

§ 206.131 Contract rights and obligations for mortgages on individual dwelling units in a condominium.

(a) *Additional requirements.* The requirements of this subpart shall be applicable to mortgages on individual dwelling units in a condominium, except as modified by this section.

(b) *References.* The term *property* as used in this subpart shall be construed to include the individual dwelling unit and the undivided interest in the common areas and facilities as may be designated.

(c) *Assignment of the mortgage.* If the mortgagee assigns the mortgage on the individual dwelling unit to the Commissioner, the mortgagee shall certify:

(1) To any changes in the plan of apartment ownership including the administration of the property;

(2) That as of the date the assignment is filed for record, the family unit is

assessed and subject to assessment for taxes pertaining only to that unit; and

(3) To the condition of the property as of the date the assignment is filed for record. Section 234.275 of this chapter concerning the certification of condition is incorporated by reference.

(d) *Condition of the multifamily structure.* The provisions of § 234.270 (a) and (b) of this chapter concerning the condition of the multifamily structure in which the property is located shall be applicable to mortgages insured under this part which are assigned to the Commissioner.

Termination of Insurance Contract

§ 206.133 Termination of insurance contract.

(a) *Payment of the mortgage.* The contract of insurance shall be terminated if the mortgage is paid in full.

(b) *Acquisition of title.* (1) If the mortgagee or a party other than the mortgagee acquires title at a foreclosure sale, or the mortgagee acquires title by a deed in lieu of foreclosure, and the mortgagee notifies the Commissioner that a claim for the payment of the insurance benefits will not be presented, the contract of insurance shall be terminated.

(2) For HECMs with Case Numbers assigned on or after September 19, 2017, if the mortgagee or a party other than the mortgagee acquires title at a foreclosure sale or the mortgagee acquires title by a deed in lieu of foreclosure and a claim for the payment of the insurance benefits will be presented, the contract of insurance shall be terminated as of claim payment.

(c) *Mortgagee fails to make payments.* If the mortgagee fails to make the payments to the borrower as required under the mortgage, and does not reimburse the Commissioner or assign the mortgage to the Commissioner within 30 days from the demand by the Commissioner for reimbursement or assignment, the contract of insurance shall automatically terminate. The Commissioner may later reinstate the contract of insurance, which shall continue in force as if no termination had occurred, upon reimbursement with interest as provided in § 206.121. Upon reinstatement, the mortgagee shall be liable for all MIP which would have been due if no termination had occurred, including late charge and interest as provided in § 206.113.

(d) *Notice of termination.* The mortgagee shall give written notice to the Commissioner, or other notice acceptable to the Commissioner, within 15 days of the occurrence of an event

under paragraphs (a) and (b) of this section. No contract of insurance shall be terminated under paragraphs (a) or (b) of this section unless such notice is given.

(e) *Voluntary termination.* The mortgagor and the mortgagee may jointly request the Commissioner to approve the voluntary termination of the mortgage insurance contract. Prior to approval, the Commissioner shall make certain that the borrower is aware of the consequences which could arise out of the voluntary termination of the contract of insurance. The mortgagee shall cancel the insurance endorsement on the Mortgage Insurance Certificate or Note upon receipt of notice from the Commissioner that the contract of insurance is terminated. Notwithstanding any provision in a mortgage instrument, there shall be no voluntary termination charge due the Commissioner on account of the voluntary termination of any mortgage insurance contract where the request for termination is received by the Commissioner.

(f) *Effect of termination.* When the insurance contract is terminated, all rights of the mortgagee shall terminate, including the right to file a claim for insurance benefits. All obligations of the Commissioner shall also cease immediately.

Additional Requirements

§ 206.134 Partial release, addition or substitution of security.

(a) A mortgagee shall not release the security or any part thereof, while the mortgage is insured, without the prior consent of the Commissioner.

(b) A mortgagee may, with the prior consent of the Commissioner, accept an addition to, or substitution of, security for the purpose of removing the dwelling to a new lot or replacing the dwelling with a similar or like kind on the existing lot under the following conditions:

(1) The mortgagee obtains a good and valid first lien on the property to which the dwelling is removed or the existing lot upon which the dwelling is rebuilt;

(2) All damages to the structure are repaired or all rebuilding of the structure is completed without cost to FHA; and

(3) The property to which the dwelling is removed or rebuilt is in an area known to be reasonably free from natural hazards or, if in a flood zone, the borrower will insure or reinsure under the National Flood Insurance Program.

(c) A mortgagee may, without the prior consent of the Commissioner, accept an addition to, or substitution of,

security for the purpose of removing the dwelling to a new lot under the following conditions:

(1) The dwelling has survived an earthquake or other disaster with little damage, but continued location on the property might be hazardous;

(2) The conditions stated in paragraph (b) of this section exist; and

(3) Immediately following the emergency removal the mortgagee notifies the Commissioner of the reasons for removal.

§ 206.135 Application for insurance benefits and fiscal data.

(a) On the date the application for assignment is filed, the mortgagee shall submit to the Commissioner:

(1) *Credit and security instrument.* The original credit and security instruments assigned without recourse or warranty, except that no act or omission of the mortgagee shall have impaired the validity and priority of the mortgage.

(2) *Proposed assignment instrument.* A copy of the proposed assignment of mortgage.

(3) *Hazard and flood insurance.* All hazard and flood insurance (if applicable) policies held in connection with the mortgaged property, together with a copy of the mortgagee's notification to the carrier authorizing the amendment of the loss payable clause substituting the Commissioner as the mortgagee.

(4) *Rights and interests.* An assignment of all rights and interests arising under the mortgage, and all claims of the mortgagee against the borrower or others arising out of the mortgage transaction.

(5) *Property.* All property of the borrower held by the mortgagee or to which it is entitled (other than the cash items which are to be retained by the mortgagee).

(6) *Records and accounts.* All records, ledger cards, documents, books, papers and accounts relating to the mortgage transaction.

(7) *Additional information.* Any additional information or data which the Commissioner may require.

(8) *Title evidence.* All title evidence held by the mortgagee. It need not be extended to include the recordation of the assignment. The title insurance policy shall be endorsed from the mortgage insurance company up to the point of assignment. At the point of assignment, the Commissioner shall be named insured under such policy.

(b) All documents required in paragraph (a) of this section must be submitted and approved before a claim for assignment may be submitted.

(c) *Recorded assignment instrument.* The original of the recorded assignment of mortgage shall be forwarded to the Commissioner as soon as received by the mortgagee, but in no case shall it be longer than 12 months after recordation. If the original of the assignment is not available, a copy shall be furnished and the original forwarded as soon as possible.

§ 206.136 Conditions for assignment.

(a) In order for a HECM to be eligible for assignment, the following must be met:

(1) *Priority of mortgage to liens.* The mortgage is prior to all mechanics' and materialmen's liens, regardless of when such liens attach, and prior to all liens and encumbrances, or defects which may arise based on any act or omission by the mortgagee except such liens or other matters as may have been approved by the Commissioner.

(2) *Amount due.* The amount stated in the instrument of assignment is actually due and owing under the mortgage.

(3) *Offsets or counterclaims.* There are no offsets or counterclaims thereto and the mortgagee has a good right to assign.

(b) The mortgagee shall certify that the conditions of paragraph (a) have been met.

§ 206.137 Effect of noncompliance with regulations.

If, for any reason, the mortgagee fails to comply with the regulations in this subpart, the Commissioner may hold processing of the application for insurance benefits in abeyance for a reasonable time in order to permit the mortgagee to comply. In the alternative to holding processing in abeyance, the Commissioner may reconvey title to the property or reassign the mortgage to the mortgagee, in which event the application for insurance benefits shall be considered as cancelled and the mortgagee shall refund the insurance benefits to the Commissioner as well as other funds required by § 206.138. The mortgagee may reapply for insurance benefits at a subsequent date; provided, however, that the mortgagee may not be reimbursed for any expenses incurred in connection with the property after it has been reconveyed or the mortgage reassigned by the Commissioner, or paid any debenture interest accrued after the date of initial conveyance, whichever is earlier, and there will be deducted from the insurance benefits any reduction in the Commissioner's estimate of the value of the property occurring from the time of reconveyance or mortgage reassignment to the time of reapplication.

§ 206.138 Mortgagee's liability for certain expenditures.

Where the Commissioner accepts an assignment, acquires a property after accepting an assignment of a mortgage, or otherwise pays a claim for insurance benefits and thereafter it becomes necessary for the Commissioner to either reconvey the property or reassign the mortgage to the mortgagee due to the mortgagee's noncompliance with these regulations, the mortgagee shall reimburse the Commissioner for all expenses incurred in connection with such acquisition and reconveyance or reassignment. The reimbursement shall include interest on the amount of insurance benefits refunded by the mortgagee from the date the insurance benefits were paid to the date of refund at an interest rate set in conformity with the Treasury Fiscal Requirements Manual, and the Commissioner's cost of holding the property or servicing the mortgage, accruing on a daily basis, from the date of assignment or claim payment to the date of reconveyance or reassignment. These costs are based on the Commissioner's estimate of the taxes, maintenance and operating expenses of the property, and administrative expenses. Appropriate adjustments shall be made by the Commissioner on account of any income received from the property.

§ 206.140 Inspection and preservation of properties.

The mortgagee, upon learning that a property subject to a mortgage insured under this part is vacant or abandoned, shall be responsible for the inspection of such property at least monthly, if the loan is in a due and payable status. When a mortgage is in due and payable status and efforts to reach the borrower or applicable party by telephone within that period have been unsuccessful, the mortgagee shall be responsible for a visual inspection of the security property to determine whether the property is vacant. The mortgagee shall take reasonable action to protect and preserve such security property when it is determined or should have been determined to be vacant or abandoned until assigned to the Commissioner or an application for insurance benefits is filed, if such action does not constitute an illegal trespass. "Reasonable action" includes the commencement of foreclosure within the time required by § 206.125.

§ 206.141 Property condition.

(a) *Condition at time of transfer.* When the mortgage is assigned to the Commissioner or the property is sold by the mortgagee, the property shall be

undamaged by fire, earthquake, flood, or tornado, except as set forth in this subpart.

(b) *Damage to property by waste.* The mortgagee shall not be liable for damage to the property by waste committed by the borrower, its heirs, successors or assigns in connection with mortgage insurance claims.

(c) *Mortgagee responsibility.* The mortgagee shall be responsible for:

(1) Damage by fire, flood, earthquake, hurricane, or tornado; and

(2) Damage to or destruction of security properties on which the loans are in default and which properties are vacant or abandoned, when such damage or destruction is due to the mortgagee's failure to take reasonable action to inspect, protect and preserve such properties as required by § 206.140.

(d) *Limitation.* The mortgagee's responsibility for property damage shall not exceed the amount of its insurance claim as to a particular property.

§ 206.142 Adjustment for damage or neglect.

(a) Except as provided for in paragraphs (a)(1) and (a)(2) of this section: if the property has been damaged by fire, flood, earthquake, hurricane, or tornado, the damage must be repaired before assignment of the mortgage to the Commissioner; if the property has suffered damage because of the mortgagee's failure to take action as required by § 206.140, the damage must be repaired before the mortgagee sells the property.

(1) If the prior approval of the Commissioner is obtained, there will be deducted from the insurance benefits the Commissioner's estimate of the cost of repairing the damage or any insurance recovery received by the mortgagee, whichever is greater.

(2) If the property has been damaged by fire and was not covered by fire insurance at the time of the damage, or the amount of insurance coverage was inadequate to repair fully the damage, only the amount of insurance recovery received by the mortgagee, if any, will be deducted from the insurance benefits, provided the mortgagee certifies, at the time that a claim is filed for insurance benefits, that:

(i) At the time the mortgage was insured, the property was covered by fire insurance in an amount at least equal to the lesser of 100 percent of the insurable value of the improvements, or the principal loan balance of the mortgage;

(ii) The insurer later cancelled this coverage or refused to renew it for

reasons other than nonpayment of premium;

(iii) The mortgagee made diligent though unsuccessful efforts within 30 days of any cancellation or non-renewal of hazard insurance, and at least annually thereafter, to secure other coverage or coverage under a FAIR Plan, in an amount described in paragraph (a)(2)(i) of this section, or if coverage to such an extent was unavailable at a reasonable rate, the greatest extent of coverage that was available at a reasonable rate;

(iv) The extent of coverage obtained by the mortgagee in accordance with paragraph (a)(2)(iii) of this section was the greatest available at a reasonable rate, or if the mortgagee was unable to obtain insurance, none was available at a reasonable rate; and

(v) The mortgagee took the actions required by § 206.140.

(b) If the property has been damaged during the time of the mortgagee's possession by events other than fire, flood, earthquake, hurricane, or tornado, or if it was damaged notwithstanding reasonable action by the mortgagee as required by § 206.140, the mortgagee must provide notice of such damage to the Commissioner and may not sell the property until directed to do so by the Commissioner. The Commissioner will either:

(1) Allow the mortgagee to sell the property damaged; or

(2) Require the mortgagee to repair the damage before sale, and the Commissioner will reimburse the mortgagee for reasonable payments not in excess of the Commissioner's estimate of the cost of repair, less any insurance recovery.

§ 206.143 Certificate of property condition.

(a) The mortgagee shall certify that as of the date the mortgagee sold the property in accordance with § 206.125(g) or assignment of the mortgage to the Commissioner, the property was:

(1) Undamaged by fire, flood, earthquake, hurricane or tornado; and

(2) Undamaged due to failure of the mortgagee to take action as required by § 206.140; and

(3) Undamaged while the property was in the possession of the mortgagee.

(b) In the absence of evidence to the contrary, the mortgagee's certificate or description of the damage shall be accepted by the Commissioner as establishing the condition of the property, as of the date of mortgage sale or assignment of the mortgage to the Commissioner.

§ 206.144 Final payment.

The mortgagee may not file any supplemental claims to its mortgage insurance claim after six months from settlement by the Commissioner of the claim payment except where the Commissioner determines it appropriate and expressly authorizes an extension of time for supplemental claim filings.

§ 206.145 Items deducted from payment.

(a) There shall be deducted from the total of the added items in § 206.129 the following cash items:

(1) All amounts received by the mortgagee on account of the mortgage after the institution of foreclosure proceedings or the acquisition of the property or otherwise after due and payable.

(2) All amounts received by the mortgagee from any source relating to the property on account of rent or other income after deducting reasonable expenses incurred in handling the property.

(3) All cash retained by the mortgagee including amounts held or deposited for the account of the borrower or to which it is entitled under the mortgage transaction that have not been applied in reduction of the outstanding loan balance.

(4) With regard to claims filed pursuant to successful short sales, all amounts received by the mortgagee relating to the sale of the property.

(b) [Reserved]

§ 206.146 Debenture interest rate.

(a) Debentures shall bear interest from the date of issue, payable semiannually on the first day of January and the first day of July of each year at the rate in effect as of the day the commitment was issued, or as of the date the mortgage was endorsed for insurance, whichever rate is higher. For applications involving mortgages originated under the single family Direct Endorsement program, debentures shall bear interest from the date of issue, payable semiannually on the first day of January and on the first day of July of each year at the rate in effect as of the date the mortgage was endorsed for insurance;

(b) For mortgages endorsed for insurance after January 23, 2004, if an insurance claim is paid in cash, the debenture interest rate for purposes of calculating such a claim shall be the monthly average yield, for the month in which the default on the mortgage occurred, on United States Treasury Securities adjusted to a constant maturity of 10 years.

Subpart D—Servicing Responsibilities

§ 206.201 Mortgage servicing generally; sanctions.

(a) *General.* This subpart identifies servicing practices that the Commissioner considers acceptable mortgage servicing practices of lending institutions servicing mortgages insured by the Commissioner. Failure to comply with this subpart shall not be a basis for denial of the insurance benefits, but a pattern of refusal or failure to comply will be cause for withdrawal of FHA mortgagee approval.

(b) *Importance of timely payments.* The paramount servicing responsibility is to make timely payments in full as required by the mortgage. Any failure of a mortgagee to make all payments required by the mortgage in a timely manner will be grounds for administrative sanctions authorized by regulations, including 2 CFR part 2424 (Debarment, Suspension, and Limited Denial of Participation), and 24 CFR part 25 (Mortgagee Review Board).

(c) *Responsibility for servicing.* (1) Servicing of insured mortgages must be performed by a mortgagee that is approved by FHA to service insured mortgages. The servicer must fully discharge the servicing responsibilities of the mortgagee as outlined in this part. The mortgagee shall remain fully responsible to the Commissioner for proper servicing, and the actions of its servicer shall be considered to be the actions of the mortgagee. The servicer also shall be fully responsible to the Commissioner for its actions as a servicer.

(2) Whenever servicing of any mortgage is transferred from one mortgagee or servicer to another, notice of the transfer of service shall be delivered:

(i) By the transferor mortgagee or servicer to the borrower. The notification shall be delivered not less than 15 days before the effective date of the transfer and shall contain the information required in 12 CFR 1024.33(b)(4); and

(ii) By the transferee mortgagee or servicer:

(A) *To the borrower.* The notification shall be delivered not less than 15 days before the effective date of the transfer and shall contain the information required in 12 CFR 1024.33(b)(4); and

(B) *To the Commissioner.* This notification shall be delivered within 15 days of the transfer, in a format prescribed by the Commissioner.

§ 206.203 Providing information.

(a) *Statements of account activity.* The mortgagee shall provide to the borrower

a monthly statement regarding the activity of the mortgage for each month, as well as for the calendar year. The statement shall summarize the total principal amount which has been paid to the borrower under the mortgage during that calendar year, the MIP paid to the Commissioner and charged to the borrower, the total amount of deferred interest added to the outstanding loan balance, the total outstanding loan balance, and the current principal limit. The mortgagee shall include an accounting of all payments for property charges. The statement shall be provided to the borrower monthly until the mortgage is paid in full by the borrower. The mortgagee shall provide the borrower with a new payment plan every time it recalculates monthly payments or the payment option is changed. The statements shall be in a format acceptable to the Commissioner.

(b) [Reserved]

(c) *Servicing—Providing information.*

(1) Mortgagees shall provide loan information to borrowers and arrange for individual loan consultation on request. The mortgagee must establish written procedures and controls to assure prompt responses to inquiries. One or more of the following means of making information readily available to borrowers is required:

(i) A servicing office staffed with competent personnel located within 200 miles of the property, capable of providing timely responses to requests for information. Complete records need not be maintained in such an office if the staff is able to secure needed information and pass it on to the borrower.

(ii) Toll-free telephone service at an office capable of providing needed information.

(2)(i) All borrowers must be informed of and reminded annually of the system available for obtaining answers to loan inquiries and the office from which needed information may be obtained. Toll-free telephone service need not be provided to a borrower other than at the office designated to serve the borrower nor other than from the immediate vicinity of the security property.

(ii) The mortgagee shall provide the borrower with the telephone number where the borrower may speak to employee(s) specifically designated by the mortgagee or its servicer to address inquiries concerning mortgages insured under this part. Such information shall be provided annually and whenever the servicer or the designated employee (or employee group) changes.

(3) Mortgagees must respond to FHA requests for information concerning individual accounts.

§ 206.205 Property charges.

(a) *General.* (1) The borrower shall be responsible for the payment of the following property charges before or on the due date: ground rents, condominium fees, planned unit development fees, and homeowners' association fees.

(2) Payment of the following property charges are obligations of the borrower and shall be made through the LESA, by the borrower, or by the mortgagee, in accordance with paragraphs (b) through (e) of this section on or before the due date: property taxes, including any special assessments levied by local or State law, hazard insurance premiums, and applicable flood insurance premiums.

(b) *Method of property charge payment—*

(1) *LESA required.* For fixed or adjustable interest rate HECMs, based on the results of the Financial Assessment, the mortgagee may require the borrower to have a Fully-Funded LESA for the payment of property charges identified in paragraph (a)(2) of this section. For adjustable interest rate HECMs, based on the results of the Financial Assessment, the mortgagee may require the borrower to have a Partially-Funded LESA for the payment of property charges identified in paragraph (a)(2) of this section.

(2) *LESA not required.* (i) If, based on the results of the Financial Assessment, the mortgagee does not require the borrower to have a LESA, the borrower shall elect one of the following at closing, whereby an election of the option in paragraph (b)(2)(i)(B) or (C) of this section cannot be cancelled by the borrower:

(A) Borrower is responsible for the independent payment of all property charges;

(B) Borrower elects to have a Fully-Funded LESA for the payment of property charges identified in paragraph (a)(2) of this section; or

(C) For adjustable interest rate HECMs only, borrower elects to have the mortgagee pay property charges listed in paragraph (a)(2) of this section which would have otherwise been required to be paid by the borrower, in accordance with paragraph (d) of this section.

(ii) Through **Federal Register** notice, the Commissioner may establish an incentive for voluntarily electing a LESA under paragraph (b)(2)(i)(B) of this section.

(c) *Life Expectancy Set Aside—*(1) *General.* (i) For a Fully-Funded LESA, the mortgagee shall:

(A) Make payments for property charges identified in paragraph (a)(2) of this section before bills become delinquent and establish controls to

ensure that the information needed to pay such bills is obtained on a timely basis;

(B) Make early payments to take advantage of a discount whenever it is to the borrower's advantage;

(C) Not charge the borrower penalties for late payments for property charges unless it can be shown that the penalty was the direct result of the borrower's error or omission;

(D) Ensure that LESA funds are not held in an escrow account;

(E) Add payments for property charges to the outstanding loan balance when the mortgagee disburses funds to the taxing authority or insurance carrier; and

(F) Provide written notification to the borrower and FHA within 30 days of the mortgagee receiving notification that a property charge payment is outstanding when there are no funds or insufficient funds remaining in the LESA, and recommend that the borrower speak with a HUD-Approved Housing Counselor.

(ii) For a Partially-Funded LESA, the mortgagee shall:

(A) Ensure that LESA funds are disbursed to the borrower semi-annually;

(B) Establish controls to ensure the taxing authority, insurance carrier, or both, received the borrower's payment;

(C) Ensure the LESA funds are not held in an escrow account;

(D) Add payments disbursed to the borrower for the payment of property charges identified in paragraph (a)(2) to the outstanding loan balance when the mortgagee disburses the funds; and

(E) Provide written notification to the borrower and FHA within 30 days of the mortgagee receiving notification that a property charge payment is outstanding when there are no funds or insufficient funds remaining in the LESA, and recommend that the borrower speak with a HUD-Approved Housing Counselor.

(2) *Calculation of property charges.* (i) The projected cost of property charges that will be required over the life expectancy of the youngest borrower shall be calculated based on a formula established by the Commissioner.

(ii) The mortgagee shall not require any LESA to be funded in excess of the projected cost of property charges.

(iii) For a Fully-Funded LESA, the amount withheld from the mortgage proceeds shall equal the projected cost of property charges.

(iv) For a Partially-Funded LESA, the amount withheld from the mortgage proceeds is based on a calculation of the gap in residual income and may not

exceed the projected cost of property charges.

(v) Mortgagees shall use the *HECM Financial Assessment and Property Charge Guide*, or subsequent guide issued by the Commissioner, to determine whether a LESA is required; view the formula for calculating the projected costs of property charges; and view the formulas for calculating the Fully- and Partially-Funded LESA amounts.

(3) *Annual analysis of LESA.* Mortgagees shall perform an annual analysis of the LESA to determine whether the funds are sufficient to make required distributions for the next year. If funds are exhausted or there is an insufficient balance determination, the mortgagee shall notify the borrower, in writing and within 15 calendar days of the annual analysis of the determination, that LESA funds are exhausted or insufficient and the borrower will be responsible for the payment of property charges.

(4) *Non-payment of property charges*—(i) *Fully-Funded LESA for an adjustable interest rate HECM with no remaining funds.* (A) If the LESA is exhausted and the borrower fails to make property charge payments, the mortgagee shall use any available principal limit to pay the outstanding property charge amount in full and charge the borrower's account.

(B) The mortgagee shall provide the borrower with a written notification within 30 days of the mortgagee receiving notification that a property charge payment is outstanding. The borrower shall have 30 days to respond to the mortgagee to explain the circumstances which resulted in the non-payment. (C) If there is no available principal limit from which the mortgagee can pay the property charge amount in full, and the borrower fails to pay the property charges, the mortgage will become due and payable under § 206.27(c)(2).

(ii) *Fully-Funded LESA for a fixed interest rate HECM with no remaining funds.* If the LESA is exhausted and the borrower fails to make property charge payments, the mortgage will become due and payable under § 206.27(c)(2).

(iii) *Partially-Funded LESA with remaining funds.* If funds remain in the LESA and the borrower fails to make property charge payments, the mortgagee shall:

(A) Immediately suspend future semi-annual payments to the borrower from the Partially-Funded LESA, although scheduled and unscheduled payments from the borrower's payment option may continue;

(B) Disburse funds from the Partially-Funded LESA to pay the full amount owed for the past due property charge; and

(C) Provide written notification to the borrower, within 30 days of the mortgagee receiving notification that a property charge payment is outstanding, that funds were advanced from the Partially-Funded LESA to pay the outstanding property charge. The borrower shall have 30 days to respond to the mortgagee to explain the circumstances which resulted in the non-payment.

(iv) *Partially-Funded LESA with no remaining funds.* (A) If the LESA is exhausted and the borrower fails to make property charge payments when due, the mortgagee shall use any funds available in the principal limit to pay the outstanding property charge amount in full and charge the borrower's account.

(B) The mortgagee shall provide written notification to the borrower within 30 days of the mortgagee receiving notification that a property charge payment is outstanding. The borrower shall have 30 days to respond to the mortgagee to explain the circumstances which resulted in the non-payment.

(C) If there is no available principal limit from which the mortgagee can pay the property charge amount in full, and the borrower fails to pay the property charges, the mortgage will become due and payable under § 206.27(c)(2).

(5) *Unused LESA funds.* During a Deferral Period or when one of the events listed in § 206.27(c)(1) or (c)(2) have occurred, no unused funds from the LESA shall be disbursed.

(6) *Assignment of mortgage to the Commissioner.* If the insured first mortgage is assigned to the Commissioner, or if payments are made through the second mortgage under the Demand Assignment process, the Commissioner is not required to assume the responsibility for property charge payments, but may continue to administer payments for property charges for a borrower with a Fully-Funded LESA or semi-annual disbursements to a borrower with a Partially-Funded LESA to the extent that there are any funds available in the LESA. For adjustable interest rate HECMs, if the LESA has a positive remaining balance but funds are insufficient to pay all property charges due or semi-annual disbursements to the borrower, the Commissioner may provide the remaining funds to the borrower as a line of credit.

(d) *Borrower elects to have mortgagee pay property charges.* If, based on the

results of the Financial Assessment, the mortgagee does not require the borrower to have a LESA, for adjustable interest rate HECMs, the borrower may elect at closing to require the mortgagee to pay property charges identified in paragraph (a)(2) of this section by withholding funds from monthly payments due to the borrower or by charging such funds to a line of credit. This voluntary election to have funds withheld by the mortgagee to pay property charges cannot be canceled by the borrower at any time. If the sum of the outstanding loan balance and any unused set aside for repairs and servicing charges has reached the principal limit or the HECM proceeds are otherwise insufficient to pay the property charges, the borrower shall pay such property charges, even though the borrower elected payment to be made by the mortgagee. Through **Federal Register** notice, the Commissioner may expand the borrower's options for property charge payment by the mortgagee.

(1) *Assignment of mortgage to the Commissioner.* If the insured first mortgage is assigned to the Commissioner under § 206.107(a)(1) or § 206.121(b), or if payments are made through the second mortgage under § 206.121(c), the Commissioner is not required to assume the mortgagee's responsibility under paragraph (d) of this section, despite the election by the borrower.

(2) *Mortgagee's responsibilities.* (i) Funds withheld from payments due to the borrower for property charges under paragraph (d) of this section shall not be paid into an escrow account. When property charges are actually paid, the mortgagee may add the amount paid to the outstanding loan balance.

(ii) It is the mortgagee's responsibility to make disbursements for property charges before bills become delinquent. Mortgagees shall establish controls to ensure that the information needed to pay such bills is obtained on a timely basis. Penalties for late payments for property charges must not be charged to the borrower unless it can be shown that the penalty was the direct result of the borrower's error or omission. Early payment of a bill to take advantage of a discount should be made whenever it is to the borrower's benefit.

(iii) Not later than the end of the second loan year the mortgagee shall establish a system for the periodic analysis of the amounts withheld from monthly payments. The analysis shall be performed at least once a year thereafter. The amount shall be adjusted, after analysis, to provide sufficient available funds to make anticipated disbursements during the

ensuing year. The borrower shall be given at least ten days' notice of adjustment in the amount of withholding and an adequate explanation of the reasons for any change. When the amount withheld is analyzed in accordance with this paragraph, any surplus shall be paid to the borrower and added to the outstanding loan balance. Any shortage shall be corrected through increasing the monthly withholding as provided in paragraph (d)(2)(iv) of this section. If amounts withheld are insufficient to pay a property charge before it is delinquent, and the borrower could request a payment equal to the shortage under § 206.26(b), then the mortgagee shall pay the full property charge and treat payment of the shortage as a payment requested by the borrower under § 206.26(b).

(iv) The mortgagee's estimate of withholding amount shall be based on the best information available as to probable payments which will be required to be made for property charges in the coming year. If actual disbursements during the preceding year are used as the basis, the resulting estimate may deviate from those disbursements by as much as ten percent. The mortgagee may not require withholding in excess of the current estimated total annual requirement, unless expressly requested by the borrower. Each monthly withholding for property charges shall equal one-twelfth of the annual amounts as reasonably estimated by the mortgagee.

(e) *Borrower elects to pay property charges.* (1) If, based on the results of the Financial Assessment, the mortgagee does not require the borrower to have a LESA, the borrower may elect to be responsible for the independent payment of all property charges and shall pay all property charges in a timely manner and shall provide evidence of payment to the mortgagee as required in the mortgage.

(2) *Failure to pay property charges.* If the borrower fails to pay the property charges in a timely manner, and has not elected to have the mortgagee make the payments in accordance with paragraph (d) of this section:

(i) The mortgagee may make the payment for the borrower and charge the borrower's account if there are available funds from which the mortgagee may make payment. If a pattern of missed payments occurs, the mortgagee may establish procedures to pay the property charges from the borrower's funds as if the borrower elected to have the mortgagee pay the property charges under this section.

(ii) The mortgagee shall provide a written notification to the borrower and notify the Commissioner that an obligation of the mortgage has not been performed within 30 days of the mortgagee receiving notification of a missed payment when there are no available HECM funds from which the mortgagee may make payment. The borrower shall have 30 days to respond to the mortgagee to explain the circumstances which resulted in the non-payment. The mortgagee may provide any permissible loss mitigation made available by the Commissioner through notice. If the borrower is unable or unwilling to repay the mortgagee for any funds advanced by the mortgagee to pay property charges outside of a LESA, the mortgagee shall submit a due and payable request under the provisions of § 206.27(c)(2).

§ 206.207 Allowable charges and fees after endorsement.

(a) *Reasonable and customary charges.* The mortgagee may collect reasonable and customary charges and fees from the borrower after insurance endorsement, only to the extent that the mortgagee is not reimbursed for such fees by FHA, by adding them to the outstanding loan balance, but only for: items listed in paragraph (a)(1) of this section; items authorized by the Commissioner under paragraph (a)(2) of this section, or as provided at § 206.26(b)(1)(iii); or charges and fees related to additional documents described in § 206.27(b)(10) and related title search costs.

(1)(i) Charges for substitution of a hazard insurance policy at other than the expiration of term of the existing hazard insurance policy;

(ii) Attorney's and trustee's fees and expenses actually incurred (including the cost of appraisals and cost of advertising) when a case has been referred for foreclosure in accordance with the provisions of this part after a firm decision to foreclose if foreclosure is not completed because of a reinstatement of the account (no attorney's fee may be charged for the services of the mortgagee's or servicer's staff attorney or for the services of a collection attorney other than the attorney handling the foreclosure);

(iii) A trustee's fee if the security instrument in deed-of-trust states provides for payment of such a fee for execution of a satisfactory, release, or trustee's deed when the deed of trust is paid in full;

(iv) Where permitted by the security instrument, attorney's fees and expenses actually incurred in the defense of any suit or legal proceeding wherein the

mortgagee shall be made a party thereto by reason of the mortgage (no attorney's fee may be charged for the services of the mortgagee's or servicer's staff attorney); and

(v) Property preservation expenses incurred pursuant to § 206.140.

(2) Such other reasonable and customary charges as may be authorized by the Commissioner, but which shall not include:

(i) Charges for servicing activities of the mortgagee or servicer;

(ii) Fees charged by independent tax service organizations which contract to furnish data and information necessary for the payment of property taxes;

(iii) *Satisfaction, termination, or reconveyance* fees when a mortgage is paid in full (other than as provided in paragraph (a)(1)(iii) of this section); or

(iv) The fee for recordation of a satisfaction of the mortgage in states where recordation is the responsibility of the mortgagee.

(b) *Servicing charges.* (1) If the following conditions are met, the mortgagee may include a servicing charge in the mortgage Note rate, starting with the month of loan closing and continuing through the life of the loan, including any applicable Deferral Period:

(i) The charge is authorized by the Commissioner;

(ii) The charge is selected by the mortgagee;

(iii) The charge is within the range established by the Commissioner, which shall be set, through notice, in an amount which shall be between 36 and 150 basis points. The Commissioner may, through a **Federal Register** notice for comment, extend the range of permissible charges below 36 basis points and above 150 basis points; and

(iv) The charge is disclosed as required by § 206.43 to the borrower in a manner acceptable to the Commissioner at the time the mortgagee provides the borrower with a loan application; or

(2) If the following conditions are met, the mortgagee may collect a fixed monthly charge for servicing activities of the mortgagee or servicer, starting with the month of loan closing and continuing through the life of the loan, including any applicable Deferral Period.

(i) The charge is authorized by the Commissioner;

(ii) The charge is disclosed as required by § 206.43 to the borrower in a manner acceptable to the Commissioner at the time the mortgagee provides the borrower with a loan application;

(iii) Amounts to pay the charge are set aside as a portion of the principal limit in accordance with § 206.19(f)(3); and

(iv) The charge is payable only from the Servicing Fee Set Aside.

§ 206.209 Prepayment.

(a) *No charge or penalty.* The borrower may repay a mortgage in full or prepay a mortgage in part without charge or penalty at any time, regardless of any limitations on repayment or prepayment stated in a mortgage.

(b) *Insurance and condemnation proceeds.* If insurance or condemnation proceeds are paid to the mortgagee, the principal limit and the outstanding loan balance shall be reduced by the amount of the proceeds not applied to restoration or repair of the damaged property.

(c) Funds received from a partial prepayment shall be applied in accordance with the Note.

§ 206.211 Determination of principal residence and contact information.

(a) *Annual certification.* At least once during each calendar year, the mortgagee shall verify the contact information for the borrower(s) and determine whether or not the property is the principal residence of at least one borrower. The mortgagee shall require each borrower to make an annual certification of his or her contact information and principal residence. As part of the annual certification, the borrower may designate an alternate individual as specified in § 206.40 to receive copies of the notifications from the mortgagee, and who the mortgagee shall contact if the borrower is unwilling or unable to reply to requests from the mortgagee. The mortgagee may rely on the certification unless it has information indicating that the certification may be false.

(b) *Requirements when an Eligible Non-Borrowing Spouse exists.* Where an Eligible Non-Borrowing Spouse has been identified, the mortgagee shall obtain an additional annual certification from the borrower confirming the Eligible Non-Borrowing Spouse remains his or her spouse and the Eligible Non-Borrowing Spouse continues to reside in the property as his or her principal residence.

(1) *Death of borrower with Eligible Non-Borrowing Spouse.* If a borrower with an Eligible Non-Borrowing Spouse has died, the mortgagee shall obtain the annual certification in paragraph (a) of this section from the Eligible Non-Borrowing Spouse. For purposes of this paragraph, the term “Eligible Non-Borrowing Spouse” shall replace the

term “borrower” in paragraph (a) of this section.

(2) *Failure of previously Eligible Non-Borrowing Spouse to reside in the property as his or her principal residence.* If a Non-Borrowing Spouse fails to reside in the property as his or her principal residence, the Non-Borrowing Spouse becomes an Ineligible Non-Borrowing Spouse and the deferral of due and payable status that would prevent the displacement of an Eligible Non-Borrowing Spouse will no longer be in effect. Once this occurs, the Eligible Non-Borrowing Spouse annual certifications are no longer required to be obtained.

Subpart E—HECM Counselor Roster

§ 206.300 General.

This subpart provides for the establishment of the HECM Counselor Roster (Roster) and sets forth the requirements for the operation of the HECM Counselor Roster.

§ 206.302 Establishment of the HECM Counselor Roster.

(a) *HECM Counselor Roster.* FHA maintains a Roster of HECM counselors. Only counselors listed on the Roster and employed by a participating agency are approved to provide HECM counseling. A prospective borrower applying for a HECM loan to be insured by FHA must receive the required HECM counseling from one of the counselors on the Roster.

(b) *Disclaimer.* The inclusion of a HECM counselor on the Roster does not create or imply a warranty or endorsement by FHA of the listed counselor to a prospective HECM borrower or to any other organization or individual, nor does it represent a warranty of any counseling provided by the listed HECM counselor. The inclusion of a counselor on the Roster means that a listed counselor has met the FHA-prescribed qualifications and conditions for inclusion on the Roster and that the counselor is approved to provide HECM counseling by telephone or face-to-face.

§ 206.304 Eligibility for placement on the HECM Counselor Roster.

(a) *Application.* To be considered for placement on the Roster, a housing counselor must apply to FHA in a form and in a manner prescribed by the Commissioner.

(b) *Eligibility.* FHA will approve an application for placement on the Roster if the application demonstrates that the housing counselor:

(1) Is employed by a HUD-approved housing counseling agency or an affiliate of a HUD-approved

intermediary or State housing finance agency;

(2) Successfully passed a standardized HECM counseling exam administered by FHA, or a party selected by FHA, within the last 3 years. In order to maintain eligibility, a HECM counselor must successfully pass a standardized HECM counseling exam every 3 years;

(3) Received training and education related to HECMs within the prior 2 years;

(4) Has access to and is supported by technology that enables FHA to track the results of the counseling offered to each loan applicant, *e.g.*, what action(s), if any, did the client take after receiving the HECM counseling; and

(5) Is not listed on:

(i) The General Services Administration's Suspension and Debarment List;

(ii) HUD's Limited Denial of Participation List; or

(iii) HUD's Credit Alert Interactive Response System.

§ 206.306 Removal from the HECM Counselor Roster.

(a) *General.* FHA reserves the right to remove a HECM counselor from the Roster, in accordance with this section.

(b) *Cause for removal.* Cause for removal of a HECM counselor from the Roster includes, but is not limited to:

(1) Failure to comply with the education and training requirements of § 206.308;

(2) Failure to respond within a reasonable time to HUD inquiries or requests for documentation;

(3) Misrepresentation or fraudulent statements;

(4) Promotion, representation, or recommendation of any specific mortgagee;

(5) Failure to comply with applicable fair housing and civil rights requirements;

(6) Failure to comply with applicable statutes and regulations;

(7) Failure to comply with applicable statutory counseling requirements found at section 255(f) of the National Housing Act, which include, but are not limited to, providing information about: options other than a HECM, the financial implications of entering into a HECM, the tax consequences of a HECM, and any other information that HUD or the applicant may request;

(8) Failure to maintain any registration, license, or certification requirements of a State or local authority;

(9) Unsatisfactory performance in providing counseling to HECM loan applicants. FHA may determine that a HECM counselor's performance is

unsatisfactory based on a review of counseling files or other monitoring activities, or if the counselor fails to employ the minimum competencies, as measured by the FHA-administered HECM counseling exam; or

(10) For any other reason HUD determines to be so serious as to justify an administrative sanction.

(c) *Automatic removal from HECM Counselor Roster for failure to maintain required State or local licensure.* A HECM counselor who is required to maintain a State or local registration, license, or certification and whose registration or certification is revoked, suspended, or surrendered will be automatically suspended from the Roster until FHA receives evidence demonstrating that the local- or State-imposed sanction has been lifted.

(d) *Removal procedure.* Except as provided in paragraph (c) of this section, the following procedures apply to removal of a HECM counselor from the Roster.

(1) FHA will give the HECM counselor written notice of the proposed removal. The notice will state the reasons for and the duration of the proposed removal.

(2) The HECM counselor will have 30 days from the date of receipt of the notice (or such time as described in the notice, but in no event less than a period of 30 days) to submit a written appeal of the proposed removal, along with a written request for a conference.

(3) An FHA official will review the appeal and render a response affirming, modifying, or canceling the removal.

The FHA official will not be a person who was involved in FHA's initial removal decision. FHA will respond with a decision within 30 days after the date of receiving the appeal or, if the HECM counselor has requested a conference, within 30 days after the conference was held. FHA may extend the 30-day period by providing written notice to the counselor.

(4) If the HECM counselor does not submit a timely written response, the removal will be effective 31 days after the date of FHA's initial removal notice (or after the period provided in the notice, if longer than 30 days). If a written response is submitted, and the removal decision is affirmed or modified, the removal will be effective on the date of FHA's notice affirming or modifying the initial removal decision.

(e) *Maximum time period of removal.* The maximum time period for removal from the Roster is 12 months from the effective date of removal for all removed counselors. A counselor who has been removed must apply for reinstatement on the Roster.

(f) *Placement on the Roster after removal.* A counselor who has been removed from the Roster must apply for reinstatement on the Roster (in accordance with § 206.304) after the period of the counselor's removal from the Roster has expired. FHA may require the counselor to retake and pass the HECM exam for reinstatement when the reason for removal from the Roster was particularly egregious. Typically, the counselor will not be required to take and pass the HECM exam; however,

FHA must be ensured by the counselor that the HECM counseling requirements are understood and will be followed. An application from a counselor for reinstatement on the Roster will be rejected if the period of the counselor's removal from the Roster has not expired.

(g) *Voluntary removal.* A HECM counselor will be removed from the Roster upon FHA's receipt of a written request from the counselor.

(h) *Other action.* Nothing in this section prohibits HUD from taking such other action against a HECM counselor or from seeking any other remedy against a counselor available to HUD by statute or other authority.

§ 206.308 Continuing education requirements of counselors listed on the HECM Counselor Roster.

A HECM counselor listed on the Roster must receive, on a continuing basis, training, education, and technical assistance related to HECMs. The HECM counselor must maintain evidence of the successful completion of such continuing education, and such evidence must be made available to FHA upon request. FHA will consider a HECM counselor's successful completion of a HECM course no less than once every 2 years as satisfying the requirements of this section.

Dated: January 12, 2017.

Nani A. Coloretti,
Deputy Secretary.

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Federal Policy for the Protection of Human Subjects

AGENCY: Department of Homeland Security; Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Social Security Administration; Agency for International Development; Department of Housing and Urban Development; Department of Labor; Department of Defense; Department of Education; Department of Veterans Affairs; Environmental Protection Agency; Department of Health and Human Services; National Science Foundation; and Department of Transportation.

ACTION: Final rule.

SUMMARY: The departments and agencies listed in this document announce revisions to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects that was originally promulgated as a Common Rule in 1991. This final rule is intended to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. These revisions are an effort to modernize, simplify, and enhance the current system of oversight.

DATES: This rule is effective on January 19, 2018. The compliance date for this rule, except for § _____.114(b) (cooperative research), is January 19, 2018. The compliance date for § _____.114(b) (cooperative research) is January 20, 2020.

ADDRESSES: Jerry Menikoff, M.D., J.D., OHRP, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jerry Menikoff, M.D., J.D., Office for Human Research Protections (OHRP), Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; telephone: 240-453-6900 or 1-866-447-4777; facsimile: 301-402-2071; email: jerry.menikoff@hhs.gov.

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Executive Summary**Purpose of the Regulatory Action**

Individuals who are the subjects of research may be asked to contribute their time and assume risk to advance the research enterprise, which benefits society at large. U.S. federal regulations governing the protection of human subjects in research have been in existence for more than three decades. The Department of Health, Education, and Welfare first published regulations for the protection of human subjects in 1974, and the Department of Health and Human Services (HHS) revised them in the early 1980s. During the 1980s, HHS began a process that eventually led to the adoption of a revised version of the regulations by 15 U.S. federal departments and agencies in 1991. The purpose of this effort was to promote uniformity, understanding, and compliance with human subject protections as well as to create a uniform body of regulations across federal departments and agencies (subpart A of 45 Code of Federal Regulations [CFR] part 46), often referred to as the “Common Rule” or “Protection of Human Subjects Regulations.” Those regulations were last amended in 2005, and have remained unchanged until the issuance of this final rule.

Since the Common Rule was promulgated, the volume and landscape of research involving human subjects have changed considerably. Research with human subjects has grown in scale and become more diverse. Examples of developments include: an expansion in the number and types of clinical trials, as well as observational studies and cohort studies; a diversification of the types of social and behavioral research being used in human subjects research; increased use of sophisticated analytic techniques to study human biospecimens; and the growing use of electronic health data and other digital records to enable very large datasets to be rapidly analyzed and combined in novel ways. Yet these developments have not been accompanied by major change in the human subjects research oversight system, which has remained largely unaltered over the past two decades.

On July 26, 2011, the Office of the Secretary of HHS, in coordination with the Executive Office of the President's Office of Science and Technology Policy (OSTP), published an advance notice of proposed rulemaking (ANPRM) to request comment on how current regulations for protecting those who participate in research might be modernized and revised to be more effective.¹

On September 8, 2015, HHS and 15 other federal departments and agencies published a Notice of Proposed Rulemaking (NPRM) proposing revisions to the regulations for protection of human subjects in research.² Like the ANPRM, the NPRM sought comment on how to better protect research subjects while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. Public comments on both the ANPRM and the NPRM have informed the final rule that is now being promulgated.

The final rule is designed to more thoroughly address the broader types of research conducted or otherwise supported by all of the Common Rule departments and agencies such as behavioral and social science research. It also benefits from continuing efforts to harmonize human subjects policies across federal departments and agencies.

Summary of the Major Changes in the Final Rule

The final rule differs in important ways from the NPRM. Most significantly, several proposals are not being adopted:

- The final rule does not adopt the proposal to require that research involving nonidentified biospecimens be subject to the Common Rule, and that consent would need to be obtained in order to conduct such research.
- To the extent some of the NPRM proposals relied on standards that had not yet been proposed, the final rule either does not adopt those proposals or includes revisions to eliminate such reliance.
- The final rule does not expand the policy to cover clinical trials that are not federally funded.
- The final rule does not adopt the proposed new concept of "excluded" activities. Generally, activities proposed to be excluded are now either described as not satisfying the definition of what constitutes research under the regulations or are classified as exempt.
- The proposed revisions to the exemption categories have been modified to better align with the long-standing ordering in the final rule. The final rule does not include the proposed requirement that exemption determinations need to be made in specified ways.
- The final rule does not include the proposed standardized privacy safeguards for identifiable private information and identifiable biospecimens. Aspects of proposals that relied on those safeguards have been modified or are not being adopted.
- The final rule does not adopt the most restrictive proposed criteria for obtaining a waiver of the consent requirements relating to research with identifiable biospecimens.

The final rule makes the following significant changes to the Common Rule:

- Establishes new requirements regarding the information that must be given to prospective research subjects as part of the informed consent process.
- Allows the use of broad consent (*i.e.*, seeking prospective consent to unspecified future research) from a subject for storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens. Broad consent will be an optional alternative that an investigator may choose instead of, for example,

conducting the research on nonidentified information and nonidentified biospecimens, having an institutional review board (IRB) waive the requirement for informed consent, or obtaining consent for a specific study.

- Establishes new exempt categories of research based on their risk profile. Under some of the new categories, exempt research would be required to undergo limited IRB review to ensure that there are adequate privacy safeguards for identifiable private information and identifiable biospecimens.

- Creates a requirement for U.S.-based institutions engaged in cooperative research to use a single IRB for that portion of the research that takes place within the United States, with certain exceptions. This requirement becomes effective 3 years after publication of the final rule.

- Removes the requirement to conduct continuing review of ongoing research for studies that undergo expedited review and for studies that have completed study interventions and are merely analyzing study data or involve only observational follow up in conjunction with standard clinical care.

Other minor changes have been to improve the rule and for purposes of clarity and accuracy.

Estimated Costs and Benefits

Table 1 summarizes the quantified and nonquantified benefits and costs of all changes to the Common Rule. Over the 2017–2026 period, present value benefits of \$1,904 million and annualized benefits of \$223 million are estimated using a 3 percent discount rate; present value benefits of \$1,494 million and annualized benefits of \$213 million are estimated using a 7 percent discount rate. Present value costs of \$528 million and annualized costs of \$62.0 million are estimated using a 3 percent discount rate; present value costs of \$474 million and annualized costs of \$67.0 million are estimated using a 7 percent discount rate. Nonquantified benefits include improved human subjects protections in research; enhanced oversight of research reviewed by IRBs not operated by a Federalwide Assurance (FWA)-holding institution; and increased uniformity in regulatory requirements among Common Rule departments and agencies. Nonquantified costs include the time needed for consultation among

¹ HHS. Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators. 76 FR 44512 (Jul. 26, 2011). Retrieved

from <https://www.gpo.gov/fdsys/pkg/FR-2011-07-26/pdf/2011-18792.pdf>

² HHS. Federal Policy for the Protection of Human Subjects. 80 FR 53931 (Sept. 8, 2015).

Retrieved from <https://www.federalregister.gov/documents/2015/09/08/2015-21756/federal-policy-for-the-protection-of-human-subjects>

Common Rule agencies before federal guidance is issued.

TABLE 1—ACCOUNTING TABLE OF BENEFITS AND COSTS OF ALL CHANGES

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|--|--|-----------|---|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |
| Benefits: | | | | |
| Quantified Benefits | 1,904 | 1,493 | 223 | 213 |
| Nonquantified Benefits: | | | | |
| Improved human subjects protections in research; enhanced oversight in research reviewed by IRBs not operated by an FWA-holding institution; and increased uniformity in regulatory requirements among Common Rule departments and agencies. | | | | |
| Costs: | | | | |
| Quantified Costs | 528 | 474 | 62.0 | 67.0 |
| Nonquantified Benefits: | | | | |
| Time for consultation among Common Rule agencies before federal guidance is issued. | | | | |

I. The Rationale for Modernizing the Common Rule

A. The Changing Nature of Research

This final rule recognizes that in the past two decades a paradigm shift has occurred in how research is conducted. Evolving technologies—including imaging, mobile technologies, and the growth in computing power—have changed the scale and nature of information collected in many disciplines. Computer scientists, engineers, and social scientists are developing techniques to integrate different types of data so they can be combined, mined, analyzed, and shared. The advent of sophisticated computer software programs, the Internet, and mobile technology has created new areas of research activity, particularly within the social and behavioral sciences. In biomedical science, the Human Genome Project laid the foundation for precision medicine and promoted an environment of data sharing and innovation in analytics and technology, and drew attention to the need for policies that support a changing research landscape. New technologies, including genomic sequencing, have quickly led to exponential growth in the data to which investigators have access. The sheer volume of data that can be generated in research, the ease with which it can be shared, and the ways in which it can be used to identify individuals were simply not possible, or even imaginable, when the Common Rule was first adopted.

Research settings are also shifting. Although much biomedical research continues to be conducted in academic medical centers, more research is being conducted in clinical care settings, thus

combining research and medical data. Biospecimen repositories and large databases have made it easier to do research on existing (stored) biospecimens and data. Clinical research networks connected through electronic health records have developed methods for extracting clinical data for research purposes and are working toward integration of research data into electronic health records in a meaningful way. The scientific community recognizes the value of data sharing and open-source resources and understands that pooling intellectual resources and capitalizing on efficient uses of data and technology represent the best ways to advance knowledge.

At the same time, the level of public engagement in the research enterprise has changed. More people want to play an active role in research, particularly related to health.

As technology evolves, so does the nature of the risks and benefits of participating in certain types of research. Many studies do not involve interaction with research subjects, but instead involve secondary analysis of data or biospecimens. Risks related to these types of research studies are largely informational, not physical; that is, harms could result primarily from the inappropriate disclosure of information and not from the research interventions themselves. Nonetheless, those harms can be significant.

Because of these shifts in science, technology, and public engagement and expectations, a wide range of stakeholders have raised concerns about the limitations of the existing regulatory framework, arguing for a re-evaluation of how the fundamental principles of

the 1979 *Belmont Report*³ that underlie the Common Rule—respect for persons, beneficence, and justice—are applied in practice to the myriad new contexts in which U.S. research is conducted in the 21st century. The changes that are being implemented in the final rule continue to be shaped by those principles (a detailed background discussion of which was provided in the NPRM).

Finally, it is important to note that, to the extent appropriate, the intent is to eventually amend the other subparts of the HHS human subjects protection regulations in 45 CFR part 46 (subparts B, C, D, and E), and consider the need for updates to FDA regulations and other relevant federal departmental or agency regulations with overlapping scope.

B. Public Comments, Expert Advice, Stakeholder Dialogue

The revisions to the Common Rule are based on a variety of sources of public, stakeholder, and expert comments and advice, including comments received on the 2011 ANPRM and the 2015 NPRM. They also benefit from guidance provided by a 2014 National Research Council consensus report, *Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences*,⁴ and

³ National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *Belmont Report*. Washington, DC: U.S. Department of Health and Human Services. 1979. Retrieved from <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>.

⁴ National Research Council of the National Academies. *Proposed Revisions to the Common Rule for the Protection of Human Subjects in the Behavioral and Social Sciences*. Washington, DC: The National Academies Press; 2014. 13–168. Retrieved from <http://www.nap.edu/catalog/18614/proposed-revisions-to-the-common-rule-for-the-protection-of-human-subjects-in-the-behavioral-and-social-sciences>.

Continued

the National Academies of Science, Engineering, and Medicine 2016 report *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century*.⁵

Since the publication of the 2011 ANPRM, HHS has continued to solicit public comment on a variety of policy issues related to human subjects protections, including consent, the use of a single IRB for multi-institutional studies, and sharing of genomic data. Although these policies were more specific than the issues raised in the ANPRM, the responses received from public comments provide insight for refining the proposals initially put forward in the ANPRM. Of particular relevance are the National Institutes of Health's (NIH's) recently issued policy on the use of a single IRB for multi-institutional research,⁶ the Office for Human Research Protection's (OHRP's) draft guidance on the required content of consent language for research conducted within the standard of care,⁷ and NIH's policy to promote sharing of large-scale human genomic data generated from studies funded or conducted by NIH.⁸

Other developments include the enactment of the Newborn Screening Saves Lives Reauthorization Act of 2014 (Pub. L. 113–240) in December 2014. The law made a number of changes relevant to the HHS regulations for protecting research subjects, including asserting that research with newborn dried blood spots (DBS) that is federally funded pursuant to the Public Health Service Act is to be considered research with human subjects, and that the provisions allowing IRBs to waive consent would not apply. By statute, the changes made by this law applied only until changes to the Common Rule are promulgated. Thus, the changes made by this statute will no longer apply after the effective date of this rule, January 19, 2018. In addition, in April 2015, the

protection-of-human-subjects-in-the-behavioral-and-social-sciences.

⁵ National Academies of Sciences, Engineering, and Medicine. *Optimizing the Nation's Investment in Academic Research: A New Regulatory Framework for the 21st Century*. Washington, DC: The National Academies Press; 2016. Retrieved from <https://www.nap.edu/read/21824/chapter/1>.

⁶ National Institutes of Health. Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research. June 21, 2016. Notice Number: NOT-OD-16-094. Retrieved from <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html>.

⁷ HHS. Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care. 79 FR 63630 (Oct. 24, 2014). Retrieved from <https://www.gpo.gov/fdsys/pkg/FR-2014-10-24/pdf/2014-25318.pdf>.

⁸ Information about the NIH Genomic Data Sharing policy is available at <https://gds.nih.gov/03policy2.html>.

Medicare Access and Children's Health Insurance Program Reauthorization Act of 2015 (Pub. L. 114–10) was passed. That law requires HHS to issue a clarification or modification of the Common Rule with regard to how the regulatory requirements should be applied to activities involving clinical data registries. In addition, in December 2016 the 21st Century Cures Act (Pub. L. 114–255) was enacted.

Finally, as a result of conducting a variety of public discussions associated with the President's Precision Medicine Initiative,^{9 10 11} many perspectives were heard, with much alignment around the central tenet that participants should be active partners in such research and not merely passive subjects of research studies.

1. Summary of Public Comments on Structural, Conceptual, and Policy Implications of the Proposed Rule

The NPRM received more than 2,100 public comments, the majority of which were from people writing in their individual capacity. The remaining comments were submitted by institutions, professional organizations and societies, and membership organizations. The proposals receiving the most comments were those related to biospecimens (expanded definition of human subject, broad consent, and tightened criteria for waiver of consent). Here we summarize comments on the overall structural, conceptual, and policy implications of the proposed rule. Comments regarding the specific provisions of the rule appear throughout this preamble.

The NPRM asked for public comment on whether the proposed changes will achieve the objectives of: (1) decreasing administrative burden, delay, and ambiguity for investigators, institutions, and institutional review boards (IRBs); and (2) strengthening, modernizing, and making the regulations more effective in protecting research subjects. In response, many public commenters expressed concern about the overall complexity and length of the NPRM, the unavailability of key deliverables, proposals being internally inconsistent,

⁹ The White House, Office of the Press Secretary. Fact Sheets: President Obama's Precision Medicine Initiative. January 30, 2015. Retrieved from <https://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative>.

¹⁰ Collins FS, Varmus H. A New Initiative on Precision Medicine. *The New England Journal of Medicine* 2015 Feb; 372:793–795.

¹¹ For more information on the Precision Medicine Initiative Cohort Program see <https://www.nih.gov/sites/default/files/research-training/initiatives/pmi/pmi-working-group-report-20150917-2.pdf>.

and proposals giving investigators too much leeway to determine if their research is exempt or falls outside the scope of the rule.

Several commenters expressed concerns that they were unable to adequately or meaningfully comment on particular provisions proposed in the NPRM because an underlying document, tool, or list had not been developed or shared with the public at the time the NPRM was published, specifically: (1) the proposed broad consent templates; (2) the proposed standards for privacy protection; (3) the proposed list of eligible expedited procedures; and (4) the proposed exemption decision tool. Several commenters suggested that these items should be removed from the final rule and developed independently, urging government personnel to work collaboratively with representatives from the research community and funding agencies in the development of such documents, tools, and lists.

Some commenters suggested issuing a new NPRM that would be more complete and would include details on the privacy protection standards, exemption decision tool, and broad consent templates. Another commenter recommended that only the fully developed, less controversial provisions of the NPRM should be adopted into a final rule. Another commenter urged the Common Rule departments and agencies to reissue the NPRM to solicit comment on several of these documents, tools, and lists, arguing that it would be unlawful for a final rule to be issued until such an action were taken. This commenter noted that for members of the public to reasonably participate in rulemaking, agencies must provide enough factual detail and rationale to allow interested parties to comment meaningfully on the rule. This commenter also argued that the NPRM did not satisfy the requirement set forth in the Administrative Procedure Act that the notice provided to the public in rulemaking include either the terms or substance of the proposed rule or a description of the subjects and issues involved. In sum, the commenter argued that the NPRM sought comments on numerous provisions without providing the “terms or substance” of the specific proposals.

Some commenters encouraged dropping the proposal to require consent for research use of nonidentified biospecimens and instead exploring a system of public notification and opportunity to opt out of such research through issuance of a new NPRM following widespread consultation. A few commenters

suggested that Common Rule departments and agencies fund pilot studies to better understand how such a system might work. Additional commenters focused on the importance of public education about the research enterprise regardless of the policy choices pursued in a final rule.

Commenters, including state health departments and other health entities involved in newborn screening activities, raised concerns that several of the NPRM proposals represented unfunded mandates, specifically the expansion of the definition of human subject to include all biospecimens regardless of identifiability, expansion of the policy to apply to all clinical trials that meet certain conditions, and mandatory single IRB review of cooperative research. Several institutions and disease advocacy groups noted that statewide newborn screening programs are often modestly funded, and the NPRM proposals would impose processes that could cost millions of dollars each year.

In addition, commenters raised concerns that HHS and other Common Rule departments and agencies are not authorized under 42 U.S.C. 289 to regulate humanities and social science research.

Public comments also discussed several ideas for consideration in a final rule that were not otherwise proposed in the NPRM, including:

- Develop or strengthen sanctions and penalties for investigators or institutions that re-identify subjects without proper authorization or review, rather than focusing solely on obtaining consent as the way to protect subjects. To this end, several commenters suggested that a separate section be added to the Common Rule focused on investigator responsibilities.
- Develop an IRB efficiency rating system.
- Deem research about IRB operations as an excluded, exempt, or expeditable activity to foster research into IRB operations.
- Include provisions about compensation for research-related injuries.
- More fully review and address how the rule should or should not apply to prisoners, children, and pregnant women and fetuses.
- Include provisions about U.S.-funded studies in developing countries with regard to defining standards of care and addressing post-trial access to proven therapies.

2. Response to Public Comments on Structural, Conceptual, and Policy Implications of the Proposed Rule

The final rule differs in numerous, major ways from what was proposed in the NPRM. Most significantly, the provisions relating to making nonidentified biospecimens subject to the Common Rule are not being implemented. That change alone addresses many of the public comments on the NPRM. Eliminating that proposal is intended to address concerns about the complexity of and lack of justification for the proposed changes in the rule, as well as concerns about embarking on significant changes without evidence that they would improve the system. Responses to public comments on specific provisions appear throughout this preamble. Below we summarize our responses to comments that addressed major structural or organizational issues or perceived insufficiencies in the NPRM proposals and their presentation.

Concerns about the overall complexity of the proposed changes have been addressed in several ways. For example, concerns about creating a new category of “excluded” activities have been addressed by not adopting that concept in the final rule. Instead, the goal of clarifying what is covered by the rule has been accomplished by modifying the definition of what constitutes research, and by adding or modifying exemptions that were already in the pre-2018 rule.¹² And, even where existing concepts are modified, we have attempted to make those modifications in ways that minimize the extent of the change (such as largely preserving much of the core structure of the previous exemption categories).

To reduce public concerns about the aspects of the proposal that were not yet developed, we chose not to implement most of those provisions. For example, given the changes made to the proposals regarding broad consent, the final rule does not reference or include the concept of broad consent templates. The requirement that the Secretary of HHS develop a list of proposed privacy safeguards has been eliminated, as has the proposed exemption decision tool. In addition, we have dropped the regulatory requirement for the Secretary

of HHS to publish a list of activities that are minimal risk (as was proposed in the NPRM in the definition of minimal risk). The final rule retains the requirement at § ___.110(a) that the Secretary of HHS will establish and publish for public comment a list of categories of research that may be reviewed by an IRB through the expedited review procedure, consistent with the pre-2018 rule.

Some of the “new ideas” for altering the system for protecting research subjects that were presented by commenters—for example, addressing compensation for research-related injuries or the meaning of equivalent protections when research is conducted in foreign countries—were either very innovative or not yet widely discussed. This made it difficult to adopt them at this point without further study and additional notice and opportunity for public comment. Therefore, the fact that one or another of these ideas was not incorporated into the final rule should not be viewed as a rejection of their possible merits, or an indication that they might not be explored in some future revision of the Common Rule or in guidance.

a. Process Issues

We carefully considered concerns voiced by commenters about the process that led to this final rule, and other legal concerns about the adequacy of that process. We concluded that the approach proposed in the NPRM and the approach adopted in this final rule are consistent with the Federal Government’s obligations under the Administrative Procedure Act.

Regarding the concerns expressed that the Common Rule departments and agencies are not authorized to regulate humanities and social science research, this challenge had been asserted previously against the 1981 HHS protection of human subjects regulations,¹³ as well as the 1991 Common Rule,¹⁴ and in each case the regulatory agencies concluded that the regulation of humanities and social science research is justified. We continue to assert the authority to regulate humanities and social science research that falls within the scope of the final rule.

¹² For purposes of this preamble, the terms “pre-2018 requirements” or “pre-2018 rule” refer to the Common Rule as published in the 2016 edition of the Code of Federal Regulations (*i.e.*, the Federal Policy for the Protection of Human Subjects, originally published on June 18, 1991 and subsequently amended on June 23, 2005). In addition, the term “this rule” or “final rule” refers to the 2018 requirements as presented in this issuance.

¹³ Federal Regulations Amending Basic HHS Policy for the Protection of Human Research Subjects; Final Rule, 46 FR8366 (January 26, 1981). Retrieved from <https://wayback.archive-it.org/all/20160202182914/http://archive.hhs.gov/ohrp/documents/19810126.pdf>.

¹⁴ Federal Policy for the Protection of Human Subjects; Notices and Rules. 56 FR 28002. (June 18, 1991). Retrieved from <https://www.hhs.gov/ohrp/sites/default/files/ohrp/policy/frcomrul.pdf>.

C. Signatories to the Common Rule

This section provides information about where each Common Rule department or agency's statutory authority for enacting and revising human subjects research protection regulation lies, and provides additional information about new signatories to the Common Rule.

The regulations are codified in each department or agency's title or chapter of the CFR. The Common Rule was based on HHS's regulations, 45 CFR part 46, subpart A, and includes identical language in the separate regulations of each department and agency.

Although they did not previously issue the Common Rule in regulations, four departments and agencies have historically complied with all subparts of the HHS protection of human subjects regulations at 45 CFR part 46. These are the Central Intelligence Agency (CIA), the Office of the Director of National Intelligence (ODNI), the Department of Homeland Security (DHS), and the Social Security Administration (SSA).

Pursuant to Executive Order 12333 of December 4, 1981, as amended, elements of the Intelligence Community must comply with the guidelines issued by HHS regarding research on human subjects found in 45 CFR part 46. This final rule does not supersede the Executive Order. The CIA will continue to adhere to the HHS regulations at 45 CFR part 46, pursuant to the Executive Order.

Through this rulemaking, DHS is codifying the final rule into its own agency regulations. DHS, which was created after issuance of the pre-2018 rule, has been required by statute (Pub. L. 108–458, title VIII, section 8306) to comply with 45 CFR part 46, or with equivalent regulations promulgated by the Secretary of Homeland Security or his designee. Through this rulemaking, DHS is issuing equivalent regulations, consistent with statute, and will comply with the DHS regulations as the requirements will be equivalent to compliance with HHS regulations at 45 CFR part 46, subpart A.

Through this rulemaking, SSA is codifying the final rule into its own agency regulations. SSA was separated from HHS in 1995 and, pursuant to the transition rules provided in Section 106 of title 1 of Pub. L. 103–296, has been required to apply regulations that applied to SSA before the separation, absent action by the Commissioner. With this rulemaking, SSA will follow the SSA regulations (adopting the provisions of this final rule) instead of HHS regulations at 45 CFR part 46,

subpart A. (See Pub. L. 103–296 §106(b), 108 Stat. 1464, 1476.)

The Department of Labor (DOL), which was not a signatory to the pre-2018 rule, is now a signatory to this rulemaking and is codifying the final rule in DOL regulations for human subjects research that DOL conducts or supports.

The Consumer Product Safety Commission (CPSC), subject to Commission vote, intends to adopt this rule through a separate rulemaking.

The legal authority for the departments and agencies that are signatories to this action is as follows:

Department of Homeland Security, 5 U.S.C. 301; Pub. L. 107–296, sec. 102, 306(c); Pub. L. 108–458, sec. 8306. Department of Agriculture, 5 U.S.C. 301; 42 U.S.C. 300v–1(b). Department of Energy, 5 U.S.C. 301; 42 U.S.C. 7254; 42 U.S.C. 300v–1(b). National Aeronautics and Space Administration, 5 U.S.C. 301; 42 U.S.C. 300v–1(b). Department of Commerce, 5 U.S.C. 301; 42 U.S.C. 300v–1(b). Social Security Administration, 5 U.S.C. 301; 42 U.S.C. 289(a). Agency for International Development, 5 U.S.C. 301; 42 U.S.C. 300v–1(b), unless otherwise noted. Department of Housing and Urban Development, 5 U.S.C. 301; 42 U.S.C. 300v–1(b) and 3535(d). Department of Labor, 5 U.S.C. 301; 29 U.S.C. 551. Department of Defense, 5 U.S.C. 301. Department of Education, 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; 42 U.S.C. 300v–1(b). Department of Veterans Affairs, 5 U.S.C. 301; 38 U.S.C. 501, 7331, 7334; 42 U.S.C. 300v–1(b). Environmental Protection Agency, 5 U.S.C. 301; 7 U.S.C. 136a(a) and 136w(a)(1); 21 U.S.C. 346a(e)(1)(C); sec. 201, Pub. L. 109–54, 119 Stat. 531; and 42 U.S.C. 300v–1(b). Department of Health and Human Services, 5 U.S.C. 301; 42 U.S.C. 289(a); 42 U.S.C. 300v–1(b). National Science Foundation, 5 U.S.C. 301; 42 U.S.C. 300v–1(b). Department of Transportation, 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

II. To what does this policy apply?

Scope and Applicability of the Regulations

This section of the preamble describes changes made in the final rule with regard to its scope and applicability. Specifically, it addresses which entities are subject to the rule; coverage of clinical trials; department and agency discretion in applying the rule; the relevance of state and local laws; coverage of research conducted in foreign countries; the goal of harmonizing guidance across the federal

entities; effective and compliance dates; and severability.

A. IRBs Not Operated by an Institution Holding a Federalwide Assurance (§ ____ .101(a)(1))

1. Background and Pre-2018 Requirements

Before this final rule, IRBs not operated by an institution holding an FWA were not directly subject to oversight for compliance with the Common Rule. In situations in which an institution relied on an IRB not operated by the institution, OHRP's practice was to hold the institution engaged in human subjects research accountable for compliance violations, even in circumstances in which the regulatory violation was directly related to the responsibilities of the IRB.

An institution might rely on an IRB not operated by that institution to review cooperative research, that is, research conducted at more than one institution. However, for some, such reliance has been considered problematic due to lack of direct regulatory accountability for these IRBs. Previously, the choice to have cooperative research reviewed by a single IRB was voluntary and, for federally funded research, most institutions have been reluctant to replace review by their own IRB with review by a single IRB not operated by that institution.

2. NPRM Proposal To Cover IRBs not Operated by an Institution Holding an FWA

For the reasons outlined above, and based on comments to OHRP's 2011 ANPRM, the NPRM proposed adding a new provision at § ____ .101(a) that would explicitly give Common Rule departments and agencies the authority to enforce compliance directly against IRBs that are not operated by an FWA-holding institution (sometimes referred to as “independent IRBs”). Under the pre-2018 rule, even if an institution engaged in research relied on an IRB operated by another FWA-holding institution, OHRP's practice has been to enforce compliance through the engaged institution and not the reviewing IRB.

Relatedly, another NPRM proposal would require single IRB review of multi-institution studies (see Section XII of this preamble). This proposal would place responsibility for meeting the relevant regulatory requirements on the IRB of record in a multi-institutional study, rather than on the institution engaged in the research.

3. Public Comments

Approximately 50 comments addressed this proposal, largely in support, because it would encourage institutions to rely on IRBs not operated by an FWA-holding institution when necessary and would place responsibility on the IRB and its decisions rather than on the institution relying on the IRB's determination. Commenters stated that this change could increase IRB accountability and protect institutions relying on IRBs that they do not operate. However, a few commenters supported the proposal only if the mandate for a single IRB of record in multi-institutional research was not implemented. That is, they supported the concept of holding IRBs not operated by the institution engaged in research accountable for compliance, but did not support it if it was intended solely to facilitate mandatory single IRB review for cooperative research, because they opposed that mandate. One organization that advocates for human subjects protections opposed the proposal because it did not believe that any research should be reviewed by an independent IRB, and feared this practice would become more frequent with this change. Several academic institutions opposed the proposal, as did a large trade organization, stating that this extension of the rule was not necessary.

4. Response to Comments and Explanation of the Final Rule: Authority To Enforce Compliance Directly Against IRBs Not Operated by an FWA-Holding Institution

New language at § ___.101(a) is adopted that gives Common Rule departments and agencies the authority to enforce compliance directly against IRBs that are not operated by an assured institution. This authority will allow Common Rule departments and agencies to avoid involving other engaged institutions in enforcement activities related to the responsibilities of the designated IRB. It is anticipated that this change will reassure institutions using an IRB that they do not operate because compliance actions could be taken directly against the IRB responsible for the regulatory noncompliance, rather than against the institutions that relied on that review.

B. Coverage of Clinical Trials

1. Background and Pre-2018 Requirements

The Common Rule has historically applied to human subjects research that is conducted or supported by a Common Rule department or agency. Research

that is not federally conducted or supported has not been subject to the Common Rule's requirements unless the U.S. institution receiving federal funding for research voluntarily extended the Common Rule to all research conducted at that institution, regardless of funding source.

The Institute of Medicine,¹⁵ the National Bioethics Advisory Commission,¹⁶ and others have stated that human subjects would be best protected by applying consistent ethical standards and a uniform system of regulatory oversight to all human subjects research conducted in the United States. Common Rule departments and agencies do not have statutory authority to directly apply the Common Rule to all human subjects research conducted in the United States. However, departments and agencies can require U.S. institutions that receive some federal funding from a Common Rule department or agency for research with human subjects to extend regulatory protections to all research studies conducted at the institution as a condition of funding. The 2011 ANPRM sought comment on this approach.

2. NPRM Proposal

The NPRM proposed changes in the regulatory language to extend the rule to all clinical trials, irrespective of funding source, that met three conditions: (1) The clinical trials are conducted at an institution that receives support from a federal department or agency for human subjects research that was not proposed to be excluded under the NPRM and was not exempt; (2) the clinical trials are not subject to FDA regulation; and (3) the clinical trials are conducted at an institution located within the United States.

The purpose of the proposed clinical trials extension was to ensure that clinical trials involving significant risks that would otherwise not be covered be subject to federal oversight. It was for that reason that the proposed extension excluded clinical trials subject to FDA oversight. The proposed extension also was based on whether an institution received funding specifically for other human subjects research that had to comply with the substantive requirements of the Common Rule. The Common Rule departments and agencies have a more substantial relationship with institutions that

receive federal support to conduct research subject to the regulatory requirements than they do with institutions that receive such support for only exempt human subjects research.

The NPRM proposed that a clinical trial be defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. By the term "behavioral health-related outcomes," the NPRM recognized that clinical trials may occur outside of the biomedical context, and further stated that the studies addressed in the proposed definition of clinical trial are more likely to present more than minimal risk to subjects, and, therefore, require the highest level of oversight.

3. Public Comments

Approximately 70 comments discussed the proposal to extend the Common Rule to cover certain clinical trials. Opinion was mixed, with a slim majority opposing the proposed change. Universities and medical centers providing comments largely opposed the proposed measure, while professional associations and advocacy groups largely supported the proposal. We note that some of those who opposed the clinical trial extension did so because they felt that the proposal did not go far enough to include additional types of research.

Those supporting the proposed change indicated that it had the potential to ensure greater consistency of rules and protections for research subjects, thereby aiding efficiency and speeding the review process of study protocols. However, even those commenters who supported the proposal indicated that such an extension must fulfill the intent of a risk-based, streamlined approach to human subject protection, considering the effects of this extension on certain minimal risk research activities, such as student research, and social, behavioral, and educational research.

Those expressing opposition to this expansion of coverage noted concerns that: (1) Because the research institutions likely to engage in clinical trials already require IRB review of such research, the expansion would only increase administrative burdens (such as federal reporting requirements) for this type of research without a meaningful increase in protections to human subjects; (2) the regulatory extension to nonfederally funded

¹⁵ Federman DD, Hanna KE, Rodriguez LL, eds. *Responsible Research: A Systems Approach to Protecting Research Participants*. Washington, DC: National Academies Press; 2002.

¹⁶ National Bioethics Advisory Commission. *Ethical and Policy Issues in Research Involving Human Participants*. Bethesda, MD; 2001.

clinical trials would encompass many minimal-risk social and behavioral research activities and currently unregulated institutional activities that involve randomization (such as nonfederally funded quality improvement or quality assurance activities); and (3) because an institution's funding status may change, implementation of this proposal would be complicated. Several commenters expressed concern about the lack of detail in the NPRM regarding the planned implementation of the proposed requirement.

Several commenters also expressed concern that the unfunded clinical trials encompassed by this proposal would be subject to the single IRB mandate without a corresponding provision of federal funds to implement that requirement.

Some commenters suggested that the proposed change in the NPRM will not address the real gap in human subjects protections—facilities that receive no federal funding—and that if broad concern exists that some subjects are not being adequately protected in research that is not federally funded, then Congress would be the appropriate body to address any such deficiency through legislation. Further, some commenters expressed concern that extending the Common Rule to nonfederally funded clinical trials might have an overall effect of decreasing human subject protections by discouraging some smaller organizations from accepting any federal funding, thus removing federal oversight of their work.

One research institution noted that, if finalized, the proposed clinical trials extension would be implemented at the same time the ability of institutions to formally extend the application of the rule to all research conducted at the institution is being eliminated. Some states, such as Virginia, have state human subjects regulations that must be applied to research when federal regulations are not required. The commenter noted that removing the option to voluntarily extend the FWA would have the effect of reducing uniform application of the federal standards, as nonfederally funded research that does not meet the proposed definition of a clinical trial would by default be subject to state law.

A few commenters challenged whether the legal authority provided by the Public Health Service Act was sufficient to extend the Common Rule to nonfederally funded clinical trials. Commenters also suggested that this proposal is an unfunded mandate from the Federal Government with no benefit

accruing to subjects or the research enterprise.

4. Response to Comments and Explanation of the Final Rule: Coverage of Certain Clinical Trials

The final rule does not adopt the NPRM proposal. Although we continue to maintain the position that increased harmonization of appropriate standards for ethical oversight of human subjects research is an important and desirable endpoint, we agree with the concerns expressed by commenters suggesting that our proposal for extending the Common Rule to currently unregulated clinical trials would benefit from further deliberation. Some commenters asserted that, in our attempt to close the perceived “gap” in oversight, the NPRM created a structure that would be both confusing and complicated for institutions to implement. We received multiple comments objecting to the administrative complexity involved in applying a regulatory extension triggered by the receipt of Common Rule department or agency funding for other nonexempt research, and asserting that the administrative burden is not offset by a corresponding increase in the meaningful protection of human subjects. Additionally, it is apparent from the public comments received that our intention to apply the Common Rule to cover the most risky types of research—clinical trials—was not accomplished through the NPRM proposal, given the definition of “clinical trial” included in the NPRM, as that definition encompassed research that would pose no more than minimal risk to subjects. Commenters were further concerned that an unintended consequence might be that the proposed extension would apply to low-risk student research and social, behavioral, or educational research, and would cause currently unregulated institutional activities, such as certain quality improvement or quality assurance activities, to fall within regulatory oversight. Upon reflection on the perspectives expressed by these commenters, we are persuaded that the proposed extension of the Common Rule is not appropriate to include in a final rule at this time. We will continue to carefully consider the related issues.

As an alternative, we contemplated explicitly limiting the extension of this policy to clinical trials that present greater than minimal risk to subjects in order to better align with the intent of this extension, as described in the preamble to the NPRM. However, such an alteration of the rule would itself introduce a variety of complexities, including the question of how a

determination would be made that a particular activity involves more than minimal risk. Thus, there would be a very real possibility that such a rule would lead to an administrative burden on substantially more activities than the rule itself would be targeting (such as many minimal risk quality improvement activities).

We also considered the alternative of maintaining the pre-2018 standard of allowing institutions to voluntarily extend their FWAs to nonfederally funded research. We concluded that this alternative would not further the expressed goal of increasing the application of consistent protections to clinical trials, regardless of the source of support, because the extension of the FWA would be optional. We therefore plan to implement the proposed nonregulatory change to the assurance mechanism to eliminate the voluntary extension of the FWA to nonfederally funded research.

We note the concern expressed by commenters that a gap in federal oversight will remain for nonfederally funded research, and the comment that Congress would be the appropriate body to address any such deficiency through legislation. We recognize that institutions may choose to establish an institutional policy that would require IRB review of research that is not funded by a Common Rule department or agency (and indeed, as commenters noted, almost all institutions already do this), and nothing in this final rule precludes institutions from providing protections to human subjects in this way. As a result, the final rule continues to allow institutions the same wide degree of flexibility that they currently have with regard to making other similar determinations regarding ethical oversight of research not regulated by the Common Rule.

Although we are not implementing the proposed extension of the Common Rule to “clinical trials” (as defined by this policy), the proposed definition of “clinical trial” is still relevant to the final rule provision requiring posting of one IRB-approved consent form used to enroll subjects for a clinical trial conducted or supported by a federal department or agency, at § ___.116(h). The definition of clinical trial is unaltered from the NPRM proposal and appears at § ___.102(b).

C. Activities Deemed Not To Be Research Appear at § ___.102(l) and Research Exempt From This Policy Appears at § ___.104

In response to the public comments, the NPRM's general approach of designating various categories of

activities as excluded is not included in the final rule. The final rule reverts to the general structure of the pre-2018 rule and integrates some of the categories proposed for exclusion in the NPRM into that structure. Some changes to the categories are also included in the final rule.

In the final rule, some of the proposed exclusions from the requirements of the Common Rule are addressed in the definition of research, which includes a provision identifying “activities that are deemed not to be research” (see Section III). In addition, some of the proposed exclusions are included as exemptions in the final rule. Under § _____.101(b) of the pre-2018 rule, six categories of research were considered exempt from this policy unless otherwise required by department or agency heads. In the final rule, exempt research is now described at § _____.104 and eight categories are included (see Section V).

D. Department or Agency Discretion in Applying the Policy (§ _____.101(c), (d), (i))

1. Background and Pre-2018 Requirements

The pre-2018 requirements included provisions at § _____.101 that allowed federal department or agency heads to determine which specific activities or classes of activities are covered by the rule and whether certain requirements could be waived. This flexibility was allowed in recognition of the varying missions of the federal departments and agencies, the possibility that there may be superseding or alternative statutes or regulations governing their activities, and the possibility that a given situation requires either more stringent oversight (e.g., “sensitive research”) or reduced requirements (e.g., a public health emergency).

2. NPRM Proposals

The NPRM proposed to retain the Common Rule’s pre-2018 requirement that federal department or agency heads retain final judgment about the coverage of particular research activities under the Common Rule (§ _____.101(c)) and proposed an additional requirement that federal department or agency heads exercise their authority consistent with the principles of the *Belmont Report*.

The NPRM also proposed at § _____.101(d) that a department or agency may require additional protections for specific types of research it supports or conducts, or that is otherwise subject to regulation by the federal department or agency but not otherwise covered by the Common Rule. However, advance public notice would

be required when those additional requirements apply to entities outside of the federal department or agency itself. This latter requirement was intended to promote harmonization among federal agencies or departments, to the extent possible, and to ensure transparency between funding entities and the regulated community.

Finally, at § _____.101(i) the NPRM proposed to amend the criteria for a department or agency waiving the applicability of some or all of the provisions of the policy, by stating that the alternative procedures to be followed must be consistent with the principles of the *Belmont Report*. The addition of this provision was to make explicit the ethical basis underpinning how waiver decisions have and must be considered. The NPRM also proposed that such waivers be posted on a publicly accessible federal Web site.

3. Public Comments

Approximately 25 comments related to the NPRM proposals at § _____.101(c) and (i) and none on § _____.101(d). Comments received on these proposals generally expressed opposition to ever granting the authority to department or agency heads to retain final judgment as to whether a particular activity is covered by this policy, or to waive certain requirements, even though these provisions existed in the pre-2018 rule. These commenters were concerned about the potential for Common Rule departments and agencies to exclude certain activities for political purposes or for expediency, such as certain activities that might involve surveillance or criminal investigative aims. With regard to § _____.101(i), some commenters stated that reference to the ethical principles of the *Belmont Report* was too narrow. That is, one might rely on additional ethical considerations to evaluate the applicability of the regulations.

4. Response to Public Comments and Explanation of the Final Rule: Department or Agency Discretion About Applicability of the Policy

The final rule adopts the NPRM proposals in § _____.101(c). Thus, under § _____.101(c), department or agency heads retain final judgment as to whether a particular activity is covered by the Common Rule, and this judgment should be exercised consistent with the ethical principles of the *Belmont Report*. We note that under the pre-2018 requirements Common Rule departments and agencies retained final authority as to whether a particular human subjects research study conducted or supported by that

department or agency is covered by the Common Rule (§ _____.101(c)) and that authority continues under the final regulations, but with the new limitation that this judgment must be consistent with the ethical principles of the *Belmont Report*. This discretion provides important flexibility given the varying missions and policies of the many departments and agencies.

Although some commenters were opposed to ever granting departments or agencies the authority permitted by § _____.101(c), we believe requiring that these decisions be consistent with the principles of the *Belmont Report* is an approach that promotes accountability while still giving federal departments and agencies the necessary flexibility to achieve their respective missions.

The final rule in § _____.101(d) does not adopt the NPRM proposals, and instead retains the pre-2018 language. The NPRM proposed to modify § _____.101(d) to say that department or agency heads could require additional protections to research activities conducted or supported by federal departments or agencies, but that were not otherwise covered by the Common Rule. This language was intended as a clarification to the pre-2018 language. However, we determined that the term “additional protections” could potentially be confusing in that the activities at issue in this provision are those for which no Common Rule protections are required; thus the protections imposed by department or agency heads might be the only protections to which these activities are subject. We also note that departments or agencies conducting or supporting an activity subject to the Common Rule may require additional protections for human subjects.

The final rule also does not incorporate the NPRM proposal in § _____.101(d) that advance public notice must be provided when a department or agency head requires that the Common Rule, or part of it, be applied to research activities not otherwise subject to the rule. Upon further assessment, we decided that such a requirement could hinder the ability of a department or agency to move quickly in cases where the department or agency determined that additional protections are warranted.

Section _____.101(i) of the final rule adopts a majority of the NPRM proposals. As proposed in the NPRM, § _____.101(i) is modified to require that any alternative procedures adopted by departments or agency heads are consistent with the principles of the *Belmont Report*. Also as proposed in the NPRM, § _____.101(i) is modified to state

that, unless otherwise required by statute or executive order, notice of these alternative procedures must be forwarded to OHRP (or any successor office), or to the equivalent office within the appropriate federal department or agency. The pre-2018 rule only listed OHRP (or any successor office) as the office to which notices must be sent. This final rule modification is intended to ensure that if a non-HHS department or agency allows for alternative procedures, the appropriate office within that same department or agency receives notification. The final rule retains the pre-2018 requirement for the notice to also be published in the **Federal Register** or in such other manner provided for in department or agency procedures.

The final rule also adopts in § _____.101(i) the NPRM proposal to require that the waiver notice include a statement that identifies the conditions under which the waiver will be applied and a justification as to why the waiver is appropriate for the research, including how the decision is consistent with the principles in the *Belmont Report*.

Section _____.101(i) of the final rule does not include the NPRM proposal that would have required each federal department or agency conducting or supporting the research to establish on a publicly accessible federal Web site a list of the research for which a waiver has been issued. We decided that the rule's requirement to publish the waiver notice in the **Federal Register**, or in such other manner as provided in department or agency procedures, adequately ensures that the waiver notice will be available to the public without also requiring that such notices be listed on a federal Web site. We note that some departments, such as HHS, currently post such notices on their Web sites.

The final rule thus formally codifies in § _____.101(c) and (i) the general practice that the ethical standards articulated in the Belmont Report are the ethical standards that Common Rule departments or agencies will use in determining whether an activity is covered under this policy or whether to grant a waiver of the applicability of some or all of the provisions (unless otherwise required by law). The addition of the reference to the Belmont Report makes explicit the ethical basis underpinning how waiver decisions have and must be considered.

E. State and Local Laws That Provide Additional Protections for Human Subjects (§ _____.101(f))

1. Background and Pre-2018 Requirements

The pre-2018 rule specified that the policy does not affect any state or local laws or regulations that may otherwise be applicable and that provide additional protections for human subjects. The NPRM did not propose any changes to this statement. However, questions raised by public comments, as described below, led to some clarifications to the final rule.

1. Public Comments

Several public comments raised questions and concerns about the ability of tribal nations to require additional protections that might be needed for research involving American Indian/Alaska Native (AI/AN) populations.

One tribal government noted the documented mistrust of research by AI/AN people and communities, and advocated for specific provisions acknowledging the authority and role of tribal nations in overseeing research that happens on their lands and with their citizens. Additionally, this entity noted that tribal nations do not always have their own regulatory bodies for human subject research protections, expressing concern about external groups deciding what constitute risks and benefits for the community.

Other AI/AN Population concerns of commenters included:

- *Tribal (i.e., group) and individual consent for secondary research with biospecimens:* Commenters noted that group consent can occur and should inform the proposed changes in the rule. They also noted that broad consent for future, unspecified research use of biospecimens presents a challenge to the ongoing ability of both tribes and individuals to choose to remove their data from research, or to understand how their information is being used to benefit, or put at risk, themselves or others.

- *Tribal and individual consent for research with biospecimens or other data from people who are no longer alive:* AI/AN groups noted the need to address protections for biospecimens initially collected from living humans after those humans pass away.

- *Research oversight by tribal IRBs and other tribal regulatory bodies:* AI/AN groups raised concerns about the use of a single IRB in cooperative and multi-institutional research, which does not foster community-based governance and oversight of research that has the

potential to improve outcomes for tribal and minority populations.

- *Research oversight for categories of research and activities important in tribal contexts:* Commenters noted concerns about the proposed changes related to the exclusion of certain categories of activities (e.g., oral history, biography), addition of exempt categories of research (e.g., educational tests, surveys, interviews), and elimination of continuing review requirements for some studies because tribal research review often extends the scope of examination beyond individual-level protections to enact community-level protections important for maintaining the integrity of culturally significant information and practices. Changes to excluded and exempt categories of research and eliminating some continuing review requirements, especially where no clear mechanism for additional tribal oversight and input has been established, are a cause for concern for the AI/AN community.

2. Response to Public Comments and Explanation of the Final Rule: State and Local Laws That Provide Additional Protections

Consistent with the pre-2018 rule, this final rule retains the language in § _____.101(f) providing that the Common Rule does not affect any state or local laws or regulations that may otherwise be applicable and that provide additional protections for human subjects. However, the final rule adds clarifying language providing that the referenced state or local laws or regulations include tribal laws passed by the official governing body of an AI/AN tribe. Thus, if the official governing body of a tribe passes a tribal law that provides additional protections for human subjects, the Common Rule does not affect or alter the applicability of such tribal law. (Note that a similar change was also made to § _____.116(i) and (j) to provide the same clarification.) In addition, for purposes of the exception to the single IRB review requirement for cooperative research, relating to circumstances where review by more than a single IRB is required by law, § _____.114(b)(2)(i) specifies that tribal law is to be considered in assessing whether more than single IRB review is required by law.

F. Research Covered by This Policy Conducted in Foreign Countries (§ _____.101(h))

1. Background and Pre-2018 Requirements

The pre-2018 requirements at § _____.101(h) stated that when research covered by this policy takes place in foreign countries, procedures normally followed in those countries to protect human subjects may differ from those set forth in this policy. The previous rule cited the Declaration of Helsinki, as amended in 1989, as an example of internationally recognized ethical standards that a foreign country might use as its ethical standard. The rule provided that if a department or agency head determined that procedures prescribed by the institution in the foreign country afforded protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy.

2. NPRM Proposal

The NPRM proposed to remove the specific reference to the Declaration of Helsinki in this provision. A concern with providing a specific example of an internationally recognized ethical document is that such a document is subject to change independent of Common Rule departments and agencies, and therefore could be modified to contain provisions that are inconsistent with future U.S. laws and regulations.

3. Public Comments

A few comments addressed the removal of the reference to the Declaration of Helsinki. These comments were equally divided between those opposed and those supportive or generally supportive. Those opposed feared that the removal of the reference would suggest that the Declaration of Helsinki does not apply and that it was cited in the pre-2018 requirements as an example, not as an equivalent replacement for the Common Rule. These commenters also noted that the United States had refused to sign on to some recent revisions to the Declaration. One organization commented that it would have been useful for the NPRM to address the issue of equivalent protections for U.S.-funded research conducted in foreign countries, as that might have addressed ongoing concerns about the use of alternative systems of protections when research is conducted outside the United States. Those supportive of

removing the reference to the Declaration of Helsinki agreed with the arguments laid out in the NPRM and felt that it was judicious to not align U.S. regulations with other standards because those standards are likely to change, perhaps in ways inconsistent with U.S. policy.

4. Response to Public Comments and Explanation of Final Rule: Removing the Reference to the Declaration of Helsinki

The final rule adopts the NPRM proposal. Although the pre-2018 requirements cited the Declaration of Helsinki as an example of internationally recognized ethical standards that a foreign country might use as its ethical base, we note that providing a specific example of an internationally recognized ethical document is concerning because such a document is subject to change independent of Common Rule department or agency policies, and therefore might be modified in ways that create standards that are inconsistent with U.S. laws and regulations.

G. Harmonization of Department and Agency Guidance (§ _____.101(j))

1. Background and Pre-2018 Requirements

Each Common Rule department and agency and the Food and Drug Administration (FDA) are authorized to issue its own guidance with regard to interpreting and implementing the regulations protecting human subjects. That guidance may differ substantially across entities. Currently, multiple efforts are underway to address variation in guidance across the Federal Government, but no regulatory requirement exists for departments and agencies to consult with other departments before issuing a policy, to the extent appropriate. As a result, interdepartmental communication has been at times uneven, leading to potentially avoidable inconsistencies. The Common Rule departments and agencies have procedures for sharing proposed guidance before it is adopted, and these procedures have generally been successful. Additionally, FDA and OHRP have worked closely to ensure harmonization of guidance to the extent possible, given the differing statutory authorities and regulatory missions. Also, as mentioned earlier in section I.B., the 21st Century Cures Act was enacted in December 2016. Among other things, it requires that the Secretary of HHS, to the extent practicable and consistent with other statutory provisions, harmonize the differences

between 45 CFR part 46, subpart A, and FDA's human subject regulations.

2. NPRM Proposal

Responses to questions in the 2011 ANPRM about the need for harmonization of guidance across Common Rule departments and agencies reflected widespread support for such efforts. Several commenters acknowledged the difficulty of getting all Common Rule departments and agencies to agree on all issues, as each has a different mission and research portfolio. However, they encouraged seeking harmonized guidance whenever possible. Thus the NPRM proposed that the regulations contain language requiring consultation among the Common Rule departments and agencies for the purpose of harmonization of guidance, to the extent appropriate, before guidance on the Common Rule is issued, unless such consultation is not feasible. The NPRM requested public comment on whether the proposed language would be effective in achieving greater harmonization of department and agency guidance, and if not, how it should be modified.

3. Public Comments

Approximately 60 comments were received regarding this proposal, and they were almost equally divided for and against it, although some of those opposed thought it did not go far enough to achieve the intended goal. Those who supported the proposal, either fully or partially, cited concerns they have as institutions, investigators, or IRBs in navigating different sets of regulations and different department or agency guidance documents. As noted above, among those who opposed the proposal, some expressed concern that the proposed language about harmonization did not go far enough. That is, they thought the language should mandate harmonization in guidance across Common Rule departments and agencies. These commenters felt that without a requirement to harmonize, federal departments and agencies will continue with business as usual and policy and guidance will continue to differ, creating complexity in the research environment. For example, one large research university emphasized the importance of harmonization across federal departments and agencies regarding guidance on the protections of human subjects for investigators, IRB administrators, and human subjects, and felt that the proposed language in the Common Rule NPRM might be ineffective in harmonizing agency

guidance. Several commenters emphasized the need, in particular, for greater harmonization between the Common Rule and FDA requirements, and between the Common Rule and the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA; Pub. L. 104–191).

Others were concerned that this provision would, in effect, mean that Common Rule departments and agencies issue fewer guidance documents because of lengthy internal government review and approval processes.

4. Response to Public Comments and Explanation of the Final Rule: Harmonization of Guidance

We believe there is a compelling case for as much consistency as is possible regarding guidance on the protections of human subjects. As such, the final rule implements the NPRM proposal at § _____.101(j). The final rule creates a requirement that guidance should be issued only after consultation among the Common Rule departments and agencies, while also permitting guidance to be issued without such consultation when it is not feasible. The proposal recognizes that harmonization will not always be possible or desirable given the varied missions of the departments and agencies that oversee the protection of human subjects and differences in their statutory authorities.

We note that some public comments expressed concern about the acceptable degree of variability among departments and agencies and encouraged attention to these concerns when diverging on guidance. The departments and agencies that oversee the protection of human subjects have a variety of missions and functions, including regulatory agencies and agencies that conduct and support research. In addition, in some cases, statutory differences among the departments and agencies have resulted in different regulatory requirements and guidance. They also oversee very different types and phases of research and thus may have reasonable justifications for differences in guidance. However, we agree that efforts should be made to issue collective guidance when possible and feasible and in a timely manner. We do not believe that this provision will result in the issuance of less guidance, because it largely codifies what has been the working practice among Common Rule departments and agencies up to this point.

H. Compliance Dates and Transition Provisions of the Final Rule (§ _____.101(l))

1. NPRM Proposal

In the NPRM, we shared the expectation that both the effective date of the final rule (meaning the date that the regulatory text is published in the Code of Federal Regulations) and the general compliance date of the final rule (meaning the date after which, as a general matter, regulated entities must comply with this rule) would be 1 year after publication of the final rule in the **Federal Register**. The NPRM also proposed two exceptions that would provide different compliance dates for two provisions. The first proposed exception pertained to the NPRM's proposal that the Common Rule be extended to cover all biospecimens regardless of identifiability. The second proposed exception pertained to the NPRM's proposal that a single IRB would be responsible for certain multi-institutional clinical trials, also described as cooperative research. The NPRM proposed that both of these provisions would have compliance dates of 3 years after publication of the final rule in the **Federal Register**. The intent behind this proposed delay was to enable institutions to develop institutional policies and procedures necessary to implement these new requirements. The NPRM sought public comments about the advisability of this proposed approach as well as possible alternatives.

The preamble to the NPRM also discussed the option for institutions or investigators to implement provisions of the final rule anticipated to provide additional regulatory flexibilities voluntarily 90 days after publication of the final rule in the **Federal Register**. This proposed approach was intended to enable institutions or investigators to gain the benefit of revisions to the Common Rule as soon as possible. The NPRM proposed a 90-day timeframe for this flexibility to enable the Common Rule departments and agencies time to develop the documents and tools needed to assist institutions in implementing the rule's regulatory flexibilities (e.g., the Secretary's broad consent templates) and the Secretary's list of privacy safeguards.

The NPRM also explained that the proposed extension of the Common Rule to clinical trials that are not directly funded by a Common Rule department or agency, but that are conducted at an institution that receives funding from a Common Rule department or agency for other human subjects research, would not apply to an

institution until the institution had received federal funding for nonexempt research in an award made after the effective date of the final rule.

The NPRM also proposed that ongoing human subjects research initiated before the effective date of the final rule would not need to comply with particular regulatory requirements.

In addition, the NPRM proposed a grandfather clause for research involving the use of biospecimens collected before the compliance date. This clause applied to the provision that would extend the Common Rule to cover all biospecimens, regardless of identifiability. Specifically, the NPRM proposed that such research would not need to comply with the final rule if any research uses of the biospecimens occurred only after removal of any individually identifiable information.

2. Public Comments

A majority of comments received on the effective dates opposed the NPRM's proposal that only nonidentified biospecimens would be grandfathered. Others commented on the proposed 3-year compliance date for the proposed expansion of the definition of human subjects to all biospecimens, regardless of their identifiability. In Section III, we discuss the determination not to finalize the biospecimen provisions, which addresses these comments. Some commenters expressed support for the general compliance date, as well as the delayed compliance date for the cooperative research provision.

Many commenters expressed the viewpoint that regulated entities would need to invest significant time and resources before they would be able to comply with the changes to the Common Rule proposed in the NPRM. Some commenters (including an academic institution and a hospital association) noted that such investments would have implications not only for research operations, but also for clinical care. Some commenters also noted their concern that 1 year was not enough time for institutions to comply with the large number of new and different regulatory requirements proposed in the NPRM and that such changes would necessitate significant modifications to their research and clinical enterprises and might impose hardships on IRBs, IRB staff, institutional leadership, and the regulated research community. Several commenters explained that the proposed 1-year general compliance period would not provide enough time to update written IRB procedures (which are required under the Common Rule), disseminate such procedures, update related documents (e.g., forms),

and develop appropriate training materials. One of these commenters explained that accredited institutions will need time for accrediting bodies to align their accreditation standards with the revised regulatory standards or risk conflicts between meeting proposed regulatory standards and losing accreditations.

Other commenters recommended 2-year or 3-year general compliance dates (including some that recommended permitting institutions to comply earlier), noting that compliance would be particularly challenging for institutions with smaller research programs. At least one commenter argued that the 3-year compliance date for the proposed cooperative research provision was inadequate given the significant costs and time that would be associated with establishing reliance agreements between collaborating research sites, maintaining required documents at the reviewing IRB, and ensuring that applicable laws were followed. At least one commenter argued that the proposed effective and compliance provisions left institutions with the discretion to remove studies from the oversight of the Common Rule without establishing any protective standards for doing so.

One group representing multiple professional societies stated that the efficiencies achieved by eliminating protracted negotiations concerning consent forms and institutional responsibilities will far outweigh any upfront costs incurred through implementation of this policy, and advocated for a faster timeframe for compliance than the proposed 3 years from the time of final publication: 1 year for clinical trials and 2 years for research studies. Another commenter echoed these views.

We did not receive many comments concerning the proposal to allow institutions to implement provisions offering regulatory flexibilities before the compliance date.

3. Response to Comments and Explanation of the Final Rule: Compliance Dates and Transition Provisions

The effective date and compliance dates included in this final rule are intended to meet the same general objectives as those described in the NPRM. Nonetheless, the approach adopted in the final rule is different in certain respects from the approach proposed in the NPRM.

As a general matter, none of the proposed dates in the NPRM related to research with biospecimens will be implemented because the proposal

included to extend the Common Rule to research with all biospecimens, regardless of identifiability, is not being implemented.

The final rule adopts an effective date and a general compliance date of 1 year from publication of this final rule in the **Federal Register**. During this 1-year timeframe, institutions will be able to revise forms, documents, and practices for consistency with the revisions reflected in this regulation. Although we recognize the work associated with compliance, we concluded that 1 year is a reasonable and adequate timeframe. We note that ongoing research studies that were initially approved by an IRB, waived pursuant to § _____.101(i), or determined to be exempt before January 19, 2018 will not be required to comply with the changes reflected in this final rule.

Section 101(l) describes the regulatory requirements that will apply to specific categories of research once the final rule goes into effect. For clarity, § _____.101(l) begins by defining two sets of requirements. First, as set forth in § _____.101(l)(1), the pre-2018 rule is described as the “pre-2018 Requirements”, which refers to the Common Rule as published in the 2016 edition of the Code of Federal Regulations. As described below, certain ongoing research may be subject to these requirements.

Section 101(l)(3)–(4) describes the different regulatory requirements that apply to different categories of research. For clarity and in order to have an easy-to-implement standard, these categories are generally based upon the date the research was initially approved by an IRB, waived pursuant to § _____.101(i), or determined to be exempt.

The first category of research, described in § _____.101(l)(3), applies to research initially approved by an IRB, waived pursuant to § _____.101(i), or determined to be exempt before January 19, 2018. We believe that such research (e.g., research for which an initial determination was made before the effective date of this final rule) should, as a general rule, be able to follow the same set of standards throughout the entire course of the research. The intent is to minimize burdens associated with research conducted over a period of time and to avoid a requirement that such research be subject to two sets of rules during the lifetime of the research. For that reason, this regulation adopts as a default rule, set forth in § _____.101(l)(3), that research initially approved by an IRB, waived pursuant to § _____.101(i), or determined to be exempted before January 19, 2018 (the effective date of this final rule) will not

be subject to this final rule but will continue to be subject to the requirements of the Common Rule in place before January 19, 2018.

However, we also recognize that institutions may prefer, for a particular study initiated before to January 19, 2018, to comply with this final rule given the benefits that it offers and for administrative simplicity such as common regulatory requirements across an institution. Thus, § _____.101(l)(3) permits institutions engaged in ongoing research that was initially approved by an IRB, waived pursuant to § _____.101(i), or determined to be exempted before January 19, 2018, to choose, on a study-by-study basis, whether such research will be subject to the pre-2018 requirements (the rule in place before January 19, 2018, or the final rule. This is an exception and is offered as an additional flexibility to regulated entities. If an institution engaged in such research determines that it prefers to comply with the final rule for a particular research study, such research will be subject to the final rule if the institution formally makes a determination that the final rule will apply to such research and an IRB documents the decision made by the institution. If these requirements are not met or if the institution makes no decision, the pre-2018 requirements will apply to such research.

The second category of research, described in § _____.101(l)(4), applies to *research initially approved by an IRB, waived pursuant to § _____.101(i), or determined to be exempted on or after January 19, 2018*. Because such research does not begin and is not conducted until after the general compliance date of this final rule, this category of research is subject to the final rule throughout its lifetime.

A single IRB requirement for cooperative research has been adopted in § _____.114(b) of this final rule. As set forth in § _____.101(l)(2), this final rule adopts the proposed 3-year compliance date for this requirement to afford affected institutions sufficient time to prepare for and implement this requirement (e.g., developing institutional policies and procedures).

Although we understand the concerns expressed concerning the complexities that will be involved in establishing reliance agreements to satisfy the cooperative research provision adopted in this final rule, this final rule reflects the conclusion that a 3-year compliance date is adequate for this provision, based on our belief that this provision will offer significant benefits to institutions, particularly as the regulated community becomes

accustomed to this requirement. In addition, we believe it is likely that the institutional policies, procedures, and standard documents needed to implement this regulatory provision will, over time, become increasingly standardized, which will significantly minimize the burden on institutions associated with this requirement. So long as all other regulatory requirements are satisfied, institutions may use a single IRB to oversee cooperative research even before this compliance date occurs with respect to any research that institutions believe may benefit from this approach.

This final rule does not adopt the proposal mentioned in the preamble to the NPRM to permit institutions and

investigators to voluntarily implement provisions in the final rule that allow additional flexibilities 90 days after publication of the final rule. We determined that the approach adopted at § _____.101(l)(3), and described above, offers institutions and investigators similar advantages with respect to the conduct of ongoing research, while providing greater clarity and more simplicity concerning which set of regulatory requirements apply to particular studies.

We disagree with the comment that the proposed timelines enable institutions to remove their studies from the oversight of the Common Rule without establishing appropriate standards for doing so. The final rule

does not enable institutions to opt out of compliance with the Common Rule. The effective dates do afford institutions the discretion to choose, on a study-specific basis whether existing research should comply with the Common Rule in place when the research was initiated (the pre-2018 requirements) or this final rule (the 2018 requirements). This flexibility is offered only for certain ongoing research studies that were initially approved, determined to be exempt, or subject to a § _____.101(i) waiver before the effective date of this final rule.

To explain the approach adopted in this final rule, the following chart describes the standards that apply to different categories of research:

| Research Study Initiation Date | Standards |
|--|---|
| Research initially approved by an IRB, waived pursuant to § _____.101(i), or determined to be exempt before January 19, 2018. | These studies are by default subject to the pre-2018 rule (the Common Rule as published in the 2016 edition of the Code of Federal Regulations). However, an institution engaged in such research may choose to comply with the final rule (2018 requirements) for such a study if the institution makes a determination to apply the final rule to the study and an IRB documents this determination. |
| Research initially approved by an IRB, waived pursuant to § _____.101(i), or determined to be exempt on or after January 19, 2018. | These studies are subject to the final rule (2018 requirements). |

I. Severability (§ _____.101(m))

A severability clause has been added as § _____.101(m), providing that if any provision of this final rule is held to be unenforceable in one set of circumstances, it should be construed to give maximum effect to the provision as applied to other persons or circumstances. Similarly, if a provision is held to be invalid or unenforceable, that provision should be severable from, and have no impact on the application of, the remainder of the rule. This provision reflects our intention regarding the way that this final rule, and the pre-2018 rule, should be construed and interpreted and is meant as a clarification.

III. Definitions for Purposes of this Policy (§ _____.102)

The final rule revises and adds new definitions of key terms for the purposes of this policy, as summarized below. Some of the changes are made to clarify new provisions that appear elsewhere in the final rule. In addition, the definitions have been placed in alphabetical order to facilitate searching by the reader. The definitions of institution, IRB, and IRB approval are unchanged but appear in a different place in the regulatory language.

A. Certification (§ _____.102(a))

Although “certification” was defined in the pre-2018 requirements, as was proposed in the NPRM, the final rule clarifies that notification by the institution that a proposed research study has been reviewed and approved is made to the supporting “federal” department or agency and that it might be a component of the agency or department that is notified rather than the entity as a whole. This clarification relates to the change included in the final rule at § _____.102(d) regarding the definition of “federal department or agency” that clarifies that this phrase refers to the department or agency itself, not its bureaus, offices, or divisions. There were no public comments on this clarification.

B. Clinical Trial (§ _____.102(b))

1. Background and Pre-2018 Requirements

The pre-2018 rule did not include a definition of “clinical trial.”

2. NPRM Proposal

The NPRM proposed defining “clinical trial,” for purposes of this policy, as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the

effects of the interventions on biomedical or behavioral health-related outcomes. In addition, the NPRM requested public comment on whether the proposed definition should include additional explanation of what is encompassed by the term behavioral health-related outcomes.

3. Public Comments

Approximately 20 comments explicitly addressed the definition of “clinical trial” included in the NPRM. All expressed concern that the proposed definition encompassed more activities than intended, given the NPRM discussion that the definition was intended to cover the riskiest research. Commenters who responded asked for some type of clarification, either in guidance or in the regulatory language itself about the term “behavioral health-related outcomes.” One commenter noted that clinical trials involving activities such as behavioral interventions, psychotherapy, or skills training, for example, should be included in the proposed regulations of clinical trials in a risk-based manner, as for nonbehavioral studies. That is, greater oversight would be required for trials with a higher potential degree of risk, regardless of what type of trial. The commenter noted that certain populations for whom behavioral health research is conducted are high risk by

nature, such as chronically suicidal individuals. Another commenter asked that the regulatory language include additional explanation of what is encompassed by the term “behavioral health-related outcomes” because practitioners and researchers conceptualize the term differently.

4. Response to Comments and Explanation of the Final Rule Definition of Clinical Trial

The final rule at § _____.102(b) adopts the NPRM definition of “clinical trial,” which is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. We generally expect that this definition will be applied harmoniously with the definition of clinical trial recently promulgated in the ClinicalTrials.gov final rule.¹⁷

In response to public concerns about an overly expansive definition of “clinical trial” given the importance of that definition to the proposed extension of the rule to clinical trials previously not covered by the rule, we have eliminated that proposed expansion of coverage in this final rule. As such, the definition that appears in the final rule will only be relevant to the requirement for posting of consent forms for clinical trials conducted or supported by Federal departments or agencies (§ _____.116(h)). It should be appropriate for that relatively narrow regulatory purpose.

C. Department or Agency Head and Federal Department or Agency/Institutions (§ _____.102(c) (d) and (f))

1. Background and Pre-2018 Requirements

The pre-2018 rule provided a definition of “department or agency head.” The phrase appeared repeatedly throughout the regulations.

2. NPRM Proposals

New definitions of “department or agency head” and “federal department or agency” were proposed in the NPRM to clarify requirements related to federal department and agency discretion in applying the policy to their funded or conducted research.

3. Public Comments

There were no comments directly related to these proposed revisions.

4. Explanation of the Final Rule: Definition of Department or Agency Head, Federal Department or Agency, and Institution

The final rule adopts the NPRM proposals to provide new definitions of “department or agency head” and “federal department or agency,” which appear at § _____.102(c) and (d). “Department or agency head” at § _____.102(c) refers to the head of any federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any federal department or agency to whom authority has been delegated. To add clarity to the definition found in the pre-2018 regulations, the example of the Secretary of HHS was inserted.

The final rule provides at § _____.102(d) a definition of “federal department or agency” in order to avoid confusion as to whether this phrase encompasses federal departments and agencies that do not follow the Common Rule. The definition also clarifies that this phrase refers to the department or agency itself, not its bureaus, offices, or divisions. This is consistent with the historical interpretation of the Common Rule. Related to this, the definition of “institution” was changed at § _____.102(f) in the final rule to clarify that departments can be considered institutions for the purposes of this policy. The final rule provides examples of what is intended by this definition: HHS, the Department of Defense, and the Central Intelligence Agency.

D. Human Subject (§ _____.102(e))

1. Background and Pre-2018 Requirements

The pre-2018 rule defined “human subject” as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. Further, the pre-2018 rule asserted that “private information” was considered individually identifiable if the identity of the subject is or may readily be ascertained by the investigator or is associated with the information.

Thus, in cases where no intervention or interaction with an individual occurred, determining the meaning of “identifiable” and “readily ascertainable” was central to determining whether human subjects were involved in a research activity

covered by the pre-2018 rule. Under the pre-2018 rule, provided the data were collected for purposes other than the currently proposed research, it was permissible for investigators to conduct research on biospecimens and data that had been stripped of all identifiers or coded without obtaining consent because the nonidentified biospecimens and data did not meet the regulatory definition of a human subject.

Moreover, “private information” was not considered to be identifiable under the pre-2018 rule if the identity of the subject is not or may not be “readily ascertained” by the investigator from the information or associated with the information.

If the definition of “human subject” was met, together with the other significant requirements, the pre-2018 rule required IRB review and approval unless the study was exempt. IRB waiver of informed consent was allowable under the Common Rule, if the research study satisfied the criteria for waiver of informed consent.

2. NPRM Proposal

The NPRM proposed to revise the definition of “human subject” to include research in which an investigator obtains, uses, studies, or analyzes biospecimens, regardless of identifiability. Thus, the focus of this proposal was to require informed consent for research involving biospecimens in all but a limited number of circumstances. In addition, the NPRM proposal would have still permitted IRBs to waive the requirement for informed consent for research use of biospecimens, but the requirements for approval of such waivers would have been very strict, and such waivers would have occurred only in rare circumstances (see Section XIV on waiver of informed consent). This expansion of the definition of “human subject” would also have triggered other provisions of the NPRM relating to the use of biospecimens, including security measures. Thus, it was a complex and far-reaching proposal.

The NPRM also offered two alternative proposals to altering the definition of “human subject,” both of which maintained “identifiability” as a major aspect of determining applicability of the Common Rule to biospecimens. The public was asked to comment on which of the three proposals achieved the most reasonable tradeoff between the principles of autonomy and beneficence.

Alternative Proposal A would have expanded the definition of “human subject” to include whole genome sequencing (WGS). Under this

¹⁷ HHS. Clinical Trials Registration and Results Information Submission. 81 FR 64981. (Sept. 21, 2016). Retrieved from <https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission>

alternative, WGS would have been considered to be the sequencing of a human germline or somatic biospecimen with the intent to generate the genome or exome sequence of that biospecimen.

Alternative Proposal B would have expanded the definition of “human subject” to include the research use of information that was produced using a technology applied to a biospecimen that generated information unique to an individual. In such a case, it was foreseeable that, when used in combination with publicly available information, the individual could have been identified. Information that met this standard would have been referred to as “bio-unique information.”

The NPRM also asked the public to comment on whether the rule should include a definition of “biospecimen” and whether the rule should be clearer and more direct about the definition of “identifiable private information.”

The NPRM also proposed some minor changes to the wording of the definition of “human subject” merely to clarify how the word “obtains” has been interpreted.

The NPRM did not propose any major substantive modifications to the descriptions of “private information” and “identifiable private information” found in the pre-2018 rule. However, the NPRM proposed clarifying language with regard to “private information” and “identifiable private information.” The pre-2018 rule used the example of a medical record as constituting private information. The NPRM added the example of a biospecimen in keeping with the proposal to expand the definition of “human subject” to include all biospecimens. In addition, the NPRM proposed adding the words “shared or” to the description of what constitutes “private information,” for the purpose of expanding the scope of the information that would be described by that term.

In addition, the NPRM asked for public comment about whether a different identifiability standard would be appropriate. One alternative discussed was to adopt the term “identifiable private information” with the term used across the Federal Government: “personally identifiable information” (PII). PII refers to information that can be used to distinguish or trace an individual’s identity (such as name, social security number, biometric records) alone, or when combined with other personal or identifying information that is linked or linkable to a specific individual, such as date and place of birth, or mother’s maiden name. It acknowledged that

replacing “identifiable private information” with “PII” would increase the scope of what is subject to the Common Rule. Subsequent to the release of the NPRM, the Office of Management and Budget (OMB) updated government-wide guidance for managing personally identifiable information.¹⁸

Related to this issue, the NPRM noted new legislative developments, specifically the Newborn Screening Saves Lives Reauthorization Act of 2014 (Pub. L. 113–240), signed into law in December 2014. The law required consent for federally funded research with newborn dried blood spots and prohibits IRBs from waiving consent. These changes were to be effective until updates to the Common Rule were promulgated, and applied whether or not the newborn dried blood spots would be considered “identifiable private information” under the regulatory definition.

3. Public Comments

a. Public Comments on the Primary NPRM Proposal

The proposal regarding revising the definition of “human subject” to include biospecimens regardless of identifiability was commented on by almost 50 percent of the commenters. Others commented on the effects such an expansion would have on consent requirements, the ability to waive consent, and the applicability of exemptions and exclusions. The vast majority of commenters who addressed this expansion (80 percent) were opposed to it for a variety of reasons, particularly because of the implications of this change for requiring consent for most research uses of biospecimens that were collected as part of clinical care.

A majority of these commenters responded as members of the general public (that is, not explicitly affiliated with a specific organization or institution) or as patients (including family members of patients). Patients tended to oppose these proposals, focusing on the additional and more stringent criteria for waiver of informed consent because they believed the effects of the proposals would be that many people would not provide consent, thus restricting access by investigators to biospecimens, which

would in turn slow research.

Investigators also expressed concerns about the negative impact on research. Organizations and institutions with some affiliation with the research enterprise expressed opposition to this suite of proposals as well, but for different reasons, as discussed further below.

Most support for the expansion of the definition of “human subject” to encompass all biospecimens and its implications for consent, waiver of consent, and exempt research came from members of the public who argued that they wanted to always be consulted before their biospecimens were used in research, without exception. Within this group, a strong majority opposed the comprehensive biospecimen-related proposals because they were uncomfortable with the concept of broad consent (as discussed in Section IV of this preamble) to any future research use of those biospecimens and the existence of any type of over-ride by an IRB of the requirement to obtain informed consent.

Many of the commenters supporting the expansion stated that it would respect autonomy by requiring that nearly all research with biospecimens be subject to IRB review and informed consent requirements. Others expressed distrust of the medical and scientific enterprises. One member of the public felt that consent should be required for government research seeking to use an individual’s biospecimens, and that researchers should be required to inform the individual of the “who, what, how, and why” of the desired research.

Many of those who expressed support for this proposal also indicated that they felt it important for their biospecimens to be anonymized in research activities. For example, a member of the public with experience in biobanking expressed a willingness to consent to the use of his biospecimens to advance science, but called for a mechanism to inform the public about such research use even if some individuals might decline to participate. The commenter stressed the importance of respecting the individual’s right to know and refuse, citing privacy concerns and stressing the importance of anonymity of biospecimens to protect individuals from potential negative consequences.

Still others supported the expansion of the definition of “human subject” to include all biospecimens because of a desire to receive research results or to financially profit from discoveries, implying that retaining identifying information with biospecimens would enable both of these possibilities. Some who felt there is an entitlement to

¹⁸ CIRCULAR NO. A–130 Memorandum to: The Heads of Executive Departments and Agencies Subject: “Managing Information as a Strategic Resource”. July 7, 2016. See especially, *Appendix II: Responsibilities for Managing Personally Identifiable Information*. Retrieved from <https://www.federalregister.gov/documents/2016/07/28/2016-17872/revision-of-omb-circular-no-a-130-managing-information-as-a-strategic-resource>

financially profit from discoveries described biospecimens as personal property. For example, one commenter compared the use of an individual's biospecimens without consent to one party illegally taking another's property such as land, a house, or an arm.

Several commenters noted that medical services should not be allowed to be contingent upon a person's consent to use of their leftover biospecimens for research despite the fact that this was not proposed in the NPRM. In fact, the pre-2018 rule states that informed consent must include a statement that "refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled" and that element appears in the final rule as well.

For example, one commenter indicated that patients should be informed and be given the opportunity to consent to the use of their body tissues, and if one declines consent, the individual should not be denied treatment or receive diminished care. In other words, they felt that consent should never be a condition of treatment.

The reasons for opposing the expansion of the definition of "human subject" to include all biospecimens were numerous, including: the feasibility of obtaining broad consent in a clinical setting; the costs of obtaining, tagging, and tracking consents given the low risk nature of the research in question; allowing autonomy to trump beneficence and justice; insufficient evidence of risk or public concern about the issue; the fact that it would result in fewer specimens collected from fewer sources, with adverse implications for rare diseases and for justice; the idea that requiring all biospecimens to remain identified poses greater privacy and confidentiality risks than the current system; and overall negative impacts on research.

Many expressed concern about the number of biospecimens that might no longer be available for research, not out of concern that individuals would decline to have their leftover tissue used in research, but rather because many hospitals and medical providers might decline to enact the expensive consent and tracking system that the NPRM envisioned. Some commenters were concerned that this would then limit the heterogeneity of biospecimens obtained and stored, as community hospitals and clinics might opt out of participating in such collections.

Several comments suggested that for academic medical centers where a large amount of research is conducted, research activities often do not result in

profits, and that the proposed policies would come at great costs to institutions already struggling to financially sustain a healthy research enterprise. For example, one commenter noted that the NPRM proposal would require additional resources to obtain consent, which would hinder smaller institutions with fewer staff or resources available in their ability to contribute to scientific and medical research, and limit the opportunities for patients at these facilities to participate in research. The commenter also pointed out that academic institutions rarely receive significant financial gain from their research, and institutions sometimes share biospecimens, which can be valuable in research, especially in the case of uncommon and poorly understood diseases. Thus, this commenter expressed concern that biospecimens might not be available for research given the requirements of the proposed policy.

Many members of the public with rare diseases commented on how research into their specific diseases might be affected should the NPRM proposal be finalized. For example, several commenters expressed interest in the proposed rule because they or a family member had been diagnosed with a desmoid tumor, which are often limb threatening and sometimes life threatening. Research using tissue blocks is critical to determine how to treat these tumors, which are rare and can vary among patients. The commenter felt that the proposed rule would make desmoid tumor research virtually impossible by reducing access to the already low number of tissue blocks available for research.

More than one academic medical center asserted that there was a lack of evidence that patients value their autonomy over the potential for innovative diagnostics, treatments, cures, or preventative interventions that could result from research with leftover biospecimens, and called for empirical research on whether patients, patient advocacy groups, and the general public value autonomy (in the form of written consent for research use of nonidentified biospecimens) above other values when explained in light of potential impact on medical advances.

Some public commenters pointed out the illogic of treating biospecimens differently from information for the purposes of defining what constitutes a human subject. For instance, one professional organization composed of investigative pathologists and dozens of individual pathologists around the country noted that there are several areas in which the NPRM proposes

treating biospecimens differently from identifiable information unjustifiably since both create the potential for identification of the donor and a potential negative impact on the individual and their family, such as employment or insurance discrimination, embarrassment, or stigmatization. That organization noted that no empirical evidence has been provided to indicate either that biospecimens pose a risk greater than that posed for identifiable information or that the public is more concerned about the use of biospecimens compared to the use of identifiable private information.

One member of the public asserted that the research use of leftover biospecimens in medical research poses less of a privacy risk to individuals than market research that analyzes one's attitudes, words, and behaviors and is used to generate commercial profit.

Several commenters noted that the proposed expansion of the definition of "human subject" creates a cascade of consequences throughout the rule that are overly complex and unnecessary given the minimal risk of such research.

Other commenters suggested that the NPRM proposals would have negative impacts on the advancement of precision medicine. For example, a research university felt that mandating consent for de-identified biospecimens would impair the ability to achieve precision medicine for all. The commenter asserted that to offer care tailored to the needs of each individual based on understanding how each person is affected by disease requires understanding differences in the origins and manifestations of disease in individual patients who differ in genetics and environmental exposures. The commenter felt that restricting access to nonidentified biospecimens would violate the principles of justice and beneficence because many health care facilities serving under-represented minorities and economically-disadvantaged individuals, particularly those in rural settings, might not have the financial resources to obtain and track consent. As a result, medical research therefore might represent a skewed population of individuals receiving care at large, research intensive referral centers. In addition, the commenter felt that compliance would impose an onerous and expensive bureaucratic burden that would result in many institutions no longer collecting and using these critically important specimens with the net effect of thwarting efforts to provide precision medicine for all citizens.

Many commenters expressed the opinion that the existing regulatory framework is adequate and that current practices should be maintained, stressing that the research use of nonidentified data or biospecimens involves minimal or low risk to the research subject. Furthermore, several commenters noted that, although it is theoretically plausible to identify a person based on their biospecimen, the likelihood remains remote enough to argue against the presumption that the sources of all biospecimens are identifiable and cited a study showing that the risk of re-identification from a system intrusion of databases was only 0.22 percent.¹⁹ Other commenters noted that the existing definition of human subject is sufficient because once a biospecimen becomes identifiable in research, such research is considered to involve human subjects and therefore IRB review and consent or waiver of consent would be required. They argued that the current policy works and there has been no evidence provided that it needs to be fixed.

The NPRM specifically asked whether the final rule should include a definition of “biospecimen” to assist the regulated community in understanding what types of activities might fall under the rule. Approximately 100 comments answered this question. A majority of these comments did not provide a suggestion for how biospecimen should be defined, but suggested that the Federal Government convene panels and solicit input from governmental and nongovernmental experts.

One university emergency medical department suggested including in this definition biological samples from human subjects which contain DNA and are being obtained for the purpose of medical analysis and provided examples of biospecimens which would fall under this definition, including excised tissue (fresh, fixed, or paraffin embedded), whole blood, urine (when hematuria is known to exist), and saliva among others. The commenter also provided examples of biospecimens which would not fit in this definition, including serum or plasma, urine (when no hematuria is known to exist), and processed tissues where the DNA has been removed as a part of the processing.

¹⁹ Kwok P, et al. Harder Than You Think: A Case Study of Re-Identification Risk of HIPAA-Compliant Records. NORC at The University of Chicago and Office of the National Coordinator for Health Information Technology. 2011. Retrieved from <http://www.amstat.org/meetings/jsm/2011/onlineprogram/AbstractDetails.cfm?abstractid=302255>.

Others indicated that the definition of biospecimen used by the National Cancer Institute²⁰ seemed appropriate and workable for this rule.

A majority of comments on the definition of “biospecimen” asked for explicit clarification on how certain biospecimens would be treated under the rule. Several comments asked whether microbiology biospecimens would be considered covered under the NPRM proposal. One research university requested specification that biologic material of organisms that use human biospecimens merely as a host (e.g., bacteria, viruses, fungi) not be considered to involve human subjects.

The NPRM also asked whether covering only biospecimens that include nucleic acids would be a reasonable definition. A majority of those who responded to this said it would not be a good line to draw. One commenter specifically noted that the presence of nucleic acids does not guarantee re-identification.

b. Public Comments on Alternative NPRM Proposals A and B

Some of the alternative NPRM proposals were partly based on the premise that biospecimens could at some point become readily identifiable as a result of increasingly sophisticated technology. Many public commenters stated that a better approach to protecting privacy than requiring consent is to impose sanctions against investigators who aim to or do re-identify biospecimens without authorization by an IRB or other body. Such an approach, they said, would be less onerous for the entire enterprise, and if accompanied by clear guidance from funding agencies, would do more to protect privacy and guard against potential harms to subject rights and welfare.

Few commenters, approximately 20, explicitly supported Alternative A or B over the NPRM proposal or the pre-2018 rule.

The Presidential Commission for the Study of Bioethical Issues explicitly supported Alternative B, noting that it is the most forward-looking of all three

²⁰ NCI defines “biospecimen” as, “A quantity of tissue, blood, urine, or other human-derived material. A single biopsy may generate several biospecimens, including multiple paraffin blocks or frozen biospecimens. A biospecimen can comprise subcellular structures, cells, tissue (e.g., bone, muscle, connective tissue, and skin), organs (e.g., liver, bladder, heart, and kidney), blood, gametes (sperm and ova), embryos, fetal tissue, and waste (urine, feces, sweat, hair and nail clippings, shed epithelial cells, and placenta). Portions or aliquots of a biospecimen are referred to as samples (NCI Best Practices working definition).” Retrieved from <http://biospecimens.cancer.gov/bestpractices/got/#B>. Last modified March 16, 2016.

proposals, using “bio-unique” data as human subjects research with a focus on the technology and its ability to identify donors using small amounts of data, as opposed to tying the definition of human subjects research to a particular kind of data.²¹ Another commenter identified alternative B as the best proposal to keep pace with advances in technology (including technologies driving personalized medicine), protect research participants, respect autonomy, increase trust, and close the gap in protection in the current regulations.

Those who supported the primary NPRM proposal—to expand the definition of “human subject” to include all biospecimens—indicated that Alternatives A and B would not give individuals who wanted to control the use of their biospecimens the opportunity to do so.

Approximately 250 commenters (about 12 percent of the total comments received) said that they endorsed the pre-2018 policy, but that if the Federal Government must do something other than maintain the current definition of human subject, Alternative A would be preferable to the NPRM proposal or to Alternative B. These comments argued that Alternative A would be the least disruptive to the research enterprise, but that the pre-2018 policy would be better.

However, the majority of those commenters addressing the alternative proposals indicated that neither struck an appropriate balance among the *Belmont Report* principles. A research university concluded that both alternatives lack balance, emphasizing respect for persons with little regard for the principles of beneficence and justice.

Additional concerns about Alternative A included the fact that while limiting the expansion of the scope of activities covered by the rule to whole genome sequencing may be a reasonable line for inclusion today, that line might not be inclusive enough in the future.

Additional concerns about Alternative B included that by requiring continual re-review of technologies and databases by the federal government, there would be an “inevitable lag” between when a technology might be identified and when it would be added to the list. Thus, these commenters argued that the list might end up being useless.

²¹ The Commission had previously addressed related issues in its October 2012 report, *Privacy and Progress in Whole Genome Sequencing*. Washington, DC: Presidential Advisory Commission for the Study of Bioethical Issues. Retrieved from http://bioethics.gov/sites/default/files/PrivacyProgress508_1.pdf.

c. Alternative Proposals Offered by Public Commenters

Many commenters proposed or endorsed alternatives to the NPRM proposals. Generally, these alternatives involved maintaining the existing schema, developing a system of notice and opt out, engaging in a public education campaign about how the research enterprise works, and developing penalties and sanctions for re-identification of biospecimens and information. A policy that requires notice, opt out, and public education were generally endorsed or discussed together.

The Secretary's Advisory Committee on Human Research Protections (SACHRP) offered one of the most detailed alternative proposals. SACHRP indicated that existing practices of research with biospecimens and data that have been collected for nonresearch uses (most often in the course of clinical care) should be revised to better protect subjects through greater transparency, public education about research with biospecimens, more exacting standards for protecting against dignity harms, allowing individuals to opt out, requiring IRB or institutional review and approval of specific research uses of identified biospecimens and identified data, and through strict legal consequences for re-identification of de-identified biospecimens and data that have been shared for research purposes.

SACHRP also proposed that data security protections be developed to safeguard biospecimen-associated data and identified data against unauthorized release or access, and focused review of the storage, maintenance, or secondary research use of identified biospecimens and identified data to determine whether the proposed activity is likely to be objectionable.

A professional organization of investigative pathologists urged consideration of opt-out broad consent models for nonidentified biospecimens collected in research and nonresearch settings, and suggested that this model would bring consent for the broad use of nonidentified biospecimens in line with HIPAA privacy practices, preserving the ability for an individual to decide not to participate in research efforts. This organization asserted that this option would be less burdensome and an inclusive, respectful, and functional way to promote ethically conducted biomedical research on biospecimens.

d. Public Comments on Identifiability

Approximately 40 comments were received in response to the request to

comment on the definition of identifiable private information. Comments were mixed. The largest proportion of those comments (approximately 13) supported the definition in the pre-2018 rule. Others felt that the pre-2018 definition of identifiable private information was sufficient, but that additional guidance would be needed to implement it. Another group of commenters supported adopting a different identifiability standard in the final rule (such as the federal government's personally identifiable information standard, or the HIPAA identifiability standard).

Several public comments claimed that the meaning of "identifiable" with regard to information and biospecimens will change as technology advances. They indicated that the technique of whole genome sequencing altered the conversations about the identifiability of biospecimens and future technological advances using advanced computing and large databases could provide methods for easily aggregating disparate data for the purposes of identifying an individual.

Public comments received from a large professional association related to the definition of identifiable private information noted that the modifier "may be readily ascertainable" that was included in the definition of identifiable private information within the definition of human subject allows for changes in scientific technology and data sharing over time since what was readily ascertainable 10 years ago has changed and will be different 10 years from now. The commenter noted that this allows IRBs and investigators to assess identifiability based on current technology, data sharing and computing capabilities, rather than comparing it to an enumerated list of identifiers or scientific technologies.

Some commenters expressed a desire for guidance to be issued on these definitions or for the definitions to be better clarified and explained in the regulatory text. Several comments specifically suggested a need for a definition of or guidance on the term "readily ascertainable."

Approximately 10 comments endorsed replacing the Common Rule's identifiability standard with either the Federal Government's concept of personally identifiable information (PII) or HIPAA's concept of protected health information (PHI).

One academic medical center felt that the concept of PII would unnecessarily broaden the scope of the Common Rule and create a larger administrative burden due to the vagueness of the PII

definition without providing substantial added protection to human subjects, and suggested replacing the term "identifiable private information" with the definition of "protected health information," which can be found at 45 CFR 160.103.

Those who supported the use of the PII concept noted that it would harmonize other definitions of identifiability used in other Federal Government regulations. One state department of health and human services noted that adopting PII would be consistent with other confidentiality laws, policies, and industry standards that require organizations to protect the privacy and security of PII, achieving consistency across standards and helping organizations comply with the various privacy and security requirements. The commenter felt that replacing the identifiable private information standard with the concept of PII should not be overly burdensome on the research community since exemptions and waivers of informed consent would likely apply in many contexts.

A few commenters also noted that regardless of how identifiability might be defined, some concerns about group harms still were not addressed in the NPRM.

Several other commenters noted that a change to the definition of PII would not increase public trust or understanding of the system, nor would it likely clarify for investigators whether biospecimens or private information are identifiable.

A majority of the commenters noted that whatever direction the final rule takes; additional guidance will be necessary to reduce ambiguity within the regulated community.

e. Public Comments on Newborn Dried Blood Spots

Approximately 50 comments discussed how issues related to research use of residual newborn dried blood spots (DBS) were addressed by the proposal to expand the definition of human subject. Of those comments, 35 supported the idea of parental consent for research with DBS. Thirty-two comments stated that specific consent should be required for all research uses, in other words, that the exemptions and exclusion categories should not apply to research involving DBS. Those who felt that parental consent should always be required for the research use of DBS expressed the need to respect autonomy and parents' rights, and frequently conveyed a distrust of medicine and scientists. These individuals generally supported the spirit of the main NPRM

proposal, but objected to any exemptions, exclusions, and waivers of informed consent.

Fifteen comments expressed concerns that the biospecimen proposals in the NPRM would impede research involving DBS, which could negatively affect the expansion and improvement of newborn screening programs due to, among other things, a possible lack of resources for obtaining consent. In this regard, an employee of a California state health department described the health department's experience of seeking and obtaining consent for the research use of DBS. This individual noted that 52 percent of new parents were offered the opportunity to consent. Of those offered the opportunity, 90 percent said yes. This employee was thus concerned that due to staffing constraints, the majority of new parents simply would not be asked to provide consent to future research uses of DBS.

Others indicated that some kind of notice and opt-out process would be acceptable, but that as a general matter the research community would benefit from guidance on the extent to which the exemptions and exclusions apply to this type of work.

4. Response to Comments and Explanation of the Final Rule: Definition of Human Subject

The final rule does not implement the proposed expansion of the definition of "human subject" to include all biospecimens regardless of identifiability. It is clear from the comments received that the public has significant and appropriate concern about both the need for obtaining consent before using such biospecimens for research, and the potential negative impacts of implementing that proposal on the ability to conduct research. And, while it does not substantially change the definition of "identifiable private information," the final rule includes a new process by which Common Rule departments and agencies can regularly assess the scientific and technological landscape to determine whether new developments merit reconsideration of how identifiability of either information or biospecimens is interpreted in the context of research. Because the final rule does not implement the NPRM's proposed expansion to the definition of "human subject," it also does not implement the NPRM proposal to exclude certain research activities involving nonidentified biospecimens.

With regard to changing the definition of "human subject" to include all biospecimens, the majority of commenters who addressed this expansion opposed it for a variety of

reasons, as described above. As explained in the NPRM, one of the core reasons for proposing that the rule be broadened to cover all biospecimens, regardless of identifiability, was based on the premise that continuing to allow secondary research with biospecimens collected without consent for research places the publicly funded research enterprise in an increasingly untenable position because it is not consistent with the majority of the public's wishes, which reflect legitimate autonomy interests. However, the public comments on this proposal raise sufficient questions about this premise such that we have determined that the proposal should not be adopted in this final rule.

Further, the current regulatory policy appears to sufficiently protect against the unauthorized research use of identifiable biospecimens. Under the pre-2018 rule, if an investigator funded by a Common Rule department or agency uses nonidentified biospecimens and manages to re-identify them, that investigator would then be conducting human subjects research without IRB approval, in violation of the rules. It should also be noted that the position adopted in the final rule does not eliminate any authority, separate and apart from the Common Rule, that Common Rule departments and agencies have to establish policies with additional requirements related to consent for research involving nonidentifiable biospecimens or nonidentifiable private information, or preclude them from exercising such authority.

Nonetheless, we acknowledge the need to also appropriately respect and promote autonomy interests. Any future proposals aimed at promoting autonomy should jointly evaluate the importance of the autonomy interests at issue, as well as explicitly quantify the potential negative impacts the proposal might have on the ability to conduct research, including such consequences on the representativeness of biospecimens available for research.

In the final rule, we have added requirements to the informed consent process to increase transparency so that potential subjects will have more information about how their biospecimens or private information might be used. Specifically, prospective subjects will be told that identifiers might be removed from their biospecimens or private information and used for future research, if this might be a possibility. Finally, as some public comments addressed the desire to share in any profits that might accrue as a result of research use of their

biospecimens, an additional element of consent will require, as appropriate, a statement that the subject's biospecimens may be used for commercial profit and whether the subject will or will not share in this commercial profit. We believe that this increased attention to transparency in the consent process will allow individuals to make informed choices about whether they want to consent to current or future research uses of their biospecimens. A few clarifying changes are made in the final rule pertaining to the definition of "human subject" and the components within that definition, particularly referring to both information and biospecimens as key determinants of whether a human subject is involved in research.

With respect to the definition of "identifiable private information," although the pre-2018 definition of "identifiable" did not incorporate a specific process for considering the growing volume of information being generated and shared in research (including from biospecimens), or consider how evolving technology can ease and speed the ability to re-identify information or biospecimens previously considered nonidentifiable, we appreciate that a change in that definition could have collateral implications with respect to imposing unwarranted consent requirements on activities that were not subject to the regulations. We appreciate the commenter requests for more guidance on how they should interpret the definition of identifiable private information. Thus, although the final rule only makes minor changes to the existing definition of "identifiable private information," it sets in place a process (§ ___.102(e)(7), discussed below) that will help facilitate any necessary future updates to the understanding of that term.

In the final rule the language at § ___.102(e)(1)(i) relating to information obtained through intervention or interaction with an individual was adopted and modified by replacing the reference to data, as proposed in the NPRM, with a reference to information or biospecimens, and by adding the NPRM-proposed language relating to using, studying, or analyzing the information or biospecimens. The explicit reference to biospecimens in this context is intended as a mere clarification of the previous understanding of how the pre-2018 rule operated.

Likewise, the final rule adopts the NPRM-proposed language at § ___.102(e)(1)(ii) relating to obtaining identifiable private information, but

modifies it by adding an explicit reference to “identifiable biospecimens.” This is also intended as a mere clarification of the previous understanding of how the pre-2018 rule operated as applied to biospecimens. Similarly, the definition of intervention has been modified to clarify that information or biospecimens might be gathered, replacing the former reference only to data. This, too, is merely a clarification of the existing understanding of that concept.

A definition of “identifiable biospecimen” has been added at § _____.102(e)(6). This new definition was not added as a result of any substantive change, but rather to enable greater clarity in other provisions of these regulations in explaining when a particular provision relates to either identifiable private information alone (not including biospecimens), or identifiable biospecimens alone, or both. The pre-2018 rule’s concept of “identifiable private information” had encompassed the concept of an identifiable biospecimen, whereas under the final rule that concept has been “cleaved off” from that definition and given its own definition. Note that a biospecimen is deemed to include private information (consistent with the understanding of this concept under the pre-2018 rule), so there is no need to add the adjective “private” in the definition of an “identifiable biospecimen.” In effect, once a biospecimen becomes identifiable (for example, by being tagged with the name or other information that indicates the person from whom the biospecimen was obtained), then an investigator using that biospecimen is already using something to which § _____.102(e)(1)(ii) would apply. There is no need to make any additional determination about the “private” aspects of what is taking place.

In addition, the minor clarifying change in the language for the concept of “private information” that was proposed in the NPRM, namely adding the phrase “shared or,” was not adopted. It was decided that because any information that should not be shared would always meet the standard of being information that should not be made public, this change would not actually expand the amount of information that is considered private information.

Although the description of when private information is identifiable was not significantly changed, a new provision has been added at § _____.102(e)(7) requiring federal departments and agencies that implement the Common Rule to

regularly, upon consultation with appropriate experts, reexamine the meaning of the terms “identifiable private information,” as defined in § _____.102(e)(5), and “identifiable biospecimen,” as defined in § _____.102(e)(6). Such reexamination shall take place at least every 4 years. This new provision specifically requires that the federal departments and agencies implementing this policy collaborate on this process to avoid a duplication of efforts and in order to have a consistent interpretation of these terms.

This new process responds to the growing volume of information being generated and shared in research (including from biospecimens), and evolving technology that can ease and speed the ability to re-identify information or biospecimens previously considered nonidentifiable. With an increase in the number of exemptions included in this final rule, it will be important to reconsider the potential identifiability of information and biospecimens and facilitate uniform interpretation to ensure adequate privacy and security measures are in place.

Section 102(e)(7) also provides that, after conducting this process, if it is determined to be appropriate and permitted by law, Common Rule departments and agencies could alter the interpretation of identifiable private information or identifiable biospecimens, including through the use of guidance.

In addition, there will occur, also at least every 4 years and as a collaborative process among those federal departments and agencies, upon consultation with appropriate experts, an assessment as to whether there are analytic technologies and techniques that should be considered by investigators to generate identifiable private information or identifiable biospecimens. The ultimate goal is to implement the Common Rule in a way that is aligned with the evolving understanding of the concept of identifiability while protecting subjects and encouraging and facilitating valuable research.

To the extent that this process leads to a determination that particular analytic technologies or techniques, when applied to information or biospecimens that are not identified, do lead to the generation of identifiable private information or identifiable biospecimens, those technologies or techniques will be placed on a list of technologies and techniques satisfying that determination, and recommendations might accordingly be

made with regard to relevant issues relating to consent and privacy and data security protections. The result may be that such technologies and techniques could therefore only be used in instances where the person has provided their consent (broad or study-specific) which meets the requirements of the Common Rule, or where an IRB has waived the requirement for consent.

Notice and the opportunity for public comment would take place before a technology or technique could be placed on this list. The expectation is that whole genome sequencing will be one of the first technologies to be evaluated to determine whether it should be placed on this list.

It is important to note that an investigator who possesses information or biospecimens to which such a technology or technique might be applied is not to be considered in possession of identifiable private information or identifiable biospecimens merely as a result of such a circumstance: that would only be true were the investigator to actually apply the technology or technique to generate identifiable private information or identifiable biospecimens.

This new provision is not being added as a result of any pre-conceived determination that there is indeed a need to change, whether by guidance or otherwise, the interpretation of “individually identifiable” as that concept is currently interpreted. Consistent with a core theme underpinning the process that led to this final rule, it would be inappropriate to expand the scope of coverage of the Common Rule with regard to activities that usually involve very little risk absent good reason to think that there is a problem that the added administrative burden will be correcting. The public comments on both the ANPRM and the NPRM do not identify a specific problem, but clarification from the regulatory agencies might be useful. Thus, apart from the consequences of placing technologies and techniques on the new list, the most significant effect of § _____.102(e)(7) may be the issuance of guidance from time to time that facilitates understanding of and compliance with existing interpretations.

Finally, with regard to the use of newborn DBS, retaining the pre-2018 approach toward nonidentified biospecimens resolves many of the concerns expressed by commenters who felt that important research involving newborn screening would be halted or inhibited under the NPRM. The Newborn Screening Saves Lives Reauthorization Act of 2014 (Pub. L.

113–240) will no longer be effective following the effective date of this final rule, given that its changes applied only until changes to the Common Rule were promulgated. As a result, under the final rule, secondary research with nonidentified newborn DBS would be treated in the same way as secondary research with any other type of nonidentified biospecimen. Such research would not be considered research with human subjects under the final rule, and thus would not be subject to the rule.

E. Legally Authorized Representative (§ ____ .102(i))

1. Background and Pre-2018 Requirements

The Common Rule contains a definition of legally authorized representative to clarify who can consent on behalf of a prospective subject who is unable to consent to research participation on his or her own behalf. Under the pre-2018 rule, a legally authorized representative was defined as an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

As there is no federal legal standard as to who, or what entity, is authorized to serve as a legally authorized representative to provide consent to a subject's research participation, the issue of who can serve as a legally authorized representative has been determined by the laws of the jurisdiction in which the research will be conducted. Within the United States, this generally means state or local law. "Applicable law" could be a state statute or regulation, case law on point, an opinion of a State Attorney General, or a combination of these.

Some states and jurisdictions have statutes, regulations, or common law that specifically address consent by someone other than the subject for participation in research. Most states and jurisdictions have no law specifically addressing the issue of consent in the research context. In these states and jurisdictions, law that addresses who is authorized to give consent on behalf of another person to specific medical procedures or generally to clinical care may be relevant if those types of procedures are the procedures involved in the research. The long-standing interpretation by OHRP has been that such laws relating to surrogate consent in the clinical context can be used for purposes of the Common Rule.

In every state, a legally authorized representative can be authorized through an advance directive or by a court through guardianship proceedings. However some states have no law specifically addressing the issue of consent by a surrogate in the research setting, and some states have no applicable statutes, regulations, or common law specifying when an individual can provide consent for another to medical treatment. In the absence of such law, it is usually the case that community or other standards (such as institutional policies) define hierarchies or identify individuals who are allowed to provide consent, for medical treatment purposes, on behalf of others who cannot consent for themselves.

SACHRP and the Presidential Commission for the Study of Bioethical Issues have raised concerns that the definition of legally authorized representative may be inappropriately hindering the conduct of research with subjects who lack capacity to consent. In the second part of its report on neuroscience and ethics, *Gray Matters: Topics at the Intersection of Neuroscience, Ethics, and Society (Volume 2)*, the Commission recommended that federal regulatory agencies establish clear requirements to identify who can serve as legally authorized representatives for individuals with impaired decision-making capacity to support their responsible inclusion in research.²²

2. NPRM Proposal

Although the NPRM did not propose regulatory text that would change the definition of "legally authorized representative," it requested public comment on whether we should modify the definition in light of the definition's reference to persons or entities "authorized under applicable law."

The NPRM sought comment on whether expansion of the current definition to permit a legally authorized representative to be defined by an accepted common practice standard within a state or jurisdiction that lacks applicable state law for determining who can legally consent to clinical care would be consistent with the ethical principles underlying the Common Rule. The NPRM proposed to allow use of this alternative standard only in jurisdictions in which there is also no

applicable law affirmatively authorizing a legally authorized representative to provide consent to the subject's research participation.

3. Public Comments

Approximately 60 commenters discussed the Common Rule's definition of "legally authorized representative." A clear majority supported the goal of addressing the barrier that the regulatory definition of "legally authorized representative" poses in jurisdictions that have no applicable law affirmatively authorizing an individual to provide consent for another. Commenters also favored the suggested approach and responded that including the allowance of an accepted common practice standard would still appropriately protect subjects. About one-third of the commenters responding to this question, including disability rights organizations, advocacy organizations, and academic institutions, did not agree with the direction of the contemplated modification or whether this issue should be addressed through regulatory change.

Those supporting a modified definition generally agreed that broadening the definition to cover anyone considered acceptable to provide consent for another individual in the clinical setting would be appropriate, would represent an alignment with accepted common practice, and would bring consistency to the consent process for the jurisdictions that are silent on both who may provide consent for clinical care and who may provide consent for research. A number of commenters who supported the proposal for modification noted that state law authorizing individuals to provide consent would continue to apply.

Among the commenters who opposed the modification, several said state law provides sufficient guidance regarding the hierarchy of those who can consent for an adult incapable of consenting on his or her own behalf, and reduces the institution's liability in the event that an inappropriate person consents for the subject. A research institution recommended that we reassess this proposal and include more specific requirements and details as to the role and authority of the legally authorized representative. A disability rights organization, while recognizing that the pre-2018 standard is not acceptable, commented that the problem is not solved by incorporating broad discretion among different jurisdictions. The organization also opined that a common practice standard does not provide

²² Presidential Commission for the Study of Bioethical Issues. *Gray Matters: Topics at the Intersection of Neuroscience, Ethics, and Society (Volume 2)*. Washington, DC: Presidential Commission for the Study of Bioethical Issues, 2015. Retrieved from http://bioethics.gov/sites/default/files/GrayMatter_V2_508.pdf

sufficient guidance to assess and balance reasonable risk, considering that a legally authorized representative's consent is not equivalent to an autonomous decision by the subject. A research subject advocacy organization expressed concern that such a change would not provide sufficient oversight of investigators, who might use this standard in a way that would violate local law. Another commenter stated that certain individuals may be considered able to give consent for participation in clinical procedures for individuals unable to do so for themselves, but may not have the best interests of the individual in mind.

Commenters responded specifically to the solicitation of comment on the proposed standard of "accepted common practice" and indicated that practices for surrogate consent should be those used in clinical settings. Several commenters provided ideas for a more specific approach to interpreting the terms "accepted" and "common." A researchers' association commented that interpretation of these terms should include standards that define hierarchies or identify individuals who may provide legally acceptable consent, for clinical purposes, on behalf of others who cannot consent for themselves. One commenter supporting the modification suggested that the terms could be defined to refer to the historically used form of governing and familial decision making within the group of subjects. A research institution commented that an IRB's careful review and documentation of who may serve as a legally authorized representative would be preferable to an accepted common practice standard, as that standard is vague. A research institution commenting in support of broadening the definition to those who are allowed to consent to clinical procedures advised that this would reduce confusion between physicians and researchers as to who can consent for whom in research situations, and suggested that the terms "accepted" and "common" should refer to the conducting institution's own policies on who can provide consent to clinical procedures.

4. Responses to Comments and Explanation of the Final Rule: Definition of Legally Authorized Representative

The definition of legally authorized representative in the final rule at § _____.102(i) has been modified to address jurisdictions in which no applicable law authorizes a legally authorized representative to provide consent on behalf of a prospective research subject. In these jurisdictions,

an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context to the subject's participation in the procedures involved in the research, will now be considered a legally authorized representative for purposes of this rule.

The change made from the NPRM discussion that "accepted common practice" could be used to identify a legally authorized representative is in response to objections to the vagueness of these terms and the potential for confusion in implementation, which was expressed by the majority of commenters opposed to the proposal. We agree with the commenters' suggestion that an institution's own policies as to surrogate consent may be a better touchstone than "accepted common practice," as a standard referencing institutional policy will provide additional clarity as to who may serve as a legally authorized representative at that particular institution.

The final rule also differs from the NPRM discussion in that it allows institutional policies applicable to surrogate consent in either the clinical context, or other nonresearch contexts, to authorize a legally authorized representative. We expect that implementation of this aspect of the final rule definition will in large part rely on institutional policies for determining surrogates for clinical decision making. In those instances, there is relatively little risk that this rule will have inappropriate consequences, as far more significant considerations, not related to the Common Rule, play a role in shaping and constraining an institution's policies relating to surrogate decision making in the clinical context.

However, we recognize that some studies could be taking place that do not relate to the types of decisions that are involved in clinical care, or that do not involve procedures utilized in the clinical context. If the institution has a policy relating to who acts as a surrogate outside of the research context for those types of decisions, then such a policy could be employed in the research context. Similar to our assessment of policies relating to surrogate decision making in the clinical context, we expect that considerations not related to the Common Rule would constrain the institution's design and implementation of policies in other nonresearch contexts, and thus see relatively little risk that this added regulatory flexibility will have inappropriate consequences.

Maintaining the pre-2018 standard would have continued to allow

disparate results in terms of when research can take place in those states that have specific laws governing either surrogate clinical consent or research consent, and those that do not. Accepting that the Common Rule has been interpreted to allow the use of laws governing surrogate consent in the clinical context to be applied to surrogate decision making in the research context, it is difficult to see why there should be different outcomes in terms of what research is allowable based on whether the standards for surrogate consent in the clinical context in a state are based on specific laws or some other accepted regime.

This outcome also appears inconsistent with the *Belmont Report* principle of justice. Individuals who lack the capacity to consent to research ought not be inappropriately excluded from research participation based solely on these circumstances. Research that an IRB has approved as ethical to conduct with the participation of subjects with impaired decision-making capacity ought not be prohibited in the few states and jurisdictions in which no affirmative law authorizing a legally authorized representative exists, while being allowed to proceed in the vast majority of states and jurisdictions that have laws specifically authorizing consent by a legally authorized representative in the clinical or research context.

Reduced ambiguity in the interpretation of the regulatory requirements will facilitate research that may offer the promise of improved medical treatment for this subject population, thus increasing beneficence. This approach reflects the calls for increased clarity in the regulatory requirements regarding who may serve as a legally authorized representative, which will serve to facilitate the responsible inclusion of subjects who cannot consent on their own behalf to research participation.

F. Minimal Risk (§ _____.102(j))

1. Background and Pre-2018 Requirements

The concept of "minimal risk" is central to numerous aspects of the Common Rule, as it affects the type of review required, the permissibility of waiver of informed consent, considerations for IRBs in the review process, and the frequency of review. In sum, the review process has been calibrated, for the most part, to the risk of the research. For example, under the pre-2018 rule at § _____.110, a research study could receive expedited review if the research activities to be conducted

appeared on the list of activities published by the Secretary of HHS that are eligible for such review,²³ and found by the reviewer(s) to involve no more than minimal risk. Under an expedited review procedure, the review could be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson.

The definition of “minimal risk” in the pre-2018 rule at § ___.102(i) encompassed research activities where the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. IRBs report challenges in assessing the level of risk presented by some studies in order to make the critical minimal risk determination. This is, in part, due to the difficulties in applying the definition of minimal risk under the pre-2018 rule, particularly because the terms “ordinarily encountered in daily life” and “routine physical or psychological examinations or tests” are not clarified.

2. NPRM Proposal

The NPRM did not propose to modify the definition of “minimal risk,” but rather proposed adding to the definition a requirement that the Secretary of HHS create and publish a list of activities that qualify as “minimal risk.” This list would be re-evaluated periodically, but at least every 8 years, based on recommendations from federal departments and agencies and the public. This would not be an exhaustive list of all activities that should be considered minimal risk under the Common Rule, but would allow IRBs to rely on the determination of minimal risk for activities appearing on the list. IRBs would still need to make minimal risk determinations about activities that do not appear on this list. The public was asked to comment on whether 8 years was a reasonable time period for updating the list and whether advice should be solicited from outside parties when updating the list. The public was also asked to comment on whether the Secretary’s list would be a useful tool for the research community, and whether it would represent a loss of IRB flexibility in risk determinations.

3. Public Comments

Approximately 100 comments were received on this proposal. A strong majority supported the proposal, stating that it would be useful to have such a list, and some even suggested that the list of minimal risk activities should be reviewed more often than once every 8 years. One research university suggested that it is impossible to determine the future direction of human research and therefore a list of minimal risk activities would need to be updated at least yearly.

Several commenters, including those who supported this proposal generally, stated that even though this list of minimal risk activities was a good idea in theory, it should be developed separately from a final rule to allow for more time to work collaboratively with other Common Rule departments and agencies and with members of the regulated community. Some of those who supported the proposal asked that there be widely solicited public input on the list. Others who supported the proposal noted the list does not represent a loss of flexibility because the IRB can still override the presumption of minimal risk as long as the rationale is documented. One large research university felt that the Secretary’s list should not replace the IRB’s discretion to review a study, particularly if it will only be updated periodically. One commenter was opposed to the NPRM proposal that the list be further codified, suggesting that it should instead be eliminated as a regulatory yardstick to simplify the regulations and remove added administrative burden.

4. Response to Comments and Explanation of the Final Rule: Definition of Minimal Risk

Although this proposal received significant support, several commenters expressed concern that the Secretary’s list was another NPRM deliverable that the public did not have a chance to see and comment on during the NPRM public comment period. These commenters suggested that this proposal be removed from a final rule and developed on a separate track. We agree that this list should be developed as a separate process from the final rule promulgation, and thus this proposal has not been included in the final rule.

Thus, no change is made to the definition of “minimal risk” in the final rule at § ___.102(j). We still intend to publish guidance on this issue and could still pursue publication of such a list in the future.

G. Public Health Authority (§ ___.102(k))

The pre-2018 rule did not provide a definition of “public health authority.” As proposed in the NPRM, the final rule now defines the term so that references to it in the definition of research are understood. Specifically, because the definition of “research” (§ ___.102(l)(2)) removes from that definition public health surveillance activities that are conducted, supported, requested, ordered, required, or authorized by a public health authority, this definition of “public health authority” clarifies the scope of the activities removed from the definition of “research” for the purposes of this final rule.

In the final rule, as in the NPRM, the term “public health authority”²⁴ means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate. We received no public comments on this definition.

H. Research (§ ___.102(l))

1. Background and Pre-2018 Requirements

The pre-2018 rule defined “research” as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that met this definition constituted research for the purposes of that rule. An activity was only subject to that rule if it met this definition (in addition to meeting various other criteria). The pre-2018 rule also included categories of research involving human subjects that would be considered exempt from the rule.

The pre-2018 rule was criticized for not being clear about how to interpret which activities were covered by the rule and which were not. Some commenters also criticized the pre-2018 rule for extending to activities that should not be covered and for inhibiting the conduct of certain activities. According to some, the definition of “research” did not provide a sufficiently clear and precise way to distinguish between similar activities in a way that made it immediately obvious which

²³ HHS. Office for Human Research Protections. Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure. November 9, 1998. Retrieved from <http://www.hhs.gov/ohrp/policy/expedited98.html>.

²⁴ Consistent with 45 CFR 164.501 in the Privacy Rule.

activities fell under the definition and which did not.

2. NPRM Proposals

The NPRM proposed creating a new section in the regulations referred to as “exclusions.” By proposing exclusion categories, the NPRM intended to make clear that these activities would not have to satisfy the regulatory requirements of the Common Rule. That is, the proposed excluded activities would have been outside the scope of the Common Rule.

Three of the proposed exclusions sought to reduce uncertainty about whether certain internal program improvement activities, historical or journalistic inquiries, or quality assurance or improvement activities satisfied the Common Rule’s definition of research.

Another three proposed exclusions pertained to activities that are part of inherently governmental functions with purposes other than research, such as responsibilities to protect public health and welfare (*i.e.*, criminal investigations, public health surveillance, and national security missions). It was proposed that these activities promote recognized specific goods that are crucial to the public welfare.

An additional four categories of proposed exclusions included human subjects research activities that were either considered low risk, or for which there were appropriate safeguards already in place independent of the Common Rule. These four categories pertained to: (1) Research that involves the use of educational tests, survey procedures, interview procedures, or observation of public behavior uninfluenced by the investigators; (2) research involving the collection or study of information that has been or will be acquired solely for non-research activities or were acquired for research studies other than the proposed research study; (3) research conducted by a federal government agency using federal government-generated non-research information when certain criteria are met; and (4) research regulated as “health care operations,” “public health activities,” or “research” under HIPAA. As noted in the NPRM, in these categories the principle of beneficence alone could support the conduct of these activities after considering the level of risk, potential benefits, and nature of human participation in these activities, without the need to add the protections of the Common Rule.

A final proposed exclusion would have applied to research involving the secondary use of nonidentified

biospecimens when the research was limited to generating information about the subject that is already known by the subject (*e.g.*, disease diagnosis). As such, this research would not need any additional protections provided by these regulations. This proposed exclusion was directly related to the proposed changes in the definition of “human subject” to include all biospecimens, regardless of whether they are identifiable (as discussed above in Section III, that proposal has not been adopted).

3. Public Comments, Response to Comments, and Description of the Final Rule: Definition of Research

a. Overview

Approximately 375 public comments discussed at least one aspect of the proposed NPRM exclusions. General concerns about the exclusions included that they added a layer of unnecessary complexity in determining what studies fall under the Common Rule, and that overlapping categories of exclusions and exemptions were proposed. Comments also expressed the concern about the lack of requirements on who would decide whether an activity met the criteria for an exclusion, including investigators, or whether those decisions would be documented in any way.

In response to the public comments, the NPRM’s general approach of designating various categories of activities as excluded has not been adopted. Instead, the final rule reverts to the general structure of the pre-2018 rule and integrates some of the categories proposed for exclusion in the NPRM into that structure, with some changes to the categories.

The final rule retains the wording of the pre-2018 definition of research, and explicitly removes four categories of activities from activities that would meet that definition. These revisions are intended to make the rule simpler, more familiar to readers who are aware of the pre-2018 rule and its definition of research, and easier to understand.

The four categories of activities removed from the definition of research are set out in order to make clear that they are not within the jurisdiction of the rule. The four categories pertain to certain scholarly and journalistic activities, public health surveillance activities, criminal justice activities, and authorized operational activities in support of national security missions. These categories were proposed as exclusions in the NPRM; the final rule retains these categories, with some

changes made in the wording for clarity, in response to public comments.

The category of certain scholarly or journalistic activities is removed from the definition in order to resolve long-standing debate and uncertainty about whether these activities are considered research in the sense of the regulatory definition. We believe that these activities should not be considered research in the context of the Common Rule, and that making this explicit in the final rule will help to resolve the uncertainty.

The final rule includes a simpler definition of national security missions not considered to be human subject research, as a response to concern that the earlier draft language in the NPRM could be interpreted too broadly or too narrowly due to the specific activities listed, such as surveys, interviews, surveillance activities and related analyses, and the collection and use of biospecimens. These authorized operational activities, as determined by each agency, do not include research activities as defined by the Common Rule, nor have they ever in the past been considered regulated by the Common Rule. This category of activity is removed from the definition of research to make explicit that the requirements of the final rule do not apply to authorized operational activities in support of national security missions.

The other two categories of activities deemed not to be research under the final rule (pertaining to public health surveillance activities and criminal justice activities) include many activities that under the pre-2018 rule do not fit the definition of research, and some activities that otherwise might. These categories are included in the final rule in order to make it explicit that the requirements of the final rule do not apply to them.

Three categories of activities proposed as exclusions have been eliminated from the final rule. The proposed exclusion for certain quality assurance/quality improvement (QA/QI) activities has been dropped because it could create more confusion than it resolved, and it might have inadvertently created inappropriate obstacles to those QA/QI activities that should not fall under the rule. The proposed exclusion for internal program improvement activities has been dropped due to similar considerations. The category regarding secondary research involving nonidentified biospecimens designed only to generate information about an individual that is already known has been dropped because it is no longer necessary given that the NPRM proposal

to modify the definition of human subject to include all biospecimens regardless of identifiability is not included in the final rule. The discussion of the proposed exclusion for certain research activities with nonidentified biospecimens appears in additional detail in Section III.D.

The four exclusions proposed in the NPRM that are incorporated into the exemptions in the final rule are: (1) The proposed exclusion for certain educational tests, survey or interview procedures or observation of public behavior; (2) the proposed exclusion for secondary research use of information that is publicly available or recorded without identifiers; (3) the proposed exclusion regarding secondary research use of information collected by the Federal Government for other purposes and subject to certain privacy laws; and (4) the proposed exclusion regarding secondary research use of information covered by HIPAA protections.

b. Scholarly and Journalistic Activities (e.g., Oral History, Journalism, Biography, Literary Criticism, Legal Research, and Historical Scholarship) (§ _____.102(l)(1))

i. Public Comments

Approximately 50 comments discussed the NPRM proposal to exclude scholarly and journalistic articles from coverage by the rule. The majority of these comments supported the intent of the exclusion, although several comments suggested possible changes. The minority of the comments expressed concerns. Those who opposed this exclusion generally opposed all exclusions, arguing that investigators should be required to get permission from subjects before engaging in these activities.

One commenter expressed concern about an exclusion that would permit oral history activities with tribal nations without oversight. This commenter noted that some oral history with tribal nations is tantamount to cultural appropriation, and the concern of tribal nations might not be adequately protected by the ethical standards of various professions.

Several commenters discussed that the wording of the NPRM regulatory text here might be more restrictive than necessary. Specifically, several commenters noted that in calling out specific disciplines and methodologies, the regulatory text seems counter to the NPRM policy goal of allowing this type of research (as opposed to research in these specific fields) to occur.

A few commenters discussed the need for ethnographic research to be

explicitly called out in this exclusion. One commenter also raised cultural anthropology as another academic discipline that should be referenced in this exclusion.

Several commenters, including academic discipline advocacy groups, noted that the exclusion conflated broad disciplines (journalism) with methodologies (oral history), which could be confusing to those attempting to implement the exclusion.

Several commenters also questioned whether the provision “that focus directly on the specific individuals about whom the information is collected” applied only to historical scholarship activities or to all of the activities and disciplines noted in the exclusion. Several other commenters indicated that they supported a full exclusion of all oral history, journalism, biographical, and historical scholarship activities, suggesting that those several individuals do not presume that the provision “that focus directly on the specific individuals about whom the information is collected” served as a limitation on what activities were covered under this exclusion.

A minority of commenters—including accreditation bodies, human research protection experts, and research universities—suggested that an exclusion for these activities was not needed, and that this topic could be addressed through guidance. These comments also indicated that addressing this topic in guidance might be clearer to the regulated community as well. Others indicated that the exclusion is not warranted because the excluded activities are those that would not contribute to generalizable knowledge and thus already would not fall under the rule.

The NPRM also asked whether biospecimens should be included in this exclusion. Very few individuals answered this question, and those that did indicated that biospecimens should not be included.

One research university indicated that with respect to oral history, the exclusion should make a distinction between oral history projects that meet the definition of research and those that do not, suggesting that the exclusion should not exempt all projects that might fall under the “oral history” banner. One commenter noted that oral history should be defined in order to distinguish that activity from interviews.

ii. Response to Comments and Explanation of the Final Rule: Scholarly and Journalistic Activities

The final rule explicitly removes a category of activities consisting of certain scholarly and journalistic activities from the definition of research and the scope of the regulations. This category of activities concerns certain activities in various fields that focus directly on the specific individuals about whom information are collected. As described above, this category is removed from the definition in order to resolve long-standing debate and uncertainty about whether these activities are considered research in the sense of the regulatory definition. We believe that these activities should not be considered research in the context of the Common Rule, and that making this explicit in the final rule will help to resolve the uncertainty.

In these activities, the ethical requirement is to provide an accurate and evidence-based portrayal of the individuals involved, and not necessarily to protect them from public scrutiny. For example, a biographer might collect and present factual information to support the biographer’s opinion about the character of an individual to show that the individual does not deserve the positive reputation he or she enjoys in society. These fields of research have their own codes of ethics, according to which, for example, consent is obtained for oral histories. We note that this consent standard should address the issue of oral histories of tribal members. For these reasons, we have determined that it is appropriate to remove these activities from the definition of research and from the scope of the Common Rule.

In response to public comments, § _____.102(l)(1) refers to more fields and methodological traditions than were proposed in the NPRM. The final rule also explicitly cites those fields and traditions as examples, in order to clarify that the focus is on the specific activities that collect and use information about specific individuals themselves, and not generalizing to other individuals, and that such activities occur in various fields of inquiry and methodological traditions. Literary criticism has been added as an example because while a piece of literary criticism might focus on information about the author(s), it would typically focus on the specific author(s) in view. Legal research has been added as an example because it would often focus on the circumstances of specific plaintiffs or parties involved in a case. It is not the particular field

that removes the activity from the definition, but rather the particular activity's focus on specific individuals.

Activities described in § _____.102(l)(1) may sometimes be performed in the fields of anthropology or sociology, but not all activities characteristic of these fields are outside of the rule. Studies using methods such as participant observation and ethnographic studies, in which investigators gather information from individuals in order to understand their beliefs, customs, and practices, and the findings apply to the studied community or group, and not just the individuals from whom the information was obtained, fall within the scope of the definition of research of the final rule.

c. Public Health Surveillance
(§ _____.102(l)(2))

i. Public Comments

Approximately 80 comments discussed the proposed exclusion for certain public health surveillance activities. Public comments were generally mixed with many comments suggesting that the regulated community will need to see additional examples of activities that satisfy this exclusion and activities that fall outside its scope. Those who supported this exclusion generally said that this would streamline important public health surveillance activities.

Several comments discussed the importance of this exclusion with respect to residual newborn DBS screening programs. These comments generally expressed the opinion that most state mandated public health reporting of such program activities would fall under this exclusion. Commenters requested additional explanation of what aspects of these state newborn screening programs would be covered under this exclusion, and listed components of the program that should be covered, including validity testing and test development. Others suggested that this exclusion should also exclude minimal risk efforts to evaluate surveillance methods. Others suggested that this exclusion should also exclude minimal risk efforts to evaluate surveillance methods. Another comment suggested that a final rule address, in this exclusion or elsewhere, the issue of research that must be conducted during public health emergencies, citing the example of HHS's emergency use provision with a waiver of informed consent, which describes limited circumstances in which a patient is physically incapacitated or otherwise unable to give consent.

Those who opposed excluding these activities argued that in some cases, research activities for which informed consent should be sought and obtained are sometimes conducted under the auspices of public health surveillance; the importance of the activity itself should not be an argument to avoid seeking and obtaining consent. Others argued that consent should always be sought and obtained for research activities and that all of the exemptions and exclusions discussed in the NPRM should be covered activities. One institution indicated that this exclusion was simply not needed because the activities described did not meet the definition of "research" and thus were not subject to the Common Rule.

Another commenter indicated that while the intent of the exclusion seemed reasonable, implementation of the regulatory intent would be difficult, and there are many examples of modern public health surveillance activities where informed consent would have been appropriate.

A few comments that opposed the exclusion indicated concern that it might be abused, and cited the Tuskegee Syphilis study²⁵ as an example of what they feared might be included under this exclusion category. We do not think that study would fall within this category, because it involved research interventions with the subjects, including the provision of substandard treatment and efforts to prevent subjects from obtaining effective treatment, which under no circumstances could be considered surveillance about a condition of public health importance.

²⁵ The Tuskegee Syphilis study "initially involved 600 black men—399 with syphilis, 201 who did not have the disease. The study was conducted without the benefit of patients' informed consent. Researchers told the men they were being treated for 'bad blood,' a local term used to describe several ailments, including syphilis, anemia, and fatigue. In truth, they did not receive the proper treatment needed to cure their illness. In exchange for taking part in the study, the men received free medical exams, free meals, and burial insurance. Although originally projected to last 6 months, the study actually went on for 40 years.

The [federal government panel investigating this study] found that the men had agreed freely to be examined and treated. However, there was no evidence that researchers had informed them of the study or its real purpose. In fact, the men had been misled and had not been given all the facts required to provide informed consent . . . The men were never given adequate treatment for their disease. Even when penicillin became the drug of choice for syphilis in 1947, researchers did not offer it to the subjects. The advisory panel [investigating this study] found nothing to show that subjects were ever given the choice of quitting the study, even when this new, highly effective treatment became widely used." Source: "The Tuskegee Timeline." Centers for Disease Control and Prevention, last updated 19 Feb 2016. Retrieved from <http://www.cdc.gov/tuskegee/timeline.htm>.)

The NPRM asked whether the parameters of this exclusion were sufficiently clear, and if not, how the exclusion could be clarified. In response, one private organization conducting public health research stated that it was unclear if this only applies to governmental entities like the Centers for Disease Control and Prevention (CDC), or if it applies to other organizations as well. Another institution suggested that the community needed additional clarification of what types of activities fall under this exclusion. One research university requested clarification on whether public health surveillance activities falling under this exclusion is subject to subpart B and C, that is, research involving pregnant women or prisoners, respectively. One organization indicated that it would be helpful for the examples used in the NPRM preamble to be published as a separate guidance document.

Another comment noted that the examples included in the preamble only addressed acute infectious disease surveillance and no other types of public health surveillance activities, specifically, chronic disease surveillance and biomonitoring for toxic chemical compounds and metabolites, which should be covered under this exclusion.

Another research organization noted that the regulatory text and examples provided might be too narrow, suggesting the exclusion be broadened to clarify that it applies to public health monitoring aimed at evaluating the degree to which affected individuals seek and obtain treatment, barriers to care, quality of care, treatment outcomes, and health disparities.

Commenters also requested additional explanation of what aspects of state newborn screening programs would be covered under this exclusion, and listed a variety of components of the program, including validity testing and development of new tests, that should be covered by the exclusion. Commenters asked that clarification of the parameters of the public health exclusion be provided so that state newborn screening programs can undertake the activities necessary for new test development. They added that if the parameters are not clarified, given the past controversies associated with the retention and secondary use of newborn DBS, many programs may not undertake activities for which they have not been given express permission to pursue.

ii. Response to Comments and Explanation of the Final Rule: Public Health Surveillance

The final rule adopts the NPRM proposal related to deeming certain public health surveillance activities as explicitly outside of the scope of the Common Rule. Several editorial modifications have been made to this category to improve readability. Additionally, the final rule explicitly specifies that the collection of information is permitted under this category of activities.

The final rule codifies the current interpretation that the definition of research does not include a category of activities that solely involve public health surveillance, including collecting and testing information or biospecimens in activities that are conducted, supported, requested, ordered, required, or authorized by a public health authority and that are limited to those necessary to allow the public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance. Such surveillance activities can include collecting information about trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products. Such activities include those associated with providing timely situational awareness and priority-setting during the course of an event or crisis that threatens public health, including natural or man-made disasters.

This codification of public health surveillance activities as outside the definition of research is designed to remove uncertainty, but is not intended to change the scope of activities subject to or not subject to the Common Rule. When a public health authority conducts public health surveillance activities to fulfill its legal mandate to protect and maintain the health and welfare of the populations it oversees, the regulatory protections of the Common Rule should not impede that authority's ability to accomplish its mandated mission of promoting this recognized public good, in keeping with the principle of beneficence. Other protections independent of the Common Rule exist that serve to protect the rights and welfare of individuals participating in such activities, including federal and state policies to protect privacy, confidentiality, and security safeguards for the information collected.

Public health surveillance refers to collecting, analyzing, and using data to target public health and disease prevention. It is the foundation of

public health practice. Surveillance uses data from a variety of sources, including mandatory reporting of certain conditions, routine monitoring, vital records, medical billing records, and public health investigations. The line between public health surveillance and epidemiological research can be difficult to draw, as the same epidemiological techniques may be used in both. Generally, the difference between the activities is the purpose or context in which the investigation is being conducted and the role of the public health authority.

The following are examples of public health surveillance activities being codified as outside of the definition of research in this regulation:

- Safety and injury surveillance activities designed to enable a public health authority to identify, monitor, assess, and investigate potential safety signals for a specific product or class of products (for example, the surveillance activities of the FDA's Adverse Event Reporting System,²⁶ the Vaccine Adverse Event Reporting System,²⁷ Manufacturer and User Facility Device Experience database,²⁸ the Medical Product Safety Network,²⁹ and the Sentinel Initiative);³⁰
- Surveillance activities designed to enable a public health authority to identify unexpected changes in the incidence or prevalence of a certain disease in a defined geographic region where specific public health concerns have been raised (e.g., the U.S. influenza surveillance system, which allows CDC to find out when and where influenza activity is occurring, track influenza-related illness, determine what strains of influenza virus are circulating, detect changes in influenza viruses, and measure the impact influenza is having on hospitalizations and deaths in the United States);
- Surveillance activities designed to enable a public health authority to identify the prevalence of known risk factors associated with a health problem in the context of a domestic or international public health emergency;
- Surveillance activities designed to enable a public health authority to locate the range and source of a disease outbreak or to identify cases of a disease outbreak;

²⁶ See <http://www.fda.gov/Drugs/InformationOnDrugs/ucm135151.htm>.

²⁷ See <https://vaers.hhs.gov/index>.

²⁸ See <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm>.

²⁹ See <http://www.fda.gov/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/>.

³⁰ See <http://www.fda.gov/Safety/FDAsSentinelInitiative/ucm2007250.htm>.

• Surveillance activities designed to enable a public health authority to detect the onset of disease outbreaks or provide timely situational awareness during the course of an event or crisis that threatens the public health, such as a natural or man-made disaster; and,

• Surveillance activities designed to enable a public health authority to identify the prevalence of a condition of public health importance, known risk factors associated with a condition of public health importance, or behaviors or medical practices related to prevalence of a known condition of public health importance (e.g., surveillance of the prevalence of: tobacco use, exposure to secondhand smoke, lung cancer, or use of smoking cessation treatments).

On the other hand, subsequent research using information collected during a public health surveillance activity, for instance, genetic analysis of biospecimens, would not be removed from the definition.

This clarification of current interpretation would not remove the following activities from the definition of "research": exploratory studies designed to better understand risk factors for chronic diseases, including genetic predisposition, for chronic diseases; exploratory studies designed to elucidate the relationships between biomarkers of exposure and biomarkers of disease; and exploratory studies of potential relationships between behavioral factors (e.g., diet) and indicators of environmental exposures. These types of activities would be considered research because they would not be conducted solely for the purposes described in § _____.102(l)(2), and thus would be covered by the Common Rule if they involved human subjects, even if conducted by a federal agency with a public health mandate. Again, they might fall within an exemption, depending on how they are carried out.

We note that this provision does apply to some activities responding to emergencies, and that various department or agency activities, not just those of HHS, will be affected. Research evaluations of public health surveillance activities are not included in this category because the nature of such evaluations is to create generalizable knowledge. We also recognize that in some public health surveillance activities, it may be appropriate to obtain consent from the individuals from whom information or biospecimens are collected.

We recognize the public comments stating that the boundaries of public health surveillance activities being removed from the definition of research

are not entirely clear. We recognize that some of the activities in this category are not research, but believe that the inclusion of this provision will help to resolve uncertainty in some circumstances about whether the rule applies. We believe that developing guidance in this area will be useful.

Finally, to clarify what public health surveillance activities are being removed from the definition of research, the final rule contains a new definition of “public health authority” at § _____.102(k).

d. Criminal Justice Activities (§ _____.102(l)(3)) and Authorized Operational Activities in Support of National Security Missions (§ _____.102(l)(4))

i. Public Comments

Approximately 60 comments discussed the exclusion for certain criminal justice activities, the exclusion for intelligence surveillance activities, or both. The majority of commenters opposed these provisions.

Several commenters stated that the two exclusions seemed to contradict President Clinton’s Memorandum of 1997, which stated that classified research activities are subject to the Common Rule and directed that the regulations be revised to include certain protections specific to classified research activities.³¹

The majority of commenters discussing these provisions also expressed concern about what appeared to be an expansion of activities not covered by the Common Rule. These commenters also discussed concerns about how this exclusion would affect human subjects protections in classified research activities.

Those who supported these exclusions generally did not provide the rationale for why they supported them.

One research organization noted that additional clarification on the exclusion for certain criminal justice activities would be needed, and noted that such activities should continue to be subject to the Common Rule because this type of research often includes the collection of sensitive, identifiable information, which, if disclosed could present risks to the subjects.

ii. Response to Comments and Explanation of the Final Rule: Criminal Justice Activities

The final rule clarifies that, consistent with current practice, data collection

and analysis that enables the conduct of certain activities carried out as part of the criminal justice system is not research. The scope of these activities is collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. The activities are necessary for the operation and implementation of the criminal justice system. The final rule changes the wording of the category from that proposed in the NPRM only by substituting the word “information” for “data,” for consistency with other parts of the rule.

The provision essentially codifies current federal interpretation that such activities are not considered to be research under the Common Rule. Revising the regulations to explicitly remove such activities from the scope of research subject to the rule is designed to avoid the imposition of disparate requirements by IRBs with overlapping jurisdictions when information collection or analysis encompasses the development of methods required by law or court order for criminal justice or criminal investigative purposes. For example, the Federal Bureau of Investigation (FBI) is charged by law with setting standards governing the collection and processing of DNA biospecimens and information taken (forcibly if necessary) from certain federal and state criminal suspects or offenders incident to their arrest or conviction for prescribed offenses under the National DNA Identification Act of 1994 and other acts. Similarly, the FBI is charged by law with setting standards governing the collection and processing of fingerprints and related biographical information taken from federal and state criminal suspects or offenders and certain sensitive civil employment applicants. Many criminal law enforcement agencies routinely collect human biospecimens at crime scenes from or relating to victims, suspects, and offenders both known and unknown. Incident to these activities, the FBI is also charged with maintaining, and authenticating through identification processes, the criminal record history of criminal offenders for federal government agencies and for the overwhelming majority of state governments that elect to participate and share information through those systems. We have determined that this category of activities does not meet the definition of research in the final rule, so that these activities can be conducted

in accordance with the legitimate goals of the criminal justice system.

We do not believe that this provision contradicts President Clinton’s 1997 memorandum, which addressed the regulatory requirements for certain activities that are considered research under the regulations. This category pertains to activities that are outside of the regulatory requirements.

This category is also not intended to include social and behavioral studies of the causes of criminal behavior. Such studies would be considered research under the final rule.

iii. Response to Comments and Explanation of the Final Rule: Authorized Operational Activities in Support of National Security Missions

The final rule clarifies current federal practice that the definition of research does not include authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions. This clarification codifies the interpretation of the pre-2018 Common Rule.

As described above, the final rule includes a simpler reference to authorized operational activities in support of national security missions not considered to be human subject research, as a response to concern that the NPRM proposal could be interpreted too broadly or too narrowly due to the specific activities listed, such as surveys, interviews, surveillance activities and related analyses, and the collection and use of biospecimens. These authorized operational activities, as determined by each agency, do not include research activities as defined by the Common Rule, nor have they ever in the past been considered regulated by the Common Rule. This category of activity is removed from the definition of research to make explicit that the requirements of the final rule do not apply to authorized operational activities in support of national security missions. This clarification is not intended to narrow the scope of the Common Rule.

We do not believe that this category contradicts President Clinton’s Memorandum of 1997 regarding classified research, because this category is merely clarifying what activities are not considered to meet the definition of research. The Clinton Memorandum calls for a number of requirements to be added to protections for classified research activities, but it does not address activities that are not considered research.

³¹ Memorandum of March 27, 1997. Strengthened Protections for Human Subjects of Classified Research. 62 FR 26367 (May 13, 1997). Retrieved from <http://www.fas.org/sgp/clinton/humexp.html>.

4. NPRM Exclusions Not Included in the Final Rule

a. Certain Quality Assurance and Quality Improvement Activities

i. Public Comments

Approximately 90 comments discussed the proposed exclusion for certain QA/QI activities in the NPRM involving the implementation of an accepted practice. A majority of comments supported the concept of excluding some QA/QI activities from the Common Rule, although some stated that the QA/QI exclusion proposed in the NPRM was too narrow to cover what has evolved as current practice.

These commenters expressed concerns that: (1) The NPRM proposed to exclude only the QA/QI activities that met the exclusion, and that all other QA/QI activities would fall under the rule; or (2) the exclusion would be interpreted to mean that the activities described in the exclusion were the only QA/QI activities that could be considered not covered by the rule.

The most commonly discussed suggestions for expanding the scope of this exclusion included:

- Expanding the exclusion beyond “accepted practices”
- Permitting the collection of outcome measures in the category of activities proposed to be excluded by the NPRM

One hospital noted that QA/QI is not limited to implementation of an “accepted practice” and that limiting the exclusion in this way might impede innovation, for example, accessing an electronic medical record system for QA/QI to test incorporating clinical information to analyze and test best-practice pop-up alerts that signal important information for healthcare providers in caring for a patient. This commenter asserted that there is no current “accepted practice” for activities like this, yet they should be excluded from the definition of research to avoid confusion and to support ongoing innovation and care improvement activities. This commenter also suggested that any QA/QI exclusion should permit activities that allow medical centers to analyze how they deliver care, improve outcomes, and modify processes to achieve healthcare reform goals.

One commenter also noted that the “accepted practice” limitation would also be problematic in the social sciences. This commenter disagreed that the proposed exclusion for quality improvement or assurance practices should be limited to “an accepted practice,” and felt that it should apply

to the evaluation of alternative practices. In social sciences research an “accepted practice” is generally not as well defined, can evolve rapidly, and vary by considerations such as timing, culture, geography, and nature of service. In social science research, this limitation could severely limit the use of this exclusion for research that is equally low in risk and therefore does not require review.

A few commenters explicitly referenced the importance of QA/QI activities in the context of a learning health care system, and discussed the need for a broader exclusion in order to achieve the goals of a learning health system.

A professional organization focused on advancing the fields of health services research and health policy noted that a basic tenet of the learning health system is the expectation of continuous learning from routine care, which often is accomplished by evaluating health outcomes. The intentional assessment of the outcomes related to a QI activity by itself should not make the activity subject to the Common Rule.

A medical education membership organization felt that routine evaluation of practices and continuous incorporation of knowledge learned into patient care is fundamental to a learning health system and should not be impeded by the regulatory framework. It stated that the current Common Rule provides insufficient guidance to distinguish research and improvement in care delivery in a consistent manner. The organization indicated that the revised Common Rule explicitly recognizes that efforts to improve care by evaluating an accepted practice and the resulting effects are not research that should be regulated under the Common Rule.

Commenters suggested many other QA/QI activities that should be explicitly excluded or exempted from the Common Rule, such as:

- Activities mandated by the Clinical Laboratory Improvement Amendments (CLIA)
- Evaluations of systems-level interventions to improve quality and safety
- Comparative assessment of alternative practices to determine relative effectiveness
- All QA/QI research for the purpose of health care operations, including patient-centered comparative effectiveness research
- Evaluation of competing QA/QI strategies for implementation of accepted medical practices, which should not be subject to IRB review

• Evaluation of competing low-risk interventions that would typically be implemented in a QA/QI framework without further research: these typically are not direct medical treatments but ancillary aspects of care.

• The use of other analytic assessment methods, such as interrupted time series analysis, or randomization of clusters (including stepped wedge designs)

• Dissemination of QA/QI results, or the intention to disseminate results, including by publication, which should not by itself make the activity subject to IRB review (consistent with current OHRP guidance)

• Multi-institution collaborations of otherwise routine QA/QI activities

• Public health-related QA/QI activities

• Comparative benchmarking

Others expressed approval for the proposed exclusion, but suggested that substantial guidance would be necessary for the regulated community to apply this exclusion appropriately. Specifically, several commenters asked about the extent to which OHRP’s current guidance on QA/QI activities would still apply. Others asked for clarification about the extent to which the NPRM proposal would apply in situations where a hospital system with several hospitals implemented different accepted practices at different hospitals within the system, and compared outcomes to determine which accepted practice would be best for that hospital system.

Several comments did not support the NPRM’s QA/QI proposal. Reasons included: believing that the activities excluded by the NPRM already did not meet the definition of research and thus did not need to be explicitly excluded; believing that these activities should be subject to some type of review because of concerns about investigator self-determination; and, believing that even in QA/QI activities, human subjects should be offered the opportunity to know that they are subjects in a research activity and should be offered the option to consent.

One patient advocacy group noted that because much research is done in the guise of administration or QI, this proposed exclusion might encourage researchers to evade human subjects protections while the projects may put primary subjects and third parties at risk. It stated that although some hospital-based projects might incur minimal risk to primary subjects, they might pose greater risk to other parties, for example, patients. Thus, the group argued that this exclusion should be

stricken and that if personal information and biospecimens are to be collected and analyzed for purposes other than the individual patient's care, then that activity should be subject to the Common Rule.

One research institution felt that the proposed change suggests that patient consent will be necessary for many activities designed to ensure QA/QI in health care settings, and could interfere with the imperative to design and evaluate new approaches to enhance patient safety and clinical outcomes. The commenter added that the implications of this provision should be assessed by clinical practitioners and hospital administrators in addition to researchers and research institutions.

Another commenter noted that the proposed exclusion of QA/QI activities fails to exclude important activities that are considered "not research" under the current Common Rule, arguing that the new NPRM exclusion is more in line with evidence-based practice than with QI. Institutions are required under The Joint Commission to perform continuous QI activities, which typically are small, iterative changes to improve clinical care; these activities are seen as part of hospital operations rather than research. The commenter stated that the proposed limitations would make certain QI activities subject to IRB review and possible informed consent requirements, which could result in overregulating an activity that is currently not subject to the Common Rule.

Several of these commenters generally indicated that they interpreted the proposed exclusion as providing a definition of QA/QI, as opposed to excluding a specific type of QA/QI activity. Several of these commenters suggested deleting a QA/QI exclusion from the rule so that IRBs and investigators would not be confused. One hospital suggested eliminating quality activities from the NPRM since by specifying that certain quality activities are not research, the NPRM seems to designate all other quality activities as research by default.

ii. Response to Comments and Explanation of the Final Rule: Certain Quality Assurance and Quality Improvement Activities

The proposed exclusion for QA/QI activities is not included in the final rule. The degree of concern expressed by the public comments on this topic is significant. We recognize that human subject protections would be meaningful and appropriate for some QA/QI research activities, but not for others. However, to avoid increasing

confusion and unnecessary obstacles to innovation, the final rule does not single out certain QA/QI activities as meeting or not meeting the definition of research.

b. Program Improvement Activities

i. Public Comments

Approximately 20 comments were received on this proposed exclusion regarding data collection and analysis for internal operational monitoring and program improvement purposes, with a strong majority in support. Commenters indicated that the proposed exclusion would require significant guidance because it was unclear what types of activities it might include and when. Several commenters supported the proposed exclusion, but noted that the exclusion should specifically reference QI activities instead of just program improvement activities. One commenter suggested that activities defined as "health care operations" under HIPAA also be included in this exclusion. One commenter opposed this exclusion because of the lack of specific reference to QI. Another opposed this exclusion because they felt it was too narrowly written.

One large private research firm indicated opposition to this proposal because it was too confusing. Further, this group questioned the need for an exclusion that seemed to only reference activities that would not be considered to fall under the rule because these activities would not satisfy the definition of research (specifically, these activities would not be designed to contribute to generalizable knowledge).

Of those who opposed this proposal, a minority suggested that the proposed exclusion could be abused by investigators, especially given that the NPRM did not propose to require any institutional oversight of exclusion determinations. One commenter noted that because many research activities might be conducted under the guise of internal improvement activities, this exclusion seemed to be giving investigators significant opportunities to conduct human research activities outside the confines of the rule.

One commenter who supported this provision suggested that it could be merged with the QA/QI exclusion proposed in the NPRM. This commenter also suggested that a definition of program improvement and operational monitoring be provided.

The NPRM asked whether the use of biospecimens should be permitted in this exclusion. Of those who answered this question, a majority indicated yes. This majority generally referenced a

belief that many activities with residual newborn DBS (see Section III.D) would fall under this exclusion. One commenter who opposed the inclusion of biospecimens in this excluded category indicated that if the goal of the NPRM was to cover all nonidentified biospecimens, then this exclusion should not include the research use of biospecimens.

ii. Response to Comments and Explanation of the Final Rule: Program Improvement Activities

The proposed exclusion for program improvement activities is not included in the final rule. Based on the public comments it does not seem useful for this category of activities to be singled out as not meeting the definition of research. As with the NPRM proposed exclusion regarding QI/QA activities implementing accepted practices, public commenters raised concerns that this exclusion would have created more misunderstanding and confusion than it would have resolved. As with QI/QA activities, some program improvement activities involve research and deserve the protections of the rule, while others are not research and are not under the rule. We believe that this topic would be better addressed through other means.

I. Written or in Writing (§ ____ .102(m))

The final rule includes a definition that was not included in the NPRM nor in the pre-2018 rule. The definition of "written or in writing" is included at § ____ .102(m) to clarify that, in accordance with the longstanding interpretation of the pre-2018 rule, these terms include electronic formats, which are increasingly used to fulfill many of the documentation requirements that appear throughout the rule.

Although public comments did not directly address this issue, we are aware that some in the regulated community are uncertain of whether, for example, consent forms may be in electronic formats. This definition is intended to address this concern. Note that the definition of "written or in writing" does not preclude the possibility that consent forms could be in media other than paper or electronic formats and still meet the requirements of the Common Rule.

IV. Ensuring Compliance With This Policy (§ ____ .103)

A. Background and Pre-2018 Requirements

Requirements in the pre-2018 rule at § ____ .103 delineated procedural requirements for institutions and IRBs to follow to comply with the rule. The

requirements pertained to written assurances (through FWAs) that institutions engaged in research are in compliance with the regulations and that the content of such assurances include: a statement of principles governing the institution in the discharge of its responsibilities to protect research subjects; designation of one or more IRBs; a detailed IRB membership roster; and written procedures for IRBs and reporting of unanticipated problems. A U.S. institution also was able to voluntarily pledge to conduct all of its nonexempt human subjects research, regardless of funding source, in compliance with the Common Rule or the Common Rule and subparts B, C, and D of 45 CFR part 46—often referred to as “checking the box” on the assurance form.

The pre-2018 rule also stated who will execute and evaluate assurances. Finally, the rule described the process by which institutions certify that nonexempt research has been reviewed and approved by an IRB. There has been concern expressed by some that the assurance process may have been unduly burdensome for institutions and did not provide meaningful protections for human subjects.

B. NPRM Proposals

The NPRM proposed a number of substantive and procedural modifications to § ___.103 of the Common Rule. First, the NPRM proposed to move several requirements from § ___.103 to § ___.108, which pertains to IRB functions and operations: (1) The IRB recordkeeping requirements; (2) the requirement in the pre-2018 rule that IRBs have sufficient meeting space and staff to support IRB reviews and record keeping requirements; and (3) the pre-2018 requirement that an up-to-date list of the IRB members and their qualifications be included in an institution’s assurance. The NPRM also proposed to modify the IRB membership requirement such that this up-to-date list would no longer be required as part of an institution’s assurance. Instead, an IRB or an institution would be required to prepare and maintain a current list of IRB members.

The NPRM proposed to delete several requirements found in the pre-2018 rule: (1) The requirement that an institution provide a statement of ethical principles by which the institution will abide, as part of the assurance process; (2) the pre-2018 rule requirement that an institution designate one or more IRBs on its FWA; (3) the provision found in the pre-2018 rule that a department or agency head’s

evaluation of an assurance will take into consideration the adequacy of the proposed IRB(s) designated under the assurance, in light of the anticipated scope of the institution’s activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution; and (4) the requirement that grant applications undergo IRB review and approval for the purposes of certification.

Note that under the NPRM federal departments or agencies would retain the ability to ask for information about which IRBs review research conducted at an institution as part of the assurance process, even if providing this information is not explicitly mandated.

According to the NPRM, an additional, nonregulatory change was proposed for the assurance mechanism. The current option of “checking the box” on an FWA (described in section IV.A above) would be eliminated.

To further strengthen the proposed new provision at § ___.101(a), giving Common Rule departments and agencies explicit authority to enforce compliance directly against IRBs that are not operated by an assured institution, language was proposed requiring that for nonexempt research involving human subjects that is covered by this policy and takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall establish and follow procedures for documenting the institution’s reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy (*e.g.*, a written agreement between the institution and the IRB, or by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not operated by the institution).

The NPRM requested public comment on whether protection for human subjects in research would be enhanced if OHRP conducted routine periodic inspections to ensure that the membership of IRBs designated under FWAs satisfy the requirements of § ___.107.

C. Public Comments

Very few comments were received on the proposals at § ___.103. Four commenters expressed their views on the proposal to delete the requirement

that an institution provide a statement of ethical principles as part of the assurance process, with three supporting the proposal and one opposing it.

Four commenters supported the proposal to eliminate the requirement that an institution designate one or more IRBs on its FWA.

Two comments were received, one in support and one opposed, on the proposed elimination of the requirement that an up-to-date list of the IRB members and their qualifications be included in an institution’s assurance. Two comments, one for and one against, were received on the proposal to remove the requirement that a department or agency head’s evaluation of an assurance take into consideration the adequacy of the proposed IRBs. Responses to the question about periodic inspections to ensure IRBs were compliant were mixed, with most commenters saying that it is not clear that ensuring IRBs are compliant would enhance human subjects protections. Others questioned the need for this requirement, given other incentives institutions have to ensure they have a duly constituted IRB, and still others asked what was meant by “periodic.”

Approximately 30 commenters supported the proposal to delete the requirement that the IRB review grant applications, with only one commenter opposed to the proposal.

D. Response to Comments and Explanation of the Final Rule: Assuring Compliance With the Policy

As proposed in the NPRM, the final rule eliminates the pre-2018 rule requirement that an institution provide a statement of ethical principles by which an institution will abide as part of the assurance process. We believe this requirement is unnecessary. Further, for international institutions that may receive federal funding for research activities, it creates the impression that these international institutions must modify their internal procedures to comport with the set of principles designated on the FWA for activities conducted at those institutions that receive no federal funding. OHRP has received many questions about the extent to which international institutions must adhere to the ethical principles designated as part of the assurance process for research activities conducted by the institution that receive no Common Rule department or agency funding. That such measures are not required will be made clear by deletion of this requirement in the final rule.

Additionally, as proposed in the NPRM, the final rule eliminates the

requirement that appeared in the pre-2018 rule that an up-to-date list of the IRB members and their qualifications be included in an institution's assurance. Instead, §§ _____.108(a)(2) and _____.115(a)(5) in the final rule require that an IRB or the institution prepare and maintain a current list of IRB members. This eliminates the previous requirement that changes in IRB membership be reported to the department or agency head, or to OHRP when the existence of an assurance approved by HHS for federal-wide use is accepted. Of note, SACHRP recommended in March, 2008 that OHRP pursue harmonizing the Common Rule with FDA's human subjects protection regulations by eliminating the requirement to submit IRB membership lists.

The final rule, as proposed in the NPRM, also eliminates the requirement that appeared in the pre-2018 rule that an institution designate one or more IRBs on its FWA. Federal departments or agencies retain the ability to ask for information about which IRBs review research conducted at an institution as part of the assurance process, even if that requirement is not explicitly mandated in the regulations.

An additional, a nonregulatory change that was described in the NPRM will be made to the assurance mechanism. The prior option that enabled institutions with an active FWA to "check the box" (described in section IV.A above) is being eliminated. Importantly, institutions could, if they so desire, continue for purposes of their own internal rules to voluntarily extend the regulations to all research conducted by the institution, but this voluntary extension will no longer be part of the assurance process and such research will not be subject to OHRP oversight. We expect this change to have the beneficial effect of encouraging some institutions to explore a variety of flexible approaches to overseeing low-risk research that is not funded by a Common Rule department or agency, without reducing protection of human subjects, thus furthering the goal to decrease inappropriate administrative burdens.

In addition, as proposed in the NPRM, the final rule removes the provision found in the pre-2018 rule that a department or agency head's evaluation of an assurance will take into consideration the adequacy of the proposed IRB(s) designated under the assurance in light of the anticipated scope of the institution's activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review

procedures in light of the probable risks, and the size and complexity of the institution. We believe this deletion aligns the regulations with changes made in December 2000 to OHRP's implementation of the FWA process. Those changes streamlined and simplified the assurance process and eliminated OHRP's institution-specific evaluation of the adequacy of each IRB designated under the assurance.

Each FWA-holding institution continues to have responsibility for ensuring that the IRBs on which it relies are registered with OHRP and are appropriately constituted to review and approve the institution's human subjects research, as required under §§ _____.107 and _____.108 of the final rule.

The final rule contains language at § _____.103(e) requiring that for nonexempt research involving human subjects (or exempt research that requires limited IRB review) that takes place at an institution for which an IRB not operated by that institution exercises oversight, the institution and the organization operating the IRB must document the institution's reliance on the IRB for its research oversight. The final rule also requires that this documentation include the responsibilities of each entity to ensure compliance with the requirements of the rule.

The requirement included in the final rule for documenting an institution's reliance on an IRB that it does not operate is more flexible than what was proposed in the NPRM. The final rule only requires that the reliance agreement between the institution and the organization operating the IRB be documented. It does not include the NPRM proposal that the institution and the organization operating the IRB establish and follow procedures for documenting the institution's reliance on the IRB for oversight of the research and delineating the responsibilities that each entity would assume to ensure compliance with the requirements of the rule.

In considering the public comments, we determined that it was unnecessary to require that such reliance relationships be described in institutional procedures. Under the final rule, compliance with this provision could be achieved in a variety of flexible ways, for example, through a written agreement between the institution and a specific IRB, through language contained in a protocol of a multi-institutional study, or more broadly, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the

institution and all IRBs that are not operated by the institution. Documenting the responsibilities of the institution and the IRB is already a requirement under the terms of an FWA, but is now a regulatory requirement. An additional requirement has been added at § _____.115(a)(9) that such documentation be part of the IRB records.

We acknowledge that the new requirement could increase administrative burden for some institutions, but believe that the examples cited above reflecting the various options an institution may use to document reliance on an IRB not operated by that institution are generally already standard practice in the regulated community.

Finally, the final rule eliminates the requirement in the pre-2018 rule at § _____.103(f) that grant applications undergo IRB review and approval for the purposes of certification. The grant application is often outdated by the time the research study is submitted for IRB review and contains detailed information about the costs of a study, personnel, and administrative issues that go beyond the mission of the IRB to protect human subjects. Therefore, experience suggests that review and approval of the grant application is not a productive use of IRB time.

V. Exempt Research (§ _____.104)

A. Applicability of Exemptions to Subparts B, C, and D

1. Background and Pre-2018 Requirements

In the pre-2018 rule, the application of the exemptions to research under subparts B, C, and D was specified through footnote 1, which stated that the exemptions do not apply to research involving prisoners, and are also limited in their application to research involving children. Regarding the latter issue, the pre-2018 exemption at § _____.101(b)(2) for research involving educational tests, survey or interview procedures or observations of public behavior did not apply to subpart D (*i.e.*, such research did not qualify for this exemption), except for research involving educational tests, or observations of public behavior when the investigator does not participate in the activities being observed. The pre-2018 exemptions did apply to subpart B.

2. NPRM Proposals

Although some of the exemptions proposed in the NPRM were based largely on exemptions in the pre-2018 rule, not all would have applied to subparts B, C, and D. Language in the

NPRM explained how the proposed exemptions may have applied to the subparts. The NPRM proposed that all of the exemptions be applied to research conducted under subpart B, and that none of the exemptions may be applied to research conducted under subpart C, except for research aimed at a broader population that consists mostly of nonprisoners but that incidentally includes some number of prisoners. The NPRM proposed that some of the exemptions may be applied to research conducted under subpart D. Under the NPRM, the exemption at proposed § _____.104(e)(1) (Research Involving Educational Tests, Surveys, Interviews, or Observation of Public Behavior if the Information is Recorded with Identifiers and even if the Information is Sensitive) could not be applied to research involving children under subpart D. This was because protections including IRB review and parental permission are appropriate for research involving educational tests, surveys or interview procedures, or observation of public behavior when the information collected may be individually identified and sensitive in nature.

Although the NPRM did not propose changes to the HHS regulations at 45 CFR part 46, subparts B, C and D, consideration was given to whether the proposed exemption categories should apply to research involving prisoners under subpart C, either if the research consists mostly of nonprisoners and only incidentally includes some number of prisoners, or if the research intends to involve prisoners as research subjects. Public comment was requested on whether the revised exemption categories should be permitted to apply to research involving prisoners. The NPRM explained considerations including the following: The history of HHS subpart C research certifications to date; the preponderance of low-risk, sociobehavioral research focused on prisoner welfare, substance abuse treatment, community reintegration, and services utilization; the occurrence of prisoner-subjects in databases or registries; and the broad interpretation of the subpart C “prisoner” definition that includes, for example, subjects in court-mandated residential substance abuse treatment.

The NPRM posed a question asking whether language in the final rule should resemble the 2003 waiver of the applicability of certain provisions of the rule for HHS-conducted or -supported epidemiologic research involving prisoners and state that the exemptions apply except for research where prisoners are a particular focus of the

research.³² The language of the 2003 waiver criteria are broader than what was proposed in the NPRM, and already familiar to the research community. They apply to epidemiological research that presents no more than minimal risk and no more than inconvenience to the prisoner/subjects. A question was also asked whether the proposed application of the exemptions to subparts B and D was appropriate.

3. Public Comments

Approximately 50 comments were received on the applicability of the proposed exclusions and exemptions to the subparts of the rule. Eight comments addressed the applicability of the exemptions to subparts B and D. However, responses to the question, “Is the proposed application of the exemptions to subparts B and D appropriate?” uniformly agreed with the proposal. A strong majority of the comments addressed the applicability of the exemptions to subpart C.

The NPRM sought comment on the proposal to allow the exemptions to apply in research that only incidentally involves prisoners, but that is enrolling a primarily nonprisoner population. This would represent a policy shift in how the exemptions historically have been applied to subpart C. Comments regarding this proposal were mixed. Some responses claimed that the proposal expanded the application of the exemptions to all research under subpart C, rather than a small subset of subpart C research. Other comments opposed the proposal, pointing to the troubled history of research with prisoners, and suggesting that research involving prisoners, regardless of the risk level, should always go through subpart C IRB review. A narrow majority of comments responded that the exemptions should be permitted to apply to subpart C in a limited way. However, responses regarding the proposed language or which exemptions should be applicable to subpart C prisoners varied. Some felt a study should be exempted only if it offered some benefit to the prison population. Others felt it could be exempt so long as there was no identifiable sensitive information or biospecimens involved. Some who supported the proposal indicated that because the NPRM did

not propose to expand the applicability of the exemptions to research targeting prisoners, the proposal seemed to be a reasonable expansion. One comment noted that permitting a broader interpretation might enable more prisoner-subjects to participate in potentially low-risk beneficial research. A few commenters addressed whether the language describing the applicability of the subparts to research involving subpart C should resemble the 2003 epidemiological waiver criteria. Of these, comments were mixed, with some indicating that the 2003 epidemiological waiver criteria would be too ambiguous, others indicating that it would be appropriate language to use, and a final minority reiterating their opinion that the exemptions should never be permitted in research conducted under subpart C.

4. Response to Comments and Explanation of the Final Rule: Applicability of Exemptions to Subparts

The NPRM proposal regarding how the proposed exemptions may be applied to the subparts is largely unchanged in the final rule. The language at § _____.104(b)(2) regarding subpart C has been modified slightly to reduce ambiguity and potential administrative burden, and in response to public comment, to narrow the scope of exemption application. The final rule does not adopt the 2003 epidemiological waiver language due to concerns from public comments that such language would be ambiguous and difficult to interpret.

The final rule section _____.104(b)(1) states that all of the exemptions at § _____.104 may be applied to research conducted under subpart B if the conditions of the exemption are met. Language at § _____.104(b)(2) states that none of the § _____.104 exemptions may be applied to research conducted under subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners. This is a modification of the NPRM language, which proposed that the exemptions could apply if research consisted “mostly of nonprisoners and only incidentally” included some number of prisoners. The language was changed in order to avoid the implied need (“mostly”) for institutions to project and track the percentage of prisoners participating in nonexempt research. The revision also more clearly describes and limits the circumstances in which exempt research may include prisoners. The language at § _____.104(b)(3) relevant to subpart D has been modified to reflect the revised structure of the final rule, and now

³² HHS. Waiver of the Applicability of Certain Provisions of Department of Health and Human Services Regulations for Protection of Human Research Subjects for Department of Health and Human Services Conducted or Supported Epidemiologic Research Involving Prisoners as Subjects. FR 68(119):36929 (June 20, 2003). Retrieved from <https://www.gpo.gov/fdsys/pkg/FR-2003-06-20/pdf/03-15580.pdf>.

states that the exemptions at paragraphs (d)(1), and (d)(4)–(8) of this section may be applied to research that is subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of this section may apply only to research activities that are subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research that is subject to subpart D, because protections, including IRB review and parental permission, are appropriate for research involving children and educational tests, surveys or interview procedures, or observation of public behavior when the information collected may be individually identified and sensitive in nature.

The final rule does not make revisions to the HHS regulations at 45 CFR part 46, subparts B, C, and D. Throughout this rulemaking process, the intent has been to revise subpart A, and to address revisions to subparts B, C, and D at a later time. However, particular consideration has been given to the specific issue of whether the proposed exemption categories should apply in the context of research that is aimed at a broad population and only incidentally includes prisoners. We concur with the comments expressing support for this change.

In such instances, the specific protections required by subpart C are frequently not relevant to the research subjects. The permitted inclusion of this subset of prisoners under the exemptions at § 46.104 is intended to allow an appropriate reduction in IRB administrative burden while preventing IRBs from necessarily prohibiting the participation of this group in exempt research activities, assuming the conditions of the exemptions are fully satisfied.

We believe this subpart C change is narrow in scope, affecting only a small subset of subjects who are prisoners. This change will permit, for example, the exempt secondary research use of information or biospecimens from subjects who are prisoners, if that analysis is not seeking to examine prisoners as a population and only incidentally includes prisoners in the broader study. Such inclusion would previously have required IRB review under subpart C, including review by an IRB prisoner representative, followed by certification to and authorization by OHRP. In addition, if the research did not fit into a § 46.306(a)(2) subpart C category of permissible research, prisoners could not be included as

subjects in the study, thereby causing problems involving identifying and removing these subjects from the analysis of repositories and databases.

Similarly, the narrow expansion would allow a subject to continue participation in exempt research if he or she became a prisoner during the course of an exempt study, assuming the study was aimed at a broad nonprisoner population, without the need for subpart C IRB review and certification to OHRP. For example, an exempt study that recruited subjects from a local community center to participate in a comparison of HIV educational materials would continue to be exempt, and would not trigger the need for review under subpart C, even if some of the subjects became prisoners after enrollment. On the other hand, a study that recruited subjects from a jail or prison to participate in a comparison of HIV educational materials would continue to be nonexempt under the final rule and require both subpart A and subpart C review, including certification to OHRP.

B. Exemption Determination

1. Background and Pre-2018 Requirements

The pre-2018 rule did not specify who at an institution may determine that research is exempt. However, in the past, OHRP has recommended that because of the potential for conflict of interest, investigators not be given the authority to make an independent determination that their human subjects research is exempt. OHRP has recommended that institutions implement exemption policies that most effectively address the local setting and programs of research. OHRP has recognized that this may result in a variety of configurations of exemption authority, any of which were acceptable assuming compliance with the pre-2018 regulations. In addition, OHRP guidance provided that institutional policies and procedures should identify clearly who is responsible for making exemption decisions. We note that under the pre-2018 and final rule a Common Rule department or agency retains final authority as to whether a particular human subjects research study conducted or supported by that department or agency is exempt from the Common Rule.

2. NPRM Proposals

The NPRM proposed to adopt a requirement that exemption determinations be documented, and that such determinations could be made only in two specified ways. To assist

investigators and institutions in making a timely and accurate determination of exemption status the NPRM proposed that federal departments or agencies would develop one or more exemption determination tools (the use of which would constitute one of the ways in which determinations could be made). Federal departments or agencies would create their own tool, or rely on a tool created by another department or agency (including a web-based tool created by HHS). Institutions would have discretion as to whether or not to implement such a tool. As proposed in the NPRM, it would be designed in such a way that if the person using the tool inputs accurate information about the study, the tool would produce a determination of whether the study is exempt. Institutions could rely on the use of the federally developed tool by investigators as a “safe harbor” for this determination. Use of the tool would be voluntary, and each institution and agency would decide whether to rely on the decision tool for their determinations, and if so, who would be allowed to use it. Institutions that chose not to use the tool for particular determinations would be required to have such determinations made by an individual who is knowledgeable about the exemption categories and who has access to sufficient information to make an informed and reasonable determination. In general, as envisioned in the NPRM, it was expected that investigators would not be allowed to make exemption determinations for themselves without the use of the decision tool, due to considerations of a conflict of interest.

The NPRM requested public comment on several aspects of the proposal to develop a decision tool: (1) The likelihood of an institution allowing investigators to use the tool; (2) the ease of investigators contriving answers in using the tool; (3) whether use of the tool should be restricted to certain exempt categories of research; (4) whether deployment of such a tool would erode public trust in research; and (5) what additional information should be required to be kept as a record other than the information submitted into the decision tool.

The NPRM also proposed that the institution or IRB be required to maintain records of exemption determinations, which records must include, at a minimum, the name of the research study, the name of the investigator, and the exemption category applied to the research study. As described in the NPRM, maintenance of the output of the completed decision tool would fulfill this recordkeeping

requirement. Although the NPRM did not propose an auditing requirement for assessing the accuracy of exemption determinations, it sought public comment about the need for one.

3. Public Comments

This was one of the more commented-on provisions of the NPRM, receiving approximately 280 comments. Public comment was generally mixed, with approximately half supporting and half opposing this proposal. A large majority noted that they felt unable to adequately respond to this proposal without seeing the decision tool first. Many of those who indicated general support for this proposal noted substantial qualifications to their support, such as the need to see the tool before deciding. Some requested that this proposal not be included in a final rule, and that a separate NPRM be issued specific to this proposal. Many commenters said that for simplicity and consistency, one tool should be agreed on by all of the sponsoring departments and agencies and that the departments and agencies should involve research administration professionals in developing such a tool so that it would have field-friendly workability and produces trustworthy results. Further, they thought that the tool should be pilot tested and validated by institutions and investigators before being deployed. For those who supported the concept of a decision tool, they felt that its use would speed the review process for exempt research. Some cited long wait times to receive an exemption determination from their institution's IRB.

Some commenters stated that the tool should clearly indicate that although it determines exemption from federal regulations, state restrictions still apply. A large academic center argued that though the tool could be useful, for institutions that provide services, treatment, and care for vulnerable populations it might be prudent to have someone with expertise in human research protections independently review research proposals to determine whether they are exempt or excluded from IRB review, rather than rely on the tool.

One large research university questioned the need for such a tool, asserting that properly designed oversight and review of exempt research should take minimal time and ensure that only exempt research is conducted without IRB approval. This commenter preferred comprehensive guidance on exempt research to support IRBs in making efficient and expeditious exemption determinations. A large academic/research organization

concurred, pointing out confusion among investigators about exempt categories, which requires careful conversation with IRB officers to understand how their project fits into the human protection framework. This organization believed that these conversations promote safe and effective research decision making and argued that use of the tool could fail to properly educate investigators about the complexities of exempt research determinations.

Some commenters noted that the decisions produced by the tool would be only as good as the tool and the materials and guidance that accompany it. Some commenters added that it is unlikely, however, that the use of a federal decision tool would shield the institution or investigator from liability in third-party actions. Still others went so far as to say that they doubted their institution would allow its use, at least for some time after which it was proven. To the extent institutions are not engaged in the exemption determination process through the tool, some argued that institutions should not be held accountable for any unintended outcomes.

Of those who commented on whether investigators should be allowed and trusted to use the exemption determination tool, some noted that it seemed inappropriate and a conflict of interest for investigators to be allowed to use the tool to generate exemption determinations for their own research activities. Others noted that an investigator might be able to use the tool, but that the proposed exemptions categories were so nuanced that experienced IRB staff might have difficulty determining what qualifies for an exemption. To that end, these comments noted that the tool would need to be accompanied with substantial guidance for an investigator to be able to accurately input information into it. Finally, some commenters expressed concern about the possibility that investigators might enter inaccurate or misleading information into the tool to "game the system," while others noted that that possibility, although remote, exists in the current protocol submission process and that a well-developed tool could include a means for validating certain types of inputs to assess accuracy.

4. Response to Comments and Explanation of the Final Rule: Exemption Determination

The final rule does not adopt the NPRM proposal at this time. Therefore, the final rule does not require that exemption determinations be

documented, as had been proposed in the NPRM, and continues to permit flexibility in how exemption determinations are made. We recognize it was difficult to provide detailed feedback in the absence of an exemption decision tool to evaluate. However, we continue to believe that a well-designed, tested, and validated exemption decision tool could offer an expedient mechanism for determining whether research studies are exempt. Thus, we will continue to explore development of an exemption decision tool. If and when an exemption decision tool is developed, we would issue a subsequent (separate) **Federal Register** notice for public comment. The notice would also give the public the opportunity to comment on whether the use of the tool would be appropriate in making exemption determinations under this final rule. Thus, members of the public would be afforded a sufficient opportunity to provide meaningful comments on such a proposed decision tool.

C. Categories of Exempt Research

The following sections describe the categories of exempt research found in the final rule. Note that several categories of activities proposed in the NPRM as exclusions appear in the final rule as exemptions.

1. Background and Pre-2018 Rule

Under the pre-2018 rule, a research activity qualified for exemption from the Common Rule if it fell into one or more of six categories at § ___.101(b)(1)–(6). Such studies were fully exempt from the regulations. That is, so long as a study did indeed fall within a category, it did not need to satisfy any other regulatory requirements that it needed to satisfy under the pre-2018 rule.

2. NPRM Proposals

The NPRM proposed that all exemption language would be found at § ___.104. The NPRM proposed retaining all of the exemption categories in the pre-2018 rule in one form or another except for the exemption pertaining to research involving the use of educational tests, survey or interview procedures or observation of public behavior if the subjects are elected or appointed officials, or if the confidentiality of the information were protected by statute. However, the NPRM proposed re-classifying some of the pre-2018 rule's exemptions as exclusions under the NPRM (and thus they would not have been subject to administrative or IRB review), while retaining some of the pre-2018 rule's

exemptions as exemptions (versus exclusions).

The NPRM proposed eight exemptions divided into three categories: (1) Low-risk interventions for which there would have been no other requirement (*e.g.*, informed consent and privacy safeguards) other than the determination and recording requirements; (2) research activities that would have required application of privacy safeguards; and (3) secondary research involving biospecimens and identifiable private information that would have required application of privacy safeguards, broad consent, and limited IRB review. The NPRM proposed to have some exempt studies meet certain other regulatory requirements while not having to meet other requirements, making them not “fully exempt” in the sense of the pre-2018 rule.

The NPRM proposed retaining exemption categories § _____.101(b)(1), (5), and (6) from the pre-2018 rule. The NPRM proposed clarifying the exemption for research on public benefit programs or demonstration projects in the pre-2018 rule and explained that OHRP’s guidance would be changed to include the applicability of the exemption to cover research on public benefit and service programs that an agency does not itself administer through its own employees or agents. The NPRM proposed requiring federal departments or agencies conducting such studies to publish a list of studies under this exemption.

The NPRM proposed that new exemptions would be created for:

- Certain research involving benign interventions;
- Certain research involving educational tests, survey or interview procedures, or observation of public behavior where identifiable private information was recorded, so long as data protection standards are met;
- Secondary research use of identifiable private information originally collected for nonresearch purposes;
- Activities relating to storing and maintaining biospecimens and identifiable private information for secondary research use, if subjects provided broad consent;
- Secondary research studies that would use the biospecimens and identifiable private information stored or maintained under the above exemption.

The NPRM asked for public comment on several aspects of these proposals, as they appeared as either exemptions or exclusions and whether their placement in the NPRM was appropriate with

regard to protecting human subjects in research. Comment was requested on whether guidance would be needed to help make exemption determinations and whether the scopes of the proposed exemptions or proposed exclusions were appropriate. That is, whether particular exclusions or exemptions were either too narrow or too broad. For example, several questions were posed about whether research should be exempt if it involved psychological risks. The NPRM asked about whether notice should be given to subjects for any of the activities. The public was asked to comment on whether and how exempt activities could comply with the NPRM’s proposed privacy safeguards.

The NPRM also inquired whether the exemption category related to research conducted in established or commonly accepted educational settings should apply only to research activities in which notice is given to prospective subjects or their legally authorized representatives as a regulatory requirement, when not already required under the Privacy Act of 1974. If so, comment was sought on the type of information to include in the notice and on how such notice should be delivered.

The NPRM asked for feedback on whether the proposed privacy safeguards should apply to research included in the proposed exempt category related to research conducted in established or commonly accepted educational setting, given that such research may involve risk of disclosing identifiable private information. The public was also asked to comment on whether the protections provided by the HIPAA Rules for identifiable health information used for health care operations, public health activities, and research activities are sufficient to protect human subjects involved in such activities, and whether the current process of seeking IRB approval meaningfully adds to the protection of subjects involved in such research studies.

The NPRM asked about the extent to which the HIPAA Rules and the Health Information Technology for Economic and Clinical Health (HITECH) Act³³ adequately address the beneficence, autonomy, and justice considerations related to collecting new information and whether any exemption for such collection should be limited to data collected or generated in the course of clinical practice.

With regard to the proposed exemption related to research and

demonstration projects conducted or supported by a federal department or agency, the public was asked to comment on: (1) Whether notice should be given to prospective subjects and the nature of such notice; (2) whether such activities can involve greater than minimal risk and whether they are appropriate as exemptions; and (3) whether existing privacy safeguards for such activities were sufficient.

A proposed new exemption category was intended to facilitate secondary research using identifiable private information that would have been or would be collected or generated for nonresearch purposes, when prior notice had been given and privacy safeguards and prohibitions on re-use of the information were in place. The public was asked to comment on what types of research should fall under this proposed exemption, whether it should be limited to research in which individuals have been informed of the potential for future research use of their information and given the opportunity to opt out, and whether the exemption would be appropriate for clinical data registries.

Finally, public comment was sought on two related proposed exemptions for research involving the use of biospecimens or identifiable private information that would have been stored or maintained for secondary research use, if consent for the storage and maintenance of the information and biospecimens had been obtained using a broad consent template that the NPRM proposed would be developed by the Secretary of HHS.

3. Public Comments, Response to Comments, and Explanation of the Final Rule: Exemption Categories

All exemption categories, of which there are eight, appear at § _____.104 in the final rule. Four of the exemption categories were proposed as exclusions under the NPRM. In addition, the proposed exclusion concerning certain research involving educational tests, survey or interview procedures, or observation of public behavior has been combined with the exemption regarding additional research activities using the same research methods. The rule includes four exemptions for research involving normal educational practices, research involving benign behavioral interventions, research involving public benefit or service programs, and research involving taste and food quality, all of which were also proposed in the NPRM.

Three exemptions pertain to secondary research uses of identifiable private information or identifiable

³³ The legislative language can be found at https://www.healthit.gov/sites/default/files/hitech_act_excerpt_from_arra_with_index.pdf.

biospecimens. One exemption, at § _____.104(d)(4), which concerns secondary research for which consent is not required, which consists of three of the proposals for exclusions in the NPRM. A second exemption, at § _____.104(d)(7), pertains to storage or maintenance of identifiable private information or identifiable biospecimens for which broad consent is required, and a third exemption, at § _____.104(d)(8), concerns secondary use of identifiable private information or identifiable biospecimens for which broad consent is required. As will be discussed in more detail below, some of the conditions associated with the finalized exemptions differ from what was proposed in the NPRM.

In the final rule, similar to what was proposed in the NPRM, “exempt” does not always mean exempt from all of the requirements of the Common Rule; the activity must fit the description of the exempt category and not include nonexempt research activities. For example, the exemption categories in the final rule at § _____.104(d)(7) and (8) identify specific regulatory requirements that must be met (*e.g.*, limited IRB review, the use of broad consent) as a condition of being exempt from other regulatory requirements.

Public comments, responses to comments, and explanations of the final rule for each exemption category follow.

a. Research Conducted in Established or Commonly Accepted Educational Settings When It Specifically Involves Normal Educational Practices (§ _____.104(d)(1))

i. Public Comments

Approximately 50 comments discussed this exemption, which was a slight modification of an exemption that existed in the pre-2018 rule. The NPRM asked two questions about this exemption: (1) whether it should require some type of notice and if so, how notice should be delivered; and (2) whether the proposed privacy safeguards should apply to this exemption.

One commenter (a research dean from a university) suggested that the wording of the exemption be modified from “research conducted in established or commonly accepted educational settings” to “research conducted in established or commonly accepted educational or other settings” in order to allow more flexibility in how this exemption could be applied.

Other commenters noted a need for guidance on how this exemption should be interpreted. For example, one comment suggested that a wide array of

“normal” educational practices exists, and the intention of this language was difficult to discern. Another comment noted that clarification was needed about permissible data collection methods under this exemption.

One commenter discussing the addition of the limitation that the study should not be likely to adversely affect students’ opportunity to learn noted that it might be difficult to predict ahead of time if the research contemplated under this exemption might have this adverse impact.

Several commenters discussed whether notice should be required. The majority of these comments indicated that some type of notice should be required. A few specifically discussed the importance of notifying subjects of these activities (with one commenter stating that parental consent should be required), stating that lack of notice could erode public trust in research.

Groups representing AI/AN tribal interests argued that notice for this type of research should be required. Specifically, they asserted that transparency around research-related activities and policies, especially in school settings, can build trust among AI/AN populations and ensure that individual and community benefits of participation in research are achieved. They also noted that tribal consultation facilitates decisions about appropriate ways to implement such notices, and observed that the rural nature of many AI/AN communities requires the use of multiple modes of communication and more time spent reaching the intended audience. The commenter also noted that potential subjects should be given the opportunity to opt out of research activities.

One commenter argued that notice is generally an insufficient standard for this type of research and is not a suitable substitute for informed consent.

Approximately 20 comments discussed whether the proposed privacy safeguards that appeared at § _____.105 in the NPRM should apply to this exclusion. Comments were generally mixed about whether this would be appropriate, with a small majority indicating that the privacy safeguards should not apply. These comments generally argued that if an activity is exempt, no additional requirements should be placed on that research activity.

A privacy advocacy organization that supported both notice and attaching the proposed privacy safeguards to this provision, stated that notice in this context is also important because other federal standards (*e.g.*, Family Educational Rights and Privacy Act

[FERPA; 20 U.S.C. 1232g; 34 CFR part 99], Protection of Pupil Rights Amendment [PPRA; 20 U.S.C. 1232h; 34 CFR part 98]) are not acceptable proxies for privacy protection. This commenter indicated that the notice should be robust with detailed information presented to parents directly. As justification for providing additional protections in this context, this group noted that the consequences for misuse of data are greater for children; that is, lost, misused, or leaked information about children could have lifelong consequences. The commenter argued that if an exemption is proposed for this class of research, then the lack of IRB oversight should require that researchers must comply with appropriate privacy safeguards.

ii. Response to Comments and Explanation of the Final Rule: Exemption for Certain Research Conducted in Certain Educational Settings

The final rule includes an exemption at § _____.104(d)(1) for research conducted in established or commonly accepted educational settings that specifically involves normal educational practices, so long as the research is not likely to adversely affect students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

This exemption is a revised version of the first exemption in the pre-2018 rule and a modified version of the exemption as proposed in the NPRM. This change is based on concerns about whether the conduct of some research projects of this type might draw enough time and attention away from the delivery of the regular educational curriculum that they could have a detrimental effect on student achievement. The wording of the exemption has been modified to include a condition that the research is not likely to have these adverse impacts. This was the original intent of the NPRM proposal, and it is an important qualification that should apply to any research activity that is exempt under this provision. It also drops the phrase “in that educational setting,” because that phrase is redundant.

The exemption is retained to allow for the conduct of education research that may contribute to the important public good of improving education, consistent with the principle of beneficence. The

exemption retains the condition that the research activity takes place in established or commonly accepted educational settings, because otherwise IRB review would be warranted for such research activities being conducted in unconventional settings.

We recognize that providing notice for this type of research could involve a significant administrative burden and that it is not always appropriate, and therefore have decided not to include it as a regulatory requirement at this time. We note that making these activities exempt does not mean that there ought not to be tribal consultation about the research activities, and that such consultation may lead to a notice requirement. Where appropriate or mandated by tribal law, tribal consultation should take place irrespective of whether the activity has to meet the requirements of this final rule. Such consultation would represent a free-standing legal obligation, as is referred to in § _____.101(f). When appropriate, investigators may provide notice in a manner that is appropriate to the research activity and the cultural context in which it occurs.

This exemption is largely unchanged from the pre-2018 rule, and does not add requirements for safeguarding privacy at this time.

b. Research That Includes Only Interactions Involving Educational Tests (Cognitive, Diagnostic, Aptitude, Achievement), Survey Procedures, Interview Procedures, or Observation of Public Behavior (Including Visual or Auditory Recording), If at Least One of Three Criteria Is Met (§ _____.104(d)(2))

This exemption in the final rule is a revised version of an exemption in the pre-2018 rule, and is a combination of a provision proposed as an exclusion in the NPRM, and a provision proposed as an exemption in the NPRM. Thus, public comments on both of these proposals follow here.

i. Public Comments

Approximately 80 comments discussed this proposed exclusion, which was an exemption in the pre-2018 rule. Public comments were mixed. Some felt that moving these activities from the exemption to exclusion category would streamline this type of low-risk, common research activity and allow IRBs to focus time and attention on more complicated and higher risk activities. Others, including SACHRP and many research universities, argued that based on their experience, investigators have difficulty making the assessments required to determine whether an activity falls

under this exemption. For example, investigators have a difficult time determining whether disclosure outside of the research context might put someone at risk of criminal or civil liability.

Commenters also expressed concern about whether the three statutes cited in the third prong of the proposed exclusion would provide a comparable level of protections to human subjects as does the Common Rule. Many of these commenters noted that they simply were not sure what types of protections would be afforded to subjects under the Privacy Act, the Paperwork Reduction Act, and the E-Government Act of 2002. Others noted that the main protections provided by these statutes involved notice and not ethics review.

The NPRM requested comment on the extent to which covering educational tests, survey procedures, interview procedures, or observation of public behavior under the Common Rule would substantially add to the protections provided to human subjects. Public comment was mixed, but the majority of commenters felt that these activities should be exempt rather than excluded. One commenter indicated that contrary to the primary justification for excluding these categories of research, these activities cannot always be considered to be low risk and could pose significant risks depending on the nature of the research and sensitivity of the data collected.

One commenter expressed strong opposition to excluding these activities from Common Rule protections, indicating that excluding them would compromise the rights and welfare of research subjects. The commenter emphasized that consent cannot be inherent to participation in the activity because researchers cannot know with certainty that participants are familiar with common forms of educational tests, surveys, and interview procedures and the potential risks inherent to information disclosure. In addition, the commenter pointed out, assuming that even vulnerable subjects know the risks associated with participation in surveys and interviews is contrary to the *Belmont Report's* assertion that vulnerable subjects need additional protection.

Some comments were mixed, for example, suggesting that observation of public behavior might be an acceptable exclusion, whereas surveys and interviews ought to remain exempt. One commenter indicated that it might be reasonable for these activities to be excluded if an exclusion determination tool was available to help investigators make the decision. Another commenter

suggested that whether the activities are exempt or excluded, notice should be required, to indicate the purpose of the activity, describe privacy safeguards, state that participation is voluntary, and provide information on opting out.

Other commenters expressed concern that investigators might not be able to effectively make these determinations, and pointed out that IRBs, with a broad range of experience and expertise in data identifiability, provide a check for researchers' judgment and are better placed to make consistent and informed decisions about exemptions.

Even so, some other commenters felt that Common Rule protections do not substantially add to the protection of human subjects in these categories of activities. Thus, categorizing them as an exemption just adds administrative burden.

The NPRM asked whether this exclusion should apply only to research activities in which notice is given to prospective subjects or their legally authorized representatives as a regulatory requirement, and if so, what information should be included in the notice. Some commenters supported a requirement for notice or at a minimum, some sort of tracking system for these activities. One emphasized that the ethical principle of respect for persons demands some sort of notice. Some indicated that requiring notice prevents these activities from being excluded and might necessitate including them on the list of activities for expedited review rather than deeming them exempt activities.

Other commenters expressed concern about the proposed exclusion. For example, one indicated that it might not be correct to assume that people agree to participate, and understand that they can opt out, by virtue of their participation, and another reiterated concern about assuming that these activities are inherently low risk and expressed a desire to keep these activities in the exempt category to maintain a level of IRB oversight.

The NPRM asked whether it is reasonable to rely on investigators to make self-determinations for the types of research activities covered in this particular exclusion category, and if so, whether documentation of any kind should be generated and retained. One commenter expressed a strong opinion that investigators should be allowed make these self-determinations. However, the majority of comments responding to this question felt that investigators should not be solely responsible for making these determinations.

Some commenters felt that self-determination might work in certain cases or with certain groups but that there would be too much variability to allow it generally. One suggested a screening system that might check whether determinations were being made correctly.

Many commenters pointed out that it is unreasonable to expect investigators to be able to reliably discern levels of risk inherent to disclosure of information, and that what might seem innocuous to researchers could cause real harm to others. Other commenters expressed concern about conflicts of interest, and that investigators might be more likely to make a determination to not delay their research. Another commenter emphasized that oversight is necessary to avoid situations in which investigators inaccurately assume that subjects understand that they are participating in research, or that they are being recorded, for example.

The NPRM requested comment on whether some or all of these activities should be exemptions rather than exclusions. Response to this question was mixed. Some commenters felt that these activities should be excluded. Others felt that surveys and interview should be considered exempt while educational tests and observation of public behavior should be excluded. Still others felt that all should be exemptions except for observations of public behavior, which could be excluded.

The NPRM asked whether these exclusions should be narrowed such that studies with the potential for psychological risk are not included and whether certain topics that involve sensitive information should not be covered by this exclusion. There was general agreement among responses to this question that the exclusions should be narrowed so that studies with the potential for psychological risk were not included in the exclusion. Some commenters, however, indicated that it would be unrealistic to expect investigators to make this determination reliably, that it might be challenging to implement such a policy, and that guidance would be required from regulatory bodies.

Commenters felt that these activities should be exemptions rather than exclusions, to preserve a level of IRB oversight. One commenter pointed out that circumstances that occur in research for which psychological risks are possible are fairly common in this category of activities and that excluding them would leave the risk unaddressed. One professional organization emphasized that the “potential for

serious psychological harms that may be associated with participation in nonbiological research . . . [is] not merely the result of inappropriate disclosure of information.” It also indicated that “the probability and magnitude of this risk may vary by characteristics of individual participants, clinical expertise of the interviewer(s), as well as the risk-minimizing protections that are in place.”

The NPRM requested comment on whether for activities captured under the third element of this exclusion, the statutory, regulatory, and other policy requirements cited provide enough oversight and protection that being subject to expedited review under the Common Rule would produce minimal additional subject protections. If so, the NPRM asked whether the exclusion should be broadened to also cover secondary analysis of information collected pursuant to such activities. Of the few responses to this question, one commenter felt that existing protections are sufficient if information is stored in a secure information technology (IT) infrastructure.

Other organizations expressed strong sentiments that neither the Paperwork Reduction Act nor the Privacy Act were protective in the research context and that current privacy protections are inadequate. They stressed the importance of safeguarding IT and cyber infrastructure and provided examples of large data breaches.

The NPRM asked about the extent to which excluding any of these research activities from the Common Rule could result in an actual or perceived reduction or alteration of existing rights or protections provided to human subjects. That is, does excluding these research activities from the Common Rule pose any risks to scientific integrity or public trust? Commenters who responded to this question generally felt that excluding any of these research activities could result in an actual or perceived reduction or alteration of existing rights or protections provided to human subjects. One indicated that reduction in oversight would lead to subjects being exposed to unintended risks that otherwise would be preventable. Other commenters felt that improper assumptions about low levels of risk in these activities and allowing for self-determination could lead to a reduction in protections for human subjects.

ii. Public Comments on the Proposed Exemption for Research Involving Educational Tests, Surveys, Interviews, or Observation of Public Behavior If the Information Is Recorded With Identifiers, and Even If the Information Is Sensitive

Approximately 50 comments discussed the proposal to exempt educational tests, surveys, interviews, or observation of public behavior if the information is recorded with identifiers and even if the information is sensitive. Public comment here was mixed, with some agreeing that by mandating privacy safeguards, the proposal effectively addresses the primary risk that occurs in this type of research. Others argued that this type of research still benefits from some type of IRB review and thus should be considered covered rather than exempted research. Yet other comments noted that it was impossible to make a determination about this proposed exemption without seeing the proposed privacy safeguards that were proposed in the NPRM.

Several commenters noted that the parameters of this exclusion might be acceptable if it excluded sensitive topics or if it excluded research studies that posed psychological harm to potential subjects. One comment by a professional organization of psychology professionals noted that IRBs often misunderstand and overstate psychological risks in research. Because of this, this group argued that the rule should not include a limitation based on psychological risks because IRBs are not able to effectively assess psychological risks.

The NPRM also asked whether this exemption should be extended to research involving children. The majority of those who responded to this question were opposed to such an extension.

iii. Response to Comments and Explanation of the Final Rule: Exemption for Certain Research Involving Educational Tests, Surveys, Interviews, or Observation of Public Behavior Under Specific Conditions

The final rule includes an exemption at § ___.104(d)(2) that is a revised version of an exemption in the pre-2018 rule. The exemption applies to research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) uninfluenced by the investigator if at least one of three criteria is met:

- The information obtained is recorded by the investigator in such a manner that the identity of the human subject cannot readily be ascertained, directly or through identifiers linked to the subjects;

- Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

- The information obtained is recorded by the investigator in such a manner that the identity of human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § _____.111(a)(7) (which relate to there being adequate provisions for protecting privacy and maintaining confidentiality).

The final rule does not include the language proposed in the NPRM that offered as one prong of the exemption (proposed as an exclusion) that the research be subject to the Privacy Act, the Paperwork Reduction Act, or the E-Government Act of 2002. The final rule simply includes § _____.104(d)(2)(iii), which requires limited IRB review as described at § _____.111(a)(7) if identifiable private information will be obtained and recorded in such a way that the identity of human subjects can readily be ascertained, either directly or through identifiers linked to the subject.

This exemption is based on the assumption that the potential risks raised by this category are largely informational and that subjects are aware of them, and thus the most important role that an IRB might play with respect to reducing potential harms is to ensure the application of privacy safeguards. Under this assumption, the exemption is consistent with the principle of respect for persons and the preservation of autonomy. In the case of observation of public behavior, even if the subject does not know that an investigator is watching his or her actions, the subject's behavior is public and could be observed by others, and thus the research observation is not inappropriately intrusive.

The term "survey" as used here refers to information collected about individuals through questionnaires or similar procedures (e.g., the Current Population Survey conducted by the U.S. Census). "Human subjects" do not include organizations or businesses. "Survey," as used here, does not include the collection of biospecimens. Thus, an activity that included the

collection of a biospecimen (e.g., a cheek swab), in addition to collecting verbal or written responses to questions, could not qualify for this exemption.

This exemption includes the research activities that appeared at § _____.101(b)(2) in the pre-2018 rule, as well as some additional information collection research activities using the same methods. As in the pre-2018 rule, this exemption includes research studies whose methods consist of the use of educational tests, survey or interview procedures, or observation of public behavior that does not involve an intervention, if the data are recorded anonymously, or the information is recorded with identifiers, but is not sensitive such that its disclosure could result in harm to the subjects. The exemption provides a list of the specific harms that must be considered, as did the pre-2018 rule, with the addition of the specific harm of potential damage to the subjects' educational advancement. This potential harm has been added because of the obvious relevance to the effects of the disclosure of responses in research involving educational tests.

This exemption has been expanded to include research using the same methods involving identifiable private information that might be sensitive or potentially harmful if disclosed, so long as the investigators adhere to the limited IRB requirements outlined in § _____.111(a)(7), and the research is not subject to Subpart D. The limited IRB review requirements are designed to provide privacy safeguards to reduce the chances that the disclosure of identifiable private information will occur and lead to harm.

The wording of the exemption is clarified to indicate (consistent with the interpretation of § _____.101(b)(2) in the pre-2018 rule) that the research cannot include interventions in addition to the educational tests, survey or interview procedures, or observation of public behavior. Research involving interventions that are distinct from those information collection methods allowable under this exemption do not satisfy the conditions of this exemption. For example, if a research study were to randomly assign students to take an educational test in a quiet room or in a room with a moderate level of noise, or to consume a snack (or not) before taking the test, this research would not be exempt under this exemption. It should be noted, however, that educational tests may include exposing test takers to certain materials as part of the test, and that such materials do not constitute interventions distinct from the test. For example, reading comprehension tests may direct test

takers to read a passage, and a geography test may present test takers with a map, and ask them to draw information from that map. Likewise, survey procedures may contain some information that the respondents are asked questions about, which would not be considered distinct interventions. However, research in which the purpose of the research is to see whether respondents answer survey questions differently depending on the gender of the interviewer would not satisfy the conditions of the exemption, because the manipulation of the interviewer would be a distinct intervention. Research involving observation of public behavior does not qualify for this exemption if the investigator intervenes with subjects, for example, by offering them an ostensibly lost wallet to see if they will accept it.

Part of the rationale for exempting the research activities at § _____.104(d)(2) from the Common Rule, even when the research is not otherwise subject to additional federal controls, is that for education tests, survey or interview procedures, agreement to participate is inherent in participation and that for much of this research the risks most likely to be experienced by subjects are related to disclosure of anonymous, nonsensitive information and are thus categorized as "low." In general, it is reasonable to expect that individuals, including vulnerable populations (other than children), would understand that actively providing responses to educational tests, surveys, or interview procedures constitutes agreement to participate and that the risks associated with such participation would be related to disclosure of the information they provided. The exemption of this type of activity rests in large part on the idea that all individuals, regardless of the setting or context in which the activity will take place, are generally familiar with common forms of educational tests and survey and interview procedures that they experience in their daily lives, and do not need additional measures to protect themselves and their privacy from investigators who seek their involvement in research activities involving these procedures. They can decline to participate, or to answer some questions. In addition, if the information collected is both identifiable and sensitive or potentially harmful, the safeguards offered by the limited IRB review requirements at § _____.111(a)(7) apply. This is accomplished through the added provision at § _____.104(d)(2)(iii).

Concerns have also been raised about psychological risks of participating in

surveys or interviews, and of situational risks where the simple awareness that someone was surveyed or interviewed poses a risk. We recognize that this is possible, but believe that this is rare enough that it does not warrant adding additional conditions to the exemption category.

With respect to applying this exemption to research with children, two subcategories of this exemption—concerning information recorded so that subjects cannot be identified (§ ____ .104(d)(2)(i)), and concerning disclosures of the subjects' responses that would not place them at certain kinds of risk or create certain kinds of damage (§ ____ .104(d)(2)(ii))—may apply to research involving children under subpart D if the research involves educational tests or observation of public behavior and the investigator does not participate in the activities being observed. The final subcategory of this exemption (§ ____ .104(d)(2)(iii)), which allows for obtaining and recording identifiable private information, may not be applied to research involving children under subpart D.

c. Research Involving Benign Behavioral Interventions in Conjunction With the Collection of Information From an Adult Subject (§ ____ .104(d)(3))

i. Public Comments

Approximately 50 comments discussed the NPRM proposed exemption involving benign interventions in conjunction with collecting information from an adult subject. Public comments here were mixed, with a majority favoring this exemption, and with the majority of commenters indicating that guidance will be needed for this exemption to be implemented properly. For example, one large research university stated, "The proposed category involving benign interventions needs further revision. While we are supportive of this category in general, the words 'benign intervention' without definition leaves too much room for different interpretations and these terms are not easily applicable to social science research, a context in which these types of activities are likely to occur." Those that favored this exemption generally agreed with the argument put forth in the NPRM that these activities were low in risk and IRB review did not provide subjects meaningful additional protections in this context.

Several comments requested clarification on the extent to which medical interventions might be covered under this exemption. For example, to

what extent could proven diagnostic methods that introduce energy but are not invasive (e.g., magnetic resonance imaging, ultrasound, computerized tomography scan) be considered a "benign intervention" for the purpose of this exemption? Another comment asked whether the provision included the use of medical devices, such as blood pressure monitors or thermometers.

Those who did not support this exemption offered a variety of reasons. One comment from a research university indicated that it did not support this exemption because it could cause studies like the "Milgram Obedience Experiment"³⁴ and the "Stanford Prison Study"³⁵ to occur without IRB review. Another comment reiterated the general stance that all research activities should require IRB review and informed consent.

One comment from a research ethics, public education, and professional organization noted that if the final rule includes an expansion of exemption categories such as the proposed benign intervention exemption in the NPRM, then investigator education on human subjects protection should be mandated.

Another comment noted that it should be clarified in the regulatory text that withholding the investigator's hypothesis from subjects is not deception.

The majority of commenters indicated that no additional requirements, be it notice or the proposed privacy safeguards, should be applied to this exemption category. A minority of comments indicated that some kind of notice should be required with this provision, generally asking for that notice to include the purpose of the study, the privacy and confidentiality protections in place, a statement that participation is voluntary, information on how to opt out of the study, and information about who to contact for more information. Comments that favored notice suggested that the notice should be study-specific.

Although commenters generally felt the examples of activities that would satisfy this exemption included in the regulatory text were sufficient, commenters also indicated that many of the terms used in this exemption

needed additional explanation, for example, "brief in duration," "painless," and "physically invasive." A large research university noted that the proposed language raised questions about what sorts of impact are significant and how long is "lasting."

One large professional organization representing research universities and organizations noted that the term "benign intervention" did not seem to encapsulate the types of activities that the NPRM contemplated. Specifically, this organization argued that "benign intervention" connotes a medical procedure, when the NPRM preamble suggested that this exemption encompasses nonmedical "benign interventions" generally. This organization also suggested that the activities contemplated by this exemption are more like interactions than interventions.

In response to a question about whether the decision tool could be relied on for making this exemption determination, a majority of those who responded indicated that it would be impossible to answer this question without first seeing the decision tool. Others indicated that without better definition of terms like "benign intervention," "prospectively agree," "long lasting," and "significant impact," it would be impossible for a tool to provide accurate determinations for this exemption.

ii. Response to Comments and Explanation of the Final Rule: Exemption for Certain Research Involving Benign Behavioral Interventions in Adults

This exemption at § ____ .104(d)(3) was not in the pre-2018 rule, but was proposed in the NPRM. In response to public comments that expressed concern over the need to further clarify the term "benign interventions," the word "behavioral" has been inserted to modify the type of intervention which may be included. The intent of this change is to exclude the use of medical interventions (including medical tests, procedures and devices). The exemption being finalized is specifically for research involving benign "behavioral" interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following is met:

- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained

³⁴ Milgram S. Behavioral Study of Obedience. *The Journal of Abnormal and Social Psychology*, 1963; 67(4):371–378. Retrieved from <http://www.columbia.edu/cu/psychology/terrace/w1001/readings/milgram.pdf>.

³⁵ Haney C, Banks WC, and Zimbardo PG. A study of prisoners and guards in a simulated prison. *Naval Research Review*, 1973, 30:4–17. Retrieved from <http://www.simplypsychology.org/zimbardo-paper.pdf>.

directly or through identifiers linked to the subjects;

- Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subject, and an IRB conducts a limited IRB review to make the determination required by § _____.111(a)(7).

For the purpose of this provision, the exemption describes benign behavioral interventions as being brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions include having the subjects play an online game, solve puzzles under various noise conditions, or decide how to allocate a nominal amount of received cash between themselves and someone else.

Unlike the exemption at § _____.104(d)(2), this exemption allows for the intervention to be distinct from the data collection method; for example, a research study comparing test performance of test takers in quiet or noisy surroundings would qualify for this exemption. Also subjects could be asked to perform cognitive tasks, and audiovisual recording could be used to collect the data, without any educational test, survey or interview procedure occurring, and this research would qualify for this exemption.

If the research involves deceiving the subjects about the nature or purposes of the research, this exemption would not be applicable unless the subject authorizes the deception. For the purpose of this provision, authorized deception would be prospective agreement by the subject to participate in research where the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research. The final rule allows this type of research to occur without the requirements of informed consent because the intervention is not likely to result in harm or offense to the subject, and the subject must prospectively agree to the intervention and the data collection.

Subjects must be adults, but the provision does not specify that they must be competent, and therefore tests of competency are not necessary. However, the presumption is that, in keeping with the principle of respect for persons, such subjects will not be exploited.

This new exemption category is added because respect for persons is accomplished through the prospective subject's forthcoming agreement or authorization to participate, the research activities pose little risk to subjects, and the use of this exemption for many social or behavioral studies will enable IRBs to devote more time and attention to research studies involving greater risks or ethical challenges. We note that the requirement for the agreement of the subject effectively serves as a kind of notice, because the subject is asked to agree to participate in the research, and the request will be tailored to the nature of the specific research study.

The final rule includes another condition that was not included in the NPRM, which broadens the type of research that may meet this exemption. The final rule at § _____.104(d)(3)(i)(C) permits investigators to obtain and record information in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subject, provided the research has undergone limited IRB review in accord with § _____.111(a)(7). This alternative condition was added to the final rule for reasons similar to the exemption at § _____.104(d)(2), as a way of providing additional protections when investigators obtain and record information in such a manner that human subjects can be identified directly or through identifiers linked to the subject. Because the risk associated with enabling investigators to obtain and record identifiable private information can be addressed by requiring adherence to the privacy safeguards provided through limited IRB review, we believe it is appropriate to allow such research to be exempt.

In addition, the final rule permits the collection of data through audiovisual recording, not just video recording, as was proposed in the NPRM. We believe that broadening the exemption in this way provides more flexibility to the permissible data collection methods without creating greater risk of harm to research subjects.

We acknowledge that guidance may be useful for interpreting some of the terms in this exemption, and that some cases will be debatable. However, we also believe that a substantial number of research activities will plainly fit this

exemption, and should be allowed to proceed without IRB review. We agree that investigator education is often desirable, but that the provisions of the exemption are not difficult to understand. We believe that Milgram's obedience experiments and the Stanford Prison Experiment would obviously not qualify for this exemption, because investigators had reason to think some subjects would find the interventions offensive or embarrassing. We acknowledge that in this exemption the word "deception" is used to include withholding the purpose of the research, which is consistent with how the term is often used in this context.

d. Secondary Research Use of Identifiable Private Information and Identifiable Biospecimens for Which Consent Is Not Required (§ _____.104(d)(4))

i. Overview

The final rule exemption at § _____.104(d)(4) is for secondary research use of identifiable private information and identifiable biospecimens for which consent is not required. This particular exemption combines several NPRM exclusion proposals. It exempts secondary research use of identifiable private information and identifiable biospecimens when:

- The identifiable private information or identifiable biospecimens are publicly available;
- The information is recorded by the investigator in such a way that the identity of subjects cannot readily be ascertained, and the investigator does not contact subjects or try to re-identify subjects;
- The secondary research activity is regulated under HIPAA; or
- The secondary research activity is conducted by or on behalf of a federal entity and involves the use of federally generated nonresearch information provided that the original collection was subject to specific federal privacy protections and continues to be protected.

By "secondary research," this exemption is referring to re-using identifiable information and identifiable biospecimens that are collected for some other "primary" or "initial" activity. The information or biospecimens that are covered by this exemption would generally be found by the investigator in some type of records (in the case of information) or some type of tissue repository (such as a hospital's department for storing clinical pathology specimens).

It is important to recognize that this exemption does not cover any primary collections of either information or biospecimens. For example, if an investigator wants to collect information directly from research subjects by asking them to complete a questionnaire, that would not be covered by this exemption. If an investigator wants to collect biospecimens by having subjects swab their cheek, that would similarly not be covered by this exemption. On the other hand, an investigator who wants to use information that is in some databank, or use biospecimens that are in a pathology laboratory, or use the "excess" portion of blood that was drawn for clinical purposes, could use this exemption assuming all of the relevant conditions are met.

Also, note that unlike the pre-2018 rule's exemption relating to certain secondary uses of information and biospecimens, the final rule has no requirement that the information and biospecimens must be pre-existing at the time that the investigator begins a particular research study. For example, an investigator could start a study that involves using biospecimens from clinical pathology laboratories, and could include specimens that are added to the laboratories during the course of the study (again assuming that the other conditions of the exemption are met).

Public comments on each of the exclusions proposed in the NPRM and combined in this exemption follow.

(1) Public Comments on the Proposed Exclusion for Research Involving the Collection or Study of Identifiable Private Information or Identifiable Biospecimens That Are Publicly Available or Recorded by the Investigator Without Identifiers

Approximately 50 commenters discussed this proposed exclusion about identifiable private information or identifiable biospecimens that are publicly available or recorded by the investigator without identifiers. Public comments were mixed, with many indicating that investigators should not themselves be allowed to determine whether their research fits under this exclusion, and many indicating that this should be an exemption rather than an exclusion. A majority supported the clarifying language that this category of activities could include information that will be collected.

One commenter indicated that the prohibition on re-identification should apply to activities in publicly available data sets. This commenter also indicated that any research involving re-identification should undergo IRB oversight. Another commenter

suggested that there should also be a prohibition in this category against the release or publication of information that would lead to re-identification.

One commenter indicated that the terminology used in this provision needed clarification. Specifically, the commenter wondered how one should interpret the term "recorded by the investigator" with respect to electronic data?

In response to a question posed in the NPRM about whether any of the exclusion categories should include biospecimens, a majority of those who responded to the question indicated that biospecimens should be included in this category.

The NPRM also asked whether this exclusion should apply to activities involving prisoners. Of those who responded to this question, responses were mixed with some indicating that this exclusion should apply to research with prisoners and others indicating that it would be inappropriate for research with prisoners to be allowed. One commenter indicated that allowing prisoners in this type of research would be a weakening of protections in activities involving vulnerable populations.

(2) Public Comments on the Proposed Exclusion for Certain Activities Covered by HIPAA

Approximately 50 comments discussed the NPRM proposal to exclude certain activities subject to HIPAA. Public comments were mixed, with many indicating that the protections required under HIPAA for "health care operations," "research," and "public health activities," were sufficient, and that for the types of activities identified by the exclusion, review under the Common Rule did not provide meaningful protections. In contrast, others argued that because the scope of a privacy review board is narrower than for an IRB, these activities should not receive a blanket exclusion from the Common Rule.

Under the HIPAA Privacy Rule, health information is de-identified and thus exempt from that rule only if it neither identifies nor provides a reasonable basis to believe that the information can be used to identify an individual. The HIPAA Privacy Rule provides two ways to de-identify information: (1) A formal determination by a qualified expert that the risk is very small that an individual could be identified; or (2) the removal of all 18 specified identifiers of the individual and of the individual's relatives, household members, and employers, as long as the covered entity has no actual

knowledge that the remaining information could be used to identify the individual (45 CFR 164.514(b)).

Otherwise, the HIPAA Privacy Rule addresses some informational risks by imposing restrictions on how individually identifiable health information collected by health plans, health care clearinghouses, and most health care providers ("covered entities") may be used and disclosed, including for research. In addition, the HIPAA Security Rule (45 CFR parts 160 and subparts A and C of part 164) requires that these entities implement certain administrative, physical, and technical safeguards to protect this information, when in electronic form, from unauthorized use or disclosure. However, the HIPAA Rules apply only to covered entities (and in certain situations to their business associates). Not all investigators are part of a covered entity and thus some investigators are not required to comply with those rules. Moreover, the HIPAA Rules do not apply specifically to biospecimens in and of themselves.

One commenter proposed that the exclusion be expanded so that investigators from noncovered entities (as defined in the HIPAA Rules) would be eligible for the exclusion as well. Another commenter suggested that the HIPAA exclusion should be expanded to cover business associates and researchers that comply with HIPAA.

The NPRM asked whether the protections provided by the HIPAA Rules for identifiable health information used for health care operations, public health activities, and research activities are sufficient to protect human subjects involved in such activities, and whether the current process of seeking IRB approval meaningfully adds to the protection of human subjects involved in such research studies. Approximately half of the comments that addressed this question suggested that HIPAA protections are sufficient and that no additional safeguards were needed. Others expressed concern, and suggested that in some, if not all, of the categories in the HIPAA exclusion, HIPAA protections would not be sufficient.

One commenter suggested that this exclusion might be appropriate for health care operations or public health activities, but that the HIPAA rules were not sufficiently protective for research activities. Specifically, one commenter expressed concern that excluding from the Common Rule the use of PHI for research activities in HIPAA-covered entities would weaken protections for patients, because HIPAA's privacy safeguards were never intended to

replace human subject protections and associated ethical and scientific review.

One commenter also noted that other HHS preambles to rules have discussed the differences between the Common Rule and HIPAA, and these preambles noted that HIPAA was not intended to replace the Common Rule. This commenter suggested that given the language included in previous HHS preambles, additional justification for this exclusion would be needed before being included in a final rule.

One commenter felt that the HIPAA rules and HITECH adequately address the *Belmont Report* principles with respect to these exclusions from the Common Rule, but felt the exclusion should not be limited to covered entities. The commenter suggested that the exclusion be extended to noncovered entities that receive PHI and are required to apply HIPAA safeguards in addition to institutions with equivalent protections. Others suggested that the HIPAA and HITECH standards are too protective for much research.

Other commenters felt that this set of exclusions violates the protective mandate because HIPAA's provisions are narrow and do not reflect research ethics concerns. They noted that HITECH addresses technical data security for covered PHI for health care use but not for research use, especially if the data are sent elsewhere. Commenters felt that data used for research should be subject to HITECH data security standards and should not be excluded from Common Rule coverage.

Few commented on whether additional collections (*i.e.*, collections beyond what would ordinarily be collected through routine medical care) should be covered by this exclusion, and those that did suggested that they should be subject to the Common Rule unless those additional collections are covered by another exemption and exclusion.

The NPRM asked whether additional or fewer activities regulated under the HIPAA Privacy Rule should be included in this exclusion. One commenter expressed concern that the HIPAA Privacy Rule was not appropriate because it both underregulates and overregulates research. Another commenter felt that the exclusion creates confusion because HHS has, in other contexts, discussed the differences between the Common Rule and HIPAA and the differing needs in separate contexts.

(3) Public Comments on Research Conducted by a Government Agency Using Government-Generated or Government-Collected Data Obtained for Nonresearch Activities

Approximately 20 comments discussed this proposed exclusion. Public comment was mixed, with several commenters suggesting that they did not understand the full scope of the information generated or collected by the government that would fall under this exclusion. A minority of comments indicated that this category of activities should be exempt rather than excluded.

The NPRM also asked whether this or a separate exclusion should also include research involving information collected for nonresearch purposes by nonfederal entities where comparable privacy safeguards have been established by state law or regulation. Few responded to this question. Of these, several indicated that this exclusion should not be expanded to cover nonresearch data, and should not be expanded to cover activities conducted by nongovernmental investigators using government-generated or -collected data. Several comments indicated that this category was acceptable as an exclusion, with a few commenters suggesting that the category could be further broadened.

One commenter suggested that this provision should apply to nonfederal entities if state laws are as protective as the federal laws cited. This commenter indicated that for these types of activities, the Common Rule protections did not provide meaningful additional protections to subjects. In contrast, several other commenters expressed concern that the privacy safeguards identified in this exclusion were not as protective of subjects as the Common Rule. One commenter indicated that clarifying what constitutes appropriate nonfederal use of this exclusion would be needed.

One commenter suggested that this exclusion might be reasonable as an exclusion if there were a public posting requirement for activities conducted under this exclusion. If this were the case, this commenter indicated that investigator self-determination of whether an activity fit under this exclusion would be reasonable.

In response generally to the question of whether any of the exclusions should apply to activities involving prisoners, a small number of comments addressed this question in the context of this exclusion. Of these responses, comments were mixed.

ii. Response to Public Comments and Explanation of the Final Rule: Exemption for Secondary Research for Which Consent Is Not Required

This exemption at § ___.104(d)(4) is for secondary research uses of identifiable private information or identifiable biospecimens when consent is not required, if at least one of the following criteria is met:

- The identifiable private information or identifiable biospecimens are publicly available;
- Information, which may include information about the biospecimens, is recorded by the investigator in such a manner that the identity of human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
- The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
- The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

The criteria for this exemption were proposed in the NPRM as three exclusions. The final rule modifies the NPRM proposal to allow this exemption to apply to secondary research involving identifiable biospecimens, provided that the exemption's conditions are met. Note that because the NPRM proposal to alter the definition of a human subject to extend to research involving nonidentified biospecimens was not adopted, an exemption for research with such biospecimens is not needed. Accordingly, this exemption is only

relevant to secondary research use of identifiable biospecimens.

The goal of the exemption at § _____.104(d)(4) is to facilitate secondary research using identifiable private information or identifiable biospecimens that have been or will be collected or generated for nonresearch purposes or from research studies other than the proposed research study. Unlike two other new exemptions that also relate to secondary research (the ones at § _____.104(d)(7) and § _____.104(d)(8), discussed below), this exemption does not depend on any consent requirements imposed by the Common Rule being met.

The first two provisions of this exemption (§ _____.104(d)(4)(i) and (ii)) are a modified version of the fourth exemption under the pre-2018 rule. The modified provisions allow the exemption to include research with information and biospecimens that do not yet exist when the research study is proposed for exemption (*i.e.*, that could be collected, for purposes not related to the proposed research study, in the future).

The third and fourth provisions of the exemption have no precursors in the pre-2018 rule. The third provision applies the exemption to secondary research using identifiable private information covered under HIPAA, and the fourth provision applies the exemption to secondary research using identifiable private information collected for nonresearch purposes by the Federal Government, if compliant with the three cited federal statutes. These new rules will allow investigators to see identifiable private information, and also allow them to retain and record that information (including the identifiers) as part of their research records.

We also note that, according to new language at § _____.104(b)(2) adopted as part of this final rule, this exemption permits the secondary research use of identifiable private information or identifiable biospecimens obtained from subjects who are prisoners, if the research is not designed in a way that seeks to recruit prisoners as a population but rather only incidentally (*i.e.*, not intentionally) includes prisoners.

(1) Response to Public Comments and Explanation of the Final Rule: Research Involving the Collection or Study of Identifiable Private Information or Identifiable Biospecimens That Are Publicly Available

The exemption criterion at § _____.104(d)(4)(i) is for secondary research if the identifiable private

information or identifiable biospecimens are publicly available. This would apply to secondary research use of archives in a public library, for example, or to government or other institutional records where public access is provided on request, or from a commercial entity if the information is provided to members of the public on request or if the only requirement for obtaining the information is paying a user fee, registering or signing in as a visitor to an archive. It would also apply if a commercial entity made identifiable biospecimens publicly available to anyone on request or for a fee. This exemption effectively acknowledges that for secondary research with publicly available information or biospecimens, IRB review would not reduce the risk.

(2) Response to Public Comments and Explanation of the Final Rule: Research Involving the Collection or Study of Information (Which May Include Information About Biospecimens) That Has Been or Will Be Collected and Is Recorded Without Identifiers

The provision at § _____.104(d)(4)(ii) exempts research involving identifiable private information, which may include information about biospecimens, if information is recorded by the investigator in such a manner that the identity of human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects. As with the provision at § _____.104(d)(4)(i), this provision is related to an exemption that existed in the pre-2018 rule. In this instance, that prior exemption is being extended to now also cover research with information for which identifiers have been removed when the original collection of information or biospecimens occurs in the future.

(3) Response to Public Comments and Explanation of the Final Rule: The HIPAA Exclusion

The provision at § _____.104(d)(4)(iii) permits the secondary research use of identifiable private information or identifiable biospecimens when the research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164 (the HIPAA Privacy Rule), subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501, or for "public health activities" as described under 45 CFR 164.512(b).

With regard to the criterion at § _____.104(d)(4)(iii), HIPAA also provides protections in the research context for the information that would be subject to this exemption (*e.g.*, clinical records), such that additional Common Rule requirements for consent should be unnecessary in those contexts. Under HIPAA, these protections include, where appropriate, requirements to obtain the individual's authorization for future, secondary research uses of protected health information, or waiver of that authorization by an IRB or HIPAA Privacy Board. This provision introduces a clearer distinction between when the Common Rule and the HIPAA Privacy Rule apply to research in order to avoid duplication of regulatory burden. We believe that the HIPAA protections are adequate for this type of research, and that it is unduly burdensome and confusing to require applying the protections of both HIPAA and an additional set of protections.

This provision was not part of the pre-2018 rule, and was proposed as an exclusion in the NPRM. It is included as a component of an exemption in the final rule, consistent with public comments supporting the proposal.

(4) Response to Public Comments and Explanation of the Final Rule: Research Conducted by a Government Agency Using Government Generated or Government Collected Data Obtained for Nonresearch Activities

The provision at § _____.104(d)(4)(iv) did not exist in the pre-2018 rule and was proposed as an exclusion in the NPRM. It appears as a component of an exemption in the final rule. The exemption permits the use of identifiable private information or identifiable biospecimens for secondary research conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the information originally involved a collection that adheres to the federal standards for safeguarding privacy as described in this part of the exemption.

We believe that the privacy protections are adequate for this type of research, and that it is unduly burdensome and confusing to require these protections and an additional set of protections. This provision has been modified to apply the federal statutory privacy safeguards identified in the exemption provision to both the original collection of the information, and to the secondary research use of the information to which the exemption applies.

e. Research and Demonstration Projects Conducted or Supported by a Federal Department or Agency (§ _____.104(d)(5))

i. Public Comments

Approximately 35 comments discussed the changes proposed in the public benefit or service program exemption. Few of the comments discussed the proposed expansion in OHRP's interpretation of this exemption to include the applicability of the exemption to cover research on public benefit and service programs that an agency does not itself administer through its own employees or agents, with a majority supporting the NPRM proposed expansion. One research university indicated that OHRP should not expand its interpretation of this exemption, and that it should be limited to "federally funded studies evaluating federal programs." This institution did not offer justification for its comment.

Few comments were received about the proposed requirement for exemption designation of research or demonstration projects to be posted to a publicly available federal Web site. The comments discussing this proposed requirement supported it.

The majority of comments indicated that no additional requirements or limitations should be imposed on this exemption. These institutions argued that because this exemption represented a mechanism through which the Federal Government evaluated its own programs, additional limitations and restrictions in the Common Rule did not seem appropriate.

Specifically, with respect to whether or not some sort of notice should be required here, several commenters noted that any notice would need to be meaningful. One commenter indicated that because meaningful notice would be difficult, a notice requirement should not be imposed. One comment suggested that notice should only be required if opt-out would be permitted, and if not, no notice requirement should be imposed. Groups representing AI/AN populations supported the notice requirement and indicated that it should be required at a minimum.

ii. Response to Comments and Explanation of the Final Rule: Exemption for Certain Research and Demonstration Projects Conducted or Supported by a Federal Department or Agency

The final rule includes this exemption as a modified version of an exemption proposed in the NPRM. The exemption at § _____.104(d)(5) in the final rule applies to research and demonstration projects involving public benefit or

service programs, and is a slightly revised version of the exemption in the pre-2018 rule. This revision is designed to clarify the scope of the exemption so that more research studies would be eligible, and to make the exemption easier to apply. It is also designed to allow the Federal Government to carry out important evaluations of its public benefit and service programs to ensure that those programs are cost effective and provide the intended benefits or services, consistent with the principle of beneficence. The wording of the exemption has added "improve" to the purposes of these activities, to make more explicit the idea that the Federal Government conducts these activities in order to enable them to make the public benefit and service programs better, and not just to gauge their current quality.

This exemption is for research and demonstration projects that are conducted or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads. It applies to activities that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including, but not limited to: Procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.

In addition, the final rule clarifies the language of the exemption to conform to OHRP's previous interpretation of public benefit and service programs that are being evaluated as part of the research. This interpretation includes public benefit or service programs that a Common Rule department or agency does not itself administer or conduct through its own employees or agents, but rather supports through a grant or contract program. Therefore, the exemption applies to research and demonstration projects supported through, for example, federal grants or cooperative agreements. These changes would bring the regulatory language into conformance with other provisions of the rule that refer to research "conducted or supported" by federal departments and agencies. These methods of administration are, of course, always subject to department or agency head approval, either directly or by delegation. In addition, some of these research and demonstration projects are conducted through waivers, interagency agreements, or other methods that also require agency head approval. Accordingly, both the previous and revised language allow for the full

panoply of methods by which research and demonstration projects on public benefit or service programs can be carried out.

The wording of the exemption also is clarified to specifically include projects involving waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, in order to make it plain that such research projects on public benefit or service programs qualify for the exemption. The relevant sections of the Social Security Act were also cited when this exemption was published in 1983.

In the interest of transparency, as was proposed in the NPRM, the final rule requires that each federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects the federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list before beginning the research involving human subjects. The department or agency head can determine what sort of information will be included on this list and maintains its oversight. Departments and agencies that already publish research and demonstration projects on a publicly accessible Web site could satisfy this proposed requirement if the existing Web site includes a statement indicating which of the studies were determined to meet this exemption.

The goal of this proposed requirement is to promote transparency of federally conducted or supported activities affecting the public that are not subject to oversight under the Common Rule. It should not cause any delay to the research. HHS will develop a resource that all Common Rule departments and agencies may use to satisfy the requirement at § _____.104(d)(5)(i). Alternatively, an agency can create or modify its own Web site for this purpose.

The exemption is not modified to require notice, to apply only to minimal risk research activities, or to require the privacy safeguards, for reasons reflected in the public comments. We agree with the public comments that argued that in many cases notice would be difficult or impossible to achieve effectively, and that this exemption enables the Federal Government to conduct important evaluations of its own programs that provide significant benefits to the public. In addition, federal departments

and agencies are already subject to other laws and policies that protect the interests of research subjects (e.g., the Privacy Act).

f. Taste and Food Quality Evaluation and Consumer Acceptance Studies (§ _____.104(d)(6))

i. Public Comments

Approximately 20 comments discussed this exemption for taste and food quality evaluation and consumer acceptance studies. The NPRM did not propose changes to this exemption from what appeared in the pre-2018 rule. However, it did ask whether this exemption should be narrowed to apply only to activities for which prospective subjects have been given prior notice, and if so, how that notice should be issued. The NPRM further asked whether subjects should be allowed to opt out of exempt research.

A majority of comments received indicated that the final rule should maintain this exemption without any additional requirements. Commenters generally did not include explanation of this position. A small minority of commenters indicated that subjects should explicitly be provided the opportunity to opt out of this type of activity. In addition, a small minority of commenters indicated that subjects should be given notice before participation. One comment suggested that this exemption include “odor” evaluations as well.

ii. Response to Comments and Explanation of the Final Rule: Exemption for Taste and Food Quality Evaluation and Consumer Acceptance Studies

The final rule retains the exemption from the pre-2018 rule, which was proposed in the NPRM without any change, for taste and food quality evaluation and consumer acceptance studies. This exemption applies if wholesome foods without additives are consumed, or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical or environmental contaminant at or below the level found to be safe by FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. This exemption is retained unchanged from the pre-2018 rule.

g. Secondary Research Use of Identifiable Private Information or Identifiable Biospecimens (or Storage or Maintenance for Such Secondary Research Use) for Which Broad Consent Is Required (§ _____.104(d)(7) and (8))

The final rule includes two exemptions related to the secondary research use (including storage or maintenance for such use) of identifiable private information and identifiable biospecimens that require a subject’s broad consent.

The first of these exemptions is in the final rule at § _____.104(d)(7), and applies to storing and maintaining identifiable private information or identifiable biospecimens for secondary research use.

The second of these exemptions is in the final rule at § _____.104(d)(8) and applies to the secondary research use of identifiable private information and identifiable biospecimens for specific secondary research studies. Secondary research under this exemption would generally be conducted with the information or biospecimens stored and maintained under the exemption at § _____.104(d)(7).

Both of these exemptions for the secondary use of identifiable private information and identifiable biospecimens require broad consent and are discussed in detail below. As with the secondary use exemptions that do not require the subject’s broad consent (discussed above in Section V.3.d. of the preamble), the two exemptions at § _____.104(d)(7) and (8) are also limited to “secondary research.” These exemptions pertain only to research that involves re-using information or biospecimens that were or will be collected for some other “primary” or “initial” activity distinct from using them in secondary research. These exemptions do not cover any primary collections of either information or biospecimens. In other words, if an investigator wants to collect information directly from research subjects, for example, by asking them to complete a questionnaire, that would not be covered by these exemptions. Or if an investigator wants to collect biospecimens by having subjects swab their cheeks, that collection would similarly not be covered by these exemptions. On the other hand, an investigator who wants to use information that is in some databank, or to use biospecimens that are in a pathology laboratory, could use these exemptions, assuming all of the relevant conditions of the exemptions were met.

i. Public Comments on the Proposed Exemptions for Secondary Research Use of Identifiable Private Information or Identifiable Biospecimens (or Storage or Maintenance for Such Secondary Research Use) for Which Broad Consent Is Required

In combination, approximately 150 comments discussed these proposals. Although commenters generally supported creating a pathway for low-risk research with biospecimens to occur without IRB review, a majority opposed the overarching proposal that these exemptions would, for the most part, be the only way (besides study-specific consent) for research with biospecimens to occur. Many of the arguments for and against these exemptions were outlined in section III.D, summarizing public comments received on the proposal to define “human subject” as including all biospecimens used in research, regardless of identifiability.

Many commenters opposed the idea that the exemption should allow specific secondary studies involving biospecimens retained with identifiers to occur without IRB review. These commenters noted that IRBs are required to assess more than privacy and confidentiality protections, and whether informed consent was sought and obtained. Other commenters noted that by effectively encouraging the retention of identifiers with biospecimens (which would likely be required to track which specimens could be used in research at an institution), the NPRM proposals effectively introduced new privacy and confidentiality risks to subjects that did not exist under the pre-2018 rule.

Some commenters who supported the expanded definition of human subject to include all biospecimens did not support these exemptions. These comments were mostly from members of the public and they generally argued that study-specific consent should be sought and obtained from subjects for every study involving that person’s biospecimens. These comments expressed concern that, with broad consent, investigators could still engage in research activities without the individuals’ knowledge.

Several commenters expressed opposition to the NPRM proposal that the exemption could not be used if the investigator intended to return research results to subjects. These commenters saw this as a disincentive to return research results and also noted that it seemed at odds with existing law (e.g., HIPAA) and policy. Specifically, they argued, because patients are entitled

under HIPAA to the contents of their medical records, investigators must always be ready to return research results to subjects enrolled in their studies.

The NPRM inquired about whether the proposed exemption was the best option, or whether there is a better way to balance respect for persons with facilitating research. Responses to this question were mixed, with a majority indicating that the proposed exemptions were not the best option. One comment indicated that broad consent would be reasonable if the consent was meaningful.

Other commenters opposed the proposal as written. One felt it provided too little information and another found the language too complex and subject to misinterpretation. One institution asserted that the exemption would pose a burden on the research enterprise, would make a significant subset of studies impracticable, and would increase costs.

Still other commenters indicated that consent should not be required for secondary research with biospecimens, noting that it was contradictory to determine that a type of research was exempt but still require consent, or that this exemption should not apply to state-mandated newborn DBS programs. One commenter suggested, "A far better option would be to include an exemption for the secondary research use of de-identified or nonidentified biospecimens, without the caveat of requiring a broad consent."

The NPRM requested public comment on whether and how the provision regarding the return of research results should be revised. Public comment was mixed in response to this question. Several comments indicated that the provision was too complex to follow.

Comments that supported the provision about the return of research results in the proposed exemption stressed the complexity of decisions around returning results and many indicated support for required IRB review of investigators' plans for returning research results. One professional organization also emphasized the need to communicate to potential participants during the informed consent process the policies concerning the return of individual research results. Many commenters also called for detailed OHRP guidance on this provision.

One commenter suggested that the broad consent required when biospecimens are collected for storage for future research use include an indication as to whether potential subjects would like to be re-contacted

with individual research results if applicable.

Other commenters were opposed to the provision as written. One large health system indicated that the provision discourages researchers from returning research results to participants and from providing participants with easy access to their individual research data. The commenter emphasized that "Respecting research participants as partners obligates us to avoid the assumptions that researchers, an IRB, or even a panel of experts . . . know best." The commenter went on to say: "While the NPRM suggests researchers cannot use the Common Rule as a shield from a request to deliver a designated record set upon request, the policy seems to discourage equitable research practices and allows informational disparities to continue. This does not serve the interest of justice."

In addition, one professional organization indicated concern that the provision might be interpreted by some to say that IRBs should not allow return of results, which it felt would create a bad situation.

The NPRM sought comment on whether there should be an additional exemption that would permit the collection of biospecimens through minimally invasive procedures (e.g., cheek swab, saliva). A strong majority of commenters indicated no need for an additional exemption to permit the collection of biospecimens through minimally invasive procedures. One professional organization asserted that specimens should not be treated differently based on how they were collected. Other commenters indicated that obtaining specimens through minimally invasive procedures is similar to data collection and should be treated the same way.

ii. Explanation of the Final Rule: Exemptions for Secondary Research Use of Identifiable Private Information or Identifiable Biospecimens (or Storage or Maintenance for Such Secondary Research Use) for Which Broad Consent Is Required

(1) Exemption for the Storage or Maintenance for Secondary Use of Identifiable Private Information or Identifiable Biospecimens for Which Broad Consent is Required (§ _____.104(d)(7))

Section _____.104(d)(7) is an exemption for the storage or maintenance for secondary research use of identifiable private information or identifiable biospecimens. It requires that an IRB conduct limited IRB review

to make the following determinations (required by § _____.111(a)(8)):

- Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of § _____.116(a)(1)–(4), and (a)(6), and (d);
- Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with § _____.117; and
- If a change is made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, adequate provisions must be in place to protect the privacy of subjects and to maintain the confidentiality of data.

This exemption is similar to the exemption proposed in the NPRM at § _____.104(f)(1), but it has been modified in some respects, and the operation of this exemption is also affected by other changes in the final rule that are different from the NPRM. Namely, the exemption has been modified to apply only to storage or maintenance for secondary research use of identifiable private information or identifiable biospecimens, because the final rule does not incorporate the NPRM proposal to alter the definition of a human subject to extend to research involving biospecimens regardless of their identifiability. This exemption was also modified given the decision not to adopt the privacy safeguards proposed in the NPRM at § _____.105.

In addition, the Secretary's template for broad consent is not being finalized for this exemption. Instead, institutions will have the flexibility to create their own consent forms that satisfy requirements at § _____.116(a)(1)–(4), (a)(6) and (d) (see Section XIV). The consent form may be electronic.

Given these changes from the NPRM proposal, the limited IRB review requirement for this exemption provided at § _____.111(a)(8) has been expanded in the final rule to require that the IRB make the following determinations, some of which are similar to those proposed in the NPRM.

The final rule requires that for the exemption to apply, the IRB must determine that broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of § _____.116(a)(1)–(4), (a)(6), and (d); This includes the requirement proposed in the NPRM that there be IRB review of the process through which broad consent will be obtained.

Also, given that we are not finalizing the proposed requirement to use the Secretary's template for broad consent, the final rule includes in this requirement that an IRB determine that the broad consent includes the requirements and elements of consent in accordance with § _____.116(a)(1)–(4), (a)(6), and (d).

The final rule also requires that the IRB determine that broad consent is appropriately documented or waived in accordance with § _____.117. Although written broad consent generally will be required for this exemption to apply, the final rule also permits the exemption to apply when broad consent is obtained and an IRB has waived the documentation requirement for written informed consent under § _____.117(c)(1).

And because the proposed privacy safeguards proposed in the NPRM at § _____.105 are not included in the final rule, if a change will be made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, the IRB must determine that when appropriate, adequate provisions are in place to protect the privacy of subjects and to maintain the confidentiality of data. This is the same IRB determination related to privacy and confidentiality that is required for nonexempt research. Importantly, this IRB determination is required only when a change is made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, and only pertains to the aspects of storage and maintenance that are changed for research purposes. In this circumstance, the investigators are assuming responsibility for the manner in which the information and biospecimens are stored and maintained, and the IRB should be required to ensure that appropriate protections for the subjects are place with regard to the aspects of storage or maintenance that were changed for research purposes.

If, on the other hand, no changes are being made for research purposes to the storage or maintenance, then this IRB determination does not apply. The institution storing and maintaining the information or biospecimens of course still has its responsibility to determine what protections distinct from those required by the Common Rule are appropriate, which may include other legal or regulatory safeguards or institutional policies. In light of application of such additional safeguards, it appears unnecessary to require additional protections through a requirement of this final rule simply

because the individuals providing broad consent have agreed that their biospecimens or information could be used for research at some point in the future. And of course this provision regarding changes made for research purposes applies only when a Common Rule department or agency supports or conducts the research activity.

Note that in many instances the only change that results from a person having signed a broad consent form for research relating to storing and maintaining that person's biospecimens or information is that the institution that is already holding the biospecimens or information (for clinical purposes, for example) merely creates a record indicating that this person has signed such a consent form. The biospecimens and information could remain stored in whatever way (and for whatever period of time) that the institution had previously been storing them, based on the legitimate nonresearch or research-related reasons that the institution has used for initially collecting and storing those biospecimens and information. Any privacy and security protections (outside of the Common Rule) that already may apply to the institution's information record-keeping or biospecimen preservation activities would continue to apply. The Common Rule's protections would not apply before a change in storage or maintenance occurs for research purposes, but rather the institution would continue to operate in accordance with its pre-existing legitimate reasons for having and storing the biospecimens and information. The fact that the broad consent form has been signed does not by itself mean that there needs to be any alteration of what the institution is already doing with the biospecimens or information.

Examples of changed aspects of storage or maintenance for research purposes that would require the IRB to find, before those changes go into effect, whether there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data include the following: If information or biospecimens are moved from one electronic or physical storage location to another due to considerations related to research plans; if information or biospecimens will be stored for longer than they otherwise would have been for the original purpose; if information or biospecimens are placed in a research registry or repository created to serve as a resource for investigators; or investigators are given electronic or physical access to the information or biospecimens. The relevant changes do not necessarily involve moving

information or biospecimens from one location to another. Rather, the relevant changes include any change for research purposes that introduces or alters risks to the privacy or security of the stored information or biospecimens, including giving access to or transferring information or biospecimens for research purposes to someone who otherwise would not have access.

The rationale for this exemption is that with the requirement for limited IRB review and the specified required IRB determinations, including subjects' broad consent, this exemption respects subjects' autonomy and provides appropriate privacy safeguards. More specifically, we believe that broad consent provides some measure of autonomy for individuals to decide whether to allow the research use of their identifiable private information or identifiable biospecimens, without imposing the kind of burden on investigators that would result from a requirement for specific informed consent for each secondary research study. We believe that it is appropriate to create a mechanism for broad consent for secondary research use, even if it involves the potential risk of having identifiers associated with the identifiable private information or identifiable biospecimens. We believe the administrative burden is also acceptable in order to allow for broad consent for secondary research use.

(2) Exemption for Research Involving the Use of Identifiable Private Information or Identifiable Biospecimens for Which Broad Consent is Required (§ _____.104(d)(8))

Section _____.104(d)(8) is an exemption that also requires that broad consent has been obtained, and is for research involving the use of identifiable private information or identifiable biospecimens. This exemption will frequently be paired with the exemption at § _____.104(d)(7), which permits the storage and maintenance of identifiable private information and identifiable biospecimens for secondary research use. The exemption at § _____.104(d)(8) would apply to a specific secondary research study, provided that the following criteria are met:

- Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § _____.116(a)(1)–(4), (a)(6), and (d);
- Documentation of informed consent or waiver of documentation of consent

was obtained in accordance with § _____.117;

- An IRB conducts a limited IRB review to make the determination required by § _____.111(a)(7), and to make the determination that the research to be conducted is within the scope of the broad consent; and
- The investigator does not include returning individual research results to subjects as part of the study plan. However, it is permissible under this exemption to return individual research results when required by law regardless of whether or not such return is described in the study plan.

This exemption could also apply if the investigator obtains appropriate broad consent from the subject in addition to the consent to an original specific study, and then proceeds to use the information or biospecimen in a secondary study.

The exemption at § _____.104(d)(8) is similar to the exemption proposed in the NPRM, but it has been modified in some respects. As with the exemption at § _____.104(d)(7), the operation of the exemption at § _____.104(d)(8) is also affected by other provisions in the final rule that are different from what was proposed in the NPRM. Namely, the exemption has been modified to apply only to storage or maintenance for secondary research use of identifiable private information or identifiable biospecimens because the final rule does not incorporate the NPRM proposal to alter the definition of a human subject to extend to research involving biospecimens regardless of their identifiability.

Due to the decision not to adopt the proposed privacy and security safeguards proposed in the NPRM at § _____.105, this exemption was also modified to require that limited IRB review include an IRB determination that, when appropriate, adequate provisions are in place to protect the privacy of subjects and the confidentiality of data (§ _____.111(a)(7)). This is the same IRB approval criteria related to privacy and confidentiality that is required for nonexempt human subjects research.

In addition, because the final rule does not include a broad consent template when a specific study has been proposed, it is required that the study be reviewed by an IRB to determine whether the proposed secondary analysis fits within the parameters of the broad consent that was obtained for secondary research use.

We believe that the final rule's requirement for limited IRB review of the privacy and confidentiality protections and the adequacy of the

broad consent is responsive to commenters who believe that IRB oversight should be retained for the secondary research use of identifiable private information and identifiable biospecimens.

We recognize commenters' point that this exemption does not provide an incentive to investigators to provide individual research results to subjects, but we believe that the challenges of how and when to return such results warrant consultation with the IRB. We note that with the other revisions to the NPRM proposals, other options for research involving identifiable private information and identifiable biospecimens exist, which would be consistent with having plans for returning individual results. Although broad consent may include a statement that clinically relevant research results might be returned to subjects, we believe that when specific secondary studies include such a plan to return research results, it would almost always be appropriate for the study to be reviewed by an IRB, in part to better ensure that research results are disclosed to subjects in an appropriate manner. The only exceptions would be if the research qualified for another exemption, an IRB waived informed consent under § _____.116(e) or (f), or the research was carried out under a Secretarial waiver at § _____.101(i). We expect that as part of the IRB's review, the IRB would consider what subjects were told in the broad consent regarding the return of research results.

It should be noted that the two exemptions in the final rule at § _____.104(d)(7) and (8) create additional options for investigators to conduct secondary research studies with identifiable private information. The final rule retains, largely unchanged, the options previously available to investigators in the pre-2018 rule. For instance, the final rule retains the pre-2018 criteria for requesting a waiver of consent in order to carry out those studies without obtaining consent. Moreover, secondary research using nonidentified biospecimens would not have to meet these requirements, because the final rule does not finalize the NPRM proposal to alter the definition of a human subject to include research involving nonidentified biospecimens under the rule.

h. NPRM Proposal To Delete the Pre-2018 Rule's Exemption for Surveys and Interviews of Public Officials

The NPRM proposed to delete language found in the pre-2018 rule that exempted surveys and interviews with public officials. Approximately 100

comments discussed this proposed deletion and it was almost universally opposed. Political science professors, students, researchers, and academics from other disciplines generally addressed this deletion.

Comments argued that this deletion would have a chilling effect on political science research and might make political science researchers more vulnerable to law suits. Other comments noted that public officials are generally treated differently in numerous laws, and it is in fact appropriate for the Common Rule to have a different standard for surveys and interviews with public officials. Comments also suggested that this deletion could negatively affect the public's ability to hold public officials accountable for their actions. One commenter suggested that instead of deleting this exemption, a final rule might consider explicitly limiting this exemption to studies that relate to the public officials in their official capacity.

The final rule removes the exemption category in the pre-2018 rule at § _____.101(b)(3)(i), which pertained to research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior, if the human subjects are elected or appointed public officials or candidates for public office, or if federal statute requires without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. We note that many of the public comment concerns are addressed by other provisions in the final rule. Almost all of the research activities in this category would already be exempted under the final rule at § _____.104(d)(2), without needing to single out elected or appointed officials as being treated differently in this way. If the research is designed to provide sensitive generalizable knowledge about officials, then the identifiable private information obtained should be kept confidential as required by this final rule. If the purpose of the activity is in fact designed to hold specific elected or appointed officials up for public scrutiny, and not keep the information confidential, such an activity is not considered research under the provision at § _____.102(l)(2).

Thus, the final rule adopts the NPRM proposal.

i. NPRM Proposal To Exempt Secondary Research Use of Identifiable Private Information Where Notice Was Given

One exemption proposed in the NPRM is not included in the final rule. Note that exclusions proposed in the

NPRM and not included in the final rule also are described in Section III.I.4 of this preamble.

The NPRM proposed to exempt certain secondary research activities involving identifiable private information where notice of such use had been given. The proposed exemption was included, in part, to be responsive to section 511 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which requires the Secretary to issue a clarification or modification with respect to the application of these regulations to certain activities involving clinical data registries. The preamble for the Common Rule NPRM noted “. . . this exemption category might allow certain research activities of these clinical data registries not otherwise covered by the proposed HIPAA-related exclusion (*i.e.*, when the clinical data registries are not part of a HIPAA covered entity or acting as a business associate), such as when a clinical data registry may receive information from a health care entity for research purposes.”

Approximately 70 comments discussed this proposal, with the vast majority from institutions. A minority of commenters (14) supported the NPRM proposal as drafted. In addition, 11 commenters who did not indicate whether they supported the inclusion of this proposal in a final rule asked questions about implementation and the meaning of “notice” under this proposal.

A majority of commenters (41) opposed the proposal as drafted in the NPRM, citing a variety of conflicting reasons:

- Sixteen commenters felt that the NPRM proposal was too permissive as drafted, and that it would not provide adequate protections to prospective subjects. Many of these commenters also suggested that the proposal as drafted did not respect subject autonomy interests sufficiently in not providing subjects with an ability to opt out. They indicated that the exemption might be acceptable if additional requirements (such as subject opt out), or additional limitations (such as limiting the nonresearch information to which this exemption applies to data governed by certain privacy-oriented laws) were implemented.

- Fourteen commenters felt that the NPRM proposal was too restrictive, and that as drafted it would not achieve the stated goal of reducing administrative burden on IRBs. These commenters specifically discussed the implementation burdens involved in providing notice to prospective subjects.

These commenters also noted that providing an option to opt out would be very burdensome to IRBs and investigators, an outcome that seemed counter to the justifications the NPRM provided for this exemption.

- Five commenters felt that the type of research encompassed by this proposal should not be exempted from the Common Rule, and that IRB review or informed consent should be required instead.

Approximately 25 comments discussed whether the NPRM proposal was necessary to enable activities involving qualified clinical data registries. A majority of these comments indicated that because the activities would be subject to the HIPAA regulations, protection of subjects would not be enhanced by the proposed NPRM exemption. Several commenters pointed out that qualified clinical data registries also might qualify for exclusion under the NPRM proposal at 101(b)(2)(ii). Additional comments suggested that other NPRM exemptions and exclusions would cover activities with qualified clinical data registries without commenting on which exemptions and exclusions applied.

The NPRM included the exemption at § _____.104(e)(2), in part, to be responsive to section 511 of MACRA, but commenters expressed little support for this exemption, even for activities carried out by clinical data registries. Section 511 of MACRA has directed the Secretary of HHS to issue a clarification or modification with respect to the application of the Common Rule to activities involving clinical data registries, including quality improvement activities. With this final rule, the Secretary of HHS is providing that clarification here. Because clinical data registries are created for a variety of purposes, and are designed and used in different ways, there is no simple, single answer regarding how the Common Rule applies to clinical data registries. The Secretary of HHS has received advice from SACHRP on this topic, and SACHRP recommended that the pre-2018 rule was adequate to apply to clinical data registries without those registries being given any distinctive status. The Secretary of HHS believes that the same is true for the final rule, and so has not created a specific provision for clinical data registries.

The final rule does not impose any requirements on a large portion of the activities related to clinical data registries. The following points are important: First, the rule does not apply to clinical data registry activities not conducted or supported by a Common Rule department or agency. Second,

many clinical data registry activities, including many quality improvement activities, do not meet the definition of research, and so the Common Rule does not apply. For example, the creation of a clinical data registry designed to provide information about the performance quality of institutional care providers, and whose design is not influenced or altered to facilitate research, is not covered by this rule even if it is known that the registry will be used for research studies. Third, the Common Rule does not apply to a clinical data registry research study that only involves obtaining and analyzing nonidentified information because that activity would not involve a “human subject” as defined by the rule. Fourth, some clinical data registry research activities may qualify for exemption under the proposed provision at § _____.104(d). Fifth, if an institution solely releases identifiable private information that was obtained in the course of patient clinical care to a clinical data registry for research, that institution is considered to be not engaged in human subjects research, and no requirements of the rule apply to that institution.

In contrast, if investigators receive funding from a Common Rule department or agency to design a clinical data registry for research purposes and the registry includes identifiable private information, or involves interacting with individuals (*e.g.*, a research survey), then such an activity involves human subjects research, but may be exempt if it meets one or more of the exemption categories under § _____.104(d)(7). Similarly, if investigators use federal support to obtain identifiable private information from a clinical data registry to conduct a research study, then such secondary research use of clinical registry information would involve human subjects research and the requirements of the rule would apply, although the research may qualify for exemption under § _____.104(d)(8). This is comparable to how the rule applies to a research study that involves chart review of identifiable private information drawn directly from hospital medical records.

VI. Protection of Identifiable Private Information and Identifiable Biospecimens

A. Background and Pre-2018 Requirements

Increasing research use of genetic information, information obtained from analysis of biospecimens, and the ability to more easily merge multiple sources of

administrative and survey datasets (e.g., medical records, claims data, vital records, and information about lifestyle behaviors from surveys) are some examples of how advances in research have increased the risks of data breaches that reveal identifiable private information. For example, the unauthorized release or use of information about subjects such as the disclosure of Social Security or Medicare numbers may pose financial risks, and disclosure of illegal behavior, substance abuse, or chronic illness might jeopardize subjects' current or future employment, or cause emotional or social harm.

Based on questions from and conversations with members of the regulated community, we are aware that IRBs are not always equipped with the expertise needed to evaluate risks to privacy and confidentiality, specifically regarding sophisticated IT security. However, we note that no data suggest that IRBs are currently approving research without requiring appropriate privacy and confidentiality safeguards. Despite this, we recognized that setting standards could assure appropriate privacy and confidentiality consideration and consequent protections to all research subjects, without the administrative burden of needing a specific committee review of the privacy and confidentiality protections of each study. To that end, the 2011 ANPRM suggested establishing mandatory data security and information protection standards for all studies that involve the collection, generation, storage, or use of identifiable or potentially identifiable information that might exist electronically or in paper form or be contained in a biospecimen. It put forward the idea that these standards might adopt the categories used in the HIPAA Rules and asked a series of questions about how best to protect private information.

B. NPRM Proposal

A goal of the NPRM was to ensure that researchers protect the privacy of their participants and the security of the data, calibrated to the likelihood of identifiability and sensitivity of the information being collected. The NPRM proposed to require that investigators and institutions conducting research subject to the Common Rule implement reasonable safeguards for protecting against risks to the security or integrity of biospecimens or identifiable private information. Given the significant concerns of public commenters about an idea discussed in the 2011 ANPRM of adopting the standards solely modeled on certain standards of the HIPAA

Rules, the NPRM proposed several sets of standards, and allowed a choice about which set to use.

First, the NPRM proposed that the Secretary of HHS could publish a list of specific measures that an institution or investigator could use to meet the security requirements. The list would be evaluated and amended, as appropriate, after consultation with other Common Rule departments and agencies. The proposed list would be published in the **Federal Register**, and public comment on the proposed list would be sought before the list was finalized.

The specific safeguards that would be identified by the Secretary would be designed so that they could be readily implemented by the individual investigator, and could build on existing safeguards already in place to protect research data. These standards would include security safeguards to assure that access to physical biospecimens or data is limited only to those who need access for research purposes. The standards would also assure that access to electronic information is authorized only for appropriate use. Finally, the safeguards, collectively referred to as "privacy safeguards," would assure that information and biospecimens posing informational risks to subjects would be protected according to appropriate standards.

Second, the NPRM proposed that if an institution or investigator is currently required to comply with the HIPAA rules, then the safeguards required by the Common Rule would be satisfied. No additional requirements were proposed to protect information subject to the HIPAA Rules. The NPRM also proposed to clarify that the proposed provisions would not amend or repeal the requirements of 45 CFR parts 160 and 164 for the institutions or investigators to which these regulations apply pursuant to 45 CFR 160.102. Institutions or investigators that are not required to follow HIPAA could voluntarily implement the HIPAA Rules and be considered as satisfying the proposed requirements. The NPRM also proposed that for federal departments and agencies that conduct research activities that are or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and the research will involve a collection of information subject to the Paperwork Reduction Act of 1995, 44

U.S.C. 3501 *et seq.*, the requirements would be satisfied.

For purposes of informing the development of the proposed privacy safeguards, the NPRM sought comment on the types of safeguards that would be appropriate for the Secretary's list. The NPRM also noted that additional statutes or acts mandate the protection of privacy and confidentiality of identifiable private information. It might be reasonable to include these as additional standards that would meet the proposed requirement if they were met in research that is subject to those standards or for which an investigator or institution has voluntarily elected to comply. Public comment was sought on whether any of these existing statutes or acts would serve the goals of proposed privacy safeguards.

The NPRM also included conditions for use and disclosure of research information to other entities. It required that protections be in place when a biospecimen or identifiable private information is shared for appropriate research or other purposes. Unless required by law, the NPRM proposed to limit the re-disclosure of identifiable private information or release of biospecimens obtained for research.

The NPRM asked for feedback on whether limiting re-disclosure to four specific circumstances unless such a disclosure was "required by law" would be too restrictive, or whether more permissive standards would better facilitate the NPRM goal of fostering the secondary research use of information. The NPRM also asked whether the proposed limitations on re-disclosure were more or less restrictive than necessary and whether there should be additional purposes for which release of biospecimens or re-disclosure of identifiable private information would be permitted should be allowed.

The NPRM justified this change by arguing that its benefit would be that IRBs would not be required to review the individual plans for safeguarding information and biospecimens for each research study. Although the NPRM presumed that the proposed privacy safeguards would be sufficient, an IRB could determine that a particular activity would require more than what was proposed. Once IRBs became familiar with standard institutional and investigator-adopted protections, the NPRM anticipated that they would become more comfortable with the fact that they need not review every protocol for privacy safeguards. In addition, it was expected that if the proposed privacy safeguards were adopted, overall reduction in regulatory burden would occur because IRBs would not

have to review security provisions on a case-by-case basis.

Finally, as discussed in Section V, the NPRM contained proposed exemptions that would have permitted a larger number of protocols to proceed without IRB review if specific conditions were met, conditioned on investigators and institutions also meeting the proposed privacy and security requirements. Note that there was no requirement for an IRB to determine whether investigators were adhering to the privacy safeguards for such exempt research.

C. Public Comments

Approximately 130 comments addressed the privacy safeguards, with a majority generally supporting the proposal. Both those who supported the proposal and those who opposed it indicated that it was difficult to comment on the adequacy of privacy standards that had yet to be developed.

Those who supported the proposal stated that having standardized, minimum safeguards would create more consistency across IRBs in how biospecimens and identifiable private information are protected. Those who were opposed to the proposal stated that patient information is already covered by HIPAA security standards and student records are already covered by FERPA, arguing that these plus an array of other standards cover financial and various other types of sensitive information, making inclusion in the Common Rule redundant.

However, several comments asserted that the HIPAA standards, while appropriate for health information, would not be appropriate for other types of research data. Others noted that the wide range and nature of research makes it too challenging to develop a blanket standard. With regard to applying the standards to exempt research, one large association of research universities, medical centers, and independent research institutes argued that research covered by the proposed exempt or excluded categories should be low risk and therefore third party evaluation of privacy safeguards was not needed. Several academic research institutions urged that if the security and privacy requirements were included in the final rule, then the measures should be as simple as possible. For example, they suggested developing a single set of standards for all identifiable data rather than calibrating the safeguards to the sensitivity of the information to be collected.

A few comments addressed the proposed re-disclosure criteria. Of these, a majority indicated concerns with the

NPRM redisclosure provision. Most of the opposition was specifically aimed at imposing the sharing criteria for nonidentified biospecimens. These commenters indicated that for sharing nonidentified biospecimens, imposing HIPAA-like privacy safeguards was unnecessary and would be extremely burdensome. Several comments suggested that the Common Rule adopt the same permissible uses and disclosures of information without authorization that exists under HIPAA.

One scientific professional organization and more than 60 institutions endorsing its comments noted that specific redisclosure considerations should exist for identifiable biospecimens, stating that redisclosure of the identity of the source of a biospecimen is appropriate in rare situations in which a confirmed research finding may have a significant impact on the health of the donor of the specimen. A large, private higher education institution noted that the limitations on use, release, and disclosure as proposed seemed at odds with the permissible uses and disclosures allowed under HIPAA.

Others suggested that the language stating that biospecimens or identifiable private information could be released for any lawful purpose with the consent of the subject was too open-ended and permissive. One data privacy and security advocacy group also noted that the introductory language to the proposed safeguards could be read as requiring an investigator to release research biospecimens or disclose identifiable private information upon receipt of a valid request, as opposed to simply permitting an institution to do so. One academic research organization suggested an alternative approach—that the Federal Government clarify that institutions and networks may designate specialized privacy and security boards to review safeguards.

D. Response to Comments and Explanation of the Final Rule: Privacy and Security Protections

The final rule does not adopt the privacy and security protections proposed in the NPRM, but rather retains and acknowledges the IRB's role in ensuring that privacy safeguards are appropriate for the research studies that require IRB review. To better ensure that appropriate privacy protections are required by IRBs, the final rule includes a new provision in the IRB review and approval criteria at § _____.111(a)(7)(i) that requires the Secretary of HHS in consultation with OMB and the Common Rule departments and agencies to issue guidance to assist IRBs

in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data. This requirement is discussed in more detail in Section XI.

Although we continue to believe that appropriately protecting the privacy of human subjects who provide identifiable private information and identifiable biospecimens as well as preventing security breaches is critically important, we agree with the public's concerns about requiring adherence to privacy and security standards when the safeguards to be issued by the Secretary of HHS have yet to be developed. The federal privacy and security laws would apply only to certain federally conducted research. Rather than promulgate a regulation that lacked sufficient specificity, we determined it would be preferable to maintain the requirement that IRBs review research studies to ensure that appropriate privacy and security safeguards are in place to protect research subjects, but include a commitment that the Secretary of HHS will issue guidance to assist IRBs in appropriately protecting subjects' privacy and confidentiality. This guidance would take into consideration, among other things, the level of identifiability and sensitivity of the information being collected. Although IRBs were not specifically designed to evaluate risk to privacy and confidentiality and the adequacy of safeguards to protect against those risks, IRBs have been responsible for evaluating such risks under the pre-2018 rule. We believe that guidance in this complex and evolving area will assist IRBs to identify appropriate protections, and may be better able than standardized protections, to address the variety of privacy and confidentiality concerns that arise in the broad range of research studies that are being carried out now and those that will be conducted in the years to come.

As discussed in Section V, certain NPRM exemption proposals required the application of the NPRM's proposed safeguards in whole or in part. To accommodate the fact that the final rule does not include the privacy safeguards, exemption categories in the final rule that are predicated on the need for some type of privacy safeguards will instead require that an IRB conduct a limited review to ensure that adequate provisions are in place to protect the privacy of subjects and to maintain the confidentiality of data.

The final rule exemptions subject to this limited IRB review requirement are:

- The exemption for research that includes only interactions involving

educational tests, survey procedures, interview procedures, or observations of public behavior regardless of the identifiability or sensitivity of the information collected/recorded (§ _____.104(d)(2)(iii));

- The exemption for research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses or video recording (regardless of the identifiability or sensitivity of the information collected/recorded (§ _____.104(d)(3)(i)(C));

- The exemption for the storage or maintenance of identifiable private information or identifiable biospecimens for which broad consent is required, when there is a change specific to the research activity in how the identifiable private information or identifiable biospecimens are stored and maintained (§ _____.104(d)(7)); and

- The exemption for the secondary research use of identifiable private information or identified biospecimens for which broad consent is required (§ _____.104(d)(8))

VII. IRB Membership and Modification to References to Vulnerability (§§ _____.107(a), _____.111(a)(3), and _____.111(b))

A. Background and Pre-2018 Requirements

The pre-2018 rule stipulated a condition of IRB membership at § _____.107(a) stating that IRBs should aim for membership that does not consist entirely of individuals of one gender, race, or cultural background. It referred again to the characteristics of IRB members at § _____.107(b), stating that efforts should be made to ensure that no IRB consists entirely of members of one gender or one profession.

The pre-2018 rule also referred to the concept of vulnerability and consideration of vulnerable populations in three provisions, one of which pertained to IRB membership (§ _____.107(a)), one with regard to selection of subjects (§ _____.111(a)(3)), and one with regard to additional protections needed for subjects vulnerable to coercion or undue influence (at § _____.111(b)). Under the pre-2018 rule, only § _____.111(b) of the three provisions specifically referred to *vulnerability to coercion or undue influence* as the type of vulnerability that should be considered. In addition, of these same three provisions in the pre-2018 rule, only § _____.107(a) identified “handicapped” individuals as a vulnerable category of subjects.

B. NPRM Proposal

The NPRM proposed eliminating the pre-2018 rule stipulation that IRBs should aim for membership that does not consist entirely of individuals of one gender or profession because the requirement that IRB membership reflect members of varying backgrounds and diversity, including gender, accomplishes the same goal.

Further, the NPRM proposed that the criterion at § _____.111(a)(3) be revised to align with the language of § _____.111(b) to reflect that the vulnerability of the populations in these research studies should be considered to be a function of the possibility of coercion or undue influence, and that this vulnerability alone should be the IRB focus of concern with respect to this criterion. The proposed change was intended to provide greater consistency and clarity in IRB consideration of vulnerability of subject populations in research activities and appropriate protections. A comparable change was also proposed at § _____.107(a), pertaining to IRB membership.

In addition, the NPRM proposed that the term “handicapped” be changed to “physically disabled” individuals. Therefore, to enhance consistency and clarity among these three provisions, it was proposed that the term “physically disabled” be inserted at § _____.111(a)(3) and (b). This would mean that physically disabled persons would be among the individuals that the IRB may consider in determining that the selection of subjects is equitable (§ _____.111(a)(3)), and that the IRB may consider to be vulnerable to coercion or undue influence (§ _____.111(b)). Public comment was sought on whether pregnant women and those with physical disabilities should be characterized as vulnerable to coercion or undue influence. Whether or not these subpopulations are considered vulnerable to coercion or undue influence would not affect the applicability of subpart B.

Finally, the NPRM proposed a change in § _____.107(a), involving the insertion of “economically or educationally disadvantaged persons” as an example of a vulnerable population, and requiring an IRB to give consideration to membership expertise in this area. This language was already included in the pre-2018 rule at § _____.111(a)(3) and § _____.111(b). Adding this category of individuals to those who may be considered vulnerable to coercion or undue influence at § _____.107(a) was intended to create greater consistency among these three provisions.

C. Public Comments

Between 40 and 50 NPRM comments discussed the language describing vulnerable populations found in §§ _____.107(a), _____.111(a)(3), and (b). A majority of these comments only discussed the inclusion of pregnant women as an example of a population that might be vulnerable. Typically, comments addressed only one of the three questions posed in the NPRM about these provisions. The questions asked whether the § _____.111(a)(3) and (b) focus on issues related to coercion or undue influence in research with vulnerable populations, and no other considerations related to vulnerability, was appropriate; whether pregnant women and those with physical disabilities should be included in the category of subpopulations that may be vulnerable to coercion or undue influence; and, whether populations should be considered vulnerable for reasons other than vulnerability to coercion or undue influence.

A majority of the comments stated that the inclusion of pregnant women as an example of a group that might be vulnerable to coercion or undue influence was inappropriate. These commenters noted that to suggest that noncognitive limitations make individuals inherently vulnerable is insulting to those populations. Of those comments that addressed these proposals, a minority discussed whether individuals with physical disabilities should be included as an example of a group that might be vulnerable to coercion and undue influence. As with pregnant women, these commenters stated that the insinuation that groups with physical disabilities might be inherently vulnerable to coercion and undue influence was insulting. One commenter noted that a physical condition might make one vulnerable to coercion or undue influence in the research context, but typically only when the research activity targets that vulnerability (as opposed to those populations always being vulnerable).

In terms of whether other types of vulnerabilities should be considered by IRBs, public comment was mixed. Some commenters indicated that in the research context, the specific concerns with respect to vulnerable populations are limited to vulnerability to coercion and undue influence, while others noted that the regulations do not preclude an IRB from considering other types of vulnerability and that because of this flexibility, additional regulatory text was not necessarily needed. Groups specifically concerned with issues related to research involving Native

American populations noted that there are issues broader than vulnerability to coercion and undue influence that should be considered, such as vulnerability to group harms; one commenter recommended that populations be considered vulnerable as a result of being historically marginalized, such as native/tribal communities; lesbian, gay, bisexual, and transgender (LGBT) individuals; and racial and ethnic groups.

Commenters who disagreed with this change generally felt that a history of societal marginalization, such as that experienced by LGBT groups or AI/AN tribes, should be a basis for determining vulnerability, and that a focus on only coercion or undue influence may be insufficient for IRB consideration.

Several comments discussed the fact that using the term mentally disabled is potentially patronizing. One commenter suggested that instead of listing mentally disabled individuals as a group that might be vulnerable to coercion and undue influence, the regulations should use the term "populations with impaired decision making ability." This suggestion echoes a recommendation made by SACHRP in 2009 as well.³⁶

Another commenter stated that vulnerability status should be based on situational context, not on membership in a population, which potentially promotes stigmatization. Rather, focus should be more on the risk of the research and the situation of each subject when asked to participate in research. Finally, it was suggested that terminally ill patients who have exhausted all standard therapies, and possibly other research interventions, should be considered vulnerable.

D. Response to Comments and Explanation of the Final Rule: References to Vulnerability

A majority of comments agreed that the focus on issues related to coercion or undue influence, and no other considerations related to vulnerability, was appropriate. We agree with this assessment, and have retained this language in the final rule. We believe this change will help guide IRBs when assessing the type of vulnerability that should be the focus of review. We note that the § _____.111(a)(3) approval criterion retains the reference to the purposes of the research and the setting in which it is conducted because these considerations are also relevant to the

assessment of the equitable selection of subjects, and may include factors such as societal marginalization or discrimination.

The language at the three provisions (§ _____.107(a), § _____.111(a)(3), and § _____.111(b)) has been made identical in referring to vulnerability as meaning vulnerability to coercion and undue influence, in recognition that coercion or undue influence refers to the ability to make an informed decision about participating in research.

We agree with comments that said that the list of example vulnerable populations listed in the pre-2018 rule is out of date.

In agreement with the majority of comments, the final rule no longer includes pregnant women or "handicapped" or physically disabled individuals as examples of populations that are potentially vulnerable to coercion or undue influence. Adopting a suggestion from public comment and SACHRP, the final rule uses the term "individuals with impaired decision-making ability" to replace the term "mentally disabled persons."

VIII. IRB Functions and Operations (§ _____.108)

A. Background and Pre-2018 Requirements

The pre-2018 rule outlined IRB functions and operations at §§ _____.103 and _____.108.

B. NPRM Proposals

The NPRM contained several proposals for changes in IRB functions and operations. Of relevance here, the requirements for recordkeeping by IRBs would no longer appear in § _____.103 of the rule but in § _____.108. Much of the discussion related to these changes appears in Section IV regarding the assurance process. The issues are summarized here.

The NPRM proposed that the requirement that a written assurance include a list of IRB members for each IRB designated under the assurance process be replaced. In its place, the NPRM proposed that the assurance include a statement for each designated IRB, prepared and maintained by the institution, or when appropriate the IRB, with a current detailed list of the IRB members including information sufficient to describe each member's chief anticipated contributions to IRB deliberation; and any employment or other relationship between each member and the institution. The regulatory requirement at § _____.103(b)(3) that changes in IRB membership be reported to the

department or agency head, or to OHRP when the existence of an HHS-approved assurance is accepted, would be deleted, eliminating the requirement. Instead, an institution would be required under proposed § _____.108(a)(2) to maintain a current IRB roster, but such a roster would not need to be submitted to OHRP or other agency managing the assurance of compliance process.

The NPRM also proposed to eliminate the requirement in § _____.103(b)(2) that an institution designate one or more IRBs on its FWA established in accordance with the Common Rule. The requirement in the pre-2018 Common Rule at § _____.103(b)(2) that IRBs have sufficient meeting space and staff to support IRB reviews and record keeping requirements was moved in the NPRM to § _____.108(a)(1). Note that under this proposal federal departments or agencies would retain the ability to ask for information about which IRBs review research conducted at an institution as part of the assurance process.

C. Public Comments

Approximately 10 comments were received on these proposals. Of those, all supported the NPRM proposal that changes in IRB membership no longer needed to be reported to the funding department or agency. All commenters supported the proposal that IRBs would simply need to prepare and maintain a current list of IRB members. Commenters agreed that the proposed changes to the IRB roster requirement would reduce administrative burden without having any significant impact on the protection of human subjects. Those who commented on the proposed deletion of the requirement to designate one or more IRBs on an institution's FWA generally supported the proposal.

No comments were received on the proposed movement of IRB policy and recordkeeping requirements from § _____.103 to § _____.108.

D. Explanation of the Final Rule: IRB Functions and Operations

The final rule adopts the NPRM proposals to move the IRB recordkeeping requirements from § _____.103(b)(3), (4), and (5) to § _____.108(a)(2), (3), and (4). (See Section IV regarding changes to § _____.103 as well.) The final rule also adopts the NPRM proposal that IRBs must maintain an accurate list of IRB members but are not required to submit changes to that roster to the funding department or agency. The final rule also adopts the NPRM proposal to delete the requirement in the pre-2018 rule

³⁶ HHS. SACHRP. Attachment: Recommendations Regarding Research Involving Individuals with Impaired Decision-making (2008, 2009). Retrieved from <http://www.hhs.gov/ohrp/sachrp-committee/recommendations/2009-july-15-letter-attachment/#>.

that institutions designate one or more IRBs on that institution's FWA.

IX. IRB Review of Research (§ _____.109)

A. Background and Pre-2018 Requirements

The pre-2018 rule listed four areas of responsibility for IRBs in the review process concerning their authority to approve, request modification, or disapprove research activities; ensure informed consent requirements are met (including documentation or waiver, as relevant); notify investigators of their determinations; and conduct continuing review of research. The rule at § _____.109(a) stated that IRBs have the authority to carry out these responsibilities for all research activities covered by the policy.

In particular, the pre-2018 rule at § _____.109(e) required that IRBs conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year. Except when an expedited review procedure was used, continuing review of research was to occur at convened meetings at which a majority of the IRB members are present, including at least one member whose primary concerns are in nonscientific areas.

An IRB could use an expedited review procedure to conduct continuing review of research for some or all of the research appearing on the list of research eligible for expedited review³⁷ and found by the reviewer(s) to involve no more than minimal risk. The Common Rule departments and agencies could restrict, suspend, terminate, or choose not to authorize an IRB's use of the expedited review procedure (§ _____.110(d)).

B. NPRM Proposals

The NPRM proposed clarifying that the Common Rule does not give IRBs the authority to review or approve, require modification in or disapprove research that qualifies for the exemptions proposed in the NPRM.

The NPRM also proposed to eliminate continuing review for many minimal risk studies (namely those that qualify for expedited review), unless the reviewer documents why continuing review should take place, which would be required according to the NPRM. Moreover, for studies initially reviewed by a convened IRB, continuing review

would not be required, unless specifically mandated by the IRB, after the study reaches the stage where it involves only one or both of the following: (1) Analyzing data (even if it is identifiable private information); or (2) accessing follow-up clinical data from procedures that subjects would undergo as part of standard care for their medical condition or disease.

In addition, the NPRM proposed that continuing review would not be required for research involving certain secondary research using information and biospecimens that requires limited IRB review in order to qualify for an exemption proposed in the NPRM.

Further, the NPRM proposed that an IRB must receive annual confirmation that research is ongoing and that no changes have been made that would require the IRB to conduct continuing review (that is, the study still qualifies for expedited review because it still meets the criteria listed above and still involves no greater than minimal risk).

The NPRM also proposed a new requirement for IRBs to maintain records of continuing reviews. Because the NPRM proposed a new provision that eliminates the need for continuing review under specific circumstances, it also proposed that IRBs need to justify the need for continuing review in cases where it was not required. If an IRB chooses to conduct continuing review even when these conditions are met, the NPRM stated that the rationale for doing so must be documented.

C. Public Comments

Approximately four comments addressed the clarification proposed in the NPRM that IRBs were not authorized by this policy to review exempt research. All who commented opposed the proposed modification. Those who commented were concerned that IRBs and institutions would interpret the modifications to mean that IRBs were precluded from ever reviewing such research and pointed to the possibility, although rare, that there might be a need to do so, particularly if the initial exemption determination was flawed.

With regard to continuing review, approximately 120 comments discussed this proposal. A strong majority of comments (approximately 95) supported this proposal and approximately 15 opposed it. Other comments were mixed. Those who supported the proposal said that it would indeed alleviate IRB administrative burden without diminishing the protections afforded to human subjects. Those who did not support this proposal believed the continuing review process served an important role in allowing an institution

to periodically re-evaluate the benefits, risks, methods, and procedures used in research activities, and whether the research had been modified without approval. Some commenters who supported the proposal were opposed to the requirement for annual confirmation to the IRB that such research is ongoing and that no changes have been made that would require the IRB to conduct continuing review. They stated that the burden alleviated by eliminating the need for continuing review was offset by the requirement to submit an annual confirmation.

D. Response to Comments and Explanation of the Final Rule: Review of Research

The final rule at § _____.109(a) modifies the language of the pre-2018 rule to state that IRBs review and have the authority to approve, require modifications in, or disapprove all research activities covered by this policy, including exempt research activities under § _____.104 for which limited IRB review is a condition of exemption (§ _____.104(d)(2)(iii), § _____.104(d)(3)(i)(C), § _____.104(d)(7), and § _____.104(d)(8)). Since the final rule requires limited IRB review for certain categories of exempt research, the provision at § _____.109(a) has been modified to clarify that IRBs have the authority needed to conduct limited IRB review.

As proposed in the NPRM, and as generally supported in public comments, continuing review is eliminated for all studies that undergo expedited review, unless the reviewer explicitly justifies why continuing review would enhance protection of research subjects (§ _____.109(f)(1)(i) and § _____.115(a)(3)). For studies initially reviewed by a convened IRB, once certain specified procedures are all that remain for the study, continuing review would not be required, unless specifically mandated by the IRB. These activities include: (1) Research eligible for expedited review in accordance with § _____.110; or (2) Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study: (a) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or (b) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care (at § _____.109(f)). In addition, the final rule states at § _____.109(f)(1)(ii) that continuing review is not required for research reviewed in accordance with the limited IRB review procedure described in § _____.104(d)(2)(iii),

³⁷ Office for Human Research Protections. Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure. November 9, 1998. Retrieved from <http://www.hhs.gov/ohrp/policy/expedited98.html>.

§ _____.104(d)(3)(i)(C), § _____.104(d)(7), or § _____.104(d)(8).

The final rule does not require investigators to provide annual confirmation to the IRB that such research is ongoing and that no changes have been made that would require the IRB to conduct continuing review. Institutions that choose to require some accounting of ongoing research not subject to continuing review have significant flexibility in how they implement their own requirements. Note that under the final rule, investigators would still have the current obligations to report various developments (such as unanticipated problems or proposed changes to the study) to the IRB.

X. Expedited Review Procedures (§ _____.110)

A. Background and Pre-2018 Requirements

Under the pre-2018 rule, a research study could receive expedited review if the research activities to be conducted appear on the list of activities published by the Secretary of HHS that are eligible for such review,³⁸ and was found by the reviewer(s) to involve no more than minimal risk. Under an expedited review procedure, the review could be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among the members of the IRB. Research that was eligible for expedited review required continuing review at least annually.

B. NPRM Proposals

The NPRM proposed changes regarding expedited review, to allow expedited review to occur for studies on the Secretary's list unless the reviewer(s) determine(s) that the study involves more than minimal risk. This was in contrast to the pre-2018 regulations, which required that an IRB use the expedited review procedure only if the reviewer determines (and documents) that the research involves no more than minimal risk. In addition, OHRP has indicated that the activities on the current list should not be deemed to be of minimal risk simply because they are included on the list. In a related change, the NPRM contained a requirement that IRBs document the rationale for an expedited reviewer's determination that research appearing on the expedited review list is more

than minimal risk (*i.e.*, an override of the presumption that studies on the Secretary's list are minimal risk).

The NPRM proposed that IRBs reviewing the consent process (and, when required, the privacy safeguards) for studies eligible for the proposed exemption at § _____.104(f)(1) could use the expedited review procedure.

As discussed in Section III of this preamble, the NPRM did not propose to modify the definition of minimal risk, but rather proposed adding to the definition a requirement that the Secretary of HHS create and publish a list of activities that qualify as "minimal risk". This Secretary's list would be re-evaluated periodically, but at least every 8 years, based on recommendations from federal departments and agencies and the public. Note that this would not be an exhaustive list of all activities that would be considered minimal risk under the Common Rule, but would allow IRBs to rely on the determination of minimal risk for activities appearing on the list. IRBs would still need to make minimal risk determinations about activities that do not appear on this list.

In addition, the NPRM proposed to eliminate the parenthetical phrase "of one year or less" when referring to the IRB approval period, since annual continuing review of research eligible for expedited review would no longer be required.

The NPRM also proposed that the regulations be revised to require evaluation of the list of expedited review categories every 8 years, followed by publication in the **Federal Register** and solicitation of public comment. A revised list would be prepared for public comment outside the scope of the NPRM.

C. Public Comments

Approximately 50 comments were received regarding the proposal to update the Secretary's list of expedited review categories every 8 years. A strong majority supported this proposal although some recommended that the mandatory period of review occur more frequently than every 8 years.

Approximately 10 comments discussed the NPRM proposal that an IRB may use the expedited review procedure to satisfy limited IRB review of the consent process as required under the proposed NPRM exemption. A strong majority of these comments supported this proposal.

D. Response to Comments and Explanation of the Final Rule: Expedited Review Procedures

Under the final rule, a study is deemed to be minimal risk and thus

eligible for expedited review if the study only involves activities on the Secretary's list, unless the reviewer determines and documents that the study involves more than minimal risk (§ _____.110(a) and (b)(1)). Thus, we anticipate that more studies that involve no more than minimal risk will undergo expedited review, rather than full review, which will relieve burden on IRBs.

Further, IRBs will be required to document their rationale when they override the presumption that studies on the Secretary's expedited review list involve greater than minimal risk (at § _____.115(a)(8)). Although public comments argued that this documentation represented an unjustified burden on IRBs, we believe that such documentation could provide a basis for the Secretary's future determinations about the appropriateness of the list, and allow for greater consistency across institutions, and thus make the Common Rule more just.

At § _____.110(b)(1)(iii) the final rule adopts the NPRM proposal that an IRB may use the expedited review process when conducting limited IRB review as required by the exemptions at § _____.104(d)(2)(iii), § _____.104(d)(3)(i)(C), § _____.104(d)(7), and § _____.104(d)(8).

Finally, as proposed in the NPRM, evaluation of the list of expedited review categories will occur every 8 years, followed by publication in the **Federal Register** and solicitation of public comment.

XI. Criteria for IRB Approval of Research (§ _____.111)

A. Background and the Pre-2018 Requirements

The determinations that an IRB must make before it can approve a study were spelled out in the pre-2018 rule at § _____.111. These relate, among other things, to minimizing risks to subjects, determining that an appropriate relationship exists between risks and benefits, and ensuring the equitable selection of subjects. The regulations generally required all of these determinations to be made for any study that must undergo IRB review.

B. NPRM Proposals

The NPRM proposed a number of changes regarding the criteria for IRB approval of research, including (1) creating a new form of IRB review for activities relating to storing or maintaining data and biospecimens for later secondary use; (2) revising two of the existing criteria for approval of

³⁸ HHS. OHRP. Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure. November 9, 1998. Retrieved from <http://www.hhs.gov/ohrp/policy/expedited98.html>.

research that have special considerations related to the involvement of vulnerable populations and for privacy and confidentiality of data provisions; and (3) adding a provision about plans to review the return of individual results to participants.

The first set of changes concerned updating the IRB review criteria for research activities relating to storing or maintaining information and biospecimens, and to the secondary use of such information and biospecimens. Paragraph (a)(9)(i) of proposed § _____.111 would have applied to a proposed exemption at § _____.104(f)(1) for storing or maintaining biospecimens or identifiable private information for use in secondary research. This provision would have eliminated the need for an IRB to make the usual determinations about such an activity. Instead, the IRB would have been required to determine that the procedures for obtaining broad consent to storing or maintaining the biospecimens or information were appropriate, and met the standards included in the introductory paragraph of § _____.116. In addition, if these storage and maintenance activities involved a change for research purposes from the way the biospecimens or information had been stored or maintained, then the IRB would have needed to determine that the proposed biospecimen and privacy safeguards at § _____.105 were satisfied for the creation of any related storage database or repository.

The second proposed change was related to the NPRM privacy safeguard proposal and clarified that it would not be an IRB responsibility to review the security plans for biospecimens and identifiable private information for every protocol (*i.e.*, on a case-by-case basis). Also, as discussed in Section VII, the NPRM proposed changing how vulnerable populations are referred to in the regulatory language at § _____.111(a)(3).

The third proposed change was the addition of section (a)(8) to § _____.111 clarifying that if an investigator submits as part of the protocol a plan for returning clinically relevant research results to subjects, the IRB would have to evaluate the appropriateness of the plan. This criterion was proposed in response to public discussions, including SACHRP, recommending that IRBs consider returning individual results to subjects.³⁹

C. Public Comments

Approximately 20 comments discussed the proposed modifications in § _____.111 related to the criteria for IRB approval of research. Of these comments, a majority discussed the proposal that an IRB be required to review the adequacy of plans to return research results, should a proposed study include such a plan. Comments on this proposal were mixed, with both those opposing and supporting the proposal indicating that HHS and other Common Rule departments and agencies would need to issue detailed guidance addressing what is considered an adequate plan in this context. Several commenters suggested deleting this provision due to the lack of clarity surrounding the IRB's role in such a review.

D. Response to Comments and Explanation of the Final Rule: Criteria for IRB Approval of Research

The final rule does not adopt all of the NPRM proposals. It does not include the NPRM proposal regarding IRB review of plans to review the return of clinically relevant results to subjects. This proposal was deleted due to concern over the criteria that would be required for an IRB to appropriately consider this area, the need for particular IRB expertise to appropriately assess the return of results, and ambiguity over the meaning of "clinically relevant."

The final rule does, however, revise two of the existing criteria for approval of research: (1) Special considerations related to the involvement of vulnerable populations, and (2) privacy and confidentiality of data provisions.

As discussed in more detail in Section VII, the language regarding vulnerable populations at § _____.111(a)(3) and (b) has been revised to reflect the current understanding of which populations should receive special consideration due to potential vulnerabilities specific to the purposes and context of human subjects studies and to parallel other references to vulnerable populations found at § _____.107(a).

Section _____.111(a)(7) in the final rule retains the pre-2018 language, but also adds an additional requirement, thereby serving a dual function as both the primary regulatory provision requiring IRB review of the adequacy of protections for the privacy of subjects and confidentiality of identifiable private information (including that obtained from the analysis of biospecimens), and as the primary limited IRB review requirement needed to satisfy certain exemption determinations in § _____.104(d).

In § _____.111(a)(7)(i) the Secretary of HHS commits to issuing guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of information, after consultation with OMB's privacy office and other federal departments and agencies that have adopted this policy. This modification is intended to serve a similar function as the privacy safeguards proposed in the NPRM (but not adopted in the final rule). The guidance might address the following considerations such as:

- The extent to which identifiable private information is or has been de-identified and the risk that such de-identified information can be re-identified;
- The use of the information;
- The extent to which the information will be shared or transferred to a third party or otherwise disclosed or released;
- The likely retention period or life of the information;
- The security controls that are in place to protect the confidentiality and integrity of the information; and
- The potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way contrary to the contours of the research under the exemption.

The final rule at § _____.111(a)(8) modifies the NPRM proposal on the limited IRB review required by § _____.104(d)(7). Section _____.111(a)(8) specifies that for the purposes of conducting the limited IRB review required by § _____.104(d)(7), the IRB must determine that broad consent for storage, maintenance, and secondary research use of identifiable biospecimens or identifiable private information is obtained in accordance with the requirements of § _____.116(a)(1)–(4), (a)(6), and (d). As part of its review of these requirements for broad consent, the IRB would review the appropriateness of the process proposed for obtaining broad consent, and ensure that the required elements of broad consent were appropriately included in the broad consent form (or process, if broad consent is to be obtained orally). Additionally, the IRB must determine that consent is appropriately documented, or that a waiver of documentation is appropriate, in accordance with § _____.117. Finally, if a change is made for research purposes in the way identifiable private information or identifiable biospecimens are stored or maintained, the IRB must determine that adequate provisions are in place to protect the privacy of subjects and to maintain the

³⁹ <http://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-return-individual-research-results/index.html>.

confidentiality of data. It is expected that the guidance to be developed by the Secretary of HHS about protecting the privacy of subjects and maintaining the confidentiality of data will also be applicable to the privacy and confidentiality considerations included in this limited IRB review requirement.

XII. Cooperative Research (§ _____.114)

A. Background and Pre-2018 Requirements

The pre-2018 rule required that each institution engaged in a cooperative research study obtain IRB approval of the study, although it did not require that a separate local IRB at each institution conduct such review. In many cases, however, a local IRB for each institution would independently review the research protocol, and informed consent forms and other materials, often resulting in multiple reviews for one study. When any one of these IRBs would require changes to the research protocol that are adopted for the entire study, investigators would have to re-submit the revised protocol to all of the reviewing IRBs. This process could take many months and significantly delay the initiation of research projects and recruitment of subjects into studies. More importantly, little evidence has suggested that the time and effort put into these activities by investigators (in providing materials to IRBs) and IRBs have significantly increased the well-being of research subjects.

B. NPRM Proposals

Taking into consideration the history of public debate on this topic and various sources of public comments, the NPRM proposed a requirement mandating that all institutions located in the United States engaged in cooperative research rely on a single IRB as their reviewing IRB for that study. Under this proposal, this requirement would not apply to: (1) Cooperative research for which more than single IRB review is required by law; or (2) research for which the federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular study. Public comment was sought on whether it would be useful for this requirement to include criteria that federal departments or agencies would need to apply in determining whether to make exceptions to the use of a single IRB requirement and what those criteria might be. Further the public was asked whether the exceptions proposed were appropriate and sufficient, or whether

this mandate should have additional exceptions for single IRB review than those proposed in the NPRM.

The change proposed by the NPRM would apply only to U.S.-conducted portions of studies because the flexibility to make use of local IRB reviews at international sites should be maintained. It might be difficult for an IRB in the United States to adequately evaluate local conditions in a foreign country that could play an important role in the ethical evaluation of the study.

This policy would apply regardless of whether the study underwent convened review or expedited review. Under the NPRM, the IRB of record would be expected to be selected either by the funding agency or, if there is no funding agency, by the lead institution conducting the study. An agency may, but is not required, to solicit input regarding which IRB would be most appropriate to designate as the IRB of record. Public comment was sought on how this would work in practice.

This policy would not relieve any site of its other obligations under the regulations to protect human subjects. Nor would it prohibit institutions from choosing, for their own purposes, to conduct additional IRB or other administrative reviews, though such reviews would no longer have any regulatory status in terms of compliance with the Common Rule.

Some concerns about a mandated single IRB review for cooperative research point to implementation logistics, and the time necessary to establish new policies, procedures, and agreements. Recognizing this concern, the proposed compliance date was 3 years from the publication of the final rule. Public comment was sought on whether this was a realistic timeframe.

The public was asked to comment on whether mandated single IRB review for all cooperative research was a realistic option, and what the likely costs and benefits to institutions might be. Further, the public was asked to comment on whether additional resources would be necessary to meet this requirement in the short term and whether savings might be anticipated in the long run. Finally, public comment was sought regarding in what areas guidance would be needed for institutions to comply with this requirement and whether the Common Rule departments and agencies could take actions to address concerns about institutional liability, such as developing model written agreements.

C. Public Comments

This proposal was one of the most commented on in the NPRM, receiving more than 300 comments. Public comment was divided on whether a final rule should implement the proposal to mandate one IRB of record in domestic cooperative research studies. Of those who commented on this proposal, approximately 130 supported the proposal, and approximately 140 opposed it. Others had mixed views.

Research institutions tended to oppose this proposal, while individuals (*i.e.*, those who were not providing comment in an official institutional capacity) and scientific organizations tended to support the proposal. A strong majority of those who opposed the proposal indicated that the final rule should encourage, rather than mandate, a single IRB of record in cooperative research studies. Arguments against the proposal cited the need for local review and potential loss of accountability, as well as operational issues such as the increased administrative capacity and technological systems required for a site to function effectively as a single IRB. One comment stated that mandated single IRB review would not eliminate the challenges associated with multi-institutional trials. The commenter argued that it would shift the burden from sponsors to investigators and at the institutional level, centralized systems would have to be developed and sustained in order to manage single IRB reviews.

Some who supported the proposal stated that it would decrease administrative burdens and inefficiencies for investigators and institutions. Conversely, some commenters stated that the proposal should not be implemented because it would ultimately increase burdens and inefficiencies for investigators and institutions.

In addition to the broad themes for and against this proposal, some commenters such as SACHRP noted that the proposed requirement seems premature at this time and suggested that more data are needed before such a provision could be implemented. Others said the scope of the proposal seemed overly broad. Many cited the alternative, narrower approach discussed in SACHRP's public comment as a reasonable option.⁴⁰ Further commenters stated that the lead institution likely would experience

⁴⁰ SACHRP's public comment to the NPRM is available here: <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2016-january-5-recommendation-nprm-attachment-a/index.html>.

increased costs if this proposal were implemented because of the obligations it would have to assume. In addition, some commenters said that the proposal does not address risk of liability to institutions and IRBs that are not considered the lead.

Commenters also noted that long review times for prospective research studies are not solely related to the IRB review and approval itself. Rather, commenters noted that long review times are caused by the sum total of the many different types of reviews either mandated by other regulations or by institutional policy (e.g., radiation safety board review, privacy board review, departmental scientific review) that must be completed. These other reviews would likely not be affected by the NPRM proposal.

Several commenters expressed concern that according to the NPRM proposal, the supporting federal department or agency would select the IRB of record as required by the provision. These commenters were concerned that the provisions did not seem to allow for grantee or awardee input on what IRB should be the IRB of record nor did they seem to suggest that funding departments or agencies should consult with the institutions receiving funding about the IRB of record. Several public comments also expressed concern about the burden this provision would place on nonfederally supported studies subject to the rule solely based on the clinical trials expansion proposed in the NPRM.

Representatives of AI/AN tribes also provided comments emphasizing the sovereign status of their governments, and stating that nonlocal review would be inappropriate for their communities.

D. Response to Public Comments and Explanation of the Final Rule: Cooperative Research

The final rule adopts the NPRM proposal with modifications that are responsive to public comment. We agree with commenters who speculated that mandated single IRB review would ultimately decrease administrative burdens and inefficiencies for investigators and institutions, while acknowledging that the transition to this model would require significant time and an adjustment to institutional structures and policies. We concur that, rather than offering additional protections, in many cases multiple IRB approvals increase burden and frequently delay the implementation of studies, increasing the costs of clinical trials and potentially stalling access to new therapies. We note comments that expressed frustration with the frequent

occurrence of central IRB participating sites insisting on separate institutional reviews. One comment noted that these additional IRB reviews generally reach the same conclusions, or conclusions with minor changes, that are then imposed solely on that site. When working optimally, we expect the central IRB model will work more efficiently and require less personnel time and fewer resources for tracking and implementing IRB changes and approvals, thereby eliminating the potential for unnecessarily duplicative reviews.

Although a large number of comments believed that single IRB review should be encouraged rather than mandated, we feel that this incentivized approach would ultimately fail to yield substantive positive change in the system. Rather, systematic efficiencies have the best chance of occurring if single IRB review is required for all review in domestic research involving more than one institution. We acknowledge that further guidance for this requirement will need to be developed and that initial cost projections may have been low. However, we feel this change supports the best interests of the research infrastructure through increasing efficiency. Note that the final rule permits appropriate flexibilities that will assist in implementation. Institutions may still choose to conduct additional internal IRB reviews for their own purposes, though such reviews would no longer have any regulatory status in terms of compliance with the Common Rule.

We agree with comments recommending that a greater role should be provided for grantee input on choosing the IRB of record, and have modified the language accordingly. The language at § _____.114(b)(1) now states that the reviewing IRB (i.e., the IRB of record) will be identified by the federal department or agency supporting or conducting the research, yet allows lead institutions to propose the reviewing IRB, subject to the acceptance of the federal department or agency supporting the research. This provision is consistent with the NIH single IRB policy, which was published on June 21, 2016.

This final rule adopts (in § _____.114(b)(2)(i)) the NPRM's proposal that cooperative research for which more than single IRB review is required by law is not subject to the requirements of § _____.114. The rule also adds clarifying language providing that this provision extends to tribal laws passed by the official governing body of an AI/AN tribe. Thus, if the official governing

body of an AI/AN tribe passes a tribal law that requires more than single IRB review for certain cooperative research, the requirement for single IRB review does not apply to such cooperative research. In addition, we highlight that § _____.114(b)(2)(ii) allows a federal department or agency the flexibility to determine that the use of a single IRB is not appropriate for certain contexts, thereby permitting additional IRB review and consideration of local and regional variations in some circumstances.

Finally, the final rule adopts the NPRM proposal for this provision to have a delayed compliance date of 3-years from the date the final rule is published in the **Federal Register**. This transition period is intended to allow the regulated community appropriate time and flexibility in adjusting to this new model.

XIII. IRB Records (§ _____.115)

A. Background and Pre-2018 Requirements

The pre-2018 rule at § _____.115 outlined requirements for IRBs in preparing and documenting its activities and for maintaining records.

B. NPRM Proposals

As discussed in Section IV, the NPRM proposed to revise the pre-2018 requirement that an up-to-date list of the IRB members and their qualifications be included in an institution's assurance. Instead, the NPRM proposed the requirement that an IRB or the institution prepare and maintain a current list of IRB members.

As discussed in Section IX, the NPRM proposed a new requirement for IRBs to maintain, as part of their records of continuing reviews, the rationale for conducting continuing review of research that was deemed eligible for elimination of continuing review per proposed changes at § _____.109(f)(1)(ii). Specifically, this would apply to research that had progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study: (1) Conducting data analysis, including analysis of identifiable private information, or (2) accessing follow-up clinical data from procedures that subjects would undergo as part of standard care for their medical condition.

Also, as discussed in Section IX, the NPRM proposed eliminating continuing review for many minimal risk studies (namely those that qualify for expedited review), unless the reviewer finds and documents why continuing review should take place for the study. Finally,

the NPRM contained a requirement that IRBs document the rationale for an expedited reviewer's determination that research appearing on the expedited review list is more than minimal risk (*i.e.*, overturning the presumption that studies on the Secretary's list are minimal risk).

New in the NPRM was a proposal to require that an IRB maintain records of exemption determinations. Additionally, the NPRM proposed that the use of the proposed exemption determination tool would satisfy the proposed documentation requirement.

In addition, a new provision was proposed to require that the institution or IRB that retains IRB records should safeguard, if relevant, individually identifiable private information contained in those records in compliance with the proposed privacy safeguards.

Finally, the NPRM proposed a modification of the pre-2018 rule clarifying that IRB records may be maintained in print or electronic form.

C. Public Comment

The proposed modifications to § _____.115 received approximately 25 comments. A majority focused on three proposed revisions. The NPRM proposed to require that reviewers document why an IRB required continuing review when continuing review was not required as proposed in the NPRM. The majority of commenters opposed this requirement stating that it merely shifted administrative burden from one activity to another with no increase in protections.

The NPRM also proposed to require that a reviewer document why a research activity appearing on the expedited review list is more than minimal risk, and thus should be subject to full IRB review. This was opposed by the majority of commenters who indicated that this proposal was an unjustified administrative burden.

One commenter stated that the proposed documentation requirements would be punitive to IRBs. Several others suggested that this requirement served as a disincentive to institutions who wanted to implement additional protections than those required by the Common Rule. These commenters noted that this seemed in contrast to the longstanding policy articulation that the Common Rule served as a "floor" for protections and that institutions could require additional protections for research conducted at their institutions.

D. Response to Comments and Explanation of the Final Rule: IRB Records

A majority of the changes proposed in the NPRM in § _____.115 have been retained in the final rule without alteration. However, the final rule differs from the NPRM in a few ways. First, the NPRM included two provisions requiring documentation of continuing review activities; these have been merged into one provision in the final rule at § _____.115(a)(3). Second, the NPRM required that the IRB keep records of the IRB reliance agreements between an institution and the IRBs not operated by that institution that review said institution's nonexempt research activities. Instead, the final rule includes language at § _____.115(a)(9) that requires each institution to maintain adequate documentation of the responsibilities that each entity will undertake to ensure compliance with this policy. This provision differs from the NPRM proposal to correspond to the more flexible provision included at § _____.103(e), which does not require the creation of a written agreement between an institution and a reviewing IRB that said institution does not operate.

Because the final rule does not include an exemption determination requirement, the exemption documentation requirement proposed in the NPRM is not included in the final rule. Additionally, because the final rule does not include specified privacy safeguards, the NPRM proposal for an IRB to safeguard records as required by the proposed privacy safeguards is not included.

The final rule includes the NPRM proposal that IRBs document decisions to require continuing review or full board review even in circumstances when such review is not required because we believe it is important to document why an IRB is making a determination that differs from the regulatory baseline. This also helps to promote the principle of justice (as applied to IRB operations). Note that nothing in these regulations prevents an institution from authorizing an IRB to apply standards that exceed those in the regulations, if indeed the institution has chosen to do so.

In addition, while the NPRM proposed to require that IRB records that contain identifiable private information be safeguarded through compliance with the proposed privacy safeguards, the final rule does not require such safeguards. Although no public comments were received on this provision, in deciding not to include the

NPRM's proposed privacy safeguard requirements in the final rule, we determined that it was unnecessary for the Common Rule to impose additional privacy requirements on IRB records as we are unaware of instances in which IRB records were breached. In addition, IRB records are not the regulatory equivalent of research records, which should be adequately secured or safeguarded against inappropriate uses or disclosures of identifiable private information. IRB records will generally be secured for a variety of reasons. These include not only protecting identifiable private information, but also, for example, protecting discrete information and intellectual property that might be included in a protocol. There are other means for ensuring institutions and IRBs protect their records beyond what is required by the Common Rule.

XIV. General Requirements for Informed Consent (§ _____.116)

The final rule contains several major revisions to the requirements for informed consent, specifically with respect to: (1) New requirements relating to the content, organization, and presentation of information included in the consent form and process to facilitate a prospective subject's decision about whether to participate in research; (2) the basic and additional elements of consent; (3) the elements of broad consent for the storage, maintenance, or secondary research use of identifiable private information and identifiable biospecimens; (4) attendant changes in the waiver or alteration criteria for consent; (5) a new provision that allows IRBs to approve a research proposal for which investigators obtain information or biospecimens without individuals' informed consent for the purpose of screening, recruiting, or determining the eligibility of prospective human subjects of research, provided certain conditions are met; and, (6) a new requirement to post to a federal Web site a copy of an IRB-approved version of the consent form that was used for enrollment purposes for each clinical trial conducted or supported by a federal department or agency. Each of the final rule provisions are discussed separately below.

A. General Requirements for Informed Consent (§ _____.116(a))

1. Background and Pre-2018 Requirements

Under the pre-2018 rule, many fundamental requirements applicable to all informed consents were set forth in

an introductory (and unnumbered) paragraph at the beginning of § _____.116.

In considering changes to the general requirements set forth in § _____.116(a), we considered arguments put forth by some that consent forms have evolved to protect institutions rather than to provide potential research subjects with the most important pieces of information that a person would need in order to make an informed decision about whether to enroll in a research study.⁴¹ Instead of presenting the information in a way that is most helpful to prospective subjects—such as explaining why someone might want to choose not to enroll—these individuals argued the forms may function more as sales documents or as a means to protect against institutional liability.⁴² We also considered a growing body of literature that suggests informed consent forms have grown too lengthy and complex, adversely affecting their ability to effectively convey the information needed for prospective participants to make an informed decision about participating in research.⁴³

2. NPRM Proposals

The NPRM proposed adding new language to the introductory text of § _____.116 to emphasize the need to first provide essential information that a reasonable person would want to know in order to make an informed decision about whether to participate in research, and to provide an opportunity to discuss that information. Furthermore, in recognition of complaints that consent forms are too often complicated documents primarily used to protect sponsors from legal liability, the NPRM proposed requiring that the information in these forms be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitated the prospective subject's or representative's understanding of the reasons why one might or might not want to participate in the research.

The NPRM also proposed that an investigator seeking to obtain informed consent be required to present first the information required by § _____.116, which has been recognized by the Common Rule departments and agencies as the most fundamental and required content of informed consent,

before providing other information, if any, to the subject. As proposed under the NPRM, the main portion of a consent document could include only the elements of informed consent that were required by the Common Rule, with any other information included in an appendix. This change was intended to lead to substantially shorter “core” sections of consent forms, with prospective subjects receiving the most important information in the body of these relatively short forms, instead of that key information being buried in long and overly complex documents. As proposed, additional information could be set forth in appendices to consent forms.

Given the consensus that informed consent forms should be written in appropriate language, this proposal reinforced the need to include information using language understandable to the subject. This goal was consistent with Federal Plain Language guidelines and the Federal Plain Writing Act of 2010. The NPRM proposed that the Secretary publish guidance at a later time to explain how consent forms could be written to comply with this regulatory requirement. Public comments were sought on what topics should be addressed in future guidance on improving the understandability of informed consents. As explained in the NPRM, it was not envisioned that the revised Common Rule would require a formal assessment to evaluate an individual's competency, but we acknowledged that such a practice might be appropriate for certain populations or studies.

In addition, the NPRM proposed to clarify in the introductory language at § _____.116 that if a HIPAA authorization is combined with a consent form, the authorization elements required by 45 CFR 164.508 (part of the HIPAA Privacy regulations) must be included in the consent document and not the appendices. In other words, when informed consent for research under the Common Rule is combined with a HIPAA authorization, the NPRM proposed that the authorization elements would be considered to constitute one of the required elements of informed consent.

3. Public Comments

Approximately 200 comments discussed the proposal to include information required by the Common Rule in the consent form and place other information in appendices. A majority of those (approximately 140) supported the proposal and approximately 35 commenters opposed

this proposal. Those who expressed support for this proposal generally noted agreement with the NPRM's rationale for the proposed revisions. Even those who supported the proposal stated that guidance would be needed for the proposal to be implemented and for the proposal to have the desired effect. Among those who opposed this proposal, all indicated support for the intention behind it. Reasons for opposing this proposal included:

- Concern that having a “dual document” system (with a primary consent form and appendices) would not actually improve subjects' understanding specifically and the informed consent process generally.
- Concerns that in some circumstances, the information that one might require to make an informed decision about research participation may not always be information required under the Common Rule when seeking and obtaining informed consent.
- Concern that the proposed language for the § _____.116 introductory paragraph should not be promulgated as regulatory text (and would be more appropriate as guidance).
- Concern that because the proposed language does not include specific standards and specific criteria, the provision would ultimately be impossible to implement and enforce.
- Concern that the language as proposed would not reduce the complexity and length of consent forms because much of the information generally contained in an informed consent document is required by various regulatory agencies. To this end, several commenters noted that the NPRM proposed an additional four required elements of consent, which would add to the quantity of information that is required to be discussed in an informed consent document.

Some comments noted that although they liked the general idea of the proposal for the introductory paragraph of § _____.116, they felt that the proposal should not focus on the length of a consent form, but rather on clarity and understandability. One comment expressed a need for guidance on how to implement the proposed language in the introductory paragraph of § _____.116 and the requirement at § _____.109(b) of the pre-2018 rule.⁴⁴ The NPRM did not

⁴¹ Levine RJ. Informed consent: Some challenges to the universal validity of the western model. *J Law Med Ethics* 1991;19(3-4):207-213.

⁴² Menikoff J., Richards E. *What the Doctor Didn't Say: The Hidden Truth about Medical Research*. New York, NY: Oxford University Press; 2006:113-123.

⁴³ Beardsley E. et al. Longer Consent Forms for Clinical Trials Compromise Patient Understanding: So Why Are They Lengthening? *Journal of Clinical Oncology*. 2007 Mar 20;25(9):e13-4.

⁴⁴ Section _____.109(b) of the pre-2018 rule states that an IRB shall require that information given to subjects as part of informed consent is in accordance with § _____.116. The IRB may require that information, in addition to that specifically mentioned in § _____.116, be given to the subjects when in the IRB's judgment the information would

propose changing the latter item, which mandated that IRBs require that information given to subjects as part of informed consent conform with the requirement. However, the NPRM also permitted IRBs to require additional information if it would meaningfully add to the protection of the rights and welfare of subjects. This comment was made in light of the NPRM's proposal that information not required as an element of consent at § _____.116 must be provided after providing the required elements of consent.

The NPRM asked about what topics should be addressed in future guidance on improving the understandability of informed consent. Approximately 35 commenters answered this question, a majority of which were universities and research institutions. Several commenters questioned whether the proposals in the introductory paragraph of § _____.116 would be enforceable, and how Common Rule departments and agencies would assess and enforce compliance.

Several commenters indicated that mandating the order in which the content of consent forms should be presented may not always facilitate increased understanding by potential subjects because the best way to facilitate understanding is likely to be study specific. In other words, the order of importance of issues could be dependent on unique aspects of a given study. Others noted that most information in consent forms is there because the regulations require it to be included. Thus, the proposal to include the information required by the regulations up front, with all other information included as an appendix, is not a requirement that will inherently improve consent forms. Some commenters suggested that more research was needed on the informed consent process before prescribing specific approaches.

Many commenters asked that future guidance be developed to assist in drafting consent forms that addresses language level, literacy, risk communication, and best practices in use of alternative media in the informed consent process (e.g., interactive presentation on a tablet, comic strips for pediatric populations). In this regard, some comments objected to the singular focus on a "form" in the proposed language, stating that this sends the message that alternative and innovative approaches to improving the informed consent process would be discouraged. Others noted that future guidance

should include topics of interest to tribal groups, such as acknowledgement of community-level implications of research and clarification about the handling of biospecimens in a study.

Several commenters noted that guidance should focus on how to foster understanding rather than focusing on mandatory length limitations on consent forms. However, a few comments endorsed a recommended page length maximum, citing it as perhaps the only way to force investigators and institutions to be brief and concise in the presentation of relevant information.

4. Response to Comments and Explanation of the Final Rule: General Requirements for Informed Consent

Before addressing how the general requirements for informed consent proposed in the NPRM have been adopted and altered in the final rule, it is important to note that the structure for this regulatory text has been altered. In the pre-2018 rule, the general requirements were included in an unnumbered introductory paragraph. The NPRM proposed the same approach. To emphasize the fact that this paragraph includes multiple independent and important regulatory requirements, and to enable stakeholders and Common Rule departments and agencies to more easily reference particular requirements, these general requirements have been redesignated into a new § _____.116(a). In addition, the general requirement for consent in the final rule at § _____.116(a)(6) removes the reference to oral or written consent that was in the pre-2018 rule. This is the provision that addresses the prohibition on including exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. The reference to oral or written consent was removed from this provision in the final rule. In its place, a similar reference was included in to § _____.116(a) to clarify that all the requirements set forth in § _____.116(a) apply to written and oral consent.

Another change made in the final rule, as compared with the pre-2018 rule and the language proposed in the NPRM, is that § _____.116(a) contains introductory language summarizing each paragraph of § _____.116 and the relationship between those paragraphs. Given that the framework for informed consent has been altered and reorganized through this regulation, this introductory language is intended to

explain the overall approach set forth in revised § _____.116, as well as the significance of each paragraph. This introductory language is also intended to explain the role of broad consent under revised § _____.116. The introductory paragraph explains that the general requirements for informed consent are now set forth in § _____.116(a) and that these general requirements apply with respect to informed consent obtained pursuant to § _____.116(b), (c), and (d) (except, as described later, § _____.116(a)(5) does not apply to broad consent obtained under § _____.116(d)). This introductory language also explains that the basic elements of informed consent (which were described in § _____.116(a) of the pre-2018 rule) are included in § _____.116(b) of this final rule and that additional elements of informed consent that pertain only to certain studies (which were described in § _____.116(b) of the pre-2018 rule) are included in § _____.116(c) of this final rule.

In addition, this introductory language explains that the requirements for broad consent (a concept not specifically addressed in the pre-2018 rule) are described in § _____.116(d) of this final rule. As discussed below, broad consent under this final rule differs from the broad consent approach proposed for § _____.116(c) in the NPRM. The introductory language of § _____.116(a) explains that broad consent may be obtained in lieu of informed consent obtained under § _____.116(b) and § _____.116(c) (which describe basic elements of informed consent as a general matter and additional elements of informed consent that apply only to certain studies, respectively) for certain purposes. Specifically, in lieu of obtaining study-specific informed consent in accordance with § _____.116(b) and (c), broad consent may be obtained under § _____.116(d) for the use of identifiable private information or identifiable biospecimens collected for either research studies other than the proposed research or nonresearch purposes for: (1) storage and maintenance for secondary research use; and (2) secondary research. For those purposes (and no others), broad consent under § _____.116(d) may be obtained instead of specific consent under § _____.116(b) and (c).

New introductory language at § _____.116(a) also summarizes the provisions describing circumstances in which waiver or alteration of the requirements of informed consent are permitted. These circumstances pertain to research involving public benefit and service programs conducted by or

meaningfully add to the protection of the rights and welfare of subjects.

subject to the approval of state or local officials at § _____.116(e), and to research more generally at § _____.116(f) (see below).

Another change reflected in the final rule is that specific requirements for informed consent have been included in subparagraphs for clarity and emphasis. For example, the requirement that information that is given to the subject or the legally authorized representative shall be in language understandable to such subject or representative is no longer included as part of a general introductory paragraph and is instead included as § _____.116(a)(3). Except as noted here, these requirements remain the same as they were under the pre-2018 rule.

The final rule adopts, almost verbatim, all of the proposals made in the NPRM to improve and clarify the general requirements for informed consent. For example, the final rule adopts the proposed requirement specifying that the information provided in an informed consent form must be presented in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate. The final rule also adopts new language clarifying that this requirement applies to the informed consent as a whole. In addition, the final rule adopts the NPRM's proposal that prospective subjects or legally authorized representative must be provided with key information that is most likely to assist a prospective subject or legally authorized representative in making a decision about participating in research, and to provide an opportunity to discuss that information. Moreover, the final rule adopts an approach, consistent with many public comments, emphasizing efforts to foster understanding overall rather than imposing specific length limitations on the entire consent forms.

The final rule also includes language slightly different from that proposed in the NPRM for clarity or for conformance with other language in the final rule. For example, the final rule replaces references to a subject's representative with references to a subject's legally authorized representative (a term defined in § _____.102) for clarity.

As discussed above, a significant proposal in the NPRM was that in obtaining informed consent, investigators would first have to present the information required by § _____.116, before presenting any other information,

if any. In addition, the NPRM proposed mandating that consent forms must include only the required information under § _____.116 and that any other information be included in appendices. The final rule does not adopt a requirement that certain information be included only in appendices. This approach is responsive to public comments expressing concerns that such a mandate might sometimes undermine the informed consent process. The final rule adopts a slight variation of that approach in response to public comments about perceived lack of flexibility in the proposed language. Whereas the NPRM referred to the "body" of the consent form as opposed to appendices to the consent form, the final rule replaces those concepts with references to material that must be at the beginning of the consent form, versus material that can appear after that beginning section. The final rule does not limit the information that can be provided in the beginning of a consent form to *only* the § _____.116 requirements, but instead offers a more flexible and meaningful approach in response to public concerns that the NPRM proposal was too prescriptive. Moreover, the approach recognizes public comments that expressed concerns about creating a "dual document" system. As such, the final rule does not address appendices to the informed consent. However, the NPRM's references to the appendices of the consent form have in general been conceptually replaced by references to the material in a consent form that follows the "beginning" section.

In particular, the final rule imposes a new requirement (set forth in § _____.116(a)(5)(i)) that the informed consent begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This provision further requires that this beginning portion of the informed consent must be organized and presented in a way that facilitates comprehension. This requirement applies to all informed consents, except for broad consents obtained pursuant to § _____.116(d), which may warrant a different presentation.

This new requirement included at § _____.116(a)(5)(i) is somewhat similar to the proposal advanced in the NPRM insofar as both emphasize the importance of presenting the information that would be most important to a subject (or a legally authorized representative) before

presenting other information. However, the requirement included in § _____.116(a)(5)(i) is more specific, detailed, and flexible. First, this provision requires that key information be included in the beginning of the informed consent in a concise and focused presentation. We recognize that how this requirement applies will depend on the nature of the specific research study and the information presented in the informed consent and believe that this requirement strikes an appropriate balance between facilitating the comprehension of subjects of key issues and allowing study-specific flexibilities. In general, our expectation is that this initial presentation of the key pieces of information will be relatively short. This section of the consent could, in appropriate circumstances, include a summary of relevant pieces of information that are explained in greater detail later in the consent form.

The requirement that key information be presented in a concise and focused way will require an assessment that is specific to a study and its informed consent. For example, for most complicated clinical trials involving cancer patients with long (e.g., 20- to 25-page) consent documents, our expectation would be that the concise and focused presentation referred to in § _____.116(a)(5)(i) would be no more than a few pages, and would provide the key pieces of information about the trial in such a manner that facilitates a person's comprehension of why they might or might not want to participate in the research.

In such cases, for example, we would not consider a 10-page description of elements such as potential risks, accompanied by lengthy and complex charts and graphs, to satisfy the "concise and focused" requirement of § _____.116(a)(5)(i). With regard to risks in the type of cancer trial mentioned above, for example, instead of needing to mention every reasonably foreseeable risk, which would be required by § _____.116(b)(2), this beginning section of the consent form should identify the most important risks, similar to the information that a doctor might deliver in the clinical context in telling a patient how sick the chemotherapy drugs will make them, but with a particular emphasis on how those risks are changed by participating in the study.

We recognize the advantages of allowing institutions to design informed consents, consistent with § _____.116(a)(5)(i), that are tailored to particular research studies to assist prospective subjects in understanding the most fundamental aspects of the

informed consent. For this reason, the final rule does not strictly specify the types of information that should or should not be included to satisfy § _____.116(a)(5)(i), or the length of such concise and focused presentations. This flexibility is responsive to public comments recommending against a rigid approach to enable institutions and individuals to tailor informed consents to the circumstances of particular studies. A discussion of the key information to be included in the beginning section of the consent form, and how it will operate in practice, may be further clarified in future guidance.

We also recognize that for some relatively simple research studies with limited risks or benefits, the entire informed consent document may be relatively brief and still satisfy § _____.116. In such circumstances, an institution may determine that virtually all of the information required by § _____.116 would also satisfy § _____.116(a)(5)(i). In such cases, the informed consent document could include the concise and focused presentation of § _____.116(a)(5)(i) at the beginning of the informed consent document, followed by limited additional information required to satisfy § _____.116.

In all circumstances (those involving lengthy and complex informed consents as well as short and relatively simple informed consents), if information included at the beginning of the informed consent satisfies both § _____.116(a)(5)(i) and the elements of informed consent under § _____.116(b) and § _____.116(c) more generally, the information included at the beginning need not be repeated later in the body of the informed consent. Thus, with respect to the example provided above concerning a clinical trial with cancer patients, the most important reasonably foreseeable risks to subjects would be summarized at the beginning of the informed consent as part of § _____.116(a)(5)(i)'s concise and focused presentation, but that a more comprehensive and detailed description of reasonably foreseeable risks to subjects would be included later in the body of the informed consent. In contrast, with respect to a relatively simple research study with limited risks, we would expect that all of the information provided to potential subjects concerning such risks might satisfy both § _____.116(a)(5)(i) (as part of a concise and focused presentation of key information) and § _____.116(b)(2) (a description of any reasonably foreseeable risks or discomforts to the subject). In such circumstances, the information provided at the beginning

of the informed consent would not need to be repeated or further detailed in the informed consent and the entire informed consent could be relatively short.

In general, we would expect that to satisfy § _____.116(a)(5)(i), the beginning of an informed consent would include a concise explanation of the following: (1) the fact that consent is being sought for research and that participation is voluntary; (2) the purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research; (3) the reasonably foreseeable risks or discomforts to the prospective subject; (4) the benefits to the prospective subject or to others that may reasonably be expected from the research; and (5) appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject. As a general matter, a brief description of these five factors would encompass the key information most likely to assist a reasonable person (or legally authorized representative) in understanding the reasons why one might or might not want to participate in research, as required by § _____.116(a)(5)(i) and § _____.116(a)(4). However, we recognize that this determination is necessarily fact-specific and that IRBs and institutions may require that somewhat different (or additional) information be presented at the beginning of an informed consent to satisfy § _____.116(a)(5)(i).

The NPRM also proposed adding a new requirement to the general introductory paragraph of § _____.116, which would provide that if an authorization required by 45 CFR parts 160 and 164 (parts of the HIPAA Privacy Rule) is combined with a consent form, the authorization elements required by 45 CFR 164.508 must be included in the consent form (and not the appendices). Because this final rule does not incorporate the distinction proposed in the NPRM between the informed consent and appendices, the final rule does not incorporate this language.

We are satisfied that the approach adopted in this final rule will enable regulated entities and individuals to pursue different and innovative approaches to obtaining informed consent, as recommended in some public comments, while ensuring that the important aspects of informed consent are clearly communicated to prospective subjects and subjects.

B. Basic Elements of Informed Consent (§ _____.116(b))

1. Background and Pre-2018 Requirements

Under the pre-2018 rule, investigators were generally required to obtain the subjects' informed consent to participate in research.⁴⁵ The regulations required that the consent form include at least eight specific items of information, including: (1) an explanation of the purposes of the research, its duration, and procedures involved, and identification of any procedures which are experimental; (2) a description of the reasonably foreseeable risks; (3) a description of any potential benefits; (4) a disclosure of appropriate alternative procedures or courses of treatment, as relevant; (5) information about confidentiality of records, compensation, and treatments if injury occurs; (6) for research involving more than minimal risk, an explanation as to whether any compensation or medical treatments are available if injury occurs; (7) contact information; and (8) a statement that participation is voluntary, and that refusal to participate or decision to withdraw will involve no penalty or loss of benefits to which the subject is otherwise entitled.

2. NPRM Proposals

In the NPRM it was proposed that research with nonidentified data continue to be considered not to involve "human subjects." However, to better ensure that subjects are informed of the possibility that identifiers collected as part of a research study could be removed from the data and then be used for secondary research studies without the protections provided by this policy, it was proposed that a new element of informed consent be required. The new basic element of consent proposed in the NPRM at § _____.116(a)(9) would apply to all research collecting identifiable private information. Based on the investigator's plans, the informed consent form and process would need to inform subjects either that: (1)

⁴⁵ For general requirements for informed consent see § _____.116 in the pre-2018 Rule, and 21 CFR 50.20, .25 in FDA's comparable requirements. There are provisions under the Common Rule, that allow for the waiver of some or all of the elements of informed consent (see § _____.116(e) and (f)). The Federal Food, Drug, and Cosmetic Act limits the circumstances under which informed consent can be waived. See, e.g., section 520(g) (21 U.S.C. 360j(g)). Currently, FDA regulations contain only two exceptions from informed consent in certain life-threatening and emergency situations under 21 CFR 50.23–24. However, the 21st Century Cures Act recently amended the Federal Food, Drug and Cosmetic Act to allow waiver of informed consent for certain FDA-regulated minimal risk investigations.

identifiers might be removed from the data and that the nonidentified data could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the representative, if this might be a possibility; or (2) the subject's data collected as part of the research, from which identifiers are removed, would not be used or distributed for future research studies.

3. Public Comments

Approximately 40 public comments were received on the proposed new required element of informed consent found in the NPRM at proposed § _____.116(a)(9). A large majority favored this proposal. Those who supported this proposal indicated that it provided useful information to prospective subjects about how private information obtained from a study might be used in the future. They also commented that it enhanced transparency in research, providing potential subjects with the information they need to decide whether to participate. Those who opposed this proposal suggested that it would increase the length of consent forms without appreciably improving potential subjects' understanding of a specific research activity.

4. Response to Comments and Explanation of the Final Rule: Basic Elements of Informed Consent

The final rule, at § _____.116(b)(9), adopts the NPRM proposal to inform potential subjects about the possible use of their identifiable private information with two clarifying changes. First, because the final rule at § _____.102(e)(1) now states that the definition of human subject, in part, includes research in which an investigator obtains, uses, studies, analyzes, or generates *identifiable* biospecimens or identifiable private information, this new element of informed consent has been clarified to specifically apply to any research that involves the collection of identifiable biospecimens, rather than all biospecimens, in addition to research that involves the collection of identifiable private information. In addition, a change to what was proposed in the NPRM has been made to the new element of consent in the final rule at § _____.116(b)(9)(ii), to clarify that it is intended to inform subjects that their information or biospecimens collected as part of the research will not be used or distributed for future research, even if identifiers are removed.

We agree with the public comments that indicated this new element of consent will provide useful information to prospective subjects about whether their identifiable private information or identifiable biospecimens might be stripped of identifiers and used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

We expect that this information can usually be provided in a brief statement, and disagree with the commenters that suggested that this new basic element of consent would increase the length of consent forms without appreciably improving potential subjects' understanding of a specific research activity. This new requirement is intended to give the potential subject a right to know that identifiers might be removed from information or biospecimens and be used for future research without additional consent, when such a possibility exists, so he or she can make a fully informed decision about whether to participate in the research. If subjects' identifiable private information or identifiable biospecimens will not be used for future research studies, even if identifiers are removed, this new element of consent requires that subjects be informed of this as well. Finally, if a specific technology or technique determined to be capable of generating identifiable private information or identifiable biospecimens through the consultative process described at § _____.102(e)(7) will be used, that information should be included in the description of the research at § _____.116(b)(1).

C. Additional Elements of Informed Consent (§ _____.116(c))

1. Background and Pre-2018 Requirements

The pre-2018 rule contained six additional elements of consent required when appropriate: (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable; (2) anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent; (3) any additional costs to the subject that may result from participation in the research; (4) the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject; (5) a statement that significant new findings

developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and (6) the approximate number of subjects involved in the study.

2. NPRM Proposals

The NPRM proposed adding three additional elements of consent that, when appropriate, would be required to be included in the informed consent form and process. These proposed additional elements of consent pertain to issues that have become more relevant in recent years as science has advanced and the nature of research has changed. One proposed new element would require that prospective subjects be informed that their biospecimens may be used for commercial profit and whether the subject will or will not share in this commercial profit. A second proposed element would require that prospective subjects be informed of whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. A third proposed new element would provide subjects or their legally authorized representatives with an option to consent, or refuse to consent, to investigators re-contacting the research subject to obtain additional information or biospecimens, or for future research.

3. Public Comments

Each of the proposed additional elements of informed consent found in the NPRM at § _____.116(b)(7)–(9) received approximately 50 comments. All three proposals were generally favored by the public. With respect to the proposed element of consent at § _____.116(b)(7), requiring that prospective subjects be informed that their biospecimens may be used for commercial profit and whether the subject will or will not share in this commercial profit, comments, especially from individual members of the public not identified with any institution or organization, indicated that the extent to which an investigator might profit from information or biospecimens collected or used during a study was an important decision point as to whether a prospective subject would want to participate in a study. In response to proposed element § _____.116(b)(8)—requiring that prospective subjects be informed of whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions—several public comments stated that knowing whether or not

research results would be returned to them was an important piece of information for them to know and understand in deciding whether to participate in a study.

Finally, comments discussing § _____.116(b)(9) regarding the potential to be contacted for future studies noted that allowing an individual to indicate whether or not he or she might be contacted for future research studies respected subject autonomy. Those who opposed the provision noted that while the intent of the provision was laudable, the ensuing tracking system that would need to be developed by institutions to track who had said “yes” or “no” to being re-contacted, and in what circumstances, would be difficult to develop and maintain, and would also represent significant costs to institutions without a corresponding tangible increase in the protections afforded to human subjects.

4. Response to Comments and Explanation of the Final Rule: Additional Elements of Consent

The final rule contains two of the three proposed additional elements of consent. The final rule does not include the additional element proposed in the NPRM relating to providing subjects or their legally authorized representatives the option to consent or refuse to consent to being re-contacted to obtain additional information or biospecimens, or for future research.

New additional elements included in the final rule are: (1) A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit (§ _____.116(c)(7)); and (2) a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions (§ _____.116(c)(8)). Because many public comments addressed a desire to share in the profits of successful products developed using their biospecimens, we believe that investigators, when appropriate, should inform prospective subjects about whether they might or might not benefit commercially from future products resulting from the research, should that possibility be important in their decision making process. Also, several comments received from individuals who reported participation in research studies described disappointment that research results were not returned to them. We believe that potential subjects should be aware of the possibility that they might not receive research results, as well as

the possibility that they might, so that they can factor that information into their decision about whether to consent to research. This provision is intended to pertain to all clinically relevant research results, including general or aggregate research findings and individual research results.

We are also including in the final rule an additional element that when appropriate for research involving biospecimens, subjects be informed of whether the research will (if known) or might include whole genome sequencing (WGS) (§ _____.116(c)(9)). This provision of the final rule describes WGS as the sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen. WGS generates an extremely large amount of information about people, including factors that will contribute to their future medical conditions. As was recognized in the NPRM’s Alternative Proposal A to expand the definition of “human subject” to include WGS (discussed in Section III), data obtained through WGS can provide important insights into the health of individuals as well as their biological family. It is also possible that WGS data gathered for one purpose may reveal important information, perhaps unanticipated and unplanned for, years later. Given the unique implications of the information that can be developed through WGS, if it is either known that a specific research study will include this technique, or might include it, we believe that this aspect of the research must be disclosed to prospective subjects as part of the informed consent process. It is recognized that under the pre-2018 rule, if a research study were to involve WGS, this research procedure would have almost always been included in the description of the research. However, to remove any ambiguity about whether such information would need to be included in the informed consent, the final rule makes this requirement explicit through this new element of consent.

The information that would have to be disclosed under these additional elements of consent is often relevant to an individual’s decision of whether to participate in a research study. Such information may have been included in informed consent forms under the pre-2018 rule. However, the final rule now requires inclusion of these additional elements, when appropriate.

The additional element of consent proposed in the NPRM that was not included in the final rule would have required providing subjects or their legally authorized representatives with

an option to consent, or refuse to consent, to investigators re-contacting the subject to seek additional information or biospecimens or to discuss participation in another research study. Although for some research studies, it will be desirable to inform prospective subjects about investigators’ plan to re-contact subjects for certain purposes, and give them the option to agree or disagree to such re-contact, we agree with the public comments that questioned the importance of requiring that such information be included in the consent form. Although the final rule does not include this additional element of consent, this information can be included in the consent form.

D. Elements of Broad Consent for the Storage, Maintenance, and Secondary Research Use of Identifiable Private Information or Identifiable Biospecimens (§ _____.116(d))

1. Background and Pre-2018 Requirements

Under the pre-2018 rule, if identifiers are removed from information and biospecimens such that the identity of the subject could not be readily ascertained by an investigator or associated with the information or biospecimens, then such information and biospecimens that have been collected for purposes other than the proposed research could be used without any requirement for informed consent. Similarly, under the HIPAA Privacy Rule, if data are de-identified or HIPAA identifiers do not accompany biospecimens, then the Privacy Rule does not apply. When identifiers have not been removed, under the pre-2018 rule investigators were allowed in certain situations to obtain a consent that is broader than for a specific research study, such as for creating a research repository that involves obtaining biospecimens from living individuals for use in future research studies. In these cases, an IRB could determine that the original consent for the creation of the research repository satisfied the requirements of the Common Rule for the conduct of the future research, provided that the elements of consent continue to be satisfied for the future research. Despite this flexibility in the Common Rule, stakeholders and the Common Rule departments and agencies believe that the elements of consent required under § _____.116 of the pre-2018 rule often were not satisfied in the case of broad consent for future unspecified research use of identifiable private information or identifiable biospecimens.

With respect to HIPAA, HHS's pre-2013 interpretation of the HIPAA Privacy Rule was that authorizations for research needed to be study-specific, and thus, that such authorizations could not authorize certain future unspecified research. However, in January 2013, the Office for Civil Rights modified its prior interpretation.⁴⁶ Under the new interpretation, an authorization now may be obtained from an individual for uses and disclosures of protected health information for future research purposes, so long as the authorization adequately describes the future research such that it would be reasonable for the individual to expect that his or her protected health information could be used or disclosed for the future research purposes.

Because biospecimens and information that have been collected for clinical use or purposes other than for the proposed research are often an important source of information and material for investigators, and the re-use of existing information and materials can be an efficient mechanism for conducting research without presenting additional physical or psychological risks to the individual, it seemed prudent to consider changes to current regulations relating to those issues.

2. NPRM Proposals

The NPRM proposed to allow broad consent to cover the storage or maintenance for secondary research use of all biospecimens (regardless of identifiability) and identifiable private information. Broad consent would be permissible for the storage or maintenance for secondary research of such information and biospecimens that were originally collected for either research studies other than the proposed research or nonresearch purposes. The broad consent document would also meet the consent requirement for the use of such stored biospecimens and information for individual research studies. The NPRM made a separate case for nonidentified private information than it did for biospecimens, stating that consent would not be required for the secondary research use of nonidentified private information, such as the research use of medical records that have had all identifiers removed. Because the NPRM proposed that the definition of human

subject be expanded to include all biospecimens, it also proposed to facilitate research using biospecimens by permitting broad consent to be obtained for their storage or maintenance for secondary research.

It was envisioned that the proposed broad consent provision would be used by institutions and investigators to give individuals the choice to either allow or disallow the use of their biospecimens and identifiable private information for secondary research. In some cases, institutions would be expected to seek broad consent as part of a research protocol to create a research repository of biospecimens or information. However, in other cases it was expected that institutions, particularly those that do not typically conduct human subjects research, might not develop a research protocol to create a research repository, but still choose to seek broad consent from individuals for the research use of their biospecimens or identifiable private information. In such cases, these institutions might simply "tag" biospecimens and information as either available or not available for secondary research.

Because broad consent is a different form of consent than the consent that is obtained for a specific research study, the NPRM proposed required elements for broad consent that would include several of the basic and additional elements of informed consent, but not all, and would include several additional required elements. The NPRM proposed to require that the information included in broad consent describe the biospecimens and identifiable private information that would be covered by the consent, recognizing that the biospecimens and information to be used in future research studies might be collected after the consent was obtained. Further, the NPRM proposed that broad consent for the research use of biospecimens or identifiable private information obtained for nonresearch purposes would be limited to covering either or both of the following: (1) Biospecimens or identifiable private information that exist at the time at which broad consent is sought; and (2) biospecimens or identifiable private information that will be collected up to 10 years after broad consent is obtained for adult subjects, and, for research involving children as subjects, biospecimens or identifiable private information that will be collected up to 10 years after broad consent is obtained or until the child reaches the legal age of consent to the treatments or procedures involved in the research, whichever comes first.

The NPRM proposed to include the standard concerning who is a child based upon the definition of "children" as defined at 45 CFR 46.402(a). At the time the child becomes an adult, the broad consent or permission would no longer be valid and either broad consent would need to be sought from the child-turned-adult, or the investigator would need to seek a waiver of informed consent in order to use the individual's biospecimens or identifiable private information for research, unless one of the exclusions or exemptions were applicable.

A proposed element of broad consent in the NPRM included a requirement that subjects be informed that they may withdraw consent, if feasible, for research use or distribution of the subject's information or biospecimens at any time without penalty or loss of benefits to which the subject is otherwise entitled. However, information that has been stripped of identifiers might not be traceable. Thus, it might not be feasible to withdraw consent for future use or distribution in this case. If, however, an investigator committed to permitting a subject to discontinue the use of such information, it was expected that the investigator would honor this commitment by not stripping identifiers and using the information or biospecimens in research. The proposed regulations would not require investigators to make such a commitment.

Another proposed element of broad consent in the NPRM related to the public posting of nonidentified data about a subject. This proposed element of broad consent would include an option, when relevant, for an adult subject or the subject's legally authorized representative to consent or refuse to consent to the inclusion of the subject's data with removal of the identifiers listed in the HIPAA Privacy Rule at 45 CFR 164.514(b)(2)(i)(A) through (Q), in a database that is publicly available and openly accessible to anyone. This provision was proposed in the context of increasing interest in inviting study participants to allow their study data, in some cases including genomic data, to be made publicly available in order to maximize the potential for research that spurs increased understanding of disease processes. Under this provision, the consent document would be required to prominently note the option for the participant to allow the investigator to publically post (e.g., on a Web site) the participant's genomic or other potentially identifiable sensitive information, and to include a

⁴⁶ HHS. Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules. 78 FR 5611 (Jan. 25, 2013). Retrieved from <https://www.gpo.gov/fdsys/pkg/FR-2013-01-25/pdf/2013-01073.pdf>.

description of the risks associated with public access to the data.

To facilitate the use of broad consent, the NPRM proposed that the Secretary of HHS would publish in the **Federal Register** templates for broad consent that would contain all of the required elements of consent in these situations. It was envisioned that at least two broad consent templates would be developed: one for information and biospecimens originally collected in the research context, and another for information and biospecimens originally collected in the nonresearch context.

Public comment was sought on whether broad consent to secondary research use of information and biospecimens collected for nonresearch purposes should be permissible without a boundary, or whether a time limitation or some other type of limitation should be imposed on information and biospecimens collected in the future that could be included in the broad consent as proposed in the NPRM. If a time limit should be required, public comment was sought on whether the NPRM proposal of up to 10 years was a reasonable limitation and whether a limitation related to an identified clinical encounter would better inform individuals of the clinical information and biospecimens that would be covered by a broad consent. Public comment was also sought on whether all of the elements of broad consent proposed in the NPRM should be required for the secondary use of biospecimens or identifiable private information originally collected as part of a research study that was conducted without consent because (1) either the original research study met an exclusion or exempt category of research, or (2) a waiver of consent was approved by an IRB.

Public comment was sought on how likely investigators are to seek broad consent for the use of identifiable private information (as contrasted with biospecimens), given that provisions within the NPRM would make it easier to do such research without consent. In this regard, the NPRM proposal to prohibit waiver of consent by an IRB if a person has been asked for broad consent and refused to provide it could create a disincentive on the part of investigators from choosing to seek broad consent for research involving secondary use of identifiable private information. Given the costs and time and effort involved in implementing the system for obtaining broad consent for the use of identifiable private information and tracking when people provide consent or refuse to do so, the public was asked to comment on

whether the benefits to the system were likely to outweigh the costs, and if so, whether the broad consent provisions should be limited to obtaining broad consent for research use of biospecimens.

3. Public Comments

Approximately 475 comments addressed broad consent, a majority of which expressed opposition to broad consent as proposed and discussed in the NPRM. The basis of this opposition was largely related to the NPRM proposal that some type of consent (broad or specific) would be required for research with nonidentified biospecimens. A smaller number of comments (approximately 150) addressed the adequacy or inadequacy of broad consent as a concept, or the proposed broad consent templates to be created by HHS.

Public comment on the proposed, but not yet developed, broad consent templates was mixed, with a majority of comments stating that it was impossible to comment on a template that had not yet been created. Even among those who supported the use of broad consent, some had questions about whether broad consent provided at one institution would be sufficient for research ultimately conducted at another institution. Many comments further noted that the entire regulatory schema around broad consent (e.g., exemptions dependent on broad consent, prohibition on an IRB waiving broad consent if broad consent had been sought and someone declined) required additional study and discussion and recommended that the department issue another NPRM on these issues following some form of systematic analysis and broader public consultation. A professional investigative pathology association and many of its members endorsed the concept of broad consent and the development of templates by the Federal Government, writing that they would be less burdensome but still a functional way of promoting ethically conducted biomedical research with biospecimens.

Several commenters suggested that institutions needed to retain the ability to create and amend broad consent forms tailored to a variety of situations rather than rely on a federal template. These comments also generally stressed the importance of retaining an IRB's active role in reviewing the broad consent process and specific secondary research studies to ensure that interests other than autonomy and concerns other than those related to privacy were considered in a proposed study. A minority of commenters additionally

expressed concern with the Federal Government's ability to develop broad consent templates that the regulated community might feel were sufficiently informative.

Public comments were also mixed on whether or not broad consent as proposed in the NPRM would constitute meaningful consent. Many comments noted that a consent form sufficiently broad to cover all potential future secondary research uses of biospecimens or identifiable private information might be so broad and vague as to be not meaningful or informative to prospective research subjects. Others doubted the meaningfulness of broad consent obtained in the clinical setting. One academic research institution questioned whether it was really consent at all, but rather an agreement or permission, and another commenter questioned whether broad consent would increase subjects' autonomy.

Many of the commenters who opposed broad consent also argued against any requirement to obtain consent for the use of nonidentified biospecimens. One academic research institution raised serious concerns about obtaining meaningful broad consent, which undermines existing privacy and other protections for subjects in research. Others noted that requiring broad consent for all secondary use of all biospecimens would require that there always be a link or code between the biospecimen and the subject's identity, which ultimately would result in an overall increase in privacy risks. Many commenters favored an opt-out system for broad consent (especially with respect to broad consent for use of nonidentified biospecimens). An AI/AN organization expressed overall concern about the concept of broad consent, noting that many AI/AN people believe that specimens and blood are considered sacred and recommending that all secondary uses of collected specimens and data should require an additional consent process, including tribal consent when specimens and data are obtained from AI/AN populations.

Few comments were received on the actual proposed elements of broad consent. Of these, a majority expressed confusion with the proposals related to the duration of the consent and the scope of the biospecimens and identifiable information that could be collected.

The NPRM also asked whether broad consent to secondary research use of information and biospecimens collected for nonresearch purposes should be permissible without a boundary, or whether a time limitation or some other

type of limitation should be imposed on information and biospecimens collected in the future that could be included in the broad consent. If a time limit should be required, the NPRM asked whether up to 10 years was a reasonable limitation. It also asked whether a limitation related to an identified clinical encounter would better inform individuals of the clinical information and biospecimens that would be covered by a broad consent document. Approximately 65 commenters specifically answered this question.

Most who commented were opposed to the 10-year limitation on the period of time that an institution could collect biospecimens and information from an individual once broad consent had been sought and obtained. They stated that the limitation was arbitrary, not supportable by anything discussed in the NPRM, and presented an administrative burden for institutions and investigators to time stamp and track the 10-year limit for each subject. A few commenters stated that a 10-year limit is a reasonable boundary, but were concerned about the need to re-consent people once they reach the legal age of consent. In large data sets, identifying such people could be very challenging as people often move locations during such lengths of time, which would create an administrative barrier. A few commenters suggested that 10-year boundary was too long and one research institution commented that in its experience individuals seem to prefer shorter time limits tied to specific periods (*e.g.*, a series of clinical encounters, participation in an ongoing study).

A few comments stated that any time limit could have a negative effect on rare disease research as the numbers of affected people are so small and, as discoveries are made, there is often a need to go back to years' worth of information or stored biospecimens to search for markers, mutations, or clinical information that is related to the new discovery. Such commenters expressed concern that this could be deleterious to individuals with rare disease seeking a diagnosis.

Some commenters were confused about how the 10-year boundary proposed in the NPRM was supposed to function. Some comments assumed that one could only use the biospecimens or data for a 10-year period and after that period one would be required to get consent again for the use of those items. Others assumed that investigators would have to re-consent people every 10 years, but the information and biospecimens could be used indefinitely. For these reasons, many

comments on the 10-year boundary said it was unreasonable and unworkable operationally. Some suggested that instead of 10-year boundary, patients could be routinely reminded that they gave consent and can be reminded that they can opt out at any time. Several large research institutions commented that the time limit would necessitate a lot of tracking for institutions and could lead to smaller health care institutions ceasing their collection of biospecimens for research, which would ultimately have a negative impact on research.

The NPRM also asked whether all of the elements of consent proposed at § _____.116(c) should be required for the secondary use of biospecimens or identifiable private information originally collected as part of a research study that was conducted without consent because either the original research study met an exclusion or exempt category of research, or a waiver of consent was approved by an IRB. Approximately 30 comments answered this question. Responses ranged from those saying the elements are not as relevant as the burden of having to seek consent every 10 years. Many stated that the elements of consent appeared to be growing in the proposed rule at the same time that the rule was requiring simpler and shorter consent forms. As such, efforts should not be made to include all of the elements required in specific consent to broad consent; otherwise the intent of broad consent would be lost.

The NPRM also asked whether oral consent should be permissible in limited circumstances as proposed under the exemption for the storage and maintenance of biospecimens and identifiable private information. More than 60 pathologists, pathology departments, and pathology organizations suggested that oral consent should not be allowed in this context because it raises too many administrative challenges and may undermine public trust. A few commenters felt oral consent should be permitted but generally did not provide a rationale.

Finally, some comments indicated that broad consent as a concept should not be included in a final rule, and that the standards that exist under the pre-2018 rule for secondary research (*i.e.*, either that an investigator obtains study specific consent or a waiver of informed consent from an IRB) should be maintained in a final rule.

4. Response to Comments and Explanation of the Final Rule: Elements of Broad Consent

The final rule includes an option to obtain broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens, as defined at § _____.102(e)(5) and (6), but several significant changes were made in response to public comments. Although in some ways the final rule's broad consent provision resembles the provision that was proposed in the NPRM, it is important to recognize a very fundamental difference between the role that this provision will play under the final rule, as compared to the role it was intended to play under the NPRM. This key difference relates to the fact that the provisions in the NPRM that would have generally required consent for secondary research use of nonidentified biospecimens, including imposing narrow stringent criteria for IRB waiver of consent with respect to such research, are not being implemented because the NPRM's proposal that all biospecimens, regardless of their identifiability, be covered under the Common Rule has not been adopted. Importantly, under the final rule, broad consent is permissible only for secondary research and no other types of research.

Thus, had all of those NPRM provisions been implemented, investigators who wanted to conduct secondary research with biospecimens would in most instances have found themselves essentially forced to use the new broad consent provisions as their only practical option for conducting such research. This is because generally, under the NPRM proposals, they would no longer have had the option to de-identify information or biospecimens, or to use them in coded form, to avoid application of the Common Rule's requirements. Under the NPRM's proposals, had investigators not obtained broad consent, they would often not practicably be able to meet the informed consent requirements relating to such research (which would have been covered under the Common Rule). Therefore, it would generally have been the case that they would have had little choice but to obtain broad consent, assuming they did not want to undertake the alternative of obtaining study-specific consent from subjects each and every time they conducted a study involving secondary use of biospecimens.

Given that we did not adopt the NPRM's proposal to cover all biospecimens regardless of their

identifiability under the Common Rule, the final rule also does not adopt proposed consent requirements for secondary research with nonidentified biospecimens. For this reason, the final rule's provisions relating to broad consent now play a very different role from those proposed in the NPRM. In most instances, these provisions will be providing new options—that is, new flexibility—to an investigator, in addition to those options that an investigator would have had under the pre-2018 rule. An investigator wishing to do secondary research with biospecimens will continue to have the option of doing secondary research with nonidentifiable biospecimens, as was the case in the pre-2018 rule. An investigator also could continue to use biospecimens that are coded, thus allowing the collection of additional information about the subjects over time.⁴⁷ In both of those instances, no additional consent would be required because the research would not involve human subjects as defined by the final rule. Furthermore, even if the investigator wanted to use the biospecimens with identifiers attached, he or she would still have the option of asking an IRB to waive the requirement to obtain informed consent: the waiver criteria are in most respects unchanged under the final rule.

For these reasons, the broad consent provisions at § _____.116(d) afford investigators wishing to conduct secondary research on identifiable private information or identifiable biospecimens an additional alternative to obtaining an IRB waiver of consent or to obtaining study-specific consent. Given that these new broad consent provisions are essentially a new alternative to other options that are very similar to those that existed under the pre-2018 rule, these provisions are not increasing any regulatory burden or making it more difficult to do research. Indeed, just the opposite is the case. The changes made in the final rule are responsive to the significant criticisms expressed by many of the commenters about what the NPRM proposed, under which obtaining broad consent would have imposed substantial new burdens on a vast amount of secondary research with biospecimens. In contrast, when investigators choose to use the broad consent provisions under the final rule, they will presumably be doing so because this new option is less

burdensome to them than their other (largely unchanged) options for conducting such research.

Although we recognize public commenters' concern that broad consent might not be as meaningful or informative as study-specific consent, it is also important to note that when an investigator chooses to use this new option, doing so will generally provide increased protection to the autonomy of research subjects. It will give them a choice to say no to such research, in contrast to most of the other routes by which an investigator might generally choose to conduct this type of research, such as with a waiver of informed consent, which allows research to take place regardless of the wishes of the person whose information or biospecimens are being studied, and without their knowledge. In addition, in response to the public's concerns that broad consent would not be meaningful, some of the elements of broad consent have changed from what was proposed in the NPRM to require more specific information about the research that may be conducted. As discussed in the NPRM, one of the main purposes of the final rule is to facilitate the conduct of minimal risk research, while enhancing subjects' autonomy. We believe that the option to obtain broad consent furthers this goal.

It is important to recognize that broad consent is a permissible option only for secondary research. Secondary research is limited to research using identifiable private information or identifiable biospecimens that are collected for either research studies other than the proposed research or nonresearch purposes. It is not permissible to obtain broad consent for any other type of research (e.g., research involving the collection of information or biospecimens through a research interaction or intervention with a subject). The informed consent requirements in § _____.116(b) and (c) will be applicable to all human subjects research for which broad consent is not an option. However, it is envisioned that research requiring study-specific consent, such as research involving the collection of information or biospecimens through a research interaction or intervention with a subject, will sometimes also involve seeking subjects' broad consent for the secondary research use of identifiable private information or identifiable biospecimens obtained as part of the original research study.

When broad consent is obtained, the general requirements for informed consent in § _____.116(a) apply, except that the requirements at § _____.116(a)(5)

(imposing certain requirements concerning the presentation of information for informed consent and prescribing the order in which consent information is presented) do not apply to broad consent.

We expect that, given the different requirements set forth for study-specific consent and broad consent, some institutions and investigators may elect to pursue study-specific consents for the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens (or for some subset of such research) whereas other institutions and investigators may elect to pursue broad consent for the same types of research (or for some subset of such research). For instance, with regard to the public comments raising concern about broad consent being sought from AI/AN peoples, it is expected that institutions, investigators, and IRBs will consider these concerns when determining when it might be appropriate to seek study-specific consent for the secondary research use of identifiable biospecimens, as well as the need for tribal consent, when appropriate.

Perhaps even more commonly, however, given that the NPRM proposal regarding generally requiring consent for research use of nonidentifiable biospecimens has not been adopted, many investigators may choose to use the routes that previously existed under the pre-2018 rule, and will continue to exist, for conducting such research without informed consent under the Common Rule. Those options include using nonidentifiable biospecimens, including perhaps having a code maintained that will allow the investigator to obtain additional information about the subjects, or obtaining a waiver from an IRB of the need to obtain informed consent.

The broad consent provision in the final rule is different in three main ways from what was proposed in the NPRM. First, consistent with the decision not to revise the definition of human subject to include biospecimens regardless of identifiability, the broad consent provision in § _____.116(d) only applies to secondary research using identifiable private information and identifiable biospecimens.

Second, the elements of broad consent have been strengthened and simplified in response to public comments. The final rule strengthens the element of broad consent proposed in the NPRM regarding the need to provide a general description of the types of research that may be conducted with identifiable private information and identifiable

⁴⁷ HHS, Office for Human Research Protections. Coded Private Information or Specimens Use in Research, Guidance. October 16, 2008. Retrieved from <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html>.

biospecimens. It does this by requiring that this description must include sufficient information to allow a reasonable person to expect that the broad consent would permit the types of research conducted. This “reasonable person” standard is consistent with the interpretation that the Office for Civil Rights provided for authorization obtained from an individual for the use or disclosure of protected health information for future research purposes. In addition, the final rule has been strengthened to require that when subjects will not be informed about the details for any specific research studies that might be conducted using their identifiable private information or identifiable biospecimens, the broad consent must disclose this fact and inform subjects that they might have chosen not to consent to some of those specific research studies. It is envisioned that for certain types of research, such as research for which there is reason to believe some subjects will find the research controversial or objectionable, a more robust description of the research will be required in order to meet this “reasonable person” standard. This requirement has been included in the final rule in recognition of the concerns raised by some public commenters that broad consent would not be meaningful because it will not provide detailed information about specific research studies that might be conducted with the individual’s identifiable private information or identifiable biospecimens.

As proposed in the NPRM, the final rule permits broad consent to be sought for either a narrow type of research to be conducted in the future (e.g., cancer research), or a broader scope of research. Given this flexibility, while the final rule includes an exemption for secondary research for which broad consent is required, the exemption is contingent on several criteria being satisfied, including that an IRB determines that the research to be conducted is within the scope of the broad consent (§ _____.104(d)(8)). This exemption is further discussed in Section V. For research that is not exempt, the IRB is expected to assess whether the description of the research included in the broad consent form is adequate to permit a reasonable person to expect that they were providing consent for the currently proposed secondary research study.

While strengthening the broad consent requirements, the final rule also adopts simplified and more flexible elements of broad consent than what was proposed in the NPRM. For example, the final rule requires that the

broad consent include a description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of such information or biospecimens might occur, and the types of institutions or investigators that might conduct research with such information or biospecimens. However, the final rule does not adopt the NPRM’s proposed limitations on the research use of biospecimens or identifiable private information obtained for nonresearch purposes, that would have only permitted a broad consent to cover either or both of the following: (1) Biospecimens or identifiable private information that exist at the time at which broad consent is sought; and (2) biospecimens or identifiable private information that will be collected up to 10 years after broad consent is obtained or until the child reaches the legal age of consent to the treatments or procedures involved in the research, whichever comes first. We were persuaded by the public comments that raised concerns about the complexity and tracking burden that such limitations would impose, without clearly offering individuals a more meaningful way to control the use of their information or biospecimens.

In addition, the broad consent requirements have been simplified to avoid creating redundant requirements with the basic elements of informed consent under § _____.116(b) that must also be included in broad consent obtained under § _____.116(d). For example, in the final rule, it is required that broad consent include a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without loss of benefits to which the subject is otherwise entitled ((§ _____.116(d)(1), incorporating § _____.116(b)(8) for broad consent). Therefore, the comparable element of broad consent that was proposed in the NPRM is not included in the final rule.

As discussed in the NPRM, we expect that, when appropriate, this element of broad consent will inform subjects that information that has been stripped of identifiers might not be traceable, and thus it might not be feasible to withdraw consent for future use or distribution in this case. However, if an investigator commits to permitting a subject to discontinue use of the subject’s identifiable private information or identifiable biospecimens, it is expected that the investigator will honor this commitment by not removing identifiers.

Similarly, the final rule also does not include the element of broad consent proposed in the NPRM that, when relevant, would have required the broad consent to include an option for an adult subject or the representative to consent, or refuse to consent, to the inclusion of the subject’s data, with removal of the identifiers listed in 45 CFR 164.514(b)(2)(i)(A) through (Q), in a database that is publicly and openly accessible to anyone, and that this option be prominently noted and include a description of the risks of public access to the data. We believe this proposed requirement is unnecessary because it overlaps with the broad consent elements included in the final rule requiring a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained (§ _____.116(d)(1), incorporating § _____.116(b)(5) for broad consent), and a description of any reasonably foreseeable risks or discomforts to the subject (§ _____.116(d)(1), incorporating § _____.116(b)(2) for broad consent).

The final rule includes a slightly different provision relating to the return of research results than that proposed in the NPRM. As set forth in § _____.116(d)(6) of the final rule, unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject must be included in the broad consent. This element of broad consent differs from the related requirement in § _____.116(c)(8) that pertains when an investigator is seeking consent for a specific study, since unlike the circumstances under which broad consent is likely to be sought, investigators seeking consent for a specific study will know if the study includes a plan to return research results to subjects. The NPRM proposed that a general element of informed consent be included as part of a broad consent, namely that the consent include a statement regarding whether clinically relevant research results, including individual research results, would be disclosed to subjects, and if so, under what conditions. The language adopted in the final rule is intended to provide transparency, but is tailored to the broad consent context as those seeking broad consent may not know whether clinically relevant research results, including individual research results, will always be disclosed to subjects, and if so, under what conditions. Nonetheless, unless investigators know that such results will

be disclosed to subjects in all circumstances, subjects will be informed through a broad consent of the possibility that such results will not be disclosed to them. This provision is intended to pertain to all clinically relevant research results, including general or aggregate research findings and individual research results. This element of broad consent will affect the applicability of the exemption set forth at § _____.104(d)(8), for secondary research for which broad consent is required. This exemption applies only if the investigator does not include returning individual research results to subjects as part of the study plan (noting, however, that this provision does not prevent an investigator from abiding by any legal requirements to return individual research results). Although it is envisioned that broad consent will often be sought with the expectation that specific secondary research studies using identifiable private information or identifiable biospecimens will be exempt under § _____.104(d)(8), this will not always be the case. Broad consent can also be obtained for secondary research that will not qualify for this exemption, such as secondary research that will involve returning clinically relevant research results to subjects. In these cases, the specific secondary research study will need to undergo IRB review and approval under § _____.111, and we expect that the IRB would consider what subjects were told in the broad consent regarding the return of research results. The only exception to the requirement for IRB review of such research, if covered by this policy, is if the research qualifies for another exemption or the research is carried out under a Secretarial waiver at § _____.101(i).

Finally, the third main difference between the NPRM and final rule provision on broad consent is that the final rule does not include broad consent templates to be established by the Secretary of HHS. We agree with the public comments that favored allowing institutions to create their own broad consent forms that could be tailored to a variety of circumstances. Therefore, under the final rule, investigators and institutions may develop broad consent forms, which, provided specified conditions are satisfied, would meet the exemption for the storage and maintenance for secondary research use of identifiable biospecimens or identifiable private information (§ _____.104(d)(7)). This exemption is further discussed in Section V. At a later time, the Secretary of HHS expects to

develop guidance on broad consent, which could include broad consent templates.

In addition, we are also including in the final rule an element that for research involving biospecimens, when appropriate, the broad consent must state whether the research will (if known) or might include whole genome sequencing (WGS) (§ _____.116(d)(1), incorporating § _____.116(c)(9)). The reasons for requiring this element in the broad consent are similar to those discussed above regarding the addition of this requirement in the additional elements of consent at § _____.116(c)(9). WGS generates an extremely large amount of data, which when analyzed can yield information about an individual, including factors that could contribute to their future medical conditions. Therefore, given the implications of WGS information for an individual and his or her biological family, if it is known that the broad consent will or might permit the use of individuals' biospecimens for WGS, we believe that this aspect of the research must be disclosed to prospective subjects as part of the broad consent process. The broad consent must include a general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens, with sufficient information to allow a reasonable person to expect that the broad consent would permit the types of research conducted (§ _____.116(d)(2)). Including an additional element of broad consent that specifically addresses WGS makes it clear that such information must be disclosed to prospective subjects.

Under the final rule, if the subject or the subject's legally authorized representative is asked to provide broad consent, the broad consent must satisfy the general informed consent requirements at § _____.116(a)(1)-(4), and (a)(6), and must include all of the following 12 elements that are applicable:

- A description of any reasonably foreseeable risks or discomforts to the subjects (§ _____.116(d)(1), incorporating basic elements of informed consent in § _____.116(b)(2));
- A description of any benefits to the subject or to others that may reasonably be expected from the research (§ _____.116(d)(1), incorporating basic elements of informed consent in § _____.116(b)(3));
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained (§ _____.116(d)(1),

incorporating basic elements of informed consent in § _____.116(b)(5));

- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled (§ _____.116(d)(1), incorporating basic elements of informed consent in § _____.116(b)(8));

- If applicable, a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit (§ _____.116(d)(1), incorporating additional elements of consent in § _____.116(c)(7));

- When appropriate, for research involving biospecimens, whether the research will (if known) or might include WGS (*i.e.*, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.) (§ _____.116(d)(1), incorporating the additional element of consent in § _____.116(c)(9));

- A general description of the types of research that may be conducted with identifiable private information or identifiable biospecimens. This description must include sufficient information to permit a reasonable person to expect that the broad consent would permit the types of research conducted (§ _____.116(d)(2));

- A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of such information or biospecimens might occur, and the types of institutions or investigators that might conduct research with such information or biospecimens (§ _____.116(d)(3));

- A description of the period of time allowed that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that such information or biospecimens may be used for research purposes (which period of time could be indefinite) (§ _____.116(d)(4));

- Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research and that they

might have chosen not to consent to some of those specific research studies (§ _____.116(d)(5));

- Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; (§ _____.116(d)(6)); and
- An explanation of whom to contact for answers to questions about the subject's rights about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm (§ _____.116(d)(7)).

The elements of broad consent described in the first six bullet points above are not unique to broad consent, while the elements described in the last six bullet points are specific to the requirements of broad consent.

E. Waiver or Alteration of Informed Consent Involving Public Benefit and Service Programs (§ _____.116(e))

1. Background and Pre-2018 Requirements

The pre-2018 rule permitted an IRB to waive the requirements for obtaining informed consent, or to alter such requirements, under two sets of circumstances described at § _____.116(c) or (d) of the pre-2018 rule. The first set of circumstances, described at § _____.116(c) of the pre-2018 rule was more narrow and was limited to certain research or demonstration projects conducted by or subject to the approval of state or local government officials. These projects are similar in some ways to the projects identified in the exemption at § _____.104(d)(5) of this final rule. The broader provisions concerning waivers or alterations of the requirements of informed consent that apply beyond the circumstances described in § _____.116(c) of the pre-2018 rule are discussed below in the section concerning § _____.116(f).

2. NPRM Proposal

The NPRM proposed retaining the waiver and alteration of informed consent provisions included in the pre-2018 rule with respect to research involving public benefit and service programs conducted by or subject to the approval of state or local officials, with two exceptions. First, the NPRM proposed (for proposed § _____.116(e)(2)), additional criteria for waiver or alteration of consent for biospecimens. This was tied to the NPRM's proposal that all biospecimens, regardless of their identifiability, be covered under the

Common Rule. Under these proposed criteria, IRBs would be able to approve waivers or alterations of the required informed consent elements only if an IRB found and documented both that there were compelling scientific reasons to conduct the research and that the research could not be conducted with other biospecimens for which informed consent was obtained or could be obtained. Second, the NPRM proposed new language (for proposed § _____.116(e)(3)), providing that if an individual was asked to consent to the storage or maintenance for secondary research use of biospecimens or identifiable private information in accordance with the proposed broad consent provisions and that individual refused to consent, the IRB would be prohibited from waiving consent for the storage, maintenance, or the secondary research use of the biospecimens or information.

3. Response to Comments and Explanation of the Final Rule: Waiver or Alteration of Informed Consent Involving Public Benefit and Service Programs

Public comments on this proposal are described in section F below because the comments submitted generally addressed the waiver and alteration criteria under both proposed § _____.116(e) and § _____.116(f).

The final rule adopts one of the two proposals made in the NPRM for proposed § _____.116(e). The final rule adopts (in § _____.116(e)(1)) the language proposed in the NPRM providing that if an individual was asked to consent to the storage or maintenance for secondary research use of identifiable private information or identifiable biospecimens in accordance with the proposed broad consent provisions and such individual refused to consent, the IRB would be prohibited from waiving consent for the storage, maintenance, or the secondary research use of such biospecimens or information. The references in this provision to biospecimens are changed to refer specifically to identifiable biospecimens as the final rule does not apply to the research use of nonidentifiable biospecimens. This change is intended to honor the autonomy of individuals and to further the *Belmont Report* principle of respect for persons, in that this provision will prevent an individual's refusal to consent to additional research use of information or biospecimens from being overridden.

The final rule does not incorporate the NPRM's proposed additional waiver criterion to apply to research involving the use of biospecimens. This change is

not necessary given that the proposal in the NPRM that the Common Rule extend to *all* biospecimens has not been adopted in the final rule. We determined that the waiver and alteration criteria included in the final rule are appropriately protective of identifiable biospecimens, as defined at § _____.102(e)(6) and that an additional waiver criterion for such biospecimens is not warranted. For example, § _____.116(e)(3)(ii) mandates that an IRB may not waive or alter the requirements of informed consent with respect to research under this category unless the research could not practicably be carried out without the waiver or alteration.

The format and organization of § _____.116(e) in the final rule is different from that included in the pre-2018 rule or proposed in the NPRM. These changes were implemented to be clearer about the effect of each requirement. Most significantly, § _____.116(e) in the final rule provides separate paragraphs concerning the applicable criteria for waiver and the applicable criteria for alteration of the requirements for informed consent. This differs from the approach proposed in the NPRM, and the approach included in the pre-2018 rule, that did not separate those discussions. We concluded that separating the discussion of waiver and the discussion of alteration would help clarify the applicable criteria, particularly given that the final rule addresses broad consent.

Section _____.116(e)(1) describes the general framework for an IRB to waive the requirements for informed consent. This paragraph explains that an IRB may waive the requirement to obtain informed consent under § _____.116(a) (general requirements for informed consent), § _____.116(b) (basic elements of informed consent), or § _____.116(c) (additional elements of informed consent that apply to certain research) if the IRB satisfies the criteria set forth at § _____.116(e)(3) (discussed below). As explained above, the ability to satisfy the requirement to obtain informed consent of a subject or a subject's legally authorized representative through use of a broad consent in particular circumstances is a flexibility offered to institutions, but institutions are never required to obtain informed consent through a broad consent process. For this reason, § _____.116(e)(1) does not provide that an IRB may waive the requirement to obtain informed consent under § _____.116(d) (broad consent) because use of broad consent is not a requirement. As noted above, and to honor the autonomy of individuals, § _____.116(e)(1) prohibits an IRB from

waiving consent for the storage, maintenance, or secondary research uses of identifiable private biospecimens or identifiable private information if an individual was asked to provide broad consent for such purposes and refused to provide such consent.

Section _____.116(e)(2) describes the general framework for an IRB to alter the requirements for informed consent. An IRB may omit or alter some or all of the elements of informed consent under § _____.116(b) (basic elements of informed consent) or § _____.116(c) (additional elements of informed consent that apply to certain research) if the IRB satisfies the criteria set forth at § _____.116(e)(3) (discussed below). This is consistent with the proposal made in the NPRM. This paragraph further explains that an IRB may not omit or alter any of the requirements described in § _____.116(a) (general requirements for informed consent). This is also consistent with the proposal made in the NPRM (which proposed permitting an IRB to omit or alter elements of informed consent, but did not propose permitting omissions or alterations of the general requirements of informed consent that were included in the unnumbered introductory paragraph in the pre-2018 rule at § _____.116). This paragraph also specifies that if a broad consent is used, an IRB may not omit or alter any of the elements required under § _____.116(d). We determined that it would not be appropriate to permit the omission or alteration of any of the broad consent elements given the fact that the required elements of broad consent are limited and given our view that each of these elements (described at § _____.116(d)) is critical for the purpose of soliciting broad consent that is both informed and ethically appropriate. This approach is different from what was proposed in the NPRM because of the NPRM's different approach to broad consent than that adopted in the final rule.

Section _____.116(e)(3) sets forth the specific criteria that an IRB must find and document to waive or alter the requirements for informed consent, consistent with the limitations set forth in § _____.116(e)(1) and § _____.116(e)(2). These criteria are the same as those proposed in the NPRM. First, the IRB must find and document that the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or

alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs. Second, the IRB must find and document that the research could not practicably be carried out without the waiver or alteration.

F. General Waiver or Alteration of Informed Consent (§ _____.116(f))

1. Background and Pre-2018 Requirements

Beyond the circumstances addressed in § _____.116(c) of the pre-2018 rule (which is limited to certain research conducted by or subject to the approval of state or local government officials), the pre-2018 rule includes a more general provision that is not limited to any particular type of research and that permits an IRB to either waive the requirements for obtaining informed consent, or to alter such requirements. Waiver or alteration of the requirements of informed consent under this general provision requires that the following four criteria be satisfied: (1) the research involves no more than minimal risk to the subjects; (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Concerns have been expressed that requirements for obtaining waivers of informed consent or waivers of documentation of informed consent were confusing and inflexible, resulting in inconsistent application and a lack of uniformity in interpretation, which led to the proposals in the NPRM.

2. NPRM Proposals

The NPRM offered three substantive proposals related to the general waiver or alteration of informed consent provisions. First, the NPRM proposed to add a new waiver criterion that would require that for research involving access to or use of identifiable biospecimens or identifiable private information, the requirements of informed consent could only be waived or altered if the research could not practicably be carried out without accessing or using identifiers. This criterion was modeled on the comparable criterion in the HIPAA Privacy Rule, which requires as a condition of waiver of the requirement to obtain an individual's authorization that the research could not practicably be conducted without access to and use of protected health information. The

principle embodied in this additional proposed criterion was that nonidentified information should be used whenever possible in order to respect subjects' interests in protecting the confidentiality of their data and biospecimens.

Second, the NPRM proposed two additional waiver criteria for research involving the use of biospecimens. For such research, the NPRM proposed that the requirements of informed consent could only be waived or altered if an IRB found and documented that: (1) there were compelling scientific reasons for the research use of the biospecimens; and (2) the research could not be conducted with other biospecimens for which informed consent was or could be obtained.

Third, the NPRM proposed that the Common Rule prohibit IRBs from waiving informed consent if individuals were asked and refused to provide broad consent to the storage and maintenance for secondary research use of biospecimens and identifiable private information. If a subject refused to provide broad consent, it was proposed that this refusal would need to be recorded by the investigator to better ensure that the subject's wishes would be honored.

3. Public Comments

Approximately 975 public comments discussed the NPRM proposals found at § _____.116(f) either directly, or as related to linked provisions related to the definition of human subject, the broad consent proposal, or proposed exemptions. A majority of these discussed the NPRM proposals related to the more stringent waiver criteria for research involving biospecimens. A majority of these comments were from patients (including family members of patients) and other individuals who commented anonymously. Patients tended to oppose these proposals because they believed they would severely restrict access to biospecimens, which would slow research. Some commenters were opposed to waiver of consent under any conditions, whether specific or broad consent.

Approximately 40 comments were received on the NPRM's proposal to prohibit an IRB from waiving consent for the storage, maintenance, or secondary research uses of identifiable biospecimens or identifiable private information if an individual was asked to provide broad consent for such purposes and refused to provide such consent. Public comment was mixed. Those who supported it indicated that this requirement made sense in order to respect subject autonomy. Those who

opposed the proposal indicated that it would be impossible for an IRB to know the reasons why an individual refused to sign a broad consent form. Thus, these individuals argued, the prohibition on waiver of consent did not seem appropriate given the difficulty in understanding why someone refused to sign a broad consent form. Several commenters noted that it would be reasonable to prohibit an IRB from waiving a subject's refusal to provide consent to a specific study, but that such a prohibition in the context of broad consent seemed unduly burdensome.

The NPRM sought comments concerning language in the pre-2018 rule (that the NPRM proposed retaining) that waiver or alteration of informed consent only occur if the IRB finds that the research could not practicably be carried out without the requested waiver or alteration. Several commenters recommended further defining or clarifying the meaning of "practicably." Some members of the public felt that this criterion was too open-ended and that greater emphasis should be placed on respect for persons over other ethical concerns and scientific validity. Several commenters favored SACHRP's recommendations on this topic, including that this requirement be interpreted to mean that it would be impracticable to perform the research, not impracticable to obtain consent due to financial or administrative burdens, without the waiver or alteration. Another commenter argued that because of a lack of clarity as to the meaning of terms including "minimal risk," "practicably," and "the rights and welfare of subjects," as well as the potential that IRBs may not apply the criteria uniformly, IRBs should not be able to waive or alter consent. The following suggestions were offered as replacement language: "reasonably done without excessive time or financial constraints to the researcher that would delay the project so significantly as to make it impossible to conduct the research," "capable of being done or accomplished with available means or resources," "reasonably feasible," "capable of being effective," and "could practicably be obtained." Several commenters favored retaining the term "practicably" and were satisfied that it was clear.

Other comments raised different issues about waiver or alteration. Many commenters who opposed all classified research conducted without consent recommended that waivers be prohibited with respect to classified research involving humans. One

commenter recommended a reorganization of the waiver and alteration provisions to clarify the different standards that apply to waivers and alterations. Another commenter expressed concern that the NPRM's proposed waiver provision would unreasonably limit the flexibility of IRBs. One commenter believed that the § ___.116(f) alteration criteria were too rigid and that the final rule should incorporate a notion of risk adjustment. Another commenter (a professional medical organization) supported SACHRP's proposed revisions to the waiver criteria at § ___.116(f) to allow an IRB to approve the storage, maintenance, and secondary research use of identified data.

The NPRM sought public comment on the proposed differences between the criteria for waiving informed consent for the research use of biospecimens versus identifiable information. Approximately 60 comments stated that no justification exists for treating biospecimens and information differently. Some also noted that the proposed criteria for waiver of consent for use of biospecimens is so high as to be virtually impossible to meet and asked why biospecimens should have a higher standard than information (which theoretically could be more easily identifiable). One commenter noted that the proposed waiver criteria promotes "biospecimen exceptionalism" and that data and biospecimens should be treated the same.

A request in the NPRM for public comment on whether the proposal to permit an IRB to waive consent for research involving the use of biospecimens should be included in the regulations received few comments. One commenter noted that it seemed incongruous to include biospecimens in the definition of "human subject," but then allow waiver based on different criteria. Others stated that IRBs should continue to have the ability to waive consent.

The NPRM sought public comment regarding how likely investigators are to seek broad consent for the use of identifiable private information (as contrasted with biospecimens), given that the NPRM contains provisions that would make it easier to do such research without consent (such as the new exemption proposed for § ___.104(e)(2)). Approximately 30 commenters responded to this question. A majority said they would not use the broad consent mechanism for secondary use of information if other options were available. Some said that they suspected that investigators would continue to seek consent waivers for secondary use

of identifiable private information instead of seeking broad consent.

The NPRM also sought public comment on several aspects of the proposed prohibition on waiving consent when an individual has been asked to provide broad consent and refused, including the following questions: In particular, how would this prohibition on waiving consent affect the secondary research use of identifiable private information? If an individual was asked to provide such consent, should the absence of a signed secondary use consent be considered a refusal? Does this prohibition on waiving consent for the secondary use of identifiable private information create a disincentive for institutions to seek broad consent for secondary use and instead seek a waiver of consent from an IRB? Under what circumstances, if any, would it be justified to permit an IRB to waive consent even if an individual declined or refused to consent?

Approximately 35 comments were received on this set of questions. Approximately half of these stated that "no means no." If someone was asked to give broad consent and the person specifically said no, researchers should not be allowed to obtain a waiver of consent. Those who opposed the idea of a prohibition on waiver argued that it would be very difficult for institutions to understand why someone said no to providing broad consent. In other words, a blanket prohibition does not accurately address all the issues that can occur in this situation.

A majority of the responses did not address the questions of how a broad consent form with no indication either way should be treated. The responses we received to this question suggested that absence of a signed form should not be treated as if the individual explicitly said no to broad consent (*i.e.*, that in those situations, waiver should be permitted).

A majority of the responses that we received on the question of whether the prohibition on waiver in the broad consent context created a disincentive for the use of broad consent with identifiable private information answered in the affirmative.

4. Response to Comments and Explanation of the Final Rule: General Waiver of Alteration of Consent

Overall, two of the three proposals made in the NPRM for proposed § ___.116(f) have been retained. The final rule adopts (in § ___.116(f)(3)(iii)) a new waiver criterion very similar to that proposed in the NPRM, which now mandates that for research involving access to or use of identifiable private

information or identifiable biospecimens, the requirements of informed consent can be waived or altered only if the research could not practicably be carried out without using such information or biospecimens in an identifiable format. The minor wording change made in the language of this provision, as compared with that proposed in the NPRM, is intended for clarity. This change is intended to protect the privacy of individuals, while not unduly inhibiting research. After considering the diversity of opinions expressed in the public comments on this issue, including many comments seeking further guidance concerning the proper interpretation of the “practicably” language, the final rule does not define this language (which was also included in the pre-2018 rule). We have concluded that the requirements for waiver and alteration in § _____.116(e) and (f) appropriately honor respect for persons and balances this with other ethical principles.

The final rule also adopts (in § _____.116(f)(1)) the language proposed in the NPRM (for § _____.116(f)(3)) prohibiting IRBs from waiving informed consent if individuals were asked and declined to provide broad consent to the storage and maintenance for secondary research use of identifiable private information or identifiable biospecimens (except that the final rule’s formulation is limited to identifiable biospecimens, consistent with changes made in the final rule). We considered public comments that opposed this prohibition and understand that IRBs may not always understand the reason that individuals refused to sign a consent form and that the effects of this broad prohibition could be significant in the context of broad consent (given the broad scope of research that such a broad consent could potentially extend to). Nonetheless, we determined that it is important to prevent an individual’s refusal to consent to additional research use of such information or biospecimens from being overridden. This change to the Common Rule is intended to honor the autonomy of individuals and to further the *Belmont Report* principle of respect for persons.

The final rule does not incorporate the NPRM’s proposed additional waiver criteria (proposed for § _____.116(f)(2)) to apply to research involving the use of biospecimens. This change is not necessary given that the proposal in the NPRM that the Common Rule extend to *all* biospecimens regardless of their identifiability has not been adopted in the final rule. We determined that the waiver and alteration criteria included

in the final rule are appropriately protective of identifiable biospecimens and that an additional waiver criterion for such biospecimens is not warranted. For example, § _____.116(f)(3)(iii) in the final rule is a research criterion specific to research that involves using identifiable private information or identifiable biospecimens. Under this criterion, an IRB may not waive or alter requirements of informed consent with respect to such research unless the IRB finds and documents that the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

The format and organization of § _____.116(f) in the final rule are different from the proposed § _____.116(f) described in the NPRM. We made these changes in an effort to be clear about the effect of each requirement. Most significantly, § _____.116(f) in the final rule provides separate paragraphs concerning the applicable criteria for waiver and the applicable criteria for alteration of the requirements for informed consent. This differs from the approach proposed in the NPRM, and the approach included in the pre-2018 rule that did not separate those discussions. We conclude that separating the discussion of waiver and alteration will help clarify the applicable criteria, particularly given that the final rule addresses the application of the waiver and alteration provisions in the context of broad consent.

Section _____.116(f)(1) describes the general framework for an IRB to waive the requirements for informed consent. This paragraph explains that an IRB may waive the requirement to obtain informed consent under § _____.116(a) (general requirements for informed consent), § _____.116(b) (basic elements of informed consent), or § _____.116(c) (additional elements of informed consent that apply to certain research) if the research satisfies the criteria set forth at § _____.116(f)(3) (discussed below). As explained above, the ability to satisfy the requirement to obtain informed consent of a subject or a subject’s legally authorized representative through use of a broad consent in particular circumstances is a flexibility offered to institutions, but institutions are never required to obtain informed consent through a broad consent process. For this reason, § _____.116(f)(1) does not provide that an IRB may waive the requirement to obtain informed consent under § _____.116(d) (broad consent) because use of broad consent is a regulatory flexibility, and not a requirement. Consistent with the proposal made in

the NPRM (proposed § _____.116(f)(3)), § _____.116(f)(1) provides that if an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens and refused to consent, an IRB cannot waive consent for either the storage, maintenance, or secondary research use of such biospecimens or information.

Section _____.116(f)(2) describes the general framework for an IRB to alter the requirements for informed consent. This paragraph explains that an IRB may omit or alter some or all of the elements of informed consent under § _____.116(b) (basic elements of informed consent) or § _____.116(c) (additional elements of informed consent that apply to certain research) if the IRB satisfies the criteria set forth at § _____.116(f)(3) (discussed below). This is consistent with the proposal made in the NPRM. This paragraph further explains that an IRB may not omit or alter any of the requirements described in § _____.116(a) (general requirements for informed consent). This is also consistent with the proposal made in the NPRM (which proposed permitting an IRB to omit or alter elements of informed consent, but did not propose permitting omissions or alterations of the general requirements of informed consent that were included in the unnumbered introductory paragraph in the pre-2018 rule at § _____.116). This paragraph also specifies that when reviewing a broad consent, an IRB may not omit or alter any of the elements required under § _____.116(d). As with § _____.116(e)(2), we determined that it would not be appropriate to permit the omission or alteration of any of the broad consent elements in § _____.116(f). The elements of broad consent reflected in this NPRM are limited. We have concluded that each of these elements (which are included at § _____.116(d)) is critical to the solicitation of an informed and ethically appropriate broad consent. For that reason, none of the elements of broad consent may be omitted or altered if broad consent is solicited. This prohibition is different than the NPRM’s proposal given the different formulation of broad consent represented in this final rule.

Section 116(f)(3) sets forth the specific criteria that an IRB must find and document in order to waive or alter the requirements for informed consent. These criteria are the same as those proposed in the NPRM, except that the third criterion includes minor wording changes that were made for clarity: (1) the research involves no more than minimal risk to the subjects; (2) the

research could not practicably be carried out without the requested waiver or alteration; (3) if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; (4) the waiver or alteration will not adversely affect the rights and welfare of the subjects; and (5) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

G. IRB Approval of Research Involving Screening, Recruiting, or Determining Eligibility of Prospective Subjects (§ _____.116(g))

1. Background and Pre-2018 Requirements

The pre-2018 rule required an IRB to determine that informed consent can be waived under § _____.116(d) before investigators could record identifiable private information for the purpose of identifying and contacting prospective subjects for a research study. This requirement to waive informed consent has been viewed as burdensome and unnecessary for protecting subjects, and is not consistent with FDA's regulations, which do not require informed consent or a waiver of informed consent for such activities.

2. NPRM Proposal

The NPRM proposed a new provision at § _____.116(g) that would authorize an IRB to approve a research proposal in which investigators obtain identifiable private information without individuals' informed consent for the purpose of screening, recruiting, or determining the eligibility of prospective human subjects of research. The IRB would be permitted to approve a research proposal only in such circumstances if the proposal included an assurance that the investigator would implement standards for protecting the information obtained, in accordance with and to the extent required by proposed § _____.105. This proposal was intended to address concerns that the pre-2018 rule required an IRB to determine that informed consent can be waived before investigators could record identifiable private information for the purpose of identifying and contacting prospective subjects for a research study.

3. Public Comments

Few comments were received regarding this proposal. All were generally supportive. One academic institution noted that "This review is

unnecessary considering the low potential risk to subjects and will expedite research endeavors and ensure harmonization between FDA's expectations and the Common Rule." However, one commenter thought that prospective subjects should be notified that this might be a possibility. Another commenter said that it should be clear that this is not an IRB waiver of consent, but rather it is an exception to the consent requirement.

4. Response to Comments and Explanation of the Final Rule: Approval of Research Involving Screening, Recruiting, or Determining Eligibility of Prospective Subjects

The final rule adopts the NPRM proposal at § _____.116(g), with minor changes made for clarity, and without a requirement that investigators adhere to the proposed privacy safeguards at § _____.105, since this provision is not included in the final rule. The provision at § _____.116(g) addresses concerns that the pre-2018 regulations required an IRB to determine that informed consent can be waived before investigators may record identifiable private information for the purpose of identifying and contacting prospective subjects for a research study. This change is intended to address these concerns by eliminating the requirement for the IRB to waive informed consent for these activities. In response to public comments, we are clarifying that this is not a waiver of the consent requirement but rather an exception to the requirement. This change is also responsive to SACHRP's recommendation regarding how the Common Rule should apply to activities that are conducted before subjects provide consent to participate in research, such as identifying potential subjects, contacting subjects, and recruiting subjects.⁴⁸

The final rule includes some minor changes from the NPRM proposal, to clarify the circumstances in which the IRB may approve the investigator's proposal to obtain information directly from a prospective subject, or to obtain already collected identifiable private information or identifiable biospecimens by accessing records or stored biospecimens, for purposes of screening, recruiting, or eligibility assessment, without the informed

consent of the prospective subject or the subject's legally authorized representative. The final rule also adds a reference to the subject's legally authorized representative at § _____.116(g)(1) to clarify that this exception to informed consent will also apply in circumstances in which the prospective subject has a legally authorized representative who will provide information about the prospective subject through oral or written communication with the investigator.

We note that in approving this exception to informed consent for the purpose of screening, recruiting, or determining the eligibility of prospective subjects, the IRB will be reviewing and approving the entire research proposal. Therefore, all of the IRB approval criteria at § _____.111 will need to be satisfied, including that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data (§ _____.111(a)(7)). Thus, as part of its review and approval of the research, the IRB must determine that there are adequate privacy and confidentiality safeguards for information obtained by investigators for these preparatory-to-research activities.

We believe that these preparatory-to-research activities are critical means by which to identify subjects that do not involve additional risks, given their limited nature. If prospective subjects are identified through these "screening" activities, then all other relevant requirements of this rule must be met if they are subsequently recruited to participate in the research.

H. Posting of Consent Forms (§ _____.116(h))

1. Background and Pre-2018 Requirements

The pre-2018 rule did not have a requirement to post consent forms from clinical trials.

2. NPRM Proposal

The NPRM proposed a new provision that would require that a copy of the final version of the consent form (absent any signatures) for each clinical trial conducted or supported by a Common Rule department or agency be posted on a publicly available federal Web site that will be established as a repository for such consent forms. The name of the protocol and contact information would be required to be included with the submission of the consent form. Under the NPRM proposal, the consent form would have to be published on the Web

⁴⁸ See Secretary's Advisory Committee on Human Research Protections (SACHRP). Attachment C: Approved by SACHRP July 20, 2011. SACHRP Recommendation regarding application of 45 CFR 46 and 21 CFR 56 to early processes in research, such as identifying potential subjects, contacting subjects and recruiting subjects. (July 20, 2011). Retrieved from <http://www.hhs.gov/ohrp/sachrp-committee/recommendations/2011-october-13-letter-attachment-c/index.html>.

site within 60 days after the trial is closed for recruitment.

3. Public Comments

The NPRM proposal received approximately 130 comments, most of which opposed the proposal in whole or in part. Many commenters expressed concern that the proposal represented administrative burden without a corresponding increase in protections to human subjects or benefit to the research community. Some commenters felt that the proposal represented a waste of resources that would not increase compliance with the regulations, and might result in longer consent forms if researchers felt the need to include an abundance of additional information to protect against perceived regulatory noncompliance or legal challenge. These commenters expressed concern that the repository of posted consent forms might be used to seek out instances of noncompliance. For example, one large medical school indicated that the posting requirement creates a rich environment for litigation and represents an effort to publicly shame investigators to improve quality of documents that will not work.

Other commenters, including some private research firms, were concerned that the proposal as drafted would not allow for the redaction of proprietary or institutionally sensitive information from consent forms before they would be posted to the Web site, and allow competing research entities access to detailed information about investigational drug or research programs beyond what is publicly available already. Additional concern was expressed about the proposed timeframe in which consent forms needed to be posted. Some felt that more time was needed. Other commenters felt it would be more beneficial to research participants if consent forms were posted before or during recruitment. In addition, some commenters felt that researchers should be allowed or encouraged to update posted consent forms if they are updated for the study. Others felt that requiring that consent forms be posted once (even if the forms were updated after being posted) would lead to potential confusion among research participants. For example, several commenters noted that should a subject participating in a trial see a consent form for a particular study that differed from the form that he or she originally signed, that discrepancy could cause unnecessary concern and confusion.

Still other commenters expressed concern that the high volume of consent forms that would be posted as a result

of this requirement would make the collection cumbersome and difficult to use, negating any potential benefit gained by increased transparency. Others expressed a concern that requiring all studies to post consent forms might lead to the perpetuation of poorly written forms, as researchers might use poor examples from the database to write their own informed consent documents in addition to excellent ones. A few major research universities suggested that guidance, best practices, or exemplary informed consent forms should be selected and shared publicly, rather than all informed consent forms. Some commenters suggested limiting the posting requirement to a subset of research studies, for example, to only high risk or large multi-institution studies.

Those who supported the proposal agreed that it would help increase accountability and promote transparency in informed consent forms. To that end, a minority of commenters said that this proposal should be extended to all research that is subject to the Common Rule, not just to studies meeting the definition of a clinical trial. Some commenters supported the idea of publicly sharing informed consent documents but felt it would be best accomplished through guidance or optional posting. One federal level advisory committee supported the proposal and recommended the creation of robust guidance with the goal of minimizing confusion and misuse of the posted documents, and facilitating the use of the posted forms to educate investigators, institutions, and regulators to improve future informed consent documents and the informed consent process generally. Others felt it would be helpful to post additional information and documents along with consent forms. For example, one investigator suggested that copies of IRB proposals and decisions be made public along with approved informed consent documents to provide additional transparency and accountability. Another commenter suggested that investigators be given the option to post assessment tools for evaluating prospective subjects' understanding of important study information.

Both those who supported and opposed the proposal indicated that in terms of implementing this proposal, consent forms should be posted to *ClinicalTrials.gov* as opposed to creating a new federal Web site in order to limit the additional administrative burden that this proposal would impose.

4. Response to Comments and Explanation of the Final Rule: Posting of Consent Forms

The final rule adopts the NPRM proposal with some modifications and clarifications. The primary purpose of this provision is to improve the quality of consent forms in federally funded research by assuring that—contrary to current practices, under which it is often very difficult to ever obtain a copy of these documents—they eventually would become subject to public scrutiny and that they will provide useful models for others. The consent form plays a key role in making sure that someone asked to enter a clinical trial receives the information they need to be making an informed decision about whether to enroll in that trial. Accordingly, it also plays a key role in supporting and justifying the public's trust in the integrity of our clinical trial enterprise.

We are not persuaded by the arguments of those commenters who suggest that potential negative consequences of this proposal outweigh its benefits. Fundamentally, this proposal is about increasing the transparency of one of the most important aspects of our human subjects protection system. Increased transparency is in general a good thing, and in this instance, as in many others, it offers multiple benefits—including increased trust—at very low cost. This provision is not a form of shaming, but rather an effort to ask people to work together to create a system that will improve the quality of informed consent. Moreover, the new standards for determining the acceptable content of a consent form—including § _____.116(a)(5), which will require a concise presentation of key information at the beginning of the consent form—should counter any consequences of attempts to pad consent forms with additional information as a response to the posting requirement.

We agree with the conclusions of SACHRP that implementing this proposal will indeed result in better consent forms. Having a repository of such forms freely available for analysis and public discussion will create multiple opportunities for improving these forms. In an era in which we have previously unheard of capabilities for analyzing textual material and processing large amounts of data, the fact that there will be a high volume of consent forms posted should be a minor impediment, if any, to the ability to learn from the content of this database.

With regard to those who suggested that it would indeed be desirable to

make consent forms more public, but that posting should be optional, we note that nothing in the pre-2018 rule prevents the people in charge of research from making their consent forms public, yet that is rarely done. In order to significantly increase the transparency of this portion of our system for protecting subjects, we are finalizing this proposal.

With regard to the commenters who were concerned that posting consent forms would create a rich environment for litigation, it is noteworthy that the existing evidence fails to suggest that there has been much of a problem with regard to inappropriate litigation over clinical trials. Whatever disincentives currently exist for such litigation, it seems unlikely that the mere fact that consent forms would now be more available will dramatically alter such disincentives. With regard to the commenters who were concerned about the added regulatory burden, we note that this change, compared to the traditional costs of clinical trials, will add a relatively small amount of additional burden, one that is well justified in comparison to the likely increase in transparency. This new provision has specifically been designed to minimize that burden. And the final rule has been modified in a number of respects from the NPRM proposal in response to public comments. As discussed below in detail, the time by which a consent form must be posted has been greatly extended. That change would also address the concerns of some commenters that the posted consent forms might create confusion among research subjects. Furthermore, provisions have been added that allow for redaction, as necessary, of portions of consent forms.

As a means of increasing transparency and facilitating the development of more informative consent forms, the final rule accordingly requires at § _____.116(h)(1) that for clinical trials conducted or supported by a Common Rule department or agency, a copy of an IRB-approved version of a consent form that was used to enroll subjects would need to be posted by the awardee or the federal department or agency conducting the trial on a publicly available federal Web site that will be established as a repository for such forms. Unlike the NPRM, which required that the “final version” of the consent form be posted, the final rule adds flexibility in merely requiring that it be an IRB-approved consent form that was used for enrollment purposes. There is accordingly no further restriction as to which version of a consent form (which might have been

subject to many modifications over the course of time) must be posted. The final rule also gives greater flexibility than the NPRM proposal in terms of when that posting needs to be done. It can take place any time after the trial is closed to recruitment, so long as the posting is no later than 60 days after the last study visit by any subject (as required by the protocol). If the federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a federal Web site (e.g., confidential commercial information), the department or agency may permit appropriate redactions to the information posted. In rare instances, it could be the case that the federal department or agency would determine that the very existence of a particular clinical trial should not be publicly disclosed, in which case no posting relating to such a trial would be required.

The final rule differs from the NPRM proposal in that it no longer specifies that certain information needs to be posted in addition to the consent form. This change eliminates the need for mandatory posting of information that might not be justified by the purposes of this provision.

Only one posting would be required for each multi-institution study. There is accordingly no expectation that a version would need to be posted for each class of subjects in the study (for example, a posting both for adults and for minors), nor for each study site.

We also note that this provision applies only to those clinical trials that are conducted or supported by a federal department or agency.

A Web site will be developed by HHS, which could be used by other federal departments or agencies, or the other federal departments or agencies could create their own Web sites for the posting of these consent forms. Public posting of consent forms is intended to increase transparency, enhance confidence in the research enterprise, increase accountability, and inform the development of future consent forms. It is anticipated that the Web site will be searchable. With regard to the comments suggesting that *ClinicalTrials.gov* might be an appropriate choice as the Web site, we agree that such a choice has the possibility of minimizing administrative burdens. Using *ClinicalTrials.gov* has another advantage, in addition to what some of the commenters said. Many clinical trials funded by HHS have records in *ClinicalTrials.gov* due to requirements that certain clinical trials register and submit results information

to that database (section 402(j) of the Public Health Service Act and 42 CFR part 11, and other policies that incentivize trial registration and results submission, such as the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information). The fact that these trials already have a record in the database will mean that the burden of submission of the informed consent document will be substantially lower. Accordingly, we will take these points into consideration as we determine what federal Web site will be used to implement this provision.

XV. Documentation of Informed Consent (§ _____.117)

A. Background and Pre-2018 Requirements

The pre-2018 rule at § _____.117 described the requirements for documenting informed consent and when the waiver for obtaining a written and signed consent form was allowable.

B. NPRM Proposals

The NPRM proposed to alter the language at § _____.117(b)(1) to specify that the consent document should include only the language required by § _____.116, with appendices included to cover any additional information.

In addition, the NPRM would make it explicit in the regulatory language at proposed § _____.117(c)(1)(iii) that if the subjects are members of a distinct cultural group or community for whom signing documents is not the norm, so long as the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained, the requirement to obtain a signed consent form may be waived. Documentation must include a description as to why signing forms is not the norm for the distinct cultural group or community.

Additionally, to facilitate the tracking of broad consent to storage or maintenance for secondary research use of biospecimens or identifiable private information, and to provide information to IRBs should IRB review be required, the NPRM proposed that waiver of documentation of consent for the research use of such biospecimens would not be allowed based upon a new provision at § _____.117(c)(3).

The NPRM also introduced the term “oral consent” in the context of the various provisions related to the broad consent for the storage, maintenance, and secondary use of biospecimens and identifiable private information. As a general matter, under the pre-2018 rule, individuals wanting to obtain oral

consent from subjects in a nonexempt research activity needed to seek a waiver of documentation of informed consent under § _____.117(c). Therefore, the NPRM proposed to permit investigators to obtain oral broad consent for the storage, maintenance, and secondary research use in limited circumstances. Specifically, the NPRM proposals would allow an investigator to obtain oral broad consent if:

- An investigator used the proposed broad consent template;
- Investigators only sought oral broad consent only for the storage, maintenance, and secondary research use context for the use of identifiable private information, not for biospecimens;

- If broad consent for the storage, maintenance, and secondary research use was obtained only as part of a separate, primary research study; and
- The oral broad consent was sought as part of the consent process in a study eligible for one specific exclusion or three specific exemptions related to the collection of identifiable information.

Finally, the regulatory language proposed at § _____.117(c)(4) was intended to clarify that waivers of documentation may not be permitted for research subject to regulation by FDA.

C. Public Comments

Approximately 15 comments were received on the proposals found in the NPRM at § _____.117. Several commenters discussing the proposed requirement at § _____.117(b)(1) indicated that even if consent forms are split into a primary document and appendices, there should be an expectation that the content included in the appendices are discussed with prospective subjects as part of the informed consent process. Although very few comments discussed the requirements of proposed § _____.117(b)(1) specifically, many of the comments discussing the NPRM proposal found in the introductory paragraph of § _____.116 discussed the concept of including only the required information in the main body of a consent form, and all additional information in appendices.

Few comments were received on the proposal found in § _____.117(c)(1)(iii) that documentation of informed consent may be waived if consent is being sought amongst subjects who are members of a distinct cultural group or community in which signing forms is not the norm. Comments received on this proposal were generally favorable.

Those who commented on the proposals related to oral broad consent indicated that the provisions were

confusing and difficult to understand. We note that these proposals were found in the NPRM through a series of interrelated cross references in §§ _____.116(d), _____.117(c), and _____.104(f)(1)–(2).

Several commenters discussed the statement found in § _____.117(c)(4) that waiver of documentation of consent is generally not permitted for research subject to regulation by the FDA. These commenters noted that this would be true regardless of whether this was included in the Common Rule. Additionally, commenters noted that if the FDA regulations ever permitted waiver of documentation of consent, the existence of this provision in the Common Rule might result in confusion and contradictory requirements for dually regulated research.

D. Response to Comments and Explanation of the Final Rule: Documentation of Informed Consent

The language at § _____.117(b)(1) and (2) are altered in the final rule to conform to the requirements included at § _____.116, which are discussed above. The goal in §§ _____.116 and _____.117 of the final rule is to facilitate a prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate in the research, in part by requiring that only the key information essential to decision making receive priority by appearing at the beginning of the consent document. In the final rule, these requirements also apply when a short form written informed consent process is used, or the requirement for written informed consent is waived.

We agree with the majority of public comments that favored adding a new provision allowing a waiver of the requirement for a signed consent form if the subjects are members of a distinct cultural group or community for whom signing documents is not the norm, provided that the research presents no more than minimal risk of harm to subjects and there is an appropriate alternative method for documenting that informed consent was obtained. Therefore, this new provision is added at § _____.117(c)(1)(iii). The final rule includes a reference to the subject's legally authorized representative to clarify that this provision applies when a subject has a legally authorized representative who is a member of a distinct cultural group or community in which signing forms is not the norm.

The final rule does not include the NPRM's proposal at § _____.117(c)(3) to prohibit a waiver of documentation of broad consent for the storage,

maintenance, or secondary research use of biospecimens.

Some of those who commented on the NPRM proposals related to oral broad consent found it to be unnecessarily confusing. In response to these comments, the final rule permits waiver of documentation of informed consent under § _____.117(c) when a broad consent procedure is used. No additional criteria or special restrictions apply. Additionally, the final rule removes all NPRM references to "oral consent" to reduce confusion.

However, we expect that it will rarely be permissible to waive documentation of broad consent for the secondary research use of medical records or stored biospecimens because there will likely be a need to track which individuals have provided broad consent and which have not, so the informed consent would not be the only record linking the subject and the research as required for a waiver under § _____.117(c)(1)(i). Additionally, when identifiable information and identifiable biospecimens are shared for a nonresearch purposes, the person's consent is usually required, so we expect that documentation of consent often could not be waived under § _____.117(c)(1)(ii), which requires that the research involves only procedures for which written consent is not normally required outside of the research context.

One instance when we believe it may be appropriate for the IRB to waive the requirement for a signed broad consent form is when the initial activity involved obtaining information from a person through oral communication, such as a phone survey, because there might not be an opportunity to obtain written broad consent from such individuals for the secondary research use of their information. In this scenario, documentation of broad consent could be waived under § _____.117(c)(1)(ii) if the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In addition, it might be appropriate for an IRB to waive the requirement for a signed broad consent document under the provision included in the final rule related to when the subjects or their legally authorized representatives are members of a distinct cultural group or community for whom signing documents is not the norm, provided that the research presents no more than minimal risk of harm to subjects and an appropriate alternative method is available for

documenting that informed consent was obtained (§ ____ .117(c)(1)(iii)).

The final rule also does not include the NPRM's proposed clarification that waivers of documentation may not be permitted for research subject to regulation by FDA. Because this is not the only difference between what is permitted under the Common Rule and the FDA regulations, we determined that clarifying only this specific difference in the final rule is likely to create more confusion rather than provide clarification.

XVI. Applications and Proposals Lacking Definite Plans for Involvement of Human Subjects (§ ____ .118)

A. Background and Pre-2018 Requirements

This provision of the pre-2018 rule stated that while an award or grant may be made for a project with indefinite plans to involve human subjects, that project must be reviewed by an IRB before human subjects may be involved.

B. NPRM Proposals

The NPRM language clarified that IRB review and approval was required before human subjects could be involved in a study unless the study was excluded under § ____ .101(b), waived under § ____ .101(i), or exempted under § ____ .104(d), (e) or (f)(2).

C. Public Comments

No comments were received.

D. Explanation of the Final Rule

The final rule adopts the language of the NPRM, with updated citations. This provision makes explicit that it applies only to nonexempt human subjects research.

XVII. Research Undertaken Without the Intention of Involving Human Subjects (§ ____ .119)

A. Background and Pre-2018 Requirements

This provision of the regulations outlines the process that an institution must undergo when a federally funded research project that was designed without the intention of involving human subjects later involves human subjects as defined by this policy.

B. NPRM Proposals

The NPRM proposed to add language to make clear that this provision applies only to nonexempt human subjects research. It also clarifies its reference to department or agency to mean a federal department or agency component supporting the research.

C. Public Comments

No comments were received.

D. Explanation of the Final Rule

The final rule adopts the language of the NPRM, with updated citations. This provision makes explicit that it applies only to nonexempt human subjects research, and clarifies the reference to department or agency to be a federal department or agency component supporting the research.

XVIII. Conditions (§ ____ .124)

A. Background and Pre-2018 Requirements

This provision of the regulations allows departments and agencies to impose additional requirements on human subjects research when such requirements are deemed necessary for the protection of human subjects.

B. NPRM Proposals

The NPRM provided more specific language at § ____ .124, stating that with respect to any research project or any class of research projects the department or agency head of either the conducting or the supporting federal department or agency may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency additional conditions are necessary for the protection of human subjects.

C. Public Comments

One commenter discussed this NPRM proposal, arguing that this would increase variance in implementation of the Common Rule, rather than promote harmonization as the NPRM suggested.

D. Explanation of the Final Rule

The final rule adopts the NPRM language, which clarifies the pre-2018 rule by stating that the head of either the conducting or the supporting federal department or agency may impose additional conditions on research, when necessary for the protection of human subjects.

XIX. Regulatory Impact Analyses

A. Introduction

HHS has examined the impacts of this final rule under Executive Order 12866 on Regulatory Planning and Review (September 30, 1993); Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011); the Regulatory Flexibility Act of 1980, Pub. L. 96–354 (September 19, 1980); the Unfunded Mandates Reform Act of 1995, Pub. L. 104–4 (March 22, 1995); and Executive Order 13132 on Federalism (August 4, 1999).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. HHS expects that this rule will have an annual effect on the economy of \$100 million or more in any one year and therefore is a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act (RFA) requires agencies that issue a regulation to analyze options for regulatory relief for small businesses if a rule has a significant impact on a substantial number of small entities.⁴⁹ The RFA generally defines a “small entity” as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000 (states and individuals are not included in the definition of “small entity”).⁵⁰ HHS considers a rule to have a significant economic impact on a substantial number of small entities if at least 5 percent of small entities experience an impact of more than 3 percent of revenue. HHS anticipates that the rule will not have a significant economic impact on a substantial number of small entities. Supporting analysis is provided in Section XIX.F below.

Section 202(a) of the Unfunded Mandates Reform Act of 1995⁵¹ requires that agencies prepare a written statement, including an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$146 million, using the most current (2015) implicit price deflator for the gross domestic product. HHS expects this rule to result in expenditures that will exceed this amount.

Executive Order 13132 establishes certain requirements that an agency

⁴⁹ 5 U.S.C. 603.

⁵⁰ 5 U.S.C. 601.

⁵¹ 2 U.S.C. 1532.

must meet when it promulgates a rule that imposes substantial direct requirement costs on state and local governments or has federalism implications. HHS has determined that the rule will not contain policies that would have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. The changes in the rule represent the Federal Government regulating its own program. Accordingly, HHS concludes that the rule does not contain policies that have federalism implications as defined in Executive Order 13132 and, consequently, a federalism summary impact statement is not required.

B. Need for the Final Rule and Summary

This final rule is being issued to modernize, strengthen, and make more effective the regulations for protecting human subjects in research. Although professional organizations have codes of conduct and guidelines for members conducting research, only the Federal Government has the authority to regulate the activities of institutions using public funds for human subjects research. Since the Common Rule was developed, the volume of research has increased, evolved, and diversified.

Thus, the final rule includes a number of measures to address the issues described above. Provisions that strengthen the requirements for informed consent and promote transparency in the informed consent process include: (1) Requiring that the informed consent form be designed and presented in such a way that facilitates a prospective subject's understanding of why one would want to participate in a

research study or not; (2) revising and adding to the required elements of consent; (3) requiring for certain clinical trials the posting of a copy of at least one version of a consent form on a publicly available federal Web site; and (4) clarifying the conditions and requirements for waiver or alteration of consent to remove ambiguity, including a new provision that, under specific conditions, an IRB may approve a research proposal in which investigators obtain information without individuals' informed consent for the purpose of screening, recruiting, or determining eligibility of prospective human subjects of research.

Provisions that strengthen the extent to which regulations promotes the principle of respect for persons include: (1) Requiring that informed consent forms present the key information to potential subjects at the beginning of a consent process; (2) allowing investigators the option of obtaining broad consent from a potential subject for future, unspecified research use of identifiable private information and identifiable biospecimens; and (3) adding a provision that would prohibit a waiver of consent if someone has been asked to provide their broad consent for the storage, maintenance, and secondary research use of identifiable biospecimens or identifiable private information and refused to do so.

New provisions that would allow IRBs greater flexibility to focus resources on higher-risk research include: (1) Distinguishing categories of activities that are deemed not to be research; and (2) expanding and clarifying categories of exempt research.

Provisions that streamline or reduce burden for IRBs or institutions include: (1) Requiring consultation among the

Common Rule agencies for the purpose of harmonizing guidance (to the extent appropriate); (2) eliminating an administrative requirement for reporting IRB membership; (3) removing the requirement that IRBs must review and approve grant applications; (4) eliminating, under certain circumstances, continuing review; (5) mandating the use of a single IRB for multi-institutional studies; and (6) holding IRBs not operated by an FWA-holding institution directly responsible for compliance when appropriate.

1. Accounting Table

Table 1 summarizes the quantified and nonquantified benefits and costs of all changes to the Common Rule. Over the 2017–2026 period, present value benefits of \$1,904 million and annualized benefits of \$223 million are estimated using a 3 percent discount rate; present value benefits of \$1,494 million and annualized benefits of \$213 million are estimated using a 7 percent discount rate. Present value costs of \$528 million and annualized costs of \$62.0 million are estimated using a 3 percent discount rate; present value costs of \$474 million and annualized costs of \$67.0 million are estimated using a 7 percent discount rate. Nonquantified benefits include improved human subjects protections in research; enhanced oversight of research reviewed by IRBs not operated by an FWA-holding institution; and increased uniformity in regulatory requirements among Common Rule departments and agencies. Nonquantified costs include the time needed for consultation among Common Rule agencies before federal guidance is issued.

TABLE 1—ACCOUNTING TABLE OF BENEFITS AND COSTS OF ALL CHANGES

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|--|---|-----------|--|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |
| Benefits: | | | | |
| Quantified Benefits | 1,904 | 1,494 | 223 | 213 |
| Nonquantified Benefits: | | | | |
| Improved human subjects protections in research; enhanced oversight in research reviewed by IRBs not operated by an FWA-holding institution; and increased uniformity in regulatory requirements among Common Rule departments and agencies. | | | | |
| Costs: | | | | |
| Quantified Costs: | 528 | 474 | 62.0 | 67.0 |
| Nonquantified Costs: | | | | |
| Time for consultation among Common Rule agencies before federal guidance is issued. | | | | |

Table 2 summarizes the quantified present value benefits and costs of each

change to the Common Rule using a 3 percent discount rate.

TABLE 2—ACCOUNTING TABLE OF QUANTIFIED BENEFITS AND COSTS OF EACH CHANGE

| Change | Present value of 10 years at a 3 percent discount rate (millions of 2015 dollars) | |
|---|---|-------|
| | Benefits | Costs |
| Costs to Learn New Requirements and Develop Training Materials; OHRP Costs to Develop Training and Guidance Materials, and to Implement the Rule | | 213 |
| Extending Oversight to IRBs Unaffiliated with an Institution Holding an FWA (impact to IRBs not operated by an FWA-holding institution) | | 85.6 |
| Excluding Activities from the Requirements of the Common Rule because They are not Research | 36.2 | |
| Clarifying and Harmonizing Regulatory Requirements and Agency Guidance | | |
| Modifying the Assurance Requirements | 5.93 | |
| Requirement for Written Procedures and Agreements for Reliance on IRBs Not Operated by the Engaged Institution (impact to FWA-holding institutions) | | 11.4 |
| Eliminating the Requirement that the Grant Application Undergo IRB Review and Approval | 326 | |
| Expansion of Research Activities Exempt from Full IRB Review | 798 | 0.37 |
| Elimination of Continuing Review of Research Under Specific Conditions | 148 | 41.0 |
| Amending the Expedited Review Procedures | 51.0 | |
| Cooperative Research (single IRB mandate in multi-institutional research) | 538 | 157 |
| Changes in the Basic Elements of Consent, Including Documentation | | 4.62 |
| Obtaining Consent to Secondary Use of Identifiable biospecimens and Identifiable private information | | |
| Elimination of Pre-2018 Rule Requirement to Waive Consent in Certain Subject Recruitment Activities | 1.25 | |
| Requirement for Posting of Consent Forms for Clinical Trials Conducted or supported by Common Rule Department or Agencies | | 15.4 |
| Alteration in Waiver for Documentation of Informed Consent in Certain Circumstances | | |

C. Public Comments and Response to Public Comments

1. General Comments

Approximately 50 comments discussed the specific cost estimates provided in the NPRM's Regulatory Impact Analyses (RIA). Several commenters strongly suggested that the final rule eliminate the proposals related to biospecimens, cooperative research, and expanding coverage to nonfederally funded clinical research because the NPRM failed to appreciate the cost and burden that would result from implementing these proposals. Although a majority of the comments received on the RIA suggested that several of the cost estimates were significantly underestimated, few commenters described specific changes to the cost and benefit estimates included in the NPRM RIA.

One commenter noted that the NPRM cost estimates are derived from a 1998 NIH-sponsored evaluation of the implementation of Section 491 of the Public Health Service Act and "because of the lack of available data about IRB effectiveness and how IRBs function operationally, many of the estimations in this analysis are based on anecdotal evidence." This commenter stated that reliance on outdated and anecdotal "evidence" means that the NPRM assumptions seriously underestimate predictable costs, such as those derived from current salary data for health care workers who would have at least some background sufficient to explain consent, and the time needed to obtain

consent. They also claimed that the NPRM analysis also seriously overestimates cost savings because excluding an activity from the Common Rule does not necessarily remove it from the purview of the IRB pursuant to other laws, such as the HIPAA regulations, and may simply shift the economic burden of responsible oversight to personnel elsewhere within the organization. This commenter also noted that the initial transition costs estimated in the NPRM are staggering, mostly due to costs related to biospecimen provisions.

One commenter stated that a review of the tables indicates that the costs used for hourly wages of individuals affected by the proposed changes may be underestimated by as much as 12 to 139 percent. Similarly, the hours associated with the proposed changes are substantially underestimated.

One commenter stated that an institutional official must be administratively high enough to insist on any necessary institutional changes, most likely a Vice President or higher, and felt that such an official would make at least \$250 per hour. This commenter stated that the \$48.20 estimate in the proposed rules may apply to liberal arts colleges, but the proportion of medical research conducted at such institutions is small and strongly recommends that salary data from medical institutions (published for public institutions) be used to generate a revised cost estimate. One commenter stated that the estimates of the salary rates presented in the

NPRM for institutional officials, IRB members and staff, and investigators are far below the national average for these roles. Likewise, they state that the anticipated benefits of the new proposed rule appear to be grossly overstated.

One commenter stated that the rule as proposed was officially estimated to add \$1.4 billion a year to the cost of the current system, but the true cost increase will be at least triple that due to egregious underestimates of wage costs, substantial underestimates of time spent on red tape by investigators, and many underestimated or omitted costs, as well as some estimates that misrepresent the effects of the rule. They claim that the rule is likely to impose about \$5 billion a year in needless costs, while reducing rather than improving protection of human subjects. One commenter stated that, at their institution, analysts average far greater pay levels than \$15 per hour, and many of the tasks will have to be borne by faculty whose salaries exceed what is identified in the current cost analyses.

One commenter proposed to mandate instead that institutions sufficiently resource their IRBs so as to protect 10 percent of their IRBs' and IRB administrators' time (about 1 meeting/year for an IRB that meets monthly; about 200 hours/year for a full-time equivalent IRB administrator with 2 weeks' vacation and 40-hour work weeks) to devote to finding efficiencies and innovations in the IRB review process.

a. Response to General Comments

We note that the NPRM discussed the fact that data about IRB effectiveness and how IRBs function operationally⁵² is generally unavailable. The NPRM further noted that many of the NPRM RIA assumptions were based on anecdotal evidence; the NPRM requested comment on the accuracy of the assumptions presented and on whether better data sources might be available to support the analyses. RIA comments did not provide the evidence necessary to improve our estimates, and thus, limited changes have been made.

We note that the NPRM RIA used a national average for the salary estimates. We received no compelling evidence to change cost estimates because we must account for the fact that personnel and salaries in affected categories vary widely.

2. Extension of the Common Rule to Certain Nonfederally Funded Clinical Trials

One commenter stated that coverage of this subset of projects will extend requirements, such as the single IRB requirement, without any consideration or mechanism for how to implement or fund this requirement and they do not believe that they should be required to accept added cost and burdens without any meaningful or measureable benefit to the welfare of human subjects.

One commenter stated that the inclusion of nonregulated, unfunded trials under the regulations for the subset of organizations that receive federal grants would lead to a significant increase in burden, delay, ambiguity, and cost, and a loss of valuable research without increasing protections for human subjects.

One commenter stated that an unintended burden would be the increased administrative costs of requiring reporting of all clinical trial Unanticipated Problems Involving Risks to Subjects or Others (unanticipated problems) to OHRP. They estimated requiring all unanticipated problems to be reported would increase their institution's necessary reporting by 25 percent.

a. Response to Comments on Extension of the Common Rule to Certain Nonfederally Funded Clinical Trials

The final rule does not adopt this proposal.

3. Biospecimens

With respect to expanding the definition of human subject to include nonidentifiable biospecimens and creating an exemption for secondary research on these specimens and identifiable information, many commenters claimed the NPRM significantly underestimated the cost of including nonidentified biospecimens under human subjects regulations and the consequent requirement for informed consent. Comments of a professional association, which were endorsed by numerous other commenters, stated that the NPRM has underestimated the financial impact of the Common Rule changes by a factor of at least 10, failing to account for the significant volume of specimens gathered outside of the federally funded environment, vastly underestimating the required time commitment and the requirements of administering a database to track consents, failing to include the expense incurred should an individual withdraw his or her consent for future research, and not including the potential expenditures required to develop a robust database that may be queried by researchers to identify biospecimens for use in future research projects. This association, and the numerous commenters who endorsed their comments, also felt that the increased administrative and cost burden to obtain informed consent for nonidentified biospecimens will disproportionately affect departments of pathology and laboratory medicine and will further increase indirect costs, which will eventually be built into the cost recovery rate from NIH, thereby reducing funds available for research when the NIH budget is fixed. One commenter stated that a major operations issue, and the one most necessary to ensure compliance with such a change, is the appropriate cataloging of biospecimens. Inherent in this new process are costs that will vary greatly based on the size of the stock of biospecimens held. Another commenter stated that the estimate for these costs was not plausible given the costs of developing or re-designing electronic systems.

a. Response to Comments on Biospecimens Proposals

As noted above in the preamble, the provisions relating to making nonidentified biospecimens subject to the Common Rule have been entirely eliminated. The final rule RIA does include impact estimates related to this proposal in Section XIX.E of this

preamble, discussing the impact of regulatory alternatives considered.

4. Broad Consent

One commenter wrote that the NPRM stated that institutions would need to obtain broad consent from only a third of the 30 million individuals who are estimated to provide research and clinical biospecimens each year.

Several commenters stated that this assertion fails to recognize that broad consent would need to be obtained from most individuals, not just those identified as research subjects, and underestimates the amount of time needed to revise consent processes and obtain such consent. For one institution, assuming staff time to obtain broad consent averages 20 minutes and the minimal staff salary is \$25 per hour, this cost alone would be \$2.54 million per year. Several commenters noted that the NPRM estimates that, per subject, the investigator or dedicated health care professional will spend 5 to 10 minutes obtaining broad consent, but this institution believes that a more appropriate standard for obtaining broad consents, particularly in the initial years, would be 20 to 30 minutes. One commenter stated that literally hundreds of employees would need extensive training and periodic retraining in research ethics to obtain broad consent, and they calculate that every procedure that involves any tissue collection should take a minimum of 10 to 15 minutes of additional staff time to be able to even attempt to make the process meaningful.

Many other commenters stated that tracking broad consent would impose significant costs, and require significant resources and infrastructure restructuring, given the complicated framework proposed by the NPRM.

One of these commenters also stated that a significant cost absent from the NPRM analysis is the potential need for rebuilding existing biorepositories and databanks that may be invalidated under the NPRM because: (1) The samples were collected without initial broad consent; (2) the samples are coded and thus not eligible for the transition provisions; (3) consenting all human sources would not be feasible; and (4) the revised and limited waiver mechanism would not be available. One commenter estimated that it will require millions of dollars to build and support the necessary IT and infrastructure required to keep track of the consents. One commenter stated that, if the NPRM's concern for "respect for persons" is really sincere, then the cost estimates involved should be increased by a factor of 4 to 10 times what is

⁵² See, e.g., Abbott L, Grady C. A Systematic Review of the Empirical Literature Evaluating IRBs: What We Know and What We Still Need to Learn. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3235475/>.

estimated in the NPRM. One commenter stated estimates that the biospecimen changes alone will cost their institution close to half a million U.S. dollars just in system changes to allow for the added administrative consent processes followed by the tracking mechanisms that will have to be put into place to accommodate the regulatory changes.

a. Response to Comments on Broad Consent

As noted above in the preamble, the provisions relating to making nonidentified biospecimens subject to the Common Rule have been entirely eliminated. Eliminating that proposal largely addresses the concerns regarding costs of the Broad Consent proposal. Note that in response to public comments, we have modified our estimates of the time it would take to seek, obtain, and document broad consent under the regulatory alternatives section of the RIA.

5. Exemptions

One commenter stated that even if a decision tool is used, IRBs will likely still need to review protocols to confirm the exempt classification, which will therefore not result in any cost savings.

a. Response to Comments on Exemptions

The final rule does not include the exemption determination and documentation requirement proposed in the NPRM.

6. Privacy Safeguards

One commenter stated that mandatory use of HIPAA or alternative, but yet-to-be determined, data security provisions would lead to a significant increase in burden, delay, ambiguity, and cost; this commenter also asserted that these safeguards might result in a loss of valuable research without increasing protections for human subjects.

One commenter noted that a large component of the data security safeguards is only necessary because of the 10-fold increase in the number of identified biospecimens due to tracking informed consent and that this adds significantly to the cost of this requirement, well beyond what was represented in the NPRM RIA.

a. Response to Comments on Privacy Safeguards

The final rule does not adopt the NPRM's proposal to implement standardized privacy safeguards.

7. Continuing Review

One commenter applauded the NPRM for recognizing the cost-benefit value of

eliminating continuing review for many studies. This will have a positive impact on the workload of investigators and IRBs.

8. Single IRB Review

Several commenters stated that mandated single IRB review would not decrease the burden for investigators but would, in fact, increase the burden in both the long and short term. They stated that investigators who currently work only with a single IRB (their institution's IRB) will now have to work with multiple IRBs, adding to burden. Further, the resources needed to use a commercial IRB would be beyond the capacity of small trials, which often have limited resources. One of these commenters estimated that, an investigator who has 50 protocols and currently two IRBs of record, would have a minimum of 10 different IRBs of record under the regulations proposed in the NPRM. As a result, the investigator would need to work with at least an additional 8 IRBs (10 in total), each with unique and complex requirements.

One commenter stated that the NPRM grossly underestimates in its assumption that a central IRB administrator would cost \$15 per hour.

One commenter stated that developing the infrastructure to support this effort will involve significant financial costs. Although using single IRBs for multi-institutional studies has the potential for long-term cost savings and reduction of burden when implemented well, reaching that point requires a substantial initial investment. Many other commenters agreed that the NPRM underestimated these initial costs. They stated that these "start-up costs" include but are not limited to: The creation of electronic management systems that are interoperable among institutions; the adaptation of automated processes to multiple institutions; the communications tools necessary to link investigators and IRBs; the staff time necessary to develop agreements, consensus documents, or standard operating procedures; and the interaction necessary to build and maintain trusting relationships among institutional officials. One university received an estimate from the vendor of such a system that costs to accommodate this change would be in excess of \$220,000 for the initial changes, with increased maintenance costs thereafter. In addition, the university would need to hire at least one full-time-equivalent (FTE) to handle the interface with all of the potential central IRBs and this position has a salary mid-point of \$54,000, to which

would be applied fringe benefits costs of \$19,500. Several commenters noted that, even for institutions not serving as the IRB of record, there are real financial implications of participating in the centralized process in terms of adapting existing software systems and protocols.

One commenter noted that the RIA section of the NPRM assigned nearly one-third of the total financial benefit of the revised Common Rule to savings achieved by the use of single IRBs for cooperative research. The RIA arrived at its estimate by assuming that when a single IRB of record reviews a protocol, all institutional costs are eliminated. The commenting institution uses numerous single IRBs, and they say they know from experience that the assumptions in the RIA are erroneous and no net savings accrue for IRB staff when using single IRBs of record. This same commenter noted that the NPRM states that its authors believe that, over time, standardization of agreements will occur so that all issues that currently take weeks or months to negotiate will be resolved. This commenter stated that no data to support this assumption and that, with each new single IRB required by NIH, they find a new set of requirements that requires the negotiation of hundreds of agreements with other institutions. They believe that study initiation will often be delayed because of this requirement and will result in additional software system needs and costs that are not even contemplated in the NPRM. They also stated that the vast majority of research-intensive universities are already over the federal mandated 26 percent facilities and administrative cap. Therefore, the commenter noted, the universities have no mechanism for funding the additional costs of serving as a central IRB because IRB costs are included in the portion of the facilities and administrative costs.

One commenter estimated the costs of ensuring an appropriate data flow between an institution and each new IRB of record, with respect to research studies conducted, to require an extra 200 hours of IRB administrator time, in addition to software customization, configuration, and development costs. This commenter estimated the true costs far exceed those included in the NPRM by a factor of 1433 percent (2150 hours required in total for 10 IRBs of record, versus 150 hours). Even splitting the difference to only a factor of 767 percent (1150 hours required in total for 10 IRBs of record versus 150 hours), the true costs of this approach virtually eclipse any possible quantified benefits estimated in the NPRM.

Two commenters cautioned that the costs to implement single IRB review in multi-institutional studies should not be factored into the overall cost breakdown of a contract or grant. In other words, federal departments and agencies supporting research should make additional funds available to cover the costs associated with implementing § _____.¹¹⁴

a. Response to Comments on Single IRB Review

We agree with commenters who felt that mandated single IRB review will ultimately decrease administrative burdens and inefficiencies for investigators and institutions, while acknowledging that the transition to this model will require time and an adjustment to institutional structures and policies. To incorporate this into our estimates, we assume that investigators for which multi-institutional reviews are eliminated will face a reduction in burden associated with the elimination of the site-specific protocol review, but will face increased burden in the form of coordination with investigators at other sites, for example to ensure that the results of the IRB review are effectively communicated. Specifically, we assume that the elimination of multi-institutional reviews will result in investigators spending half as much time engaging with the review process as they would have if IRB review had taken place at all sites. As a result, the estimated quantified benefits associated with the elimination of multi-institutional review have been revised downward by 27 percent.

9. Posting of Clinical Trial Informed Consent Forms

Several commenters stated that they do not see the utility of the proposed provision to publish consent forms to a public Web site as it creates a new administrative burden without providing any clear additional protection for research subjects or benefit to the public at large. One commenter stated that the cost estimates that the NPRM attaches to this proposed requirement are unrealistically low. One commenter stated that if the site is either *ClinicalTrials.gov* or some future site that is of equal difficulty to use, the cost estimates for investigators and institutions to upload to the site are greatly underestimated. This institution has found that their investigators have found *ClinicalTrials.gov* sufficiently difficult that they have had to add and train staff devoted solely to meet this requirement.

a. Response to Comments on Posting of Consent Forms

We note that this change, compared to the huge costs of clinical trials, will add a relatively small amount of additional burden. The time by which a consent form must be posted has been greatly extended. Furthermore, provisions have been added that allow for redaction of certain portions of consent forms, including the entire form in appropriate instances. We estimate that the revised rule will not affect the quantified and nonquantified costs summarized in the NPRM.

D. Analysis of Benefits and Costs

In this section, we present the analysis of the quantified and nonquantified benefits and costs of the changes to the Common Rule. First, we discuss the common assumptions of the analysis. Then we present the estimated quantified and nonquantified benefits and costs of the specific changes. As discussed above and in the NPRM, because of the lack of available data about IRB effectiveness and how IRBs function operationally, many of the estimations in this analysis are based on anecdotal evidence.

1. Analytic Assumptions

The analysis relies on common data elements and assumptions, detailed below, concerning the domestic entities, individuals, and IRB reviews affected by the changes to the Common Rule. Many of the estimates are derived from a 1998 NIH-sponsored evaluation of the implementation of Section 491 of the Public Health Service Act, which involved nationally representative surveys of IRBs, institutions, and investigators. Based on a review of the literature, this study contains the best available data on the time spent on protocol reviews as well as the characteristics of the reviews themselves. Additionally, OHRP processes the majority of FWAs and IRB registrations for all Common Rule departments or agencies. Thus, using information from the OHRP database of assured institutions and registered institutions or organizations and their IRBs is a reasonable way to estimate the number of institutions and IRBs regulated by all Common Rule departments or agencies that will be affected by these changes. OHRP's IRB registration process requires institutions and organizations to provide information about the approximate number of active protocols reviewed by IRBs during the preceding 12 months. Thus, OHRP's IRB database is the best source for determining the total number

of protocols reviewed by IRBs at this time.

According to the OHRP database of assured institutions and registered institutions or organizations and their IRBs, approximately 8,035 institutions in the United States have an FWA, of which 2,871 have an IRB. Some institutions have multiple IRBs and some IRBs are not affiliated with an institution with an FWA. In total, 3,499 registered IRBs are in the United States.

The OHRP database of assured institutions and registered institutions or organizations and their IRBs shows that 675,390 annual reviews of nonexempt protocols involving human subjects are conducted. It is estimated that of this total, 324,187 are initial protocol reviews (48 percent) and 351,203 are continuing protocol reviews (52 percent) based on estimates reported in Bell et al.⁵³ In each category, it is estimated that 69 percent of these reviews are convened and 31 percent are expedited based on estimates reported in Bell et al.

It is estimated that 472,773 reviews of single-site protocols (70 percent) and 202,617 reviews of multi-institutional protocols (30 percent) take place, based on estimates reported in Bell et al. This analysis also assumes that, on average, 5 IRB reviews take place per multiple-site protocol. This implies 472,773 single-site protocols and 40,523 multi-institutional protocols, for a total of 513,296 protocols. The above also implies approximately 246,382 new protocols each year.

Based on queries of *ClinicalTrials.gov*, we estimated that HHS supports 909 new clinical trials annually, of which 575 are regulated by FDA. In addition, based on queries of *ClinicalTrials.gov*, non-HHS Common Rule departments and agencies support approximately 5,270 studies.

Many individuals in various occupations would be affected by the changes to the Common Rule. We estimated that an average of one institution official at each institution with an FWA would be affected by these changes, for a total of 2,871 institution officials. The OHRP database of registered IRBs shows that IRBs have 10,197 full-time equivalents (FTEs) staff persons working as administrators or administrative staff, and that 89.8 percent of IRBs have an administrator. It is assumed that these individuals work full-time, implying a total of 3,193 IRB administrators and 7,004 IRB

⁵³ Bell J., Whiton J., and Connelly S., Final Report: Evaluation of NIH Implementation of Section 491 of the Public Health Service Act, Mandating a Program of Protection for Research Subjects, 1998.

administrative staff. The OHRP database of IRB membership rosters contains 3,359 individuals who serve as IRB chairs and an additional 32,518 voting members. The number of IRB chairs is less than the number of IRBs because some individuals chair multiple IRBs. It is assumed that 439,968 investigators conduct human subjects research in the United States.⁵⁴

We estimated the hourly wages of individuals affected by the changes to the Common Rule using information on annual salaries provided by the U.S. Bureau of Labor Statistics and the U.S. Office of Personal Management. The salary of postsecondary education administrators is used as a proxy for the salary of institution officials; the salary of lawyers is used as a proxy for the salary of institution legal staff and IRB administrators; the salary of office and administrative support workers is used as a proxy for the salary of IRB administrative staff; the salary of postsecondary health teachers is used as

a proxy for the salary of IRB chairs and IRB voting members; the salary of postsecondary teachers is used as a proxy for the salary of investigators; the salary of database and systems administrators and network architects is used as a proxy for the salary of database administrators; and the salary of all occupations, as a proxy for the salary of prospective human subjects. The federal employees affected by the changes to the Common Rule are assumed to be Step 5 within their GS-level and earn locality pay for the District of Columbia, Baltimore, and Northern Virginia. Annual salaries are divided by 2,087 hours to derive hourly wages. To project wages over 2017–2026, wages are adjusted for growth over time using the average annual per capita growth in real wage income over 1929–2012 reported by the U.S. Bureau of Economic Analysis, which is 2.1 percent. The total dollar value of labor, which includes wages, benefits, and

overhead, is assumed to be equal to 200 percent of the wage rate.

We calculated person-hours by occupation per initial protocol review and per continuing protocol review based on each occupation's share of total person-hours reported in Bell et al. In particular, Bell et al. reports that institution officials account for 4 percent, IRB administrators account for 28 percent, IRB administrative staff account for 30 percent, IRB chairs account for 7 percent, and IRB voting members account for 31 percent of total person-hours. We assumed that the average number of person-hours spent per review equals the weighted average of the person-hours spent per convened review and the person-hours spent per expedited review. We further assumed that convened review requires twice as many person-hours as expedited review.

Table 3 shows the number of entities affected by the changes to the Common Rule and other common assumptions of the analysis (described above).

TABLE 3—NUMBER OF AFFECTED ENTITIES AND OTHER COMMON ASSUMPTIONS

| Description | Estimate |
|--|----------|
| U.S. Institutions and IRBs: | |
| Institutions with an FWA | 8,035 |
| FWA Institutions with an IRB | 2,871 |
| FWA Institutions without an IRB | 5,164 |
| U.S. IRBs | 3,499 |
| Occupations: | |
| Institution officials | 2,871 |
| IRB administrators | 3,193 |
| IRB administrative staff | 7,004 |
| IRB chairs | 3,359 |
| IRB voting members | 32,518 |
| Investigators | 439,968 |
| Hourly Wages: | |
| Institution officials (2015) | \$49.17 |
| Institution legal staff (2015) | \$65.29 |
| IRB administrators (2015) | \$65.29 |
| IRB administrative staff (2015) | \$17.41 |
| IRB chairs (2015) | \$50.06 |
| IRB voting members (2015) | \$50.06 |
| Investigators (2015) | \$37.13 |
| Database administrators (2015) | \$40.37 |
| Prospective Human Subjects (2015) | \$23.15 |
| Federal employees in the District of Columbia, Baltimore, and Northern Virginia (2015) | |
| GS–11 Step 5 | \$34.60 |
| GS–13 Step 5 | \$49.32 |
| GS–14 Step 5 | \$58.28 |
| GS–15 Step 5 | \$68.56 |
| Average annual per capita growth in real wage income | 2.1% |
| IRB Reviews of Human Subjects Research Protocols at U.S. Institutions: | |
| Annual reviews of nonexempt protocols | 675,390 |
| Initial protocol reviews (48%) | 324,187 |
| Convened reviews (69%) | 223,689 |
| Expedited reviews (31%) | 100,498 |
| Continuing protocol reviews (52%) | 351,203 |
| Convened reviews (69%) | 242,30 |
| Expedited reviews (31%) | 108,873 |
| Annual reviews of single-site protocols (70%) | 472,773 |

⁵⁴ To derive this estimate, the number of new protocols, estimated above, is divided by the average number of new protocol submissions reported per investigator. This is estimated to be 2.8

based on Bell et al. This number is then multiplied by the average number of investigators working on each protocol (which is assumed to be 5). This allows for an accounting of investigators working

on multiple protocols as well as protocols with multiple investigators.

TABLE 3—NUMBER OF AFFECTED ENTITIES AND OTHER COMMON ASSUMPTIONS—Continued

| Description | Estimate |
|---|----------|
| Annual reviews of multi-institutional protocols (30%) | 202,617 |
| Human Subjects Research Protocols at U.S. Institutions: | |
| Active protocols | 513,296 |
| Single-site protocols | 472,773 |
| Multi-site protocols | 40,523 |
| New protocols (48%) | 246,382 |
| Average number of IRB reviews per active multi-institutional protocol | 5 |
| Clinical Trials: | |
| New clinical trials supported by HHS annually | 909 |
| Regulated by FDA | 575 |
| Clinical Trials supported by Common Rule Agencies | 5,270 |
| Person-Hours per Protocol Reviewed by Occupation and Type of Review: | |
| Institution officials: | |
| Initial protocol reviews: | |
| Convened reviews | 0.52 |
| Expedited reviews | 0.26 |
| Continuing protocol reviews: | |
| Convened reviews | 0.10 |
| Expedited reviews | 0.05 |
| IRB administrators: | |
| Initial protocol reviews: | |
| Convened reviews | 3.64 |
| Expedited reviews | 1.82 |
| Continuing protocol reviews: | |
| Convened reviews | 0.68 |
| Expedited reviews | 0.34 |
| IRB administrative staff: | |
| Initial protocol reviews: | |
| Convened reviews | 3.91 |
| Expedited reviews | 1.95 |
| Continuing protocol reviews: | |
| Convened reviews | 0.73 |
| Expedited reviews | 0.36 |
| IRB chairs: | |
| Initial protocol reviews: | |
| Convened reviews | 0.91 |
| Expedited reviews | 0.46 |
| Continuing protocol reviews: | |
| Convened reviews | 0.17 |
| Expedited reviews | 0.08 |
| IRB voting members: | |
| Initial protocol reviews: | |
| Convened reviews | 2.70 |
| Expedited reviews | 1.35 |
| Exempt reviews | 0.50 |
| Continuing protocol reviews: | |
| Convened reviews | 0.75 |
| Expedited reviews | 0.38 |
| Investigators: | |
| Initial protocol reviews: | |
| Convened reviews | 13.65 |
| Expedited reviews | 7.15 |
| Exempt reviews | 0.50 |
| Continuing protocol reviews: | |
| Convened reviews | 6.83 |
| Expedited reviews | 3.58 |

2. Analysis of Changes

We present below an analysis of the quantified and nonquantified benefits and costs of the changes to the Common Rule. For each change, we describe the change, provide a qualitative summary of the anticipated benefits and costs, describe the methods we use to quantify benefits and costs, and then present estimates.

a. Costs for the Regulated Community To Learn New Requirements and Develop Training Materials; Costs for OHRP To Develop Materials and Guidance

Domestic institutions, IRBs, and investigators would need to spend time learning the changes to the Common Rule once training materials become available to them. In addition, IRBs and OHRP would need to update training

materials for investigators. OHRP also would need to develop guidance, templates, and a number of electronic resources.

We estimate that institution officials, IRB administrators, IRB administrative staff, IRB chairs, IRB voting members, and investigators would each spend 5 hours to learn the changes to the Common Rule. We also estimate that institution officials would spend 2

hours to learn new procedures, IRB administrators would spend 20 hours, and administrative staff would spend 80 hours. Based on the estimates presented in Table 3, the dollar value of their time is calculated by multiplying hours by their estimated 2016 wages and adjusting for overhead and benefits. For example, to calculate the dollar value of time spent by institution officials to learn the changes to the Common Rule in 2017, we multiply the number of institution officials (2,871) by the number of hours spent per institutional official (5), by the projected hourly wage of institution officials (\$49.17), and by the adjustment factor for benefits and overhead (2).

In order to develop the resources required by the final rule, we anticipate that OHRP would need:

- Three staff people at the GS–14 level and three staff people at the GS–13 level to: (1) Promote harmonization efforts to issue guidance across Common Rule agencies and departments; (2) develop guidance for the regulated community; (3) develop template

agreements for use by the regulated community; (4) manage the administrative transition to the new processes in the final rule; and, (5) develop web-based posting portals.

- One staff person at the GS–13 level to manage process changes in the final rule, and assist with implementation for the web-based portals.

- One staff person at the GS–11 level to provide technical support for the web-based portals in the final rule.

In addition, the first year after the final rule is published staffing resources beyond what is described above would be necessary:

- Three staff people at the GS–14 level to draft new guidance and revise old guidance.
- One staff person at the GS–14 level to conduct educational seminars.

OHRP also anticipates the following in nonpersonnel costs:

- Technical development of two Web-based portals for investigators to post final consent forms for HHS-funded clinical trials, and for investigators who conduct certain types of demonstration

projects to post information about said projects (\$350,000)

- Developing five educational seminars (including travel) to educate the public about the requirements of the new rule (\$150,000)

- Upgrading equipment for education activities (\$50,000)

We also note that additional staff time throughout the Common Rule departments and agencies will be needed to fulfill the consultation requirement found in § _____.102(e)(7). As we assume that this consultation will not involve the hiring of additional personnel to fulfill, we consider this a nonquantified cost.

Present value costs of \$214 million and annualized costs of \$25.0 million are estimated using a 3 percent discount rate; present value costs of \$204 million and annualized costs of \$29.1 million are estimated using a 7 percent discount rate. Table 4 summarizes the quantified and nonquantified benefits and costs to learn new requirements and develop training materials.

TABLE 4—SUMMARY OF ESTIMATED BENEFITS AND COSTS TO LEARN NEW REQUIREMENTS AND DEVELOP TRAINING MATERIALS

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|--|---|-----------|--|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |
| BENEFITS: | | | | |
| Quantified Benefits: | | | | |
| None | | | | |
| Nonquantified Benefits: | | | | |
| None. | | | | |
| COSTS: | | | | |
| Quantified Costs: | | | | |
| Time and money to learn new requirements, update training materials, develop tools and conduct consultations | 214 | 204 | 25.0 | 29.1 |
| Nonquantified Costs: | | | | |
| Implementation of consultation requirements. | | | | |

b. Extending Oversight to IRBs Unaffiliated With an Institution Holding an FWA (§ _____.101(a))

As outlined in the NPRM, and as generally supported by public commenters, the final rule includes a new provision at § _____.101(a) that gives Common Rule departments and agencies the authority to enforce compliance directly against IRBs that are not operated by an assured institution. We anticipate that this change will encourage institutions to rely on IRBs not operated by an FWA-holding institution more often and also will assist in the implementation of the

requirements at § _____.114. Here, we estimate the impact that this proposal will have on IRBs that are not operated by an FWA-holding institution. The estimated impact of this and other related proposals on FWA-holding institutions is addressed in Section XIX.D.2.f of this RIA.

The OHRP database of assured institutions and registered IRBs shows that approximately 449 IRBs not affiliated with an institution holding an FWA will now be subject to oversight. These IRBs will develop an estimated average of 10 written agreements with other institutions each year as a result

of this rule. It is further estimated that each agreement will require an average of 10 hours of institution legal staff time and 5 hours of IRB administrator time to complete.

The estimated costs to institution officials, IRB administrators, IRB administrative staff, IRB chairs, IRB voting members, and investigators of conducting these reviews are based on the estimates presented in Table 3. The dollar value of their time is calculated by multiplying hours by their estimated 2017–2026 wages and adjusting for overhead and benefits.

Present value costs of \$85.6 million and annualized costs of \$10.0 million

are estimated using a 3 percent discount rate; present value costs of \$70.0 million and annualized costs of \$10.0 million

are estimated using a 7 percent discount rate. Table 5 summarizes the quantified and nonquantified benefits and costs of

extending oversight to IRBs unaffiliated with an institution holding an FWA.

TABLE 5—SUMMARY OF ESTIMATED BENEFITS AND COSTS OF EXTENDING OVERSIGHT TO IRBS UNAFFILIATED WITH AN INSTITUTION HOLDING AN FWA (§ _____.101(a))

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|--|---|-----------|--|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |
| BENEFITS: | | | | |
| Quantified Benefits: | | | | |
| None | | | | |
| Nonquantified Benefits: | | | | |
| Encouraging institutions to rely on single IRBs of record in multi-institutional studies when appropriate. | | | | |
| COSTS: | | | | |
| Quantified Costs: | | | | |
| Developing IRB authorization agreements or other procedures | 85.6 | 70.0 | 10.0 | 10.0 |
| Nonquantified Costs: | | | | |
| None. | | | | |

c. Explicit Carve-Outs of Activities From the Definition of Research (§ _____.102(l))

The final rule includes four categories that are explicitly deemed to be not research (final rule at § _____.102(l)(1)–(4)). These categories include: (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research and historical scholarship), including the collection and use of information that focuses directly on the specific individuals about whom the information is collected; (2) certain public health surveillance activities; (3) certain collection and analysis activities conducted by a criminal justice agency; and (4) certain activities conducted by a defense, national security, or homeland security authority.

Institutions, investigators, and IRBs involved in supporting, conducting, or

reviewing these activities will no longer incur the costs of IRB review and approval and continuing review. Activities that were not intended to be subject to the regulations will clearly be removed from the definition of research, allowing such activities to proceed without delays caused by the need for IRB submission, review, and approval.

We estimate that 3,376 annual reviews of protocols (0.5 percent) will no longer be conducted as a result of the activities deemed not to be research in § _____.102(l)(1)–(4). Of these reviews, 1,118 will have undergone convened initial review, 502 will have undergone expedited initial review, 1,212 will have undergone convened continuing review, and 544 will have undergone expedited continuing review based on the distribution of reviews presented in Table 3.

The estimated costs to institution officials, IRB administrators, IRB administrative staff, IRB chairs, IRB voting members, and investigators of conducting these reviews are based on the estimates presented in Table 3. The dollar value of their time is calculated by multiplying hours by their estimated 2017–2026 wages and adjusting for overhead and benefits.

Present value benefits of \$36.2 million and annualized benefits of \$4.24 million are estimated using a 3 percent discount rate, and present value benefits of \$29.6 million and annualized benefits of \$4.22 million are estimated using a 7 percent discount rate. Table 6 summarizes the quantified and nonquantified benefits and costs of excluding these activities from the requirements of the Common Rule.

TABLE 6—SUMMARY OF ESTIMATED BENEFITS AND COSTS OF § _____.102(l)

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|--|---|-----------|--|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |
| BENEFITS: | | | | |
| Quantified Benefits: | | | | |
| Reduction in number of reviews | 36.2 | 29.6 | 4.24 | 4.22 |
| Nonquantified Benefits: | | | | |
| Increased clarity in what must be reviewed; ability for IRBs to focus efforts on reviews of higher-risk, more complex research activities. | | | | |
| COSTS: | | | | |
| Quantified Costs: | | | | |
| None | | | | |
| Nonquantified Costs: | | | | |
| None. | | | | |

d. Clarifying and Harmonizing Regulatory Requirements and Agency Guidance (§ _____.101(j))

The final rule at § _____.101(j) requires consultation among the Common Rule departments and agencies for the purpose of harmonization of guidance (to the extent appropriate) before federal guidance on the Common Rule is

issued, unless such consultation is not feasible.

As this change likely will not affect staffing requirements in the Federal Government, no costs are quantified here. It is possible however, that the harmonization requirement could result in it taking longer for Common Rule department or agency guidance to be

approved and issued to the public. Similarly, as the extent to which this change will reduce the time IRBs spend on reviewing protocols is unclear, benefits are also not quantified. Table 7 summarizes the nonquantified benefits and costs of clarifying and harmonizing regulatory requirements and agency guidance.

TABLE 7—SUMMARY OF ESTIMATED BENEFITS AND COSTS OF CLARIFYING AND HARMONIZING REGULATORY REQUIREMENTS AND AGENCY GUIDANCE (§ _____.101(j))

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|---|---|-----------|--|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |
| BENEFITS: | | | | |
| Quantified Benefits: | | | | |
| None | | | | |
| Nonquantified Benefits: | | | | |
| Increased uniformity in regulatory requirements among Common Rule agencies; increased clarity to the regulated community about how regulations should be interpreted. | | | | |
| COSTS: | | | | |
| Quantified Costs: | | | | |
| None | | | | |
| Nonquantified Costs: | | | | |
| Time for consultation among Common Rule agencies before federal guidance is issued. | | | | |

e. Modifying the Assurance Requirements (§ _____.103)

The final rule modifies the requirements of the assurance process in the following ways. First, the final rule does not include the pre-2018 requirement of identifying a statement of principles governing all research at an institution. The requirement for institutions to designate a set of ethical principles by which that institution will abide in all research activities was generally not enforced. Further, for international institutions that received U.S. Government funding for research activities, it created the impression that these international institutions must modify their internal procedures to comport with the set of principles designated on the FWA for activities conducted at those institutions that received no U.S. Government funding. This provision was deleted from the final rule to provide clarity to these international institutions that such measures are not required for activities that receive no Common Rule department or agency support.

The requirement in the pre-2018 rule that a written assurance include a list of IRB members for each IRB designated under the assurance has been moved to

§ _____.108(a)(2) and modified. The final rule requires that an institution, or when appropriate the IRB, prepare and maintain a current detailed list of the IRB members with information sufficient to describe each member's chief anticipated contributions to IRB deliberation, and any employment or other relationship between each member and the institution. The final rule also deletes the pre-2018 requirement that changes in IRB membership be reported to the department or agency head, or to OHRP when the existence of an HHS-approved assurance is accepted.

The changes to the IRB roster requirement are expected to reduce administrative burden without having any significant impact on the protection of human subjects:

Finally, the requirement in the pre-2018 rule that a department or agency head's evaluation of an assurance take certain factors into consideration has been deleted. These factors include the adequacy of the proposed IRB in light of the anticipated scope of the institution's activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in

light of the probable risks, and the size and complexity of the institution. Deletion of that provision eliminates an administrative process that was no longer meaningful given the purpose and design of the FWA and OHRP's processes for reviewing IRB registrations and reviewing and approving FWAs. This change also harmonizes the Common Rule with FDA's human subjects protection regulations by eliminating the requirement to submit IRB membership lists.

We estimate that administrative staff at each IRB would spend 5 fewer hours complying with the assurance requirements. Based on the estimates presented in Table 3, the dollar value of their time is calculated by multiplying hours by their estimated 2017–2026 wages and adjusting for overhead and benefits.

Present value benefits of \$5.93 million and annualized benefits of \$0.69 million are estimated using a 3 percent discount rate; present value benefits of \$4.18 million and annualized benefits of \$0.60 million are estimated using a 7 percent discount rate. Table 8 summarizes the quantified and nonquantified benefits and costs of the proposed change to the IRB roster requirement.

TABLE 8—SUMMARY OF ESTIMATED BENEFITS AND COSTS OF CHANGES TO MODIFYING THE ASSURANCE REQUIREMENTS (PRE-2018 RULE AT § ___.103(b)(1), (b)(3), (d))

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|---|---|-----------|--|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |
| BENEFITS: | | | | |
| Quantified Benefits: | | | | |
| Reduction in time for IRB administrative staff and OHRP staff to submit, review, and process IRB membership lists | 5.93 | 4.18 | 0.69 | 0.60 |
| Nonquantified Benefits: | | | | |
| Reduction in volume of records created by an institution. | | | | |
| COSTS: | | | | |
| Quantified Costs: | | | | |
| None | | | | |
| Nonquantified Costs: | | | | |
| None. | | | | |

f. Requirement for Documenting Reliance on IRBs Not Operated by the FWA-Holding Institution (§§ ___.103(e) and ___.115(a)(9))

The final rule contains a requirement at § ___.103(e) that, to ensure compliance with the requirements of the Common Rule, nonexempt human subjects research subject to this policy that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake. This requirement could be satisfied, for example, by: (1) Developing a written agreement between the institution and the IRB; (2) implementing an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution; or (3)

describing the allocation of responsibilities in a research protocol. In addition, a requirement is added at § ___.115(a)(9) of the final rule that institutions or IRBs retain this written agreement or other procedures undertaken to ensure compliance with the requirements of this policy, as described in § ___.103(e).

Initially, costs would be involved in drafting, revising, and conducting managerial review of agreements to ensure they satisfy these new requirements. Anticipated benefits include greater reliance on IRBs not operated by the institutions as the IRB of record for cooperative research.

Table 3 shows that 5,164 FWA-holding institutions do not have an IRB and 2,871 FWA-holding institutions have an IRB. We assume that the 5,164 FWA-holding institutions without an IRB have an average of 1 IRB authorization agreement that will need to be modified as a result of the new requirements for agreements between institutions and IRBs not operated by

the institutions in 2017. In addition, we assume that the 2,871 FWA-holding institutions with an IRB have an average of 0.20 IRB authorization agreements that would need to be modified in 2017. We estimate that each agreement will require an average of 10 hours of institution legal staff time and 5 hours of IRB administrator time to complete. The dollar value of their time is calculated by multiplying hours by their estimated 2017 wages and adjusting for overhead and benefits.

Present value costs of \$11.4 million and annualized costs of \$1.33 million are estimated using a 3 percent discount rate; present value costs of \$10.9 million and annualized costs of \$1.56 million are estimated using a 7 percent discount rate. Table 9 summarizes the quantified and nonquantified benefits and costs of the requirement for written procedures and agreements for reliance on IRBs not operated by the FWA-holding institution (§§ ___.103(e) and ___.115(a)(9) in the final rule).

TABLE 9—SUMMARY OF REQUIREMENT FOR WRITTEN PROCEDURES AND AGREEMENTS FOR RELIANCE ON IRBs NOT OPERATED BY THE FWA-HOLDING INSTITUTION (§§ ___.103(e) AND ___.115(a)(10))

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|---|---|-----------|--|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |
| BENEFITS: | | | | |
| Quantified Benefits: | | | | |
| None | | | | |
| Nonquantified Benefits: | | | | |
| None. | | | | |
| COSTS: | | | | |
| Quantified Costs: | | | | |
| Time to modify written agreements between IRBs and institutions | 11.4 | 10.9 | 1.33 | 1.56 |

TABLE 9—SUMMARY OF REQUIREMENT FOR WRITTEN PROCEDURES AND AGREEMENTS FOR RELIANCE ON IRBS NOT OPERATED BY THE FWA-HOLDING INSTITUTION (§§ ____ .103(e) AND ____ .115(a)(10))—Continued

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|-------------------------------|---|-----------|--|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |
| Nonquantified Costs: None. | | | | |

g. Eliminating the Requirement That the Grant Application Undergo IRB Review and Approval (Pre-2018 Rule at § ____ .103(f))

The final rule eliminates the requirement in the pre-2018 rule that grant applications undergo IRB review and approval for the purposes of certification. The grant application is often outdated by the time the research study is submitted for IRB review and contains detailed information about the costs of a study, personnel, and administrative issues that go beyond the mission of the IRB to protect human subjects. Therefore, experience suggests that review and approval of the grant application is not a productive use of IRB time, and the change likely will not

reduce protections for human subjects or impose other costs.

We estimate that 324,187 initial reviews of protocols occur annually, of which 223,689 involve convened review and 100,498 involve expedited review based on the distribution of reviews presented in Table 3. For the purpose of this analysis, we assume that each protocol reviewed by an IRB is associated with one grant application or other funding proposal. We estimate that investigators spend an average of 15 minutes compiling their grant applications when they submit a protocol for initial review. Further, we estimate that IRBs typically use two primary reviewers for convened review and one primary reviewer for expedited review, and that primary reviewers

spend an average of 30 minutes reviewing the grant application. Based on the estimates in Table 3, the dollar value of their time is calculated by multiplying hours by their estimated 2017–2026 wages and adjusting for overhead and benefits.

Present value benefits of \$326 million and annualized benefits of \$38.2 million are estimated using a 3 percent discount rate and present value benefits of \$230 million and annualized benefits of \$32.7 million are estimated using a 7 percent discount rate. Table 10 below summarizes the quantified and nonquantified benefits and costs of eliminating the requirement that the grant application undergo IRB review and approval.

TABLE 10—SUMMARY OF ESTIMATED BENEFITS AND COSTS OF ELIMINATING THE REQUIREMENT THAT THE GRANT APPLICATION UNDERGO IRB REVIEW AND APPROVAL (PRE-2018 RULE AT § ____ .103(f))

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|---|---|-----------|--|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |
| BENEFITS: | | | | |
| Quantified Benefits: | | | | |
| Decreased time associated with reviewing grant applications | 326 | 230 | 38.2 | 32.7 |
| Nonquantified Benefits: None. | | | | |
| COSTS: | | | | |
| Quantified Costs: | | | | |
| None | | | | |
| Nonquantified Costs: None. | | | | |

h. Expansion of Exemption Categories (§ ____ .104(d))

The final rule includes eight exemption categories. Some of these categories include subcategories of exemptions.

We note that one pre-2018 exemption does not appear in the final rule (exemption for educational tests, survey procedures, interview procedures, or observation of public behavior where a statute requires confidentiality of the information collected, or where the

human subjects involved in the activity are public figures). We also note that several of the final rule exemptions were proposed in the NPRM as exclusions. Finally, we note that only one pre-2018 exemption has been unmodified in the final rule (the exemption for taste and food quality evaluations).

The exemptions included in the final rule are:

- Certain research involving normal educational practices

- Certain research that involves the use of educational tests, survey procedures, interview procedures, or observation of public behavior

- Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses or video recording

- Research involving the secondary use of identifiable private information or identifiable biospecimens provided that:

- The sources are publicly available
- The information is recorded in such a manner that the identity of subjects is not readily ascertainable by the investigator

- The research is regulated as “health care operations,” “public health activities,” or “research” under HIPAA

- The research is conducted by or on behalf of a federal department or agency using government-generated or government-collected nonresearch information, provided that certain conditions are met

- Research and demonstration projects conducted or supported by a federal department or agency

- In addition to OHRP’s interpretation of this exemption expanding under the final rule, and language being modified in this exemption to reflect that expanded interpretation, the final rule also includes a requirement that federal departments or agencies conducting or supporting demonstration projects post information about these studies on a publicly accessible federal Web site

- Taste and food quality evaluation and consumer acceptance studies

- The storage and maintenance of identifiable biospecimens or identifiable private information for unspecified secondary research studies

- The secondary research use of identifiable biospecimens or identifiable private information where broad consent has been sought and obtained

The goal of the posting requirement in the exemption for research and demonstration projects (final rule at § _____.104(d)(5)) is to promote transparency in federally conducted or supported activities affecting the public that are not subject to oversight under the Common Rule. It should not create any delay in research. HHS will develop

a resource that all Common Rule departments and agencies may use to satisfy the posting requirement (accounted for in Section XIX.D.2.a of this RIA). Alternatively, an agency can create or modify its own Web site for this purpose. Thus, increased transparency in federally funded or supported demonstration projects is a non-quantified benefit of the final rule modifications.

Other nonquantified benefits of the expansion to the modifications of exempt research include clearer instructions to the regulated community about the extent to which creating a system for storing and maintaining identifiable biospecimens and identifiable private information for future, unspecified secondary research activities is governed by this rule. Additionally, by reducing the IRB burden associated with approving this type of activity, the new exemption for storing and maintaining identifiable biospecimens and identifiable private information also incentivizes the creation of institution-wide, comprehensive systems for storing and maintaining such biospecimens and information. We anticipate that this will, in turn, foster research while also giving human subjects increased control over how their identifiable biospecimens and identifiable private information will be used (promoting the principle of respect for persons).

Consistent with the NPRM, we estimate that 70,916 annual reviews of protocols (10.5 percent) would no longer be conducted as a result of the changes at § _____.104(d). Of these reviews, 23,487 will have undergone convened initial review, 10,552 will have undergone expedited initial review, 25,445 will have undergone

convened continuing review, and 11,432 will have undergone expedited continuing review based on the distribution of reviews presented in Table 3.

Further, we estimate that that 1,000 exempt research and demonstration studies are currently conducted each year.⁵⁵ We further estimate that due to the change in OHRP’s interpretation of the research and demonstration project exemption at § _____.104(d)(5), an additional 3,376 annual reviews of protocols (0.5 percent) will no longer be conducted. Of these 3,376 reviews, 1,118 would have undergone convened initial review, 502 would have undergone expedited initial review, 1,212 would have undergone convened continuing review, and 544 would have undergone expedited continuing review based on the distribution of reviews presented in Table 3. The 4,376 estimated annual studies conducted under this exemption will need to be posted on a federal Web site as required by § _____.104(d)(5)(i). We anticipate that it will take individuals at the IRB administrative staff level 15 minutes per study to post the study on the Web site.

Present value benefits of \$798 million and annualized benefits of \$93.6 million are estimated using a 3 percent discount rate, and present value benefits of \$653 million and annualized benefits of \$93.0 million are estimated using a 7 percent discount rate. Present value costs of \$0.37 million and annualized costs of \$0.04 million are estimated using a 3 percent discount rate; present value costs of \$0.30 million and annualized costs of \$0.04 million are estimated using a 7 percent discount rate. Table 11 summarizes the quantified and nonquantified benefits and costs of amending an exempt category.

TABLE 11—SUMMARY OF ESTIMATED BENEFITS AND COSTS OF EXPANDING THE EXEMPTION CATEGORIES (§ _____.104(d))

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|--|---|-----------|--|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |
| BENEFITS: | | | | |
| Quantified Benefits: | | | | |
| Reduction in number of reviews | 798 | 653 | 93.6 | 93.0 |
| Nonquantified Benefits: | | | | |
| Clarity in what research activities must be reviewed; ability for IRBs to focus efforts on reviews of higher-risk, more complex, research activities; fostering research with biospecimens and identifiable private information. | | | | |
| COSTS: | | | | |
| Quantified Costs: | | | | |
| None | 0.37 | 0.30 | 0.04 | 0.04 |

⁵⁵ Estimates based on queries of *ClinicalTrials.gov* and a search of the CMS Web site. See e.g., <http://www.medicare.gov/medicaid-chip-program->

[information/by-topics/waivers/waivers_faceted.html](http://www.medicare.gov/medicaid-chip-program-information/by-topics/waivers/waivers_faceted.html), and <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics->

[Trends-and-Reports/ActiveProjectReports/APR_2011_Edition.html](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ActiveProjectReports/APR_2011_Edition.html).

TABLE 11—SUMMARY OF ESTIMATED BENEFITS AND COSTS OF EXPANDING THE EXEMPTION CATEGORIES (§ _____.104(d))—Continued

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|--|--|-----------|---|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |

Nonquantified Costs:
None.

i. Elimination of Continuing Review of Research Under Specific Conditions (§§ _____.109(f) and _____.115(a)(3))

The final rule eliminates continuing review for many minimal risk studies, as detailed at § _____.109(f). Unless an IRB determines otherwise, continuing review of research is not required if: (1) The research is eligible for expedited review in accordance with § _____.110; (2) the research is reviewed by the IRB in accordance with the limited IRB review procedure described in several of the exemption categories (specifically, § _____.104(d)(2)(iii), § _____.104(d)(3)(i)(C), § _____.104(d)(7), or § _____.104(d)(8)); or (3) the research has progressed to the point that it only involves data analysis (including analysis of identifiable information or identifiable biospecimens) or access to follow-up clinical data from procedures that subjects would undergo as part of clinical care. If an IRB chooses to conduct continuing review even when these conditions are met, the rationale for doing so must be documented

according to a new provision at § _____.115(a)(3).

We estimate that 108,873 expedited continuing reviews of protocols occur annually, based on the distribution of reviews presented in Table 3. Of these reviews, we further estimate that 81,546 reviews (75 percent) will not be eliminated by other changes to the Common Rule (such as the modifications at § _____.104(d)). It is estimated that 40,773 of these 81,546 reviews (50 percent) will be discontinued under § _____.109(f), and the remaining 40,773 reviews (50 percent) will still require documentation of the rationale for doing so (as required under § _____.115(a)(3)). We also estimate that IRB voting members will spend 1 hour per review providing the necessary documentation. In addition, administrative staff at each IRB will spend an estimated 10 hours in 2017 updating their communication systems to no longer send continuing review reminders to affected investigators.

The estimated costs to institution officials, IRB administrators, IRB administrative staff, IRB chairs, IRB voting members, and investigators of conducting these reviews are based on the estimates presented in Table 3. The dollar value of their time is calculated by multiplying hours by their estimated 2017–2026 wages and adjusting for overhead and benefits.

Present value benefits of \$148 million and annualized benefits of \$17.4 million are estimated using a 3 percent discount rate, and present value benefits of \$121 million and annualized benefits of \$17.3 million are estimated using a 7 percent discount rate. Present value costs of \$41.0 million and annualized costs of \$4.80 million are estimated using a 3 percent discount rate; present value costs of \$33.7 million and annualized costs of \$4.80 million are estimated using a 7 percent discount rate. Table 12 summarizes the quantified and nonquantified benefits and costs of the elimination of continuing review of research under specific conditions.

TABLE 12—SUMMARY OF ESTIMATED BENEFITS AND COSTS OF THE ELIMINATION OF CONTINUING REVIEW OF RESEARCH UNDER SPECIFIC CONDITIONS (§§ _____.109(f) AND _____.115(a)(3))

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|--|--|-----------|---|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |
| BENEFITS: | | | | |
| Quantified Benefits: | | | | |
| Reduction in number of continuing reviews | 148 | 121 | 17.4 | 17.3 |
| Nonquantified Benefits: | | | | |
| None. | | | | |
| | 3 Percent | 7 Percent | 3 Percent | 7 Percent |
| COSTS: | | | | |
| Quantified Costs: | | | | |
| Time to document rationale for conducting continuing review and update IRB communication systems | 41.0 | 33.7 | 4.80 | 4.80 |
| Nonquantified Costs: | | | | |
| None. | | | | |

j. Expedited Review Procedures (§§ ____ .110 and ____ .115(a)(8))

The final rule changes the default position such that any research activity appearing on the expedited review list is presumed to be minimal risk. Additionally, the final rule requires that, in consultation with other Common Rule departments or agencies, the expedited review categories be reviewed every 8 years and amended as appropriate, followed by publication in the **Federal Register** and solicitation of public comment. Finally, the final rule contains a new requirement at § ____ .115(a)(8) concerning IRB records, requiring that IRBs document the rationale for an expedited reviewer's determination that research activities appearing on the expedited review list are more than minimal risk (*i.e.*, an override of the presumption that studies

on the Secretary's list of expedited review activities are minimal risk). We note that because the final rule does not include a proposal to develop guidance with a list of activities presumed to be minimal risk, cost estimates in the final rule have been modified accordingly.

Changes to the expedited review procedures are expected to reduce IRB workload by decreasing the amount of time IRB voting members spend making minimal risk determinations and documenting such determinations. Nonquantified benefits include a reduction in the number of studies that require full, convened IRB review should more categories of activities be added to the expedited review list.

According to the estimates presented in Table 3, 209,371 protocols undergo expedited review each year. For these protocols, we estimate that, as a result

of these changes, IRB voting members will spend an average of 15 fewer minutes per protocol developing and documenting a rationale for why certain activities that are permitted to be reviewed under the expedited review procedure are minimal risk.

The dollar value of IRB voting member time is calculated by multiplying hours by their estimated 2017–2026 wages and adjusting for overhead and benefits.

Present value benefits of \$51.0 million and annualized benefits of \$5.98 million are estimated using a 3 percent discount rate, and present value benefits of \$41.7 million and annualized benefits of \$5.94 million are estimated using a 7 percent discount rate. Table 13 summarizes the quantified and nonquantified benefits and costs of amending expedited review procedures.

TABLE 13—SUMMARY OF ESTIMATED BENEFITS AND COSTS OF AMENDING THE EXPEDITED REVIEW PROCEDURES (§§ ____ .110 AND ____ .115(a)(8))

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|--|--|-----------|---|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |
| BENEFITS: | | | | |
| Quantified Benefits: | | | | |
| Reduction in time spent making and documenting minimal risk determinations and documenting such determinations | 51.0 | 41.7 | 5.98 | 5.94 |
| Nonquantified Benefits: | | | | |
| None. | | | | |
| COSTS: | 3 Percent | 7 Percent | 3 Percent | 7 Percent |
| Quantified Costs: | | | | |
| None | | | | |
| Nonquantified Costs: | | | | |
| None. | | | | |

k. Cooperative Research (§ ____ .114))

The final rule requires under § ____ .114 that any institution located in the United States that is engaged in cooperative research shall rely on approval by a single IRB for that portion of the research that is conducted in the United States. This policy has two exceptions (detailed in § ____ .114(b)(2)): (1) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of a American Indian or Alaska Native tribe); and (2) research for which any federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular study. Nonquantified benefits of this change include standardization of

human subjects protections in multi-institutional studies.

Ultimately, these revisions are expected to lower costs associated with multiple reviews for investigators, institutions, and IRBs. Some cost shifting may occur as certain IRBs assume the role of reviewing IRB. However, these will be offset by savings at other IRBs that are no longer required to conduct additional reviews of the same research study. Initially, IRBs and institutions will have to draft and revise their policies regarding their reliance on single IRBs. It is expected that, over time, reliance agreements and other methods of documenting external reliance will become standardized, which will result in reduced costs associated with multiple reviews and

time savings for investigators who no longer must wait for multiple reviews.

The OHRP database of registered institutions and IRBs shows that 8,035 institutions have an FWA. We estimate that these institutions will develop an average of 10 written joint review agreements with other institutions in 2019 before the first year of compliance. We further estimate that each agreement will require an average of 10 hours of institution legal staff time and 5 hours of IRB administrator time to complete. The dollar value of their time is calculated by multiplying hours by their estimated wages and adjusting for overhead and benefits.

We estimate that 202,617 annual reviews of multi-institutional protocols take place, and an average of 5 reviews per multi-institutional protocol,

implying that 40,523 multi-institutional protocols are reviewed each year. We further estimate that 16,209 (40 percent) of these multi-institutional studies are funded by NIH⁵⁶ and thus will already be subject to NIH's single IRB review policy. Accordingly, we estimate that approximately 97,256 annual reviews of protocols will no longer be conducted as a result of these proposed changes. Of these reviews, 32,211 would have undergone convened initial review, 14,472 would have undergone expedited initial review, 34,896 would have undergone convened continuing review, and 15,678 would have undergone expedited continuing review based on the distribution of reviews presented in Table 3.

In response to comments on the NPRM RIA, we have modified our assumptions of how much time would ultimately be saved by the implementation of this proposal (see

Section XIX.C of this RIA). We assume that investigators for whom multi-institutional reviews are eliminated will face a reduction in burden associated with the elimination of the site-specific protocol review, but will face increased burden in the form of coordination with investigators at other sites, for example, to ensure that the results of the IRB review are effectively communicated. Specifically, we assume that the elimination of multi-institutional reviews will result in investigators spending half as much time engaging with the review process as they would have if IRB review had taken place at all sites.

The estimated costs to institution officials, IRB administrators, IRB administrative staff, IRB chairs, IRB voting members, and investigators of conducting these reviews are based on the estimates presented in Table 3, adjusted accordingly to account for our

assumption that the time savings for these eliminated reviews is reduced by half for investigators. The dollar value of their time is calculated by multiplying hours by their estimated 2020–2026 wages and adjusting for overhead and benefits.

Present value benefits of \$538 million and annualized benefits of \$63.1 million are estimated using a 3 percent discount rate, and present value benefits of \$414 million and annualized benefits of \$59.0 million are estimated using a 7 percent discount rate. Present value costs of \$157 million and annualized costs of \$18.3 million are estimated using a 3 percent discount rate; present value costs of \$140 million and annualized costs of \$19.9 million are estimated using a 7 percent discount rate. Table 14 summarizes the quantified and nonquantified benefits and costs of cooperative research.

TABLE 14—SUMMARY OF ESTIMATED BENEFITS AND COSTS OF COOPERATIVE RESEARCH (\$ _____.114)

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|---|--|-----------|---|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |
| BENEFITS: | | | | |
| Quantified Benefits: | | | | |
| Reduction in number of reviews | 538 | 414 | 63.1 | 59.0 |
| Nonquantified Benefits: | | | | |
| Standardization of human subjects protections in multi-institutional studies. | | | | |
| COSTS: | 3 Percent | 7 Percent | 3 Percent | 7 Percent |
| Quantified Costs: | | | | |
| Time required to develop model reliance agreement and written joint review agreements | 157 | 140 | 18.3 | 19.9 |
| Nonquantified Costs: | | | | |
| None. | | | | |

1. Changes in the Elements of Consent, Including Documentation (§§ _____.116(a)(5), (b)(9), (c)(7)–(9), and _____.117(b))

The final rule imposes a new requirement at § _____.116(a)(5)(i) that informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This provision further mandates that this part of the informed consent must be organized and presented in a way that facilitates comprehension. This requirement

applies to all informed consent processes, except for broad consent obtained pursuant to § _____.116(d), which may warrant a different presentation.

The final rule includes a new element of consent at § _____.116(b)(9) that requires one of the following statements be included for any research that involves the collection of identifiable private information or identifiable biospecimens:

- A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future

research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

- A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

This new requirement is intended to give the potential subject the knowledge that identifiers might be removed from information or biospecimens for their use in future research without additional consent, when such a

⁵⁶ *Moral Science: Protecting Participants in Human Subjects Research*. Washington, DC:

Presidential Advisory Commission for the Study of Bioethical Issues. Retrieved from [http://](http://bioethics.gov/sites/default/files/Moral%20Science%20June%202012.pdf)

bioethics.gov/sites/default/files/Moral%20Science%20June%202012.pdf, p. 34.

possibility exists, so he or she can make a fully informed decision about whether to participate in the research. If subjects' identifiable private information or identifiable biospecimens will not be used for future research studies, even if identifiers are removed, this new element of consent requires that subjects be informed of this as well.

The final rule's three additional elements of consent are in § _____.116(c)(7), (8), and (9). These require that a subject be informed of the following, when appropriate:

- That the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- Whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.*, sequencing of a human germline or somatic specimen

with the intent to generate the genome or exome sequence of that specimen.

These three additional elements of consent will promote respect for persons and greater transparency in the research enterprise. Additionally, including the information referenced in these provisions in a consent form will help ensure that prospective subjects are given information necessary for understanding why one might want to participate (or not) in a research study.

The language at § _____.117(b)(1) in the final rule was modified to reference § _____.116(a)(5)(i) and state that if a short form consent process is used, the key information required by § _____.116(a)(5)(i) must be presented first to the prospective subject, before other information, if any, is provided.

We estimate that 246,382 new protocols annually use identifiable information. For each protocol, we estimate that investigators will spend an average of 15 minutes in 2017 updating consent forms to comply with the new requirements found in the final rule at § _____.116(a)(5), (b)(9), (c)(7), (c)(8), or

(c)(9). Based on the estimates presented in Table 3, the dollar value of investigators' time is calculated by multiplying hours by their estimated 2017 wages and adjusting for overhead and benefits.

We assume that few additional investigators will elect to offer the second option at § _____.116(b)(9), and that the investigators who currently offer equivalent options already track the permissible and impermissible uses of information in line with the requirements discussed above. As a result, we estimate that no additional costs are associated with tracking.

Present value costs of \$4.62 million and annualized costs of \$0.54 million are estimated using a 3 percent discount rate; present value costs of \$4.32 million and annualized costs of \$0.62 million are estimated using a 7 percent discount rate. Table 15 summarizes the quantified and nonquantified benefits and costs of changes in the basic elements of consent, including documentation.

TABLE 15—SUMMARY OF ESTIMATED BENEFITS AND COSTS OF CHANGES IN THE ELEMENTS OF CONSENT, INCLUDING DOCUMENTATION (§§ _____.116(a)(5), (b)(9), (c)(7), (c)(8) AND _____.117(b))

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|---|---|-----------|--|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |
| BENEFITS: | | | | |
| Quantified Benefits: | | | | |
| None | | | | |
| Nonquantified Benefits: | | | | |
| Improved informed consent forms and processes; greater transparency in the research enterprise. | | | | |
| COSTS: | | | | |
| Quantified Costs: | | | | |
| Time to update consent forms | 4.62 | 4.32 | 0.54 | 0.62 |
| Nonquantified Costs: | | | | |
| None. | | | | |

m. Obtaining Consent to Secondary Use of Identifiable Biospecimens and Identifiable Private Information (§ _____.116(d))

Because the final rule does not adopt the NPRM proposal to consider all biospecimens as human subjects regardless of identifiability, the costs associated with seeking, obtaining, and tracking broad consent are reduced significantly. As noted above, comments on the NPRM suggest that the costs associated with building systems to track broad consent are very burdensome. Therefore, we expect that broad consent and institution-wide

tracking systems will be pursued only in situations where it generates net benefits. As a result, in the short term, we are unsure of the extent to which institutions will adopt institution-wide mechanisms to seek, obtain, and track broad consent. We anticipate in the short term that broad consent (and the attendant tracking and maintenance obligations) will be a system used and managed by investigators or teams of investigators in their research portfolios. However, we believe that it will be adopted more over time at an institutional level as IT systems evolve at research institutions through normal practice. We lack data to estimate the

number of research studies for which this option will be adopted. Each of these studies will have some variable costs (*e.g.*, consent, tracking) and fixed costs (IT infrastructure). Because this is optional, we believe that it will be pursued only if private benefits exceed private costs. Therefore, we anticipate benefits, in terms of improvements in the quality and efficiency of human subjects research, proportional to the adoption of broad consent. We note that the voluntary nature of adoption implies that broad consent may not be sought in some situations where its social benefit exceeds its social cost.

TABLE 16—SUMMARY OF ESTIMATED BENEFITS AND COSTS OF OBTAINING CONSENT TO SECONDARY USE OF IDENTIFIABLE BIOSPECIMENS AND IDENTIFIABLE PRIVATE INFORMATION (§ ____ .116(d))

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|--|---|-----------|--|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |
| BENEFITS: | | | | |
| Quantified Benefits: | | | | |
| None | | | | |
| Nonquantified Benefits: | | | | |
| Improvements in the quality and efficiency of human subjects research. | | | | |
| COSTS: | | | | |
| Quantified Costs: | | | | |
| None | | | | |
| Nonquantified Costs: | | | | |
| Time and infrastructure required to obtain and track broad consent. | | | | |

n. Allowing IRBs To Approve a Research Proposal for Subject Recruitment Activities Without Granting a Waiver of Consent (§ ____ .116(g))

The final rule will allow an IRB to approve a research proposal in which investigators obtain information or biospecimens without individuals' informed consent for the purpose of screening, recruiting, or determining the eligibility of prospective human subjects of research in certain circumstances.

This addresses concerns that the pre-2018 regulations required an IRB to determine that informed consent could be waived before investigators could record identifiable private information for the purpose of screening, recruiting, or determining the eligibility of prospective subjects for a research study. The pre-2018 rule requirement was viewed as burdensome without

providing meaningful protections to subjects.

The policy adopted in the final rule should result in time and cost savings for investigators and IRBs, but they likely will be small. The savings will come from IRBs no longer needing to consider whether informed consent can be waived for such preparatory-to-research activities. Savings will accrue for investigators who can proceed with such activities in less time.

We estimate that 1,620 annual initial reviews of protocols (0.5 percent) involve a waiver of consent for recruitment activities that will not be required as a result of these changes. Of these reviews, 1,118 will have undergone convened initial review and 502 will have undergone expedited initial review based on the distribution of reviews presented in Table 3. We estimate that investigators spend an average of 15 minutes requesting a waiver of consent for recruitment

activities when they submit a protocol for initial review. We further estimate that IRBs typically use two primary reviewers for convened review and one primary reviewer for expedited review, and that primary reviewers spend an average of 15 minutes determining whether informed consent can be waived. Based on the estimates in Table 3, the dollar value of their time is calculated by multiplying hours by their estimated 2017–2026 wages and adjusting for overhead and benefits.

Present value benefits of \$1.25 million and annualized benefits of \$0.15 million are estimated using a 3 percent discount rate, and present value benefits of \$0.88 million and annualized benefits of \$0.13 million are estimated using a 7 percent discount rate. Table 17 summarizes the quantified and nonquantified benefits and costs of eliminating the requirement to waive consent in certain subject recruitment activities.

TABLE 17—SUMMARY OF ESTIMATED BENEFITS AND COSTS OF ELIMINATION OF REQUIREMENT TO WAIVE CONSENT IN CERTAIN SUBJECT RECRUITMENT ACTIVITIES (§ ____ .116(g))

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|---|---|-----------|--|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |
| Quantified Benefits: | | | | |
| Decreased time associated with review | 1.25 | 0.88 | 0.15 | 0.13 |
| BENEFITS: | | | | |
| Nonquantified Benefits: | | | | |
| None. | | | | |
| COSTS: | | | | |
| Quantified Costs: | | | | |
| None. | | | | |

TABLE 17—SUMMARY OF ESTIMATED BENEFITS AND COSTS OF ELIMINATION OF REQUIREMENT TO WAIVE CONSENT IN CERTAIN SUBJECT RECRUITMENT ACTIVITIES (§ _____.116(g))—Continued

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|-------------------------------|---|-----------|---|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |
| Nonquantified Costs: None. | | | | |

o. Requirement for Posting of Consent Forms for Common Rule Department or Agency-Supported Clinical Trials (§ _____.116(h))

The final rule requires that for each clinical trial conducted or supported by a Federal department or agency, one IRB-approved form used to recruit subjects must be posted by the awardee or the federal department or agency component conducting the trial on a publicly available federal Web site that will be established as a repository for such informed consent forms. The consent form must be posted after the clinical trial is closed to recruitment and no later than 60 days after the last study visit by any subject, as required by the protocol. This provision permits federal departments or agencies to require or permit redactions to these consent forms. As described in Section XIV.H, federal departments or agencies have great latitude in what they may permit or require be redacted.

We believe that public posting of consent forms will increase transparency, enhance confidence in the research enterprise, increase accountability, and inform the

development of future consent forms, possibly resulting in future savings in time for investigators developing consent forms. Costs to the Federal Government in creating and maintaining such a repository are described in Section XIX.D.2.a of this RIA.

According to queries of ClinicalTrials.gov, estimated 5,270 clinical trials are conducted or supported by Common Rule agencies, of which an estimated 575 are regulated by provisions in the Federal Food, Drug, and Cosmetic (FD&C) Act and Trade Secrets Act based on the information presented in Table 3. For the purpose of this analysis, it is assumed that each clinical trial is associated with one consent form that must be submitted to the federal system by an investigator.

It is unknown at this time in what other circumstances federal departments or agencies might permit or require redaction, thus the RIA calculates redaction time only in those studies for which the FD&C Act and Trade Secrets Act applies. For the 575 clinical trials regulated by provisions in the FD&C Act and Trade Secrets Act, it is estimated that investigators will spend an average of 30 minutes redacting information

before submission. We estimate that investigators will spend an average of 15 minutes submitting each consent form.

Based on the estimates presented in Table 3, the dollar value of investigator time is calculated by multiplying hours by their estimated 2017–2026 wages and adjusting for overhead and benefits.

In addition, submitted consent forms must be reviewed and made accessible to persons with disabilities in compliance with Section 508 Amendment to the Rehabilitation Act of 1973. We estimate that each consent form contains an average of 10 pages and that making each page 508-compliant costs an average of \$30 per page.

Present value costs of \$15.4 million and annualized costs of \$1.80 million are estimated using a 3 percent discount rate; present value costs of \$11.0 million and annualized costs of \$1.56 million are estimated using a 7 percent discount rate. Table 18 summarizes the quantified and nonquantified benefits and the requirement for posting of consent forms for Common Rule department or agency-supported clinical trials.

TABLE 18—SUMMARY OF ESTIMATED BENEFITS AND COSTS OF REQUIREMENT FOR POSTING OF CONSENT FORMS FOR COMMON RULE DEPARTMENT OR AGENCY-SUPPORTED CLINICAL TRIALS (§ _____.116(h))

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|---|---|-----------|---|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |
| Quantified Benefits: None | | | | |
| BENEFITS: | | | | |
| Nonquantified Benefits: Increase transparency of Common Rule department or agency-supported clinical trials; improvement of clinical trial informed consent forms. | | | | |
| COSTS: | 3 Percent | 7 Percent | 3 Percent | 7 Percent |
| Quantified Costs: Preparation and submission of consent forms for posting, and redaction of information | 15.4 | 11.0 | 1.80 | 1.56 |
| Nonquantified Costs: None. | | | | |

p. Alteration in Waiver for Documentation of Informed Consent in Certain Circumstances (§ ____ .117(c)(1)(iii))

The final rule adds a provision allowing a waiver of the requirement to obtain a signed informed consent form if the subjects are members of a distinct cultural group or community in which signing documents is not the norm. This will be allowed only if the research presents no more than minimal risk of harm to subjects and provided an appropriate alternative method is

available to document that informed consent was obtained.

Under the pre-2018 rule, IRBs could waive the requirement for the investigator to obtain a signed consent form for some or all subjects. The pre-2018 criteria for such a waiver may not have been flexible enough for dealing with a variety of circumstances, such as when federally sponsored research is conducted in an international setting where, for example, cultural or historical reasons suggest that signing documents may be viewed as offensive and problematic.

This should not involve cost as its intent is to improve the informed consent process by providing more flexibility regarding the documentation of consent (an ethical gain) while reducing administrative requirements for investigators and research subjects in specific circumstances. Thus, benefits and costs of this new provision are not quantified. Table 19 summarizes the nonquantified benefits and costs of alteration in waiver for documentation of informed consent in certain circumstances.

TABLE 19—SUMMARY OF ESTIMATED BENEFITS AND COSTS OF ALTERATION IN WAIVER FOR DOCUMENTATION OF INFORMED CONSENT IN CERTAIN CIRCUMSTANCES (§ ____ .117(c)(1)(iii))

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|---|---|-----------|--|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |
| BENEFITS: | | | | |
| Quantified Benefits: | | | | |
| None | | | | |
| Nonquantified Benefits: | | | | |
| Improved informed consent process for distinct cultural groups and communities. | | | | |
| COSTS: | | | | |
| Quantified Costs: | | | | |
| None | | | | |
| Nonquantified Costs: | | | | |
| None. | | | | |

E. Alternative Approaches to the Definition of Human Subject (NPRM at § ____ .102(e)) and Related Provisions

1. Overview

We carefully considered the option of not pursuing regulatory action. However, because of shifts in science, technology, public engagement, and public expectations in the past 2 decades, a wide range of stakeholders have raised concerns about the limitations of the existing ethical framework in research, arguing for a re-evaluation of how the fundamental principles that underlie the Common Rule—respect for persons, beneficence, and justice—are applied in practice to the myriad new contexts in which U.S. research is conducted in the 21st century.

The final rule addresses these concerns through three aims. The first aim is to increase human subjects' ability and opportunity to make informed decisions. The second aim is to reduce potential for harm and promote justice by increasing the uniformity of human subject protections. The third aim is to facilitate current and evolving types of research

that offer promising approaches to treating and preventing medical and societal problems by reducing ambiguity in interpretation of the regulations, increasing efficiencies in the review system, and reducing requirements on investigators when said requirements do not appear to provide meaningful protections to human subjects. We hope that these changes will also build public trust in the research system. We estimate that the benefits of this regulatory action exceed its costs, and as a result we have chosen to pursue this regulatory action.

The NPRM proposed to expand the definition of human subjects to include research in which an investigator obtains, uses, studies or analyzes a biospecimen. This would have applied regardless of the identifiability of the biospecimen. Generally, investigators would not have been allowed to remove identifiers from biospecimens without obtaining informed consent or a waiver of consent. The NPRM also proposed to modify the criteria for waiver of consent in research involving biospecimens such that a waiver would be very rare. Written consent would generally have been required for such activities. Thus,

this change would have significantly expanded the amount of research subject to the Common Rule. This requirement would not have applied to biospecimens and information already collected at the time the final rule is published. The NPRM proposed to exclude from its scope research activities involving nonidentified biospecimens where no new information about an individual is generated. Although activities such as developing new testing assays could have been excluded under this provision, it is anticipated that under the NPRM proposals, most research with biospecimens would have come under the rule.

In addition to promoting respect for persons in the research enterprise, the alternative regulatory structure for research with biospecimens (whereby consent is sought for almost all research activities involving biospecimens) would have encouraged investigators to retain identifiers, which can enhance research by preserving the ability to link biospecimens to important additional information about the subject. Additionally, members of the regulated community have reported situations

where, even though not currently required by regulation, investigators were told by an IRB that they needed to obtain study-specific consent for research activities involving nonidentified biospecimens. Under the NPRM proposals, such a situation would not occur because consent—be it broad or study-specific—would always be obtained for research involving biospecimens.

Though this proposal would promote the ethical principle of respect for persons, it also would have significantly increased the volume of studies for which investigators must seek and document informed consent (unless more stringent waiver criteria were met). Additionally, the NPRM acknowledged, and the regulated community reiterated, during the public comment period, that the majority of the studies that the NPRM proposal would have newly regulated were studies involving no more than minimal risk to human subjects.

As an example of the tradeoffs between the NPRM proposal and the ultimate position taken in the final rule, some commenters noted that the proposal to cover all biospecimens under the Common Rule regardless of identifiability might privilege the *Belmont Report's* principle of autonomy over the principle of justice. Because the NPRM would have required investigators to obtain informed consent in all but rare circumstances for research involving biospecimens, concern was expressed that this could result in lower representation rates in research of minority groups, marginalized members of society, and citizens receiving care in community health clinics (which would be less able to cover the costs of tracking consent status over time). We note that although the available literature suggests that minority consent rates are generally high, minority consent rates in some cases may be lower than for nonminorities.^{57 58 59} This discrepancy in turn could create issues in the applicability of research discoveries on the population as a whole. Respecting persons is a worthy goal, but the need to achieve representative samples (and thus helping to ensure the applicability

of research findings across a population) also must be taken into consideration. In addition, the principle of beneficence requires that all reasonable efforts be made to improve the public good. To balance these sometimes competing interests, the final rule incentivizes asking potential subjects for permission in minimal risk activities (even if a waiver of informed consent could be sought from an IRB), while still allowing other avenues for this research to occur should compelling reasons exist or not obtaining informed consent.

2. Estimated Impact of Alternative Approaches to the Final Rule

The benefit and cost estimations presented below are based upon the proposals and structure presented in the NPRM, not the provisions included in the final rule.

a. Estimating How Many Studies Involving Nonidentified Biospecimens Occur Each Year

We estimate that each year 250,000 studies are not currently subject to oversight by either the Common Rule or FDA regulations because they use biospecimens that have been stripped of identifiers. Extrapolations from 1999 data⁶⁰ suggest that biospecimens are collected from as many as 30 million individuals each year and are stored for both clinical and research purposes. Based on conversations with experts in this area, this 1999 report represents the most recent, comprehensive analysis of the volume of nonidentified biospecimens used in research activities.

Approximately 9 million individuals' biospecimens (30 percent of those collected) are collected for research purposes. Approximately 6.3 million individuals' biospecimens (30 percent) could potentially be used in future research studies. Thus, it is possible that investigators would have had to seek consent to secondary use of biospecimens or a waiver of consent for an additional 15 million individuals annually for secondary use of biospecimens.

In the absence of comprehensive data, to calculate the number of protocols that would have been covered, we proposed two approaches. Under method one, we estimated that approximately 50 biospecimens would have been used on average per research protocol involving biospecimens. This gave a potential 300,000 new research protocols using nonidentified biospecimens. This

estimate of 300,000 new research protocols was rounded down to 250,000 new studies based on ANPRM comments and industry data, because it seemed reasonable to assume that the number of new biospecimen studies covered by the alternative proposal would equal the total number of new protocols conducted each year (*i.e.*, the number of new biospecimen studies was likely close to the estimate of 246,382 new annual studies each year).

Under method two, biospecimen repository representatives reported that roughly 90 percent of their collections were used in nonidentified form in research activities that did not fall under the pre-2018 rule. Thus, only 10 percent of biospecimen studies were covered under the pre-2018 rule, representing a 9:1 ratio of studies involving nonidentified biospecimens to studies involving identifiable biospecimens. Of the 246,382 new protocols each year that were nonexempt (Table 3), we assumed that 10 to 15 percent used identifiable biospecimens. This equated to between 24,638 and 36,957 new studies each year using identifiable biospecimens. We estimated that the number of biospecimen studies that occurred on nonidentified biospecimens each year was approximately 9 times the number of studies using identifiable biospecimens, or between 221,742 and 332,613 studies each year. Thus, under method two, an estimate of 250,000 new studies on nonidentified biospecimens each year was also reasonable.

To facilitate research with biospecimens, the NPRM proposed to create separate elements of broad consent such that investigators and institutions could seek, and individuals could grant, consent for future unspecified research activities. The NPRM also proposed an exemption that relied on obtaining broad consent for future, unspecified research studies. To be eligible for the proposed exemption for specific secondary studies, broad consent must have been sought and obtained using the proposed Secretary's template for broad consent, and the investigator must not have anticipated returning individual research results to subjects.

b. Facilitating Research With Nonidentified Biospecimens Under the NPRM: Exemption for Specific, Secondary Studies When Broad Consent Had Been Sought and Obtained

The NPRM proposed to allow broad consent to secondary research use of biospecimens or identifiable private information for unspecified research purposes. Such broad consent would

⁵⁷ Pentz RD, et al. Research on Stored Biological Samples: Views of African American and White American Cancer Patients. *American Journal of Medical Genetics*, Part A. 2006 Apr; 140(7):733–739.

⁵⁸ Chen, DT et al. Research With Stored Biological Samples; What Do Research Participants Want? *Archives of Internal Medicine* 2005 Mar; 165(6):652–655.

⁵⁹ Scott EA, et al. Biospecimen Repositories: Are Blood Donors Willing to Participate? *Transfusion*. 2010 September; 50(9):1943–1950.

⁶⁰ Eiseman E., Haga S. *Handbook of Human Tissue Sources: A National Resource of Human Tissue Samples*. Washington, DC: RAND Corporation; 1999.

have specified elements and limitations, and could have been obtained in both the research and nonresearch setting.

The proposed exemption was specifically for secondary research studies involving biospecimens and identifiable private information that had been or would have been acquired for purposes other than the currently proposed research study. If a secondary research study did not meet the requirements of this exemption, the investigator would have needed to seek IRB review of the study, and would have needed to obtain either study-specific consent or a waiver of informed consent. Note that for biospecimens, an IRB would have applied the more stringent waiver criteria under which waiver of informed consent in research involving biospecimens would have been rare. For identifiable private information, an IRB would have applied the waiver criteria almost identical to the criteria in the pre-2018 rule.

We anticipated that a majority of studies that would have used this exemption would have been biospecimen studies. The extent to which individuals conducting secondary research studies involving identifiable private information would have used this exemption is unknown, given the proposed rule provided additional pathways to facilitate such studies. To that end, the benefits and costs associated take into consideration only secondary research involving biospecimens. We further anticipated that the NPRM proposals would have resulted in higher value research with biospecimens being conducted with subjects' consent and without the need for full IRB review, or the need to go back to subjects to obtain consent for every secondary research study, as long as certain conditions were met.

Because the estimated 250,000 biospecimen studies each year that would have been newly covered under the rule as a result of the proposed modification to the definition of human subject would likely have been minimal risk, we assume that all of these would have been eligible for the exemption for secondary use as long as broad consent had been sought and obtained.

Benefits and costs associated with obtaining and tracking broad consent under this alternative proposal are discussed below.

Because the compliance date for the expansion to the definition of human subject would have been 3 years after the date of publication of a final rule, the benefits and costs described below assume a start date of 2020. In the absence of the proposed exemption for secondary research studies, but taking

into consideration the expansion to the definition of human subject, we estimate that each year, all 250,000 of these studies would undergo convened initial review. In subsequent years, we estimate that 120,000 protocols would undergo convened initial review, 89,700 would undergo convened continuing review, and 40,300 would undergo expedited continuing review based on the distribution of reviews presented in Table 3. The estimated costs to institution officials, IRB administrators, IRB administrative staff, IRB chairs, IRB voting members, and investigators conducting these reviews are based on the estimates presented in Table 3. The dollar value of their time is calculated by multiplying hours by their estimated 2017–2026 wages and adjusting for overhead and benefits.

c. Facilitating Research With Nonidentified Biospecimens Under the NPRM: Seeking and Obtaining Broad Consent

To facilitate secondary research using biospecimens and identifiable private information, the NPRM also proposed an exemption for storing and maintaining biospecimens and identifiable private information for future, unspecified, secondary research activities. Given the creation of this exemption, the NPRM envisioned that institutions would need to develop tracking systems to monitor which biospecimens or information could be used in secondary research by investigators. Because both the exemption for secondary research use described above, and the exemption required using the proposed Secretary's broad consent, the NPRM assumed that a majority of investigators and institutions would employ the Secretary's consent template. Thus, the NPRM anticipated that minimal time would have been spent updating consent forms or drafting new broad consent forms.

We estimate that 6,428 FWA-holding institutions (80 percent) would have stored and maintained clinical and nonclinical biospecimens and identifiable private information for unspecified future research studies in the manner prescribed under the NPRM. As also discussed previously, extrapolations from 1999 data suggest that biospecimens are collected from as many as 30 million individuals each year and stored for both clinical and research purposes. Approximately 9 million individuals' biospecimens (30 percent) are collected for research purposes, and thus consent would be sought in the research context for the secondary use of these biospecimens.

For these 9 million individuals per year, an investigator would spend an estimated 20 minutes per person conducting the consent process specific to seeking broad consent, and the subjects would spend an estimated 20 minutes engaging in the process of having their broad consent for future research uses of their biospecimens or information sought. This estimate of the investigator's time also includes the time for the investigator to log the information into the appropriate database. We note that the NPRM RIA estimated that it would take 5 minutes for an investigator to seek broad consent in the research setting, and that prospective subjects would spend 5 minutes having their broad consent sought. Based on public comments, we have revised this estimate to better reflect experience in the regulated community about how long it takes to seek and obtain consent. We further estimate that investigators would spend 10 minutes of time per protocol updating their study specific consent form to include the language from the Secretary's consent template.

In the clinical setting, approximately 21 million individuals' biospecimens (70 percent of the estimated 30 million individuals' biospecimens collected each year) are collected for clinical purposes. In the first year that the proposed changes would have been implemented, as many as 21 million broad, secondary use consent forms could have been collected from individuals. We anticipate 30 minutes of a subject's time to engage in the consent process. We further anticipate 30 minutes of an institutional employee's time at the IRB Administrative Staff level to seek consent and put the information in the appropriate tracking system. As with the estimate for seeking and obtaining broad consent in the clinical setting, we have increased the estimate of how long it would take institutional employees to seek broad consent and how long prospective subjects would spend participating in the broad consent process based on public comments.

The NPRM proposed that once an individual gave broad consent to use his or her biospecimens in future, unspecified research studies, that consent could cover any biospecimen collected from that individual over the course of a 10-year period. Note that an institution could retain and use the biospecimens collected indefinitely. This provision merely stated that every 10 years an institution must ask people whether or not they may use newly collected biospecimens in research. Given that an institution needed to seek

broad consent from an individual only once over the course of a 10-year period, we assumed that after the first year the NPRM was implemented, the number of individuals from whom an institution would seek broad consent would decrease.

To account for this, the RIA alternative approach assumes that after the first year, a fraction of the clinical subjects from whom broad consent was sought in year one would be sought in subsequent years. We anticipate that in year two, secondary use consent would be sought in the clinical context from 10.5 million subjects (50 percent of the number of individuals involved in the year one estimates). We anticipate that in year three and after, secondary use consent would be sought in the clinical context from approximately 6.3 million subjects each year (30 percent of the number of individuals involved in the year one estimates). As in year one, we assume that a prospective subject would spend 30 minutes of time undergoing the consent process and that an institutional employee at the IRB Administrative Staff level would spend 30 minutes of time conducting the consent process with an individual and

updating the appropriate tracking system.

d. Estimating the Cost of the Broad Consent Tracking System

To appropriately track biospecimens or identifiable private information for which broad consent had been sought and obtained on an institutional level, an institution would need to develop an institution-wide repository-like schema. The costs include the design, implementation, and operation of the informatics system that would be required to document and keep current thousands of consent documents per year. In addition, the institution would have to come up with a system to mark or otherwise flag which biospecimens and pieces of identifiable private information could be used in future unspecified secondary research studies.

Under the NPRM proposal, we estimate that 80 percent of the 8,035 institutions with FWAs would develop these informatics systems (or modify existing systems) to facilitate research with nonidentified biospecimens. We estimate that under this proposal, institutions on average would require 1.0 database administrator FTE to develop and maintain these systems. We note that as this estimate is a

nationwide average, and we expect some institutions would require more database administrators, and others would require fewer.

For all of the estimates described above, the estimated costs to institution officials, IRB administrators, IRB administrative staff, IRB chairs, IRB voting members, database administrators, and investigators of are based on the estimates presented in Table 3. The dollar value of their time is calculated by multiplying hours by their estimated 2017–2026 wages and adjusting for overhead and benefits.

For the alternative proposal (*i.e.*, the NPRM proposal to treat all biospecimens regardless of identifiability as covered under the Common Rule), present value costs of \$19.7 billion and annualized costs of \$2.31 billion are estimated using a 3 percent discount rate; and present value costs of \$14.2 billion and annualized costs of \$2.02 billion are estimated using a 7 percent discount rate. Table 20 summarizes the quantified and nonquantified benefits and costs of amending the definition of human subject and obtaining consent to secondary use of biospecimens and identifiable private information.

TABLE 20—ALTERNATIVE PROPOSAL TO TREAT ALL BIOSPECIMENS AS COVERED UNDER THE COMMON RULE

| | Present value of 10 years by discount rate (millions of 2015 dollars) | | Annualized value over 10 years by discount rate (millions of 2015 dollars) | |
|--|---|-----------|--|-----------|
| | 3 percent | 7 percent | 3 percent | 7 percent |
| BENEFITS: | | | | |
| Quantified Benefits: | | | | |
| None | | | | |
| Nonquantified Benefits: | | | | |
| Increased protections for human subjects. | | | | |
| COSTS: | | | | |
| Quantified Costs: | | | | |
| Increase in number of reviews; time to update consent forms; document and track permissible and impermissible secondary uses of information and biospecimens; and cost to develop and maintain tracking system | 19,670 | 14,214 | 2,306 | 2,024 |
| Nonquantified Costs: | | | | |
| None. | | | | |

F. Regulatory Flexibility Analysis

As discussed above, the RFA requires agencies that issue a regulation to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. HHS considers a rule to have a significant economic impact on a substantial number of small entities if at least 5 percent of small entities

experience an impact of more than 3 percent of revenue.

We calculate the costs of the proposed changes to the Common Rule over 2017–2026 to institutions with an FWA. The estimated annualized cost to institutions with an FWA, on average, is \$2,516 using a 3 percent discount rate. The U.S. Small Business Administration establishes size standards that define a small entity. According to these

standards, colleges, universities, and professional schools with revenues below \$27.5 million and hospitals with revenues below \$38.5 million are considered small entities. It is not anticipated that a majority of institutions with an FWA are in any of these categories.

XX. Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XXI. Paperwork Reduction Analysis

This final rule contains collections of information that are subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), as amended (44 U.S.C. 3501–3520). A description of these provisions is given in this document with an estimate of the annual reporting and recordkeeping burden.

Title: Federal Policy for the Protection of Human Subjects.

Description: In this document is a discussion of the regulatory provisions we believe are subject to the PRA and the probable information collection burden associated with these provisions. In general, the following actions trigger the PRA: (i) Reporting; (ii) Recordkeeping.

Description of Respondents: The reporting and recordkeeping requirements in this document are imposed on institutions, institutional review boards, and investigators involved in human subjects research conducted or supported or otherwise subject to regulation by any federal department or agency that takes administrative action that makes the policy applicable to such research.

§ _____.101(a)(1) *Extending Oversight to IRBs-Not Operated by an Institution Holding an FWA (OMB Control No 0990–0260)*

Section _____.101 is amended, as described in § _____.101(a), to give Common Rule departments and agencies the authority to enforce compliance directly against IRBs that are not operated by an assured institution. It is anticipated that institutions using an IRB that it does not operate will be reassured because compliance actions can be taken directly against the IRB responsible for the regulatory noncompliance, rather than the institutions that relied on that review. As a result of this change, we anticipate that FWA-holding institutions will increase their reliance on IRBs not operated by an FWA-holding institution when appropriate.

The OHRP database of assured institutions and registered IRBs shows that approximately 449 IRBs not

operated by an institution holding an FWA will now be subject to oversight. These IRBs will develop an estimated average of 10 written agreements with other institutions each year as a result of this rule. We further estimate that each agreement will require an average of 10 hours of institution legal staff time and 5 hours of IRB administrator time to complete. We note that elsewhere in the final rule (specifically §§ _____.103(e) and _____.115(a)(9)) requires that IRBs document the specific responsibilities that an institution and an organization operating an IRB each will undertake, when an institution relies on an IRB that it does not operate. The impact of these provisions on FWA-holding institutions is described below.

§ _____.103(e) *Documentation of IRB Oversight Reliance Requirement for Institution and Organization Operating the IRB (OMB Control No 0990–0260)*

To further strengthen the compliance enforcement authority provision in § _____.101(a) and provide a record for oversight and compliance purposes, the final rule contains a requirement at § _____.103(e), that for nonexempt research involving human subjects covered by this policy (or exempt research for which limited IRB takes place pursuant to § _____.104(d)(2)(iii), § _____.104(d)(3)(i)(C), § _____.104(d)(7), or § _____.104(d)(8)) that take place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy. This might be accomplished through a written agreement between the institution and the IRB, or by implementing an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol). In addition, a requirement is included at § _____.115(a)(9) that an institution include documentation of such arrangements in the IRB records.

Table 3 of the RIA section of the preamble shows that 5,164 FWA-holding institutions do not have an IRB and 2,871 FWA-holding institutions have an IRB. We assume that the 5,164 FWA-holding institutions without an IRB have an average of 1 IRB authorization agreement that will need to be modified as a result of the new requirements for agreements between

institutions and IRBs not operated by the institutions in 2017. In addition, we assume that the 2,871 FWA-holding institutions with an IRB have an average of 0.20 IRB authorization agreements that will need to be modified in 2017. We estimate that each agreement will require an average of 10 hours of institution legal staff time and 5 hours of IRB administrator time to complete. The dollar value of their time is calculated by multiplying hours by their estimated 2017 wages and adjusting for overhead and benefits.

§ _____.104(d)(5)(i) *Posting of Information About Federally Funded or Supported Demonstration Projects*

Section 104(d)(5)(i) requires each federal department or agency conducting or supporting the research or demonstration projects covered under this exemption to establish, on a publicly accessible federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the federal department or agency conducts or supports under this provision. We estimate that under the pre-2018 rule, approximately 1,000 demonstration projects occurred each year. Under the modifications to this exemption in the final rule, we estimate that an additional 3,376 studies will fall under this exemption. Thus, approximately 4,376 studies will be subject to this posting requirement each year. We anticipate that investigators will spend approximately 15 minutes per study submitting information about these studies to the federal Web site.

§ _____.114 *Cooperative Research (OMB Control No 0990–0260)*

The final rule requires any institution located in the United States that is engaged in cooperative research to rely upon approval by a single IRB for that portion of the research that is conducted in the United States, as detailed in § _____.114 (b)(1). The following research is not subject to the requirements of this provision, as described in § _____.114 (b)(2): (1) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of a Native American or Alaska Native tribe); or (2) research for which any federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular study.

The OHRP database of assurances shows that 8,035 institutions in the United States have an FWA. We estimate that these institutions will

develop an average of 10 written joint IRB review agreements with other institutions or organizations in 2019 before the first year of compliance. We further estimate that each agreement will require an average of 10 hours of institution legal staff time and 5 hours of IRB administrator time to complete.

We estimate that 202,617 annual reviews of multi-institutional protocols take place, and an average of 5 reviews per multi-institutional protocol, implying that 40,523 multi-institutional protocols are reviewed each year. We further estimate that 16,209 (40 percent) of these multi-institutional studies are funded by NIH and thus will already be subject to NIH's single IRB review policy. Accordingly, we estimate that approximately 97,256 annual reviews of protocols will no longer be conducted as a result of these proposed changes. Of these reviews, 32,211 would have undergone convened initial review, 14,472 would have undergone expedited initial review, 34,896 would have undergone convened continuing review, and 15,678 would have undergone expedited continuing review based on the distribution of reviews presented in Table 3 in the RIA section of the preamble.

§ _____.115(a)(3) Documenting the Rationale for Conducting Continuing Review of Research That Otherwise Would Not Require Continuing Review (OMB Control No 0990-0260)

The final rule eliminates continuing review for many minimal risk studies, as detailed at § _____.109(f). Unless an IRB determines otherwise, continuing review of research is not required if: (1) The research is eligible for expedited review in accordance with § _____.110; (2) the research is reviewed by the IRB in accordance with the limited IRB review procedure described in several of the exemption categories (specifically, § _____.104(d)(2)(iii), § _____.104(d)(3)(i)(C), § _____.104(d)(7), or § _____.104(d)(8)); or (3) the research has progressed to the point that it involves data analysis (including analysis of identifiable information or identifiable biospecimens) or access to follow-up clinical data from procedures that subjects would undergo as part of clinical care. If an IRB chooses to conduct continuing review even when these conditions are met, the rationale for doing so must be documented according to a new provision at § _____.115(a)(3).

We estimate that 40,773 reviews will require documentation of the rationale for doing so (as required under § _____.115(a)(3)). We also estimate that IRB voting members will spend 1 hour

per review providing the necessary documentation.

§§ _____.116(a)(5), (b)(9), (c)(7)–(9) and _____.117(b) Changes in the Elements of Consent, Including Documentation (OMB Control No 0990-0260)

The final rule imposes a new requirement at § _____.116(a)(5)(i) informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of informed consent must be organized and presented in a way that facilitates comprehension. This requirement applies to all informed consent process, except for broad consent obtained pursuant to § _____.116(d), which may warrant a different presentation.

The final rule includes a new element of consent at § _____.116(b)(9) that requires one of the following statements be included for any research that involves the collection of identifiable private information or identifiable biospecimens: (1) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or (2) a statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

The final rule's three additional elements of consent are in § _____.116(c)(7), (8), and (9). These require that a subject be informed of the following, when appropriate:

- That the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- Whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.*, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.

These additional elements of consent will promote respect for persons and greater transparency in the research enterprise. Additionally, including the information referenced in these provisions in a consent form will help ensure that prospective subjects are given information necessary for understanding why one might choose whether to participate in a research study.

The language at § _____.117(b)(1) in the final rule was modified to reference § _____.116(a)(5)(i) and state that if a short form consent process is used, the key information required by § _____.116(a)(5)(i) must be presented first to the prospective subject, before other information, if any, is provided.

We estimate that 246,382 new protocols annually will use identifiable private information. For each protocol, we estimate that investigators will spend an average of 15 minutes in 2017 updating consent forms to comply with the new requirements found in the final rule at § _____.116(a)(5), (b)(9), (c)(7), (c)(8), or (c)(9) (in Table 3 in the RIA section).

We assume that few additional investigators will elect to offer the second option at § _____.116(b)(9), and that the investigators who currently offer equivalent options already track the permissible and impermissible uses of information in line with the requirements discussed above. As a result, we estimate that tracking will have no additional associated impacts.

§ _____.116(h) Requirement for Posting of Consent Forms for Common Rule Department or Agency-Supported or Conducted Clinical Trials (OMB Control No 0990-0260)

A new provision in the final rule, § _____.116(h), requires that, for each clinical trial conducted or supported by a federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or federal department or agency component conducting the trial on a publicly available federal Web site that is established as a repository for such informed consent forms. The informed consent form must be published on the federal Web site after the trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

If the federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a federal Web site (*e.g.*, confidential commercial information), such Federal department or agency may permit or

require redactions to the information posted.

We believe that public posting of consent forms will increase transparency, enhance confidence in the research enterprise, increase accountability, and inform the development of future consent forms, possibly resulting in future savings in time for investigators developing consent forms.

According to queries of *ClinicalTrials.gov*, an estimated 5,270 clinical trials are conducted or supported by Common Rule agencies, of which an estimated 575 are regulated by provisions in the FD&C Act and Trade Secrets Act based on the information presented in Table 3 in the RIA section of the preamble. We assume that each clinical trial is associated with one consent form that must be submitted to

the HHS system by an investigator. We estimate that investigators will spend an average of 15 minutes submitting each consent form. In addition, for the 575 clinical trials regulated by provisions in the FD&C Act and Trade Secrets Act, we estimate that investigators will spend an average of 30 minutes redacting information before submission.

TABLE 21—ESTIMATED ANNUAL REPORTING BURDEN

| Sec. description | Description of burden | Number of respondents | Number of responses per respondent | Total annual responses | Average hours per response | Total hours |
|--|--|-----------------------|------------------------------------|------------------------|----------------------------|-------------|
| 101(a)—Extending Oversight Authority to IRBs not operated by an FWA-holding institution. | Develop agreements | 449 | 10 | 4,490 | 15 | 67,350 |
| 103(e)—IRB Reliance Documentation (institutions without an internal IRB). | Modify agreements | 5,164 | 1 | 5,164 | 15 | 77,460 |
| 103(e)—IRB Reliance Documentation (institutions with an internal IRB). | Develop agreements | 2,871 | 0.20 | 574.20 | 15 | 8,613 |
| 104(d)(5)(i)—Posting information about demonstration projects. | Posting information | 4,376 | 1 | 4,376 | 0.25 | 1,094 |
| 114—Cooperative Review .. | Time to create agreements for all institutions involved in a study will rely on one IRB of record. | 8,035 | 10 | 80,350 | 15 | 1,205,250 |
| 115(a)(3)—Continuing Review Rationale Documentation. | Provide rationale | 40,773 | 1 | 40,773 | 1 | 40,773 |
| 116(a)(5), (b)(9), (c)(7)—(8) & 117(b)—Changes in elements of informed consent, including documentation. | Updating IC forms with new elements. | 246,382 | 1 | 246,382 | 0.25 | 61,596 |
| 116(h)—Requirement for posting consent forms for Common Rule department or agency-supported clinical trials. | Posting consent forms for new clinical trials. | 5,270 | 1 | 5,270 | 0.25 | 1,318 |
| 116(h)—Requirement for posting consent forms for Common Rule department or agency-supported clinical trials. | Redact information from consent forms. | 575 | 1 | 575 | 0.50 | 288 |
| Total | | | | | | 1,422,968 |

The total estimated burden imposed by these information collection requirements is 1,422,968 burden hours.

It should be noted that the burden estimates for the Common Rule include approved information requirements in OMB No. 0990–0260, Protection of Human Subjects: Compliance with Federal Policy/IRB Recordkeeping/Informed Consent/Consent Documentation, approved through May 31, 2018. As such, it will be amended and submitted to OMB as revisions to currently approved collections once the

rule is finalized and the collections are due for renewal.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the information collection provisions of this rule will be submitted to OMB for review. These requirements will not be effective until OMB approves them.

XXII. Tribal Consultation Statement

We are committed to consulting with AI/AN tribes and tribal leadership to the extent practicable and permitted by law before promulgating any regulation that has tribal implications. As we

developed this rule, we engaged with tribes through tribal consultation and the public comment process. The requirements in this final rule were informed by consultations with and comments from tribal representatives.

On January 5, 2016, HHS conducted a tribal consultation through conference call in accordance with the HHS Tribal Consultation Policy⁶¹ with tribal representatives to obtain comments on

⁶¹ U.S. Department of Health and Human Services Tribal Consultation Policy. Retrieved from <https://www.hhs.gov/sites/default/files/iea/tribal/tribalconsultation/hhs-consultation-policy.pdf>.

the proposed changes to the Common Rule. This conference call was moderated by Elizabeth Carr, a Tribal Affairs Specialist within HHS and a federal representative of HHS's American Indian and Alaska Native Health Research Advisory Council. Tribal leaders and other interested parties were informed of this consultation through written communication. The written invitation included a solicitation for formal comments and information on how to submit a formal comment to the public docket. Public comments were also solicited during the consultation conference call. A transcript of this call was posted to the *Regulations.gov* public docket for the Common Rule on January 13, 2016.

During the tribal consultation conference call, participants discussed:

- Concern about the NPRM not acknowledging the role of tribal governments in research oversight of research occurring on tribal land or with tribal citizens;
- Concern about the pre-2018 rule and the NPRM not explicitly acknowledging tribal sovereignty. HHS representatives acknowledged an outstanding legal question about whether rules created by tribal governments were encompassed by the provision in the pre-2018 rule and the NPRM's statement that the policy does not affect any state or local laws or regulations that may otherwise be applicable and that provide additional protections for human subjects;
- Concern about the NPRM not acknowledging the unique and significant impact that the proposed changes would have on American Indian and Alaska Native populations;
- Concern that the NPRM does not address risks of research to communities and only addresses individual risks;
- Concern that the NPRM proposals seem to reduce institutional responsibility but increase investigator responsibility. This presents a unique challenge when institutions have entered into agreements with tribal governments or tribal representatives, as opposed to individual investigators entering into these arrangements. The exemption decision tool was cited as an example of the proposals placing more responsibility on the investigators while perhaps reducing responsibility on the institutions; and
- Concern about the single IRB review mandate for multi-institutional studies affecting the ability of tribal communities to conduct local reviews of research involving tribal citizens or research that takes place on tribal land. One commenter noted that a one size

fits all approach to addressing American Indian and Alaska Native concerns in human subjects protections might not be appropriate as needs and concerns might vary from tribe to tribe.

HHS reiterated its commitment to engaging in an ongoing dialogue with tribal communities and tribal representatives, and welcomed ongoing discussion and comment on how the Common Rule affects these groups.

In addition to the January 2016 tribal consultation, we reviewed public comments from tribal representatives, and individuals and groups representing tribal interests to the ANPRM and NPRM. We received one comment on the ANPRM from a group representing tribal interests. This group noted "the long and challenging history" of research involving AI/AN populations, and how this history informs current research activities involving these groups. This comment argued that, for research involving AI/AN populations:

- Continuing review should be required;
- IRBs, not investigators or other parties, should determine whether a prospective study is exempt or excluded from the Common Rule;
- IRBs should be required to consider potential harms to populations or groups, not just individuals, when reviewing research activities;
- Incorporating tribal IRBs into the process for multi-institutional studies is a crucial aspect of respecting these populations and ensuring human subjects protections;
- Study-specific informed consent forms should be required, and general, multi-purpose consent forms should be avoided;
- Mandated information and biospecimen privacy safeguards would be a welcome improvement to the current research landscape and would help prevent harm to human subjects; and
- Consultation with tribal representatives would be crucial should a proposed rule or final rule mandate single IRB review for multi-institutional studies.

We received approximately 15 comments on the NPRM from groups representing tribal interests. As described in Section II.E of this preamble, overarching concerns raised by these groups in comments to the NPRM included:

- Lack of group consent requirements proposed in the NPRM;
- Concern about the allowance for broad consent for future unspecified research uses;
- Lack of consideration for research activities involving research with

biospecimens or information from individuals who are no longer alive;

- Mandating the use of single IRB review in multi-institutional research activities undermining the ability of tribal groups to conduct local review of studies; and
- Concern about the breadth and depth of exclusions and exemptions proposed in the NPRM exempting or excluding activities that tribal populations might find sensitive and requiring IRB review.

Commenters also raised concerns about the timing of the tribal consultation call and noted that the tribal consultation call occurred one day before the closing of the extended comment period for the NPRM. When HHS received notice that tribal representatives desired to consult on this proposed rule, a consultation was immediately scheduled in accordance with HHS policy.

The final rule includes a modification to the provision requiring single IRB review, and several clarifications specifying that regulatory references to state and local law are intended to include tribal law, in response to concerns raised during the tribal consultation and in the NPRM public comments. As described in this preamble, the final rule clarifies in § ___.101(f) that tribal governments can develop laws related to the protection of human subjects that are more protective than the Common Rule, and that these laws must be followed by federally funded researches in activities involving these populations. Section ___.114 now provides that if a tribal government requires review by more than one IRB by law in multi-institutional research, the single IRB review requirement in § ___.114 does not apply. Additional clarification has also been made to § ___.116(i) that tribal governments can develop their own informed consent standards that provide additional protections to subjects and that investigators conducting research involving populations under the jurisdiction of the tribal governments would have to follow these rules. Finally, additional language has been added to § ___.116(j) noting that nothing in § ___.116 is intended to limit the authority of a treating physician to the extent the authority is granted by tribal law.

Additional details of public comments from individuals representing tribal interests are included above in the relevant public comment summaries for the various final rule provisions discussed in Sections II through XVIII of this preamble.

For the reasons set forth in this preamble, the Federal Policy for the Protection of Human Subjects is amended.

Text of the Final Common Rule

The text of the final common rule appears below:

1. Part/subpart ____ is amended/
revised/added to read as follows:

PART ____—PROTECTION OF HUMAN SUBJECTS

- ____.101 To what does this policy apply?
- ____.102 Definitions for purposes of this policy.
- ____.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.
- ____.104 Exempt research.
- ____.105 [Reserved]
- ____.106 [Reserved]
- ____.107 IRB membership.
- ____.108 IRB functions and operations.
- ____.109 IRB review of research.
- ____.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- ____.111 Criteria for IRB approval of research.
- ____.112 Review by institution.
- ____.113 Suspension or termination of IRB approval of research.
- ____.114 Cooperative research.
- ____.115 IRB records.
- ____.116 General requirements for informed consent.
- ____.117 Documentation of informed consent.
- ____.118 Applications and proposals lacking definite plans for involvement of human subjects.
- ____.119 Research undertaken without the intention of involving human subjects.
- ____.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.
- ____.121 [Reserved]
- ____.122 Use of Federal funds.
- ____.123 Early termination of research support: Evaluation of applications and proposals.
- ____.124 Conditions.

§ ____ .101 To what does this policy apply?

(a) Except as detailed in § ____ .104, this policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research

conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States. Institutions that are engaged in research described in this paragraph and institutional review boards (IRBs) reviewing research that is subject to this policy must comply with this policy.

(b) [Reserved]

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy and this judgment shall be exercised consistent with the ethical principles of the Belmont Report.⁶²

(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the Federal department or agency but not otherwise covered by this policy comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations that provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations that may otherwise be applicable and that provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the **Federal Register** or will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive

the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy, provided the alternative procedures to be followed are consistent with the principles of the Belmont Report.⁶³ Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, or to the equivalent office within the appropriate Federal department or agency, and shall also publish them in the **Federal Register** or in such other manner as provided in department or agency procedures. The waiver notice must include a statement that identifies the conditions under which the waiver will be applied and a justification as to why the waiver is appropriate for the research, including how the decision is consistent with the principles of the Belmont Report.

(j) Federal guidance on the requirements of this policy shall be issued only after consultation, for the purpose of harmonization (to the extent appropriate), with other Federal departments and agencies that have adopted this policy, unless such consultation is not feasible.

(k) [Reserved]

(l) Compliance dates and transition provisions:

(1) For purposes of this section, the *pre-2018 Requirements* means this subpart as published in the 2016 edition of the Code of Federal Regulations.

(2) For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this subpart. The compliance date for § ____ .114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) Research initially approved by an IRB, for which such review was waived pursuant to § ____ .101(i), or for which a determination was made that the research was exempt before January 19, 2018, shall comply with the pre-2018 Requirements, except that an institution engaged in such research on or after January 19, 2018, may instead comply with the 2018 Requirements if the institution determines that such ongoing research will comply with the 2018 Requirements and an IRB documents such determination.

(4) Research initially approved by an IRB, for which such review was waived pursuant to § ____ .101(i), or for which a

⁶² The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.— Belmont Report. Washington, DC: U.S. Department of Health and Human Services. 1979.

⁶³ *Id.*

determination was made that the research was exempt on or after January 19, 2018, shall comply with the 2018 Requirements.

(m) **Severability:** Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances.

§ 102 Definitions for purposes of this policy.

(a) **Certification** means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

(b) **Clinical trial** means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

(c) **Department or agency head** means the head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.

(d) **Federal department or agency** refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (e.g., the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).

(e)(1) **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private

information or identifiable biospecimens.

(2) **Intervention** includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

(3) **Interaction** includes communication or interpersonal contact between investigator and subject.

(4) **Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

(5) **Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

(6) **An identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

(7) Federal departments or agencies implementing this policy shall:

(i) Upon consultation with appropriate experts (including experts in data matching and re-identification), reexamine the meaning of "identifiable private information," as defined in paragraph (e)(5) of this section, and "identifiable biospecimen," as defined in paragraph (e)(6) of this section. This reexamination shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies implementing this policy. If appropriate and permitted by law, such Federal departments and agencies may alter the interpretation of these terms, including through the use of guidance.

(ii) Upon consultation with appropriate experts, assess whether there are analytic technologies or techniques that should be considered by investigators to generate "identifiable private information," as defined in paragraph (e)(5) of this section, or an "identifiable biospecimen," as defined in paragraph (e)(6) of this section. This assessment shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies implementing this policy. Any such technologies or techniques will be included on a list of technologies or

techniques that produce identifiable private information or identifiable biospecimens. This list will be published in the **Federal Register** after notice and an opportunity for public comment. The Secretary, HHS, shall maintain the list on a publicly accessible Web site.

(f) **Institution** means any public or private entity, or department or agency (including federal, state, and other agencies).

(g) **IRB** means an institutional review board established in accord with and for the purposes expressed in this policy.

(h) **IRB approval** means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(i) **Legally authorized representative** means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, **legally authorized representative** means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

(j) **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(k) **Public health authority** means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

(l) **Research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and

service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

(m) *Written, or in writing*, for purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format.

§ ____ .103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.

(a) Each institution engaged in research that is covered by this policy, with the exception of research eligible for exemption under § ____ .104, and that is conducted or supported by a Federal department or agency, shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements of this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Human Research Protections, HHS, or any

successor office, and approved for Federal-wide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Human Research Protections, HHS, or any successor office. Federal departments and agencies will conduct or support research covered by this policy only if the institution has provided an assurance that it will comply with the requirements of this policy, as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB (if such certification is required by § ____ .103(d)).

(b) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes.

(c) The department or agency head may limit the period during which any assurance shall remain effective or otherwise condition or restrict the assurance.

(d) Certification is required when the research is supported by a Federal department or agency and not otherwise waived under § ____ .101(i) or exempted under § ____ .104. For such research, institutions shall certify that each proposed research study covered by the assurance and this section has been reviewed and approved by the IRB. Such certification must be submitted as prescribed by the Federal department or agency component supporting the research. Under no condition shall research covered by this section be initiated prior to receipt of the certification that the research has been reviewed and approved by the IRB.

(e) For nonexempt research involving human subjects covered by this policy (or exempt research for which limited IRB review takes place pursuant to § ____ .104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8)) that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy (e.g., in a written agreement between the institution and the IRB, by implementation of an institution-wide

policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol).

(Approved by the Office of Management and Budget under Control Number 0990–0260)

§ ____ .104 Exempt research.

(a) Unless otherwise required by law or by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the categories in paragraph (d) of this section are exempt from the requirements of this policy, except that such activities must comply with the requirements of this section and as specified in each category.

(b) Use of the exemption categories for research subject to the requirements of subparts B, C, and D: Application of the exemption categories to research subject to the requirements of 45 CFR part 46, subparts B, C, and D, is as follows:

(1) *Subpart B*. Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

(2) *Subpart C*. The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

(3) *Subpart D*. The exemptions at paragraphs (d)(1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

(c) [Reserved.]

(d) Except as described in paragraph (a) of this section, the following categories of human subjects research are exempt from this policy:

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques,

curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 111(a)(7).

(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no

reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the

Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(ii) [Reserved]

(6) Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the

determinations required by § _____.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § _____.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § _____.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by § _____.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

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§ _____.105 [Reserved.]

§ _____.106 [Reserved]

§ _____.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or

educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

(b) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(c) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(d) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(e) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ _____.108 IRB functions and operations.

(a) In order to fulfill the requirements of this policy each IRB shall:

(1) Have access to meeting space and sufficient staff to support the IRB's review and recordkeeping duties;

(2) Prepare and maintain a current list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant;

(3) Establish and follow written procedures for:

(i) Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;

(ii) Determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and

(iii) Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of

the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject.

(4) Establish and follow written procedures for ensuring prompt reporting to the IRB; appropriate institutional officials; the department or agency head; and the Office for Human Research Protections, HHS, or any successor office, or the equivalent office within the appropriate Federal department or agency of

(i) Any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and

(ii) Any suspension or termination of IRB approval.

(b) Except when an expedited review procedure is used (as described in § _____.110), an IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

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§ _____.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities under § _____.104 for which limited IRB review is a condition of exemption (under § _____.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8)).

(b) An IRB shall require that information given to subjects (or legally authorized representatives, when appropriate) as part of informed consent is in accordance with § _____.116. The IRB may require that information, in addition to that specifically mentioned in § _____.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with § _____.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB

approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in § _____.109(f).

(f)(1) Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

(i) Research eligible for expedited review in accordance with § _____.110;

(ii) Research reviewed by the IRB in accordance with the limited IRB review described in § _____.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8);

(iii) Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

(A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or

(B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

(2) [Reserved.]

(g) An IRB shall have authority to observe or have a third party observe the consent process and the research.

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§ _____.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary of HHS has established, and published as a Notice in the **Federal Register**, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The Secretary will evaluate the list at least every 8 years and amend it, as appropriate, after consultation with other federal departments and agencies and after publication in the **Federal Register** for public comment. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b)(1) An IRB may use the expedited review procedure to review the following:

(i) Some or all of the research appearing on the list described in paragraph (a) of this section, unless the reviewer determines that the study involves more than minimal risk;

(ii) Minor changes in previously approved research during the period for which approval is authorized; or

(iii) Research for which limited IRB review is a condition of exemption under § _____.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (8).

(2) Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the nonexpedited procedure set forth in § _____.108(b).

(c) Each IRB that uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals that have been approved under the procedure.

(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

§ _____.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized:

(i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and

(ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable.

In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the

special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, § _____.116.

(5) Informed consent will be appropriately documented or appropriately waived in accordance with § _____.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(i) The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

(ii) [Reserved.]

(8) For purposes of conducting the limited IRB review required by § _____.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations:

(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of § _____.116(a)(1)-(4), (a)(6), and (d);

(ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with § _____.117; and

(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ ____ .112 Review by Institution

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ ____ .113 Suspension or Termination of IRB Approval of Research

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

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§ ____ .114 Cooperative Research

(a) Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

(b)(1) Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

(2) The following research is not subject to this provision:

(i) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or

(ii) Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

(c) For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar

arrangements for avoiding duplication of effort.

§ ____ .115 IRB Records

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in § ____ .109(f)(1).

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in § ____ .108(a)(2).

(6) Written procedures for the IRB in the same detail as described in § ____ .108(a)(3) and (4).

(7) Statements of significant new findings provided to subjects, as required by § ____ .116(c)(5).

(8) The rationale for an expedited reviewer's determination under § ____ .110(b)(1)(i) that research appearing on the expedited review list described in § ____ .110(a) is more than minimal risk.

(9) Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy, as described in § ____ .103(e).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research that is conducted shall be retained for at least 3 years after completion of the research. The institution or IRB may maintain the records in printed form, or electronically. All records shall be accessible for inspection and copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner.

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§ ____ .116 General Requirements for Informed Consent

(a) *General.* General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials is described in paragraph (e) of this section. General waiver or alteration of informed consent is described in paragraph (f) of this section. Except as provided elsewhere in this policy:

(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

(5) Except for broad consent obtained in accordance with paragraph (d) of this section:

(i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

(ii) Informed consent as a whole must present information in sufficient detail

relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

(6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

(b) *Basic elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others that may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

(9) One of the following statements about any research that involves the

collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

(c) *Additional elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;

(6) The approximate number of subjects involved in the study;

(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.*, sequencing of a human germline or somatic specimen

with the intent to generate the genome or exome sequence of that specimen).

(d) *Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.* Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements in paragraphs (b) and (c) of this section. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:

(1) The information required in paragraphs (b)(2), (b)(3), (b)(5), and (b)(8) and, when appropriate, (c)(7) and (9) of this section;

(2) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;

(3) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;

(4) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

(5) Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

(6) Unless it is known that clinically relevant research results, including individual research results, will be

disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and

(7) An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

(e) *Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials*—(1) *Waiver*. An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (e)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

(2) *Alteration*. An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (e)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.

(3) *Requirements for waiver and alteration*. In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

(i) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

(A) Public benefit or service programs;

(B) Procedures for obtaining benefits or services under those programs;

(C) Possible changes in or alternatives to those programs or procedures; or

(D) Possible changes in methods or levels of payment for benefits or services under those programs; and

(ii) The research could not practicably be carried out without the waiver or alteration.

(f) *General waiver or alteration of consent*—(1) *Waiver*. An IRB may waive

the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (f)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

(2) *Alteration*. An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (f)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.

(3) *Requirements for waiver and alteration*. In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

(i) The research involves no more than minimal risk to the subjects;

(ii) The research could not practicably be carried out without the requested waiver or alteration;

(iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

(g) *Screening, recruiting, or determining eligibility*. An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

(1) The investigator will obtain information through oral or written communication with the prospective

subject or legally authorized representative, or

(2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

(h) *Posting of clinical trial consent form*. (1) For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.

(2) If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (e.g. confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

(3) The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

(i) *Preemption*. The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.

(j) *Emergency medical care*. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

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§ __.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.

(b) Except as provided in paragraph (c) of this section, the informed consent form may be either of the following:

(1) A written informed consent form that meets the requirements of § _____.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.

(2) A short form written informed consent form stating that the elements of informed consent required by § _____.116 have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by § _____.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.

(c)(1) An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

(i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

(ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for

documenting that informed consent was obtained.

(2) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

(Approved by the Office of Management and Budget under Control Number 0990-0260)

§ _____.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to Federal departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. Except for research waived under § _____.101(i) or exempted under § _____.104, no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the Federal department or agency component supporting the research.

§ _____.119 Research undertaken without the intention of involving human subjects.

Except for research waived under § _____.101(i) or exempted under § _____.104, in the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted by the institution to the Federal department or agency component supporting the research, and final approval given to the proposed change by the Federal department or agency component.

§ _____.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.

(a) The department or agency head will evaluate all applications and proposals involving human subjects

submitted to the Federal department or agency through such officers and employees of the Federal department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ _____.121 [Reserved]

§ _____.122 Use of Federal funds.

Federal funds administered by a Federal department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§ _____.123 Early termination of research support: Evaluation of applications and proposals.

(a) The department or agency head may require that Federal department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

§ _____.124 Conditions.

With respect to any research project or any class of research projects the department or agency head of either the conducting or the supporting Federal department or agency may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head

additional conditions are necessary for the protection of human subjects.

Adoption of the Common Rules

The adoption of the common rules by the participating agencies, as modified by agency-specific text, is set forth below.

DEPARTMENT OF HOMELAND SECURITY

List of Subjects in 6 CFR Part 46

Human research subjects, Reporting and record-keeping requirements, Research.

■ For the reasons stated in the preamble, the Department of Homeland Security adds 6 CFR part 46 as set forth at the end of the common preamble of this document.

PART 46—PROTECTION OF HUMAN SUBJECTS

- Sec.
- 46.101 To what does this policy apply?
- 46.102 Definitions for purposes of this policy.
- 46.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.
- 46.104 Exempt research.
- 46.105 [Reserved]
- 46.106 [Reserved]
- 46.107 IRB membership.
- 46.108 IRB functions and operations.
- 46.109 IRB review of research.
- 46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 46.111 Criteria for IRB approval of research.
- 46.112 Review by institution.
- 46.113 Suspension or termination of IRB approval of research.
- 46.114 Cooperative research.
- 46.115 IRB records.
- 46.116 General requirements for informed consent.
- 46.117 Documentation of informed consent.
- 46.118 Applications and proposals lacking definite plans for involvement of human subjects.
- 46.119 Research undertaken without the intention of involving human subjects.
- 46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.
- 46.121 [Reserved]
- 46.122 Use of Federal funds.
- 46.123 Early termination of research support: Evaluation of applications and proposals.
- 46.124 Conditions.

Authority: 5 U.S.C. 301; Pub. L. 107–296, sec. 102, 306(c); Pub. L. 108–458, sec. 8306.

Reginald Brothers,

Under Secretary for Science and Technology, DHS.

DEPARTMENT OF AGRICULTURE

List of Subjects in 7 CFR Part 1c

Human research subjects, Reporting and record-keeping requirements, Research.

■ For the reasons stated in the preamble, the Department of Agriculture revises 7 CFR part 1c as set forth at the end of the common preamble of this document.

PART 1c—PROTECTION OF HUMAN SUBJECTS

- Sec.
- 1c.101 To what does this policy apply?
- 1c.102 Definitions for purposes of this policy.
- 1c.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.
- 1c.104 Exempt research.
- 1c.105 [Reserved]
- 1c.106 [Reserved]
- 1c.107 IRB membership.
- 1c.108 IRB functions and operations.
- 1c.109 IRB review of research.
- 1c.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 1c.111 Criteria for IRB approval of research.
- 1c.112 Review by institution.
- 1c.113 Suspension or termination of IRB approval of research.
- 1c.114 Cooperative research.
- 1c.115 IRB records.
- 1c.116 General requirements for informed consent.
- 1c.117 Documentation of informed consent.
- 1c.118 Applications and proposals lacking definite plans for involvement of human subjects.
- 1c.119 Research undertaken without the intention of involving human subjects.
- 1c.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.
- 1c.121 [Reserved]
- 1c.122 Use of Federal funds.
- 1c.123 Early termination of research support: Evaluation of applications and proposals.
- 1c.124 Conditions.

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

Ann M. Bartuska,

Acting Under Secretary for Research, Education, and Economics, USDA.

DEPARTMENT OF ENERGY

List of Subjects in 10 CFR Part 745

10 CFR Part 745

Human research subjects, Reporting and record-keeping requirements, Research.

■ For the reasons stated in the preamble, the Department of Energy revises 10 CFR part 745 as set forth at the end of the common preamble of this document.

PART 745—PROTECTION OF HUMAN SUBJECTS

- Sec.
- 745.101 To what does this policy apply?
- 745.102 Definitions for purposes of this policy.
- 745.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.
- 745.104 Exempt research.
- 745.105 [Reserved]
- 745.106 [Reserved]
- 745.107 IRB membership.
- 745.108 IRB functions and operations.
- 745.109 IRB review of research.
- 745.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 745.111 Criteria for IRB approval of research.
- 745.112 Review by institution.
- 745.113 Suspension or termination of IRB approval of research.
- 745.114 Cooperative research.
- 745.115 IRB records.
- 745.116 General requirements for informed consent.
- 745.117 Documentation of informed consent.
- 745.118 Applications and proposals lacking definite plans for involvement of human subjects.
- 745.119 Research undertaken without the intention of involving human subjects.
- 745.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.
- 745.121 [Reserved]
- 745.122 Use of Federal funds.
- 745.123 Early termination of research support: Evaluation of applications and proposals.
- 745.124 Conditions.

Authority: 5 U.S.C. 301; 42 U.S.C. 7254; 42 U.S.C. 300v–1(b).

Elizabeth Sherwood-Randall,
Deputy Secretary of Energy.

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

List of Subjects in 14 CFR Part 1230

14 CFR Part 1230

Human research subjects, Reporting and record-keeping requirements, Research.

■ For the reasons stated in the preamble, the National Aeronautics and Space Administration revises 14 CFR part 1230 as set forth at the end of the common preamble of this document.

PART 1230—PROTECTION OF HUMAN SUBJECTS

Sec.

- 1230.101 To what does this policy apply?
- 1230.102 Definitions for purposes of this policy.
- 1230.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.
- 1230.104 Exempt research.
- 1230.105 [Reserved]
- 1230.106 [Reserved]
- 1230.107 IRB membership.
- 1230.108 IRB functions and operations.
- 1230.109 IRB review of research.
- 1230.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 1230.111 Criteria for IRB approval of research.
- 1230.112 Review by institution.
- 1230.113 Suspension or termination of IRB approval of research.
- 1230.114 Cooperative research.
- 1230.115 IRB records.
- 1230.116 General requirements for informed consent.
- 1230.117 Documentation of informed consent.
- 1230.118 Applications and proposals lacking definite plans for involvement of human subjects.
- 1230.119 Research undertaken without the intention of involving human subjects.
- 1230.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.
- 1230.121 [Reserved]
- 1230.122 Use of Federal funds.
- 1230.123 Early termination of research support: Evaluation of applications and proposals.
- 1230.124 Conditions.

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

James D. Polk,
Chief Health and Medical Officer, NASA.

DEPARTMENT OF COMMERCE

List of Subjects in 15 CFR Part 27

15 CFR Part 27

Human research subjects, Reporting and record-keeping requirements, Research.

■ For the reasons stated in the preamble, the Department of Commerce revises 15 CFR part 27 as set forth at the end of the common preamble of this document.

PART 27—PROTECTION OF HUMAN SUBJECTS

Sec.

- 27.101 To what does this policy apply?
- 27.102 Definitions for purposes of this policy.
- 27.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.
- 27.104 Exempt research.
- 27.105 [Reserved]
- 27.106 [Reserved]
- 27.107 IRB membership.
- 27.108 IRB functions and operations.
- 27.109 IRB review of research.
- 27.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 27.111 Criteria for IRB approval of research.
- 27.112 Review by institution.
- 27.113 Suspension or termination of IRB approval of research.
- 27.114 Cooperative research.
- 27.115 IRB records.
- 27.116 General requirements for informed consent.
- 27.117 Documentation of informed consent.
- 27.118 Applications and proposals lacking definite plans for involvement of human subjects.
- 27.119 Research undertaken without the intention of involving human subjects.
- 27.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.
- 27.121 [Reserved]
- 27.122 Use of Federal funds.
- 27.123 Early termination of research support: Evaluation of applications and proposals.
- 27.124 Conditions.

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

James Hock,
Chief of Staff, Department of Commerce.

SOCIAL SECURITY ADMINISTRATION

List of Subjects in 20 CFR Part 431

20 CFR Part 431

Human research subjects, Reporting and record-keeping requirements, Research.

■ For the reasons stated in the preamble, the Social Security Administration adds 20 CFR part 431 as set forth at the end of the common preamble of this document.

PART 431—PROTECTION OF HUMAN SUBJECTS

Sec.

- 431.101 To what does this policy apply?
- 431.102 Definitions for purposes of this policy.
- 431.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.
- 431.104 Exempt research.
- 431.105 [Reserved]
- 431.106 [Reserved]
- 431.107 IRB membership.
- 431.108 IRB functions and operations.
- 431.109 IRB review of research.
- 431.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 431.111 Criteria for IRB approval of research.
- 431.112 Review by institution.
- 431.113 Suspension or termination of IRB approval of research.
- 431.114 Cooperative research.
- 431.115 IRB records.
- 431.116 General requirements for informed consent.
- 431.117 Documentation of informed consent.
- 431.118 Applications and proposals lacking definite plans for involvement of human subjects.
- 431.119 Research undertaken without the intention of involving human subjects.
- 431.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.
- 431.121 [Reserved]
- 431.122 Use of Federal funds.
- 431.123 Early termination of research support: Evaluation of applications and proposals.
- 431.124 Conditions.

Authority: 5 U.S.C. 301; 42 U.S.C. 289(a).

Carolyn W. Colvin,

Acting Commissioner of Social Security.

AGENCY FOR INTERNATIONAL DEVELOPMENT

List of Subjects in 22 CFR Part 225

22 CFR Part 225

Human research subjects, Reporting and record-keeping requirements, Research.

■ For the reasons stated in the preamble, the Agency for International Development revises 22 CFR part 225 as set forth at the end of the common preamble of this document.

PART 225—PROTECTION OF HUMAN SUBJECTS

Sec.

- 225.101 To what does this policy apply?
- 225.102 Definitions for purposes of this policy.
- 225.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.
- 225.104 Exempt research.
- 225.105 [Reserved]
- 225.106 [Reserved]
- 225.107 IRB membership.
- 225.108 IRB functions and operations.
- 225.109 IRB review of research.
- 225.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 225.111 Criteria for IRB approval of research.
- 225.112 Review by institution.
- 225.113 Suspension or termination of IRB approval of research.
- 225.114 Cooperative research.
- 225.115 IRB records.
- 225.116 General requirements for informed consent.
- 225.117 Documentation of informed consent.
- 225.118 Applications and proposals lacking definite plans for involvement of human subjects.
- 225.119 Research undertaken without the intention of involving human subjects.
- 225.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.
- 225.121 [Reserved]
- 225.122 Use of Federal funds.
- 225.123 Early termination of research support: Evaluation of applications and proposals.
- 225.124 Conditions.

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b), unless otherwise noted.

Irene Koek,

Acting Deputy Assistant Administrator for Global Health, U.S. Agency for International Development.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

List of Subjects in 24 CFR Part 60

24 CFR Part 60

Human research subjects, Reporting and record-keeping requirements, Research.

■ For the reasons stated in the preamble, the Department of Housing and Urban Development revises 24 CFR part 60 as set forth at the end of the common preamble of this document.

PART 60—PROTECTION OF HUMAN SUBJECTS

Sec.

- 60.101 To what does this policy apply?
- 60.102 Definitions for purposes of this policy.
- 60.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.
- 60.104 Exempt research.
- 60.105 [Reserved]
- 60.106 [Reserved]
- 60.107 IRB membership.
- 60.108 IRB functions and operations.
- 60.109 IRB review of research.
- 60.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 60.111 Criteria for IRB approval of research.
- 60.112 Review by institution.
- 60.113 Suspension or termination of IRB approval of research.
- 60.114 Cooperative research.
- 60.115 IRB records.
- 60.116 General requirements for informed consent.
- 60.117 Documentation of informed consent.
- 60.118 Applications and proposals lacking definite plans for involvement of human subjects.
- 60.119 Research undertaken without the intention of involving human subjects.
- 60.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.
- 60.121 [Reserved]
- 60.122 Use of Federal funds.
- 60.123 Early termination of research support: Evaluation of applications and proposals.
- 60.124 Conditions.

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b) and 3535(d).

Katherine M. O'Regan,

Assistant Secretary for Policy Development and Research, Department of Housing and Urban Development.

DEPARTMENT OF LABOR

List of Subjects in 29 CFR Part 21

29 CFR Part 21

Human research subjects, Reporting and record-keeping requirements, Research.

■ For the reasons stated in the preamble, the Department of Labor adds 29 CFR part 21 as set forth at the end of the common preamble of this document.

PART 21—PROTECTION OF HUMAN SUBJECTS

Sec.

- 21.101 To what does this policy apply?
- 21.102 Definitions for purposes of this policy.
- 21.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.
- 21.104 Exempt research.
- 21.105 [Reserved]
- 21.106 [Reserved]
- 21.107 IRB membership.
- 21.108 IRB functions and operations.
- 21.109 IRB review of research.
- 21.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 21.111 Criteria for IRB approval of research.
- 21.112 Review by institution.
- 21.113 Suspension or termination of IRB approval of research.
- 21.114 Cooperative research.
- 21.115 IRB records.
- 21.116 General requirements for informed consent.
- 21.117 Documentation of informed consent.
- 21.118 Applications and proposals lacking definite plans for involvement of human subjects.
- 21.119 Research undertaken without the intention of involving human subjects.
- 21.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.
- 21.121 [Reserved]
- 21.122 Use of Federal funds.
- 21.123 Early termination of research support: Evaluation of applications and proposals.
- 21.124 Conditions.

Authority: 5 U.S.C. 301; 29 U.S.C. 551.

Christopher P. Lu,
Deputy Secretary of Labor.

DEPARTMENT OF DEFENSE

List of Subjects in 32 CFR Part 219

32 CFR Part 219

Human research subjects, Reporting and record-keeping requirements, Research.

■ For the reasons stated in the preamble, the Department of Defense revises 32 CFR part 219 as set forth at the end of the common preamble of this document.

PART 219—PROTECTION OF HUMAN SUBJECTS

Sec.

- 219.101 To what does this policy apply?
- 219.102 Definitions for purposes of this policy.
- 219.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.
- 219.104 Exempt research.
- 219.105 [Reserved]
- 219.106 [Reserved]
- 219.107 IRB membership.
- 219.108 IRB functions and operations.
- 219.109 IRB review of research.
- 219.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 219.111 Criteria for IRB approval of research.
- 219.112 Review by institution.
- 219.113 Suspension or termination of IRB approval of research.
- 219.114 Cooperative research.
- 219.115 IRB records.
- 219.116 General requirements for informed consent.
- 219.117 Documentation of informed consent.
- 219.118 Applications and proposals lacking definite plans for involvement of human subjects.
- 219.119 Research undertaken without the intention of involving human subjects.
- 219.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.
- 219.121 [Reserved]
- 219.122 Use of Federal funds.
- 219.123 Early termination of research support: Evaluation of applications and proposals.
- 219.124 Conditions.

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

Stephen P. Welby,
Assistant Secretary of Defense (Research and Engineering).

DEPARTMENT OF EDUCATION

List of Subjects in 34 CFR Part 97

Human research subjects, Reporting and record-keeping requirements, Research.

■ For the reasons stated in the preamble, the Department of Education amends 34 CFR part 97 as follows:

PART 97—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 5 U.S.C. 301; 20 U.S.C. 1221e–3, 3474; 42 U.S.C. 300v–1(b).

■ 2. Subpart A is revised as set forth at the end of the common preamble of this document.

Subpart A—Federal Policy for the Protection of Human Subjects (Basic ED Policy for Protection of Human Research Subjects)

Sec.

- 97.101 To what does this policy apply?
- 97.102 Definitions for purposes of this policy.
- 97.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.
- 97.104 Exempt research.
- 97.105 [Reserved]
- 97.106 [Reserved]
- 97.107 IRB membership.
- 97.108 IRB functions and operations.
- 97.109 IRB review of research.
- 97.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 97.111 Criteria for IRB approval of research.
- 97.112 Review by institution.
- 97.113 Suspension or termination of IRB approval of research.
- 97.114 Cooperative research.
- 97.115 IRB records.
- 97.116 General requirements for informed consent.
- 97.117 Documentation of informed consent.
- 97.118 Applications and proposals lacking definite plans for involvement of human subjects.
- 97.119 Research undertaken without the intention of involving human subjects.
- 97.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.
- 97.121 [Reserved]
- 97.122 Use of Federal funds.
- 97.123 Early termination of research support: Evaluation of applications and proposals.

97.124 Conditions.

John B. King Jr.,
Secretary of Education.

DEPARTMENT OF VETERANS AFFAIRS

List of Subjects in 38 CFR Part 16

38 CFR Part 16

Human research subjects, Reporting and record-keeping requirements, Research.

■ For the reasons stated in the preamble, the Department of Veterans Affairs revises 38 CFR part 16 as set forth at the end of the common preamble of this document.

PART 16—PROTECTION OF HUMAN SUBJECTS

Sec.

- 16.101 To what does this policy apply?
- 16.102 Definitions for purposes of this policy.
- 16.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.
- 16.104 Exempt research.
- 16.105 [Reserved]
- 16.106 [Reserved]
- 16.107 IRB membership.
- 16.108 IRB functions and operations.
- 16.109 IRB review of research.
- 16.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 16.111 Criteria for IRB approval of research.
- 16.112 Review by institution.
- 16.113 Suspension or termination of IRB approval of research.
- 16.114 Cooperative research.
- 16.115 IRB records.
- 16.116 General requirements for informed consent.
- 16.117 Documentation of informed consent.
- 16.118 Applications and proposals lacking definite plans for involvement of human subjects.
- 16.119 Research undertaken without the intention of involving human subjects.
- 16.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.
- 16.121 [Reserved]
- 16.122 Use of Federal funds.
- 16.123 Early termination of research support: Evaluation of applications and proposals.
- 16.124 Conditions.

Authority: 5 U.S.C. 301; 38 U.S.C. 501, 7331, 7334; 42 U.S.C. 300v–1(b).

Gina S. Farrisee,

Deputy Chief of Staff, U.S. Department of Veterans Affairs.

ENVIRONMENTAL PROTECTION AGENCY

List of Subjects in 40 CFR Part 26

40 CFR Part 26

Human research subjects, Reporting and record-keeping requirements, Research.

■ For the reasons stated in the preamble, the Environmental Protection Agency amends 40 CFR part 26 as follows:

PART 26—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for part 26 continues to read as follows:

Authority: 5 U.S.C. 301; 7 U.S.C. 136a(a) and 136w(a)(1); 21 U.S.C. 346a(e)(1)(C); sec. 201, Pub. L. 109–54, 119 Stat. 531; and 42 U.S.C. 300v–1(b).

■ 2. Subpart A is revised as set forth at the end of the common preamble of this document.

Subpart A—Basic EPA Policy for Protection of Subjects in Human Research Conducted or Supported by EPA

Sec.

- 26.101 To what does this policy apply?
- 26.102 Definitions for purposes of this policy.
- 26.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.
- 26.104 Exempt research.
- 26.105 [Reserved]
- 26.106 [Reserved]
- 26.107 IRB membership.
- 26.108 IRB functions and operations.
- 26.109 IRB review of research.
- 26.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 26.111 Criteria for IRB approval of research.
- 26.112 Review by institution.
- 26.113 Suspension or termination of IRB approval of research.
- 26.114 Cooperative research.
- 26.115 IRB records.
- 26.116 General requirements for informed consent.
- 26.117 Documentation of informed consent.
- 26.118 Applications and proposals lacking definite plans for involvement of human subjects.
- 26.119 Research undertaken without the intention of involving human subjects.
- 26.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.
- 26.121 [Reserved]
- 26.122 Use of Federal funds.

26.123 Early termination of research support: Evaluation of applications and proposals.

26.124 Conditions.

A. Stanley Meiburg,

Acting Deputy Administrator, Environmental Protection Agency.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

List of Subjects in 45 CFR Part 46

45 CFR Part 46

Human research subjects, Reporting and record-keeping requirements, Research.

■ For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR part 46 as follows:

PART 46—PROTECTION OF HUMAN SUBJECTS

■ 1. The authority citation for part 46 is revised to read as follows:

Authority: 5 U.S.C. 301; 42 U.S.C. 289(a); 42 U.S.C. 300v–1(b).

■ 2. Subpart A is revised as set forth at the end of the common preamble of this document.

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

Sec.

- 46.101 To what does this policy apply?
- 46.102 Definitions for purposes of this policy.
- 46.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.
- 46.104 Exempt research.
- 46.105 [Reserved]
- 46.106 [Reserved]
- 46.107 IRB membership.
- 46.108 IRB functions and operations.
- 46.109 IRB review of research.
- 46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 46.111 Criteria for IRB approval of research.
- 46.112 Review by institution.
- 46.113 Suspension or termination of IRB approval of research.
- 46.114 Cooperative research.
- 46.115 IRB records.
- 46.116 General requirements for informed consent.
- 46.117 Documentation of informed consent.
- 46.118 Applications and proposals lacking definite plans for involvement of human subjects.
- 46.119 Research undertaken without the intention of involving human subjects.
- 46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.
- 46.121 [Reserved]
- 46.122 Use of Federal funds.

46.123 Early termination of research support: Evaluation of applications and proposals.

46.124 Conditions.

Sylvia M. Burwell,

Secretary, HHS.

NATIONAL SCIENCE FOUNDATION

List of Subjects in 45 CFR Part 690

45 CFR Part 690

Human research subjects, Reporting and record-keeping requirements, Research.

■ For the reasons stated in the preamble, the National Science Foundation revises 45 CFR part 690 as set forth at the end of the common preamble of this document.

PART 690—PROTECTION OF HUMAN SUBJECTS

Sec.

- 690.101 To what does this policy apply?
- 690.102 Definitions for purposes of this policy.
- 690.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.
- 690.104 Exempt research.
- 690.105 [Reserved]
- 690.106 [Reserved]
- 690.107 IRB membership.
- 690.108 IRB functions and operations.
- 690.109 IRB review of research.
- 690.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
- 690.111 Criteria for IRB approval of research.
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- 690.119 Research undertaken without the intention of involving human subjects.
- 690.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.
- 690.121 [Reserved]
- 690.122 Use of Federal funds.
- 690.123 Early termination of research support: Evaluation of applications and proposals.
- 690.124 Conditions.

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

Lawrence Rudolph,
General Counsel, National Science Foundation.

DEPARTMENT OF TRANSPORTATION

List of Subjects in 49 CFR Part 11

49 CFR Part 11

Human research subjects, Reporting and record-keeping requirements, Research.

■ For the reasons stated in the preamble, the Department of Transportation revises 49 CFR part 11 as set forth at the end of the common preamble of this document.

PART 11—PROTECTION OF HUMAN SUBJECTS

Sec.

- 11.101 To what does this policy apply?
- 11.102 Definitions for purposes of this policy.
- 11.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.
- 11.104 Exempt research.
- 11.105 [Reserved]
- 11.106 [Reserved]
- 11.107 IRB membership.
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- 11.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.
- 11.121 [Reserved]
- 11.122 Use of Federal funds.
- 11.123 Early termination of research support: Evaluation of applications and proposals.
- 11.124 Conditions.

Authority: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

Anthony R. Foxx,
Secretary of Transportation.

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Part X

Department of Energy

10 CFR Part 430

Energy Conservation Program: Energy Conservation Standards for General Service Lamps; Final Rules

DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket Number EERE–2013–BT–STD–0051]

RIN 1904–AD09

Energy Conservation Program: Energy Conservation Standards for General Service Lamps

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule.

SUMMARY: On March 17, 2016, the U.S. Department of Energy (DOE) published a notice of proposed rulemaking (NPR) proposing standards for general service lamps (GSLs) pursuant to the Energy Policy and Conservation Act of 1975 (EPCA), as amended. DOE responds to comments received on the NOPDDA in this final rule and adopts a revised definition of GSL and other supplemental definitions.

DATES: The effective date of this rule is January 1, 2020.

ADDRESSES: The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at www.regulations.gov. All documents in the docket are listed in the www.regulations.gov index. However, some documents listed in the index may not be publicly available, such as those containing information that is exempt from public disclosure.

A link to the docket Web page can be found at: https://www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=4. This Web page contains a link to the docket for this document on the www.regulations.gov site. The www.regulations.gov Web page contains simple instructions on how to access all documents, including public comments, in the docket.

FOR FURTHER INFORMATION CONTACT: Ms. Lucy deButts, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–2J, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 287–1604. Email: ApplianceStandardsQuestions@ee.doe.gov.

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I. Introduction

Title III, Part B of the Energy Policy and Conservation Act of 1975 (EPCA or the Act), Public Law 94–163 (42 U.S.C. 6291–6309, as codified) established the Energy Conservation Program for Consumer Products Other Than

Automobiles, a program covering most major household appliances (collectively referred to as “covered products”).¹ Subsequent amendments expanded Title III of EPCA to include additional consumer products, including general service lamps (GSLs)—the products that are the focus of this final rule.

In particular, amendments to EPCA in the Energy Independence and Security Act of 2007 (EISA 2007) directed DOE to engage in rulemakings regarding GSLs. (42 U.S.C. 6295(i)(6)(A)–(B)) EPCA, as amended by EISA 2007, directs DOE to initiate a rulemaking no later than January 1, 2014, to determine whether standards in effect for GSLs should be amended and determine whether exemptions for certain incandescent lamps should be maintained or discontinued. (42 U.S.C. 6295(i)(6)(A)(i)) The scope of the rulemaking is not limited to incandescent lamp technologies. (42 U.S.C. 6295(i)(6)(A)(ii)) Further, for this first cycle of rulemaking, the EISA 2007 amendments provide that DOE must consider a minimum standard of 45 lumens per watt (lm/W). (42 U.S.C. 6295(i)(6)(A)(ii)) If DOE fails to complete a rulemaking in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv) or a final rule from the first rulemaking cycle does not produce savings greater than or equal to the savings from a minimum efficacy standard of 45 lm/W, the statute provides a “backstop” under which DOE must prohibit sales of GSLs that do not meet a minimum 45 lm/W standard beginning on January 1, 2020. (42 U.S.C. 6295(i)(6)(A)(v))

In March 2016, DOE published a notice of proposed rulemaking (NPR) that proposed a revised definition of GSL and energy conservation standards for certain GSLs (hereafter the “March 2016 GSL ECS NOPR”). 81 FR 14528 (March 17, 2016). In conjunction with the March 2016 GSL ECS NOPR, DOE also published on its Web site the complete technical support document (TSD) for the proposed rule, which described the analyses DOE conducted and included technical documentation for each analysis. The TSD also included the life cycle cost (LCC) spreadsheet, the national impact analysis spreadsheet, and the manufacturer impact analysis (MIA) spreadsheet.²

DOE held a public meeting on April 20, 2016, to hear oral comments on and

¹ Part B was re-designated Part A on codification in the U.S. Code for editorial reasons.

² The spreadsheets developed for this rulemaking proceeding are available at: https://www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=4.

solicit information relevant to the proposed rule. At this meeting, DOE heard concerns from stakeholders regarding the expansion of scope in the proposed GSL definition and DOE's approach to analyzing the 22 GSL exemptions. In addition, DOE received written comments that reiterated concerns, and also provided additional data for DOE's consideration. Specifically, the National Electrical Manufacturers Association (NEMA) provided new data and information on the 22 exempted lamp types to inform DOE's evaluation of whether the exemptions should be maintained or discontinued as required by 42 U.S.C. 6295(i)(6)(A)(i)(II).

After the publication of the March 2016 GSL ECS NOPR, DOE analyzed the data submitted by NEMA and collected additional data where available. DOE published a notice of proposed definition and data availability (hereafter the "October 2016 NOPDDA") to: (1) Propose a revised definition of GSL; (2) announce the availability of the NEMA data and supplemental data collected by DOE; (3) request public comment on proposed definitions and compiled data; and (4) request any additional data that stakeholders may have in support of this evaluation. 81 FR 71794 (October 18, 2016). DOE also held a public meeting on October 21, 2016 to hear oral comments and solicit information relevant to the October 2016 NOPDDA.

Utility Coalition urged DOE to finalize this rulemaking before the January 1, 2017 deadline set by EISA 2007. Additionally, Utility Coalition recommended that if any of their comments would cause DOE to miss the deadline, then the comments should be deferred to the next GSL rulemaking. (Utility Coalition, No. 95 at pp. 1–2) Philips Lighting (Philips) also urged DOE to complete the rulemaking on time. (Philips, No. 96 at p. 2)

The following sections of this preamble respond to comments received on the October 2016 NOPDDA and during the NOPDDA public meeting, except those specifically related to incandescent reflector lamps, and describe the adopted GSL definition and additional data in more detail. In a separate final rule DOE is responding to comments specifically related to incandescent reflector lamps.

II. Authority and Rulemaking Process

DOE is required under the EISA 2007 amendments to EPCA to undertake the present rulemaking. Under EPCA, DOE shall initiate a rulemaking to determine whether standards in effect for GSLs should be amended to establish more

stringent standards; and determine whether exemptions for certain incandescent lamps should be maintained or discontinued. (42 U.S.C. 6295(i)(6)(A)(i)) In addition to that mandate, DOE has the authority to qualify lamps as general service lamps upon determining that they are "used to satisfy lighting applications traditionally served by general service incandescent lamps." (42 U.S.C. 6291(30)(BB)(i)(IV))

An additional statute relevant to this rulemaking is section 312 of the Consolidated and Further Continuing Appropriations Act, 2016 (Pub. L. 114–113, 129 Stat. 2419; hereafter referred to as the "Appropriations Rider") that prohibits expenditure of funds appropriated by that law to implement or enforce: (1) 10 CFR 430.32(x), which includes maximum wattage and minimum rated lifetime requirements for GSILs; and (2) standards set forth in section 325(i)(1)(B) of EPCA (42 U.S.C. 6295(i)(1)(B)), which sets minimum lamp efficiency ratings for incandescent reflector lamps (IRLs).³

This final rule constitutes a decision on whether to maintain or discontinue various lamp exemptions and, in addition, DOE is determining that certain types of lamps should be included as GSLs because they are used for lighting applications traditionally served by GSILs. This final rule does not determine whether DOE should impose or amend standards for any category of lamps, such as GSILs or GSLs.

As discussed in more detail, DOE is grounding the first of those decisions, namely which exemptions to maintain or discontinue, on an assessment of whether lamps within a given exemption would provide a convenient unregulated alternative to lamps that will be subject to energy conservation standards. In DOE's view, EPCA exempted certain categories of lamps because, on the one hand, some lamps in those categories have specialty applications; and on the other hand, it was not clear, when these lamp provisions were enacted, whether those lamps were part of the broader lamp market to which Congress wished to apply energy conservation standards. The purpose, then, of the decision that Congress entrusted to DOE, to maintain or to discontinue a given exemption, was that DOE should assess the role of

lamps of that type in the broader lighting market, bearing in mind the evident statutory purpose of achieving energy conservation by imposing efficiency standards for general lighting.

While the statute does not expressly state a criterion by which DOE should decide which exemptions to maintain—it simply identifies one important evidentiary input, sales data—DOE understands its instruction to be that DOE should maintain an exemption if doing so would be consistent with that statutory purpose, and discontinue the exemption if it would not. To carry out that instruction, DOE has assessed for each exemption whether lamps within that exemption are readily substitutable for lamps that are already categorized as general service lamps. Sales data, as the statute directs, are an important type of evidence informing that assessment.

The discontinuation of certain exemptions will render the lamps within those exemptions GSLs, to the extent they would otherwise qualify as GSLs, and for some lamps GSILs. As the October 2016 NOPDDA observed, DOE will then either impose standards on these lamps pursuant to its authority to develop GSL standards or apply the backstop standard prohibiting the sale of lamps not meeting a 45 lm/W efficacy standard.

Commenters, chief among them LEDVANCE, objected to both the procedures that DOE undertook and the substance of what it proposed to determine. In general, LEDVANCE contended that DOE cannot make lamps subject to a given standard—whether a DOE-developed standard or the backstop—simply by undertaking a definitional exercise such as it proposed in the October 2016 NOPDDA. (LEDVANCE, No. 90 at p. 3) LEDVANCE offered multiple, connected arguments in support of that general position.

First, LEDVANCE pointed out that, in general, section 6295 requires DOE to conduct certain analyses and carry out certain procedures when it amends standards. Under section 6295(o), "[a]ny new or amended energy conservation standard prescribed by the Secretary under this section . . . shall be designed to achieve the maximum improvement in energy efficiency" that is "technologically feasible and economically justified." 42 U.S.C. 6295(o)(2)(A). DOE cannot generally prescribe a new or amended standard if it has not prescribed a test procedure for the relevant product, or if DOE determines that the standard will not result in "significant conservation of energy." 42 U.S.C. 6295(o)(3). DOE also generally cannot prescribe a new or amended standard if it finds that the

³ This provision of the Consolidated and Further Continuing Appropriations Act, 2016 has been extended to the current appropriations authorization. See, The Continuing Appropriations and Military Construction, Veteran Affairs, and Related Agencies Appropriations Act, 2017 and Zika Response and Preparedness Act, 2017 (Pub. L. 114–223, 130 Stat. 908).

standard would “result in the unavailability in the United States” of a type of product “of performance characteristics . . . that are substantially the same as those generally available” at the time. 42 U.S.C. 6295(o)(4). Procedurally, in general to impose a new or amended standard, DOE must publish a proposed rule and permit 60 days of comment, and it cannot publish a final rule less than 90 days after the proposed rule. 42 U.S.C. 6295(p). In addition, DOE has typically taken various other procedural steps, such as publication of a framework document before the proposed rule, when it amends a standard. (LEDVANCE, No. 90 at pp. 4–5)

LEDVANCE observed that DOE is evidently not engaging in comparable substantive analyses with respect to its definition of GSL, and that DOE has not undertaken comparable procedures (including 60 days of comment). (LEDVANCE, No. 90 at pp. 4–6) DOE acknowledges those observations to be correct, and it considers its approach appropriate and consistent with the statute. The requirements that LEDVANCE cited apply, by their terms, only when DOE prescribes a new or amended standard. This final rule does neither. Rather, DOE is deciding which lamp exemptions to discontinue and which to maintain and determining that certain lamps should be GSLs because they are used to satisfy lighting applications traditionally served by GSILs.

DOE acknowledges, of course, that a likely consequence of DOE’s including additional lamps in the definition of GSL is that those lamps will be subject to energy conservation standards. DOE has the authority to impose standards for GSLs; and if it does not impose such standards or does not impose standards that meet a certain condition, then EPCA specifies a minimum standard of 45 lm/W. In LEDVANCE’s view, this consequence means that DOE must, before including a given lamp as a GSL, carry out the same type of rulemaking (in both procedure and substance) as it would in prescribing a new or amended standard.

DOE sees a difference between the two modes in which GSLs may be subject to standards. Where DOE develops its own energy conservation standards, it carries out the analyses that section 6295(o) calls for and provides the procedure that section 6295(p) mandates. But it does so in the course of developing the standards, just as sections 6295(o) and 6295(p) provide. The decision to include a lamp within the scope of GSLs would only be a precursor to that standards

development. If DOE does not develop its own energy conservation standards for GSLs, section 6295(i)(6)(A)(v) requires it to impose a standard of 45 lm/W. If that obligation were to come into force, DOE would not perform the section 6295(o) analyses or follow the section 6295(p) procedure to fulfill it. Because in that circumstance the statute itself would require DOE to prohibit sales of lamps below that standard, DOE would not be “prescrib[ing] a new or amended standard,” the situation in which sections 6295(o) and 6295(p) apply. In addition, reading those provisions harmoniously with section 6295(i)(6), DOE does not believe the section 6295(o) and section 6295(p) requirements were meant to apply to a rulemaking imposing the section 6295(i)(6)(A)(v) backstop. The backstop provision specifies by number a particular efficacy standard and says DOE “shall” prohibit sales of lamps below that standard. If the general standards-setting provisions applied in that context, DOE would have discretion, depending on the evidence, to conclude that the 45 lm/W standard is not technologically feasible or not economically justified (on the basis of the multiple factors, including “other factors the Secretary considers relevant,” that inform that assessment under section 6295(o)). For DOE to retain that discretion would be inconsistent with the mandatory language of the backstop.

Of course, for lamps that will be GSLs only as a consequence of this final rule, DOE is exercising some discretion that will result in those lamps being subject to some standard (potentially the backstop or some standard that DOE develops). Nonetheless, DOE does not believe that fact obligates it to engage in section 6295(o) analyses or section 6295(p) procedures for this rule—either as a matter of law or for the sake of sound decision making.

The scheme that section 6295(i)(6) establishes for GSLs differs in important ways from what is in place for consumer products in general under section 6295. For most products, DOE has discretion to develop the initial standards or to amend, in the course of periodic reviews, standards initially set by statute. Using that authority, DOE could in principle set any type of standard, such as a level of performance or a design requirement, with far-reaching consequences for the products at issue. To guide that exercise of discretion, Congress has laid out various restrictions on the standards-setting authority and substantive factors that DOE must consider. By contrast, in section 6295(i)(6), Congress expressed a

strong preference for 45 lm/W as an efficacy standard. If DOE takes no other action, that will be the standard for GSLs. Congress permitted DOE to establish different standards if DOE chooses to do so and can demonstrate that an alternative set of standards would produce at least as much energy savings. But in the rulemaking to consider whether to set different standards, DOE must consider the alternative of effectively setting a 45 lm/W standard for all GSLs, whereby DOE would simply not take the option that Congress provided for setting other standards, and instead adopt Congress’s default standard.

At the same time, Congress exempted certain lamps from the GSL definition, and included within the scope of GSLs a category that left room for some additions. In both of these areas, DOE’s authority is tightly circumscribed. With respect to the exemptions, DOE maintains or discontinues the exemptions as written. With respect to additions to the scope of GSLs, DOE can include additional lamps only if they satisfy lighting applications traditionally served by GSILs. In DOE’s view, Congress simply deferred the last details of the definition of GSL for final assessment by DOE. By postponing the decision in that manner, Congress did not implicitly invoke, with respect to its 45 lm/W, the whole machinery of DOE standards rulemaking under EPCA.

The backstop reflects a congressional determination that a 45 lm/W standard is appropriate. For DOE to conduct an independent assessment of the technological feasibility, economic justification, and other such factors for the 45 lm/W standard as applied to a given set of lamps would risk being inconsistent with that congressional determination. DOE believes that the most important consideration with respect to the scope of GSLs is whether leaving a given set of lamps outside GSLs would undermine the regulation that Congress mandated for GSLs, by making readily available an unregulated substitute for lamps that are subject to the standard. If so, DOE cannot freely conduct its own evaluation of the 45 lm/W standard in the course of defining the scope of GSLs. For DOE to exclude from the definition of GSLs a lamp that consumers can use and do use in the same way they use GSLs, and do so on the ground that the 45 lm/W standard is not sound policy for that type of lamp, would be inconsistent with the policy Congress set in enacting EISA 2007.

DOE acknowledges that paragraph (i)(6)(A) did not, upon enactment, require that the 45 lm/W default or a DOE-developed substitute apply to

lamps within the exemptions. But DOE believes it would be inconsistent with the EISA 2007 policy for DOE to decide whether to maintain or discontinue an exemption by assessing whether the 45 lm/W standard would be economically justified—in the sense of section 6295(o)—for the exempt lamps. Conducting that analysis could mean that even though a lamp is readily substitutable for GSLs, so that the lamp would serve as a loophole to GSL standards, DOE would find GSL standards not economically justified for that lamp. That conclusion would imply that GSL standards are not economically justified in themselves, which would contravene the statutory policy.

Similarly, if DOE were to conclude that a lamp is readily substitutable for GSLs, yet the GSL standard is not technologically feasible for that lamp—in the sense of section 6295(o)—that conclusion would imply that the GSL standard is not technologically feasible overall. While it may not be possible to make incandescent lamps suitable for many current applications that meet a 45 lm/W standard, and consequently the paragraph (i)(6)(A) standards may result in the elimination of incandescent lamps covered by the standards, that outcome is the evident policy set by EISA 2007 regarding energy use in lighting. Therefore it is reasonable not to engage in a section 6295(o) analysis of technological feasibility in reviewing the GSL exemptions.

DOE bases the preceding discussion on the overall structure of section 6295(i)(6). The particular language describing DOE's tasks regarding the definition of GSLs further supports DOE's conclusion. With respect to the exemptions, section 6295(i)(6)(A)(i)(II) says that DOE shall make its decision to maintain or discontinue exemptions “based, in part, on exempted lamp sales collected . . . from manufacturers.” If DOE were supposed to carry out a full section 6295(o) analysis for this decision, lamp sales would be one among very many strands of evidence; under section 6295(o) DOE is to consider factors like the operating costs of a product over its lifetime, the energy savings from a proposed standard, how the standard will affect the utility of the product, the impact on competition, and other factors. 42 U.S.C. 6295(o)(2)(B). It seems odd that, among all the things at issue in a section 6295(o) analysis, section 6295(i)(6)(A)(i)(II) would call out just one specific item, sales data. By contrast, DOE believes its task is to assess whether lamps in a given exemption are a ready substitute for lamps that are not exempt, as that assessment relies upon sales data as an

important input. Thus, the statutory reference to a decision “based, in part, on exempted lamp sales” makes much more sense under DOE's reading of the statute.

With respect to the fourth type of GSLs provided for under the statutory definition, the statute requires a specific finding. DOE can include a lamp within GSLs if it determines that such lamps satisfy lighting applications traditionally served by GSILs. 42 U.S.C. 6291(30)(BB)(i)(IV). The particularity of that finding is not consistent with the notion that DOE should, in making that finding, carry out a section 6295(o) analysis. The factual question is whether a lamp satisfies traditional GSIL applications. Questions about, for example, how a given standard would affect the lamp's operating costs do not seem relevant to that factual question.

LEDVANCE offered several arguments against DOE's interpretation of section 6295(i)(6)(A). First, LEDVANCE pointed out that in some other parts of section 6295, a decision about what products are covered is subject to section 6295(o) analysis and section 6295(p) procedures. As examples, LEDVANCE cited sections 6295(g)(7)(B) and 6295(i)(5). The former says that DOE shall publish a rule to determine “whether to amend the standards in effect for fluorescent lamp ballasts, including whether such standards should be amended such that they would be applicable to additional fluorescent lamp ballasts.” The latter requires DOE to begin a rulemaking “to determine if the standards in effect for fluorescent lamps and incandescent lamps should be amended so that they would be applicable to additional” lamps. (LEDVANCE, No. 90 at pp. 4–6)

By their terms, however, these provisions say that certain decisions about scope involve setting standards, and therefore are textually different from sections 6295(i)(6)(A) and 6291(30)(BB). That textual difference is also consistent with the preceding framework. In a section 6295(g)(7)(B) or 6295(i)(5) rule, DOE would be developing its own “amended” standard and simultaneously might be imposing that amended standard on a new set of products. That is the sort of situation in which, pursuant to the preceding explanation, sections 6295(o) and 6295(p) could come into play. Here, by contrast, DOE is conducting a circumscribed coverage decision, in light of considerations coming from sections 6291(30)(BB) and 6295(i)(6)(A), that may result in products being subject to a standard already set by Congress.

LEDVANCE also observed that in final rules in 2009 and 2015, DOE engaged in section 6295(o)-type analysis when deciding what products to subject to the standards set in those rules. (LEDVANCE, No. 90 at p. 5) However, those past situations were different from today's. Both rules were, in relevant part, responses to section 6295(i)(5). Thus, the statutory requirements were different from those at issue in this rule, for the reasons just given. And, apart from the statutory mandate, the substantive factors that were important for the decisions were different, for the preceding reasons.

LEDVANCE offered an additional statutory argument based on EISA 2007. Section 321 of EISA included a provision under which “[a]ny person may petition the Secretary to establish standards for lamp shapes or bases that are excluded from the definition of general service lamps.” DOE “shall grant a petition,” said section 321, if the evidence shows “that commercial availability or sales of exempted incandescent lamp types of have increased significantly . . . and likely are being widely used in general lighting applications” and “significant energy savings could be achieved by covering exempted products.” If DOE were to grant such a petition, then it would have to conduct a rulemaking “to determine standards for the exempted lamp shape or base,” and it would be required to complete that rulemaking “not later than 18 months after the date on which notice is provided granting the petition.” Public Law 110–140, section 321(a)(3), 121 Stat. 1579.⁴ According to LEDVANCE, Congress would not have simultaneously prescribed this procedure and given DOE what LEDVANCE calls “nearly unfettered discretion to unilaterally remove these same exclusions without any substantive economic or technical analysis.” (LEDVANCE, No. 90 at p. 5)

DOE notes that its discretion regarding the exemptions is far from unfettered, and it rejects the notion that it is allowed to remove them, or is removing them, “without any substantive economic or technical analysis.” As laid out in the October 2016 NOPDDA, and as discussed in detail in section III.A.1, DOE's consideration of whether lamps in a

⁴ Section 321 added this provision as paragraph 325(i)(1)(E) of EPCA. Section 322(b) of EISA purported to strike paragraph 325(i)(1) in its entirety and replace it with a different text that did not include the material previously quoted. In its consideration of the argument that LEDVANCE put forward, DOE need not resolve how sections 321 and 322 interact and what is the current status of the provisions that section 321 added to EPCA section 325(i)(1).

given exemption are ready substitutes for lamps already considered GSLs reflects a range of factors. For example, DOE has considered sales data as evidence of how lamps are being used. These considerations are not the same as the analysis DOE would conduct in developing an amended standard, but it is incorrect to suggest that DOE has performed no substantive analysis at all.

In any case, the language in EISA section 321 is more consistent with DOE's understanding of its current task. DOE notes that the petition process was to proceed in two stages. First, DOE was to decide whether to grant a petition. The statute laid out certain criteria for that decision, including whether a given lamp type is likely being widely used in general lighting applications. Those criteria are different from the considerations described in 42 U.S.C. 6295(o). Second, if DOE granted a petition, it was to conduct a rulemaking to decide what standards to impose. Presumably, DOE would conduct a section 6295(o) analysis in evaluating standards at that point. But the section 321 language clearly distinguishes the two stages: It instructs DOE to do a standards-setting rulemaking "if" it grants a petition, and to complete the rulemaking within 18 months "after the date on which notice is provided granting the petition." Evidently, the decision on the petition itself is not a rule prescribing standards. Similarly and by analogy, the current rule defines what are GSLs, and is not a rule prescribing standards to which sections 6295(o) and 6295(p) apply.

LEDVANCE further contended that the adoption of the petition process forecloses DOE's authority to maintain or discontinue exemptions as it does in this rule. (LEDVANCE, No. 90 at p. 5) However, section 321 itself provided both mechanisms: The response to petitions and the decision whether to continue or maintain exemptions.⁵ Section 321 established certain procedures and criteria for responding to petitions. For the second type of decision, it did not prescribe the same considerations, either explicitly or by reference.

DOE does not read 42 U.S.C. 6295(i)(6)(A)(i)(II) to implicitly invoke the same considerations. The petition process is distinct and independent from the decision to discontinue an exemption. When DOE discontinues an exemption, the previously exempted

lamp is included among GSLs. By contrast, the petition provision from EISA section 321 does not suggest that DOE would end an exemption, thus rendering a type of lamp a GSL. To the contrary, the petition process applies only to lamps that *are* exempted. Through that process, DOE could, if the petition satisfies certain prerequisites, establish standards even though the lamps are exempted from being GSLs. Further, because discontinuing an exemption under section 6295(i)(6)(A)(i) causes the affected lamps to be GSLs, the lamps become susceptible to the backstop GSL standard; and, if DOE establishes GSL standards to substitute for the backstop, it must include the formerly exempt lamps in its analysis of whether the substitute standards are adequate. By contrast, the petition process from EISA section 321 does not purport to be part of the GSL standards-setting process. Indeed, the section 321 language specifically requires DOE to assess whether sales of a given lamp have "increased significantly since the date on which the standards on general service lamps were established." Thus, the section 321 process is only available after the initial GSL standards process. Then, after granting a petition, DOE would establish whatever standard was appropriate in the circumstances, without regard to the 45 lm/W backstop. In short, the petition process would be a separate mechanism, under which DOE had considerably more latitude regarding standards than it does for GSLs. Accordingly, EISA section 321 prescribed specific gating criteria before DOE could grant a petition.

To be sure, the fundamental concerns motivating the petition process and the authority granted to DOE to discontinue exemptions seem to be similar. The purpose of both, DOE believes, was to ensure that unregulated lamps do not present a loophole that would undermine the effect and purpose of energy conservation standards. To fulfill that purpose with respect to the exemptions, DOE is discontinuing an exemption if, considering sales data and technical features, it concludes that lamps within the exemption are already used in general lighting applications or are ready substitutes for GSLs. That analysis is comparable to what the petition provision prescribed. But it is not identical, because the processes are not identical.

The analysis DOE has conducted is more appropriate for the current decision, and indeed, the analysis that EISA section 321 describes would not be appropriate. EISA section 321 states that the Secretary shall grant a petition if "the petition presents evidence that

demonstrates that commercial availability or sales of exempted incandescent lamp types have increased significantly since the standards on general service lamps were established." DOE understands the point of that assessment to be that if lamp sales have increased significantly since the establishment of standards, that increase may show the lamp has become a less regulated alternative to GSLs. Thus, the baseline—the volume of sales when standards were established—is critical for the analysis. At this point, when no standards have yet been established, the sales analysis described in EISA section 321 would not be possible. DOE could assess whether sales of a lamp have increased in recent years, but increases or decreases, without reference to the baseline and the establishment of standards, would not demonstrate in the same way that a lamp has become a loophole to GSL standards.

The other substantive criterion for granting an EISA section 321 petition is whether "significant energy savings could be achieved by covering exempted products." As explained, the various conditions in the EISA section 321 petition provision do not apply to this final rule, because the paragraph (i)(6)(A)(i) decision about exemptions is different. Nonetheless, DOE acknowledges that it would not choose to discontinue an exemption unless doing so could achieve significant energy savings compared to maintaining the exemption. As discussed in the sections that follow, discontinuing the exemptions described in section III.A.1 could indeed lead to significant energy savings. As shown in Table III.1, six of the lamp categories for which DOE discontinued an exemption have annual sales that are several times the sales of the 15 lamp categories for which DOE maintained the exemption. The seventh lamp exemption that DOE is discontinuing, shatter-resistant lamps, presents a significant risk of lamp switching and maintaining its exemption could otherwise undermine potential standards for general service lamps.

Fourth, LEDVANCE urged that the D.C. Circuit's decision in *Hearth, Patio & Barbecue Ass'n v. U.S. Department of Energy*, 706 F.3d 499 (D.C. Circuit 2013), forecloses DOE from altering a product definition in a way that will have standards consequences without performing a section 6295(o) analysis. (LEDVANCE, No. 90 at p. 6) The *Hearth, Patio & Barbecue* opinion did not say so on its face. The case involved a question of whether DOE's inclusion of decorative fireplaces within the definition "direct heating equipment"

⁵ The apparent conflict between sections 321 and 322 of EISA does not affect EPCA section 325(i)(6)(A), the provision that is the basis for DOE's decisions on the various exemptions. EISA section 321 added section 325(i)(6), and section 322 did not alter it.

was impermissible; the court held that DOE's interpretation of "direct heating equipment" to permit that coverage was unreasonable. However, LEDVANCE argued that the case was "analogous" to the current situation, in that "altering a definition to change what falls within . . . a category of regulated products . . . 'is the essence of regulation.'" (LEDVANCE, No. 90 at p. 6 [quoting 706 F.3d at 508]). DOE does not consider the analogy sound. To be sure, this final rule is a species of regulation, and will bring certain products newly within the scope of regulation as GSLs. But the question, as ever in such matters, is what sort of regulation the statute authorizes, and what considerations and procedures it prescribes as prerequisites. LEDVANCE's comment suggests that because it has labeled sections 6295(o) and 6295(p) the "Rulemaking Requirements," DOE must comport with those provisions every time it engages in regulation under EPCA. Having considered the specific statutory provisions that authorize this rule, as discussed, DOE concludes that it is not obligated to conduct this rulemaking as though it were "prescrib[ing] a new or amended standard" pursuant to section 6295(o) or 6295(p).

LEDVANCE raised a second category of objection to the process by which it anticipated DOE would reach this final rule. Noting that DOE had proposed in March 2016 to amend standards for GSLs, and that the October 2016 NOPDDA seemed to contemplate finalizing a definition for GSLs without finalizing a standards amendment based on the March 2016 GSL ECS NOPR, LEDVANCE stated that DOE cannot bifurcate those procedures. (LEDVANCE, No. 90 at p. 3) In LEDVANCE's view, the statute does not permit DOE to issue multiple notices proposing different aspects of its GSL decisionmaking—whether to amend standards and whether to discontinue the exemptions. LEDVANCE contends that DOE must conclude those determinations in a single final rule, and that by finalizing amendments to the GSL definition, DOE is impermissibly circumventing EPCA rulemaking requirements and the Appropriations Rider. (LEDVANCE, No. 90 at p. 3) (LEDVANCE also argues, in what DOE takes to be an alternative argument, that lamps that qualify as GSLs only because of this final rule will not in fact be subject to the backstop standard; in this line of argument, LEDVANCE says the backstop standard can only apply to lamps that were already subject to standards.) Further,

LEDVANCE commented that DOE failed to provide appropriate notice of the standards that would apply to lamps considered under the October 2016 NOPDDA and that DOE must provide, in detail, the content and basis of a proposal to allow for meaningful and informed comment. (LEDVANCE, No. 90 at pp. 11–12)

DOE believes that EPCA does permit flexibility with respect to the rulemaking process it undertakes under section 6295(i)(6)(A)(i). Clause (i) says that DOE "shall initiate a rulemaking procedure" to make two distinct decisions: Whether to amend standards, and whether to maintain or discontinue exemptions. Because the statute says "a . . . procedure," LEDVANCE appears to believe it permits only a single NOPR and a single final rule. However, the general presumption in interpreting a federal statute is that the singular encompasses the plural. 1 U.S.C. 1. Thus, a reference to "a . . . procedure" would ordinarily permit a single procedure or multiple procedures.

DOE recognizes that context can lead in some instances to a contrary conclusion that a singular word truly means the singular and not the plural. But DOE has not identified any such contextual clues with respect to section 6295(i)(6)(A). Indeed, it would be unusual and counterproductive for a statute to restrict an agency to a single NOPR and a single final rule to achieve a specified objective. The decisions with which section 6295(i)(6)(A) tasks DOE are complex. DOE, like other agencies, often supplements its proposals with additional proposals and notices of further data and analysis. Yet if "a . . . procedure" permitted only a single proposal, then if DOE failed to prepare and assemble all of its analyses into a single proposal document the entire 6295(i)(6)(A) enterprise would fail for lack of authority. It seems unlikely that, having called for the 6295(i)(6)(A) assessments, Congress intended to make it so uncertain whether they could be achieved.

Further, even if "a rulemaking procedure" only permitted a single procedure, the statute leaves unclear what constitutes a "rulemaking procedure." LEDVANCE appears to take for granted that a "rulemaking procedure" consists of a single notice and a single final rule. But that is not the evident and unambiguous, or even the best, understanding of the phrase. A "rulemaking procedure" may include multiple notices and lead to multiple final rule documents, as and when appropriate under the circumstances. For example, in *Airtouch Paging v. FCC*, 234 F.3d 815 (2d Cir. 2000), the FCC

followed a proposed rule with "two principal reports and orders"; after a petition for reconsideration the agency issued a third order, in which it announced that it would take up certain issues in yet further orders. The court described this series of events as "a rulemaking procedure." Of course it was not significant in that case whether the several reports and orders constituted a single procedure or multiple procedures. But that is consistent with DOE's conclusion here. Whether to conceive of a set of proposals and decisions as a single "rulemaking procedure" or as several "rulemaking procedures" is rarely important. To infer that because section 6295(i)(6)(A) uses the singular form, DOE can only issue a single proposal and a single final rule, would read far too much precision into the concept of a "rulemaking procedure." DOE declines to do so, especially given how—as discussed—that interpretation would undermine the purposes of section 6295(i)(6).

LEDVANCE suggests that the entire scheme of section 6295(i)(6) requires DOE to make its decision in a single integrated rulemaking. According to LEDVANCE, DOE is required to decide what standards to apply to GSLs in the same rule in which it decides what lamps will be GSLs. The backstop standard would come into play only if the standards that DOE has set do not "produce savings that are greater than or equal to the savings from a minimum efficacy standard of 45 lm/W." That savings analysis, LEDVANCE asserts, must be holistic and market-wide rather than product-by-product. In other words, to avoid the backstop standard DOE need not impose a standard of 45 lm/W on each and every GSL. Rather, DOE can impose a more or less stringent standard on various types of lamps so long as the aggregate savings are at least the same as a uniform 45 lm/W standard would have achieved. Because, LEDVANCE says, DOE cannot know what overall savings its standards will achieve unless it knows what lamps will be subject to GSLs, it follows that DOE must define GSLs and set standards in the same final rule.

This argument does not lead to the conclusion LEDVANCE seems to draw. If, indeed, DOE were prohibited from imposing the 45 lm/W backstop standard unless it had conducted an overall market savings analysis, and if that analysis were impossible without defining the scope of GSLs, it would only follow that DOE must define GSLs before imposing the backstop standard. Once DOE had defined GSLs, it could decide what standards to impose, then conduct the savings analysis that

LEDVANCE stated is required. DOE does not see why this analytical process would have to take place in a single final rule. LEDVANCE may be suggesting that it is unavoidably arbitrary and capricious for DOE to include a lamp as a GSL without simultaneously deciding what standards will apply. But DOE regards those questions as analytically distinct. Its task with respect to the exemptions is to determine which among the lamps currently exempted from regulation as GSLs should be brought within the scope of the GSL definition and the applicable EPCA standards-setting authority. In that decision, the relevant issue is whether maintaining or discontinuing an exemption would better serve the purposes of section 6295(i)(6). As discussed, DOE believes an exemption should be discontinued if lamps within that exemption would be convenient substitutes for GSLs, so that exempting the lamps entirely from regulation (or maintaining a less stringent standard for the lamps) would open up a possibility for manufacturers and consumers to undercut EPCA lamp standards. That potential loophole would exist and be damaging regardless what standards DOE might then apply to the formerly exempted lamps or to other GSLs.

Moreover, LEDVANCE's argument seems premised on a notion that EPCA obligates DOE to develop standards for GSLs and then analyze the overall energy savings from those standards, and that absent the development of standards and an analysis that results in insufficient savings, the backstop standard would not be applicable. The statutory language and structure do not support that premise. Section 6295(i)(6) requires DOE to "initiate" a rulemaking procedure to decide whether to amend the GSL standards and to decide whether to maintain or discontinue lamp exemptions. It does not, by its plain terms, require DOE to conclude that rulemaking procedure via a final rule on either topic, except in one case. If DOE "determines that the standards in effect for [GSLs] should be amended," then DOE must publish a final rule doing so. (42 U.S.C. 295(i)(6)(A)(iii)) To be clear, DOE infers, from the language instructing it to initiate a rulemaking procedure, that EPCA authorizes it to complete the rulemaking by issuing final rules taking one or more of the actions on which section 6295(i)(6)(A)(i) calls for rulemaking. Otherwise the mandate to initiate a rulemaking would be pointless. It does not follow, and DOE does not infer, that DOE *must* issue final

rules on each of those items—aside, of course, from the circumstance just mentioned in which DOE determines GSIL standards should be amended.

The structure of section 6295(i)(6)(A) itself is consistent with DOE's interpretation. DOE notes that the statute explicitly and specifically requires DOE to issue a final rule in one particular situation. If the statute were meant to require DOE to issue 6295(i)(6)(A) rules regardless, it would presumably have said so rather than identifying that particular circumstance. (Conversely, reading section 6295(i)(6)(A)(iii) to require DOE to finalize the subparagraph (i) rules in all circumstances would make superfluous the clause in subparagraph (iii) that specifies a particular circumstance.)

The structure of section 6295 overall also supports DOE's interpretation. Repeatedly, the section specifies a point at which DOE must issue a proposed rule, and it follows that instruction with a requirement to publish a final rule. For example, subsection (b)(3) says DOE "shall publish a proposed rule" by a certain date on whether to amend refrigerator standards; it then says DOE "shall publish a final rule" by a second date "which shall contain such amendment, if any." (42 U.S.C. 6295(b)(3)(A)(i)) Subsection (m) says that within six years after amending a given standard, DOE shall publish either a notice of a determination that the standard does not at that time need to be amended, or "a notice of proposed rulemaking including new proposed standards." If DOE publishes the second type of notice, then within two years it "shall publish a final rule amending the standard." (42 U.S.C. 6295(m)) As a third example (among many that could be cited), if DOE receives a petition for an amended standard, it must publish a notice either granting or denying the petition. If it grants the petition, it must within three years publish either "a final rule that contains the new or amended standards" or "a determination that no new or amended standards are necessary." (42 U.S.C. 6295(n))

Thus, throughout section 6295, the statute distinguishes an obligation to propose a rule from an obligation to publish a final rule. When Congress wanted to require DOE to publish a final rule, it specified the conditions in which the requirement holds; the deadline for the final rule; and something about the content (*e.g.*, a final rule that includes amended standards). Section 6295(i)(6)(A) follows that pattern quite closely. It says that if DOE decides GSIL standards should be amended (the conditions leading to the

requirement), then by January 1, 2017 (the deadline), DOE must publish a final rule with an effective date at least three years later (the content). Given that pattern, DOE believes the most sensible interpretation of section 6295(i)(6)(A) is that it means exactly what it says. DOE was required to initiate rulemaking to decide whether to amend GSL standards and to decide which exemptions to maintain or to discontinue. DOE is only obligated to issue a final rule if it decides that GSIL standards should be amended. DOE has fulfilled the obligation to initiate a rulemaking through the publication of a notice announcing the availability of a framework document for general service lamps. 78 FR 73737 (December 9, 2013). It has not thus far concluded that GSIL standards should be amended, and therefore nothing in EPCA currently obligates DOE to issue a final rule amending GSL standards.

LEDVANCE contended that DOE cannot finalize a rule pursuant to section 6295(i)(6)(A)(i)(II)—regarding the exemptions—without finalizing a rule under subclause (I) on amending standards, because it cannot exercise the two authorities independently. (LEDVANCE, No. 90 at p. 8) But LEDVANCE identifies no language in EPCA that would impose such a restriction. As discussed, DOE does not believe paragraph (6)(A) requires it to complete a standards-setting rule at all. The regulatory program that EISA 2007 established was a preference and presumption for a 45 lm/W standard. The statute gives DOE the option to establish an alternative set of standards, on condition that those standards achieve energy savings at least as great as the 45 lm/W standard would. At the same time, Congress set some exemptions from the GSL regulatory scheme, and it authorized DOE to discontinue those exemptions if appropriate. Nothing in this framework would necessitate DOE's exercising the authorities just described in a single final rule. Consistent with that understanding of the policy underlying paragraph (6)(A), the text of the statute does not say DOE must do so.

LEDVANCE did contend that clause (iv) can support an inference that DOE must consider amended standards and discontinued exemptions in a single document. Clause (iv) says that DOE "shall consider phased-in effective dates under this subparagraph after considering" various economic issues such as "the impact of any amendment on manufacturers." In LEDVANCE's view, Congress would not have required DOE to consider those economic factors in isolation. That Congress specified

those factors therefore, LEDVANCE continued, demonstrates that Congress intended DOE to consider the section 6295(o) factors in a unitary rule about GSLs. (LEDVANCE, No. 90 at p. 8)

DOE regards that inference as inconsistent with the text of subparagraph (A) and with its purposes. Clause (iv) refers to “the impact of any amendment.” Evidently clause (iv) comes into play when DOE is considering an amendment to standards. Consistent with that understanding, clause (iii) says that if DOE decides to amend the standards, the final rule shall be published by January 1, 2017, “with an effective date that is not earlier than 3 years after the date” of publication. 42 U.S.C. 6295(i)(6)(A)(iii). Thus, when DOE establishes amended standards pursuant to subparagraph (A), it has discretion to set the effective date of the amendment (subject to the limitation that the effective date cannot be sooner than three years after publication). Clause (iv), then, instructs DOE, in the exercise of that discretion, to consider phased-in effective dates in light of certain factors like “the impact of [the] amendment.” However, if DOE fails to complete a rulemaking in accordance with clauses (i) through (iv) or if the final rule does not produce savings that are greater than or equal to the savings from a minimum efficacy standard of 45 lm/W, clause (v) says that DOE “shall prohibit” sales of lamps below the backstop standard “effective beginning January 1, 2020.” In that case, DOE would not have discretion regarding the effective date of the backstop standard. It would be odd, then, for the statute to require DOE to consider phased-in dates for the backstop. Clause (iv) can readily be interpreted to avoid that inconsistency.

Thus, all that clause (iv) requires is that DOE consider phased-in effective dates if and when it establishes amended standards under subparagraph (A). It seems like a *non sequitur* to conclude, from that requirement, that DOE must establish amended standards. That conclusion would be particularly strained in light of the preceding observation that Congress regularly in section 6295 specified when DOE must initiate and when it must conclude a rulemaking. If the intent was to require DOE to issue a final rule on amended standards, the ordinary way to set that requirement in EPCA would have been to say exactly that. To imply it, via the discussion of phased-in effective dates, would be an unusual and obscure way to require DOE to amend GSL standards. And, as discussed, DOE does not believe the policy of paragraph (6)(A) is that DOE must establish GSL standards.

Rather, Congress established a presumptive standard of 45 lm/W and allowed DOE, if it met the qualifications, to vary from that standard. Reading clause (iv) to apply only if DOE does vary from the 45 lm/W standard is consistent with that policy.

As an alternative argument, LEDVANCE suggested that even if DOE can issue this rule discontinuing certain GSL exemptions, the backstop would not apply to the formerly exempted lamps because there were no “standards in effect” for those lamps at the time of the rulemaking. (LEDVANCE, No. 90 at p. 8) DOE notes that the phrase “standards in effect” does not appear in clause (v), the text that describes the backstop. However, DOE takes LEDVANCE’s argument to be as follows. Clause (i)(I) instructs DOE to initiate a rulemaking to decide whether to amend “standards in effect for general service lamps.” Under clause (iii), if DOE decides that “the standards in effect” should be amended, it must publish a final rule to that effect by January 1, 2017. Clause (v) imposes the backstop “[i]f the Secretary fails to complete a rulemaking in accordance with clauses (i) through (iv).” Because such a rulemaking would be amending “the standards in effect,” and no standards were previously “in effect” for lamps that are currently exempt from being GSLs, LEDVANCE seems to be saying, the rulemaking “in accordance with clauses (i) through (iv)” cannot be about the standards for the previously exempt lamps. Therefore, LEDVANCE seems to infer, the backstop would not apply to those lamps.

However, the backstop provision does not limit itself to lamps for which standards were in effect. The status and content of the “rulemaking in accordance with clauses (i) through (iv)” determine whether the backstop will apply. But if it does, clause (v) says DOE shall prohibit the sale of “any general service lamp” that does not meet the backstop standard. The word “any” sweeps in all general service lamps, including those that were exempt before DOE discontinued an exemption. Clause (v) describes a prospective standard; it does not limit its scope to lamps that were subject to standards *before* the “rulemaking in accordance with clauses (i) through (iv).”

Moreover, LEDVANCE’s argument, as DOE understands it, risks making clause (i)(II) pointless. The argument would logically imply that DOE can only, under clause (i)(I), amend standards that were already “in effect”; thus, on LEDVANCE’s argument, DOE would not

be able to establish standards applicable to lamps for which it discontinued exemptions. If that were so, and if (as LEDVANCE posits) the backstop would not apply to those lamps either, there would be little point in discontinuing the exemption. DOE considers it more sensible and more consistent with the policies of paragraph (6)(A) to read clause (i) to permit it to establish standards for previously exempt lamps.

As a third category of objection, LEDVANCE stated that paragraph (6)(A) requires DOE to conduct a “fleet-wide analysis” of total energy savings from standards established by DOE. Under clause (v), after DOE sets its own standards pursuant to clauses (i) through (iv), the backstop would come into force if DOE’s standards do not “produce savings that are greater than or equal to the savings from” a uniform 45 lm/W standard. 42 U.S.C. 6295(i)(6)(A)(v). According to LEDVANCE, the “fleet-wide energy savings determination is integral to the EISA Rulemaking Proceeding and is a prerequisite to application of the EISA backstop provision.” (LEDVANCE, No. 90 at p. 9)

DOE notes that a “fleet-wide energy savings determination” is not in fact an exclusive prerequisite to the backstop. Under clause (v), DOE will be obligated to effectuate the backstop in either of two circumstances: If the energy savings from standards that DOE develops are insufficient, or “if the Secretary fails to complete a rulemaking in accordance with clauses (i) through (iv).” Thus, clause (v) expressly contemplates the possibility that DOE will not finalize a rule that develops alternative standards for GSLs. In that case, clause (v) by its text does not call for an analysis of energy savings; and of course there would be no energy savings to analyze. This structure is consistent with the understanding of paragraph (6)(A) as laid out before, that it sets 45 lm/W as a default and gives DOE the option—not the obligation—to develop alternative standards for GSLs. Thus, DOE disagrees that it must analyze fleet-wide energy savings from a DOE-imposed standard; and DOE disagrees that a rule defining GSLs is improper without an analysis of hypothetical DOE-imposed standards.⁶

⁶ LEDVANCE observed that under section 6295(o)(2)(B)(III), DOE must, in developing a standard, consider the “total projected amount” of energy savings; and LEDVANCE said DOE has typically “conducted a lifetime energy savings analysis for the entire class of covered products at issue.” (LEDVANCE, No. 90 at p. 9.) DOE need not address whether an analysis of energy savings pursuant to clause (v) would be on a similar basis, because DOE has not, at this point, developed

LEDVANCE suggested that it would also be impermissible for DOE to apply the backstop to lamps newly included in the definition of GSLs for a reason arising from the Administrative Procedure Act: That DOE did not provide adequate notice that application of the backstop would be a consequence of defining certain lamps to be GSLs. (LEDVANCE, No. 90 at p. 16) However, the October 2016 NOPDDA said that if DOE does not complete a standards rulemaking pursuant to clauses (i) through (iv), the backstop standard will come into effect for GSLs. 81 FR 71794, 71795 (October 18, 2016). It pointed out that when it discontinues an exemption, the lamps within that exemption will become GSLs (to the extent they otherwise fall within the definition of GSL). *Id.* at 71798. And DOE proposed “to discontinue a given exemption if the continuation of the exemption would undermine the 45 lm/W standard by providing a convenient unregulated alternative to GSLs.” *Id.* at 71799. Thus, an important premise of the decision as set forth in the notice was that DOE would include lamps as GSLs if it was important—in light of the considerations described in the notice—to ensure those lamps would be subject to the clause (v) backstop provision. Thus, DOE believes it provided adequate notice of the possibility that lamps newly included as GSLs would be subject to regulation as GSLs, including the clause (v) backstop provision if that becomes the standard for GSLs. DOE notes that many commenters, including LEDVANCE, discussed the issue in written comments and at the NOPDDA public meeting, indicating they were indeed aware of it.

A fourth category of objection, raised by LEDVANCE and by other commenters, was that DOE is not authorized to discontinue the exemptions set forth in section 6291(30)(D)(ii) and (BB)(ii)—the 22 exemptions for particular types of lamp that the notice discussed. (LEDVANCE, No. 90 at pp. 12–13) DOE notes that clause (i)(II) instructs DOE to initiate a rulemaking to decide whether “the exemptions . . . should be maintained or discontinued.” This language, particularly the reference to “the” exemptions, strongly suggests that Congress had a particular set of exemptions in mind about which DOE might make this decision. Consistent with ordinary principles of statutory interpretation and in order to fulfill the purposes of paragraph (6)(A), DOE is inclined to identify exemptions that it

can maintain or discontinue pursuant to clause (i)(II).

LEDVANCE argued that the “exemptions” at issue are the exemptions that EISA section 321(a)(3) authorized DOE to grant, upon petition. (LEDVANCE, No. 90 at p. 13) DOE does not believe those are the exemptions to which clause (i)(II) refers. Clause (i)(II) calls for a rulemaking, initiated by January 1, 2014, to decide whether “the exemptions” should be maintained or discontinued; that mandate presumes that “the exemptions” at issue existed as of January 2014. But the discretionary exemptions that EISA section 321(a)(3) permitted would only exist if persons had petitioned for exemptions, and if DOE had then granted those petitions. Were clause (i)(II) referring to those exemptions that might or might not exist at the beginning of 2014, a more natural phrasing would have been something like “any exemptions under this subsection.” Further, DOE could only grant an exemption under the process described in EISA section 321(a)(3) if it found, after a hearing, “that it is not technically feasible to serve a specialized lighting application . . . using a lamp that meets the requirements of this subsection,” and also found that “the exempted product is unlikely to be used in a general service lighting application.” Thus, to grant an exemption under that process DOE would have to engage in an assessment of specific technical issues. It seems unlikely, and contrary to the purpose of that petition process, that Congress would have called for DOE to initiate an overall rulemaking to decide whether to continue any exemptions it might have granted. Such a review would seem particularly odd because, given the timing of the requirements set in EISA section 321, DOE would not have received any petitions earlier than 2011. (In fact, DOE has not received any such petitions.) The clause (i)(II) rulemaking was to begin just a few years later. It seems unlikely that the technical facts underlying DOE’s decision on a petition would have changed in such a brief time.

Given DOE’s understanding of the framework Congress set up for GSLs, as described, DOE believes it is more consistent with the purposes of the statute to read “the exemptions” as referring to the lamp types that the original definition said are not GSILs or are not GSLs. Unlike lamps that DOE might exempt under the EISA section 321(a)(3) petition process, there has been no determination that these lamp types are unlikely to be used for general service lighting. DOE believes Congress

deferred that determination for DOE’s later assessment under clause (i)(II).

LEDVANCE did not identify any other exemptions to which clause (i)(II) might refer. However, DOE has also considered whether clause (i)(II) might address solely an exemption provided by an amendment in EISA section 322.⁷ That amendment imposed minimum efficiency standards on certain general service fluorescent lamps and incandescent reflector lamps. In delimiting the coverage of those standards, it said that “the standards specified in subparagraph (B) shall not apply to the following types of incandescent reflector lamps”: ER30, BR30, BR40, or ER40 lamps rated at 50 watts or less; BR30, BR40, or ER40 lamps rated at 65 watts; and R20 lamps rated 45 watts or less. DOE does not believe clause (i)(II) is solely about these exemptions. Clause (i)(II) in subparagraph (6)(A) is paired with clause (i)(I), which calls for a general rulemaking to review standards for GSLs across the board. It seems unlikely that, together with that broad-based rulemaking, Congress would have mandated a rulemaking just to assess the specific, narrow exemptions from the IRL standards set by EISA section 322. It bears mention that the scope of that rulemaking would be particularly narrow. Clause (i)(II) refers to “the exemptions for certain incandescent lamps,” but according to the definition of “incandescent lamp” only reflector lamps above 40 watts are incandescent lamps. 42 U.S.C. 6291(30)(C)(ii). Thus, the “incandescent lamps” exempted from the EISA section 322 standards are only ER30, BR30, BR40, or ER40 lamps between 40 and 50 watts; BR30, BR40, or ER40 lamps of 65 watts; and R20 lamps between 40 and 45 watts. While DOE has determined to address the exemption for IRLs in a separate document (discussed later in this section), limiting consideration of the exemptions only to this narrow set of lamp types would be an odd focus for a rulemaking alongside the broad clause (i)(I) standards review.

One commenter suggested that the clause (i)(II) authority to discontinue exemptions relates only to five types of lamps addressed by section 6295(I)(4). That paragraph requires DOE to collect sales data on five types of lamps (rough service lamps, vibration service lamps, 3-way incandescent lamps, 2,601–3,300

⁷ As noted, EISA sections 321 and 322 made conflicting amendments to section 325(i)(1) of EPCA. In assessing whether clause (i)(II) refers solely to the exemptions stated in the EISA section 322 amendment, DOE need not resolve the conflict; DOE assumes for purposes of argument that the EISA section 322 amendments are part of EPCA.

lumen general service incandescent lamps, and shatter-resistant lamps), and construct a model to extrapolate sales after 2006 from historical sales. 42 U.S.C. 6295(I)(4). For each type, if annual sales grow to be more than 100 percent above the extrapolated historical sales would have been, DOE is required to establish either a backstop mandated by the statute or come up with its own energy conservation standard.

DOE does not believe section 6295(i)(6)(A)(i)(II), which requires DOE to initiate a rulemaking on whether to maintain or discontinue “the exemptions for certain incandescent lamps,” refers to this framework of comparisons to forecast sales. The language of section 6295(I)(4), unlike that of section 6291(30)(D)(ii) and (BB)(ii), does not seem to describe exemptions. Paragraph (I)(4) simply says DOE “shall prescribe an energy efficiency standard” for the five types of lamp “in accordance with this paragraph.” It does not purport to exclude the five lamp types from being GSILs or GSLs; it simply sets a framework including a default standard for when sales grow more than expected. By contrast, section 6291(30)(D)(ii) and (BB)(ii) actually say certain lamps are “not included” as GSILs or GSLs; that language sounds much more like an exemption. Furthermore, subsection (I)(4) specifies conditions and timing for when DOE is to undertake a rulemaking for each of the five lamp types. It would be odd if subsection (i)(6)(A) required DOE to assess, separately, whether to cancel subsection (I)(4) for each type.

The remaining exemptions are those in the definitions of GSIL and GSL at 42 U.S.C. 6291(30)(D)(ii) and (BB)(ii). For the reasons discussed, DOE believes that those are the “exemptions” to which clause (i)(II) applies. It bears emphasis that DOE interprets clause (i)(II) to address both the (D)(ii) and the (BB)(ii) exemptions. DOE recognizes that clause (i)(II) refers to “the exemptions for certain incandescent lamps,” and subparagraph (BB)(ii) relates to GSLs rather than GSILs. However, the first type of exemption in subparagraph (BB)(ii) simply refers back to subparagraph (D)(ii): It says GSL does not include “any lighting application or bulb shape described in any of subclauses (I) through (XXII) of subparagraph (D)(ii).” DOE takes “the exemptions” to encompass the subparagraph (D)(ii) exemptions both as exemptions from the definition of GSIL and through their effect on the definition of GSL.

DOE recognizes that clause (i)(II) is ambiguous on this point because, as previously noted, it does not identify “the exemptions” specifically and does not say what “the exemptions” are exemptions from. However, DOE believes the interpretation described here appropriately fulfills the purposes of subsection (i)(6)(A). DOE notes that clause (i)(II) is a counterpart to clause (i)(I), which instructs DOE to consider developing standards for GSLs. Thus, clause (i) as a whole is about GSL standards, and it would be natural for “the exemptions” involved in subclause (II) to include exemptions from the definition of GSL. If subclause (II) only involved the definition of GSIL, it would be hard to see why Congress would require DOE to initiate a rulemaking on that issue at the same time as it initiated a rulemaking on GSL standards; DOE already maintained GSIL standards and would have reviewed them periodically as for other consumer products.

DOE recognizes that because discontinuing an exemption from being GSILs makes the corresponding lamps GSILs (to the extent they otherwise satisfy the criteria in the GSIL definition), those lamps will also become GSLs. That fact actually further motivates DOE’s interpretation. As discussed in the NOPDDA and in section III.A.4.f.i, many of the 22 exemptions in clause (30)(D)(ii) encompass technologies besides incandescent filaments. If “the exemptions” in subclause (II) nonetheless included only exemptions from the GSIL definition, the result of discontinuing an exemption would be that a set of incandescent lamps become subject to GSL standards without the corresponding non-incandescent lamps being subject to the same standards. For example, DOE is discontinuing the exemption for CA shape lamps. If DOE were only permitted to regulate incandescent CA shape incandescent lamps as GSLs, and not other CA shape lamps such as CA shape compact fluorescent lamps, the result would be a skewed regulatory regime that seems inconsistent with the purposes of subsection (i)(6)(A).

Subsection (i)(6)(A) actually instructs DOE to avoid that result: Clause (ii) of subsection (i)(6)(A) specifies that “[t]he rulemaking”—the rulemaking that clause (i) calls for—“shall not be limited to incandescent technologies.” DOE interprets that language to mean that in setting standards and deciding on exemptions under clause (i), it should consider non-incandescent lamps alongside incandescent lamps. With respect to the exemptions, that means

addressing the section 6291(30)(BB)(ii) exemptions from the GSL definition.

LEDVANCE, along with other commenters, contended that the definitional provisions—particularly those listing the 22 types of lamp in (D)(ii) and (BB)(ii)—cannot be the subject of the clause (i)(II) rulemaking because they are “exclusions” rather than “exemptions.” (LEDVANCE, No. 90 at pp. 12–13) DOE notes that the texts of section 6291(30)(D)(ii) and (BB)(ii) do not actually state that they provide “exclusions.” That word appears only in the headings of the provisions. Headings “can be a useful aid in resolving a statutory text’s ambiguity,” *United States v. Quality Stores, Inc.*, 134 S. Ct. 1395, 1401 (2014); but titling subparagraphs (D) and (BB) “Exclusions” does not clearly indicate that the substance of those provisions describe exclusions and not exemptions.

The texts of those provisions say that the respective defined terms (GSIL and GSL) “do[] not include” certain lamps. 42 U.S.C. 6291(30)(D)(ii); 6291(30)(BB)(ii). The language “does not include” is consistent with stating an exemption. “Exemption,” in ordinary English, simply means freeing or excusing one set of persons or things from an obligation to which others are subject (see *American Heritage Dictionary*). GSILs and GSLs are subject to regulatory requirements under EPCA; by stating that certain lamps are “not include[d]” in those categories, subparagraphs (D) and (BB) exempt them from the regulatory requirements.

LEDVANCE stressed that the words “exclusion” and “exemption” are different, and urged that DOE’s interpretation of clause (i)(II) must reflect that difference.⁸ (LEDVANCE, No. 90 at pp. 12–13) While DOE recognizes that differences in statutory language are usually significant, “Congress sometimes uses slightly different language to convey the same message,” *DePierre v. United States*, 564 U.S. 70, 83 (2011). See also *McNeil v. United States*, 508 U.S. 106, 112 (1993) (“In its statutory context, we think the normal interpretation of the word ‘institute’ is synonymous with the words ‘begin’ and ‘commence.’”). The words “exemption” and “exclusion” can be synonymous in ordinary English.⁹ See, e.g., *Public Investors*

⁸ This argument is somewhat misplaced because, as just noted, the text of the GSIL and GSL definitions does not use the word “exclusions.”

⁹ LEDVANCE said that the D.C. Circuit’s *Hearth, Patio & Barbecue* decision held that “exclusions” and “exemptions” are different. The opinion actually seems to use the words “exclude” and

Arbitration Bar Ass'n v. SEC, 771 F.3d 1, 8 (D.C. Cir. 2014) (Brown, J., concurring) (“We began in 1978 by interpreting Exemption 8’s categorically narrow exclusion broadly.”); *Friends of Animals v. Jewell*, 824 F.3d 1033, 1036 (D.C. Cir. 2016) (citing agency decision titled “Exclusion of U.S. Captive-Bred Scimitar-Horned Oryx, Addax, and Dama Gazelle from Certain Prohibitions (‘Captive-Bred Exemption’)”).

Indeed, Congress used them synonymously in other parts of subsection (i) added by the same provision of EISA 2007 that added both paragraph (6)(A) and the list of 22 lamp types not included as GSILs or GSLs. The provision in EISA section 321(a)(3) allowing the public to petition DOE to regulate additional types of lamps, discussed, reads as follows. “Any person may petition the Secretary to establish standards for lamp shapes or bases that are excluded from the definition of general service lamps.” “The petition shall include evidence that the availability or sales of exempted incandescent lamps have increased significantly.” Surely what Congress had in mind is that when a petitioner asks for standards on a given type of lamp, the petition should demonstrate that the availability or sales of that type of lamp have increased. But in the first sentence refers to the subject of the petition as “lamps excluded from the definition of general service lamps,” and the second calls it “exempted lamps.” Evidently Congress considered the text that “exclude[s]” certain lamps from the definition of GSLs to be an exemption.

A commenter also argued that DOE cannot discontinue exemptions for any set of lamps for which EPCA already imposes standards—or for lamps for which EPCA specifies future standards like the five lamp types addressed by subsection (I)(4). According to this commenter, such lamps are not “exempt” so there are no “exemptions” to discontinue. In considering this argument, DOE observes that to complete a concept of an “exemption” or of “exempting,” it is necessary to say what the exemption is protecting from. In referring to “the exemptions,” section 6295(i)(6)(A)(i)(II) does not provide that information, leaving an unavoidable ambiguity for DOE to reconcile. On the commenter’s view, “the exemptions” means exemptions from regulation

under EPCA; thus if a type of lamp is subject to regulation of any kind under EPCA, it does not enjoy an “exemption” that DOE may discontinue under subsection (i)(6)(A)(i). However, DOE considers it more sensible to read “the exemptions” as meaning exemptions from being regulated as GSLs. That understanding would be consistent with the structure of clause (i), which calls for DOE to consider amending GSL standards and to consider discontinuing exemptions. If these two parts of clause (i) are about the same content, “the exemptions” would be exemptions that protect lamps from GSL standards.

DOE believes its interpretation appropriately fulfills the purposes of subsection (i)(6) and of EPCA as a whole. As discussed, DOE believes subsection (i)(6) was meant to establish a particular level of energy savings, namely the amount that could be achieved by imposing a 45 lm/W standard on GSLs. As the fourth category of GSL indicates, Congress left some flexibility about the concept of GSL, so that it could encompass lamps that fulfill the same sorts of functions as GSILs. Consistent with that understanding, DOE believes the purpose of discontinuing exemptions is to ensure that a given type of lamp does not provide a ready substitute for lamps regulated as GSLs, because the availability of such a substitute will significantly erode the savings achieved by GSL regulation. On that understanding, it is straightforward that Congress would want DOE to assess whether a given type of lamps should be exempt from GSL regulation.

By contrast, to leave lamps out—as the commenter suggested—simply because they are subject to other types of regulation and different standards would largely defeat the purpose of GSL regulation just described. For some lamp types, the criterion that commenters label a “standard” is a definitional limit; for example a G shape lamp is exempt only if it has a diameter of 5 inches or more, and a T shape lamp is exempt only if it uses less than 40 watts or has a length of 10 inches or more. Commenters disagree with DOE’s characterization of these limits as definitional criteria rather than standards. Regardless, they are not GSL standards, and they are not of the same character or stringency as the GSL backstop that is the default GSL standard, and are presumably less stringent than any standard that DOE might develop to achieve energy savings comparable to those from the 45 lm/W backstop standard. It seems unlikely that Congress would have considered such criteria adequate alternatives to

GSL standards. Therefore, DOE considers it more consistent with the scheme of subsection (i)(6) that DOE should assess whether to subject to GSL regulation the lamps within such an exemption. For example, with respect to T shape lamps, DOE must assess whether lamps over 10 inches or lamps under 40 watts are ready substitutes for GSLs.

Commenters also argued that DOE cannot discontinue the exemption for incandescent reflector lamps in particular. DOE will address these comments in a separate rule. This final rule does not include a determination whether to maintain or discontinue the exemption for incandescent reflector lamps and does not include those lamps within the definition of GSLs. This rule does address the exemption for “reflector lamps”; as discussed in section III.A.1.a, the rule addresses only reflector lamps that are not “incandescent reflector lamps” as defined in EPCA.

In the following sections, DOE provides detailed discussions of how the definition of GSL adopted in this final rule is consistent with the authorities discussed in this section.

III. Adopted Definition of General Service Lamp

A. General Service Lamp Definition

The term general service lamp (GSL) includes general service incandescent lamps (GSILs), compact fluorescent lamps (CFLs), general service light-emitting diode (LED) and organic light-emitting diode (OLED) lamps, and any other lamps that DOE determines are used to satisfy lighting applications traditionally served by GSILs; however, GSLs do not include any lighting application or bulb shape that under 42 U.S.C. 6291(30)(D)(ii) is not included in the “general service incandescent lamp” definition, or any general service fluorescent lamp or incandescent reflector lamp. (42 U.S.C. 6291(30)(BB)) The October 2016 NOPDDA revisited the proposed definition of GSL from the March 2016 GSL ECS NOPR, including the exemptions contained in the GSIL and GSL definitions, and proposed a revised definition of “general service lamp” in § 430.2 to capture various criteria and delineate the lamp types considered to be GSLs. 81 FR 71806–71807. More specifically, DOE proposed the a definition for GSL in the October 2016 NOPDDA A general service lamp, as proposed, would be a lamp that has an ANSI base, operates at any voltage, has an initial lumen output of greater than or equal to 310 lumens (or 232 lumens for modified spectrum general

“exempt” interchangeably. At any rate, DOE acknowledges that in many contexts “exclusion” and “exemption” can refer to different concepts. Its observation here is simply that the two words can also be synonymous, and that statutory context and purpose must inform DOE’s interpretation of the word “exemption” here.

service incandescent lamps) and less than or equal to 4,000 lumens, is not a light fixture, is not an LED downlight retrofit kit, and is used in general lighting applications. General service lamps include, but are not limited to, general service incandescent lamps, compact fluorescent lamps, general service light-emitting diode lamps, and general service organic light-emitting diode lamps, but do not include general service fluorescent lamps; linear fluorescent lamps of lengths from one to eight feet; circline fluorescent lamps; fluorescent lamps specifically designed for cold temperature applications; impact-resistant fluorescent lamps; reflectorized or aperture fluorescent lamps; fluorescent lamps designed for use in reprographic equipment; fluorescent lamps primarily designed to produce radiation in the ultra-violet region of the spectrum; fluorescent lamps with a color rendering index of 87 or greater; R20 short lamps; specialty MR lamps; appliance lamps; black light lamps; bug lamps; colored lamps; infrared lamps; left-hand thread lamps, marine lamps, marine signal service lamps; mine service lamps; plant light lamps; sign service lamps; silver bowl lamps, showcase lamps, and traffic signal lamps.

DOE received general comments on its proposed definition.

California Energy Commission (CEC), Southern California Edison (SCE), National Resources Defense Council (NRDC), Rutgers Law School Environmental Law Society (RELS), Northeast Energy Efficiency Partnerships (NEEP), Utility Coalition, and Appliance Standard Awareness Project (ASAP) expressed strong support for DOE's proposed definition of GSL. CEC and RELS commented that the revised proposal encourages high performance requirements for technology-neutral GSLs and will result in significant additional energy savings for the nation as well as increased consumer savings. NRDC and NEEP noted that the revised definition addressed stakeholder input including many of their concerns on previous proposals. In particular, NRDC and CEC agreed with DOE's approach of including lamps regardless of shape or base type in order to prevent gaming of the system. Citing reflector lamps as an example, NRDC stated that manufacturers have taken advantage of definitions in the past by creating new lamp shapes outside of the product definition that then increase in sales. NEEP stated its overall support for proposed scope of GSLs, and asserted there will be a wide variety of highly efficacious and low cost lamps that will

fill the needs for consumers. ASAP added that with a few minor changes to the definitions, the definitions will be consistent with the statute, and DOE will be able to implement the backstop standard as required by Congress and issue a final rule to complete this critical rulemaking. (CEC, No. 81 at p. 1; SCE, No. 83 at pp. 23–24; NRDC, No. 83 at pp. 9–10; ASAP, No. 83 at pp. 20–21; NEEP, No. 83 at p. 13; NRDC, No. 85 at pp. 1–2; RELS, No. 86 at p. 1; CEC, No. 91 at p. 1)

SCE stated that both utilities and industry played a critical role in transforming the market and added that progress will continue after the rulemaking ends. ASAP also emphasized the role of utilities, noting that utilities have spent billions of dollars to move the market to the level of efficiency available today and remain interested in how to make the transition to a GSL standard successful. (SCE, No. 83 at pp. 23–24; ASAP, No. 83 at pp. 17–19)

In contrast, Avalos stated that the expanded definition simply broadens the scope of GSL and does not clarify what lamps are considered GSLs. Avalos added that several lamps are included under the revised definition that are not general service lamps and suggested defining GSL to include lamps that are used on a regular basis. (Avalos, No. 80 at p. 1)

NEMA also commented that the scope of the proposed GSL definition is too broad. NEMA stated that available sales and market data should be used to determine the scope rather than speculating whether lamp types may become loopholes in the future. NEMA added that the sales data collected from the section 6295(l) rulemaking indicates that some of the lamp types that look like 60 W incandescent lamps, such as rough service and vibration service, are being used as substitutes. However, NEMA also noted that there are very small or large lamps, such as 2,000 lumen sign lamps and G40 lamps, which would fall within DOE's proposed definition but that are not effective substitutes for GSILs because they cannot fit in the same fixtures or applications. (NEMA, No. 83 at pp. 50–52) Westinghouse also expressed concern about DOE's proposed definition, stating that because it is so broad some lamp types will be inadvertently included in the scope of the GSL definition. (Westinghouse, No. 83 at p. 135)

DOE acknowledges that it has proposed a broad definition for general service lamp. However, DOE does not intend for the definition to include lamps that are not properly considered

general service lamps. In the following sections, DOE discusses key aspects of the definition and revisions implemented for this final rule.

1. GSILs

As stated previously, GSILs include GSILs. (42 U.S.C. 6291(30)(BB)(i)(I)) The current definition of “general service incandescent lamp” is a standard incandescent or halogen type lamp that is intended for general service applications; has a medium screw base; has a lumen range of not less than 310 lumens and not more than 2,600 lumens or, in the case of a modified spectrum lamp, not less than 232 lumens and not more than 1,950 lumens; and is capable of being operated at a voltage range at least partially within 110 and 130 volts; however this definition does not apply to the following incandescent lamps: An appliance lamp; A black light lamp; A bug lamp; A colored lamp; An infrared lamp; A left-hand thread lamp; A marine lamp; A marine signal service lamp; A mine service lamp; A plant light lamp; A reflector lamp; A rough service lamp; A shatter-resistant lamp (including a shatter-proof lamp and a shatter-protected lamp); A sign service lamp; A silver bowl lamp; A showcase lamp; A 3-way incandescent lamp; A traffic signal lamp; A vibration service lamp; A G shape lamp (as defined in ANSI C78.20 and ANSI C79.1–2002) with a diameter of 5 inches or more; A T shape lamp (as defined in ANSI C78.20 and ANSI C79.1–2002) and that uses not more than 40 watts or has a length of more than 10 inches; and A B, BA, CA, F, G16–1/2, G–25, G30, S, or M–14 lamp (as defined in ANSI C79.1–2002 and ANSI C78.20) of 40 watts or less. 10 CFR 430.2.

In the March 2016 GSL ECS NOPR, DOE declined to make a determination about discontinuing the 22 GSIL exemptions from the GSIL definition. DOE initially concluded that, because the Appropriations Rider prohibits DOE from using appropriated funds to implement or enforce standards for GSILs, DOE could not re-evaluate the existing exemptions for GSILs in the GSL rulemaking. 81 FR 14540. Specifically, DOE stated that, by definition, GSL does not apply to any lighting application or bulb shape that, under 42 U.S.C. 6291(30)(D), is not included within the “general service incandescent lamp” definition. (42 U.S.C. 6291(30)(BB)) Therefore, based on the GSL definition, the 22 incandescent lamps that are excluded in EPCA from the definition of GSIL would not be GSILs. Further, DOE stated that the formerly exempted lamp types would have to be considered GSILs in

order for DOE to regulate the lamps under its authority to promulgate standards for GSLs. Since the Appropriations Rider prohibits the expenditure of funds to implement or enforce standards for GSILs, DOE reasoned that it would not be able to establish or amend energy conservation standards for any of these lamps. As a result, making a determination about discontinuing the exemption from the GSIL definition for any of the 22 medium screw base lamps would make no difference in the GSL rulemaking, and DOE declined to address the exemptions at that time. 81 FR 14541.

Upon consideration of the comments received on the March 2016 GSL ECS NOPR and further review of the relevant authorities, DOE revisited its interpretation in the October 2016 NOPDDA with respect to the proposed definition of GSL and application of the Appropriations Rider. DOE noted that the focus of the March 2016 GSL ECS NOPR was to propose new energy conservation standards for GSLs; in that context, DOE did not propose to modify the GSIL exemptions and then impose new standards for GSILs. By contrast, the October 2016 NOPDDA neither implemented nor sought to enforce any standard. Rather, the October 2016 NOPDDA sought to define what constitutes a GSIL and what constitutes a GSL under 42 U.S.C. 6295(i)(6)(A)(i)(II), an exercise distinct from establishing standards. As previously noted, the Appropriations Rider restricts DOE from “implementing or enforcing” the standards imposed on GSILs by 10 CFR 430.32(x). However, it does not preclude DOE from utilizing its authority under EPCA to revisit and alter the scope of GSIL and GSL, even if a consequence of that decision will be that additional incandescent lamps may become subject to the backstop standard.

In the October 2016 NOPDDA, DOE noted it believes this is a reasonable interpretation of the Appropriations Rider because, in evaluating the exemptions, DOE followed a directive related to a GSL rulemaking to define the scope of GSLs. DOE did not conduct any analysis in support of establishing energy conservation standards for GSILs. Although a collateral effect is to broaden the scope of the GSIL definition, DOE simply proposed to define what lamps constitute GSLs so that both manufacturers and DOE can understand how the regulations apply to the market. As discussed, DOE’s defining the scope of GSL in light of the 45 lm/W backstop standard set in 42 U.S.C. 6295(i)(6)(A)(v) is not the same as DOE establishing standards.

Furthermore, as previously noted, in the event standards were established, leaving certain exemptions in place would diminish the energy savings that would otherwise be achieved because the excluded lamps would provide a less efficient option to meet the same general service lighting application. 81 FR 71797–71798.

Commenters inquired why DOE had apparently changed its interpretation of the Appropriations Rider. As noted, the March 2016 GSL ECS NOPR focused on establishing amended standards. The October 2016 NOPDDA and this final rule are addressed solely to the definition of GSL, recognizing that the additional lamps that DOE includes as GSILs will become subject to either a DOE-developed standard or to the 45 lm/W backstop standard that EPCA set as the default. In this context, interpreting the Appropriations Rider to block DOE from assessing the 22 exemptions would risk undermining the 45 lm/W backstop standard that Congress set. That consequence is quite different from what DOE faced with respect to the March 2016 GSL ECS NOPR, with respect to which a broad interpretation of the Appropriations Rider would only have restricted DOE’s ability to develop its own standards. DOE, therefore, interpreted the Appropriations Rider as applying differently in the context of the October 2016 NOPDDA, and similarly does not interpret the Appropriations Rider as precluding its assessment of the exemptions in this final rule.

In the October 2016 NOPDDA, DOE evaluated the 22 lighting applications or bulb shapes exempted under the GSIL definition to determine whether such exemptions should be maintained or discontinued. 81 FR 71798. In the October 2016 NOPDDA, DOE proposed to discontinue eight GSIL exemptions (for reflector lamps, rough service lamps, shatter-resistant lamps, 3-way incandescent lamps, vibration service lamps, and lamps with specific shapes) based on compiled sales data and consideration of additional, applicable factors. DOE proposed to maintain 14 of the GSIL exemptions due to low sales and low potential for use in GSL applications.

In this final rule, DOE is maintaining 15 of the exemptions and discontinuing seven of them. To summarize the analytical approach discussed later with reference to comments, DOE believes the purpose of the decision that subsection (i)(6)(A)(i)(II) calls for is to ensure that a given exemption will not impair the effectiveness of GSL standards by leaving available a convenient substitute that is not

regulated as a GSL. Therefore, DOE has based its decision on each exemption on an assessment of whether the exemption encompasses lamps that can provide general illumination and can functionally be a ready substitute for lamps already covered as GSLs.

The technical characteristics of lamps in a given exemption and the volume of sales of those lamps are among the considerations relevant to that assessment. High annual sales indicates that the product is likely used in general lighting applications,¹⁰ because the sales of lamps for specialty applications tend to be relatively small compared to sales for general-purpose lighting. However, sales data are not the only consideration. It may be appropriate to discontinue an exemption even though current sales are relatively low, if technical characteristics of the exempted lamps make them likely to serve as ready substitutes for GSLs once GSL standards are in place. For example, as discussed in section III.A.1.a, DOE believes shatter-resistant lamps are similar enough to rough service and vibration service lamps that shatter-resistant lamps will be substitutable for GSILs just as rough service and vibration service lamps have become substitutes for GSILs. Further, as discussed later in this section, for a lamp to be a viable substitute for GSILs, DOE does not think the lamp has to fit into the same existing fixtures as some type of GSL. Markets will shift in response to GSL standards, and DOE would expect some substitution of fixtures to occur as part of substituting non-GSL lamps for GSILs.

DOE received several comments regarding its authority to reconsider the 22 GSIL exemptions. NEMA stated that DOE was not authorized to redefine GSIL to include any of the 22 lighting applications or bulb shapes exempted from the definition of GSIL. (NEMA No. 93 at p. 3) NEMA further stated that Congress defined GSIL in very specific terms, limiting the term to “standard incandescent or halogen type lamps” and that the 22 listed lamps are not standard incandescent lamps, and are therefore excluded from the GSIL definition. (NEMA No. 93 at p. 3) NEMA stated that in contrast to the “standard” incandescent lamp, some of the 22 excluded lamps lack a “medium screw base,” some have lower lumen output than the minimum lumens for GSILs, and some of them are separately regulated. (NEMA, No. 93 at p. 3) NEMA

¹⁰ DOE notes that the annual sales of six lamp categories for which exemptions were discontinued in this notice were several times greater than the fifteen lamp categories for which exemptions were maintained.

stated DOE has no authority to change the GSIL definition and urged DOE to retain the existing definition. (NEMA, No. 93 at p. 22)

EPCA does not define “standard” in the context of incandescent lamp.¹¹ However, DOE considers it unlikely that the exemptions encompass solely lamps that are not “standard.” Were that the case, the exemptions would be superfluous, because the word “standard” in the definition of GSIL would on its own have ensured that none of those lamps are GSILs. For example, one of the 22 exemptions is for 3-way incandescent lamps. With respect to this type of lamp, the GSIL definition reads: “a standard incandescent or halogen type lamp that” meets four qualifications (“intended for general service applications,” medium screw base, 310–2,600 lumens, and functional at 110–130 volts), but not including 3-way incandescent lamps. If no 3-way incandescent lamps are “standard,” then the exemption for those lamps was unnecessary. To be clear, DOE acknowledges that this argument does not imply that all 3-way incandescent lamps are “standard,” or that all 3-way incandescent lamps would meet the other GSIL qualifications (such as lumen range or screw base). Nonetheless, it seems likely that the 22 exemptions cover some lamps that would, absent the exemption, be GSILs.

Regarding DOE’s decision to maintain or discontinue the 22 GSIL exemptions, PG&E supported DOE’s decision to bring previously exempted lamp types into the scope of coverage of the GSL rule. PG&E added that these lamp types pose a significant risk to energy savings as they can easily replace GSLs in many applications. Further PG&E stated that LED versions are dropping in price while increasing in efficiency and are available in range of shapes, sizes, lumen outputs, correlated color temperature (CCT), beam angles, and base types. (PG&E, No. 83 at pp. 14–15) CEC, Utility Coalition, NEEP, and NRDC also supported DOE’s proposed approach and agreed with the eight lamp types DOE proposed to no longer exempt based on the sales of these lamp types and their potential for lamp switching. NEEP and NRDC added that these categories all have high-efficiency alternatives that produce general illumination. (CEC, No. 81 at p. 1; Utility Coalition, No. 95 at p. 3; NEEP, No. 92 at p. 1; NRDC, No. 85 at pp. 1–2) However, NEMA stated that DOE should maintain all 22 GSIL exemptions except for vibration service lamps and

rough service lamps. (NEMA, No. 83 at p. 93)

In support of its analysis of whether to maintain or discontinue the 22 GSIL exemptions, in the October 2016 NOPDDA DOE presented estimated sales data for the 22 exempted lamp types. NEMA stated that sales for most of the 22 exempted lamps are declining and that it was the intent of Congress to require that DOE find sales increasing as a prerequisite to discontinue an exemption. (NEMA, No. 83 at p. 34; NEMA No. 93 at p. 12) NEMA pointed to the petition process established under section 321 of EISA 2007 as indicative of that intent. (NEMA, No. 93 at p. 12–13) NEMA and LEDVANCE noted that Congress required a demonstration of increased sales as a prerequisite for DOE to grant a petition submitted by the public to reconsider an exemption, and that DOE must be guided by the same consideration when determining whether an exemption should be maintained under 42 U.S.C. 6295(i)(6)(A)(i)(II). (NEMA, No. 83 at pp. 33–34; LEDVANCE, No. 90 at pp. 25–27) NEMA and LEDVANCE cited the requirement under 42 U.S.C. 6295(i)(6)(A)(i)(II) for DOE to consider, in part, “exempted lamp sales” collected by DOE as supporting the requirement for increased lamp sales in order to discontinue an exemption. (NEMA, No. 93 at 5; LEDVANCE, No. 90 at p. 26) NEMA and LEDVANCE added that a determination of lamp switching must be driven by data showing increased sales. (NEMA No. 93 at p. 13; LEDVANCE, No. 90 at pp. 25–27) NEMA and LEDVANCE concluded that the October 2016 NOPDDA did not provide data indicating that lamp switching was occurring, and rather data from the Energy Information Administration¹² shows that sales are decreasing. NEMA and LEDVANCE commented that if DOE was petitioned under section 325(i)(3)(E), it would not grant the petition or decide to regulate these specialty lamps and therefore any other action taken under section 325(i)(6)(A) is illogical. (NEMA, No. 93 at p. 13; LEDVANCE, No. 90 at pp. 25–27) John Taxpayer stated that DOE’s inclusion of these specialty lamps was regulatory overreach and Congress had specifically stated these lamps should be regulated if and only if their sales increased over 100 percent. Taxpayer commented that many excluded specialty lamps are not available at

hardware stores and will not fit in normal table lamps or recessed ceiling fixtures. (Taxpayer, No. 84 at p. 1)

While NRDC found the sales data presented by DOE in the October 2016 NOPDDA to be accurate, it commented that historical lamp sales are only one factor for consideration in DOE’s determination of whether an exemption should be maintained. The California Investor Owned Utilities (CA IOUs) and NRDC cautioned that the presented data reflected current standards and sales could increase dramatically for exempted lamp types when the next more efficient standards go into effect in 2020. (CA IOUs, No. 83 at pp. 64–65; NRDC, No. 83 at pp. 29–30, 35) NRDC and CA IOUs both commented that the market has previously seen the sales volume of lamps increase when the lamps were exempted from standards or subject to less stringent standards (e.g., BR lamps and modified spectrum lamps) and that historic sales records do not necessarily capture the potential for lamp switching. (NRDC, No. 85 at p. 1; CA IOUs, No. 83 at pp. 64–65) ASAP noted that market dynamics change as a result of setting standards for an inefficient lamp and that in some cases, an exempted low-volume, high-priced niche variant of an inefficient lamp can become a high-volume, low-priced loophole, thus undercutting the effect of the standard. ASAP added that DOE’s definition of “designed and marketed” has not prevented inefficient low-volume high-priced specialty lamps from becoming loopholes in standards thus far. (ASAP, No. 94 at p. 5)

As discussed, the petition process from EISA section 321(a)(3) is distinct from the decision that subparagraph (6)(A)(i)(II) calls for about maintaining or discontinuing exemptions. The statute does not require DOE to consider the same factors in the clause (i)(II) decision that it would in reviewing a petition. In particular, it does not restrict DOE to discontinuing an exemption only if sales of lamps within that exemption are increasing. While increases or decreases in lamp sales are an important consideration, DOE believes it can in some circumstances be appropriate to discontinue an exemption even at a time when sales of those lamps are decreasing. As described by GE, LEDVANCE, and Westinghouse, incandescent sales can be decreasing because consumers are purchasing LED versions of the same lamp. Thus, the lamp itself is not unpopular but rather is undergoing a shift in technology. For example, GE stated that sales of reflector lamps that are incandescent have been declining significantly over the last five years but

¹¹ DOE’s understanding of the word “standard” in this context is discussed in section III.A.4.b.

¹² See Energy Information Administration, Sales of specialty incandescent bulbs decline despite exemption from efficiency standards (April 2, 2013) available at: <http://www.eia.gov/todayinenergy/detail.php?id=10631>.

that was in large part caused by the increasing sales of LED reflector lamps. (GE, No. 83 at pp. 38, 84–85; LEDVANCE, No. 90 at p. 35; Westinghouse, No. 83 at pp. 128–129) Consequently, it can in some circumstances be appropriate to consider the overall volume of sales in assessing an exemption, even if the volume is currently decreasing.

DOE also considered the potential of lamp switching that may occur in response to any GSL standard. If an exempted lamp has the same utility to lamp users as a lamp subject to a standard as a GSL, DOE considered the potential increase in the use of the exempted lamp in response to a standard. As noted by the comments from CA IOUs and NRDC, prior to the effective date of any new standard the sales trends of exempted lamps do not necessarily capture the potential for lamp switching. As such, current lamp sale trends are only part of the consideration. DOE is permitted to account for future changes in consumer behavior so as to avoid the creation of loopholes.

DOE received several comments regarding whether a lamp could serve as a replacement for a GSL and therefore present a risk of lamp switching. CA IOUs stated that evaluations of the exemptions should be based on whether the exempted lamp type could serve as a replacement for a general service lamp. (CA IOUs, No. 83 at p. 107) Westinghouse stated that there are low-cost products on the market that consumers do not use as replacements for GSLs because they are not the appropriate shape or design. Avalos noted that a couple of exempted lamp types could be considered GSILs but are not due to their lamp structure. (Westinghouse, No. 83 at p. 30; Avalos, No. 80 at p. 1)

GE and LEDVANCE stated that DOE should consider the traditional omnidirectional incandescent lamp when considering the potential for lamp switching. (GE, No. 83 at pp. 37–38; LEDVANCE No. 83 at p. 59) GE stated that the definition of GSIL describes a lamp with a medium screw base, that produces between 310 and 2,600 lumens, and can operate on a voltage between 110 and 130 V, and that in order for a lamp to be considered as having the potential for “lamp switching” the lamp must maintain these same attributes. (GE, No. 88 at pp. 2–3) NEMA further stated that the definition of GSL authorizes DOE to consider “other lamps” and that “other lamps” must be used to satisfy lighting applications traditionally served by GSILs. (NEMA, No. 93 at p. 6) NEMA

stated that the use of the word “used,” past tense, establishes that there must be evidence for the basis of a finding that other lamps are operating in applications traditionally served by GSILs. (NEMA, No. 93 at p. 6) Westinghouse stated that consideration of lamp switching should be limited to whether a consumer could use an exempted lamp to replace a lamp that the consumer is currently using, and that consideration of how the use of fixtures may change in response to standards (*e.g.*, changes in fixtures used in new home construction) would be inconsistent with EPCA. (Westinghouse, No. 83 at pp. 39–40)

Other commenters stated that consideration of lamp switching should include the ability of an exempted lamp to provide similar function as a traditional GSIL, regardless of the fixture traditionally used with GSILs. ASAP stated that the presence of directional lamps in residences in the U.S. has grown significantly over time due to changes in new construction. (ASAP, No. 83 at pp. 38–39) ASAP stated that lighting in homes that traditionally was provided by A shape lamps in floor and table fixtures is being provided in newer construction through reflector lamps in recessed can lighting. (ASAP, No. 83 at pp. 58–59)

As previously noted, DOE understands the purpose of the decision that EPCA calls for on maintaining or discontinuing exemptions to be to ensure that consumers and manufacturers do not switch to readily available substitutes once standards for GSLs come into force. In making this assessment, the potential for an exempted lamp to be placed in a fixture that traditionally used a GSIL, and the potential change in the fixtures used to provide lighting in an application that was traditionally served by a GSIL are important considerations that DOE appropriately takes into account. Separate from the determinations to be made regarding certain exemptions, DOE is authorized to include in the definition of GSL other lamps that are used to satisfy lighting applications traditionally served by GSILs. (42 U.S.C. 6291(30)(BB)(i)(IV)) While 42 U.S.C. 6295(i)(6)(A)(i)(II) does not expressly direct DOE to consider whether an exempted lamp is used to satisfy the lighting applications traditionally served by GSILs, DOE has determined this consideration to be instructive in the overall assessment regarding the exemptions. As noted by commenters, the function traditionally provided by GSILs can, in some instances, be provided by more than one type of fixture. In order to minimize the

potential for loopholes, DOE has considered the potential for a consumer to change the type of lamp used in an existing fixture, and the potential change in the type of fixture used to provide the same function as traditionally provided by a fixture using a GSIL.

CA IOUs stated that evaluations of the 22 GSIL exemptions should also be based on whether the exempted lamp type can be made as an LED lamp. (That consideration would be relevant because it is almost certain that incandescent lamps will not be able to satisfy the 45 lm/W backstop standard if it comes into force.) (CA IOUs, No. 83 at p. 107) ASAP further stated that of the 15 lamp types that DOE is proposing to continue to exempt there are LED replacements available for all but the infrared lamp. ASAP noted LED replacements that are able to function in high temperature applications could serve as replacements for appliance lamps. (ASAP, No. 83 at pp. 98–99)

DOE is aware that LED replacements may exist for some of the exempt lamp categories. DOE did consider the existence or absence of LED replacements, though not as the only reason to discontinue or maintain a GSIL exemption. DOE’s consideration of lamps for which no equivalent LED replacements exist is discussed in section III.A.4.f.

NEMA provided updated sales information for this final rule. NEMA provided sales data from four members, which represents a significant portion of the market, for each of the exemptions that DOE proposed to discontinue. NEMA stated that although not all members are included, it conferred with other members that did not provide data to confirm the general trend of decreasing sales and shipments of specialty incandescent lamps since standards went into effect for GSILs between 2010 and 2012. (NEMA, No. 93 at pp. 9–10) DOE has updated Table III.1 to reflect this new data. DOE notes that, except with respect to certain lamps discussed in the sections that follow, the data from NEMA are consistent with the estimates and data that the October 2016 NOPDDA presented.

NEMA estimated the annual domestic sales of general service lamps (as defined in 42 U.S.C. 6291(BB)(I)–(III)) to be 600 million units. NEMA noted that this estimate excludes the shipments of the exemption categories proposed to be discontinued noting that each of the exempt lamp categories represents well below 1 percent of the total number of GSLs. NEMA and LEDVANCE stated that the October 2016 NOPDDA appeared to arbitrarily determine that

any number of annual unit sales above 3 million qualifies to be included in the definition of “general service lamp” regardless of whether lamp switching is occurring. NEMA and LEDVANCE cited the example in NEMA’s comments on the March 2016 GSL ECS NOPR that standards for globe lamps, which had an estimated 7 million annual unit sales, would not be justified because these lamps would not consume an average of 100 kWh of electricity per year as required by section 322(b) of EPCA. NEMA and LEDVANCE concluded that the decision to regulate a specialty lamp with declining sales and energy consumption that would not justify regulation as a new consumer product is arbitrary and capricious and contrary to law. (NEMA, No. 93 at pp. 13–14; LEDVANCE, No. 90 at pp. 25–27)

As discussed previously, DOE is not limited to considering only lamp sales when determining whether to maintain or discontinue an exemption. EPCA states lamps sales are only to be a part of the consideration, signifying that DOE is authorized to include other considerations. (42 U.S.C. 6295(i)(6)(A)(i)) As previously discussed, DOE considered the potential for lamp switching in order to minimize the potential for loopholes to any

standard(s) that may be established. Lamp sales are part of that consideration. Again, DOE recognized that historical sales data are not always predictive of future lamp switching. Lamp sales, therefore, were considered in conjunction with the characteristics of a lamp.

Additionally, the specific direction from Congress to consider whether to maintain or discontinue exemptions for certain lamps is separate and distinct from the EPCA requirements for classifying a consumer product as a covered product under 42 U.S.C. 6292(b), which requires minimum energy savings, and from the requirements set out in 42 U.S.C. 6295(o) for establishing new or amended standards. EPCA directs DOE to determine whether to include in the definition of an existing covered product lamps currently excluded. DOE is not designating previously exempt lamps as separate covered products. DOE is determining the scope of an existing covered product pursuant to a specific mandate from section 6295(i)(6)(A), and as such, 42 U.S.C. 6292(b) is inapplicable.

DOE continues to believe it is reasonable to make decisions about the various exemptions without assessing

the average household energy consumption of each, as it would if it conducted a separate section 6292(b) analysis for each exemption. For GSLs as a whole, Congress has determined that regulation is appropriate. (Although DOE of course respects Congress’s decision as sufficient, DOE notes that average household energy consumption of GSLs is well above the section 6292(b) threshold.) The nature of the exemptions is that most of them currently represent relatively small portions of the overall lamp market. Consistent with the preceding framework, DOE believes the exemption decision is meant to ensure that a given type of lamp does not become a loophole for the GSL standards at the time when manufacturers are required to comply with those standards. If a lamp is a ready substitute for GSLs and DOE leaves that type of lamp exempt, energy consumption for that lamp type would presumably increase in the future; but the average rate of current energy consumption for a particular exempt lamp type is not as important a consideration.

Table III.1 summarizes the exemptions maintained or discontinued in this final rule and the sales data for each exemption.

TABLE III.1—DETERMINATIONS REGARDING EXEMPTIONS

| GSIL exempted lamp category | Estimated sales data (units annual sales) | DOE’s determination on exemption status |
|---|---|---|
| Appliance Lamp | Approximately 2 million | Maintain exemption. |
| Black Light Lamp | <1 million | Maintain exemption. |
| Bug Lamp | <1 million | Maintain exemption. |
| Colored Lamp | <2 million | Maintain exemption. |
| Infrared Lamp | <1 million | Maintain exemption. |
| Left-Hand Thread Lamp | <1 million | Maintain exemption. |
| Marine Lamp | <1 million | Maintain exemption. |
| Marine Signal Service Lamp | <1 million | Maintain exemption. |
| Mine Service Lamp | <1 million | Maintain exemption. |
| Plant Light Lamp | <1 million | Maintain exemption. |
| Reflector Lamp | Approximately 30 million | Discontinue exemption. |
| Rough Service Lamp* | 10,914,000 | Discontinue exemption. |
| Shatter-Resistant Lamp | 689,000 | Discontinue exemption. |
| Sign Service Lamp | Approximately 1 million | Maintain exemption. |
| Silver Bowl Lamp | Approximately 1 million | Maintain exemption. |
| Showcase Lamp | <1 million | Maintain exemption. |
| 3-way Incandescent Lamp | 32,665,000 | Discontinue exemption. |
| Traffic Signal Lamp | <1 million | Maintain exemption. |
| Vibration Service Lamp | 7,071,000 | Discontinue exemption. |
| G shape Lamp with diameter of 5 inches or more | 859,867 | Maintain exemption. |
| T shape lamp of 40 W or less or length of 10 inches or more | 9,750,395 | Discontinue exemption. |
| B, BA, CA, F, G16–1/2, G25, G30, S, M–14 lamp of 40 W or less | 71,702,637 | Discontinue exemption. |

*NEMA submitted revised data for rough service lamps following the publication of the notice of data availability for five lamp types. See 81 FR 20261 (April 7, 2016). The revised data showed sales of 10,914,000 rough service lamps in 2015, which results in a requirement for DOE under 42 U.S.C. 6295(l)(4), to initiate an accelerated rulemaking to establish an energy conservation standard for rough service lamps. See ex parte memorandum published in the docket at: <https://www.regulations.gov/document?D=EERE-2011-BT-NOA-0013-0019>.

As shown in Table III.1, based on the revised sales data and a consideration of additional, applicable factors, DOE has determined to discontinue seven GSIL

exemptions. As discussed in section II, DOE believes the lamp categories for which it discontinued exemptions represent significant energy savings

potential either due to high annual sales or by preventing a loophole from forming. DOE is maintaining 15 of the GSIL exemptions due to low sales and

low potential for use in GSL applications. DOE discusses each of the exemptions and comments received on the proposal in the October 2016 NOPDDA in the sections that follow.

a. Exemptions Proposed To Be Discontinued in October 2016 NOPDDA

In the October 2016 NOPDDA, DOE proposed to discontinue eight exemptions from the definition of GSIL. 81 FR 71799. DOE assessed data available for medium screw base reflector lamps that are incandescent and preliminarily concluded that these lamps have high annual sales. To be clear, the following discussion relates only to reflector lamps that are not IRLs. The market includes many reflector lamps that use incandescent technology but do not fall within the statutory definition of IRL, for example, medium screw base reflector lamps with diameters of 2.25 inches or less (*e.g.*, PAR16 or MR16 lamps) or with rated wattages less than 40 W (*e.g.*, 39 W PAR20 lamps). At present, IRLs are exempt from being GSLs; while DOE proposed to discontinue that exemption, DOE will be addressing that proposal in a separate final rule and does not discuss it here. Accordingly, in the following discussion, except where noted, DOE uses the phrase “reflector lamp” to refer only to lamps that are not IRLs.

DOE estimated the sales of medium base reflector lamps that are incandescent as approximately 30 million units per year. DOE believed medium screw base reflector lamps are capable of providing overall illumination and could be used as a replacement for GSILs. Therefore, DOE found there was also high potential for lamp switching and subsequently creating a loophole. For these reasons, DOE proposed to discontinue the exemption for reflector lamps in the October 2016 NOPDDA. *Id.* at 71800.

DOE received several comments in support of its decision to expand the scope of the GSL definition to include reflector lamps. ASAP commented that they strongly supported covering all reflector lamps in the scope of this rulemaking and noted that hundreds of millions of reflector lamps (including IRLs) are sold each year. ASAP stated that directional lamps of all technology types are a growing presence in homes. ASAP noted that there are more efficient alternatives widely available at affordable prices, and including reflector lamps that are incandescent as GSLs is a step towards technological neutrality which will benefit the environment, industry and consumers. (ASAP, No. 83 at pp. 38–39; ASAP, No.

94 at pp. 1–2) NRDC and Utility Coalition supported DOE’s proposal to discontinue the exemption for reflector lamps and noted that there would be a significant impact on energy savings as a result. (NRDC, No. 83 at p. 11; NRDC, No. 85 at p. 2; Utility Coalition, No. 95 at p. 2) Soraa also supported DOE’s proposal to include reflector lamps as GSILs noting that they are used or can be used to provide overall illumination. (Soraa, No. 87 at p. 2) CEC also commented in support of DOE’s proposal to discontinue the GSIL exemption for reflector lamps due in part to their high lamp sales and potential for lamp switching. (CEC, No. 91 at pp. 4–5)

In contrast, GE recommended that reflector lamps (in GE’s comment, primarily IRLs) continue to be regulated separately and that it is not appropriate to evaluate reflector type lamps as GSLs because these products cannot successfully be used to satisfy lighting applications traditionally served by GSILs. (GE, No. 88 at p. 2) GE added that each reflector lamp has unique optical properties that must be considered when applying a minimum efficacy requirement and noted that these products cannot meet the same efficiency limits designed for general service A shape lamps. (GE, No. 88 at p. 2)

In support of their assertion that reflector lamps should be regulated separately, several commenters disagreed with DOE’s determination that reflector lamps posed a risk of lamp switching. GE stated that reflector lamps would not fit in most fixtures in which GSILs are used. Even if a reflector lamp could fit in such a fixture it could not deliver the omnidirectional light output provided by the GSIL. Therefore, GE asserted reflector lamps would not be suitable replacements for the standard GSILs and needed to be evaluated in their own rulemaking. (GE, No. 83 at pp. 37–38) LEDVANCE agreed and stated that the consumer will not obtain effective light by putting a reflector lamp in a fixture that does not have some type of directional functionality. (LEDVANCE, No. 83 at pp. 59–61)

CA IOUs stated that while it may not be always be optimal, reflector lamps can be used in general service applications. (CA IOUs, No. 83 at p. 66) NRDC stated that reflector lamps can be used in applications other than down lights. NRDC pointed out that reflector lamps come in various shapes and there was nothing to prevent a manufacturer from altering the reflector lamp design so more light goes in different directions. (NRDC, No. 83 at p. 45) CA IOUs further noted that as the cheaper

product, the use of reflector lamps that are incandescent in general service applications may increase due to new market pressures in 2020. (CA IOUs, No. 83 at p. 66) CEC agreed that medium screw base reflector lamps represent a lamp switching risk adding that lamp shape does not determine whether a lamp can provide general service lighting and general service lamps are not limited to omnidirectional lighting. (CEC, No. 91 at pp. 4–5) Utility Coalition also stated that LED lamps are suitable replacements for GSLs in many applications because they have the same base types and therefore represent a significant risk of undercutting the energy savings of the 45 lm/W standard if they are not included. (Utility Coalition, No. 95 at pp. 1–2)

Additionally, Utility Coalition commented that there are LED versions of reflector lamps available in a wide variety of shapes and sizes, lumen outputs, CCT, beam angles, and base types and that decreasing prices and increasing efficiency make these products cost-effective to consumers. NRDC also noted that there are several cost-effective, dimmable LED lamps available that serve as excellent replacements for reflector lamps that are incandescent in a variety of form factors, light outputs, and colors and urged DOE to move forward with its proposal to remove the exemption for these lamps. (NRDC, No. 83 at pp. 45–46; Utility Coalition, No. 95 at pp. 1–2) CEC stated that as of June 15, 2015, 658 models of medium screw base reflector lamps complied with Tier 1 of the adopted California standard thus indicating that cost effective, highly-efficacious LED alternatives exist. CEC added that making incremental improvements to existing LED reflector lamps was extremely cost-effective and technically feasible. (CEC, No. 91 at pp. 4–5) Soraa also stated that LED replacements that provide a wide variety of product features, such as color rendering index (CRI), CCT, beam angle, whiteness rendering, and low flicker, are available for the majority of directional incandescent lamps. Soraa noted that customers in quality-sensitive fields such as high-end retail and hospitality have transitioned from halogen to LED technology. Soraa added while there are still some lamp types that are difficult to replicate in LED technology, such as narrow-beam MR16 lamps with the highest wattages, incremental progress in technology will likely make these products available by 2020. Additionally, Soraa stated that the limit of 45 lm/W can be met by

currently-existing products with higher-level features. (Soraa, No. 87 at p. 2)

As discussed previously in this document, DOE did not limit its consideration of lamp switching to the ability to replace a lamp in a fixture currently used by a consumer that had been using a traditional incandescent lamp. As indicated by comments from ASAP previously in this document, the presence of reflector lamps in residences in the U.S. has grown significantly over time due to changes in new construction. (ASAP, No. 83 at pp. 38–39) Lighting in homes that traditionally was provided by A shape lamps in floor and table fixtures is being provided in newer construction through reflector lamps in recessed lighting. (ASAP, No. 83 at pp. 58–59)

The basic design characteristic of a reflector lamp, as defined in the industry standard by the Illuminating Engineering Society of North America (IES) RP–16–10, is that it directs the light. But it is possible to direct the omnidirectional light from an incandescent filament into a somewhat more limited set of angles and still have a lamp that provides general illumination. The reflector lamps now being widely used in recessed can lighting are an important example. In such an application (with the lamp mounted in the ceiling), the reflector redirects light that was initially emitted upward. But the resulting light distribution spreads broadly over the area downward from the lamp, so that a consumer can readily use the lamp to provide general illumination for a room. In light of these observations, DOE concludes that “omnidirectional illumination” is not a prerequisite for the traditional functions of incandescent lamps, as GE suggested. Rather, DOE may consider a lamp a ready substitute for GSILs—for purposes of assessing an exemption—if the lamp can provide the same sort of general illumination that GSILs provide.

As presented in Table III.1, DOE estimates that the sales of medium base reflector lamps that are incandescent (and, as noted, do not meet the definition of IRL) are approximately 30 million units per year. 81 FR 71794, 71800. DOE notes that of the 22 exempted lamp types, the category of medium screw base reflector lamps that are incandescent and do not meet the definition of IRL is the third highest annual unit sales, thus indicating that these lamps are likely used in general lighting applications. In addition, because medium screw base reflector lamps are capable of providing overall illumination and could be used as replacements for GSILs, there is also

high potential for lamp switching. For these reasons, DOE is discontinuing the exemption from the GSIL definition for reflector lamps that are incandescent lamps.

While DOE proposed to discontinue the exemption for reflector lamps generally, DOE noted R20 short lamps would continue not to be subject to standards. R20 short lamps are defined as R20 incandescent reflector lamps that have a rated wattage of 100 W; have a maximum overall length of 3 and 5/8, or 3.625, inches; and are designed, labeled, and marketed specifically for pool and spa applications. In a final rule published on November 14, 2013, DOE determined that standards for these lamps would not result in significant energy savings because such lamps are designed for special applications or have special characteristics not available in reasonably substitutable lamp types. 78 FR 68331, 68340. Pursuant to 42 U.S.C. 6291(30)(E), one consequence of DOE’s determination is that these lamps are specifically not incandescent lamps and therefore do not become GSILs when the reflector lamp exemption is discontinued. 81 FR 71800.

ASAP stated that DOE’s analysis on R20 lamps was performed in 2013, before LED substitutes were available for R20 lamps. ASAP asserted that if DOE performed this analysis again that LED substitutes would be available. (ASAP, No. 94 at p. 2)

DOE acknowledges that the analysis on R20 short lamps was conducted in 2013. DOE did consider available LED substitutes at that time. DOE has not reconsidered the lamps in this rulemaking. The final determination regarding R20 lamps was not based solely on the lack of an available substitute. As provided by EPCA, a lamp may be excluded from the definition of “incandescent lamp” by DOE, by rule, as a result of a determination that standards for such lamp would not result in significant energy savings because such lamp is designed for special applications or has special characteristics not available in reasonably substitutable lamp types. (42 U.S.C. 6291(30)(E), emphasis added) DOE determined that in addition to lacking reasonably substitutable lamp types, the application-specific design characteristics of the R20 short lamp and the marketing and non-traditional distribution channels used by these lamp types, are evidence that R20 lamps are designed for pool and spa applications (*i.e.*, a specialty application). 78 FR 68331, 68334. Indeed, R20 lamps must be labeled and marketed specifically for pool and spa

applications. 10 CFR 430.2. Also relevant to DOE’s decision not to include R20 lamps as GSILs under this rulemaking, the lamp did not experience a market migration to other applications even when R20 lamps were perceived not to be regulated (*i.e.*, lamp switching did not occur). 78 FR 68331, 68334. For these reasons, DOE is maintaining the exclusion of R20 lamps from the definition of “incandescent lamp.”

In the October 2016 NOPDDA, DOE also provided data for medium screw base incandescent lamps of the following specific shapes: B, BA, CA, F, G16–1/2, G25, G30, S, M–14 lamps (as defined in ANSI C78.20 and ANSI C79.1–2002) of 40 W or less; G shape lamps (as defined in ANSI C78.20 and ANSI C79.1–2002) with a diameter of 5 inches or more; T shape lamps (as defined in ANSI C78.20 and ANSI C79.1–2002) that use not more than 40 W or have a length of more than 10 inches. For B, BA, CA, F, G16–1/2, G25, G30, S, and M–14 lamps of 40 W or less, DOE estimated the annual sales as approximately 42 million. For G shape lamps with a diameter of 5 inches or more, DOE estimated the annual sales as approximately 8 million units. In addition to the sizeable sales of larger globe shape lamps, DOE noted it is likely that larger globe shape lamps may be used as substitutes for the G16.5, G25, and G30 lamps if the exemption is not also discontinued. Regarding T shape lamps that use not more than 40 W or have a length of more than 10 inches, DOE estimated the annual sales of these lamps as roughly 7 million units. Further, the lamps of the specific shapes discussed in this paragraph are frequently used in general lighting applications and thus DOE believed there is a significant risk for lamp switching. Therefore, due to the high potential for lamp switching—reflected in part by high sales—DOE proposed to discontinue the GSIL exemption for these specific shapes in the October 2016 NOPDDA. 81 FR 71800.

Regarding T shape lamps, NEMA and LEDVANCE stated that they are often used in applications such as museum or other display cases and in music stands. NEMA and LEDVANCE stated that 40 W T shape lamps (the maximum allowable wattage for these lamps) have low sales volume, and because the majority of T shape lamps are 15 W and 25 W lamps, applying a 45 lm/W standard to this lamp would not yield significant energy savings. They also noted that there is a continuing need for incandescent T shape lamps in exit sign fixtures designed for T-shaped incandescent lamps, pointing out that the UL–1993

safety standard specifically warns that CFLs and LED lamps should not be used in these fixtures. Therefore, NEMA and LEDVANCE commented that eliminating these lamps forces building owners to replace entire exit sign fixtures without an analysis of payback or higher initial costs to consumers. NEMA also provided sales data that show that over the past four years the reported sales of these lamps have fallen by 12.7 percent. (NEMA, No. 93 at p. 17; LEDVANCE, No. 90 at p. 29)

As presented in Table III.1, DOE revised its estimate of the annual sales of T shape lamps of 40 W or less or length of 10 inches or more based on the sales data submitted by NEMA. For the year 2015, the most recent year for which NEMA submitted data, NEMA estimated the annual sales of these T shape lamps as 9,750,395 units. Based on the revised estimate, the T shape lamp category has one of the highest annual sales of the 22 exempted lamp categories, thus suggesting that these lamps are likely used in general lighting applications. In addition to the sizable sales of these T shape lamps, DOE determined that T shape lamps are capable of providing overall illumination and therefore have a high potential for lamp switching. Due to the high potential for lamp switching—reflected in part by high sales—DOE is discontinuing the exemption from the GSIL definition for T shape lamps of 40 W or less or length of 10 inches or more.

Regarding NEMA and LEDVANCE's concern that incandescent T shape lamps are required for use in installed exit signs, DOE was unable to find a UL safety requirement that supported this claim. UL–1993, the standard cited by NEMA and LEDVANCE, states that emergency exit fixtures are outside of the scope of the standard. DOE is aware that certain incandescent lamps, particularly those without equivalent LED replacements, may need to be maintained for safety reasons. DOE has exempted certain specialty lamps as described in section III.A.4.f.

DOE also received feedback on its estimate of sales for the G shape lamp with a diameter of 5 inches or more. NEMA, with LEDVANCE's concurrence, stated that unit sales of G shape lamps with a diameter of 5 inches or more comprise a small portion of the overall unit sales of G shape lamps and noted that DOE's sales estimate of 8 million units attributed to these G shape lamps is inaccurate. NEMA provided data showing that sales of G shape lamps with a diameter of 5 inches have decreased each year since 2012 and were under 1 million units in 2015. (NEMA, No. 83 at pp. 81–82; NEMA,

No. 93 at p. 17; LEDVANCE, No. 90 at p. 27)

Several commenters also disagreed with DOE's assessment that G shape lamps with a diameter of 5 inches or more posed a risk for lamp switching. NEMA commented that this lamp type, due to its large shape, will not fit in most fixtures. Therefore, NEMA noted that instead of consumers switching to this lamp type in applications served by GSILs, they will continue to use it in the specialty applications that it is used in currently. NEMA added that for this reason, and the declining annual sales discussed previously, this lamp type does not pose a risk for lamp switching. (NEMA, No. 83 at p. 85; NEMA, No. 93 at p. 17) LEDVANCE agreed, noting that a consumer is unlikely to replace an A19 shape lamp with a 5-inch diameter lamp. (LEDVANCE, No. 83 at pp. 59–61) NEMA and Westinghouse also argued that the G40 shape incandescent lamp typically is more expensive than GSILs, medium screw base CFLs, and many general service LED lamps on the market. They concluded that the higher price point would also decrease the likelihood of lamp switching. (NEMA, No. 83 at p. 85; NEMA, No. 93 at p. 17; Westinghouse, No. 83 at pp. 87–88) Westinghouse added that LED products that are not UL certified or that are failed market attempts may be priced lower and therefore assessments should be based on average prices rather than the lowest price. (Westinghouse, No. 83 at pp. 87–88) ASAP cautioned that lamp prices are fluid and not necessarily tied to the cost of materials; instead they often fluctuate with demand. ASAP also stated that filament-style G shape LED lamps have become popular in retail food establishments and are reasonably priced. ASAP added that if the volume of G shape lamps were to increase, the price of G shape lamps would likely decrease as well. (ASAP, No. 83 at pp. 82–83, 86–87, 89)

In this final rule, DOE has revised its sales estimate for G shape lamps with a diameter of 5 inches or greater based on the data submitted by NEMA. As shown in Table III.1, the estimated annual sales of this lamp category are 859,867 units. In the October 2016 NOPDDA, DOE had estimated the sales of this lamp category to be approximately 8 million units. As described in the October 2016 NOPDDA, in the absence of actual data DOE estimated annual shipments by extrapolating from DOE's product database based on an inventory of available products. DOE accepts the actual data that NEMA submitted as a more accurate representation of the level of sales of these lamps.

These annual sales, which are substantially lower than what DOE had previously estimated, have motivated DOE to maintain the exemption for G shape lamps with diameter of 5 inches or greater. Low annual sales is not, on its own, a dispositive fact. DOE's previous estimate of annual sales suggested to DOE that consumers were using G shape lamps with large diameters in general lighting applications. However, given the low actual sales, DOE believes that the exempt G shape lamps (*i.e.*, G shape lamps with diameters over 5 inches) are not used in such applications. DOE will continue to monitor the market and may reconsider this decision in the future if G shape lamps with a diameter of 5 inches or greater are used in general lighting applications.

DOE also received comments on medium screw base incandescent lamps of the following specific shapes: B, BA, CA, F, G16–1/2, G25, G30, S, M–14 lamps (as defined in ANSI C78.20 and ANSI C79.1–2002) of 40 W or less. NEMA and LEDVANCE stated that medium screw base decorative lamps (*e.g.*, B, BA, CA, and F shape lamps) have lower lumen output than GSILs and cannot be used interchangeably. They also noted that the sales of the medium screw base versions of these lamps are much smaller than the candelabra base versions. NEMA and LEDVANCE noted that the decorative shape lamps are designed for longer lifetimes, and extend the lifetime of incandescent lamp at the expense of lumen output. NEMA and LEDVANCE added that the statutory wattage cap of 40 W considerably limits the lumen output of decorative shapes compared to typical incandescent or halogen lamps. NEMA and LEDVANCE stated that the smaller size of these lamps prevents manufacturers from making suitable LED alternatives as aesthetically pleasing as incandescent versions or as efficient as larger A shape LED lamps, adding that there is insufficient room to put the required electronics in these lamps to match the efficiency of the A shape LED lamps. NEMA also provided data from its members that show sales of these lamps are declining and that the reported sales are lower in 2015 than they were in 2012. (NEMA, No. 93 at p. 18; LEDVANCE, No. 90 at p. 29)

NEMA and LEDVANCE continued that S-shaped lamps are service lamps typically used as sign lamps. They noted that this is a commercial product that is unlikely to be used in residential applications or in general service lamp fixtures. NEMA and LEDVANCE also commented that M–14 lamps are no longer manufactured as it is an outdated

lamp type. NEMA added that as a result, its annual sales have been zero units over the past four years. (NEMA, No. 93 at pp. 19–20; LEDVANCE, No. 90 at p. 29)

Regarding the other globe shape categories within this list, NEMA and LEDVANCE stated that G16–1/2 shape lamps are the smallest version of a globe shape lamp and that their primary application is in lighting used around dressing room mirrors in theaters. They added that lamp switching is unlikely with this lamp type due to its small size and low lumen output. NEMA and LEDVANCE also noted that the G25 shape is the most popular of the globe shape lamps and that it is used primarily in bathroom vanities and bathroom lamp strips. They argued that lamp switching is also unlikely with this lamp type because of its low lumen output. NEMA and LEDVANCE stated that the G30 shape lamp has declined in popularity in favor of G25 shape lamps, thus its market share has declined significantly. NEMA provided sales data that show sales of these globe shape lamps have been declining over the last four years. (NEMA, No. 93 at p. 19; LEDVANCE, No. 90 at p. 28)

In addition, NEMA disagreed with DOE's decision to include B, BA, CA, F, G16–1/2, G25, G30, S, and M–14 shape lamps all in the same category. NEMA argued that they should be categorized separately because they are used in different lighting applications. NEMA stated that Congress only included these lamps in the same clause of the exclusions list to prevent the list of exclusions from being too lengthy. NEMA added that several of these lamp shape types currently have less than a million units of annual sales with declining sales, which makes lamp switching unlikely. (NEMA, No. 93 at p. 14)

In contrast, NRDC argued that DOE's annual sales estimate of 42 million lamps for the decorative lamps' category is underestimated. NRDC added that the estimate seems low based on DOE's LED adoption report, "Adoption of Light Emitting Diodes in Commercial Lighting Applications," that estimates an installed base of 1.2 billion decorative shape lamps, which would primarily be 25 W and 40 W decorative shaped lamps. (NRDC, No. 85 at p. 5) Thus, NRDC asked DOE to not only focus on the A shape, 5-inch G shape, or 10-inch T shape lamps but also on the B, BA, CA shape lamps as they are very common and could fit in many applications including table or desk lamps. NRDC commented that the pear shape of these decorative lamps (*i.e.*, B, BA, CA, and F shape lamps) does not prevent them

from providing the same amount of light at a low cost. NRDC also added that these lamps, of typically 25 W or 40 W, are used in applications that have high annual hours of use, so they present an opportunity for significant energy savings. NRDC noted that the incandescent CA shape lamps, which are used in sets of 5 or 10 in chandeliers, can be replaced by 7 W LED versions. Further, NRDC stated that by discontinuing these exemptions, though technological limitations may currently exist, there are tremendous benefits that could be gained. (NRDC, No. 83 at pp. 85–86; NRDC, No. 85 at p. 3)

Westinghouse elaborated that the challenge for these decorative lamp shapes is lumen range and efficiency scale. Westinghouse noted that there are not many versions of the decorative lamp shapes in halogen technology because it is not easy to put a double-ended halogen burner in a small size lamp due to heat and space issues. (Westinghouse, No. 83 at pp. 87–88)

While NRDC encouraged a conversation regarding potential hardships in making LED replacements for these lamp shapes in larger form factors, it cautioned DOE not to lose sight of the benefits of discontinuing these exemptions. (NRDC, No. 83 at pp. 85–86) ASAP also acknowledged that not every application of the LED version can be technically and economically feasible. However, citing the popularity of the 500 W double-ended halogen lamp ten years ago, ASAP asserted that the selection of products manufactured and their price points are dictated by market demands. (ASAP, No. 83 at pp. 89–90)

DOE revised its estimate in this final rule for the sales of lamps with specific shapes based on the additional data submitted by NEMA. As shown in Table III.1, the estimated annual sales of this lamp category is 71,702,637 units. While DOE understands that some of these lamps are smaller than A shape lamps, they can still be used to provide overall illumination. DOE further notes that the pear shapes and globe shapes characterized by the majority of lamps in this category would not prevent consumers from using them in general service lighting applications. As indicated by the very high sales data of this category, DOE believes that these lamps are very common and can be used in general lighting applications. Regarding the technical limitations of more efficient versions of these products, DOE reviewed product availability to determine which form factor and light output combinations may not be available in fluorescent or

LED technology. For more information on DOE's consideration of technical feasibility issues, see section III.A.4.a.

Regarding the comment from NEMA suggesting that DOE consider the lamps excluded under 42 U.S.C.

6291(30)(D)(ii)(XXII) separately, DOE notes that Congress listed these lamps together in paragraph (XXII). If the lamps were grouped merely for the purpose of drafting convenience, as suggested by NEMA, it is not clear why Congress would not have also included G shape and T shape lamps in the grouping as well. Instead, G shape and T shape lamps are each listed separately in paragraphs (XX) and (XXI), respectively. (42 U.S.C. 6291(30)(D)(ii)(XX) and (XXI))

DOE has considered whether to maintain the exemption for these lamps as a group due to its concern with lamp switching. DOE recognizes that the lamps listed in clause (XXII) may each not be substituted for one another in existing fixtures. However, as discussed previously, DOE also considers the potential for lamp switching through the future use of different fixtures. There is the potential that inclusion of some but not all of the lamps in the group would shift the market to the lamp or lamps that remain exempt. Thus, due to the very high sales volume and risk of lamp switching of the lamp types, DOE is discontinuing exemptions for B, BA, CA, F, G16–1/2, G25, G30, S, M–14 lamp of 40 W or less.

Regarding other exempt lamp categories, pursuant to 42 U.S.C. 6295(l)(4), DOE is required to collect unit sales data for rough service, shatter-resistant, 3-way incandescent lamps, and vibration service lamps. Section 321(a)(3)(B) of EISA 2007 in part amends subsection 325(l)(4) of EPCA by adding paragraphs (D) through (H), which direct DOE to take regulatory action if the actual annual unit sales of any of these lamp types are more than 200 percent of the predicted shipments (*i.e.*, more than double the benchmark unit sales estimate). (42 U.S.C. 6295(l)(4)(D)–(H)) DOE published a notice of data availability (NODA) in April 2016, which indicated that the shipments of vibration service lamps were over 7 million units in 2015, which equates to 272.5 percent of the benchmark estimate. 81 FR 20261, 20263 (April 7, 2016). Furthermore, NEMA submitted revised data for rough service lamps that showed sales of 10,914,000 rough service lamps in 2015, which exceeds 200 percent of their benchmark estimate. Although the sales of shatter-resistant and 3-way incandescent lamps have not yet exceeded their estimated benchmarks,

DOE expects these sales will likely increase since these lamps could be used as replacements for other regulated lamp types. Based on the high sales volume and probability of consumers switching to these lamp types, DOE proposed to discontinue the exemptions of rough service, shatter-resistant, 3-way incandescent, and vibration service lamps from GSILs in the October 2016 NOPDDA. 81 FR 71800.

NEMA supported the regulation of rough service and vibration service incandescent lamps but opposed treating these lamps as “general service incandescent lamps” because they are specialty lamps that were intended to be regulated using a wattage cap as indicated by the statute (see 42 U.S.C. 6295(i)(4)(D)(ii) and (E)(ii)) rather than a lumens per watt or modified lumens per watt regulation. NEMA encouraged DOE to adopt NEMA’s proposal of maximum wattage caps for regulating these two specialty products, which NEMA asserted is consistent with the congressional intent reflected in EISA 2007. (NEMA, No. 93 at p. 12) Additionally, NEMA, LEDVANCE, and Philips asserted that DOE is authorized to establish standards for rough service lamps, shatter-resistant, 3-way incandescent, and vibration service lamps only under the provisions in 42 U.S.C. 6295(l)(4) and that the sales thresholds required under that section to regulate shatter-resistant and 3-way incandescent lamps have not been met. (NEMA, No. 93 at p. 12; LEDVANCE, No. 90 at pp. 19–20; Philips, No. 96 at p. 4) LEDVANCE stated that the more specific reference to regulate rough service lamps, shatter-resistant lamps, 3-way incandescent lamps and vibration service lamps must be read as governing the regulation of these lamps, as opposed to the more general provision in 42 U.S.C. 6295(i)(6)(A)(i)(II). (LEDVANCE, No. 90 at p. 20)

Under 42 U.S.C. 6295(l)(4), DOE is required to undertake a standards rulemaking for rough service lamps, shatter-resistant lamps, 3-way incandescent lamps and vibration service lamps when the sales of these lamps meet specified thresholds. DOE is also required, in consultation with NEMA, to collect sales data for these lamps and construct a model to predict future sales. (42 U.S.C. 6295(l)(4)(B)) DOE must then track the actual sales data, and when sales exceed sales projected by the model by 100 percent, DOE must initiate a rulemaking. (42 U.S.C. 6295(l)(4)(D), (E), (F), (H)) If DOE does not complete the accelerated rulemaking in the specified time period, it must impose a backstop requirement

for that lamp. (42 U.S.C.

6295(l)(4)(D)(ii), (E)(ii), (F)(ii), (H)(ii))

However, this is not the only way in which DOE can regulate these lamps. The text of section 6295(i) and 6295(l) does not state that the section 6295(l) process operates to the exclusion of regulating these lamps as GSILs. As commenters noted with respect to the section 6295(i)(6)(A)(v) backstop, GSILs may become subject to a default standard of 45 lm/W; but DOE is authorized to impose alternative standards for GSILs in general so long as the overall savings from such a rule are at least as great as a uniform 45 lm/W standard would achieve. Thus, in regulating the five types of section 6295(l) lamp as GSILs, DOE would be able to establish a range of possible standards. However, for these particular lamps, when sales have increased to a certain point, section 6295(l) requires DOE to conduct an accelerated rulemaking, and absent that rulemaking, specifies certain minimum standards. That requirement is not inconsistent with the regulatory framework applicable to GSILs, and Congress’s decision to set a separate backstop for these lamps (conditioned on factual circumstances) does not suggest that Congress meant to exclude them from the broader regulatory program.

Additionally, as DOE explained in the October 2016 NOPDDA, DOE understands the reference to “data collected” by DOE under the GSL rulemaking provision to mean the data collected as required for rough service lamps, vibration service lamps, 3-way incandescent lamps, and shatter-resistant lamps. 81 FR 71794, 71798. As noted, DOE is required to collect sales data for these lamps. (42 U.S.C. 6295(l)(4)(B)) The consideration of sales data collected by DOE in making a determination under 42 U.S.C. 6295(i)(6)(A)(i)(II) further demonstrates that the determination is to include rough service lamps, vibration service lamps, 3-way incandescent lamps, and shatter-resistant lamps.

GE agreed with regulating vibration service lamps and rough service lamps as the sales of these lamps have been increasing and have surpassed the allowed sales threshold. GE added that these lamps resemble and, therefore, are being purchased to replace the standard incandescent A shape lamp. (GE, No. 83 at p. 72; GE, No. 88 at p. 2) However, GE stated that shatter-resistant lamps and 3-way lamps are declining in sales, indicating low risk of lamp switching. GE added that the risk of lamp switching is particularly low for the 3-way lamp. GE explained that these lamps are made in A21 and A23 shapes

because the filament must be placed farther from the glass due to the increased heat. Therefore, these lamps may not fit in existing fixtures where A19 shape lamps are used and also may not meet the UL wattage limit on many fixtures in the home. (GE, No. 83 at pp. 72–73; GE, No. 88 at p. 2) NEMA agreed that lamp switching for 3-way lamps is unlikely because the A21 lamp size is larger than the size of the regular A19 lamp and is not a suitable replacement for a regular incandescent lamp. NEMA also added that the safety standard UL 1598 contains a thermal requirement for most common general service lighting fixtures that limits lamp wattage to 100 W and thus higher 150 W 3-way incandescent lamps cannot be used in these fixtures. Further, NEMA commented that many light switches are incapable of controlling the 3-way functionality of a 3-way lamp and it is unlikely a consumer would purchase a more expensive 3-way lamp if the functionality is not desired or cannot be used. (NEMA, No. 93 at p. 16)

NEMA also disagreed with DOE’s proposal to consider shatter-resistant lamps as GSILs noting that sales have fallen 50 percent since 1997, did not increase when traditional GSILs were phased out from 2010–2012, and have not exceeded the statutory threshold under section 325(l)(4)(H). NEMA noted that DOE cannot justify regulating shatter-resistant lamps using a potential for lamp switching because Congress established a clear threshold for the regulation of these lamps of exceeding the estimated sales by 100 percent. Thus, NEMA concluded that DOE does not have the discretion to determine that shatter-resistant lamps are GSILs and must adhere to the limits of the statute. (NEMA, No. 93 at p. 15) Additionally, NEMA commented that the coating on the shatter-resistant lamp reduces the lumen output significantly, making it not ideal as a replacement for a GSIL or general service LED lamp. NEMA added that the lumen output of a 60 W shatter-resistant lamp is identical to the lumen output of a 40 W standard incandescent lamp. As a result of the lumen output differences, NEMA noted that lamp switching is not likely to occur as consumer will not treat a lower lumen lamp as an effective substitute. (NEMA, No. 93 at pp. 15–16) Westinghouse noted that when standards from EISA 2007 became effective consumers did not switch to 3-way lamps, rough service lamps, or shatter-resistant lamps at the time. (Westinghouse, No. 83 at pp. 74–76)

In contrast, CA IOUs, NRDC, and Utility Coalition supported the proposal to discontinue exemptions for shatter-

resistant lamps, rough service lamps, vibration service lamps, and 3-way lamps because these lamps pose a lamp switching risk. (NRDC, No. 83 at p. 74; CA IOUs, No. 83 at p. 77; Utility Coalition, No. 95 at p. 3) NRDC stated that these lamp types look and operate like a standard incandescent lamp and can be used in general service lighting applications. NRDC and Utility Coalition further noted that there are a wide range of efficient alternatives available for these lamp types and NRDC added if they are not regulated their sales would increase dramatically when the next standards go into effect. NRDC also countered that while the sales of 3-way lamps may not be increasing today, there was nothing to prevent them from doing so in the future. It would cost very little to put a coating over a standard incandescent lamp and make it a shatter-resistant lamp, which would dramatically increase sales and reduce purchase price. NRDC added that these lamps would also use considerably more energy than lamps that must comply with a standard and cost consumers significantly more to operate. (NRDC, No. 83 at pp. 10–11, 73–74; NRDC, No. 85 at pp. 1–2; Utility Coalition, No. 95 at p. 3) Utility Coalition noted that LED lamps are inherently durable and provide the necessary utility to serve in the applications of rough service, shatter-resistant, and vibration service. Thus, Utility Coalition concluded that these lamp types should be held to the same standard as all other LED lamps. Additionally, Utility Coalition noted that the incandescent versions of these lamps are even less efficient than standard GSILs, with rough service lamps commonly performing around 10 lm/W. (Utility Coalition, No. 95 at p. 3)

CA IOUs agreed that LED replacements that provide the same functionality are available for these lamp types, in particular the 3-way lamp type. CA IOUs noted that many of the major manufacturers provide 3-way LED replacements and these lamps are highly efficient and reasonably priced in the \$10–\$14 range. Utility Coalition added that DOE testing confirmed that 3-way LED lamps are highly efficient with an efficiency of 111.4 lm/W at the middle setting. (CA IOUs, No. 83 at p. 77; Utility Coalition, No. 95 at p. 3) Westinghouse disagreed citing a high cost differential for consumers to switch to 3-way LED lamps. Westinghouse stated that a 3-way incandescent lamp costs \$2.19 while a 3-way LED lamp is in the \$20–\$22 range with older versions on clearance at \$15–\$16. (Westinghouse, No. 83 at pp. 74–76)

DOE reviewed the sales data submitted by NEMA for the shatter-resistant and 3-way incandescent lamps. The sales of shatter-resistant lamps declined between 2012 and 2015. The sales of 3-way incandescent lamps increased between 2012 through 2014 and then decreased in 2015. However, sales of these lamps have declined over a limited time period. Further, NEMA submitted data for 2015 that indicated that almost 32 million¹³ 3-way incandescent lamps (67.2 percent of the benchmark estimate) and nearly 700,000 shatter-resistant lamps (41.1 percent of the benchmark estimate) were sold in that year. 81 FR at 20263–64 (April 7, 2016).

Regarding the lamp switching potential of 3-way lamps, as stated by NEMA and GE, UL 1598 prescribes wattage requirements for certain luminaires. However, UL 1598 is not a comprehensive standard of all fixtures that could be used in general lighting applications. DOE notes that, as stated previously, lamp switching includes shifting to the use of different fixtures in the future and therefore lamp size does not necessarily prevent switching. Regarding the lamp switching potential of shatter-resistant lamps, DOE notes that shatter-resistant lamps are capable of providing overall illumination despite the lower lumen output resulting from the shatter-resistant coating. As noted by NEMA, a 60 W shatter-resistant lamp is still an appropriate replacement for a 40 W standard incandescent lamp.

DOE also expects the sales of these lamps to increase since they could be used as replacements for other regulated lamp types. Shatter-resistant lamps are similar to rough service and vibration service lamps, two lamp categories for which sales have already increased as a result of standards for GSILs. Whereas rough service and vibration service lamps possess a filament strengthened with additional supports, shatter-resistant lamps possess a reinforced outer bulb to contain glass pieces in the event that the bulb breaks. For all three lamp types the consumer may be under the impression that they are purchasing primarily a more durable product rather than a lamp with subpar performance as claimed by NEMA. Some lamps are even offered with more than one of these criteria (e.g., a shatter-resistant lamp with vibration service filaments). Although these lamps must be designated as rough service, vibration service, or shatter-resistant on the lamp packaging, that designation did not

prevent rough service and vibration service lamps from serving as a loophole to standards for GSILs.¹⁴ Furthermore, for all three of these lamp types, LED versions inherently provide the consumer the desired functionality in the sense that LED lamps do not have metal filaments and typically do not use glass outer bulbs. Because the sales of rough service and vibration service lamps have already showed that consumers view these lamps as convenient, unregulated substitutes for GSILs and choose them even though LED lamps provide the same functionality, DOE expects that sales of shatter-resistant lamps will similarly increase if left unregulated. Therefore, based on the high sales volume and probability of consumers switching to these lamp types, DOE is discontinuing the exemptions of shatter-resistant and 3-way incandescent lamps.

As noted, the sales threshold set by EPCA for vibration service incandescent lamps and rough service incandescent lamps has been exceeded. The increasing sales of these lamp types and industry's feedback on their use indicate that these products are used in general lighting applications as substitutes for GSILs. (Westinghouse, No. 83 at pp. 41–42; NEMA, No. 83 at pp. 52–53; GE, No. 83 at p. 73). Therefore, DOE is also discontinuing the exemptions of rough service and vibration service lamps from GSILs in this final rule.

In summary, DOE is discontinuing the following exemptions from the definition of GSIL in this final rule: Reflector lamps; T shape lamps that use not more than 40 W or has a length of more than 10 inches; B, BA, CA, F, G16–1/2, G25, G30, S, M–14 lamps of 40 W or less; rough service lamps; shatter-resistant lamps; 3-way incandescent lamps; and vibration service lamps.

¹⁴ NEMA points out that the coating used to protect shatter-resistant lamps causes such a lamp to provide less output light, for a given wattage, than a comparable non-protected lamp. DOE recognizes also that, while it considers shatter-resistant lamps to be similar in important respects to rough service and vibration service lamps, sales of the former have not thus far increased alongside sales of the latter two. These observations do not undermine DOE's conclusion here. They may reveal that shatter-resistant lamps are less desirable substitutes for GSILs at a time when GSILs are subject only to their own standards. DOE is discontinuing the exemption for shatter-resistant lamps because it believes they will be convenient substitutes for GSILs at a time when GSIL standards effectively preclude the use of incandescent technology for GSILs. In that context, DOE does not believe the reduction in light output that the shatter-resistant glass coating causes will discourage customers from buying these lamps for GSIL-type applications.

¹³ This value was incorrectly stated as 38 million in the October 2016 GSL NOPDDA.

b. Exemptions Proposed To Be Maintained in October 2016 NOPDDA

In the October 2016 NOPDDA, DOE proposed to maintain 14 exemptions from the definition of GSIL. DOE found that medium screw base incandescent lamps that are appliance; black light; bug; colored; infrared; left-hand thread; marine; marine signal service; mine service; plant light; sign service; silver bowl; showcase; and traffic signal lamps had low sales data thus indicating that these are low volume products. DOE estimated that 12 of the 14 exemptions have annual unit sales of 1 million units or less. The remaining two exemptions, appliance lamps and colored lamps, were estimated to have less than 3 million annual unit sales and less than 2 million annual unit sales, respectively. DOE also tentatively concluded that several of these exempted lamp types are unable to serve in general lighting applications and cannot provide overall illumination. Specifically, black light; bug; colored; infrared; and plant light lamps produce radiant power in specific wavelengths of the electromagnetic spectrum that would prevent these lamps from serving in general lighting applications. Further, DOE noted that proposing definitions for these exempted lamp types will help to prevent them from becoming loopholes. (See section III.B for a discussion of the definitions proposed for exemptions.) 81 FR 71801. DOE received comments on the 14 GSIL exemptions proposed to be maintained in the October 2016 NOPDDA.

CEC supported DOE's decision to maintain the 14 exemptions from the GSIL definition that it believes are unable to serve in general lighting applications and cannot provide overall illumination. (CEC, No. 91 at p. 5) NEMA, Philips, and GE also agreed with the 14 exemptions from the GSIL definition that DOE proposed to maintain. (NEMA, No. 93 at p. 22; Philips, No. 96 at p. 3; GE, No. 88 at p. 2) GE commented that sales of the 14 exemption categories are small and decreasing, while offering little opportunity for energy savings. (GE, No. 88 at p. 2) Philips added that these lamps serve many niche applications that currently do not have LED replacements in the same form factor and are unlikely to in the future due to technology limitations. Philips stated that it prefers to leverage improvements in SSL technology to improve performance, reduce cost, and offer innovative versions of mainstream products rather than invest in low volume R&D intensive niche products.

Philips concluded that this will encourage consumer adoption and increase energy savings. (Philips, No. 96 at p. 3)

In contrast, ASAP recommended discontinuing several of the 14 exemptions from the GSIL definition noting that the proposed definitions were not specific enough to prevent potential loopholes.

ASAP recommended discontinuing the exemptions for marine and mine lamps because there is little difference in manufacturing or performance of these lamps compared to GSILs, and there are energy-efficient replacements available. (ASAP, No. 94 at p. 5) Utility Coalition also recommended DOE not exempt marine lamps noting that they agreed with DOE's determination that marine lamps provide overall illumination and argued that DOE should not exempt the incandescent versions of these lamps because a potential loophole may result. In addition, Utility Coalition stated that LED versions of marine lamps are now available with substantially higher efficiencies than the incandescent versions. (Utility Coalition, No. 95 at p. 7)

For marine lamps and mine service lamps, as shown in Table III.1, DOE estimates that the annual sales were less than 1 million units for each lamp type and therefore concludes that marine lamps and mine service lamps are low volume products. Further, DOE has adopted definitions in this final rule requiring that these lamps are designed and labeled for their respective applications in order to discourage their use in general lighting applications. (See sections III.B.10 and III.B.4 for the adopted definitions of mine service lamp and marine lamp, respectively.) For these reasons, DOE has maintained the exemptions from the GSIL definition for marine lamps and mine service lamps.

ASAP also recommended discontinuing the exemption for showcase lamps to prevent a potential loophole noting they are widely available, can fit in many light fixtures, and are similar to the T shape lamps that DOE proposed to include. (ASAP, No. 94 at p. 5) DOE determined that showcase applications generally have space constraints and therefore typically require the use of lamps with specific shapes and characteristics to serve in this specialty application. As shown in Table III.1, DOE estimates the annual sales of showcase lamps to be less than 1 million units and thus concludes that these lamps are low volume products. In addition, DOE has adopted a definition in this final rule that includes only

specific shapes and wattages and requires that showcase lamps be designed and labeled for their specialty application in order to discourage their use in general lighting applications. (See section III.B.5 for the adopted definition of showcase lamp.) Given the specific characteristics of showcase lamps outlined in the definition, DOE concluded that the continued exemption of showcase lamps is unlikely to create a loophole. Thus, DOE has maintained the exemption for showcase lamps from the GSIL definition in this final rule.

ASAP noted that the exemption for bug lamp should be discontinued because it was found recently in a study presented at the American Academy of Arts and Sciences 2016 Annual Meeting that warm light LED lamps attracted fewer bugs than incandescents, CFLs, halogens, cool light LED lamps, and incandescent bug lamps. (ASAP, No. 94 at p. 5) DOE understands that research has been conducted to assess the most effective sources for preventing bug attraction. The abstract of the study¹⁵ cited by ASAP stated that it was the first and only study to directly compare the effectiveness of different lamp technologies designed for outdoor residential use in preventing the attraction of bugs. Further, the study appears to be limited to a specific geographic region and time of year. DOE appreciates ASAP directing its attention to the study but is withholding from making a determination on the effectiveness of various technologies based on the limited research available thus far. DOE estimates the annual sales of bug lamps to be less than 1 million units and thus concludes that these lamps are low volume products. In addition, DOE determined that the features of a bug lamp, including radiant power in a specific portion of the electromagnetic spectrum and visible yellow coating, would discourage its use in general lighting applications and limit its ability to provide overall illumination. Further, DOE has adopted a definition for bug lamp in this final rule reflecting these unique characteristics and requiring that bug lamps be specifically designed and labeled for their specialty application in order to discourage their use in general lighting applications. (See section III.B.1 for the adopted definition of bug lamp.) For these reasons, DOE has maintained

¹⁵ Light Pollution and Insects: Insect Attraction to Various Types of Residential Lights abstract is available at: <http://www.aas.org/abstract/light-pollution-and-insects-insect-attraction-various-types-residential-lights>.

the exemption for bug lamp from the GSIL definition in this final rule.

Regarding plant light lamps, ASAP commented that the LED versions of these lamps are a better alternative to incandescent plant light lamps and less expensive to operate. (ASAP, No. 94 at p.5) DOE acknowledges the potential for LED lamps to be well suited to provide light in specific spectral ranges to encourage plant growth; however, DOE also believes this to be an area of continuing research¹⁶ and is not assessing the effectiveness of different technologies on plant growth. As shown in Table III.1, DOE estimates the annual sales of plant light lamps to be less than 1 million units and thus concludes that these lamps are low volume products. In addition, DOE determined that plant light lamps produce radiant power in specific wavelengths of the electromagnetic spectrum that would prevent these lamps from serving in general lighting applications. DOE has adopted a definition in this final rule specifying radiant power requirements and requiring that these lamps be designed and marketed for their specialty application in order to discourage their use in general lighting applications. (See section III.B.1 for the adopted definition of plant light lamp.) For these reasons, DOE has maintained the exemption for plant light lamp from the GSIL definition in this final rule.

ASAP recommended including traffic signal lamps in the definition of GSL. (ASAP, No. 94 at p. 4) NRDC stated that the exemption for traffic signal lamps is not warranted because these lamps are suitable for general lighting applications and are comparable to rough service or vibration service lamps through the use of a sturdier filament. NRDC noted that these lamps available in medium screw bases, have input voltages of 120 V and 130 V, and have significant light output comparable to 40 W or 60 W lamps. NRDC added that LED lamps can serve as suitable replacements for traffic signal lamps, as they are physically durable, have long lifetimes, and already exist at the desired voltages and light output levels. (NRDC, No. 83 at pp. 12, 95; NRDC, No. 85 at p. 8) Utility Coalition also recommended DOE not exempt traffic signal lamps from the GSL definition. Utility Coalition noted that they agreed with DOE's determination that traffic signal lamps provide overall illumination and argued that DOE should not exempt the

incandescent versions of these lamps because a potential loophole may result. In addition, Utility Coalition noted that LED versions of traffic signal lamps are now available with substantially higher efficiencies than the incandescent versions. (Utility Coalition, No. 95 at p. 7)

DOE understands that traffic signal lamps may share characteristics with rough service or vibration service lamps; however, DOE also identified a characteristic of traffic signal lamps—a very long lifetime, which indicated they were designed for a specialty application. As shown in Table III.1, DOE estimates the annual sales of traffic signal lamps to be less than 1 million units and thus concludes that these lamps are low volume products. In addition, DOE believes removing the exemption for traffic signal lamps could result in safety concerns or stranded equipment. DOE has adopted a definition in this final rule specifying a minimum lifetime requirement and requiring that these lamps be designed and marketed for their specialty application in order to discourage their use in general lighting applications. (See section III.B.6 for the adopted definition of traffic signal lamp.) For the reasons discussed in this paragraph, DOE has maintained the exemption for traffic signal lamp from the GSIL definition in this final rule. DOE will continue to monitor the market and may reconsider this decision in the future if traffic signal lamps are used in general lighting applications.

CA IOUs acknowledged that silver bowl lamps are unique in that they have an aluminum cover at the top that reflects light back into the fixture. However, CA IOUs stated that these lamp types are becoming more popular and being used for general illumination, often in restaurants, because they can still project light into an area and provide overall illumination. CA IOUs and ASAP added that silver bowl LED lamps are also becoming more common and offered in different form factors. Therefore, CA IOUs recommended that the exemption for silver bowl lamps from GSILs be discontinued. (CA IOUs, No. 83 at pp. 107–108; ASAP, No. 94 at p.5) Utility Coalition also recommended that DOE not exempt silver bowl lamps from the GSL definition. Utility Coalition noted that they agreed with DOE's determination that silver bowl lamps provide overall illumination and argued that DOE should not exempt the incandescent versions of these lamps because a potential loophole may result. (Utility Coalition, No. 95 at p. 7)

As shown in Table III.1, DOE estimates the annual sales of silver bowl

lamps to be approximately 1 million units and thus concludes that these lamps are low volume products. In addition, DOE has determined that silver bowl lamps use an opaque reflective coating to provide diffuse light concentrated in an upward direction which other lamps, such as omnidirectional or reflector lamps, are unable to provide without the use of additional components. DOE has adopted a definition in this final rule specifying the inclusion of an opaque reflective coating and requiring that these lamps be designed and marketed for their specialty application in order to discourage their use in general lighting applications. (See section III.B.7 for the adopted definition of silver bowl lamp.) For these reasons, DOE has maintained the exemption for silver bowl lamp from the GSIL definition in this final rule.

Utility Coalition also recommended that DOE not exempt left-hand thread lamps from the GSL definition. Utility Coalition noted that they agreed with DOE's determination that left-hand thread lamps provide overall illumination and argued that DOE should not exempt the incandescent versions of these lamps because a potential loophole may result. In addition, Utility Coalition noted that LED versions of left-hand thread lamps are now available with substantially higher efficacies than the incandescent versions. (Utility Coalition, No. 95 at p. 7)

As shown in Table III.1, DOE estimates the annual sales of left-hand thread lamps to be less than 1 million units and thus concludes that these lamps are low volume products. In addition, DOE has adopted a definition in this final rule requiring that these lamps be designed and marketed for their specialty application in order to discourage their use in general lighting applications. (See section III.B.10 for the adopted definition of left-hand thread lamp.) Given the very low sales and the adopted definition, DOE concluded that the continued exemption of left-hand thread lamps is unlikely to create a loophole. Thus, DOE has maintained the exemption for left-hand thread lamps from the GSIL definition in this final rule. DOE will continue to monitor the market and may reconsider this decision in the future if left-hand thread lamps are used in general lighting applications.

Westinghouse stated that the lumen output of heat lamps (or infrared lamps) is low but was not sure if it is below 310 lumens which would exclude them from the GSL definition. (Westinghouse, No. 83 at p. 43) DOE notes that

¹⁶ Massa, G., Kim, H.-H., & Wheeler, R. *Plant Productivity in Response to LED Lighting*. HortScience. December 2008. (Last accessed November 20, 2016.) <<http://hortsci.ashspublications.org/content/43/7/1951.full>>

information available for infrared lamps is very limited and lumen output was generally not available since the primary purpose of these lamps is to provide heat. DOE determined that infrared lamps predominately provide radiant power in the infrared region of the electromagnetic spectrum and also typically have a wattage of 125 W or greater. As shown in Table III.1, DOE estimates the annual sales of infrared lamps to be less than 1 million units and thus concludes that these lamps are low volume products. In addition, DOE has adopted a definition in this final rule specifying the design parameters and requiring that infrared lamps be designed and marketed for their specialty application in order to discourage their use in general lighting applications. (See section III.B.2 for the adopted definition of infrared lamp.) For these reasons, DOE has maintained the exemption for infrared lamp from the GSIL definition in this final rule.

DOE also estimated the sales data of medium screw base incandescent lamps that are appliance lamps; black light lamps; colored lamps; marine signal service lamps; and sign service lamps. As indicated in Table III.1, the annual sales of black light, marine signal service, and sign service lamps were 1 million units or less. Appliance lamps and colored lamps were estimated to have annual sales of 2 million units or less. Having received no comments to the contrary, DOE has maintained the exemptions for these lamps due to low sales and the inability or unlikelihood of these lamps to serve in general lighting applications. Further, DOE adopted definitions for these exempted lamp types to prevent them from becoming loopholes. (See section III.B for a discussion of the adopted definitions.)

As discussed in section III.A.1.a, in this final rule, DOE is also maintaining the exemption of G shape lamps with a diameter of 5 inches or greater. As stated previously, DOE will continue to monitor the market and may reconsider this decision in the future if G shape lamps with a diameter of 5 inches or greater are used in general lighting applications.

c. Amended Definition for GSIL

Based on the preliminary determinations in the October 2016 NOPDDA, DOE proposed a new definition for GSIL. GSILs are included in the definition of GSL. (42 U.S.C. 6291(30)(BB)(i)(I)) Thus, any lamp that meets the definition of a GSIL would be a GSL. ASAP supported DOE's proposed revisions to the GSIL definition stating that it is clearer and reduces the chances

of loophole products emerging that can undercut the energy savings from the 45 lm/W backstop standard. (ASAP, No. 94 at p. 3)

In this final rule, DOE is adopting a revised definition of GSIL. A general service incandescent lamp is a standard incandescent or halogen type lamp that is intended for general service applications; has a medium screw base; has a lumen range of not less than 310 lumens and not more than 2,600 lumens or, in the case of a modified spectrum lamp, not less than 232 lumens and not more than 1,950 lumens; and is capable of being operated at a voltage range at least partially within 110 and 130 volts; however this definition does not apply to the following incandescent lamps: An appliance lamp; a black light lamp; a bug lamp; a colored lamp; a G shape lamp with a diameter of 5 inches or more as defined in ANSI C79.1–2002; a n infrared lamp; a left-hand thread lamp; a marine lamp; a marine signal service lamp; a mine service lamp; a plant light lamp; an R20 short lamp; a sign service lamp; a silver bowl lamp; a showcase lamp; and a traffic signal lamp. See the amendments to § 430.2 for the revised definition in its entirety.

2. CFLs

CFLs are also included in the definition of GSL; however, the term “compact fluorescent lamp” was not previously defined. DOE adopted a definition for CFL in the August 2016 CFL test procedure final rule. 81 FR 59386, 59403 (August 29, 2016). DOE incorporated language from the industry standards published by IES RP–16–10 and IES LM–66–14 to define CFL without inappropriately excluding or including lamps. A CFL is an integrated or non-integrated single-base, low pressure mercury, electric-discharge source in which a fluorescing coating transforms some of the ultraviolet energy generated by the mercury discharge into light; the term does not include circline or U-shaped lamps. 10 CFR 430.2.

DOE did not receive any comments regarding this definition and therefore considers CFLs to be lamps as described in the definition adopted in the August 2016 CFL test procedure final rule.

3. General Service LED Lamps and OLED Lamps

General service LED and OLED lamps are included in the definition of GSL under 42 U.S.C. 6291(30)(BB). DOE proposed definitions for both terms in the October 2016 NOPDDA. 81 FR 71803. NEMA recommended and LEDVANCE supported their recommendation that the definition of

general service LED lamp be modified to include lamps marketed for vibration service, rough service, and vibration resistance and exclude specialty lamps and specialty base lamps as defined by NEMA. (NEMA, No. 93 at p. 26; LEDVANCE, No. 90 at pp. 32–33)

As described in section III.A.1.a, DOE discontinued exemptions for vibration service and rough service lamps from the definition of GSIL and therefore these lamps are also included in the definition of GSL. 81 FR 71801. DOE has addressed other specialty lamps as they relate to the definition of GSL in section III.A.4. Therefore, DOE has not revised the definition of “general service LED lamp” in this final rule.

DOE is definitions for “general service LED lamp” and “general service OLED lamp” as detailed in the amendments to § 430.2.

4. Other Lamps

As stated previously, the definition of GSL includes (subject to the exemptions to the extent DOE maintains them) any other lamps that DOE determines are used to satisfy lighting applications traditionally served by GSILs. (42 U.S.C. 6291(30)(BB)(i)(IV)) In addition to GSILs, CFLs, and general service LED and OLED lamps, DOE proposed in the October 2016 NOPDDA a determination that any other lamps that are intended to serve in general lighting applications and have specific features would meet the statutory criterion of lamps used to satisfy lighting applications traditionally served by GSILs. To implement this determination in the October 2016 NOPDDA, DOE proposed to define general service lamp as a lamp capable of serving in general lighting applications and that has the following basic characteristics: (1) An ANSI base (with the exclusion of light fixtures and LED downlight retrofit kits); (2) a lumen output of greater than or equal to 310 lumens and less than or equal to 4,000 lumens; (3) an ability to operate at any voltage; and (4) no designation or label for use in non-general applications. 81 FR 71807. “General lighting application” is currently defined at 10 CFR 430.2 as lighting that provides an interior or exterior area with overall illumination. The key aspects of the proposed definition of GSL and specific comments received regarding these features are discussed in the following sections.

a. Product Availability

Regarding DOE's authority to include other lamps as GSILs, DOE received several comments regarding the availability of equivalent LED substitutes. Westinghouse commented

that there should be two considerations: (1) Whether a lamp type can be made in an LED form and (2) whether it makes economic sense to make the LED version of a lamp type. Westinghouse added that while it is sometimes possible to make the LED version of a specialty lamp, it may not make sense if the sales are declining and potential energy savings are very small. (Westinghouse, No. 83 at pp. 62–64) Westinghouse stated that there are products with small form factors and high lumen output that simply cannot be made as LED replacements. Westinghouse added that they are not aware of any current technology pathways to make certain lamps despite funding opportunities offered by DOE and the utilities. (Westinghouse, No. 83 at pp. 22–23) GE agreed with Westinghouse that there are many halogen lamps used for commercial applications for which it would be physically impossible to make LED replacements. (GE, No. 83 at pp. 129–130) Westinghouse stated that halogen lamps are declining in sales due to a shift towards integrated LED fixtures, but that as long as these sockets remain, consideration should be given to lamps that cannot be made using LED technology. (Westinghouse, No. 83 at pp. 126–129)

After reviewing product availability, technical information, and comments from stakeholders, DOE believes there are three main categories of lamps: (1) Lamps with more efficient, equivalent replacements (*i.e.*, the same form factor and light output); (2) lamps currently without equivalent replacements but for which replacements can likely be made in the future; and (3) lamps for which industry is unlikely to ever be able to create equivalent replacements using more efficient technology.

Regarding the third category of lamps, DOE believes that there are certain lamps that cannot be made with fluorescent or LED technology while reasonably maintaining the same form factor and light output, and thus more efficient, equivalent replacements are technically infeasible for these lamps. For example, certain bipin and double-ended halogen lamps have such small form factors that current information shows it is unlikely that these lamps can be made using a more efficient technology while maintaining a similar form factor and light output. DOE is aware of ongoing research regarding the design challenges when adapting LED technology to the compact form factors of the incandescent and halogen lamps

they are intending to replace.¹⁷ One of the most significant challenges for LED lamps is thermal management, as LED lamps must dissipate a substantial amount of the heat generated to avoid degrading performance (*e.g.*, efficiency, lifetime, color). LED lamps use conduction and convection to transfer heat away from the LEDs and circuitry to a heat sink and eventually to the ambient environment. Comparatively, incandescent lamps dissipate heat generated by the filament to the ambient environment directly through infrared radiation (*i.e.*, absent a heat sink component).¹⁸ The additional components required for LED lamps create design constraints when attempting to maintain the compact form factors of the lamps they are intended to replace. Thus, DOE believes that the dimensions of certain lamps prevent the development of equivalent LED replacement lamps in the desired form factors and lumen outputs.

DOE believes this conclusion is significant because the unavailability of non-incandescent substitutes for a given lamp suggests that lamp is not being used for traditional GSIL applications. The applications traditionally served by GSILs involve general illumination, and DOE believes non-incandescent lamps such as CFLs and LED lamps can adequately serve that application. Indeed, that premise is fundamental to the policy set by EISA 2007 regarding energy use in lighting; the 45 lm/W default standard would likely preclude the use of incandescent technology for any lamp to which it applied. DOE recognizes that various lighting applications do not involve general illumination, and that many of those applications involve technical requirements that necessitate design features in lamps such as specific sizes, shapes, and lumen outputs. If the design characteristics of lamps for a given application are such that non-incandescent lamps cannot be made with the same characteristics, DOE believes it cannot, at present, conclude that those lamps are being used for general illumination. Consequently, DOE is not including such lamps as “other lamps” in its definition of GSL. In the discussion that follows, DOE refers to lamps that it, for this reason, is excluding from GSLs as “specialty products.” But DOE emphasizes that it uses that language only for convenience in explaining its decisions. It is not in

fact determining that such lamps are “specialty products.” Rather, and consistent with the “other lamps” clause, DOE is simply declining to determine that such lamps are used for traditional GSIL applications.

DOE has reviewed product availability to determine which form factor and light output combinations may not be available in fluorescent or LED technology. For the second category of lamps, products that do not currently have more efficient replacements with the same form factor and light output but for which replacements can likely be made in the future, DOE believes that it is possible to manufacture equivalent replacements but that companies have chosen not to do so because the market demand has not yet been great enough. These products have been included in the definition of general service lamp, to the extent they satisfy other aspects of the definition. As discussed in the following sections, DOE has developed multiple criteria that together justify a determination that a lamp is used for traditional GSIL applications. For lamps that cannot be made with non-incandescent technology, those criteria may be insufficient and DOE has excluded such lamps from being GSLs. But for lamps that can be made with non-incandescent technology, DOE believes the criteria it has developed will be adequate for the “other lamps” determination, just as for lamps that are already available with non-incandescent technology.

b. General Lighting Applications

As stated previously, EISA 2007 added the definition of GSL to EPCA and defined the term, in part, to include GSILs, CFLs, general service LED and OLED lamps, and any other lamp that DOE determines is used to satisfy lighting applications traditionally served by GSILs (“other lamps” authority). (42 U.S.C. 6291(30)(BB)(i)(IV)).

To implement this provision, DOE must determine what types of lighting applications have been traditionally served by GSILs; and then it must establish criteria for determining whether a given lamp is used in such applications. With respect to the first issue, the October 2016 NOPDDA noted that GSILs have traditionally provided overall illumination. DOE bases that conclusion on the definition of GSIL and its review of lamps in the market that fulfill that definition. A GSIL, as defined in section 6291(30)(D), is (subject to exemptions) “a standard incandescent or halogen type lamp” that “is intended for general service

¹⁷ Chen, H., S.Y. Hui, S. Li, S. Tan, and E. Waffenschmidt. Power Flow Analysis and Critical Design Issues of Retrofit Light-Emitting Diode (LED) Light Bulb. IEEE Transactions on Power Electronics. 2015. 30(7): pp. 3830–3840.

¹⁸ *Id.*

applications”; that “has a medium screw base”; that has a lumen range as specified in the definition; and that is capable of being operated between 110 and 130 volts. DOE believes that traditionally, lamps that are standard incandescent or halogen and that satisfy the other criteria have served general lighting applications. By “general lighting applications,” DOE means lighting that provides an interior or exterior area with overall illumination. As described in the October 2016 NOPDDA, DOE considers the term “overall illumination” to be similar in meaning to the term “general lighting” as defined in the industry standard ANSI/IES RP-16-10 (hereafter “RP-16”). RP-16 states that “general lighting” means lighting designed to provide a substantially uniform level of illuminance throughout an area, exclusive of any provision for special local requirements.

GE stated that the phrase “used in general lighting applications” that DOE included in the proposed definition of GSL was too vague and DOE should instead include the phrase “used to satisfy lighting applications traditionally served by general service incandescent lamps.” GE explained that for a product to satisfy light applications traditionally served by GSILs it should have a medium screw base, produce between 310 and 2,600 lumens, and operate on a voltage between 110 and 130 V per the current definition of GSILs. (GE, No. 83 at p. 130; GE, No. 88 at pp. 2–4)

NEMA commented that the authority to include other lamps that are used to satisfy lighting applications traditionally served by GSILs is limited to consideration of new technologies given that the EISA 2007 amendment establishing the GSL definition was enacted when halogen technology was just beginning to be introduced and development of LED technology was underway. (NEMA, No. 93 at pp. 3–4)

DOE acknowledges that the phrase identified by GE is the same one used in the statutory definition of GSL. While including the phrase would ensure consistency with the statutory definition, it is clear from the comments on this rulemaking that the phrase is ambiguous and needs further clarification.

With respect to NEMA’s comment, nothing in the language of the statute limits the consideration of “other lamps” to “new technologies.” EPCA directs DOE to consider how GSILs have traditionally been used (*i.e.*, in what applications GSILs served). Also, it would frustrate the purposes of the statute for DOE to assess what counts as

a “new technology.” DOE would have to conduct a historical assessment to see what the status of a given lighting technology was in 2007, and DOE would need to know what degree of development would have been sufficient for Congress to have considered in 2007 whether to include that technology explicitly in the statute. Moreover, DOE would be presuming that if a technology had reached a certain degree of development, then Congress certainly would have decided whether to include or exclude the technology. Yet there are no signs in the statute or the legislative history that Congress engaged in that searching analysis of technological developments. If DOE were mistaken in its presumption that Congress would have considered a technology during the 2007 deliberations, then it might end up overlooking a set of lamps that could be widely used to provide general illumination. This “new technology” assessment, for which the statute provides no guidance, seems inconsistent with the framework established by EISA 2007. Rather, DOE believes that Congress deferred to DOE the assessment whether, over the course of time, a given set of lamps is being used for GSIL-type applications—regardless whether that set of lamps existed in 2007 as a technological matter.

In developing a definition for GSL that includes “other lamps,” DOE has also considered how to determine whether a lamp is used for traditional GSIL applications. EPCA does not specify to what extent a lamp must be used to satisfy those applications in order to be considered a GSL, and DOE does not interpret the definition to require that the use of other lamps be extensive. As in its consideration of whether to maintain an exemption under the GSL definition, DOE also considered the potential of lamp switching that may occur in response to any GSL standard when evaluating “other lamps.” Even if a lamp is currently used in only very limited instances to satisfy lighting applications traditionally served by GSILs, that use has the potential to increase in response to a standard for GSLs.

DOE does not have data on every application in which a lamp is used, so absent complete data on actual use, DOE considers the characteristics of a lamp relevant for assessing whether it is used to satisfy lighting applications traditionally served by GSILs. In looking at the application of a GSIL, DOE considered the lighting characteristics of a GSIL, *i.e.*, DOE considered what lighting characteristics allow a GSIL to

meet the needs of a general service application and what lighting characteristics would satisfy a lighting application traditionally served by a GSIL. DOE believes that if a lamp is capable of being used in general lighting applications and has the additional features that DOE is including in the definition of GSL, that lamp is actually being used to some extent in applications traditionally served by GSILs. As GSILs have traditionally provided overall illumination, a lamp that would satisfy the same application as traditionally served by GSILs is one that would provide overall illumination. 81 FR 71803–71804.

Utility Coalition and CA IOUs asserted that the scope of GSL is not limited to residential products. The definition of “general lighting application” means “lighting that provides an interior or exterior area with overall illumination,” with no mention of sector. Utility Coalition stated that the inclusion of all voltages and bases in the proposed GSL definition reinforces that this rulemaking is not specific to only residential products. Further Utility Coalition asserted that the existence of exemptions for clearly non-residential lamps, such as marine lamps and traffic signal lamps, indicated that the scope of GSLs is not only residential products. (Utility Coalition, No. 95 at p. 4; CA IOUs, No. 83 at p. 136)

With respect to whether “other lamps” must be for residential use, DOE notes that GSLs are regulated under Title III, Part B of EPCA, The Energy Conservation Program for Consumer Products Other Than Automobiles; *i.e.*, GSILs are regulated as consumer products. (42 U.S.C. 6291–6309) “Consumer product” is not necessarily restricted to a product used in a residential setting. EPCA defines “consumer product,” in part, as any article of a type which to any significant extent is distributed in commerce for personal use or consumption by individuals, without regard to whether such article of such type is in fact distributed in commerce for personal use or consumption by an individual. (42 U.S.C. 6291(1)(B)) Because a consumer product need only be distributed “to a significant extent” for consumer use, evidently many sales of the product type could be for non-consumer uses; and the definition explicitly says that a particular product with no consumer sales can still be a consumer product if it is of a type that is “to a significant extent” sold for consumer use. Meanwhile, the phrase “applications traditionally served by general service incandescent lamps” is

not limited to residential applications. Thus, GSILs can be sold extensively for non-consumer applications and the “other lamps” provision does not suggest DOE should regard “applications traditionally served” by GSILs as comprising only consumer use. Accordingly, DOE did not limit its analysis to certain market sectors when considering which lamps served in these applications.

Nothing in the language of the statute limits the consideration of “other lamps” to “new technologies.” EPCA directs DOE to consider how GSILs have traditionally been used (*i.e.*, in what applications GSILs served). Also, it would frustrate the purposes of the statute for DOE to assess what counts as a “new technology.” DOE would have to conduct a historical assessment to see what the status of a given lighting technology was in 2007, and DOE would need to know what degree of development would have been sufficient for Congress to have considered in 2007 whether to include that technology explicitly in the statute. Moreover, DOE would be presuming that if a technology had reached a certain degree of development, then Congress certainly would have decided whether to include or exclude the technology. Yet there are no signs in the statute or the legislative history that Congress engaged in that searching analysis of technological developments. If DOE were mistaken in its presumption that Congress would have considered a technology during the 2007 deliberations, then it might end up overlooking a set of lamps that could be widely used to provide general illumination. This “new technology” assessment, for which the statute provides no guidance, seems inconsistent with the framework established by EISA 2007. Rather, DOE believes that Congress deferred to DOE the assessment whether, over the course of time, a given set of lamps is being used for GSIL-type applications—regardless of the state of the technology of the set of lamps in 2007.

As described in the October 2016 NOPDDA, GSILs have traditionally provided overall illumination. Therefore, a lamp that would satisfy the same application as traditionally served by GSILs is one that would provide overall illumination. DOE included the phrase “is used in general lighting applications” in the definition of GSL because “general lighting application” means lighting that provides an interior or exterior area with overall illumination. As described in the October 2016 NOPDDA, DOE considers the term “overall illumination” to be

similar in meaning to the term “general lighting” as defined in the industry standard ANSI/IES RP-16-10 (hereafter “RP-16”). RP-16 states that “general lighting” means lighting designed to provide a substantially uniform level of illuminance throughout an area, exclusive of any provision for special local requirements.

DOE acknowledges the point that some commenters made, that the “other lamps” subclause in the GSL definition refers to lamps that “are used” for traditional GSIL applications, not lamps that could be so used or are likely to be so used. DOE’s approach is consistent with that language. A lamp that is capable of being used for general illumination could, in many cases, be used for traditional GSIL applications. But, as previously described, that capability is not sufficient, on its own, to qualify a lamp as an “other lamp” under DOE’s definition. Rather, a lamp must have specific additional characteristics, described in later sections. DOE believes that this set of market characteristics, in light of market realities, is sufficient to identify lamps that *are* used for traditional GSIL applications.

As noted, DOE does not interpret “are used” to impose a particular threshold of how prevalent a GSIL-type use must be before a lamp can qualify as an “other lamp.” In addition, the statute does not specify that the GSIL-type uses be the only uses of a lamp for it to qualify as an “other lamp.”

Finally, DOE does not believe that by referring to lamps that “are used” for GSIL-type applications, EPCA requires DOE to have direct evidence of such uses. As usual with factual determinations, this one can be made on the basis of expert judgment and circumstantial evidence. The criteria discussed in later sections are relevant in that respect; these are characteristics that make a lamp particularly suitable for consumers’ use as a substitute for GSILs. DOE notes that lamps—like other products—tend to be designed and optimized for the applications in which buyers actually use them. Consistent with that observation, specialty lamps tend to have a range of design characteristics which make them especially suitable for their particular applications, and at the same time make it more difficult to use them in the same applications as GSILs. Thus, if a lamp that is capable of providing general illumination has design features that make it highly suitable for performing that task in the sort of application that GSILs have traditionally served, DOE infers that manufacturers of that lamp are, to some extent, serving buyers that

use the lamps in that way. The marketing or labeling of a lamp also helps reveal the uses to which a lamp is actually put. If a lamp is marketed solely for specialty purposes, that fact makes it less likely that the lamp is used for traditional GSIL applications. DOE has reflected this consideration by excluding from the definition of GSL certain specialty lamps.

c. ANSI Bases

In the October 2016 NOPDDA, DOE proposed that a GSL must have an ANSI base, with the exclusion of light fixtures and LED downlight retrofit kits. DOE noted that it considers an ANSI base to be a lamp base standardized by the American National Standards Institute. To better clarify the term ANSI base, DOE proposed a definition in the October 2016 NOPDDA. 81 FR 71804. More specifically, an

ANSI base, as proposed, would be a base type specified in ANSI C81.61-2016 or IEC 60061-1:2005. Id.

Utility Coalition supported DOE’s proposal to include all bases specified in ANSI C81.61-2016 or IEC 60061-1:2005 in the GSL definition and noted the wide availability of base types in LED lamps. (Utility Coalition, No. 95 at p. 4) ASAP also commented that the ANSI base type specification is appropriate. ASAP noted that bases commonly found in residential applications are driven by the applications or fixture types that are popular at that point in time and can be driven by changes in the market or manufacturing decisions to take advantage of existing standards. (ASAP, No. 83 at pp. 117–118)

However, GE commented that base type needs to be limited because lamps are included in the GSL scope that have never been nor cannot ever be used in a home, and instead are intended for use in specialty commercial or industrial applications. GE explained that most fixtures in homes have predominantly medium screw base sockets with some candelabra base sockets and very few intermediate base sockets. (GE, No. 83 at p. 130) NEMA stated that DOE should include only common base types as only they would be used to satisfy lighting applications traditionally served by GSILs. Maxlite agreed that the ANSI base specification is too broad and suggested limiting general service lamps to those with bases that are common in consumer and residential products. (NEMA, No. 93 at pp. 27–28; Maxlite, No. 83 at p. 123)

As noted in section III.A.4.b, EPCA directs DOE to include as GSLs lamps that are used to satisfy lighting

applications traditionally served by GSILs. DOE has determined that lamps that would satisfy the same applications as traditionally served by GSILs are ones that would provide overall illumination. DOE is not directed to limit its analysis to lamps that provide overall illumination in only the residential sector or, more specifically, only in homes. Therefore, DOE has not used this criterion in deciding whether certain lamps are general service lamps.

For this final rule, DOE reviewed available product offerings by ANSI base type. While DOE is maintaining the specification that GSLs must have an ANSI base, DOE has concluded that certain incandescent/halogen lamps without more efficient, equivalent replacements should not—for the reasons previously given—be included in the definition of GSL. As described in more detail in section III.A.4.f, DOE is excluding lamps with the following ANSI bases from the definition of GSL: Wedge bases; prefocus bases; reflector lamps with a diameter less than 2 inches that do not have E26/24, E26d, E26/50x39, E26/53x39, E29/28, E29/53x39, E39, E39d, EP39, or EX39 bases; and J, JC, JCD, JCS, JCV, JCX, JD, JS, and JT shape lamps that do not have Edison screw bases. DOE did not receive comments specific to its proposed definition of ANSI base. However, upon further deliberation, DOE has concluded that the term “ANSI base” is clear enough that it does not need a specific regulatory definition.

d. Lumen Range

In the October 2016 NOPDDA, DOE proposed to prescribe a maximum lumen output when defining GSL. DOE noted that it believes that lamps with lumen outputs greater than 2,600 can be used in overall illumination and therefore would meet the definition of GSL. However, DOE reviewed available product information and proposed a maximum lumen output in the definition of GSL. At the time of the October 2016 NOPDDA, DOE noted that overall product offerings of general service lamps significantly decreased around 4,000 lumens. Using product offerings as a proxy for overall sales, DOE concluded that sales of lamps with lumen outputs greater than 4,000 lumens were also much lower than lamps with lumen outputs between 310 and 4,000 lumens. While sales are not necessarily an indication of use in general lighting applications, DOE tentatively concluded that the limited and unique product offerings above 4,000 lumens indicated that these lamps may be used mainly in specialty applications rather than for applications

traditionally served by GSILs. Therefore, DOE proposed that general service lamps must have lumen outputs greater than or equal to 310 lumens and less than or equal to 4,000 lumens. 81 FR 71804.

NEMA and LEDVANCE argued that DOE cannot regulate high lumen lamps (2,601–3,300 lumen lamps) unless the sales threshold specified in 42 U.S.C. 6295(l)(4)(G) is met (*i.e.*, at least 100 percent higher than modeled unit sales). (NEMA, No. 93 at p. 20; LEDVANCE, No. 90 at p. 21) NEMA stated that sales for high lumen lamps have declined each year from 2012. (NEMA, No. 93 p. 20) Additionally, LEDVANCE stated that high lumen lamps are not in any “exclusion” or “exemption” from the definition of GSIL and that DOE does not have authority to amend the definition of GSIL to alter the lumen range. (LEDVANCE No. 90, at p. 21)

NEMA commented that DOE does not acknowledge that sales of high lumen incandescent lamps have been decreasing over the last several years and that DOE states that most product offerings between 2,601 and 3,300 lumens are CFLs and LED lamps without providing sales data to support this claim. NEMA stated that although this observation may be correct, DOE is proposing to eliminate high lumen incandescent lamps from the market by applying the 45 lm/W backstop standard without considering the statutory requirement for regulating this lamp type. NEMA stated that DOE cannot include all three lamp technologies in one category noting that DOE has not provided evidence that such a standard would be economically justified for high lumen CFL and LED lamps or would achieve significant energy savings. NEMA added that DOE did not identify high lumen incandescent lamps as posing a lamp switching risk and noted that, following DOE’s proposed reasoning, these lamps provide no lamp switching risk. In addition, NEMA stated that DOE must adhere to the requirements outlined by Congress for regulating these lamps and cannot use its discretion alone. Further, NEMA concluded that these lamps are not used to satisfy lighting applications traditionally served by GSILs, noting that high lumen incandescent lamps are mostly used in commercial and outdoor applications where very bright light is required. (NEMA, No. 93 at p. 21)

As DOE explained for shatter-resistant incandescent and 3-way incandescent lamps in III.A.1.a, 42 U.S.C. 6295(l)(4)(G) requires DOE to complete a rulemaking for high lumen lamps when the sales threshold is met. However, as previously explained, the

mandatory rulemaking under 42 U.S.C. 6295(l)(4) is not the only avenue for DOE to regulate high lumen lamps. Additionally, DOE is not making a determination as to the lumen limit in the definition of GSIL. As commenters noted, the definition of GSIL applies to lamps that have a lumen range of not less than 310 lumens and not more than 2,600 lumens (or, in the case of a modified spectrum lamp, not less than 232 lumens and not more than 1,950 lumens). The definition of GSIL remains limited to lamps that have a lumen range of not less than 310 lumens and not more than 2,600 lumens (or, in the case of a modified spectrum lamp, not less than 232 lumens and not more than 1,950 lumens). DOE is adding a lumen range of greater than or equal to 310 lumens (or 232 lumens for modified spectrum general service incandescent lamps) and less than or equal to 3,300 lumens to the definition of GSL for “other lamps.” As discussed previously in this document, consideration of including lamps in the definition of GSL under the “other lamps” authority is a separate consideration from whether to maintain or discontinue an exemption from the GSL (and GSIL) definition. DOE is establishing this lumen range as part of the definition of GSL as authorized under the “other lamps” provision in the statutory definition of GSL. (42 U.S.C. 6291(30)(BB)(i)(IV)).

The consideration of “other lamps” is not limited by a lumen range. Where Congress intended to limit the definition of GSL based on certain lamp characteristics, it did so (*e.g.*, Congress initially excluded from the definition of GSL the lighting applications and bulb shapes excluded from the definition of GSIL). (42 U.S.C. 6291(30)(BB)(ii)(I)) While the statutory definition of GSIL includes a lumen limit, Congress did not provide a comparable lumen range for lamps that may be determined to be “other lamps.” DOE is to consider whether a lamp is used to satisfy a lighting application traditionally served by a GSIL. The lumen range of a GSIL may be informative for this consideration, but Congress did not impose it as a limit. Instead Congress directed DOE to consider a lamp’s application. As previously discussed, DOE considers the characteristics of a lamp to determine whether it is used to satisfy lighting applications traditionally served by GSILs. In the October 2016 NOPDDA, DOE proposed that lamps within the lumen range of greater than or equal to 310 lumens (or 232 lumens for modified spectrum general service incandescent lamps) and less than or equal to 4,000 lumens and

that meet the other characteristics of GSL as defined in this final rule have the capacity to satisfy lighting applications traditionally served by general service incandescent lamps.

DOE also received comments recommending both raising and lowering the upper lumen limit. NRDC commented that they support the upper lumen limit of 4,000 lumens but noted that they identified several lamps around 3,910 lumens, and therefore suggested increasing the lumen range to around 4,500 lumens to prevent a potential loophole. (NRDC, No. 83 at pp. 10; 138) While supporting an upper lumen bound, NEMA and GE stated that DOE should not set the maximum lumens for GSLs beyond 3,300 lumens per Congress' definition of high lumen incandescent lamps (42 U.S.C. 6295(l)(4)(G)). (NEMA, No. 93 at p. 23; GE, No. 88 at p. 3) NEMA stated that high lumen lamps above 3,300 lumens are too bright to be used in households, where GSILs are predominantly used. NEMA further stated that 200 W incandescent lamps and 40–45 W CFLs in the 2,650–3,600 lumen range are not found in homes because, in addition to being too bright, they are extremely expensive (*i.e.*, about \$15–16 for CFLs and \$10–\$12 for incandescent lamps). (NEMA, No. 93 at p. 23–24) GE stated that fixtures typically have wattage limits prescribed by UL and very few fixtures found in homes can accommodate 200 W (*i.e.*, 4,000 lumen) lamps. (GE, No. 83 at pp. 139–140) Philips recommended DOE align with the definition of GSILs and set the upper lumen limit of GSLs at 2,600 lumens. Philips stated that while the proposed 4,000 lumen maximum would exclude higher wattage high intensity discharge (HID) lamps, it does not exclude all such lamp types. (Philips, No. 96 at p. 4)

For this final rule, DOE reviewed available product offerings to determine whether to raise, lower, or maintain the 4,000 lumen upper limit proposed in the October 2016 NOPDDA. As described in section III.A.4.b, DOE did not limit its analysis to lamps used in only the residential sector. DOE is aware that implementing any lumen limits, regardless of the value, may encourage industry to develop products just outside of the prescribed range. However, DOE believes that lumen output is an important characteristic for determining whether a lamp is used in traditional GSIL applications, particularly since the definition of GSIL itself includes only lamps up to 2,600 lumens in output. While, as noted, that limit in the definition of GSIL does not circumscribe DOE's authority to include

lamps as "other lamps," it does illustrate what applications GSILs have traditionally served. Applications that require high-output lamps have not traditionally been served by lamps up to 2,600 lumens. DOE's current approach recognizes that fact, but also recognizes that lamps with higher outputs are actually used for some of the same applications as GSILs.

Upon reviewing current product offerings, DOE has concluded that it is appropriate to lower the upper lumen bound from 4,000 to 3,300 lumens. DOE determined that there are lamps within the range of 3,301 to 4,000 lumens not intended for use in general lighting applications. For example, lamps marketed for use in stage and studio applications fall within the range of 3,301 to 4,000 lumens. Further, as noted in the October 2016 NOPDDA, although the reported sales of these incandescent lamps are declining, the majority of product offerings between 2,601 and 3,300 lumens are CFLs or LED lamps and are thus not captured in the sales data. Based on product offerings, DOE found that establishing the upper lumen limit at 3,300 was appropriate for including lamps used in applications traditionally served by GSILs.

DOE also received several comments regarding the lower lumen bound in the proposed definition of GSL. NRDC, NEEP, and ASAP stated that DOE should reduce its proposed minimum lumen output for GSLs from 310 to 120 to include 25 W and 40 W equivalent decorative lamps. NRDC added that this would prevent manufacturers from tweaking the lumen output of their current incandescent products, such as globe shape lamps at 320 lumens, to exclude them from the GSL definition. (NRDC, No. 85 at pp. 5–6; NEEP, No. 92 at p. 3) NRDC further stated that lamps between 120 and 310 lumens should be included in the GSL definition because hundreds of millions of sockets contain these lamps; they have high hours of use in commercial settings; and they are available in LED replacements that are mostly dimmable and offered in a variety of shapes, base types, and optics. (NRDC, No. 85 at p. 6; NEEP, No. 92 at p. 3; ASAP, No. 94 at p. 3) RELS agreed with NRDC's proposal, stating that a more inclusive GSL definition would lead to more energy savings, lowering the environmental impact of these products. (RELS, No. 86 at p. 1)

NEEP noted that when many bulbs are used together (*e.g.*, in a chandelier), 25 W and 40 W equivalent lamps can provide acceptable general illumination. NEEP further stated that there are over 80 ENERGY STAR® LED lamps with less than 310 lumens. NEEP

recommended lowering the lower lumen limit from 310 to 120 lumens for all GSILs or, if that change would cause unintended consequences, to lower it to 120 lumens for B, BA, CA, F, G16–1/2, G–25, G30, S or M–14 lamps that are less than or equal to 40 W. (NEEP, No. 92 at p. 3)

CEC recommended a few changes to the lower lumen limit in the definition of GSL to maintain consistency with its own regulations. CEC stated that its general service LED lamp regulation applies to E12 base lamps with 150 lumens or greater and all other lamps of 200 lumens or greater. CEC stated that because 25 W equivalent lamps with lumens less than 310 are used for general illumination (*e.g.*, chandeliers) and have more efficient replacements, they should be included in the GSL definition. (CEC, No. 91 at p. 7) Utility Coalition also recommended DOE align the GSL minimum lumen limit with CEC's general service LED lamps rulemaking but added that DOE should apply the 150 lumen minimum to E17 bases as well. Utility Coalition provided examples of products less than 310 lumens that, it asserted, are marketed and sold for general service applications. (Utility Coalition, No. 95 at p. 4)

Similar to establishing an upper lumen bound, establishing a lower lumen bound can provide an incentive for manufacturers to create products just below the lumen limit. Stakeholders are concerned about this result and have provided several suggestions regarding where this lower lumen bound should be to prevent this problem. Stakeholders have suggested lowering the lower lumen bound from 310 lumens to 120, 150, or 200 lumens to include 25 W equivalent lamps. DOE acknowledges that some lamps with lumen outputs less than 310 lumens can be marketed as 25 W equivalents. However, there is inconsistency in how these lamps are marketed. There are no Federal guidelines that govern the "equivalency" claims of lamps. As such, there is great variety in equivalency claims. Even when equivalency guidelines exist, there is variety in what a 25 W equivalent may be. For example, the ENERGY STAR Lamps V2.0 Specification defines the typical light output of a 25 W omnidirectional lamp to be at least 250 lumens and the typical lumen output of an 25 W omnidirectional decorative lamp (which is also omnidirectional) to be at least 150 lumens. DOE has reviewed available product offerings and instead of trying to include every lamp that is marketed as a 25 W equivalent, DOE has determined the minimum lumen output

of lamps that provide overall illumination. At this time, DOE has determined that lumen output to be 310 lumens, and DOE has therefore established the lower lumen bound at 310 lumens.

GE stated that high lumen lamps, which it considered to be the 150 W and 200 W incandescent lamps, also tend to have larger bulb sizes. GE stated that these lamps are made in A21 and A23 shapes because the filament must be placed farther from the glass due to the increased heat. Therefore, these lamps may not fit in existing fixtures where A19 size lamps are used and also may not meet the UL wattage limit on many fixtures in the home (NEMA estimates that about 95 percent of GSL fixtures will not accommodate 200 W incandescent lamps because it is prohibited by UL 1598). (GE, No. 83 at pp. 72–73) In contrast, NRDC disagreed that the slightly larger size of the 150 W and 200 W incandescent lamps would be too large to be used as a replacement for a standard incandescent lamp in household fixtures. (NRDC, No. 83 at pp. 73–74)

DOE reviewed the lamp dimensions of the A19, A21, and A23 bulb shapes. Per the typical naming convention, the number after the “A” indicates the diameter of the bulb in eighths of an inch. DOE agrees that the bulb shapes of higher lumen lamps are generally larger than those with lumen outputs between 310 and 2,600 lumens. DOE notes that this difference is a quarter to a half of an inch increase in lamp diameter. While there are potentially fixtures that cannot accommodate this increase in size, there is no requirement that all lamps that meet the definition of general service lamp have the same size as GSILs (as currently defined). General service lamps included through the “other lamps” category are those that are used in lighting applications traditionally served by GSILs. Larger diameters would not preclude use of a higher-output lamp in a different fixture. DOE does not believe that, in light of the complete set of characteristics it is using to define “other lamps,” a larger diameter would mean that a lamp is not used in those applications.

e. Operating Voltage

In the October 2016 NOPDDA, DOE did not propose a specific voltage range when defining GSL. 81 FR 71804. ASAP and Utility Coalition agreed with the operating voltage criterion. ASAP commented that they support not specifying a voltage range because adding a range creates the opportunity for manufacturers to specify that

products operate outside of the range even though the products can also operate at common voltages, thus creating a loophole. (ASAP, No. 83 at p. 118; Utility Coalition, No. 95 at p. 4) However, several stakeholders commented that including lamps that operate at all voltages would have unintended consequences.

Westinghouse and Maxlite noted that the voltage range is too broad and could have unintended consequences if products are inadvertently included. (Westinghouse, No. 83 at pp. 119–120; Maxlite, No. 83 at p. 123) GE asserted that by not limiting the operating voltage, DOE was including lamps intended for use in specialty commercial or industrial applications such as airplanes, trains, and automobiles. (GE, No. 83 at p. 130)

Maxlite suggested limiting the operating voltage range to voltages that are common in consumer and residential products. (Maxlite, No. 83 at p. 123) GE stated that 98 percent of GSILs are used in homes according to the 2010 LMC, and nearly all lighting systems in homes operate at 120 V, with a few at 12 V. (GE, No. 88 at p. 4) NEMA stated and Philips agreed that the GSL definition should specify a voltage range from 110 to 130 V or 11 to 13 V. (NEMA, No. 93 at pp. 27–28; Philips, No. 96 at p. 5) NEMA provided a list of specialty applications in which lamps of uncommon voltages are used. (NEMA, No. 93 at pp. 27–28) In order to narrow the scope while preventing loopholes, Westinghouse suggested writing the regulatory language to prevent manufacturers from rating a lamp for an exempted voltage if the lamp is intended to operate at 12 V or 120 V by stating that if the lamp “can operate at 120 V” or “can operate at 12 V,” it would meet the definition of GSL. (Westinghouse, No. 83 at pp. 119–120)

NRDC commented that an operating voltage cap at 120 V does not make sense because 130 V products are increasingly being sold and therefore should be covered too. (NRDC, No. 83 at p. 132) Maxlite added that they agreed with including 130 V products but requested that 277 V products and other voltages not be included. (Maxlite, No. 83 at pp. 132–133) CEC stated that while it agrees with DOE not proposing a specific voltage range in the definition for GSILs, voltage limitations may be useful when defining what is not covered within the GSL definition. (CEC, No. 91 at p. 4)

Northwest Energy Efficiency Alliance (NEEA) and Philips requested clarification on whether certain lamps, such as non-integrated CFLs and HID lamps, are included in the definition of

GSL because these lamps operate on a ballast rather than “at any voltage” as specified in the proposed GSL definition. Philips noted these lamps will not operate if placed directly on a DC or AC sinusoidal waveform and therefore requested that DOE clarify the language in the proposed GSL definition. NEEA noted that these are popular products and that they should be included in the scope. (NEEA, No. 83 at pp. 134–135; Philips, No. 83 at p. 124)

As noted in section III.A.4.b, EPCA directs DOE to include as GSILs lamps which are used to satisfy lighting applications traditionally served by GSILs. DOE has determined that lamps that would satisfy the same applications as traditionally served by GSILs are ones that would provide overall illumination. DOE is not directed to limit its analysis to lamps that provide overall illumination in only the residential sector or, more specifically, only in homes. Therefore, DOE has not used this criterion in deciding whether certain lamps are general service lamps.

DOE reviewed available product offerings to determine whether lamps of all operating voltages are used in general lighting applications. DOE found that certain operating voltages could be an indicator that the lamp is used in specialty applications. For example, lamps with an input voltage of 6.6 V are typically used in airport or aviation applications. DOE has therefore revised the operating voltage criteria for this final rule. Instead of including lamps that operate at all input voltages, DOE is including integrated lamps that are capable of operating at or between input voltages of 12 V, 24 V, 100 to 130 V, 220 to 240 V, or 277 V. DOE determined that lamps capable of operating at these voltages generally provide overall illumination. For example, lamps operating at 12 V and 24 V are commonly MR16 lamps, and lamps operating at 277 V are commonly spiral CFLs. All non-integrated lamps of any voltage are included, assuming they meet the other specified criteria. DOE found that the operating voltage of non-integrated lamps did not correlate to use in specialty applications.

f. Exempted Lamps From GSL

i. GSIL Exemptions

By definition, GSL does not apply to any lighting application or bulb shape that under 42 U.S.C. 6291(30)(D) is not included in the “general service incandescent lamp” definition. (42 U.S.C. 6291(30)(BB))(ii)(I)) DOE tentatively determined in the October 2016 NOPDDA that the language of the

“exclusions provision” under 42 U.S.C. 6291(30)(BB)(ii)(I) is not limited to lamps that are medium screw base or lamps that use incandescent technology. The GSL definition excludes lamps that serve the lighting application or are of the same lamp shape described in the GSIL “exclusions” provision, and makes no express reference to lighting technology or base type. Nonetheless, although the language of 42 U.S.C. 6291(30)(BB)(ii)(I) is not specific to incandescent technology, some of the lamp applications and bulb shapes described under the exemptions to the GSIL definition may be specific to incandescent lamps. 81 FR 71805.

In the October 2016 NOPDDA, DOE assessed each of the 22 lamp categories within the GSIL exemptions to determine whether the Secretary should discontinue or maintain these exemptions for purposes of the GSL definition. DOE tentatively concluded that 14 of the 22 GSIL exemptions for medium screw base incandescent lamps should be maintained, while eight of the GSIL exemptions should be discontinued and considered as GSLs. Consistent with that tentative determination, DOE then assessed the remaining 14 lamp categories in the GSIL exemptions to determine whether the application or lamp shape described is specific to an incandescent technology in order to determine the applicability of each exemption to GSLs other than GSILs. DOE tentatively determined that appliance lamps; black light lamps; bug lamps; colored lamps; infrared lamps; left-hand thread lamps; marine lamps; marine signal service lamps; mine service lamps; plant light lamps; sign service lamps; silver bowl lamps; showcase lamps; and traffic signal lamps are not specific to incandescent technology. Therefore, DOE proposed to extend the exemptions for all 14 lamp categories to all GSLs. 81 FR 71805.

Philips agreed with DOE’s determination of exemption types that are not specific to incandescent technology and that the exemption should be technology neutral. However, Philips cautioned DOE that certain wattages and shapes may be specific only to incandescent technology due to size and heat management issues. (Philips, No. 96 at p. 3) NEEP also agreed that many exempt lamp categories are not specific to incandescent technology. In support of their point, NEEP cited the following as having high efficiency replacements: Appliance lamps; black light lamps; bug lamps; colored lamps; left-hand thread lamps; marine lamps; plant light lamps; sign service lamps; silver bowl lamps;

showcase lamps; and traffic signal lamps. (NEEP, No. 92 at p. 3)

NEMA and LEDVANCE stated that the exemptions for incandescent, CFL, and LED versions of these 14 lamp categories should be maintained, noting that some do not have a CFL or LED replacement. (LEDVANCE, No. 90 at pp. 29–30; NEMA, No. 93 at p. 22) For any specialty lamp types with a CFL or LED replacement, NEMA explained that there is no evidence that lamp shifting is occurring to these lamps, and therefore saw no reason to discontinue exemptions for the CFL or LED versions. NEMA stated that an exemption from energy conservation standards should extend to all technologies for a particular lamp type if no energy conservation standards have been set for that lamp. However, NEMA did remind DOE of its comments in response to the March 2016 GSL ECS NOPR to consider energy conservation standards for certain specialty LED lamps excluded from the definition of general service lamp. (NEMA, No. 93 at p. 22) NEMA also referenced a table from its comments in response to the March 2016 GSL ECS NOPR explaining what sort of technologies are available for the lamp types that may be impacted by the general service lamp rulemaking. (NEMA, No. 66 at pp. 38–40)

As described section III.A.1, in this final rule, DOE concluded that 15 of the 22 GSIL exemptions for medium screw base incandescent lamps should be maintained. Consistent with that determination, DOE then assessed the 15 lamp categories to determine whether the application or lamp shape described is specific to an incandescent technology in order to determine the applicability of each exemption to GSLs other than GSILs. DOE determined that appliance lamps; black light lamps; bug lamps; colored lamps; G shape lamps with a diameter of 5 inches or more; infrared lamps; left-hand thread lamps; marine lamps; marine signal service lamps; mine service lamps; plant light lamps; sign service lamps; silver bowl lamps; showcase lamps; and traffic signal lamps are not specific to incandescent technology. Therefore, DOE is extending the exemptions for all 15 lamp categories to all GSLs.

ii. Specialty MR Lamps

In addition to the aforementioned exempted lamp types, DOE surveyed the market in the October 2016 NOPDDA for MR-shaped lamps with smaller diameters than the common MR16 lamps that are used in non-general lighting applications. DOE found and confirmed that these lamps are typically marketed for use in non-general lighting

applications such as projectors, scientific illumination equipment, theater lighting, studio lighting, stage lighting, film lighting, medical equipment lighting, and emergency lighting. In addition, DOE found that these lamps are significantly more expensive and have shorter lifetimes than MR-shaped lamps designed for general lighting applications. Further, DOE noted it is unsure whether higher efficiency replacements are technologically feasible for these lamps due to their specific optical working distances and smaller form factors. Due to their use in specialty applications and lack of more efficacious equivalent replacements, DOE proposed in the October 2016 NOPDDA that MR-shaped lamps with diameters less than 2 inches that are designed and marketed for use in projectors, scientific illumination equipment, theater lighting, studio lighting, stage lighting, film lighting, medical equipment lighting, and emergency lighting not be included in the GSL definition. 81 FR 71806.

DOE received several comments regarding whether specialty MR lamps should be exempt from the definition of GSL. NRDC agreed with exempting specialty MR16 lamps but stated that regular MR16 lamps should not be exempted because there are LED versions available. (NRDC, No. 83 at pp. 150–151) NRDC and ASAP suggested defining specialty MR16 lamps by specifying a maximum lifetime or voltage requirement. (NRDC, No. 83 at pp. 150–151; NRDC, No. 85 at pp. 2–3; ASAP, No. 94 at p. 2) NEEP also agreed that specialty MR lamps should be exempted. However, NEEP expressed support for covering all MR lamps and requiring petitions to consider individual lamps as specialty MR lamps. NEEP reasoned that this requirement would avoid any potential loopholes for MR-shaped lamps that have a diameter just less than 2 inches and also for higher efficiency replacements. NEEP stressed that there are LED MR14 and MR11 lamps currently being used in general service applications and that unless technical restrictions prevent them from being used as replacements for small form factors, they should be included in the GSL definition. (NEEP, No. 92 at pp. 3–4)

GE commented that MR lamps originated from specialty equipment and have since become commonly used for accent lighting. GE noted that the MR lamps used in general service lighting applications typically operate at 12 V and have a lifetime from 2,000 to 5,000 hours. However, GE stated that MR lamps designed for specialty

equipment typically have very high light output, operate at odd voltages, and have short lifetimes because light output is more important than lifetime. Specifically, GE stated that specialty MR lamps may operate at strange voltages, such as 42, 52, or 82 V, because the lamps are designed for the voltage of the equipment. In addition, specialty MR lamps have lifetimes as low as 200 to 600 hours because they are designed for short operating periods. Additionally, GE noted that the light output is more focused. The ellipsoidal reflector shape has two focal points and the second focal point of specialty MR lamps is designed for the specific distances of the equipment in which it operates. GE further noted that specialty MR lamps are expensive and are not typically sold into the residential market since they are designed for specific applications such as projectors, and medical, scientific, optical equipment, air rail, and roadway. GE concluded that due to their odd voltages, shorter lifetimes and high prices, specialty MR lamps would not be an acceptable replacement for general service lighting. (GE, No. 83 at pp. 143–146; 148–150; GE, No. 88 at p. 2) NEMA noted that for the California regulations, a short lifetime was required for specialty MR16s, thus discouraging use in homes along with their higher price point. (NEMA, No. 83 at pp. 147–148)

NEMA commented that while MR16 lamps are used in both specialty and general lighting applications, if MR16 lamps are eliminated, millions of dollars in equipment designed to use these lamps, such as medical and ophthalmology equipment, will be stranded. NEMA added that because of the small form factor, an LED alternative cannot be made that fits older equipment. (NEMA, No. 83 at pp. 147–148)

NEMA again drew attention to its proposal submitted in response to the March 2016 GSL ECS NOPR to establish wattage caps of 15 W for LED versions and 50 W for incandescent versions of MR lamps. NEMA explained that the 45 lm/W limit would be problematic for LED MR-shaped lamps and the wattage caps would be technologically feasible, economically justified, and reduce testing and certification burden. (NEMA, No. 93 at pp. 25–26) LEDVANCE added that there are no lamps that can replace the functionality of MR lamps and therefore DOE cannot impose an efficacy standard and make them unavailable. (LEDVANCE, No. 90 at pp. 21–22)

After reviewing available product offerings, DOE agrees that certain MR lamps are specialty lamps. These lamps

are labeled for use in applications such as projector lighting, film lighting, and audio/visual lighting. In addition, certain MR lamps are used in specialized equipment (such as scientific illumination and medical equipment) or emergency lighting installations which would be either inoperable or lose their UL safety rating if these lamps were to be removed from the market.

DOE received several comments regarding how to revise the definition of specialty MR lamp. CEC recommended that DOE align its specialty MR lamp definition with CEC's definition for small diameter directional lamps (SDDLs) which it had worked with NEMA to develop. CEC stated the definition of specialty MR lamps should be based on physical and electrical characteristics instead of applications. CEC recommended the definition require the MR bulb shape to be as defined in ANSI C79.1 with a diameter of 2.25 inches or less and meet one of the following criteria: Not be capable of operating at 12 V, 24 V, or 120 V, not have an ANSI compliant pin base or E26 base, have a lumen output of more than 850 lumens, have a wattage of more than 75 W, or have a lifetime of 300 hours or less. (CEC, No. 91 at pp. 7–8)

Utility Coalition also recommended that DOE refer to CEC's definition of SDDL to inform its definition of specialty MR lamps. Utility Coalition stated their research found specialty MR lamps to have extremely high wattages, high lumens, and short lifetimes (50–100 hours) and LED SDDLs are currently not available as adequate substitutes. Utility Coalition further noted that a 300-hour lifetime maximum would prevent them from being used in general service applications. (Utility Coalition, No. 95 at pp. 11–12)

GE, LEDVANCE, and NEMA disagreed with DOE's proposed requirement that specialty MR lamps have a diameter less than 2 inches noting that many MR16 lamps, with a diameter of exactly 2 inches, are specialty lamps. (GE, No. 88 at p. 2; LEDVANCE, No. 90 at pp. 21–22; NEMA, No. 93 at pp. 24–25) GE suggested defining specialty MR lamps to have a maximum diameter of 2.25 inches, to operate at voltages other than 12 or 120 volts, to have a lifetime less than 1,000 hours, or to have a wattage of more than 75 W. (GE, No. 88 at p. 3) NEMA and LEDVANCE recommended the same diameter requirements. NEMA also recommended the same lifetime and wattage criteria as GE but specified the lamps not operate at 11–13 V or 120–130 V. Further, NEMA specified that if any of these characteristics are

not applicable, it could also be considered a specialty MR lamp if it is listed in Table 8 of ANSI Special Report 24f. LEDVANCE stated that Table 8 shows various lamp voltages, wattages, bases, lengths, working distances (which are application critical), and beam characteristics. LEDVANCE asserted that none of the lamps in Table 8 have characteristics that are identical to a 20 W, 30 W, or 50 W GU5.3 bipin base, less than 4 inch length MR16 lamp. Philips expressed support for NEMA's proposed definition. (NEMA, No. 93 at pp. 24–25; LEDVANCE, No. 90 at pp. 31–32; Philips, No. 96 at pp. 4–5)

Additionally, LEDVANCE and NEMA stated that the applications outlined in the proposed specialty MR lamp definition were limiting as they did not capture all of the specialty uses of these lamps, in particular aviation applications, and therefore should be removed. (NEMA, No. 93 at pp. 24–25; LEDVANCE, No. 90 at pp. 31–32) Philips explained that some halogen MR lamps are used in exit sign applications and any LED replacements for the lamps would need to meet several different lighting and electrical safety requirements from NFPA, UL, and local safety codes. (Philips, No. 96 at pp. 4–5)

After reviewing available MR lamps, DOE agrees that revisions to the definition of specialty MR lamp are appropriate. In addition to product offerings in catalogs, DOE reviewed the Lighting Facts database and ANSI Special Report 24f to determine which MR lamps were specialty products and should therefore be included in the definition of specialty MR lamp. DOE considered factors such as whether the lamp had a specific feature that prevented or made it unlikely for use in general lighting applications; whether the lamp was labeled for a specialty application; and whether the lamp must exist for reasons of safety. Regarding whether equivalent LED replacements exist (*i.e.*, lamps with reasonably the same form factor and light output but that use LED technology), see section III.A.4.f.iv.

DOE has decided to revise specifications for lamp diameter and a specialty application label in the definition of specialty MR lamp. To include specialty MR16 lamps, DOE has revised the diameter requirement to include MR lamps with diameters of 2.25 inches or less. DOE continues to include smaller MR-shaped lamps (such as MR11s and MR14s) in the definition of specialty MR lamp because DOE found numerous smaller MR-shaped lamps marketed for use in specialty

applications. DOE agrees that by listing all applications of specialty MR lamps in the definition, it may inadvertently fail to include one. As such, DOE has removed the long list of applications from the specialty MR lamp definition. However, DOE has maintained the requirement that the lamp be designed and marketed for a specialty application. DOE believes this requirement will further convey to consumers that the lamp is not intended for general service applications.

DOE has also decided to add a specification for lifetime in the definition of specialty MR lamp. DOE has reviewed available product information and agrees that this qualifier should be added to ensure only specialty MR lamps are included in the definition. DOE agrees with stakeholders that specialty MR lamps tend to have short lifetimes because lumen output is valued over their longevity. CEC suggested a lifetime requirement of 300 hours or less whereas industry suggested a lifetime requirement of 1,000 hours or less. DOE notes that 1,000 hours is the same lifetime as many lamps used in general service applications, such as GSILs. Furthermore, DOE reviewed available specialty lamps and found that the majority had a lifetime of 300 hours or less. DOE is therefore including a requirement that specialty MR lamps have a lifetime of 300 hours or less in the definition adopted in this final rule.

Although DOE also received comments regarding voltage and wattage (or lumen output), DOE is not including requirements for these quantities in the definition of specialty MR lamp. As described in section III.A.4.e, DOE has modified the input voltage requirements for all general service lamps. DOE has included in the definition of GSL non-integrated lamps that operate at any voltage and integrated lamps that are capable of operating at 12 V, 24 V, 100 to 130 V, 220 to 240 V, and 277 V. Lamps that cannot operate at these voltages are not included in the definition of general service lamp. DOE has found that it is not necessary to limit input voltage requirements for specialty MR lamps beyond the requirements already established for general service lamps. Regarding light output, DOE believes that there are certain lamps that cannot be made with fluorescent or LED technology while reasonably maintaining the same form factor and light output. These lamps are discussed in section III.A.4.a.

iii. R20 Short Lamps

As recounted in the October 2016 NOPDDA, DOE determined in a final

rule published on November 14, 2013 that standards for R20 short lamps would not result in significant energy savings because such lamps are designed for special applications or have special characteristics not available in reasonably substitutable lamp types. 78 FR 68331, 68340. Therefore, DOE proposed in the October 2016 NOPDDA to maintain the exemption for these lamps from GSIL and exempt R20 short lamps from the definition of GSL. 81 FR 71806. As described in section III.A.1.a, DOE is maintaining this exemption in this final rule.

iv. Other Specialty Lamps

As described in section III.A.4.a, DOE believes there are three main categories of lamps: (1) Lamps with more efficient, equivalent replacements (*i.e.*, the same form factor and light output); (2) lamps currently without equivalent replacements but for which replacements can likely be made in the future; and (3) lamps for which industry is unlikely to ever be able to create equivalent replacements using more efficient technology. Regarding the third category of lamps, DOE has concluded that some form factor and light output combinations are unlikely to ever be available using more efficient technology due to technical limitations. As discussed in section III.A.4.a, DOE is declining to determine that lamps with those particular characteristics are used for traditional GSIL applications, and DOE is accordingly not including those lamps as GSILs.

Utility Coalition agreed with DOE's process to begin with a broad scope and exempt products that do not have general service applications or do not have an LED replacement. Utility Coalition stressed that DOE should only exempt products if commenters can specifically explain why a product cannot be manufactured with LED technology. (Utility Coalition, No. 95 at p. 4)

Several stakeholders provided specific examples of lamps that do not have more efficient, equivalent replacements. Westinghouse noted that for certain incandescent/halogen specialty lamps there is no design path to develop LED products with equivalent lumen output and similar form factor. Hence Westinghouse noted that because they are specialty and not available in more efficient technology, they should not be included in the GSL definition. Specifically, Westinghouse noted the following lamps: JC and JCD shaped lamps with G4, G8, G9, GU4, GU7.9, GU8, GY6.35, GY7.9, GY8, and GY8.6 base types; T shape lamps with

diameters of 1 inch or less (T8 or smaller) that do not have medium screw bases; lamps with wedge bases; T shape lamps with diameters of 0.75 inch or less (T6 or smaller) with double-ended double contact, metal fin bases; and miniature reflector lamps with diameter less than 2 inches. (Westinghouse, No. 83 at pp. 126–129; Westinghouse, No. 89 at pp. 1–2) Maxlite agreed, commenting that lamps operating at 12 V with small bases such as G4, G9, wedge, and festoon, are typically halogen lamps with high lumens and when made in LED form, are significantly larger and no longer fit in the traditional luminaires for which they were designed. GE and NEMA added that halogen bipin lamps cannot be made using LED technology and should not be included as general service lamps. (Maxlite, No. 83 at pp. 133–134; NEMA, No. 83 at pp. 52–53; GE, No. 88 at p. 4)

GE stated that if specialty MR lamps are exempt from the GSL definition, specialty PAR lamps should be exempted as well. GE explained that only PAR20, 30, and 38 lamps with medium screw bases that operate at 120 V are used in general service applications. All other PAR lamps should be considered specialty PAR lamps. (GE, No. 88 at p. 3)

NEMA and GE expressed concern that including lamps of all voltages and base types in the GSL definition would include specialty lamps. (NEMA, No. 93 at pp. 27–28; GE, No. 88 at p. 5) NEMA stated that LED replacements do not exist for the following applications: Airport; airplane; airway; locomotive; automobiles; photographic; stage; studio; medical; and dental. GE added the following to NEMA's list of applications for which equivalent LED replacements do not exist: Projection; television service; headlight; street railway or other transportation service; microscope; map; and microfilm or other specialized equipment service. Hence the inclusion of these lamp types in the GSL definition may create an absence of products resulting in safety and security concerns. Philips also stated that it was important to maintain the incandescent/halogen versions because recent Caliper reports indicate issues with compatibility of LED reflector lamps with dimming/control systems. (Philips, No. 96 at p. 6) NEMA submitted ANSI Special Report 24f that provides details on some but not all specialty lamps. (NEMA, No. 93 at pp. 27–28; GE, No. 88 at p. 4)

In contrast, Utility Coalition stated that LED replacements are widely available in an array of screw bases like medium screw bases (E26/E27);

candelabra bases (E12); mogul bases (E39); intermediate bases (E17); E5 and E10 bases; pin bases such as G4 and G13; various sizes of GX, GU, GY, and GZ bases; wedge bases; and bayonet bases (BA). Additionally LED replacements of double-ended halogen lamps with recessed single contact bases are available. Utility Coalition also noted the availability of LED replacements in a wide array of lamp shapes including A, R, PAR, BR, ER, MR, C, CA, F, G, E, and T shapes. Utility Coalition asserted that high efficiency lamps are affordable, noting that CFLs are below \$2–3, and LED lamp prices are declining dramatically, with some available below \$3–5. (Utility Coalition, No. 95 at pp. 1–2) Utility Coalition also provided price data and trends on LED lamps based on data it has been collecting since 2013, which show that lamps with the highest efficiencies have dropped in price by at least 30 percent since 2013. (Utility Coalition, No. 95 at p. 13) Several other commenters, including NRDC, Soraa, ASAP, and NEEP, noted the wide spread availability of various LED lamp replacements. (NRDC No. 85 at p. 6; NRDC, No. 83 at p. 11; Soraa, No. 87 at p. 2; NEEP, No. 83 at pp. 13–14; ASAP, No. 83 at pp. 98–99, 170–171)

ASAP suggested using a similar approach as DOE's motors rulemaking and defining the specific base types and voltages that are problematic and excluding them from the definition of GSL. (ASAP, No. 83 at pp. 120–121)

In section III.A.4.a, DOE discusses the three categories of lamp identified: (1) Lamps with more efficient, equivalent replacements (*i.e.*, the same form factor and light output); (2) lamps currently without equivalent replacements but for which replacements can likely be made in the future; and (3) lamps for which industry is unlikely to ever be able to create an equivalent replacement using more efficient technology. DOE has reviewed available product offerings to identify lamps that do not have equivalent replacements (*i.e.*, the same form factor and light output) using more efficient technology. For some of those lamps DOE concluded that, based on information available at this time, it was unlikely that industry would ever be able to create an equivalent replacement using more efficient technology. DOE has therefore excluded them from the definition of GSL in this final rule, for the reasons given in section III.A.4.a. DOE has concluded that the remaining lamps without more efficient equivalent replacements can likely be made, but manufacturers have chosen not to do so because market demand is not yet sufficient. DOE has included those

lamps as general service lamps. See section V for information regarding DOE's enforcement policy.

After identifying lamps without more efficient equivalent replacements, DOE considered the size of the ANSI base, the dimensions of the bulb shape, and the lumen output gap between existing incandescent products and existing LED replacements to evaluate whether equivalent replacements could be produced. DOE determined that the larger the ANSI base, the greater the bulb volume, and the smaller the lumen gap between existing incandescent and LED products, the more likely that an equivalent LED replacement could be produced. Larger ANSI bases and bulb shapes allow for more space to accommodate a heat sink and/or additional electronics needed to support LED technology. For example, a medium screw base LED filament lamp can accommodate the electronics of an LED driver in the ANSI base. However, lamps with very small bases, such as wedge bases, or lamps with very small shapes, such as T shape lamps with diameters of 1 inch or less, cannot accommodate the LED driver and/or the LEDs themselves in the same form factor and light output combinations as is possible with incandescent technology. Furthermore, certain lamp types have already shown progress in developing equivalent LED replacements. For example, incandescent/halogen candelabra base lamps with B10 shapes are available with lumen outputs up to 760 lumens. Equivalent LED replacements are currently available with lumen outputs only up to 500 lumens. A small lumen output gap between existing incandescent and LED products indicates that only modest improvements in technology, electronics, or design are necessary to increase product performance.

After reviewing these factors, DOE concludes that lamps were included in the definition of GSL proposed in the October 2016 NOPDDA that should not have been included because they do not and likely cannot have equivalent replacements using more efficient technology. DOE is excluding these lamps from the definition of general service lamp for the reasons given in section III.A.4.a. DOE has determined that it must use a combination of shape, base, length, and diameter to capture all of these specialty lamps. The excluded products include:¹⁹

- T shape lamps that have a first number symbol less than or equal to 8 (diameter less than or equal to 1 inch) as defined in ANSI C79.1–2002, nominal overall length less than 12 inches, and that are not compact fluorescent lamps;

- S shape or G shape lamps that have a first number symbol less than or equal to 12.5 (diameter less than or equal to 1.5625 inches) as defined in ANSI C79.1–2002;

- Reflector lamps that have a first number symbol less than 16 (diameter less than 2 inches) as defined in ANSI C79.1–2002 and that do not have E26/24, E26d, E26/50x39, E26/53x39, E29/28, E29/53x39, E39, E39d, EP39, or EX39 bases;

- MR shape lamps that have a first number symbol equal to 16 (diameter equal to 2 inches) as defined in ANSI C79.1–2002, operate at 12 volts, and have a lumen output greater than or equal to 800;

- J, JC, JCD, JCS, JCV, JCX, JD, JS, and JT shape lamps that do not have Edison screw bases; and

- Lamps that have a wedge base or prefocus base.

g. Lamps Subject to Other Rulemakings

In the March 2016 GSL ECS NOPR, DOE proposed that a GSL cannot be a lamp that is the subject of other ongoing rulemakings. 81 FR 14528, 14543. In the October 2016 NOPDDA, DOE proposed to discontinue this criteria regarding other rulemakings. DOE continued to exempt GSFLs from the definition of GSL. 81 FR 71806. Because the definition of GSFL and the supporting definition of fluorescent lamp are structured in a certain way, DOE added some exemptions to the proposed rule to exclude lamps from the definition of GSL that are specifically and currently excluded from the GSFL and fluorescent lamp definitions. For example, DOE exempted circline lamps, which were considered to be GSFLs in the January 2015 rulemaking but for which DOE did not evaluate standards, and DOE exempted fluorescent lamps with a CRI of 87 or greater because they are statutorily exempt from standards. However, DOE did not propose to exempt other lamps that were the subject of other ongoing rulemakings. For example, DOE did not specifically propose to exempt HID lamps that otherwise meet the GSL criteria. 81 FR 71806.

NEMA agreed with exempting GSFLs from the definition of general service lamp, noting that Congress intended to

¹⁹ DOE notes that for several of these exclusions, the October 2016 NOPDDA included references to appropriate industry standards to define terms like "wedge base" or "EX39 base." DOE is omitting those references from this final rule because on further deliberation, it believes those terms are

terms of art whose meaning will be clear to participants in the lighting market.

keep GSFLs out of this rulemaking because there were already energy conservation standards for these products. (NEMA, No. 83 at pp. 48–49) However, ASAP voiced concern that the proposed definition in the October 2016 NOPDDA was unintentionally applying exemptions for linear fluorescent lamps, such as those for cold temperature, impact-resistant, and reflectorized lamp types, to CFLs. (ASAP, No. 83 at pp. 20–21, 109–110)

After reviewing the proposed exemptions for fluorescent lamps, DOE agrees that some revisions are necessary to ensure terms related to fluorescent lamps are used consistently. In this final rule, DOE is adopting a definition of “other fluorescent lamps, which grouped these exemptions and made clear that the lamps included are circline lamps and certain double-ended lamps that use fluorescent technology. An “other fluorescent lamps” is a low pressure mercury electric-discharge sources in which a fluorescing coating transforms some of the ultraviolet energy generated by the mercury discharge into light and include circline lamps and include double-ended lamps with the following characteristics: Lengths from one to eight feet; designed for cold temperature applications; designed for use in reprographic equipment; designed to produce radiation in the ultra-violet region of the spectrum; impact-resistant; reflectorized or aperture; or a CRI of 87 or greater.

GE, NEMA and LEDVANCE pointed to what they saw as a contradiction in DOE attempting to include HID lamps in the GSL definition to be regulated when in a recent rulemaking DOE had determined that regulations on HID lamps were either not technologically feasible, economically justified, or would not result in significant energy savings. (GE, No. 88 at p. 4, NEMA, No. 93 at pp. 23–24, LEDVANCE, No. 90 at p. 22, Philips, No. 96 at p. 4) NEMA noted that in the HID determination DOE had stated that significant energy savings would not result from standards for directional HID lamps. (NEMA, No. 93 at pp. 23–24)

GE stated that HID fixtures are never found in the home and are rarely found outside it. (GE, No. 88 at p. 4) Philips stated that because HID lamps require a ballast, are extremely expensive, and have a warm-up time, they are not typically used by consumers and thus do not pose a risk for lamp switching. (Philips, No. 96 at p. 5) NEMA added that 2015 sales for HID lamps with 4,000 lumens or lower were 33 percent below 2012 sales and expected to fall. (NEMA, No. 93 at pp. 23–24) LEDVANCE pointed out that currently there are no

viable replacements for HID lamps.

(LEDVANCE, No. 90 at p. 22)

NEMA asserted that, had Congress intended for HID lamps to be included as GSLs, it would have done so expressly, but instead authorized DOE to regulate HID lamps as commercial equipment. (NEMA, No. 93 at pp. 23–24) Finally, NEMA and Philips stated there is no DOE test procedure for HID lamps. (Philips, No. 96 at p. 4; NEMA, No. 93 at pp. 23–24)

LEDVANCE stated that should DOE regulate HID lamps as GSLs, it needs to exclude the lamps exempted from analysis in DOE’s final determination for HID lamps. 80 FR 76355, December 9, 2015. Specifically, these were for lamps less than 50 W, directional lamps, specialty lamps, and lamps that run exclusively on electronic ballasts, which LEDVANCE asserted would eliminate most HID lamps from the scope of this final rule. LEDVANCE added that while direct LED lamp replacements are available for high wattage HID lamps, there are no such lamp replacements for low wattage lamps. LEDVANCE explained that to replace low wattage HID lamps, consumers would have to replace the entire fixture and DOE has not done the necessary payback analysis for this scenario. (LEDVANCE, No. 90 at pp. 30–31)

DOE acknowledges the various comments that HID lamps are primarily used for specialty applications. Given the particular characteristics of HID lamps regarding startup, DOE believes that the criteria it has developed for the “other lamps” category may not be adequate to support an inference that an HID lamp, in particular, is actually used in traditional GSIL applications. Accordingly, DOE will not include HID lamps as GSLs in this rulemaking and will continue to study the issue. DOE notes that if it notices an influx of HID lamps for the general service lamp market, then DOE may revisit this decision.

DOE further notes that although DOE determined in the recent HID lamps rulemaking that standards for HID lamps are either not technologically feasible or not economically justified, that analysis was based on a different set of lamps than would be analyzed as part of a rulemaking for GSLs. For example, the HID lamp determination considered only mercury vapor, high pressure sodium, and metal halide technology. In addition, the determination did not analyze self-ballasted or directional HID lamps, among other types. Thus, the previous determination is not relevant and an analysis conducted in the context of a rulemaking for GSLs could well come to

a different conclusion. However, per the preceding discussion, DOE has determined to exclude HID lamps from the definition of GSL.

5. Summary and Adopted Regulatory Text Definition

DOE proposed a revised definition of GSL in the October 2016 NOPDDA. Westinghouse recommended DOE revise the definition of GSL to capture only those products intended by Congress to be regulated and exclude lamps which are specialty products or covered by existing regulations. (Westinghouse, No. 89 at p. 2)

NEMA recommended the following changes to the proposed GSL definition: Include lamps that operate only at voltages between 110 to 130 V or 11 to 13 V and have maximum lumens of 3,300; and exclude incandescent reflector lamps, specialty lamps, and specialty base lamps. NEMA also provided definitions for specialty lamp and specialty base lamps. NEMA defined specialty lamp as a lamp designed for and used in special applications and listed the current 22 exempted lamp types specified in the GSIL definition. NEMA defined a specialty base lamp as a lamp with an intermediate base (E17), candelabra base (E12), mini-candelabra base (E11), bayonet base, double ended base, screw terminal base, medium side prong base, mogul prong base, recessed single contact, mogul screw, mogul bi-post, G53, double contact prefocus, 2-pin GY6.35, 2-pin G8, and 2-pin G9 when used with any lamp; or 2-pin G4 when used with non-reflector lamp. (NEMA, No. 93 at p. 27) LEDVANCE supported NEMA’s recommended changes for the GSL definition. (LEDVANCE, No. 90 at pp. 32–33) Philips agreed with NEMA’s proposed voltage range for the GSL definition. (Philips, No. 96 at p. 6)

GE recommended DOE modify the GSL definition to include only lamps with medium screw bases and candelabra bases; that operate between 110 and 130 V or at 12 V, have maximum lumens at 3,300, and “satisfy lighting applications traditionally served by general service incandescent lamps;” and exclude HID lamps. Additionally, GE suggested the definition exclude lamps with the following applications: Airway, airport, aircraft, photo, projection, stage, studio or television service, headlight, locomotive, street railway, or other transportation service; medical or dental service, microscope, map, microfilm, or other specialized equipment service. (GE, No. 88 at pp. 3–4)

In the preceding sections, DOE has reviewed all aspects of the GSL

definition. DOE has identified the criteria pertinent to lamps that serve in general lighting applications and also identified specialty products that should be exempt from the definition of GSL. In this final rule, DOE is defining general service lamp as a lamp intended to serve in general lighting applications and that has the following basic characteristics: (1) An ANSI base (with the exclusion of light fixtures, LED downlight retrofit kits, and exemptions for specific base types); (2) a lumen output of greater than or equal to 310 lumens and less than or equal to 3,300 lumens; (3) an ability to operate at or between 12 V, 24 V, 100 to 130 V, 220 to 240 V, or 277 V; and (4) no designation or label for use in non-general applications. Regarding the fourth criteria, DOE notes that this requirement is not explicitly stated in the regulatory definition of GSL adopted in this rule. Rather, DOE has listed each of the non-general applications identified or lamps used in such applications in order to clearly define the scope of the definition. The definition excludes certain types of lamp, as discussed elsewhere in this notice.

DOE notes that the definition adopted in this final rule excludes incandescent reflector lamps. That exclusion simply mirrors the exemption for IRLs from the statutory definition of GSL. DOE had proposed to discontinue the IRL exemption. But it is not reaching a decision on that issue in this final rule; DOE will address the status of IRLs in a separate final rule. Accordingly, as of this final rule the exemption for IRLs stands and DOE is replicating that exemption in its definition of GSL.

Thus, DOE is adopting a definition of “general service lamp” in § 430.2 to capture the criteria and the exemptions discussed in previous sections. A general service lamp is a lamp that has an ANSI base; is able to operate at a voltage of 12 volts or 24 volts, at or between 100 to 130 volts, at or between 220 to 240 volts, or of 277 volts for integrated lamps (as defined in this section), or is able to operate at any voltage for non-integrated lamps (as defined in this section); has an initial lumen output of greater than or equal to 310 lumens (or 232 lumens for modified spectrum general service incandescent lamps) and less than or equal to 3,300 lumens; is not a light fixture; is not an LED downlight retrofit kit; and is used in general lighting applications. General service lamps include, but are not limited to, general service incandescent lamps, compact fluorescent lamps, general service light-emitting diode lamps, and general service organic light-

emitting diode lamps. General service lamps do not include:²⁰ Appliance lamps, black light lamps, bug lamps, colored lamps, G shape lamps with a diameter of 5 inches or more as defined in ANSI C79.1–2002, general service fluorescent lamps, high intensity discharge lamps, infrared lamps, J, JC, JCD, JCS, JCV, JCX, JD, JS, and JT shape lamps that do not have Edison screw bases, lamps that have a wedge base or prefocus base, left-hand thread lamps, marine lamps, marine signal service lamps, mine service lamps, MR shape lamps that have a first number symbol equal to 16 (diameter equal to 2 inches) as defined in ANSI C79.1–2002, operate at 12 volts, and have a lumen output greater than or equal to 800, other fluorescent lamps, plant light lamps, R20 short lamps, reflector lamps that have a first number symbol less than 16 (diameter less than 2 inches) as defined in ANSI C79.1–2002, and that do not have E26/E24, E26d, E26/50x39, E26/53x39, E29/28, E29/53x39, E39, E39d, EP39, or EX39 bases, S shape or G shape lamps that have a first number symbol less than or equal to 12.5 (diameter less than or equal to 1.5625 inches) as defined in ANSI C79.1–2002, sign service lamps, silver bowl lamps, showcase lamps, specialty MR lamps, T shape lamps that have a first number symbol less than or equal to 8 (diameter less than or equal to 1 inch) as defined in ANSI C79.1–2002, nominal overall length less than 12 inches, and that are not compact fluorescent lamps, traffic signal lamps, incandescent reflector lamps. See the amendments to § 430.2 for the definition of general service lamp in its entirety.

B. Supporting Definitions

In the October 2016 NOPDDA, DOE proposed several definitions to support its proposed definition of “general service lamp.” Specifically, DOE proposed definitions for “integrated lamp,” “non-integrated lamp,” “light fixture,” “pin base lamp,” “GU24 base,” “LED downlight retrofit kit,” and several terms to better define the lamp types described in section III.A.4 that are exempt from the definition of general service lamp.

LEDVANCE and Philips agreed with the proposed supporting definitions and emphasized that further specifications were not necessary since manufacturers

have produced no products that would take advantage of any potential loopholes. (LEDVANCE, No. 90 at p. 34; Philips, No. 96 at p. 5) CEC stated DOE should base definitions of exempted lamp types on physical and electrical characteristics rather than application, whenever possible. (CEC, No. 91 at p. 5) DOE discusses specific comments regarding the proposed definitions in the following sections.

1. Black Light Lamp, Colored Lamp, Plant Light Lamp, and Bug Lamp

DOE proposed definitions for “black light lamp,” “colored lamp,” “plant light lamp,” and “bug lamp” in the October 2016 NOPDDA. 81 FR 71807. DOE received several comments regarding these definitions.

ASAP commented that while they supported DOE’s approach of using the electromagnetic spectrum to define bug lamps, colored lamps, infrared lamps, and black light lamps, they would suggest defining exempted lamps by specifying a percentage of radiated power within a band of the spectrum rather than just a peak as stated in the proposed definitions. ASAP noted that fluorescent lamps, which can have multiple peaks in the spectrum, could become a loophole and therefore the definitions should be more specific. (ASAP, No. 83 at pp. 44, 99, 105)

The proposed definition of black light lamp would require radiant power peaks in UV–A portion of the electromagnetic spectrum. Typical incandescent lamps and fluorescent lamps do not have their highest radiant power peak in the UV–A portion of the electromagnetic spectrum. Hence, DOE finds that specifying this limited region of the lower end of the electromagnetic spectrum is sufficiently distinctive for identifying black light lamps. Therefore, in this final rule, DOE is adopting the definition of “black light lamp” as proposed in the October 2016 NOPDDA. A black light lamp is a lamp that is designed and marketed as a black light lamp and is an ultraviolet lamp with the highest radiant power peaks in the UV–A band (315 to 400 nm) of the electromagnetic spectrum.

The proposed definition for colored lamp would apply to lamps that satisfy one of two conditions—either a CRI less than 40 or a CCT lower than or greater than a designated value. NRDC, NEEP, and ASAP requested that DOE modify the definition of colored lamp to require that lamps meet both the CRI and the CCT requirement in order to be considered colored lamps. In addition, several stakeholders suggested modifying the lower CCT value. NRDC suggested changing the lower bound

²⁰ DOE notes that for several of these exclusions, the October 2016 NOPDDA included references to appropriate industry standards to define terms like “JT shape” or “EX39 base.” DOE is omitting those references from this final rule because on further deliberation, it believes those terms are terms of art whose meaning will be clear to participants in the lighting market.

CCT value to 2,100 K instead of 2,500 K because incandescent lamps have a CCT around 2,700 K, which is very close to 2,500 K. NEEP, ASAP, and Utility Coalition suggested changing the lower bound CCT value to 2,000 K. NEEP noted that with advancements in color tunable lamps, there is little risk of eliminating lamps with lower CCT values from the market. In addition, NRDC and NEEP stated that the ENERGY STAR Lamps Specification V2.0 includes CCT values of 2,200 K and 2,500 K for filament lamps. Further, NRDC and Utility Coalition pointed out that filament LED lamps have CCT values below 2,500 K. NEEP added that while the lamps with a CCT of 2,000 K are quite visually orange, they are gaining popularity, and coupled with a high CRI, could serve as general illumination bulbs. (NRDC, No. 83 at pp. 12–13, 96; NRDC, No. 85 at p. 10; ASAP, No. 83 at p. 20; ASAP, No. 94 at p. 6; NEEP, No. 83 at p. 97; NEEP, No. 92 at pp. 1–3; Utility Coalition, No. 95 at pp. 10–11)

Maxlite noted that it had supported the inclusion of 2,200 K and 2,500 K for filament lamps in ENERGY STAR Lamps Specification V2.0 as these are becoming popular colors for ultra-warm products. However, Maxlite cautioned DOE not to make categorizations of these CCTs part of the colored lamp definition. Maxlite explained that filament LED lamps with a CCT of 2,200 K or 2,400 K that are designed to mimic incandescent lamps were very popular when introduced. However, Maxlite stated that recent market feedback has shown a preference for a slightly higher CCT of 2,700 K. Westinghouse agreed that consumers may prefer a different color temperature because they have experienced consumers returning lamps with CCTs of 2,200 K and 2,400 K. (Maxlite, No. 83 at pp. 105–106; Westinghouse, No. 83 at pp. 101–102)

NEMA, LEDVANCE, and GE stated the proposed definition of colored lamp was one that has been used by industry for many years and has proven to be both clear and effective. NEMA, LEDVANCE, and GE noted that changing the definition could have the unintended consequence of preventing colored lamps from being produced. In particular, NEMA and LEDVANCE explained that if the definition included CCT and CRI requirements instead of one or the other, then a number of colored lamps would no longer be included in the definition. NEMA and LEDVANCE stated that meeting just one criteria was sufficient to be considered a colored lamp. (GE, No. 83 at p. 104; NEMA, No. 93 at pp. 28–29; LEDVANCE, No. 90 at p. 34)

CCT and CRI are both metrics that characterize the color of light emitted by a light source. CCT is measured by examining how close the light source's chromaticity is to the reference blackbody locus. CRI is calculated from the differences in the chromaticities of eight standard color samples when illuminated by a light source compared to a reference illuminant of the same CCT. Hence, each measurement provides an independent method of determining if the light emitted by a light source is colored. Regarding the proposed requirement of CCT less than 2,500 K, DOE notes that ENERGY STAR Lamps Specification V2.0 includes CCTs of 2,200 K for only filament lamps. As noted by stakeholders, lamps with a CCT of 2,200 K are relatively new products and it is still uncertain how they will be used. Therefore, DOE is maintaining the lower bound threshold of 2,500 K for colored lamps. DOE will continue monitor the market to understand the impact of new products at low CCTs and may revise the definition of colored lamp in the future.

ASAP also noted that in the “colored lamp” definition, as well as specifying that the lamp be designed and marketed as a colored lamp, DOE stated the lamp not be designed and marketed for general service applications. ASAP commented DOE had not added the latter prohibitive phrase in any other definition of an exempted lamp type and suggested DOE either remove it or specify it in all definitions. (ASAP, No. 94 at p. 7)

DOE agrees that the term “designed and marketed” should be consistently used in definitions of exempted lamp types. Therefore, in this final rule, DOE removes the phrase “not designed and marketed for general lighting applications” because the definition of colored lamp already includes the phrase “designed and marketed as a colored lamp.” DOE is adopting a slightly modified definition of colored lamp in the final rule. A colored lamp is a colored fluorescent lamp, a colored incandescent lamp, or a lamp designed and marketed as a colored lamp with either of the following characteristics (if multiple modes of operation are possible [such as variable CCT], either of the below characteristics must be maintained throughout all modes of operation): a CRI less than 40, as determined according to the method set forth in CIE Publication 13.3; or a CCT less than 2,500 K or greater than 7,000 K.²¹

The proposed definition of plant light lamp would require radiant power

peaks in the red and blue region of the electromagnetic spectrum. NRDC commented that plant light lamps could have radiant power peaks in the green portion of the spectrum in addition to the blue or red portions thus making them suitable for general lighting applications. NRDC recommended adding a maximum allowable CRI to ensure general service lamps are not characterized as plant light lamps. (NRDC, No. 83 at pp. 96–97; NRDC, No. 85 at p. 10) ASAP agreed that the radiant power peak requirements specified for plant light lamps could easily be met by fluorescent lamps and possibly by incandescent lamps. ASAP also noted the availability and growing market of efficient LED lamps that emit light beneficial for plants and recommended that plant light lamps be included in the definition of GSILs. (ASAP, No. 94 at pp. 3–7)

A high CRI is not required for the lamp to effectively function and emit the highest radiant power peaks in blue and red wavelengths. Hence, a CRI requirement is not appropriate for defining a plant light lamp. While DOE finds that requirements for radiant power peak may not be exclusively applicable to plant light lamps, the additional requirement that the lamp be designed and marketed for plant growing applications is sufficient to discourage consumers from using plant light lamps in general light applications. For discussion regarding the inclusion of this lamp type in the GSIL definition, see section III.A.1.b. In this final rule DOE is adopting the definition of “plant light lamp” as proposed in the October 2016 NOPDDA. A plant light lamp is a lamp that is designed to promote plant growth by emitting its highest radiant power peaks in the regions of the electromagnetic spectrum that promote photosynthesis: Blue (440 nm to 490 nm) and/or red (620 to 740 nm), and is designed and marketed for plant growing applications.

NRDC commented that the definition of bug lamp, which requires the lamp to have a visible yellow coating, should also specify the amount of coating to prevent possible loopholes. However, GE commented that the requirement that bug lamps produce the majority of radiant power above 550 nm paired with the requirement of a visible yellow coating would prevent general service lamps from meeting the definition of bug lamp. They stated that the definition as proposed is sufficient and well understood by industry. (NRDC, No. 83 at p. 153; GE, No. 83 at p. 154) ASAP stated that fluorescent lamps exhibit peak radiant power above 550 nm and therefore could easily meet the

²¹ DOE notes that the October 2016 NOPDDA included references to appropriate industry standards to define “CCT.” DOE is omitting those references from this final rule because on further deliberation, it believes CCT is a term of art well understood in the lighting industry.

definition of a bug lamp. ASAP added that some fluorescent lamps naturally appear yellowish due their phosphor mix. Noting a study that found that warm light LED lamps attracted fewer insects than conventional and bug incandescent lamps, CFLs, halogens, and cool light LED lamps, ASAP stated DOE should discontinue the exemption of bug lamps from the definition of GSILs. (ASAP, No. 94 at pp. 3–7)

DOE concludes that requiring the yellow coating to be visible on the lamp is sufficient and quantifying it is unnecessary. DOE understands that the requirements for radiant power peak may not be exclusively applicable to bug lamps. However, DOE finds that the combination of requirements for radiant power peak and visible yellow coating should discourage this lamp type from being used in general service applications. For discussion regarding the inclusion of this lamp type in the GSIL definition, see section III.A.1.b. In this final rule, DOE is adopting the definition of “bug lamp” proposed in the October 2016 NOPDDA. A bug lamp is a lamp that is designed and marketed as a bug lamp, has radiant power peaks above 550 nm on the electromagnetic spectrum, and has a visible yellow coating.

2. Infrared Lamp

In the October 2016 NOPDDA, DOE proposed a definition for “infrared lamp” to support the definition of “general service lamp.” 81 FR 71809. NRDC, Utility Coalition, ASAP, and NEEP stated that the proposed definition of infrared lamp, which states that the highest radiant power peaks are in the infrared region of the electromagnetic spectrum, describes any incandescent lamp. They noted that the definition’s requirement that the primary purpose is to provide heat is the only difference from a standard incandescent lamp. NRDC, Utility Coalition, ASAP, and NEEP suggested several possible modifications to the definition. First, they recommended specifying a limit on the percentage of radiant power in the visible spectrum. Specifically, NEEP suggested stating that the lamp must generate more than 95 percent of energy towards heat rather than lighting and ASAP suggested that the share of radiant power in visible range be limited to a maximum of 1 percent. NEEP and ASAP suggested applying a wattage minimum to ensure that only infrared lamps were included, while NRDC recommended a wattage minimum of 125 W coupled with a minimum lamp diameter of 5 inches. Utility Coalition recommended an approach of using maximum lumen

output whereas NEEP suggested using a lumens per watt limit. (NRDC, No. 83 at pp. 12–13, 94–95; NRDC, No. 85 at pp. 6–7; NRDC, No. 85 at p. 7; NEEP, No. 92 at pp. 1–3; Utility Coalition, No. 95 at p. 10; ASAP, No. 94 at p. 6)

Westinghouse commented that the proposed definition of infrared lamp is sufficient and that these lamps are not at risk for use in general service applications because of their low lumen output. Westinghouse added that a lumen range could be added if necessary. (Westinghouse, No. 83 at pp. 41–42) LEDVANCE and NEMA supported the definition. They explained that using “and” in the definition, to require an infrared lamp to have radiant power peaks in the infrared region and have a primary purpose of providing heat, means that these lamps would be distinct from any GSIL and prevent any lamp switching. (NEMA, No. 93 at p. 29; LEDVANCE, No. 90 at pp. 34–35)

DOE understands that the requirement of a radiant power peak is not exclusively applicable to infrared lamps. In this final rule, DOE reviewed the definition of “infrared lamp” and determined that most infrared lamps are at least 125 W. This high wattage aligns with the use of this lamp type to provide heat. Hence, DOE is including a wattage minimum in the definition of “infrared lamp.” In this final rule, DOE is adopting a slightly modified definition for “infrared lamp.” An infrared lamp is a lamp that is designed and marketed as an infrared lamp; has its highest radiant power peaks in the infrared region of the electromagnetic spectrum (770 nm to 1 mm); has a rated wattage of 125 watts or greater; and which has a primary purpose of providing heat.

3. Appliance Lamp

DOE received comments on its use of the statutory definition of “appliance lamp,” which is defined at 42 U.S.C. 6291(30)(T).

NRDC and NEEP stated that appliance lamps resemble a conventional incandescent light bulb to a consumer, except they have smaller bulb dimensions, and therefore can serve as a replacement for 40 W incandescent lamps. NEEP explained that these lamps would particularly be attractive as a replacement due to their low price. NRDC recommended that appliance lamps should be able to operate in high temperature environments throughout the product’s rated lifetime. This requirement would make the lamp more robust and expensive and therefore, an unsuitable replacement for general light applications. NEEP suggested adding

the criteria of high temperature operation or a lumen maximum. (NRDC, No. 85 at p. 8; NEEP, No. 92 at pp. 1–3)

Most appliance lamps are intended for use in a variety of appliances and therefore are designed to operate in low and high temperature environments. Therefore, a criterion for high temperature operation would not be appropriate for defining these lamp types. DOE finds that the specifications in the definition for designating and marketing the lamp for use in appliances is sufficiently clear, thus discouraging consumers from using appliance lamps in general lighting applications. DOE will continue to monitor the market and may revise this definition if needed in the future.

4. Marine Lamp

In the October 2016 NOPDDA, DOE proposed a definition of “marine lamp.” 81 FR 71808. NRDC and NEEP commented that additional detail was needed for the definition of marine lamps to avoid potential loopholes. NRDC noted that these lamps likely operate on 12 or 24 V and recommended that marine lamps be defined as not able to operate at more than 25 V. NEEP suggested adding at least one qualifier to this definition relating to either operating voltage, outdoor temperature operation, or waterproof capability. (NRDC, No. 83 at pp. 95–96; NRDC, No. 85 at p. 9; NEEP, No. 92 at pp. 1–3)

DOE reviewed the performance characteristics of marine lamps and determined that most operate at voltages 12 V to 13.5 V. DOE finds that these operating voltages likely align with the use of these lamps in marine applications. Hence in this final rule DOE is adopting the definition of “marine lamps” with a voltage specification. A marine lamp means a lamp that is designed and marketed for use on boats and can operate at or between 12 volts and 13.5 volts.

5. Showcase Lamp

ASAP commented that the proposed definition for showcase lamp is insufficient to prevent loopholes and that widely available incandescent showcase lamps could fit into many light fixtures. Additionally, ASAP noted that DOE is proposing to include many T shape lamps in the definition of GSILs and recommended that showcase lamps also be included. (ASAP, No. 94 at pp. 3–7)

DOE finds that the shape and wattage specifications as well as the requirement that these lamps be designed and marketed as a showcase lamp is sufficient to discourage consumers from

using these lamps in general lighting applications. For discussion regarding the exemption of this lamp type in the definition of GSIL, see section III.A.1.b. In this final rule DOE is adopting the definition of “showcase lamp” as proposed in the October 2016 NOPDDA. A showcase lamp is a lamp that has a T shape as specified in ANSI C78.20–2003 and ANSI C79.1–2002, is designed and marketed as a showcase lamp, and has a maximum rated wattage of 75 watts. See the amendments to § 430.2 for the definition in its entirety.

6. Traffic Signal Lamp

NRDC stated that given their medium screw base and residential voltage as well as likeness to incandescent lamps, traffic signal lamps would appeal to consumers. Further, the unique characteristics of a strengthened filament and longer life liken these lamps to vibration and rough service lamps. NRDC recommended that DOE remove the exemption for traffic signal lamps to avoid potential lamp switching scenarios. NRDC also commented that LED lamps already meet the needs of traffic signal lamps. (NRDC, No. 85 at p. 8)

NEMA and LEDVANCE agreed with the proposed definition of traffic signal lamp. LEDVANCE explained that these replacement traffic signal lamps have a low lumen output, longer life, A21 shapes; and are more robustly constructed and expensive compared to a GSIL. LEDVANCE stated that due to these factors consumers would not use these lamps as replacements. LEDVANCE added that these lamps cannot be found in typical distribution channels such as retail stores. NEMA and LEDVANCE also stated that this type of lamp has seen dramatic decreases in sales because of the EPCA mandate to use LED technology in new traffic signal modules. (NEMA, No. 93 at p. 30; LEDVANCE, No. 90 at p. 35)

In its review of the definition for traffic signal lamps, DOE found that most traffic signal lamps have a lifetime of 8,000 hours, which is longer than typical incandescent lamps. This distinctive characteristic aligns with the use of these lamp types in traffic signals, in which long lifetimes are likely a desirable feature. Hence, DOE is amending its proposed definition of “traffic signal lamps” to include a lifetime specification. A traffic signal lamp means a lamp that is designed and marketed for traffic signal applications and has a lifetime of 8,000 hours or greater.

7. Silver Bowl Lamp

NEMA and LEDVANCE agreed with DOE’s proposed definition of silver bowl lamp. Both stated that this is a specialty lamp used for pendant and hanging light fixtures and that the lamp has an opaque silver coating causing the light to reflect towards the ceiling to create a specific lighting atmosphere. NEMA and LEDVANCE asserted that these lamps are not suitable for general service lighting applications. (NEMA, No. 93 at pp. 29–30; LEDVANCE, No. 90 at p. 35)

ASAP disagreed and recommended that the definition for “silver bowl lamp” be revised to include a minimum requirement for the percentage of total bulb surface that has a reflective coating. ASAP also suggested that the coating be required to be opaque. Finally, ASAP noted that more efficient alternatives to the incandescent silver bowl lamps are available and that silver bowl lamps should also be included in the definition of GSILs. (ASAP, No. 94 at p. 4)

Manufacturer catalogs and product specifications do not provide the amount of coating used in silver bowl lamps and therefore, it is difficult to determine a consistent value applicable across all products. DOE agrees that an opaque coating is necessary for the primary purpose of the lamp to reflect light towards the lamp base. DOE has therefore included the term “opaque” in the definition. For discussion regarding the exclusion of this lamp type in the GSIL definition, see section III.A.1.b. In this final rule, DOE amends the proposed definition to specify an opaque coating and is adopting a definition of “silver bowl lamp.” A silver bowl lamp is a lamp that has an opaque reflective coating applied directly to part of the bulb surface that reflects light toward the lamp base and that is designed and marketed as a silver bowl lamp.

8. Specialty MR Lamp

In the October 2016 NOPDDA, DOE proposed to exempt certain MR-shaped lamps that have smaller diameters than MR16 lamps and are marketed for use in specialty applications. In doing so, DOE found it necessary to establish a definition for “specialty MR lamp” to describe the lamps used in these specialty applications. As described in section III.A.4.f, DOE has revised the definition of specialty MR lamp for this final rule. A specialty MR lamp is a lamp that has an MR shape as defined in ANSI C79.1–2002, a diameter of less than or equal to 2.25 inches, a lifetime of less than or equal to 300 hours, and

that is designed and marketed for a specialty application.

NEMA recommended and LEDVANCE supported a definition for “MR lamp,” describing it as “a curved focusing reflectorized bulb which may have a multifaceted inner surface that is generally dichroic coated and referred to as a multifaceted reflector lamp with a GU10, GU11, GU5.3, GUX5.3, GU8, GU4, or E26 base” and providing information regarding common light sources and diameters used in the lamp type. (NEMA, No. 93 at p. 27; LEDVANCE, No. 90 at pp. 32–33) DOE does not find that a general definition for MR-shaped lamps is necessary to clarify the scope of this rulemaking. Additionally, the details regarding the bulb shape provided in NEMA’s proposed definition are very similar to those in the ANSI standard that DOE references in its definition of “specialty MR lamp.”

9. Designed and Marketed

In the October 2016 NOPDDA, DOE proposed a definition for “designed and marketed” to provide additional detail regarding the use of the term in several of the supporting definitions. 81 FR 71809. NEEP, Utility Coalition, and ASAP recommended the addition of the words “prominently displayed” in the definition to provide clarity in product labels regarding the application of the product. NEEP commented that this requirement would not overly impact the manufacturer’s packaging process. Further, Utility Coalition and ASAP explained that this requirement would reduce confusion among consumers about how the lamp should be used. (NEEP, No. 92 at pp. 1–3; Utility Coalition, No. 95 at p. 11; ASAP, No. 94 at p. 7)

DOE agrees that the specification of “prominently displayed” would help ensure that the application for which the product is intended is clearly communicated to consumers. Hence in this final rule, DOE amends the proposed definition of “designed and marketed” to specify that the application designation be prominently displayed. Designed and marketed is exclusively designed to fulfill the indicated application and, when distributed in commerce, designated and marketed solely for that application, with the designation prominently displayed on the packaging and all publicly available documents (e.g., product literature, catalogs, and packaging labels). This definition is applicable to terms related to the following covered lighting products: Fluorescent lamp ballasts; fluorescent lamps; general service fluorescent

lamps; general service incandescent lamps; general service lamps; incandescent lamps; incandescent reflector lamps; medium base compact fluorescent lamps; and specialty application mercury vapor lamp ballasts.

10. Other Definitions

In the October 2016 NOPDDA, DOE also proposed definitions for “GU24 base,” “integrated lamp,” “LED downlight retrofit kit,” “left-hand thread lamp,” “light fixture,” “marine signal service lamp,” “mine service lamp,” “non-integrated lamp,” “non-reflector lamp,” “pin base lamp,” “reflector lamp,” and “sign service lamp.” 81 FR 71807, 71809. DOE believes the definitions for “GU24 base” and “non-reflector lamp” are no longer necessary. DOE did not receive any comments on the other definitions and is adopting a definition for integrated lamp, LED downlight retrofit kit, left hand thread lamp, light fixture, marine signal service lamp, mine service lamp, non-integrated lamp, pin-base lamp, sign-service lamp in § 430.2 in this final rule.²²

Although DOE received no comments on the definition of reflector lamp, DOE believes the phrase “is used to provide directional light” describes the function of a reflector lamp better than “is used to direct light.” DOE has therefore revised the definition of reflector lamp in the final rule. A reflector lamp is a lamp that has an R, PAR, BPAR, BR, ER, MR, or similar bulb shape (as defined in ANSI C78.20–2003 and ANSI C79.1–2002) and is used to provide directional light.

IV. Energy Conservation Standards

A. Energy Conservation Standards Proposed in the March 2016 GSL ECS NOPR

In the March 2016 GSL ECS NOPR, DOE proposed standards for GSLs. Although the October 2016 NOPDDA did not specifically address the proposed standards, DOE received a number of general comments regarding the proposed standards. CEC and RELS urged DOE to consider a minimum efficiency standard that achieves feasible and prospective energy savings for products in the GSL scope once the definition of GSL is finalized. (CEC, No. 81 at p. 1; CEC, No. 83 at pp. 32–33;

RELS, No. 86 at p. 1) CEC stated that significant energy savings would result in shifting from an incandescent lamp to an LED lamp or shifting from an LED lamp to a more efficient LED lamp for SDDLs and medium screw base LED reflector lamps. CEC also provided an estimate of current availability of LED replacements at 80 lm/W or higher for SDDLs and medium screw base directional lamps. (CEC, No. 91 at pp. 7–8)

NEEP commented that given the range of LED products available on the market that are high quality and high efficiency, NEEP believes that the federal minimum standard for 2020 and corresponding scope are very achievable. (NEEP, No. 83 at pp. 13–14)

This final rule adopts a definition for GSL, as well as related definitions. DOE is not addressing proposed standards in this final rule. DOE acknowledges the comments regarding the proposed standards for GSLs, and will address them at such time as standards may be finalized.

B. Backstop

If DOE fails to complete a rulemaking in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv) or a final rule from the first rulemaking cycle does not produce savings greater than or equal to the savings from a minimum efficacy standard of 45 lm/W, the statute provides a “backstop” under which DOE must prohibit sales of GSLs that do not meet a minimum 45 lm/W standard beginning on January 1, 2020. (42 U.S.C. 6295(i)(6)(A)(v)) DOE received a number of comments regarding the backstop standard.

CEC commented on the potential for DOE to exercise enforcement discretion if the backstop standard was applicable. (CEC, No. 91 at p. 10) CEC stated that if DOE were to exercise enforcement discretion, that the backstop standard would still be applicable in the context of California building codes (which incorporate Federal appliance standards), and in the context of California’s appliance efficiency standards (which require product certification for federally covered products). (CEC, No. 91 at p. 10)

As of the issuance date of this document the backstop standard would not be applicable. The backstop standard is not applicable unless DOE fails to complete the rulemaking as prescribed by EPCA by January 1, 2017, or the final rule does not produce savings that are greater than or equal to the savings from a minimum efficacy standard of 45 lm/W. (42 U.S.C. 6295(i)(6)(A)(iv))

C. Preemption

Federal energy conservation requirements generally supersede state laws or regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6297(a)–(c)) Generally, preemption applies both before an energy conservation standard becomes effective, and after an energy conservation standard becomes effective. (42 U.S.C. 6297(b) and (c)) For energy conservation standards applicable to GSLs, EISA 2007 established additional preemption provisions specific to California and Nevada. Namely, beginning January 1, 2018, no provision of law can preclude these states from adopting: (1) Standards established in a final DOE rule adopted in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv); (2) the minimum efficacy standard of the backstop standard (45 lm/W) if no final rule was adopted in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv); or (3) for the State of California, any California regulations related to the covered products adopted pursuant to state statute in effect as of the date of enactment of EISA 2007 (*i.e.*, December 19, 2007). (42 U.S.C. 6295(i)(6)(A)(vi)) Other than these narrow exceptions, EPCA’s statutory preemption provision prohibits any state from adopting energy conservation standards for any type of GSL regardless of whether DOE sets standards for that type of GSL.

CEC stated that California has already established a 45 lm/W standard with an effective date of January 1, 2018. (CEC, No. 91 at p. 10) CEC stated that the technology neutral approach to the scope of GSLs would minimize lamp switching that would otherwise limit the energy savings and consumer benefits achieved by the 45 lm/W requirement effective January 1, 2018 in California and in January 1, 2020 in the rest of the nation. (CEC, No. 91 at p. 1) Philips asked if CFL and LED reflector lamps would be GSLs under the definitions proposed in the October 2016 NOPDDA, whether they would be subject to the backstop standard, and if so, whether the backstop standard would preempt the California Title 20 regulation. (Philips, No. 96 at p. 6)

Except for the narrow exception to the preemption provision provided in 42 U.S.C. 6295(i)(6)(A)(vi), the general EPCA preemption provisions apply to GSLs. Federal test procedures for GSLs supersede state test procedures that require testing in any manner other than the Federal test procedure. (42 U.S.C. 6297(a)(1)(A)) Prior to the effective date of standards for GSLs, no state regulation regarding energy efficiency or

²² DOE notes that for several of these definitions, the October 2016 NOPDDA included references to appropriate industry standards to define terms like “retrofit kit” or “single pin base system.” DOE is omitting those references from this final rule because on further deliberation, it believes those terms are terms of art whose meaning will be clear to participants in the lighting market.

energy use shall be effective with respect to such covered products.²³ (42 U.S.C. 6297(b)) Preemption continues to apply after a Federal energy conservation standard for GSLs becomes effective. (42 U.S.C. 6297(c))

V. Manufacturer Impacts

NEMA noted that in response to the March 2016 ECS NOPR, it had commented that in 2020 manufacturers would have to supply the entire nation with general service LED lamps as incandescent lamps would not be available. NEMA had explained in its comment that this would mean a 300 percent increase in the steady state demand and require tripling capacity for only that year. NEMA stated that the proposed definitions in the October 2016 NOPDDA increased the scope of GSLs to a wider range of specialty products than what was proposed in the March 2016 GSL ECS NOPR. Hence the projected spike in demand in 2020 would now be even higher. Therefore, NEMA encouraged DOE to either not impose regulations or postpone them for a few years on niche products. (NEMA, No. 83 at pp. 157–158)

NRDC noted that stakeholders have known that standards set by DOE and/or the 45 lm/W backstop standard would be implemented in 2020. NRDC stated that sales from a recent quarter showing LED market share was at 25 percent indicated that industry has done an amazing job preparing for this standard. Further NRDC noted that supply chains worldwide would be impacted as Europe and China are also phasing out incandescent lamps. Hence, NRDC asserted that industry would be adequately prepared for to meet demand in 2020. (NRDC, No. 83 at pp. 164–165)

GE, NEMA and LEDVANCE urged DOE to reconsider its interpretation of the Appropriations Rider and EISA 2007 and pointed out that expanding the scope of GSLs will further increase the amount of stranded inventory and consequently the time it will take to sell the lamps, adding that a minimum of 2–3 years will be required to sell stranded inventory and exit the businesses. GE, NEMA and LEDVANCE stated that typically DOE allows existing inventory of noncompliant products to be sold after a standard goes into effect while the backstop standard prohibits sale of noncompliant products at a certain date.

(GE, No. 88 at pp. 5–6; NEMA, No. 93 at p. 31; LEDVANCE, No. 90 at p. 36) Philips and LEDVANCE added that enforcement of a prohibition of sale date would also impact the electrical distribution market. Philips recommended DOE consider a prohibition on manufacturing and not sales. LEDVANCE stated DOE should allow manufacturers and retailers to sell inventory they have on-hand before the date of prohibition. (Philips, No. 96 at p. 6; LEDVANCE, No. 90 at pp. 16–17) To avoid imposing severe financial burdens on industry, NEMA stated that DOE should withdraw its proposed expansion of GSL scope and evaluate discontinuing exemptions in the second GSL rulemaking Congress authorized to begin in 2020. (NEMA, No. 93 at p. 31)

CEC agreed that a prohibition on sale would pose difficulties for the industry. CEC noted that use of date-of-manufacture for the compliance date would be more easily enforced and would ensure that retailers are not unfairly penalized for incorrectly determining the exact amount of stock that can be sold prior to the compliance date, but CEC also commented that it understood the backstop standard to establish a date-of-sale compliance date. (CEC, No. 91 at pp. 9–10)

NEMA also encouraged DOE to consider establishing an energy conservation standard that caps energy use (wattage) as it is significantly less burdensome compared to a lumens per watt requirement. NEMA explained a wattage limit is particularly applicable to rough service, vibration service, and shatter-resistant lamps, appliance lamps, intermediate base lamps, candelabra base lamps, T shape lamps and other lamps that have 40 W restrictions as well as high lumen lamps. NEMA stated because there is no hard evidence that lamp switching from general service LED lamps to specialty versions is even possible and will result in loss of significant energy savings, there is no reason for DOE to impose testing burden on manufacturers by regulating specialty LED lamps. (NEMA, No. 93 at p. 11) In addition to test burden, Philips and NEMA noted the significantly increased burden on manufacturers if DOE required certification reports to be submitted for all products to certify to the 45 lm/W standard. (Philips, No. 83 at p. 163; Philips, No. 96 at p. 6; NEMA, No. 93 at p. 11)

NEMA noted that they, as well as domestic lighting manufacturers, are advocates for domestic manufacturing and employment. Thus, in addition to energy savings and energy efficiency, NEMA argued that DOE must consider

the fact that the proposed rule will destroy domestic jobs. (NEMA, No. 83 at p. 16)

However, NRDC and ASAP commented that many LED lamps are designed and produced by domestic companies, and therefore recommended comparing the number of jobs in the U.S. associated with making LED lamps compared to less efficient products. (NRDC, No. 83 at p. 46; ASAP, No. 94 at p. 7) NRDC and Utility Coalition added that, to their knowledge, incandescent/halogen lamps by leading manufacturers such as GE and Philips Lighting are not made in the U.S. They cited domestic producers of SSLs and their employee numbers and asserted that domestic jobs related to designing, testing, and marketing LED lamps and their components would outnumber domestic jobs related to production of incandescent lamps. (Utility Coalition, No. 95 at pp. 5–6; NRDC, No. 85 at pp. 10–11)

DOE acknowledges that manufacturers may face a difficult transition if required to comply with a 45 lm/W standard. Manufacturers have voiced concern regarding the loss of domestic manufacturing jobs, the stranding of inventory, the ability to meet the demand for all general service lamps with lamps using LED technology, and the burden associated with testing and certifying compliance for all general service lamps in DOE's Compliance Certification Management System (CCMS). Manufacturers have requested an end to or delay in imposing any new standards for general service lamps and a two to three year delay in enforcing the backstop standard.

DOE is committed to working with manufacturers to ensure a successful transition if the backstop standard goes into effect.²⁴ DOE will continue to have an active dialogue with industry, including meetings and other stakeholder outreach, throughout the period between publication of this rule and the compliance date of any backstop standard for general service

²⁴ In that vein, DOE also notes NEMA's comment that because the backstop requires DOE to "prohibit sales," it could present a substantial practical difficulty regarding compliance. For most products, NEMA states, after a standard comes into effect distributors can continue to sell inventory still on hand that complied with the previous standard. If, by contrast, distributors cannot sell old lamp inventory after January 1, 2020, that inventory will be stranded. Although it is premature for DOE to explain in detail how the backstop would work if it comes into force, DOE notes that under subsection (i)(2), "it shall not be unlawful for a manufacturer to sell a lamp which is in compliance with the law at the time such lamp was manufactured." DOE expects it would interpret and apply the backstop with subsection (i)(2) in mind.

²³ 42 U.S.C. 6297(b)(1)(B) provided California and Nevada a limited exception to the preemption of the standards for general service incandescent lamps, intermediate base incandescent lamps, or candelabra base lamps established in EISA prior to their effective date. The Federal standards have since gone into effect and that preemption provision is no longer relevant.

lamps. During this period, DOE will keep stakeholders and the public apprised of its plans for any broad exercise of enforcement discretion with respect to the standard.

VI. Clarifications to Regulatory Text

In the October 2016 NOPDDA, DOE proposed editorial modifications to regulatory text to align with the recently adopted test procedure for integrated LED lamps. Specifically, DOE proposed changes to 10 CFR 429.56 regarding the certification and reporting requirements of integrated LED lamps. In the July 2016 LED test procedure (TP) final rule, DOE adopted the requirement that testing of integrated LED lamps be conducted by test laboratories accredited by an Accreditation Body that is a signatory member to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). 81 FR 43404, 43419 (July 1, 2016). To align with this requirement, DOE proposed in the October 2016 NOPDDA to modify the certification report language in 429.56(b)(2) to specify that the testing laboratory's ILAC accreditation body's identification number or other approved identification assigned by the ILAC accreditation body must be included in the certification report. In addition, DOE proposed that manufacturers must also report CRI in the certification report for integrated LED lamps. 81 FR 71809.

LEDVANCE requested clarification on DOE's citation of an ILAC accreditor identification number while NEMA pointed out that there are no identification numbers for ILAC accreditors. NEMA, LEDVANCE, and Philips also asked DOE to reconsider including CRI in the certification reporting requirements to minimize the regulatory and testing burden especially because CRI is not a part of the energy conservation standard for general service incandescent lamps or general service LED lamps. (LEDVANCE, No. 90 at p. 35; NEMA, No. 93 at p. 30; Philips, No. 96 at p. 5)

This final rule document finalizes the definition for GSL and related definitions. DOE is not making changes to the certification and reporting requirements in this final rule. DOE recognizes the comments received regarding the reporting of a testing laboratory's ILAC accreditation number and the reporting of the CRI for integrated lamps, and will address these comments to the extent the proposed revisions are considered at a later date.

VII. Effective Date

For the changes described in the various definitions in this final rule,

DOE is adopting a January 1, 2020 effective date.

VIII. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866 and 13563

This final rule neither implements nor seeks to enforce any standard. Rather, this final rule merely defines what constitutes a GSIL and what constitutes a GSL. Lamps that are GSLs will become subject to either a standard developed by DOE or to a 45 lm/W backstop standard, but this rule does not determine what standard will be applicable to lamps that are being newly included as GSLs. Accordingly, this action does not constitute a significant regulatory action under Executive Orders 12866 and 13563.

NEMA commented that DOE failed to meet the requirements of Executive Order 12866 in that DOE did not consider regulatory alternatives to the regulation adopted in this document including the alternative of not regulating and that DOE must choose the regulatory approach that maximizes net benefits unless a statute requires another regulatory approach. (NEMA, No. 93 at p. 10)

As explained throughout the preamble, DOE has undertaken revisions to the GSIL and GSL definitions as authorized by EPCA. (42 U.S.C. 6295(i)(6)(A)(i)(II)) In amending the definitions, DOE considered the potential that lamps exempted from the definition of GSL would create loopholes should a GSL standard or standards be adopted. However, this rule does not establish standards.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires that when an agency promulgates a final rule under 5 U.S.C. 553, after being required by that section or any other law to publish a general NOPR, the agency shall prepare a final regulatory flexibility analysis (FRFA), unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, "Proper Consideration of Small Entities in Agency Rulemaking," 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General

Counsel's Web site (<http://energy.gov/gc/office-general-counsel>).

DOE reviewed the definitions for GSL and related terms adopted in this final rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. DOE certifies that this final rule does not have a significant economic impact on a substantial number of small entities. The factual basis for this certification is set forth in the following paragraphs.

For manufacturers of GSLs, the SBA has set a size threshold, which defines those entities classified as "small businesses" for the purposes of the statute. DOE used the SBA's small business size standards to determine whether any small entities would be subject to the requirements of the rule. (See 13 CFR part 121.) The size standards are listed by NAICS code and industry description and are available at http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf. Manufacturing of GSLs is classified under NAICS 335110, "Electric Lamp Bulb and Part Manufacturing." The SBA sets a threshold of 1,250 employees or less for an entity to be considered as a small business for this category.

To estimate the number of companies that could be small businesses that manufacture GSLs covered by this rulemaking, DOE conducted a market survey using publicly available information. DOE's research involved information provided by trade associations (e.g., NEMA²⁵) and information from DOE's CCMS Database,²⁶ EPA's ENERGY STAR Certified Light Bulbs Database,²⁷ DOE's LED Lighting Facts Database,²⁸ previous rulemakings, individual company Web sites, SBA's database, and market research tools (e.g., Hoover's reports²⁹). DOE used information from these sources to create a list of companies that potentially manufacture or sell GSLs and would be impacted by this

²⁵ National Electric Manufacturers Association | Member Products | Lighting Systems | Related Manufacturers, <http://www.nema.org/Products/Pages/Lighting-Systems.aspx> (last accessed November 21, 2016).

²⁶ DOE's Compliance Certification Database | Lamps—Bare or Covered (No Reflector) Medium Base Compact Fluorescent, <http://www.regulations.doe.gov/certification-data> (last accessed November 21, 2016).

²⁷ ENERGY STAR Qualified Lamps Product List, http://downloads.energystar.gov/bi/qpllist/Lamps_Qualified_Product_List.xls?dee3-e997 (last accessed November 21, 2016).

²⁸ LED Lighting Facts Database, <http://www.lightingfacts.com/products> (last accessed November 21, 2016).

²⁹ Hoovers | Company Information | Industry Information | Lists, <http://www.hoovers.com> (last accessed November 21, 2016).

rulemaking. DOE screened out companies that do not offer products covered by this rulemaking, do not meet the definition of a “small business,” or are completely foreign owned and operated. DOE determined that nine companies are small businesses that maintain domestic production facilities for general service lamps.

DOE notes that this final rule merely defines what constitutes a GSIL and what constitutes a GSL. Manufacturers of general service lamps are required to use DOE’s test procedures to make representations and certify compliance with standards, if required. The test procedure rulemakings for CFLs, integrated LED lamps, and other general service lamps³⁰ addressed impacts on small businesses due to test procedure requirements. 81 FR 59386 (August 29, 2016); 81 FR 43404 (July 1, 2016). The effective date allows reasonable time for manufacturers to transition, while reducing the number of redesigns needed, should manufacturers need to comply with a 45 lm/W statutory standard beginning on January 1, 2020. For these reasons, DOE concludes and certifies that the new adopted definitions do not have a significant economic impact on a substantial number of small entities, and the preparation of an FRFA is not warranted.

C. Review Under the Paperwork Reduction Act

Manufacturers of GSLs must certify to DOE that their products comply with any applicable energy conservation standards. In certifying compliance, manufacturers must test their products according to DOE test procedures for GSLs, including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment. 76 FR 12422 (March 7, 2011). The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement has been approved by OMB under OMB control number 1910–1400. DOE requested OMB approval of an extension of this information collection for three years, specifically including the collection of information adopted in the present rulemaking, and estimated that the

annual number of burden hours under this extension is 30 hours per company. In response to DOE’s request, OMB approved DOE’s information collection requirements covered under OMB control number 1910–1400 through November 30, 2017. 80 FR 5099 (January 30, 2015).

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

D. Review Under the National Environmental Policy Act of 1969

Pursuant to the National Environmental Policy Act (NEPA) of 1969, DOE has determined that the rule fits within the category of actions included in Categorical Exclusion (CX) B5.1 and otherwise meets the requirements for application of a CX. (See 10 CFR part 1021, App. B, B5.1(b); 1021.410(b) and App. B, B(1)–(5).) The rule fits within this category of actions because it is a rulemaking that changes the definition of a covered class of products for which there are existing energy conservation standards, and for which none of the exceptions identified in CX B5.1(b) apply. Therefore, DOE has made a CX determination for this rulemaking, and DOE does not need to prepare an Environmental Assessment or Environmental Impact Statement for this rule. DOE’s CX determination for this rule is available at <http://energy.gov/nepa/categorical-exclusion-cx-determinations-cx>.

E. Review Under Executive Order 13132

Executive Order 13132, “Federalism,” 64 FR 43255 (August 10, 1999), imposes certain requirements on federal agencies formulating and implementing policies or regulations that preempt state law or that have Federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the states and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by state and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this rule and has determined

that it would not have a substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes federal preemption of state regulations as to energy conservation for the products that are the subject of this final rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297) Therefore, no further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, “Civil Justice Reform,” imposes on federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; (3) provide a clear legal standard for affected conduct rather than a general standard; and (4) promote simplification and burden reduction. 61 FR 4729 (Feb. 7, 1996). Regarding the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each federal agency to assess the effects of federal regulatory actions on state, local, and tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a

³⁰ The pre-publication of the general service lamps test procedure final rule was issued on September 30, 2016 and is available at: <http://energy.gov/sites/prod/files/2016/09/f33/General%20Service%20Lamps%20TP%20Final%20Rule.pdf>.

regulatory action likely to result in a rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a federal agency to develop an effective process to permit timely input by elected officers of state, local, and tribal governments on a proposed “significant intergovernmental mandate,” and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE’s policy statement is also available at http://energy.gov/sites/prod/files/gcprod/documents/umra_97.pdf.

DOE examined this final rule according to UMRA and its statement of policy and determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of \$100 million or more in any year, so these requirements do not apply.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

Pursuant to Executive Order 12630, “Governmental Actions and Interference with Constitutionally Protected Property Rights,” 53 FR 8859 (March 15, 1988), DOE has determined that this rule would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for federal agencies to review most disseminations of information to the public under information quality guidelines established by each agency pursuant to general guidelines issued by OMB. OMB’s guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE’s guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,” 66 FR 28355 (May 22, 2001), requires federal agencies to prepare and submit to OIRA at OMB, a Statement of Energy Effects for any significant energy action. A “significant energy action” is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

This regulatory action to adopt definitions for GSL and related terms is not a significant regulatory action under Executive Order 12866. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

L. Review Under Section 32 of the Federal Energy Administration Act of 1974

Under section 301 of the Department of Energy Organization Act (Pub. L. 95–91; 42 U.S.C. 7101), DOE must comply with section 32 of the Federal Energy Administration Act of 1974, as amended

by the Federal Energy Administration Authorization Act of 1977. (15 U.S.C. 788; FEAA) Section 32 essentially provides in relevant part that, where a rule authorizes or requires use of commercial standards, the NOPR must inform the public of the use and background of such standards. In addition, section 32(c) requires DOE to consult with the Attorney General and the Chairman of the Federal Trade Commission (FTC) concerning the impact of the commercial or industry standards on competition.

The modifications to the definition of general service lamp and the associated supporting definitions adopted in this final rule references the following commercial standards that are already incorporated by reference in 10 CFR part 430:

- (1) ANSI C78.20–2003, Revision of ANSI C78.20–1995 (“ANSI C78.20”), American National Standard for electric lamps—A, G, PS, and Similar Shapes with E26 Medium Screw Bases, approved October 30, 2003.
- (2) ANSI C79.1–2002, American National Standard for Electric Lamps—Nomenclature for Glass Bulbs Intended for Use with Electric Lamps, approved September 16, 2002.
- (3) CIE 13.3–1995 (“CIE 13.3”), Technical Report: Method of Measuring and Specifying Colour Rendering Properties of Light Sources, 1995, ISBN 3 900 734 57 7.

DOE previously consulted with both the Attorney General and the Chairman of the FTC about the impact on competition of referencing these standards and at that time received no comments objecting to their use.

M. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this rule prior to its effective date. The report will state that it has been determined that the rule is not a “major rule” as defined by 5 U.S.C. 804(2).

IX. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this final rule.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by reference, Intergovernmental relations, Small businesses.

Issued in Washington, DC, on December 29, 2016.

David Nemtzw,

Acting Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

For the reasons set forth in the preamble, DOE amends part 430 of chapter II, subchapter D, of title 10 of the Code of Federal Regulations, as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. Section 430.2 is amended by:

- a. Adding in alphabetical order the definitions of “Black light lamp,” “Bug lamp,” “Colored lamp,” “General service light-emitting diode (LED) lamp,” “General service organic lighting-emitting diode (OLED) lamp,” “Infrared lamp,” “Integrated lamp,” “LED Downlight Retrofit Kit,” “Left-hand thread lamp,” “Light fixture,” “Marine lamp,” “Marine signal service lamp,” “Mine service lamp,” “Non-integrated lamp,” “Other fluorescent lamp,” “Pin base lamp,” “Plant light lamp,” “Reflector lamp,” “Showcase Lamp,” “Sign service lamp,” “Silver bowl lamp,” “Specialty MR lamp,” and “Traffic signal lamp;” and
- b. Revising the definitions of “designed and marketed,” “general service incandescent lamp,” and “general service lamp.”

The additions and revisions read as follows:

§ 430.2 Definitions.

* * * * *

Black light lamp means a lamp that is designed and marketed as a black light lamp and is an ultraviolet lamp with the highest radiant power peaks in the UV–A band (315 to 400 nm) of the electromagnetic spectrum.

* * * * *

Bug lamp means a lamp that is designed and marketed as a bug lamp, has radiant power peaks above 550 nm on the electromagnetic spectrum, and has a visible yellow coating.

* * * * *

Colored lamp means a colored fluorescent lamp, a colored incandescent lamp, or a lamp designed and marketed as a colored lamp with either of the following characteristics (if multiple modes of operation are possible [such as variable CCT], either of the below characteristics must be

maintained throughout all modes of operation):

(1) A CRI less than 40, as determined according to the method set forth in CIE Publication 13.3 (incorporated by reference; see § 430.3); or

(2) A CCT less than 2,500 K or greater than 7,000 K.

* * * * *

Designed and marketed means exclusively designed to fulfill the indicated application and, when distributed in commerce, designated and marketed solely for that application, with the designation prominently displayed on the packaging and all publicly available documents (e.g., product literature, catalogs, and packaging labels). This definition is applicable to terms related to the following covered lighting products: Fluorescent lamp ballasts; fluorescent lamps; general service fluorescent lamps; general service incandescent lamps; general service lamps; incandescent lamps; incandescent reflector lamps; medium base compact fluorescent lamps; and specialty application mercury vapor lamp ballasts.

* * * * *

General service incandescent lamp means a standard incandescent or halogen type lamp that is intended for general service applications; has a medium screw base; has a lumen range of not less than 310 lumens and not more than 2,600 lumens or, in the case of a modified spectrum lamp, not less than 232 lumens and not more than 1,950 lumens; and is capable of being operated at a voltage range at least partially within 110 and 130 volts; however this definition does not apply to the following incandescent lamps—

- (1) An appliance lamp;
- (2) A black light lamp;
- (3) A bug lamp;
- (4) A colored lamp;
- (5) A G shape lamp with a diameter of 5 inches or more as defined in ANSI C79.1–2002 (incorporated by reference; see § 430.3);
- (6) An infrared lamp;
- (7) A left-hand thread lamp;
- (8) A marine lamp;
- (9) A marine signal service lamp;
- (10) A mine service lamp;
- (11) A plant light lamp;
- (12) An R20 short lamp;
- (13) A sign service lamp;
- (14) A silver bowl lamp;
- (15) A showcase lamp; and
- (16) A traffic signal lamp.

General service lamp means a lamp that has an ANSI base; is able to operate at a voltage of 12 volts or 24 volts, at or between 100 to 130 volts, at or between

220 to 240 volts, or of 277 volts for integrated lamps (as defined in this section), or is able to operate at any voltage for non-integrated lamps (as defined in this section); has an initial lumen output of greater than or equal to 310 lumens (or 232 lumens for modified spectrum general service incandescent lamps) and less than or equal to 3,300 lumens; is not a light fixture; is not an LED downlight retrofit kit; and is used in general lighting applications. General service lamps include, but are not limited to, general service incandescent lamps, compact fluorescent lamps, general service light-emitting diode lamps, and general service organic light-emitting diode lamps. General service lamps do not include:

- (1) Appliance lamps;
- (2) Black light lamps;
- (3) Bug lamps;
- (4) Colored lamps;
- (5) G shape lamps with a diameter of 5 inches or more as defined in ANSI C79.1–2002 (incorporated by reference; see § 430.3);
- (6) General service fluorescent lamps;
- (7) High intensity discharge lamps;
- (8) Infrared lamps;
- (9) J, JC, JCD, JCS, JCV, JCX, JD, JS, and JT shape lamps that do not have Edison screw bases;
- (10) Lamps that have a wedge base or prefocus base;
- (11) Left-hand thread lamps;
- (12) Marine lamps;
- (13) Marine signal service lamps;
- (14) Mine service lamps;
- (15) MR shape lamps that have a first number symbol equal to 16 (diameter equal to 2 inches) as defined in ANSI C79.1–2002 (incorporated by reference; see § 430.3), operate at 12 volts, and have a lumen output greater than or equal to 800;
- (16) Other fluorescent lamps;
- (17) Plant light lamps;
- (18) R20 short lamps;
- (19) Reflector lamps (as defined in this section) that have a first number symbol less than 16 (diameter less than 2 inches) as defined in ANSI C79.1–2002 (incorporated by reference; see § 430.3) and that do not have E26/E24, E26d, E26/50x39, E26/53x39, E29/28, E29/53x39, E39, E39d, EP39, or EX39 bases;
- (20) S shape or G shape lamps that have a first number symbol less than or equal to 12.5 (diameter less than or equal to 1.5625 inches) as defined in ANSI C79.1–2002 (incorporated by reference; see § 430.3);
- (21) Sign service lamps;
- (22) Silver bowl lamps;
- (23) Showcase lamps;
- (24) Specialty MR lamps;
- (25) T shape lamps that have a first number symbol less than or equal to 8

(diameter less than or equal to 1 inch) as defined in ANSI C79.1–2002 (incorporated by reference; see § 430.3), nominal overall length less than 12 inches, and that are not compact fluorescent lamps (as defined in this section);

(26) Traffic signal lamps;

(27) Incandescent reflector lamps.

General service light-emitting diode (LED) lamp means an integrated or non-integrated LED lamp designed for use in general lighting applications (as defined in this section) and that uses light-emitting diodes as the primary source of light.

General service organic light-emitting diode (OLED) lamp means an integrated or non-integrated OLED lamp designed for use in general lighting applications (as defined in this section) and that uses organic light-emitting diodes as the primary source of light.

* * * * *

Infrared lamp means a lamp that is designed and marketed as an infrared lamp; has its highest radiant power peaks in the infrared region of the electromagnetic spectrum (770 nm to 1 mm); has a rated wattage of 125 watts or greater; and which has a primary purpose of providing heat.

* * * * *

Integrated lamp means a lamp that contains all components necessary for the starting and stable operation of the lamp, does not include any replaceable or interchangeable parts, and is connected directly to a branch circuit through an ANSI base and corresponding ANSI standard lamp-holder (socket).

* * * * *

LED Downlight Retrofit Kit means a product designed and marketed to install into an existing downlight, replacing the existing light source and related electrical components, typically employing an ANSI standard lamp base, either integrated or connected to the downlight retrofit by wire leads, and is a retrofit kit. LED downlight retrofit kit does not include integrated lamps or non-integrated lamps.

Left-hand thread lamp means a lamp with direction of threads on the lamp base oriented in the left-hand direction.

* * * * *

Light fixture means a complete lighting unit consisting of light source(s) and ballast(s) or driver(s) (when applicable) together with the parts designed to distribute the light, to position and protect the light source, and to connect the light source(s) to the power supply.

* * * * *

Marine lamp means a lamp that is designed and marketed for use on boats and can operate at or between 12 volts and 13.5 volts.

Marine signal service lamp means a lamp that is designed and marketed for marine signal service applications.

* * * * *

Mine service lamp means a lamp that is designed and marketed for mine service applications.

* * * * *

Non-integrated lamp means a lamp that is not an integrated lamp.

* * * * *

Other fluorescent lamp means low pressure mercury electric-discharge sources in which a fluorescing coating transforms some of the ultraviolet energy generated by the mercury discharge into light and include circline lamps and include double-ended lamps with the following characteristics: Lengths from one to eight feet; designed for cold temperature applications; designed for use in reprographic equipment; designed to produce radiation in the ultra-violet region of the spectrum; impact-resistant; reflectorized or aperture; or a CRI of 87 or greater.

* * * * *

Pin base lamp means a lamp that uses a base type designated as a single pin base or multiple pin base system.

* * * * *

Plant light lamp means a lamp that is designed to promote plant growth by emitting its highest radiant power peaks in the regions of the electromagnetic spectrum that promote photosynthesis: Blue (440 nm to 490 nm) and/or red (620 to 740 nm), and is designed and marketed for plant growing applications.

* * * * *

Reflector lamp means a lamp that has an R, PAR, BPAR, BR, ER, MR, or similar bulb shape as defined in ANSI C78.20–2003 (incorporated by reference; see § 430.3) and ANSI C79.1–2002 (incorporated by reference; see § 430.3) and is used to provide directional light.

* * * * *

Showcase lamp means a lamp that has a T shape as specified in ANSI C78.20–2003 (incorporated by reference; see § 430.3) and ANSI C79.1–2002 (incorporated by reference; see § 430.3), is designed and marketed as a showcase lamp, and has a maximum rated wattage of 75 watts.

* * * * *

Sign service lamp means a vacuum type or gas-filled lamp that has sufficiently low bulb temperature to permit exposed outdoor use on high-speed flashing circuits, is designed and

marketed as a sign service lamp, and has a maximum rated wattage of 15 watts.

Silver bowl lamp means a lamp that has an opaque reflective coating applied directly to part of the bulb surface that reflects light toward the lamp base and that is designed and marketed as a silver bowl lamp.

* * * * *

Specialty MR lamp means a lamp that has an MR shape as defined in ANSI C79.1–2002 (incorporated by reference; see § 430.3), a diameter of less than or equal to 2.25 inches, a lifetime of less than or equal to 300 hours, and that is designed and marketed for a specialty application.

* * * * *

Traffic signal lamp means a lamp that is designed and marketed for traffic signal applications and has a lifetime of 8,000 hours or greater.

* * * * *

[FR Doc. 2016–32013 Filed 1–18–17; 8:45 am]

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DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket Number EERE–2013–BT–STD–0051]

RIN 1904–AD09

Energy Conservation Program: Energy Conservation Standards for General Service Lamps

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule.

SUMMARY: On March 17, 2016, the U.S. Department of Energy (DOE) published a notice of proposed rulemaking (NPR) proposing standards for general service lamps (GSLs) pursuant to the Energy Policy and Conservation Act of 1975 (EPCA), as amended. In this final rule DOE responds to comments received on the October 2016 NOPDDA regarding IRLs and amends the definition of GSL.

DATES: The effective date of this rule is January 1, 2020.

ADDRESSES: The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at www.regulations.gov. All documents in the docket are listed in the www.regulations.gov index. However, some documents listed in the index may not be publicly available, such as those containing information that is exempt from public disclosure.

A link to the docket Web page can be found at: https://www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=4. This Web page contains a link to the docket for this document on the www.regulations.gov site. The www.regulations.gov Web page contains simple instructions on how to access all documents, including public comments, in the docket.

FOR FURTHER INFORMATION CONTACT: Ms. Lucy deButts, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE-2J, 1000 Independence Avenue SW., Washington, DC 20585-0121. Telephone: (202) 287-1604. Email: ApplianceStandardsQuestions@ee.doe.gov.

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I. Introduction

Title III, Part B of the Energy Policy and Conservation Act of 1975 (EPCA or the Act), Public Law 94-163 (42 U.S.C. 6291-6309, as codified) established the Energy Conservation Program for Consumer Products Other Than Automobiles, a program covering most major household appliances (collectively referred to as “covered products”).¹ Subsequent amendments expanded Title III of EPCA to include additional consumer products,

including general service lamps (GSLs)—the products that are the focus of this final rule.

In particular, amendments to EPCA in the Energy Independence and Security Act of 2007 (EISA 2007) directed DOE to engage in rulemakings regarding GSLs. (42 U.S.C. 6295(i)(6)(A)–(B)) EPCA, as amended by EISA 2007, directs DOE to initiate a rulemaking no later than January 1, 2014, to determine whether standards in effect for GSLs should be amended and determine whether exemptions for certain incandescent lamps should be maintained or discontinued. (42 U.S.C. 6295(i)(6)(A)(i)) The scope of the rulemaking is not limited to incandescent lamp technologies. (42 U.S.C. 6295(i)(6)(A)(ii)) Further, for this first cycle of rulemaking, the EISA 2007 amendments provide that DOE must consider a minimum standard of 45 lumens per watt (lm/W). (42 U.S.C. 6295(i)(6)(A)(ii)) If DOE fails to complete a rulemaking in accordance with 42 U.S.C. 6295(i)(6)(A)(i)–(iv) or a final rule from the first rulemaking cycle does not produce savings greater than or equal to the savings from a minimum efficacy standard of 45 lm/W, the statute provides a “backstop” under which DOE must prohibit sales of GSLs that do not meet a minimum 45 lm/W standard beginning on January 1, 2020. (42 U.S.C. 6295(i)(6)(A)(v))

In March 2016, DOE published a notice of proposed rulemaking (NOPR) that proposed a revised definition of GSL and energy conservation standards for certain GSLs (hereafter the “March 2016 GSL ECS NOPR”). 81 FR 14528 (March 17, 2016). In conjunction with the March 2016 GSL ECS NOPR, DOE also published on its Web site the complete technical support document (TSD) for the proposed rule, which described the analyses DOE conducted and included technical documentation for each analysis. The TSD also included the life cycle cost (LCC) spreadsheet, the national impact analysis spreadsheet, and the manufacturer impact analysis (MIA) spreadsheet.²

DOE held a public meeting on April 20, 2016, to hear oral comments on and solicit information relevant to the proposed rule. At this meeting, DOE heard concerns from stakeholders regarding the expansion of scope in the proposed GSL definition and DOE’s approach to analyzing the 22 GSIL exemptions. In addition, DOE received

written comments that reiterated these concerns, and also provided additional data for DOE’s consideration.

Specifically, the National Electrical Manufacturers Association (NEMA) provided new data and information on the 22 exempted lamp types to inform DOE’s evaluation of whether the exemptions should be maintained or discontinued as required by 42 U.S.C. 6295(i)(6)(A)(i)(II).

After the publication of the March 2016 GSL ECS NOPR, DOE analyzed the data submitted by NEMA and collected additional data where available. DOE published a notice of proposed definition and data availability (hereafter the “October 2016 NOPDDA”) to: (1) Propose a revised definition of GSL that included, among other lamp types, IRLs; (2) announce the availability of the NEMA data and supplemental data collected by DOE; (3) request public comment on proposed definitions and compiled data; and (4) request any additional data that stakeholders may have in support of this evaluation. 81 FR 71794 (October 18, 2016). DOE also held a public meeting on October 21, 2016 to hear oral comments and solicit information relevant to the October 2016 NOPDDA.

In a separate final rule being published in the same issue of the **Federal Register**, DOE has adopted a definition of GSL that reflects its discontinuation of certain exemptions and its maintaining of others, and its interpretation and application of certain clauses of the statutory definition of GSL (hereafter the “GSL definition final rule”). In that rule, DOE postponed its decision on the IRL exemption, which it had previously proposed to discontinue. Accordingly, that rule perpetuated the IRL exemption in DOE’s regulatory definition. In this final rule, DOE determines to discontinue the IRL exemption, and it is amending its definition of GSL accordingly.

The following sections of this final rule respond to comments received on the October 2016 NOPDDA and during the NOPDDA public meeting regarding IRLs in more detail.

II. Authority and Rulemaking Process

DOE is required under the EISA 2007 amendments to EPCA to undertake the present rulemaking. Under EPCA, DOE shall initiate a rulemaking to determine whether standards in effect for GSLs should be amended to establish more stringent standards; and determine whether exemptions for certain incandescent lamps should be maintained or discontinued. (42 U.S.C. 6295(i)(6)(A)(i)) In addition to that mandate, DOE has the authority to

¹ Part B was re-designated Part A on codification in the U.S. Code for editorial reasons.

² The spreadsheets developed for this rulemaking proceeding are available at: https://www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=4.

qualify lamps as general service lamps upon determining that they are “used to satisfy lighting applications traditionally served by general service incandescent lamps.” (42 U.S.C. 6291(30)(BB)(i)(IV))

An additional statute relevant to this rulemaking is section 312 of the Consolidated and Further Continuing Appropriations Act, 2016 (Pub. L. 114–113, 129 Stat. 2419; hereafter referred to as the “Appropriations Rider”) that prohibits expenditure of funds appropriated by that law to implement or enforce: (1) 10 CFR 430.32(x), which includes maximum wattage and minimum rated lifetime requirements for GSILs; and (2) standards set forth in section 325(i)(1)(B) of EPCA (42 U.S.C. 6295(i)(1)(B)), which sets minimum lamp efficiency ratings for incandescent reflector lamps (IRLs).³

This final rule constitutes a decision on whether to maintain or discontinue the exemption for IRLs, and include IRLs as GSLs if discontinued. This final rule does not determine whether DOE should impose or amend standards for any category of lamps, such as GSILs or GSLs.

As discussed in more detail, DOE is grounding the decision of whether to maintain or discontinue the IRL exemption on an assessment of whether IRLs would provide a convenient unregulated alternative to lamps that will be subject to energy conservation standards. In DOE’s view, EPCA exempted certain categories of lamps from the definition of GSL because, on the one hand, some lamps in those categories have specialty applications; and on the other hand, it was not clear, when these lamp provisions were enacted, whether those lamps were part of the broader lamp market to which Congress wished to apply energy conservation standards. For certain lamps exempted from regulation as a GSL, EPCA established standards. With regard to IRLs, EPCA imposed efficiency standards ranging from 10.5 to 15 lm/W. (42 U.S.C. 6295(i)(1)(B)). The purpose, then, of the decision that Congress entrusted to DOE, to maintain or to discontinue a given exemption, was that DOE should assess the role of lamps of that type in the broader lighting market, bearing in mind the evident statutory purpose of achieving energy

conservation by imposing efficiency standards for general lighting.

While the statute does not expressly state a criterion by which DOE should decide which exemptions to maintain—it simply identifies one important evidentiary input, sales data—DOE understands its instruction to be that DOE should maintain an exemption if doing so would be consistent with that statutory purpose, and discontinue the exemption if it would not. To carry out that instruction, DOE has assessed whether lamps within the IRL exemption are readily substitutable for lamps that are already categorized as general service lamps. Sales data, as the statute directs, are an important type of evidence informing that assessment.

The discontinuation of the IRL exemption will render the lamps within that exemption GSLs, to the extent they would otherwise qualify as GSLs. As the October 2016 NOPDDA observed, DOE will then either impose standards on these lamps pursuant to its authority to develop GSL standards or apply the backstop standard prohibiting the sale of lamps not meeting a 45 lm/W efficacy standard.

Commenters on the March 2016 GSL ECS NOPR and October 2016 NOPDDA contended that DOE lacked authority to discontinue exemptions in the way it proposed and objected to the procedures DOE had undertaken. DOE discussed those comments in the GSL definition final rule that is being published in the same issue of the **Federal Register**. In many ways, DOE’s interpretations of EPCA relevant to this final rule are similar to those in the GSL definition final rule; and the procedures are comparable in that this final rule proceeds from the same notices that led to the GSL definition final rule. That said, DOE’s decision regarding IRLs is independent from the decisions it made in the GSL definition final rule, and it has considered the comments and issues independently with respect to this rule. After reviewing those comments and issues again, DOE has come to the same conclusions as it did in the GSL definition final rule, for the reasons given in the preamble to that rule. For convenience, DOE does not repeat those discussions here, as the explanations provided in the GSL definition final rule—regarding which exemptions DOE has the authority to discontinue, what factors DOE is considering in a decision whether to discontinue an exemption, and what procedures DOE has followed—are adequate. In this rule, DOE discusses its consideration of comments and issues specifically related to IRLs.

Besides the 22 lamp types listed in section 6291(30)(D)(ii), which the GSL definition final rule addressed, DOE is also interpreting “the exemptions” in section 6291(i)(6)(A)(i)(II) to include the exemption in section 6291(30)(BB)(ii) for incandescent reflector lamps. Clause (i)(II) refers to “the exemptions for certain incandescent lamps”; and the (BB)(ii) carve-out for “incandescent reflector lamps” readily fits that description so long as it can properly be viewed as an “exemption.” In the GSL definition final rule that is being published in the same issue of the **Federal Register**, DOE explained its understanding of what clause (i)(II) means by an “exemption.” DOE adheres to its conclusion in the GSL definition final rule that the 22 lamp types listed in subparagraph (D)(ii) are “exemptions” for these purposes, and the language of the IRL carve-out is the same as that for the 22 types. Therefore, DOE believes it is also an “exemption.”

DOE recognizes that, as a commenter pointed out, IRLs are already subject to standards under EPCA. The GSL definition final rule that is being published in the same issue of the **Federal Register** explained DOE’s view that a lamp subject to some standards under EPCA can still be “exempt” for purposes of the clause (i)(II) rulemaking, because the “exemptions” that DOE is reviewing are exemptions from GSL regulation. DOE adheres to that view in this final rule.

For IRLs, the existing standards are much less stringent than the 45 lm/W backstop standard, and presumably less stringent than any standard that DOE might develop to achieve energy savings comparable to those from the 45 lm/W backstop standard. For example, when EISA 2007 was adopted, the standard for incandescent reflector lamps ranged from 10.5 to 15 lm/W. It seems unlikely that Congress would have considered that standard an adequate alternative to GSL standards. Therefore, DOE considers it consistent with the scheme of subsection (i)(6) that DOE should assess whether to subject to GSL regulation the lamps within the IRL exemption.

Commenters also argued that DOE cannot discontinue the exemption for IRLs because, the commenters observed, the statute exempts these lamps from being GSLs twice. First, “reflector lamps” are one of the 22 types of lamp exempted by section 6291(30)(BB)(ii)(I); and second section 6291(30)(BB)(ii)(II) specifically exempts incandescent reflector lamps. By exempting them twice, the commenters suggest, Congress made quite clear that incandescent

³ This provision of the Consolidated and Further Continuing Appropriations Act, 2016 has been extended to the current appropriations authorization. See, The Continuing Appropriations and Military Construction, Veteran Affairs, and Related Agencies Appropriations Act, 2017 and Zika Response and Preparedness Act, 2017 (Pub. L. 114–223, 130 Stat. 908).

reflector lamps are not to be considered GSLS.

The interpretation that these commenters advance would significantly impair the standards regime established by EISA 2007. That statute's amendments to EPCA imposed standards for general service fluorescent lamps and incandescent reflector lamps, the two categories of lamp that subclause (30)(BB)(ii)(II) exempts from being GSLS. For general service fluorescent lamps, when EISA was enacted the standards ranged from 64 to 80 lm/W, substantially above the backstop that the EISA amendments specify as the default for GSLS. For incandescent reflector lamps, the standards when EISA 2007 was enacted ranged from 10.5 to 15.0 lumens per watt, well below the backstop. Today, incandescent reflector lamps are widely used for general illumination just as GSILs are. If EPCA mandated that IRLs continue being exempt from GSLS, then they would present a convenient alternative product, subject to much less stringent standards than GSLS. The GSL standards (potentially the backstop or standards developed by DOE) would save far less energy if consumers and manufacturers can switch many lighting applications to less-efficient IRLs. That outcome would be especially odd in light of the authority that Congress provided DOE to assess whether to maintain or discontinue exemptions—a decision that, as DOE has explained, DOE believes was meant to focus on which exempted lamps would be substitutes for regulated GSLS. DOE's interpretation, under which paragraph (i)(6) authorizes it to make the same sort of determination with respect to IRLs, is a more consistent and coherent interpretation of the EISA amendments.

Of course, if the statute unambiguously foreclosed that interpretation or indicated that DOE must not discontinue the IRL exemption, that command would trump the policy considerations just discussed. But with respect to IRLs, the statute does permit DOE's interpretation that the IRL exemption is one that DOE can discontinue in a subsection (i)(6)(A)(i)(II) rulemaking. As explained in the paragraphs that follow, through a careful exploration of sections 6291 and 6295, DOE believes the “reflector lamp” exemption in section 6291(30)(D)(ii) is not necessarily as broad as the IRL exemption. DOE believes “reflector lamp” was meant to encompass a different range of lamps, with a scope left to DOE to interpret, while IRL is a defined term with a broad scope. Thus, the “reflector lamp” and IRL exemptions are somewhat different in

nature, and EPCA calls on DOE to decide whether to maintain or discontinue each. DOE addressed the “reflector lamp” exemption, as applied to lamps that are not IRLs, in the GSL definition final rule that is being published in the same issue of the **Federal Register**.

Paragraph (30)(C) defines “incandescent lamp” to “includ[e] only the following”: “[a]ny lamp . . . that is not a reflector lamp” and meets certain criteria, such as a rated wattage between 30 and 199 watts; “[a]ny lamp (commonly referred to as a reflector lamp) which is not colored or designed for rough or vibration services applications, that contains an inner reflective coating on the outer bulb to direct the light,” and meets additional technical criteria like bulb shape; and “[a]ny general service incandescent lamp” rated above 199 watts. DOE notes that paragraph (30)(C) did not define “reflector lamp” to mean a lamp described in the terms just quoted; rather, paragraph (30)(C) noted that such lamps commonly are called reflector lamps. By contrast, paragraph (30)(F) does define the term IRL to mean “a lamp described in subparagraph (C)(ii).” Finally, paragraph (30)(D) defines GSIL, and that definition states that GSILs do not include any of 22 lamp types, one of which is “reflector lamps.”

From this set of definitions, DOE infers that “reflector lamp” does not necessarily mean the same thing as “incandescent reflector lamp.” Had Congress wanted to define “reflector lamp,” it could easily have done so. That it did not suggests that Congress left the term, as used in the list of 22 lamp types, for DOE to elaborate. Furthermore, if “reflector lamp” was meant to be necessarily coextensive with subparagraph (C)(ii), the definition of GSIL contains a curious circular redundancy. The statute defines “incandescent lamp” to include the lamps described in subparagraph (C)(ii); it defines “general service incandescent lamp” to be an incandescent lamp or halogen lamp with certain additional attributes; and then it says general service incandescent lamps do not include “reflector lamp[s].” If that usage of “reflector lamp” necessarily has the same scope as subparagraph (C)(ii), the statute included them in GSILs only to exclude them.

The context further suggests that “reflector lamp,” as used in the list of 22 exempted lamp types, was meant to exempt a scope different from, and in some respects narrower than, paragraph (C)(ii). Each of the other exemptions describes a narrow category of lamp, such as “mine service lamp,” “traffic

signal lamp,” or “vibration service lamp,” that has specialty applications and that Congress could have thought might have few or no general service applications. The statute does not reflect a final judgment on that point; instead it defers the decision for DOE to make in a section 6295(i)(6)(A)(i)(II) rulemaking. Still, the general character of the 22 exemptions is that they are lamp types about which such a judgment—whether the exempted lamps have substantial general service applications—would be necessary in deciding whether to impose general lamp standards. By contrast, subparagraph (C)(ii), which defines IRLs, encompasses a wide range of lamps which certainly had general service applications; and EPCA reflected that reality by imposing efficiency standards (ranging from 10.5 to 15 lm/W) on IRLs since 1995. Public Law 102–486, section 123(f), 106 Stat. 2824.

It bears mention also that EPCA first added “reflector lamps” among the 22 exempted lamp types as a result of EISA amendments in 2007. EISA 2007 section 321 also established the first statutory standards for GSILs. Public Law 110–140, section 321(a)(3), 121 Stat. 1577. While those standards were expressed in terms of a maximum wattage for a given range of lumen output, the minimum efficiency needed to satisfy those standards would be from 17 to 36 lm/W in the wattage range that includes IRLs.⁴ If the “reflector lamp” exemption was necessarily coextensive with IRLs, then the statute imposing the new standard simultaneously created a major loophole by leaving IRLs—a category of lamp that already in 2007 was widely used for general illumination—subject only to the much older and lower efficiency standard effective at the time, which was 10.5 to 15 lm/W. That would be an odd outcome. Had Congress intended to undermine its own standard in that way, it could have done so explicitly by defining “reflector lamp” to have the same scope (with respect to incandescent lamps) as IRL. Instead, in a statute which tweaked subparagraph (C)(ii) and added definitions for various specific lamp types, it left “reflector lamp” undefined.

In light of these observations, DOE understands the definition of “general service lamp” as follows (as concerns reflector lamps and IRLs): Until DOE discontinued the relevant exemptions, no “reflector lamps,” as the term is used in section 6291(30)(D)(ii), were GSILs or

⁴ The EISA section 321 standards imposed a maximum wattage of 29 watts for lamps between 310 and 749 lumens of output. Meanwhile IRLs, according to section 6291(30)(C)(ii), include only lamps above 40 watts.

GSLs. Depending on how DOE interprets the “reflector lamp” exemption, some IRLs may be GSILs (due to not falling in the possibly narrower “reflector lamp” exemption).⁵ However, even those that are GSILs are not GSLs, because the definition of GSLs says they include GSILs but do not include IRLs.

In principle, then, DOE has had two tasks regarding exemptions relevant for reflector lamps. With respect to “reflector lamps,” it was to assess whether that one of the relatively narrow 22 listed lamp types—the scope of which the statute does not make clear—has uses in general illumination, and whether sales data and other evidence indicate that such lamps are ready substitutes for lamps that are already included as GSLs. DOE has finalized this analysis in a separate final rule, the GSL definition final rule. By contrast, as noted previously, the category of IRLs includes lamps that, as of 2007, it was already evident were being used in general lighting applications. However, DOE must still analyze whether, in light of sales data and other evidence, IRLs are an important enough substitute for lamps already included as GSLs to warrant discontinuing their exemption. This analysis is the subject of this final rule and discussed in more detail in the section that follows.

III. Definition of General Service Lamp

A. Incandescent Reflector Lamps

The term general service lamp (GSL) includes general service incandescent lamps (GSILs), compact fluorescent lamps (CFLs), general service light-emitting diode (LED) and organic light-emitting diode (OLED) lamps, and any other lamps that DOE determines are used to satisfy lighting applications traditionally served by GSILs; however, GSLs do not include any lighting application or bulb shape that under 42 U.S.C. 6291(30)(D)(ii) is not included in the “general service incandescent lamp” definition, or any general service fluorescent lamp or incandescent reflector lamp. (42 U.S.C. 6291(30)(BB)) The October 2016 NOPDDA revisited the proposed definition of GSL from the March 2016 GSL ECS NOPR, including the exemptions contained in the GSIL and GSL definitions, and proposed a revised definition of “general service lamp” in § 430.2 to capture various criteria and delineate the lamp types considered to be GSLs. 81 FR 71806–71807. More specifically, DOE proposed

a definition for GSL in the October 2016 NOPDDA. A general service lamp, as proposed, would be a lamp that has an ANSI base, operates at any voltage, has an initial lumen output of greater than or equal to 310 lumens (or 232 lumens for modified spectrum general service incandescent lamps) and less than or equal to 4,000 lumens, is not a light fixture, is not an LED downlight retrofit kit, and is used in general lighting applications. General service lamps include, but are not limited to, general service incandescent lamps, compact fluorescent lamps, general service light-emitting diode lamps, and general service organic light-emitting diode lamps, but do not include general service fluorescent lamps; linear fluorescent lamps of lengths from one to eight feet; circline fluorescent lamps; fluorescent lamps specifically designed for cold temperature applications; impact-resistant fluorescent lamps; reflectorized or aperture fluorescent lamps; fluorescent lamps designed for use in reprographic equipment; fluorescent lamps primarily designed to produce radiation in the ultra-violet region of the spectrum; fluorescent lamps with a color rendering index of 87 or greater; R20 short lamps; specialty MR lamps; appliance lamps; black light lamps; bug lamps; colored lamps; infrared lamps; left-hand thread lamps, marine lamps, marine signal service lamps; mine service lamps; plant light lamps; sign service lamps; silver bowl lamps, showcase lamps, and traffic signal lamps.

In support of its analysis of whether to maintain or discontinue an exemption, in the October 2016 NOPDDA DOE presented estimated sales data. NEMA stated that sales for most of the exempted lamps are declining and that it was the intent of Congress to require that DOE find sales increasing as a prerequisite to discontinue an exemption. (NEMA, No. 83 at p. 34; NEMA No. 93 at p. 12) NEMA pointed to the petition process established under section 321 of EISA 2007 as indicative of that intent. (NEMA, No. 93 at pp. 12–13) NEMA and LEDVANCE noted that Congress required a demonstration of increased sales as a prerequisite for DOE to grant a petition submitted by the public to reconsider an exemption, and that DOE must be guided by the same consideration when determining whether an exemption should be maintained under 42 U.S.C. 6295(i)(6)(A)(i)(II). (NEMA, No. 83 at pp. 33–34; LEDVANCE, No. 90 at pp. 25–27) NEMA and LEDVANCE cited the requirement under 42 U.S.C.

6295(i)(6)(A)(i)(II) for DOE to consider, in part, “exempted lamp sales” collected by DOE as supporting the requirement for increased lamp sales in order to discontinue an exemption. (NEMA, No. 93 at 5; LEDVANCE, No. 90 at p. 26) NEMA and LEDVANCE added that a determination of lamp switching must be driven by data showing increased sales. (NEMA No. 93 at p. 13; LEDVANCE, No. 90 at pp. 25–27) NEMA and LEDVANCE concluded that the October 2016 NOPDDA did not provide data indicating that lamp switching was occurring, and rather data from the Energy Information Administration⁶ shows that sales are decreasing. NEMA and LEDVANCE commented that if DOE was petitioned under section 325(i)(3)(E), it would not grant the petition or decide to regulate these specialty lamps and therefore any other action taken under section 325(i)(6)(A) is illogical. (NEMA, No. 93 at p. 13; LEDVANCE, No. 90 at pp. 25–27)

As DOE has explained in the GSL definition final rule that is being published in the same issue of the **Federal Register**, the petition process from EISA section 321(a)(3) is distinct from the decision that subparagraph (6)(A)(i)(II) calls for about maintaining or discontinuing exemptions. The statute does not require DOE to consider the same factors in the clause (i)(II) decision that it would in reviewing a petition. In particular, it does not restrict DOE to discontinuing an exemption only if sales of lamps within that exemption are increasing. While increases or decreases in lamp sales are an important consideration, DOE believes it can in some circumstances be appropriate to discontinue an exemption even at a time when sales of those lamps are decreasing. As described by GE, LEDVANCE, and Westinghouse, incandescent sales can be decreasing because consumers are purchasing LED versions of the same lamp. Thus, the lamp itself is not unpopular but rather is undergoing a shift in technology. For example, GE stated that sales of IRLs have been declining significantly over the last five years but that was in large part caused by the increasing sales of LED reflector lamps. (GE, No. 83 at pp. 38, 84–85; LEDVANCE, No. 90 at p. 35; Westinghouse, No. 83 at pp. 128–129) Consequently, it can in some circumstances be appropriate to

⁵ DOE has not thus far articulated an interpretation of the “reflector lamp” exemption that would resolve the status of IRLs.

⁶ See Energy Information Administration, Sales of specialty incandescent bulbs decline despite exemption from efficiency standards (April 2, 2013) available at: <http://www.eia.gov/todayinenergy/detail.php?id=10631>.

consider the overall volume of sales in assessing an exemption, even if the volume is currently decreasing.

DOE also considered the potential of lamp switching that may occur in response to any GSL standard. If an exempted lamp has the same utility to lamp users as a lamp subject to a standard as a GSL, DOE considered the potential increase in the use of the exempted lamp in response to a standard. As noted by commenters, prior to the effective date of any new standard the sales trends of exempted lamps do not necessarily capture the potential for lamp switching. As such, current lamp sale trends are only part of the consideration. DOE is permitted to account for future changes in consumer behavior so as to avoid the creation of loopholes.

DOE received several comments regarding whether a lamp could serve as a replacement for a GSL and therefore present a risk of lamp switching. California Investor Owned Utilities (CA IOUs) stated that evaluations of the exemptions should be based on whether the exempted lamp type could serve as a replacement for a general service lamp. (CA IOUs, No. 83 at p. 107) Westinghouse stated that there are low-cost products on the market that consumers do not use as replacements for GSLs because they are not the appropriate shape or design. Avalos noted that a couple of exempted lamp types could be considered GSILs but are not due to their lamp structure. (Westinghouse, No. 83 at p. 30; Avalos, No. 80 at p. 1)

GE and LEDVANCE stated that DOE should consider the traditional omnidirectional incandescent lamp when considering the potential for lamp switching. (GE, No. 83 at pp. 37–38; LEDVANCE No. 83 at p. 59) GE stated that the definition of GSIL (a type of GSL) describes a lamp with a medium

screw base, that produces between 310 and 2,600 lumens, and can operate on a voltage between 110 and 130 V, and that in order for a lamp to be considered as having the potential for “lamp switching” the lamp must maintain these same attributes. (GE, No. 88 at pp. 2–3) Westinghouse stated that consideration of lamp switching should be limited to whether a consumer could use an exempted lamp to replace a lamp that the consumer is currently using, and that consideration of how the use of fixtures may change in response to standards (e.g., changes in fixtures used in new home construction) would be inconsistent with EPCA. (Westinghouse, No. 83 at pp. 39–40)

Other commenters stated that consideration of lamp switching should include the ability of an exempted lamp to provide similar function as a traditional GSIL, regardless of the fixture traditionally used with GSILs. ASAP stated that the presence of directional lamps in residences in the U.S. has grown significantly over time due to changes in new construction. (ASAP, No. 83 at pp. 38–39) ASAP stated that lighting in homes that traditionally was provided by A shape lamps in floor and table fixtures is being provided in newer construction through reflector lamps in recessed can lighting. (ASAP, No. 83 at pp. 58–59)

As noted previously, DOE understands the purpose of the decision that EPCA calls for on maintaining or discontinuing exemptions to be to ensure that consumers and manufacturers do not switch to readily available substitutes once standards for GSLs come into force. In making this assessment, the potential for an exempted lamp to be placed in a fixture that traditionally used a GSIL, and the potential change in the fixtures used to provide lighting in an application that was traditionally served by a GSIL are

important considerations that DOE appropriately takes into account. As noted by commenters, the function traditionally provided by GSILs can, in some instances, be provided by more than one type of fixture. In order to minimize the potential for loopholes, DOE has considered the potential for a consumer to change the type of lamp used in an existing fixture, and the potential change in the type of fixture used to provide the same function as traditionally provided by a fixture using a GSIL.

CA IOUs stated that evaluations of the exemptions should also be based on whether the exempted lamp type can be made as an LED lamp. (That consideration would be relevant because it is almost certain that incandescent lamps will not be able to satisfy the 45 lm/W backstop standard if it comes into force.) (CA IOUs, No. 83 at p. 107) DOE is aware that LED replacements may exist for some of the exempt lamp categories. DOE did consider the existence or absence of LED replacements for IRLs, though not as the only reason to discontinue or maintain an exemption.

NEMA provided updated sales information for this final rule. NEMA provided sales data from four members, which represents a significant portion of the market, for each of the exemptions that DOE proposed to discontinue. NEMA stated that although not all members are included, it conferred with other members that did not provide data to confirm the general trend of decreasing sales and shipments of specialty incandescent lamps since standards went into effect for GSILs between 2010 and 2012. (NEMA, No. 93 at pp. 9–10) DOE has updated Table III.1 to reflect this new data.

Table III.1 summarizes the IRL exemption discontinued in this final rule.

TABLE III.1—DETERMINATION REGARDING IRLS

[Units annual sales]

| GSL exempt lamp category | Estimated sales data | DOE's determination on exemption status |
|--------------------------|---------------------------------|---|
| IRLs | Approximately 270 million | Discontinue exemption. |

DOE believes that discontinuing the exemption for IRLs could lead to significant energy savings. As shown in Table III.1, IRLs have annual sales that are several times the sales of the largest-volume lamp category among those exemptions that DOE has already discontinued. See the GSL definition final rule for more information that is

being published in the same issue of the **Federal Register**.

In the October 2016 NOPDDA, DOE assessed data available for IRLs and preliminarily concluded that these lamps have high annual sales. Specifically, DOE estimated that the sales of IRLs are approximately 270 million units per year. DOE believed

IRLs are capable of providing overall illumination and could be used as a replacement for GSILs. Therefore, DOE found there was also high potential for lamp switching and subsequently creating a loophole. For these reasons, DOE proposed to discontinue the exemption for IRLs in the October 2016 NOPDDA. *Id.* at 71800.

As noted at the outset of this document, this final rule amending the definition of GSL does not establish standards for GSLs. Inclusion of IRLs in the definition of GSL does not amend the standards currently applicable to IRLs. EPCA directs DOE to consider whether to amend the standards for GSLs, and whether the definition of GSL should be amended. (42 U.S.C. 6295(i)(6)(A)(i)(II)) In order to evaluate any potential standards or amendments to standards for GSL, DOE must first determine the scope of the GSL definition. As explained previously, DOE has considered lamp sales and the potential for lamp switching in an effort to ensure all lamps that can be used in general lighting applications are included.

Of course, DOE makes this decision cognizant of the fact that IRLs are already subject to minimum efficiency standards. However, DOE does not believe section 6295(i)(6) reveals an intention that, because of those standards, DOE should maintain the IRL exemption from being regulated as GSLs. The IRL standards in the statute dating from 1992—which were the extant standards when EISA added subsection (i)(6)—are substantially less stringent than the standards that EISA section 321 specified for GSILs and even further less stringent than the GSL backstop. Given that some IRLs have long been used for general illumination, as discussed previously, it would be odd for Congress to have left open, unalterably, such a large loophole to its own standards. Rather, DOE believes that in enacting EISA 2007, Congress chose not to update the statutory standards for IRLs because instead it was directing DOE to decide whether to regulate those lamps as GSLs. Thus, the fact that IRLs are already subject to IRL-specific standards does not preclude DOE's decision in this final rule. It simply means that, consistent with EPCA, DOE is to perform a particular assessment for IRLs bearing in mind the existing standards. DOE has carried out that assessment.

DOE received several comments in support of its decision to expand the scope of the GSL definition to include IRLs. ASAP commented that they strongly supported covering IRLs in the scope of this rulemaking noting that hundreds of millions of IRLs are sold each year. ASAP stated that IRLs of all technology types are a growing presence in homes. ASAP noted that there are more efficient alternatives widely available at affordable prices, and including IRLs as GSLs is a step towards technological neutrality which will benefit the environment, industry and

consumers. ASAP added that the fact IRLs are regulated under their own standards does not preclude them from inclusion as GSLs. (ASAP, No. 83 at pp. 38–39; ASAP, No. 94 at pp. 1–2) NRDC and Utility Coalition supported DOE's proposal to include IRLs as GSLs. NRDC stated this was indicative of a shift to a technology-based approach which has been discussed at DOE for many years. NRDC and Utility Coalition added that including IRLs as GSLs will deliver significant energy and consumer savings when considering DOE's estimate of 270 million IRLs sold per year. (NRDC, No. 83 at p. 11; NRDC, No. 85 at p. 2; Utility Coalition, No. 95 at pp. 1–2) Soraa also supported DOE's proposal to include IRLs as GSLs noting that reflector lamps are used or can be used to provide overall illumination. (Soraa, No. 87 at p. 2)

CEC supported DOE's proposal to discontinue the exemption for reflector lamps due in part to their high lamp sales and potential for lamp switching. CEC agreed with DOE's estimate of the annual sales of IRLs of approximately 270 million units, noting that California's existing stock of medium screw base incandescent and halogen reflector lamps is estimated to be more than 60 million units with annual shipments in 2016 estimated at nearly 35 million units. CEC added that although LED reflector lamps are gaining market share from IRLs, CEC's recent general service LED lamps rulemaking determined that incandescent technology would represent the vast majority of medium screw base directional lamp shipments in 2029 if the IRL exemption were maintained. (CEC, No. 91 at pp. 4–5)

In contrast, GE recommended that reflector lamps (in GE's comment, primarily IRLs) continue to be regulated separately and that it is not appropriate to evaluate reflector type lamps as GSLs because these products cannot successfully be used to satisfy lighting applications traditionally served by GSILs. (GE, No. 88 at p. 2) GE added that each reflector lamp has unique optical properties that must be considered when applying a minimum efficacy requirement and noted that these products cannot meet the same efficiency limits designed for general service A shape lamps. (GE, No. 88 at p. 2) Westinghouse stated that while there is energy savings potential in regulating IRLs, it should be done in an IRL standards rulemaking rather than in a GSL standards rulemaking. (Westinghouse, No. 83 at pp. 21–22) Westinghouse stated it is not suggesting that LED versions for R20, BR30, and R40 shapes used in the residential

sector for general purposes are not suitable replacements. However, Westinghouse asserted that to ensure that efficiencies are achievable for this shape and due consideration is given to economic feasibility, IRLs should be considered in their own rulemaking. (Westinghouse, No. 83 at pp. 47–48; Westinghouse, No. 83 at pp. 55–56)

In support of their assertion that reflector lamps should be regulated separately, several commenters disagreed with DOE's determination that reflector lamps posed a risk of lamp switching. GE stated that while a large number of IRLs are still in use, sales have declined significantly over the past 5 years, in large part, due to a shift to LED reflector lamps. Further GE stated that reflector lamps would not fit in most fixtures in which GSILs are used. Even if a reflector lamp could fit in such a fixture it could not deliver the omnidirectional light output provided by the GSIL. Therefore, GE asserted reflector lamps would not be suitable replacements for the standard GSILs and needed to be evaluated in their own rulemaking. (GE, No. 83 at pp. 37–38) LEDVANCE agreed and stated that the consumer will not obtain effective light by putting a reflector lamp such as a PAR30 in a fixture that does not have some type of directional functionality. (LEDVANCE, No. 83 at pp. 59–61)

CA IOUs stated that while it may not be always be optimal, reflector lamps can be used in general service applications. (CA IOUs, No. 83 at p. 66) NRDC stated that reflector lamps can be used in applications other than down lights. NRDC pointed out that reflector lamps come in various shapes and there was nothing to prevent a manufacturer from altering the reflector lamp design so more light goes in different directions. (NRDC, No. 83 at p. 45) CA IOUs further noted that as the cheaper product, the use of IRLs in general service applications may increase due to new market pressures in 2020. (CA IOUs, No. 83 at p. 66) CEC agreed that medium screw base reflector lamps represent a lamp switching risk adding that lamp shape does not determine whether a lamp can provide general service lighting and general service lamps are not limited to omnidirectional lighting. (CEC, No. 91 at pp. 4–5) Utility Coalition also stated that LED lamps are suitable replacements for GSLs in many applications because they have the same base types and therefore represent a significant risk of undercutting the energy savings of the 45 lm/W standard if they are not included. (Utility Coalition, No. 95 at pp. 1–2)

Additionally, Utility Coalition commented that there are LED versions

of reflector lamps available in a wide variety of shapes and sizes, lumen outputs, CCT, beam angles, and base types and that decreasing prices and increasing efficiency make these products cost-effective to consumers. NRDC also noted that there are several cost-effective, dimmable LED lamps available that serve as excellent replacements for IRLs in a variety of form factors, light outputs, and colors and urged DOE to move forward with its proposal to remove the exemption for these lamps. (NRDC, No. 83 at pp. 45–46; Utility Coalition, No. 95 at pp. 1–2) CEC stated that as of June 15, 2015, 658 models of medium screw base reflector lamps complied with Tier 1 of the adopted California standard thus indicating that cost effective, highly-efficient LED alternatives exist. CEC added that making incremental improvements to existing LED reflector lamps was extremely cost-effective and technically feasible. (CEC, No. 91 at pp. 4–5) Soraa also stated that LED replacements that provide a wide variety of product features, such as color rendering index (CRI), CCT, beam angle, whiteness rendering, and low flicker, are available for the majority of existing IRLs. Soraa noted that customers in quality-sensitive fields such as high-end retail and hospitality have transitioned from halogen to LED technology. Soraa added while there are still some lamp types that are difficult to replicate in LED technology, incremental progress in technology will likely make these products available by 2020. Additionally, Soraa stated that the limit of 45 lm/W can be met by currently-existing products with higher-level features. (Soraa, No. 87 at p. 2)

As discussed previously in this document, DOE did not limit its consideration of lamp switching to the ability to replace a lamp in a fixture currently used by a consumer that had been using a traditional incandescent lamp. As indicated by comments from ASAP previously in this document, the presence of reflector lamps in residences in the U.S. has grown significantly over time due to changes in new construction. (ASAP, No. 83 at pp. 38–39) Lighting in homes that traditionally was provided by A shape lamps in floor and table fixtures is being provided in newer construction through reflector lamps in recessed lighting. (ASAP, No. 83 at pp. 58–59)

The basic design characteristic of an “incandescent reflector lamp,” as EPCA defines the term, is that it directs the light. But it is possible to direct the omnidirectional light from an incandescent filament into a somewhat more limited set of angles and still have

a lamp that provides general illumination. The reflector lamps now being widely used in recessed can lighting are an important example. In such an application (with the lamp mounted in the ceiling), the reflector redirects light that was initially emitted upward. But the resulting light distribution spreads broadly over the area downward from the lamp, so that a consumer can readily use the lamp to provide general illumination for a room. In light of these observations, DOE concludes that “omnidirectional illumination” is not a prerequisite for the traditional functions of incandescent lamps, as GE suggested. Rather, DOE may consider a lamp a ready substitute for GSLs—for purposes of assessing an exemption—if the lamp can provide the same sort of general illumination that GSLs provide.

As presented in Table III.1, DOE estimates that the sales of incandescent reflector lamps are approximately 270 million units per year. 81 FR 71794, 71800. DOE notes that incandescent reflector lamps have higher annual sales than any of the 22 exempt lamp types, thus indicating that these lamps are likely used in general lighting applications. In addition, because IRLs are capable of providing overall illumination and could be used as replacements for GSILs, there is also high potential for lamp switching. For these reasons, DOE is discontinuing the exemption from the GSL definition for IRLs.

LEDVANCE noted that in January 2015, DOE said it found new standards for IRLs not economically justified. 80 FR 4042, 4043 (Jan. 26, 2015). (LEDVANCE, No. 90 at pp. 6–7) NEMA asserted that inclusion of IRLs in the definition of GSL given DOE’s previous determination that standards for IRLs would not be economically justified or technically feasible can only be understood as an attempt by DOE to eliminate the product from the market, an outcome prohibited under EPCA. (NEMA, No. 93 at p. 14)

DOE acknowledges that a recent rulemaking was completed for IRLs. DOE completed a final rule in January 2015 that concluded that amended energy conservation standards for IRLs (other than ER30, BR30, BR40, and ER40 lamps of 50 W or less; BR30, BR40, and ER40 lamps of 65 W; and R20 lamps of 45 W or less) would not be economically justified. 80 FR 4042 (January 26, 2015). DOE notes that there are established test procedures for IRLs. See, Appendix R to 49 CFR 430 subpart B. While the recent IRL rulemaking considered energy conservation standards for a limited segment of IRLs,

this rule defines what is and is not a general service lamp. As such, DOE is addressing a fundamentally different question. The purpose of this rulemaking is not to establish energy conservation standards, but to determine whether certain lamps because of functional and design characteristics should be included in the definition of general service lamp.

DOE has determined that lamps of different shapes, even those that are not omnidirectional, can provide overall illumination. Therefore, even though reflector lamps are designed to direct the light they provide, DOE has concluded that they should be included as general service lamps. DOE’s previous conclusion regarding energy conservation standards for a subset of IRLs (less than half of the IRL market) has no bearing on their ability to be a general service lamp, assuming they meet the other criteria in the adopted definition.

Further, DOE notes that the conclusion reached in the previous rulemaking was based on an analysis of incandescent technology. The January 2015 IRL rulemaking concluded that an amended standard based on more efficient incandescent technology would not be economically justified. An analysis conducted under the general service lamps authority could well come to a different conclusion because more efficient replacements could use incandescent, fluorescent, or LED technology. Thus, the cost-benefit analysis would be different and the cost-benefit analysis from the January 2015 rulemaking is not applicable here.

DOE notes that incandescent reflector lamps have high annual sales, indicating that they are likely used in general lighting applications. Further, as noted by several commenters, IRLs that are currently exempt from standards have ballooned in sales and have gone from representing a minority of the market to a majority of the market. Thus, industry has shown that consumers of IRLs find various distributions of light acceptable in their applications because the ER- and BR-shaped lamps that increased in sales have broader distributions of light than the PAR-shaped lamps they replaced.

DOE also received comments regarding the impacts on manufacturers of including IRLs in the definition of GSL. NEMA noted that in response to the March 2016 ECS NOPR, it had commented that in 2020 manufacturers would have to supply the entire nation with general service LED lamps as incandescent lamps would not be available. NEMA had explained in its comment that this would mean a 300

percent increase in the steady state demand and require tripling capacity for only that year. NEMA stated that the proposed definitions in the October 2016 NOPDDA increased the scope of GSLs to a wider range of specialty products than what was proposed in the March 2016 GSL ECS NOPR. Hence the projected spike in demand in 2020 would now be even higher. Therefore, NEMA encouraged DOE to either not impose regulations or postpone them for a few years on niche products. (NEMA, No. 83 at pp. 157–158) LEDVANCE requested clarification on whether an employment impact analysis was conducted for IRLs given that DOE's proposal to remove the exemption for IRLs could have an impact on domestic manufacturing. (LEDVANCE, No. 83 at pp. 59–61)

DOE acknowledges that manufacturers may face a difficult transition if required to comply with a 45 lm/W standard, particularly for IRLs. Regarding concerns that the application of the backstop standard would eliminate domestic manufacturing of IRLs, DOE determined that manufacturers are already planning to close or move out of the country several domestic production facilities related to the manufacturing of IRLs due to reduced demand. In press releases regarding these closures, manufacturers noted that the market is moving away from traditional technologies, such as IRLs and other incandescent lamps, and transitioning to LED technology.⁷

DOE is committed to working with manufacturers to ensure a successful transition if the backstop standard goes into effect.⁸ DOE will continue to have an active dialogue with industry, including meetings and other stakeholder outreach, throughout the period between publication of this rule and the compliance date of any backstop standard for general service lamps, including IRLs. During this period, DOE will keep stakeholders and

the public apprised of its plans for any broad exercise of enforcement discretion with respect to the standard.

B. Summary and Regulatory Text Definition

DOE is amending the definition of “general service lamp” in § 430.2 to include IRLs. A general service lamp is a lamp that has an ANSI base; is able to operate at a voltage of 12 volts or 24 volts, at or between 100 to 130 volts, at or between 220 to 240 volts, or of 277 volts for integrated lamps (as defined in this section), or is able to operate at any voltage for non-integrated lamps (as defined in this section); has an initial lumen output of greater than or equal to 310 lumens (or 232 lumens for modified spectrum general service incandescent lamps) and less than or equal to 3,300 lumens; is not a light fixture; is not an LED downlight retrofit kit; and is used in general lighting applications. General service lamps include, but are not limited to, general service incandescent lamps, compact fluorescent lamps, general service light-emitting diode lamps, and general service organic light-emitting diode lamps. General service lamps do not include:

- Appliance lamps;
- Black light lamps;
- Bug lamps;
- Colored lamps;
- G shape lamps with a diameter of 5 inches or more as defined in ANSI C79.1–2002;
- General service fluorescent lamps;
- High intensity discharge lamps;
- Infrared lamps;
- J, JC, JCD, JCS, JCV, JCX, JD, JS, and JT shape lamps that do not have Edison screw bases;
- Lamps that have a wedge base or prefocus base;
- Left-hand thread lamps;
- Marine lamps;
- Marine signal service lamps;
- Mine service lamps;
- MR shape lamps that have a first number symbol equal to 16 (diameter equal to 2 inches) as defined in ANSI C79.1–2002, operate at 12 volts, and have a lumen output greater than or equal to 800;
- Other fluorescent lamps;
- Plant light lamps;
- R20 short lamps;
- Reflector lamps (as defined in this section) that have a first number symbol less than 16 (diameter less than 2 inches) as defined in ANSI C79.1–2002 and that do not have E26/E24, E26d, E26/50x39, E26/53x39, E29/28, E29/53x39, E39, E39d, EP39, or EX39 bases;
- S shape or G shape lamps that have a first number symbol less than or equal to 12.5 (diameter less than or equal to

1.5625 inches) as defined in ANSI C79.1–2002;

- Sign service lamps;
- Silver bowl lamps;
- Showcase lamps;
- Specialty MR lamps;
- T shape lamps that have a first number symbol less than or equal to 8 (diameter less than or equal to 1 inch) as defined in ANSI C79.1–2002, nominal overall length less than 12 inches, and that are not compact fluorescent lamps (as defined in this section);
- Traffic signal lamps.

IV. Effective Date

For the changes described in this final rule, DOE is adopting a January 1, 2020 effective date.

V. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866 and 13563

This final rule neither implements nor seeks to enforce any standard. Rather, this final rule merely defines what constitutes a GSL. Lamps that are GSLs will become subject to either a standard developed by DOE or to a 45 lm/W backstop standard, but this rule does not determine what standard will be applicable to lamps that are being newly included as GSLs. Accordingly, this action does not constitute a significant regulatory action under Executive Orders 12866 and 13563.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires that when an agency promulgates a final rule under 5 U.S.C. 553, after being required by that section or any other law to publish a general NOPR, the agency shall prepare a final regulatory flexibility analysis (FRFA), unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, “Proper Consideration of Small Entities in Agency Rulemaking,” 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel’s Web site (<http://energy.gov/gc/office-general-counsel>).

DOE reviewed the definition of GSL amended in this final rule under the provisions of the Regulatory Flexibility

⁷ See press releases from OSI and GE regarding domestic manufacturing closures available in the docket at: <https://www.regulations.gov/#!docketDetail;D=EERE-2013-BT-STD-0051>.

⁸ In that vein, DOE also notes NEMA’s comment that because the backstop requires DOE to “prohibit sales,” it could present a substantial practical difficulty regarding compliance. For most products, NEMA states, after a standard comes into effect distributors can continue to sell inventory still on hand that complied with the previous standard. If, by contrast, distributors cannot sell old lamp inventory after January 1, 2020, that inventory will be stranded. Although it is premature for DOE to explain in detail how the backstop would work if it comes into force, DOE notes that under subsection (i)(2), “it shall not be unlawful for a manufacturer to sell a lamp which is in compliance with the law at the time such lamp was manufactured.” DOE expects it would interpret and apply the backstop with subsection (i)(2) in mind.

Act and the procedures and policies published on February 19, 2003. DOE certifies that this final rule does not have a significant economic impact on a substantial number of small entities. The factual basis for this certification is set forth in the following paragraphs.

For manufacturers of IRLs, the SBA has set a size threshold, which defines those entities classified as “small businesses” for the purposes of the statute. DOE used the SBA’s small business size standards to determine whether any small entities would be subject to the requirements of the rule. (See 13 CFR part 121.) The size standards are listed by NAICS code and industry description and are available at http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf. Manufacturing of GSLs is classified under NAICS 335110, “Electric Lamp Bulb and Part Manufacturing.” The SBA sets a threshold of 1,250 employees or less for an entity to be considered as a small business for this category.

To estimate the number of companies that could be small businesses that manufacture IRLs covered by this rulemaking, DOE conducted a market survey using publicly available information. DOE’s research involved information provided by trade associations (e.g., NEMA⁹) and information from DOE’s CCMS Database,¹⁰ previous rulemakings, individual company Web sites, SBA’s database, and market research tools (e.g., Hoover’s reports¹¹). DOE used information from these sources to create a list of companies that potentially manufacture or sell IRLs and would be impacted by this rulemaking. DOE screened out companies that do not offer products covered by this rulemaking, do not meet the definition of a “small business,” or are completely foreign owned and operated. DOE determined that there are no small businesses that maintain domestic production facilities for IRLs.

DOE notes that this final rule merely includes IRLs in the regulatory definition of GSLs. Manufacturers of GSLs, including IRLs, are required to use DOE’s test procedures to make representations and certify compliance

with standards, if required. The effective date allows reasonable time for manufacturers to transition, while reducing the number of redesigns needed, should manufacturers need to comply with a 45 lm/W statutory standard beginning on January 1, 2020. For these reasons, DOE concludes and certifies that the new amended definition of GSL, which includes IRLs, does not have a significant economic impact on a substantial number of small entities, and the preparation of an FRFA is not warranted.

C. Review Under the Paperwork Reduction Act

Manufacturers of GSLs must certify to DOE that their products comply with any applicable energy conservation standards. In certifying compliance, manufacturers must test their products according to DOE test procedures for GSLs, including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment. 76 FR 12422 (March 7, 2011). The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement has been approved by OMB under OMB control number 1910–1400. DOE requested OMB approval of an extension of this information collection for three years, specifically including the collection of information adopted in the present rulemaking, and estimated that the annual number of burden hours under this extension is 30 hours per company. In response to DOE’s request, OMB approved DOE’s information collection requirements covered under OMB control number 1910–1400 through November 30, 2017. 80 FR 5099 (January 30, 2015).

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

D. Review Under the National Environmental Policy Act of 1969

Pursuant to the National Environmental Policy Act (NEPA) of 1969, DOE has determined that the rule fits within the category of actions included in Categorical Exclusion (CX) B5.1 and otherwise meets the requirements for application of a CX. (See 10 CFR part 1021, App. B, B5.1(b);

1021.410(b) and App. B, B(1)–(5).) The rule fits within this category of actions because it is a rulemaking that changes the definition of a covered class of products for which there are existing energy conservation standards, and for which none of the exceptions identified in CX B5.1(b) apply. Therefore, DOE has made a CX determination for this rulemaking, and DOE does not need to prepare an Environmental Assessment or Environmental Impact Statement for this rule. DOE’s CX determination for this rule is available at <http://energy.gov/nepa/categorical-exclusion-cx-determinations-cx>.

E. Review Under Executive Order 13132

Executive Order 13132, “Federalism,” 64 FR 43255 (August 10, 1999), imposes certain requirements on federal agencies formulating and implementing policies or regulations that preempt state law or that have Federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the states and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by state and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this rule and has determined that it would not have a substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes federal preemption of state regulations as to energy conservation for the products that are the subject of this final rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297) Therefore, no further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, “Civil Justice Reform,” imposes on federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; (3)

⁹ National Electric Manufacturers Association | Member Products | Lighting Systems | Related Manufacturers, <http://www.nema.org/Products/Pages/Lighting-Systems.aspx> (last accessed November 21, 2016).

¹⁰ DOE’s Compliance Certification Database | Lamps—Bare or Covered (No Reflector) Medium Base Compact Fluorescent, <http://www.regulations.doe.gov/certification-data> (last accessed November 21, 2016).

¹¹ Hoovers | Company Information | Industry Information | Lists, <http://www.hoovers.com> (last accessed November 21, 2016).

provide a clear legal standard for affected conduct rather than a general standard; and (4) promote simplification and burden reduction. 61 FR 4729 (Feb. 7, 1996). Regarding the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each federal agency to assess the effects of federal regulatory actions on state, local, and tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a regulatory action likely to result in a rule that includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a federal agency to develop an effective process to permit timely input by elected officers of state, local, and tribal governments on a proposed “significant intergovernmental mandate,” and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE’s policy

statement is also available at http://energy.gov/sites/prod/files/gcprod/documents/umra_97.pdf.

DOE examined this final rule according to UMRA and its statement of policy and determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of \$100 million or more in any year, so these requirements do not apply.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

Pursuant to Executive Order 12630, “Governmental Actions and Interference with Constitutionally Protected Property Rights,” 53 FR 8859 (March 15, 1988), DOE has determined that this rule would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for federal agencies to review most disseminations of information to the public under information quality guidelines established by each agency pursuant to general guidelines issued by OMB. OMB’s guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE’s guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,” 66 FR 28355 (May 22, 2001), requires federal agencies to prepare and submit to OIRA at OMB, a Statement of Energy Effects for any significant energy action. A “significant energy action” is defined as any action

by an agency that promulgates or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

This regulatory action to amend a definition for GSL is not a significant regulatory action under Executive Order 12866. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

L. Review Under Section 32 of the Federal Energy Administration Act of 1974

Under section 301 of the Department of Energy Organization Act (Pub. L. 95–91; 42 U.S.C. 7101), DOE must comply with section 32 of the Federal Energy Administration Act of 1974, as amended by the Federal Energy Administration Authorization Act of 1977. (15 U.S.C. 788; FEAA) Section 32 essentially provides in relevant part that, where a rule authorizes or requires use of commercial standards, the NOPR must inform the public of the use and background of such standards. In addition, section 32(c) requires DOE to consult with the Attorney General and the Chairman of the Federal Trade Commission (FTC) concerning the impact of the commercial or industry standards on competition. DOE has not incorporated by reference any industry standards in this rulemaking that were not already incorporated and therefore there is no impact on competition.

M. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this rule prior to its effective date. The report will state that it has been determined that the rule is not a “major rule” as defined by 5 U.S.C. 804(2).

VI. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this final rule.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by reference, Intergovernmental relations, Small businesses.

Issued in Washington, DC, on December 29, 2016.

David Nemptow,

Acting Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

For the reasons set forth in the preamble, the final rule for part 430 of chapter II, subchapter D, of title 10 of the Code of Federal Regulations effective beginning January 1, 2020, is amended as set forth below:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. In § 430.2, the definition for general service lamp is amended by removing paragraph (27).

[FR Doc. 2016–32012 Filed 1–18–17; 8:45 am]

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Part XI

Department of Labor

Employee Benefits Security Administration

29 CFR Part 2550

Proposed Best Interest Contract Exemption for Insurance Intermediaries;
Proposed Rule

DEPARTMENT OF LABOR**Employee Benefits Security Administration****29 CFR Part 2550**

[Application No. D-11926]

ZRIN 1210-ZA26**Proposed Best Interest Contract Exemption for Insurance Intermediaries**

AGENCY: Employee Benefits Security Administration, U.S. Department of Labor.

ACTION: Notification of Proposed Class exemption.

SUMMARY: This document contains a notice of pendency before the Department of Labor of a proposed class exemption from certain prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974, as amended (ERISA), and the Internal Revenue Code of 1986, as amended (the Code). The provisions at issue generally prohibit fiduciaries with respect to employee benefit plans and individual retirement accounts (IRAs) from engaging in self-dealing and receiving compensation from third parties in connection with transactions involving the plans and IRAs. The exemption proposed in this document, if granted, would allow certain insurance intermediaries, and the insurance agents and insurance companies they contract with, to receive compensation in connection with fixed annuity transactions that may otherwise give rise to prohibited transactions as a result of the provision of investment advice to plan participants and beneficiaries, IRA owners and certain plan fiduciaries (including small plan sponsors). The proposed exemption includes protective conditions to safeguard the interests of the plans, participants and beneficiaries and IRA owners and is similar to the Department's Best Interest Contract Exemption (PTE 2016-01) granted on April 8, 2016, at 81 FR 21002, as corrected at 81 FR 44773 (July 11, 2016).

DATES: *Comments:* Written comments and requests for a public hearing on the proposed exemption must be submitted to the Department within 30 days from the date of publication of this **Federal Register** document. *Applicability:* The Department proposes to make this exemption available on April 10, 2017. Transition relief is proposed for the period from April 10, 2017, through August 15, 2018; see "Transition Relief," below.

ADDRESSES: All written comments and requests for a hearing concerning the proposed class exemption should be sent to the Office of Exemption Determinations by any of the following methods, identified by ZRIN 1210-ZA26:

Federal eRulemaking Portal: <http://www.regulations.gov> at Docket ID number: EBSA-2016-0026. Follow the instructions for submitting comments.

Email to: e-OED@dol.gov.

Fax to: (202) 693-8474.

Mail: Office of Exemption

Determinations, Employee Benefits Security Administration, (Attention: D-11926), U.S. Department of Labor, 200 Constitution Avenue NW., Suite 400, Washington, DC 20210.

Hand Delivery/Courier: Office of Exemption Determinations, Employee Benefits Security Administration, (Attention: D-11926), U.S. Department of Labor, 122 C St. NW., Suite 400, Washington, DC 20001.

Instructions: All comments and requests for a hearing must be received by the end of the comment period. Requests for a hearing must state the issues to be addressed and include a general description of the evidence to be presented at the hearing. The comments and hearing requests will be available for public inspection in the Public Disclosure Room of the Employee Benefits Security Administration, U.S. Department of Labor, Room N-1513, 200 Constitution Avenue NW., Washington, DC 20210. Comments and hearing requests will also be available online at www.regulations.gov, at Docket ID number: EBSA-2016-0026 and www.dol.gov/ebsa, at no charge.

Warning: All comments and hearing requests will be made available to the public. Do not include any personally identifiable information (such as Social Security number, name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments and hearing requests may be posted on the Internet and can be retrieved by most Internet search engines.

FOR FURTHER INFORMATION CONTACT:

Brian Shiker or Erin Hesse, telephone (202) 693-8540, Office of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department is proposing this class exemption on its own motion pursuant to ERISA section 408(a) and Code section 4975(c)(2), and in accordance with procedures set forth in 29 CFR part

2570, subpart B (76 FR 66637, 66644, October 27, 2011). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978, 5 U.S.C. App. 1 (1996), transferred the authority of the Secretary of the Treasury to issue exemptions of the type proposed by the Secretary of Labor.

Executive Summary**Purpose of Regulatory Action**

The Department is proposing this exemption in connection with its regulation under ERISA section 3(21)(A)(ii) and Code section 4975(e)(3)(B) (Regulation), published in the **Federal Register** on April 8, 2016, and effective on April 10, 2017.¹ The Regulation defines who is a "fiduciary" of an employee benefit plan under ERISA as a result of giving investment advice to a plan or its participants or beneficiaries. The Regulation also applies to the definition of a "fiduciary" of a plan (including an IRA) under the Code. The Regulation amended a prior regulation, dating to 1975, specifying when a person is a "fiduciary" under ERISA and the Code by reason of the provision of investment advice for a fee or other compensation regarding assets of a plan or IRA. The Regulation takes into account the advent of 401(k) plans and IRAs, the dramatic increase in rollovers, and other developments that have transformed the retirement plan landscape and the associated investment market over the four decades since the 1975 regulation was issued. In light of the extensive changes in retirement investment practices and relationships, the Regulation updates existing rules to distinguish more appropriately between the sorts of advice relationships that should be treated as fiduciary in nature and those that should not.

In conjunction with the Regulation, the Department granted Prohibited Transaction Exemption (PTE) 2016-01 (the Best Interest Contract Exemption), also on April 8, 2016, and corrected on July 11, 2016. The Best Interest Contract Exemption is designed to promote the provision of investment advice that is in the best interest of retail investors such as plan participants and beneficiaries, IRA owners, and certain plan fiduciaries, including small plan sponsors (Retirement Investors). ERISA and the Code generally prohibit fiduciaries from receiving payments from third parties and from acting on conflicts of interest, including using their authority to affect or increase their

¹ See Definition of the Term "Fiduciary"; Conflict of Interest Rule—Retirement Investment Advice, 81 FR 20946.

own compensation, in connection with transactions involving a plan or IRA. Certain types of fees and compensation common in the retail market, such as brokerage or insurance commissions, 12b–1 fees and revenue sharing payments, may fall within these prohibitions when received by fiduciaries as a result of transactions involving advice to the plan, plan participants and beneficiaries, and IRA owners.

To facilitate continued provision of advice to Retirement Investors under conditions designed to safeguard the interests of these investors, the Best Interest Contract Exemption allows certain investment advice fiduciaries (Financial Institutions and Advisers) to receive various forms of compensation that, in the absence of an exemption, would not be permitted under ERISA and the Code. “Financial Institutions,” defined in the exemption to include banks, investment advisers registered under the Investment Advisers Act of 1940 or state law, broker-dealers, and insurance companies, and individual “Advisers” must adhere to basic standards of impartial conduct (Impartial Conduct Standards), namely, giving prudent advice that is in the customer’s best interest, avoiding misleading statements, and receiving no more than reasonable compensation. Additionally, Financial Institutions must exercise supervisory authority over Advisers by adopting anti-conflict policies and procedures and insulating the Advisers from incentives to violate the exemption’s Impartial Conduct Standards.

The class exemption proposed in this document would provide relief that is similar to the Best Interest Contract Exemption for certain insurance intermediaries that commit to act as Financial Institutions. Insurance intermediaries typically recruit, train and support independent insurance agents and market and distribute insurance products such as traditional fixed rate annuities and fixed indexed annuities. The intermediaries include organizations commonly referred to as independent marketing organizations (IMOs), field marketing organizations (FMOs) and brokerage general agencies (BGAs). The exemption would apply to recommendations of “Fixed Annuity Contracts,” which are generally defined as fixed rate annuities and fixed indexed annuities. If the conditions of the exemption are satisfied, insurance intermediaries that satisfy the definition of “Financial Institution,” as well as the insurance agents and insurance companies that they contract with, would be permitted to receive

compensation and other consideration as a result of the provision of investment advice to Retirement Investors in connection with transactions involving these annuities.

ERISA section 408(a) specifically authorizes the Secretary of Labor to grant administrative exemptions from ERISA’s prohibited transaction provisions.² Regulations at 29 CFR 2570.30 to 2570.52 describe the procedures for applying for an administrative exemption. Before granting an exemption, the Department must find that the exemption is administratively feasible, in the interests of plans and their participants and beneficiaries and IRA owners, and protective of the rights of participants and beneficiaries of plans and IRA owners. Interested parties are permitted to submit comments to the Department through February 21, 2017.

Summary of the Major Provisions

The proposed exemption would be available for insurance intermediaries satisfying the definition of “Financial Institution,” and insurance agents (Advisers) and insurance companies with whom they contract, as well as their affiliates and related entities (as defined in the proposal), when they

² Code section 4975(c)(2) authorizes the Secretary of the Treasury to grant exemptions from the parallel prohibited transaction provisions of the Code. Reorganization Plan No. 4 of 1978 (5 U.S.C. app. at 214 (2000)) (the Reorganization Plan) generally transferred the authority of the Secretary of the Treasury to grant administrative exemptions under Code section 4975 to the Secretary of Labor. To rationalize the administration and interpretation of dual provisions under ERISA and the Code, the Reorganization Plan divided the interpretive and rulemaking authority for these provisions between the Secretaries of Labor and of the Treasury, so that, in general, the agency with responsibility for a given provision of Title I of ERISA would also have responsibility for the corresponding provision in the Code. Among the sections transferred to the Department were the prohibited transaction provisions and the definition of a fiduciary in both Title I of ERISA and in the Code. ERISA’s prohibited transaction rules, 29 U.S.C. 1106–1108, apply to ERISA-covered plans, and the Code’s corresponding prohibited transaction rules, 26 U.S.C. 4975(c), apply both to ERISA-covered pension plans that are tax-qualified pension plans, as well as other tax-advantaged arrangements, such as IRAs, that are not subject to the fiduciary responsibility and prohibited transaction rules in ERISA. Specifically, section 102(a) of the Reorganization Plan provides the Department of Labor with “all authority” for “regulations, rulings, opinions, and exemptions under section 4975 [of the Code]” subject to certain exceptions not relevant here. Reorganization Plan section 102. In President Carter’s message to Congress regarding the Reorganization Plan, he made explicitly clear that as a result of the plan, “Labor will have statutory authority for fiduciary obligations. . . . Labor will be responsible for overseeing fiduciary conduct under these provisions.” Reorganization Plan, Message of the President. This exemption would provide relief from the indicated prohibited transaction provisions of both ERISA and the Code.

make investment recommendations regarding Fixed Annuity Contracts to retail “Retirement Investors.” Retirement Investors are plan participants and beneficiaries, IRA³ owners, and non-institutional (or “retail”) fiduciaries. As a condition of receiving compensation that would otherwise be prohibited under ERISA and the Code, the exemption would require the Financial Institutions to acknowledge their fiduciary status and the fiduciary status of the Advisers with whom they contract in writing. The Financial Institution and Advisers would have to adhere to enforceable standards of fiduciary conduct and fair dealing with respect to their advice. In the case of IRAs and non-ERISA plans, the exemption would require that the standards be set forth in an enforceable contract with the Retirement Investor. Under the exemption’s terms, the Financial Institution would not be required to enter into a contract with ERISA plan investors, but it would be obligated to adhere to these same standards of fiduciary conduct, which the investors could effectively enforce pursuant to ERISA section 502(a)(2) and (3).

The proposed exemption is designed to cover commissions and other forms of compensation received in connection with the recommendation of Fixed Annuity Contracts. Rather than prohibit such compensation structures, the exemption would permit individual Advisers⁴ and related Financial Institutions to receive commissions and other common forms of compensation, provided that they implement appropriate safeguards against the harmful impact of conflicts of interest on investment advice. The proposed exemption strives to ensure that Advisers’ recommendations reflect the best interest of their Retirement Investor customers, rather than the conflicting financial interests of the Advisers and the Financial Institutions with whom they contract. Protected Retirement Investors include plan participants and beneficiaries, IRA owners, and “retail” fiduciaries of plans or IRAs (generally persons who hold or manage less than \$50 million in assets, and are not banks, insurance carriers, registered investment

³ For purposes of the proposed exemption, “IRA” means any account or annuity described in Code section 4975(e)(1)(B) through (F).

⁴ By using the term “Adviser,” the Department does not intend to limit the exemption to investment advisers registered under the Investment Advisers Act of 1940 or under state law. For purposes of this proposal, an Adviser is an employee, independent contractor, or agent of an insurance intermediary that satisfies the definition of Financial Institution in the proposed exemption.

advisers or broker dealers), including small plan sponsors.

In order to protect the interests of plan participants and beneficiaries, IRA owners, and plan fiduciaries, the exemption would require the Financial Institution to acknowledge fiduciary status for itself and its Advisers. The Financial Institutions and Advisers would have to adhere to basic standards of impartial conduct. In particular, under the proposal's standards-based approach, the Adviser and Financial Institution must give prudent advice that is in the customer's best interest, avoid misleading statements, and receive no more than reasonable compensation. Additionally, Financial Institutions generally must adopt policies and procedures reasonably designed to mitigate any harmful impact of conflicts of interest, and disclose basic information about their conflicts of interest, the recommended Fixed Annuity Contract and the cost of their advice. The exemption is calibrated to align the Adviser's interests with those of the plan or IRA customer, while leaving the Adviser and Financial Institution the flexibility and discretion necessary to determine how best to satisfy the exemption's standards in light of the unique attributes of their business.

Background

Regulation Defining a Fiduciary

As explained more fully in the preamble to the Regulation, ERISA is a comprehensive statute designed to protect the interests of plan participants and beneficiaries, the integrity of employee benefit plans, and the security of retirement, health, and other critical benefits. The broad public interest in ERISA-covered plans is reflected in its imposition of fiduciary responsibilities on parties engaging in important plan activities, as well as in the tax-favored status of plan assets and investments. One of the chief ways in which ERISA protects employee benefit plans is by requiring that plan fiduciaries comply with fundamental obligations rooted in the law of trusts. In particular, plan fiduciaries must manage plan assets prudently and with undivided loyalty to the plans and their participants and beneficiaries.⁵ In addition, they must refrain from engaging in "prohibited transactions," which ERISA does not permit because of the dangers posed by the fiduciaries' conflicts of interest with respect to the transactions.⁶ When

fiduciaries violate ERISA's fiduciary duties or the prohibited transaction rules, they may be held personally liable for the breach.⁷ In addition, violations of the prohibited transaction rules are subject to excise taxes under the Code.⁸

The Code also has rules regarding fiduciary conduct with respect to tax-favored accounts that are not generally covered by ERISA, such as IRAs. In particular, fiduciaries of these arrangements, including IRAs, are subject to the prohibited transaction rules and, when they violate the rules, to the imposition of an excise tax enforced by the Internal Revenue Service. Unlike participants in plans covered by Title I of ERISA, IRA owners do not have a statutory right to bring suit against fiduciaries for violations of the prohibited transaction rules.

Under this statutory framework, the determination of who is a "fiduciary" is of central importance. Many of ERISA's and the Code's protections, duties, and liabilities hinge on fiduciary status. In relevant part, ERISA section 3(21)(A) and Code section 4975(e)(3) provide that a person is a fiduciary with respect to a plan or IRA to the extent he or she (i) exercises any discretionary authority or discretionary control with respect to management of such plan or IRA, or exercises any authority or control with respect to management or disposition of its assets; (ii) renders investment advice for a fee or other compensation, direct or indirect, with respect to any moneys or other property of such plan or IRA, or has any authority or responsibility to do so; or, (iii) has any discretionary authority or discretionary responsibility in the administration of such plan or IRA.

The statutory definition deliberately casts a wide net in assigning fiduciary responsibility with respect to plan and IRA assets. Thus, "any authority or control" over plan or IRA assets is sufficient to confer fiduciary status, and any persons who render "investment advice for a fee or other compensation, direct or indirect" are fiduciaries, regardless of whether they have direct control over the plan's or IRA's assets and regardless of their status as an investment adviser or broker under the federal securities laws. The statutory definition and associated responsibilities were enacted to ensure that plans, plan participants and beneficiaries, and IRA owners can depend on persons who provide investment advice for a fee to provide recommendations that are untainted by conflicts of interest. In the absence of

fiduciary status, the providers of investment advice are neither subject to ERISA's fundamental fiduciary standards, nor accountable under ERISA or the Code for imprudent, disloyal, or biased advice.

As amended, the Regulation provides that a person renders investment advice with respect to assets of a plan or IRA if, among other things, the person provides, directly to a plan, a plan fiduciary, plan participant or beneficiary, IRA or IRA owner, the following types of advice, for a fee or other compensation, whether direct or indirect:

(i) A recommendation as to the advisability of acquiring, holding, disposing of, or exchanging, securities or other investment property, or a recommendation as to how securities or other investment property should be invested after the securities or other investment property are rolled over, transferred or distributed from the plan or IRA; and

(ii) A recommendation as to the management of securities or other investment property, including, among other things, recommendations on investment policies or strategies, portfolio composition, selection of other persons to provide investment advice or investment management services, types of investment account arrangements (brokerage versus advisory), or recommendations with respect to rollovers, transfers or distributions from a plan or IRA, including whether, in what amount, in what form, and to what destination such a rollover, transfer or distribution should be made.

In addition, in order to be treated as a fiduciary, such person, either directly or indirectly (*e.g.*, through or together with any affiliate), must: Represent or acknowledge that it is acting as a fiduciary within the meaning of ERISA or the Code with respect to the advice described; represent or acknowledge that it is acting as a fiduciary within the meaning of ERISA or the Code; render the advice pursuant to a written or verbal agreement, arrangement or understanding that the advice is based on the particular investment needs of the advice recipient; or direct the advice to a specific advice recipient or recipients regarding the advisability of a particular investment or management decision with respect to securities or other investment property of the plan or IRA.

The Regulation also provides that as a threshold matter in order to be fiduciary advice, the communication must be a "recommendation," which is defined as "a communication that, based on its content, context, and

⁵ ERISA section 404(a).

⁶ ERISA section 406. ERISA also prohibits certain transactions between a plan and a "party in interest."

⁷ ERISA section 409; *see also* ERISA section 405.

⁸ Code section 4975.

presentation, would reasonably be viewed as a suggestion that the advice recipient engage in or refrain from taking a particular course of action.”⁹ The Regulation, as a matter of clarification, provides that a variety of other communications do not constitute “recommendations,” including non-fiduciary investment education; general communications; and specified communications by platform providers. These communications which do not rise to the level of “recommendations” under the Regulation are discussed more fully in the preamble to the final Regulation.¹⁰

The Regulation also specifies certain circumstances where the Department has determined that a person will not be treated as an investment advice fiduciary even though the person’s activities technically may satisfy the definition of investment advice. For example, the Regulation contains a provision excluding recommendations to independent fiduciaries with financial expertise that are acting on behalf of plans or IRAs in arm’s length transactions, if certain conditions are met. The independent fiduciary must be a bank, insurance carrier qualified to do business in more than one state, investment adviser registered under the Investment Advisers Act of 1940 or by a state, broker-dealer registered under the Securities Exchange Act of 1934 (Exchange Act), or any other independent fiduciary that holds, or has under management or control, assets of at least \$50 million, and:

(i) The person making the recommendation must know or reasonably believe that the independent fiduciary of the plan or IRA is capable of evaluating investment risks independently, both in general and with regard to particular transactions and investment strategies (the person may rely on written representations from the plan or independent fiduciary to satisfy this condition);

(ii) the person must fairly inform the independent fiduciary that the person is not undertaking to provide impartial investment advice, or to give advice in a fiduciary capacity, in connection with the transaction and must fairly inform the independent fiduciary of the existence and nature of the person’s financial interests in the transaction;

(iii) the person must know or reasonably believe that the independent fiduciary of the plan or IRA is a fiduciary under ERISA or the Code, or both, with respect to the transaction and is responsible for exercising

independent judgment in evaluating the transaction (the person may rely on written representations from the plan or independent fiduciary to satisfy this condition); and

(iv) the person cannot receive a fee or other compensation directly from the plan, plan fiduciary, plan participant or beneficiary, IRA, or IRA owner for the provision of investment advice (as opposed to other services) in connection with the transaction.

Similarly, the Regulation provides that the provision of any advice to an employee benefit plan (as described in ERISA section 3(3)) by a person who is a swap dealer, security-based swap dealer, major swap participant, major security-based swap participant, or a swap clearing firm in connection with a swap or security-based swap, as defined in section 1a of the Commodity Exchange Act (7 U.S.C. 1a) and section 3(a) of the Exchange Act (15 U.S.C. 78c(a)) is not investment advice if certain conditions are met. Finally, the Regulation describes certain communications by employees of a plan sponsor, plan, or plan fiduciary that would not cause the employee to be an investment advice fiduciary if certain conditions are met.

Prohibited Transactions

The Department anticipates that the Regulation will cover many investment professionals who did not previously consider themselves to be fiduciaries under ERISA or the Code. Under the Regulation, these entities will be subject to the prohibited transaction restrictions in ERISA and the Code that apply specifically to fiduciaries. ERISA section 406(b)(1) and Code section 4975(c)(1)(E) prohibit a fiduciary from dealing with the income or assets of a plan or IRA in his own interest or his own account. ERISA section 406(b)(2), which does not apply to IRAs, provides that a fiduciary shall not “in his individual or in any other capacity act in any transaction involving the plan on behalf of a party (or represent a party) whose interests are adverse to the interests of the plan or the interests of its participants or beneficiaries.” ERISA section 406(b)(3) and Code section 4975(c)(1)(F) prohibit a fiduciary from receiving any consideration for his own personal account from any party dealing with the plan or IRA in connection with a transaction involving assets of the plan or IRA.

Parallel regulations issued by the Departments of Labor and the Treasury explain that these provisions impose on fiduciaries of plans and IRAs a duty not to act on conflicts of interest that may affect the fiduciary’s best judgment on

behalf of the plan or IRA.¹¹ The prohibitions extend to a fiduciary causing a plan or IRA to pay an additional fee to such fiduciary, or to a person in which such fiduciary has an interest that may affect the exercise of the fiduciary’s best judgment as a fiduciary. Likewise, a fiduciary is prohibited from receiving compensation from third parties in connection with a transaction involving the plan or IRA.¹²

Investment professionals often receive compensation for services to Retirement Investors in the retail market through a variety of arrangements that violate the prohibited transaction rules applicable to plan fiduciaries. These include commissions paid by the plan, participant or beneficiary, or IRA, or commissions and other payments from third parties that provide investment products. A fiduciary’s receipt of such payments would generally violate the prohibited transaction provisions of ERISA section 406(b) and Code section 4975(c)(1)(E) and (F) because the amount of the fiduciary’s compensation is affected by the use of its authority in providing investment advice, unless such payments meet the requirements of an exemption.

Prohibited Transaction Exemptions

As the prohibited transaction provisions demonstrate, ERISA and the Code strongly disfavor conflicts of interest. In appropriate cases, however, the statutes provide exemptions from their broad prohibitions on conflicts of interest. For example, ERISA section 408(b)(14) and Code section 4975(d)(17) specifically exempt transactions involving the provision of fiduciary investment advice to a participant or beneficiary of an individual account plan or IRA owner if the advice, resulting transaction, and the Adviser’s fees meet stringent conditions carefully designed to guard against conflicts of interest.

In addition, the Secretary of Labor has discretionary authority to grant administrative exemptions under ERISA and the Code on an individual or class basis, but only if the Secretary first finds that the exemptions are (1)

¹¹ Subsequent to the issuance of these regulations, Reorganization Plan No. 4 of 1978, 5 U.S.C. App. (2010), divided rulemaking and interpretive authority between the Secretaries of Labor and the Treasury. The Secretary of Labor was given interpretive and rulemaking authority regarding the definition of fiduciary under both Title I of ERISA and the Internal Revenue Code. *Id.* section 102(a) (“all authority of the Secretary of the Treasury to issue [regulations, rulings opinions, and exemptions under section 4975 of the Code] is hereby transferred to the Secretary of Labor”).

¹² 29 CFR 2550.408b–2(e); 26 CFR 54.4975–6(a)(5).

⁹ 29 CFR 2510.3–21(b)(1).

¹⁰ See 81 FR 20946 (April 8, 2016).

administratively feasible, (2) in the interests of plans and their participants and beneficiaries and IRA owners, and (3) protective of the rights of the participants and beneficiaries of such plans and IRA owners. Accordingly, fiduciary advisers may always give advice without need of an exemption if they avoid the sorts of conflicts of interest that result in prohibited transactions. However, when they choose to give advice in situations in which they have a conflict of interest, they must rely upon an exemption.

Pursuant to its exemptive authority, the Department has previously granted several conditional administrative class exemptions that are available to fiduciary advisers in defined circumstances. As a general proposition, these exemptions focused on specific advice arrangements and provided relief for narrow categories of compensation. However, the new Best Interest Contract Exemption (PTE 2016–01) is specifically designed to address the conflicts of interest associated with the wide variety of payments advisers receive in connection with retail transactions involving plans and IRAs. Similarly, the Department has granted a new exemption for principal transactions, Exemption for Principal Transactions in Certain Assets between Investment Advice Fiduciaries and Employee Benefit Plans and IRAs (Principal Transactions Exemption) (PTE 2016–02),¹³ that permits investment advice fiduciaries to sell or purchase certain debt securities and other investments in principal transactions and riskless principal transactions with plans and IRAs.

At the same time that the Department granted the new exemptions, it also amended existing exemptions to, among other things, ensure uniform application of the Impartial Conduct Standards, which are fundamental obligations of fair dealing and fiduciary conduct, and include obligations to act in the customer's best interest, avoid misleading statements, and receive no more than reasonable compensation.¹⁴ Taken together, the new exemptions and amendments to existing exemptions ensure that Retirement Investors are consistently protected by Impartial Conduct Standards, regardless of the particular exemption upon which the adviser relies.

The amendments also revoked in whole or in part certain existing exemptions, which provided little or no protections to IRA and non-ERISA plan participants, in favor of a more uniform application of the Best Interest Contract Exemption in the market for retail investments. Most notably for purposes of this proposal, PTE 84–24,¹⁵ an exemption previously providing relief for transactions involving all annuity contracts, was amended to apply only to transactions involving “fixed rate annuity contracts,” as defined in the exemption.¹⁶ As a result, the exemption no longer provides relief for variable annuities, indexed annuities and any other annuities that do not satisfy the definition of fixed rate annuity contracts.

With limited exceptions, it is the Department's intent that investment advice fiduciaries in the retail investment market rely on statutory exemptions, the Best Interest Contract Exemption or this proposed exemption, if granted, to the extent that they receive conflicted forms of compensation that would otherwise be prohibited. The new and amended exemptions reflect the Department's view that Retirement Investors should be protected by a more consistent application of fundamental fiduciary standards across a wide range of investment products and advice relationships, and that retail investors, in particular, should be protected by the stringent protections set forth in the Best Interest Contract Exemption or this proposed exemption, if granted. When fiduciaries have conflicts of interest, they will uniformly be expected to adhere to fiduciary norms and to make recommendations that are in their customer's best interest.

¹⁵ Class Exemption for Certain Transactions Involving Insurance Agents and Brokers, Pension Consultants, Insurance Companies, Investment Companies and Investment Company Principal Underwriters, 49 FR 13208 (April 3, 1984), as amended, 71 FR 5887 (February 3, 2006), as amended 81 FR 21147 (April 8, 2016).

¹⁶ The definition of “fixed rate annuity contract” in PTE 84–24, as amended, is “a fixed annuity contract issued by an insurance company that is either an immediate annuity contract or a deferred annuity contract that (i) satisfies applicable state standard nonforfeiture laws at the time of issue, or (ii) in the case of a group fixed annuity, guarantees return of principal net of reasonable compensation and provides a guaranteed declared minimum interest rate in accordance with the rates specified in the standard nonforfeiture laws in that state that are applicable to individual annuities; in either case, the benefits of which do not vary, in part or in whole, based on the investment experience of a separate account or accounts maintained by the insurer or the investment experience of an index or investment model. A Fixed Rate Annuity Contract does not include a variable annuity or an indexed annuity or similar annuity.”

The Best Interest Contract Exemption

In broadest outline, the Best Interest Contract Exemption permits Advisers and the Financial Institutions (as defined in the exemption) that employ or otherwise retain them to receive many common forms of compensation that ERISA and the Code would otherwise prohibit, provided that they give advice that is in their customers' best interest and the Financial Institution implements basic protections against the dangers posed by conflicts of interest. More specifically, under the Best Interest Contract Exemption, Financial Institutions generally must:

- Acknowledge fiduciary status with respect to investment advice to the Retirement Investor;
- Adhere to Impartial Conduct Standards requiring them to:
 - Give advice that is in the Retirement Investor's best interest (*i.e.*, prudent advice that is based on the investment objectives, risk tolerance, financial circumstances, and needs of the Retirement Investor, without regard to financial or other interests of the Adviser, Financial Institution, or their affiliates, related entities or other parties);
 - Charge no more than reasonable compensation; and
 - Make no misleading statements about investment transactions, compensation, and conflicts of interest;
- Implement policies and procedures reasonably and prudently designed to prevent violations of the Impartial Conduct Standards;
- Refrain from giving or using incentives for Advisers to act contrary to the customer's best interest; and
- Fairly disclose the fees, compensation, and material conflicts of interest, associated with their recommendations.

Advisers relying on the exemption must adhere to the Impartial Conduct Standards when making investment recommendations. In order for relief to be available under the exemption, there must be a “Financial Institution” that meets the definition set forth in the exemption and that satisfies the applicable conditions.

Section VIII(e) of the Best Interest Contract Exemption states that a “Financial Institution” can be a registered investment adviser (RIA), a bank or similar financial institution, a broker-dealer or an insurance company. The Department noted in the preamble to the exemption that these entities were identified by Congress as advice providers in the statutory exemption for investment advice under ERISA section 408(g) and Code section 4975(f)(8) and

¹³ 81 FR 21089 (April 8, 2016), as corrected at 81 FR 44784 (July 11, 2016).

¹⁴ The amended exemptions are Prohibited Transaction Exemption (PTE) 75–1; PTE 77–4; PTE 80–83; PTE 83–1; PTE 84–24, and PTE 86–128. *See* 81 FR 21208; 21139; 21147; and 21181 (April 8, 2016).

that they are subject to well-established regulatory conditions and oversight.¹⁷ However, in response to requests to broaden the definition to include marketing and distribution intermediaries, the Department added section VIII(e)(5), which states that a Financial Institution also includes “an entity that is described in the definition of Financial Institution in an individual exemption . . . that provides relief for the receipt of compensation in connection with investment advice provided by an investment advice fiduciary, under the same conditions as [the Best Interest Contract Exemption].”¹⁸

Thus, although the definition of Financial Institution in the Best Interest Contract Exemption was limited to certain specified entities, the exemption provided a mechanism under which the definition can be expanded if an individual exemption is granted to another type of entity, under the same conditions. In that event, the individual exemption would provide relief to the applicants identified in the exemption, but the definition of Financial Institution in the Best Interest Contract Exemption would be expanded so that other entities that satisfy the definition in the individual exemption can rely on the Best Interest Contract Exemption. In the preamble to the Best Interest Contract Exemption, the Department stated that “[i]f parties wish to expand the definition of Financial Institution to include marketing intermediaries or other entities, they can submit an application to the Department for an individual exemption, with information regarding their role in the distribution of financial products, the regulatory oversight of such entities, and their ability to effectively supervise individual Advisers’ compliance with the terms of this exemption.”¹⁹

Pursuant to section VIII(e)(5) of the Best Interest Contract Exemption, the Department received 22 applications for individual exemptions from insurance intermediaries that contract with independent insurance agents to sell fixed annuities (applicants). The applicants describe themselves as “independent marketing organizations,” “insurance marketing organizations” and “field marketing organizations.”

Collectively, the Department refers to the applicants and similar entities as either “insurance intermediaries” or “IMOs.” The applicants sought individual exemptions under the same conditions as the Best Interest Contract

Exemption, but with a new definition of “Financial Institution” incorporating insurance intermediaries.

Because of the large number of applications, the Department determined to propose, on its own motion, a class exemption for such intermediaries based on the facts and representations in the individual applications received by the Department. The applicants employ a wide variety of business models and approaches, however, and the proposal, while designed to provide class relief for insurance intermediaries, may not be available to all the applicants depending on their individual circumstances. As discussed below, there are a variety of compliance options available to the insurance industry under the Best Interest Contract Exemption. This proposed exemption would supplement these options by permitting the IMO or other intermediary to act as a covered “Financial Institution” with supervisory responsibilities under specified conditions, many of which parallel the conditions of the Best Interest Contract Exemption. To the extent insurance intermediaries wish to pursue additional exemptive relief, the Department will consider such additional requests.

Primarily, it is important to note that insurance intermediaries are not required to act as Financial Institutions under this exemption, if granted, in order to participate in the marketplace. They may provide valuable compliance assistance and other services to insurance companies or other insurance intermediaries that act as Financial Institutions under the Best Interest Contract Exemption or this exemption, if granted, and receive compensation for their services. In this regard, both the Best Interest Contract Exemption and this proposal, if granted, would specifically provide relief for compensation paid to “affiliates” and “related entities” of an Adviser and Financial Institution, which would typically include IMOs.²⁰ Therefore, an IMO that does not meet the definition of Financial Institution under this proposal can nevertheless continue to work with an insurance company or other intermediary, and receive compensation, if the insurance agent and the insurance company or other intermediary complies with the conditions applicable to Advisers and Financial Institutions, respectively, in

the Best Interest Contract Exemption or this exemption, if granted.²¹ As the Department noted in recent guidance, even if it decided not to grant this exemption, an insurer could bolster its oversight by contractually requiring an IMO to implement policies and procedures designed to ensure that all of the agents associated with the IMO adhere to the Impartial Conduct Standards. See *FAQs about Conflict of Interest Rules and Exemptions, Part I*, FAQs 22 and 23. Under this approach, the IMO could eliminate potentially troubling compensation incentives across all the insurance companies that work with the IMO. While the insurance company would remain responsible for compliance with the full Best Interest Contract Exemption, nothing in that exemption would preclude insurers from contracting with other parties, such as IMOs, for compliance work.

Alternatively, even without this new exemption, an insurer could take direct responsibility for supervising agents, regardless of whether it chooses to market its products through a captive sales force, independent agents, or other channels, much as insurers currently have responsibility to oversee the activities of their agents—including independent agents—under state-law suitability rules. As FAQ 22 noted, the insurer’s responsibility under the Best Interest Contract Exemption is to oversee the recommendation and sale of its products, not recommendations and transactions involving other insurers. See *FAQs about Conflict of Interest Rules and Exemptions, Part I*, FAQ 22. Under the Best Interest Contract Exemption, the insurer must adopt and implement prudent supervisory and review mechanisms to safeguard the agent’s compliance with the Impartial Conduct Standards when recommending the insurer’s products; avoid improper incentives to preferentially push the products, riders, and annuity features that are the most lucrative for the insurer at the customer’s expense; ensure that the insurer and agent receive no more than reasonable compensation for their services in connection with the transaction; and adhere to the disclosure and other conditions set forth in its exemption. Thus, for example, an insurer could adopt policies and procedures that require agents (including independent agents) to engage in a process specified by the

²⁰ If an IMO is not an affiliate or related entity, or otherwise a party in interest or disqualified person with respect to the plan or IRA, the IMO’s receipt of payments as a result of an Adviser’s advice would not be a prohibited transaction requiring compliance with an exemption.

²¹ See *FAQs about Conflict of Interest Rules and Exemptions, Part I*, FAQs 22 and 23, <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/coi-rules-and-exemptions-part-1.pdf>.

¹⁷ See 81 FR at 21067.

¹⁸ See *id.*; *id.* at 21083.

¹⁹ See *id.* at 21067.

insurer for making prudent recommendations; review the agent's final recommendation in light of the customer's investment objectives, risk tolerance, financial circumstances, and needs; ensure that its own compensation practices are in line with industry standards for reasonable compensation for the agent's services; and avoid creating any misaligned incentives that encourage the Adviser to choose between the insurer's various offerings based on the financial interests of the insurer or its affiliates, rather than the customer's interest. If the insurer believes that an independent agent may be improperly motivated by the size of the insurer's commissions as compared to its competitors, it may need to review the agent's recommendations particularly carefully and seek additional assurances from the agent as to the basis of its recommendations. However, nothing in the Best Interest Contract Exemption requires the insurer to pay precisely the same compensation to its agents as its competitors, as long as the compensation is reasonable in relation to the services rendered, and the insurer carefully oversees the recommendations for compliance with the Impartial Conduct Standards.²²

Applicants for Individual Exemptions

The following entities submitted applications for individual exemptions permitting them to act as Financial Institutions under the Best Interest Contract Exemption: Gradient Insurance Brokerage, Inc., C2P Advisory Group, LLC dba Clarity to Prosperity, Legacy Marketing Group, LLC, InForce Solutions, LLC, Futurity First Insurance Agency, Financial Independence Group, Brokers International Ltd, Insurance Advocates, Advisors Excel, AmeriLife Group, LLC, InsurMark, Annexus, Ideal Producers Group, ECA Marketing, Saybrus Partners, Inc., Alpine Brokerage Services, The Annuity Source, Inc., M&O Financial, Inc., Kestler Financial Group, Inc., First Income Advisors, Crump Life Insurance Services, Inc., and The IMPACT Partnership, LLC. The applicants provided background information on the distribution of fixed

annuities, described their business models and discussed their anticipated approaches to compliance with the proposed exemption.

Distribution of Fixed Annuities

As described by various applicants, fixed annuities—and in particular, fixed indexed annuities—are commonly distributed by independent insurance agents. Independent insurance agents distribute the products of not one insurance company, but rather multiple insurance companies.

Typically, insurance intermediaries recruit, train and support independent insurance agents and market and distribute insurance products. Since the independent agents are not associated with any one particular insurance company, the intermediary steps in to develop sales processes, provide marketing material, and formulate supervisory procedures and methods for the independent agents to use. The insurance companies and the agents have come to rely on these insurance intermediaries to serve a wide variety of functions relating to the distribution of fixed annuities through the independent insurance agent channel. Insurance intermediaries commonly provide services that include: Agent recruitment and screening, licensing and contracting services, creation of product illustrations, case management, IT services, marketing services, new business processing, training and supervising agents and ensuring compliance with existing standards under state insurance law.

Further, insurance intermediaries can serve an important compliance function. Insurance intermediaries may serve to facilitate statutory and regulatory compliance as well as help to resolve compliance issues that may arise between state regulators, the insurance company and an agent. In performing this role, insurance intermediaries can perform compliance reviews, create policies and procedures and vet the practices of agents. Many insurance intermediaries contractually require that an agent comply with specific standards that are set by the insurance intermediary, as well as the federal and state laws and regulations that govern insurance.

Some insurance intermediaries currently work with the insurance companies to ensure that annuities sold by agents are “suitable” for their clients. This suitability standard generally requires agents and insurance companies to review detailed information about the client to determine if the fixed annuity purchase complies with the suitability standards

under state insurance law (see 2010 NAIC Suitability in Annuity Transactions Model Regulation, which applicants state has been adopted by most state insurance regulators). In order to assist the insurance company and the agent, the insurance intermediary will ensure that the agent has considered, at a minimum, the client's prospective age, annual income, financial situation and needs (including the source of the funds used to purchase the annuity), financial experience, financial objectives, intended use of the annuity, financial time horizon, existing assets (including investment and life insurance), liquidity needs, liquid net worth, risk tolerance and tax status.

The distribution services provided by the insurance intermediary generate multiple forms of compensation for the insurance intermediary. Most prominently, the sale of an annuity usually triggers the payment of a commission to the insurance intermediary. The commission can be based on many factors, including, but not limited to, the specific annuity product sold, the state in which it is sold, the premium amount and the age of the annuity owner. An insurance intermediary can also receive compensation for additional services, including, but not limited to, product development, marketing, administrative and compliance services and field support services. The specific compensation terms are generally spelled out in the contracts between the insurance intermediary and the insurance company and the insurance intermediary and the agent.

The compensation payments received by insurance intermediaries may trigger prohibited transaction concerns under both ERISA and the Code. After the applicability date of the Regulation, insurance agents who recommend fixed annuity products will generally be fiduciaries with respect to a Retirement Investor's account. The receipt of a commission or other compensation by a fiduciary, or an entity in which the fiduciary has an interest that would affect its judgment as a fiduciary, as a result of the provision of investment advice is a prohibited transaction for which an exemption is needed.

Under this fixed annuity distribution and compensation model, an insurance company could serve as a “Financial Institution” for purposes of the Best Interest Contract Exemption. However, the applicants express concern that insurance companies may not necessarily agree to satisfy the role of the Financial Institution under the Best Interest Contract Exemption with respect to independent insurance

²² In general, as noted in the Department's FAQs Part I, the Financial Institution can comply with its obligations to pay no more than reasonable compensation by being attentive to market prices and benchmarks for the services; providing the investor proper disclosure of relevant costs, charges, and conflicts of interest, prudently evaluating the customer's need for the services; and avoiding fraudulent or abusive practices with respect to the service arrangement. See *FAQs about Conflict of Interest Rules and Exemptions, Part I*, FAQ 33, <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/coi-rules-and-exemptions-part-1.pdf>.

agents, or may prefer to rely upon a captive sales force when relying upon that exemption. Additionally, some of the applicants stated that independent insurance agents do not want to lose the flexibility of their independent status.

The applicants represent that the independent insurance agent model benefits consumers because independent agents can offer a wider variety of products to satisfy consumers' goals. Thus, the applicants take the position that permitting insurance intermediaries to serve as Financial Institutions will facilitate independent insurance agents' continued sale of fixed annuities in the Retirement Investor marketplace under a single set of policies and procedures. The exemption proposed herein would apply to commissions and other compensation received by an insurance agent, insurance intermediary, insurance companies and any other affiliates and related entities, as a result of a plan's or IRA's purchase of Fixed Annuity Contracts.

Business Models

Many of the applicants stated that they had direct contractual relationships with the majority of the insurance companies for which they distribute fixed annuities. Frequently, these direct contractual relationships with the insurance companies assigned responsibility for the oversight of agents and sub-IMOs to the intermediaries. Some applicants indicated they are at the highest level of an insurance company's distribution hierarchy, or at the "top-tier" or "top-level."

As top-level IMOs, most applicants represented that they oversee independent, insurance-only agents or sub-IMOs (which in turn oversee independent insurance-only agents), or both. This oversight is accomplished through the top-level IMO's use of its compliance structure and other business and administrative tools. The applicants use their compliance structure to directly oversee agents or to assist sub-IMOs in the distribution of fixed annuities and the oversight of their agents. One applicant, however, stated that it is a sub-IMO. As a sub-IMO, the applicant represents that it has contractual relationships with the insurance companies for which it distributes fixed annuities, but that it also has a contractual relationship with a top-level IMO. The top-level IMO provides the sub-IMO with distribution and other support services. Further, the top-level IMO assists the sub-IMO in accessing a wide variety of insurance products. The sub-IMO represents that contracting with a top-level IMO to

provide this access and these services allows it to focus on the training and support of its agents.

Further, other applicants, in addition to describing themselves as top-level IMOs, also represented that they are affiliated with large insurance companies. One of these applicants wholly owns numerous sub-IMOs. Despite the differences in the ownership structure, the applicants represent that they, like the other top-level IMOs, assist in the distribution of fixed annuities, both their affiliates' and those sold by other insurance companies, and provide valuable business and administrative assistance to sub-IMOs and agents.

Finally, some applicants indicated that their services extend to assisting insurance companies in the design of insurance products.

Compliance Approach

The applicants represented to the Department that they have broad experience that will contribute to their ability to satisfy the conditions of the exemption. Some applicants pointed to their experience in providing oversight of independent agents for insurance law compliance. A number of the applicants indicated that they planned to rely on affiliated registered investment advisers and/or broker-dealer entities in developing systems to comply with the exemption.

The applicants generally indicated that they would maintain internal compliance departments and adopt supervisory structures to ensure compliance with the exemption. Several applicants pointed to technology that they would use to ensure compliance. Some applicants indicated that insurance agents would be required to use the intermediary's technology to ensure that clients receive the disclosures and a contract, where required. Agents would also be required to use the intermediary's Web site services and maintain records centrally.

Some of the applicants additionally described how their sales practices would ensure best interest recommendations. A number of the applicants plan to require centralized approval of agent recommendations; in some cases, the recommendations would be reviewed by salaried employees of the intermediary with additional credentials, such as Certified Financial Planners. One applicant indicated that internal review would include a comparison of the proposed product to other similar fixed indexed annuity products available in the marketplace in order to ensure it is appropriate for the purchaser, and that

the analysis would include utilizing third party benchmarking services and industry comparisons. Another applicant indicated that it would ensure that an RIA representative would work with insurance-only agents where a recommendation would involve the liquidation of securities, to ensure that both state and federal securities laws are properly followed.

Some applicants additionally stated that their contracts with insurance agents would include certain specific requirements, including: Adherence to the intermediary's policies and procedures with respect to advertising, market conduct and point of sale processes, transparency and documentation; provision of advice in accordance with practices developed by the intermediary; and agreement that the agents will not accept any compensation, direct or indirect, from an insurance company, except as specifically approved by the intermediary. A number of the applicants indicated that they would perform background checks and rigorous selection processes before working with agents and would require ongoing training regarding compliance with the exemption.

A few of the applicants addressed product selection. These applicants indicated that agents making recommendations pursuant to the exemption would be limited to certain products and insurance companies. The applicants indicated there would be ongoing due diligence with respect to insurance companies and product offerings under the exemption.

After consideration of the applicants' representations and the information provided in the applications, the Department has decided to propose a class exemption for insurance intermediaries. The proposal is described below.

Description of the Proposed Exemption

General

Section I of the proposed exemption would provide relief for the receipt of compensation by insurance intermediary Financial Institutions and their "Advisers," "Affiliates," and "Related Entities," as a result of the Adviser's or Financial Institution's provision of investment advice within the meaning of ERISA section 3(21)(A)(ii) or Code section 4975(e)(3)(B) to a "Retirement Investor" regarding the purchase of a Fixed Annuity Contract. The proposed exemption would broadly provide relief from the restrictions of ERISA section 406(b) and the sanctions imposed by

Code section 4975(a) and (b), by reason of Code section 4975(c)(1)(E) and (F).²³

The definitions and conditions of the proposal vary in certain respects from those in the Best Interest Contract Exemption, as discussed below. The differences are intended to ensure that transactions involving fixed annuity contracts that are sold by independent insurance agents through insurance intermediaries occur only when they are in the best interest of Retirement Investors. Fixed indexed annuities, with their blend of limited financial market exposures and minimum guaranteed values, can play an important and beneficial role in retirement preparation, as the Department noted in its Regulatory Impact Analysis for the Regulation.²⁴ At the same time, however, these annuities, which are anticipated to be the primary type of fixed annuities sold under this exemption, often pose special risks and complexities for investors.²⁵ Furthermore, when the Department promulgated the Best Interest Contract Exemption, it limited Financial Institution status to entities with well-established regulatory conditions and oversight.²⁶ Insurance intermediaries are not subject to the same regulatory oversight, and often have not played the same supervisory role with respect to advisers, as the Financial Institutions covered by that exemption. As a result of such considerations, this proposal contains a restricted definition of Financial Institution and additional required policies and procedures and disclosures.

These additional protections correspond to concerns, noted previously by the Department and expressed by other regulators, including the Securities and Exchange Commission (SEC) staff, the Financial Industry Regulatory Authority (FINRA), and the North American Securities Administrators Association, regarding fixed indexed annuities and the way they are marketed. Although indexed annuities are often sold as simple “no risk” products, they are neither simple nor risk free. Without proper care, Retirement Investors can all too easily be misled about the terms, guarantees, and risks associated with these products.

As FINRA noted in its Investor Alert, “Equity-Indexed Annuities: A Complex Choice”:

Sales of equity-indexed annuities (EIAs) . . . have grown considerably in recent years. Although one insurance company at one time included the word ‘simple’ in the name of its product, EIAs are anything but easy to understand. One of the most confusing features of an EIA is the method used to calculate the gain in the index to which the annuity is linked. To make matters worse, there is not one, but several different indexing methods. Because of the variety and complexity of the methods used to credit interest, investors will find it difficult to compare one EIA to another.²⁷

FINRA also explained that equity-indexed annuities “give you more risk (but more potential return) than a fixed annuity but less risk (and less potential return) than a variable annuity.”²⁸

Similarly, in its 2011 “Investor Bulletin: Indexed Annuities,” the SEC staff stated: “You can lose money buying an indexed annuity. If you need to cancel your annuity early, you may have to pay a significant surrender charge and tax penalties. A surrender charge may result in a loss of principal, so that an investor may receive less than his original purchase payments. Thus, even with a specified minimum value from the insurance company, it can take several years for an investment in an indexed annuity to ‘break even.’”²⁹ As the SEC staff additionally observed, “[i]t is important to note that indexed annuity contracts commonly allow the insurance company to change the participation rate, cap, and/or margin/spread/asset or administrative fee on a periodic—such as annual—basis. Such changes could adversely affect your return.”³⁰

The North American Securities Administrators Association, the association of state securities regulators, issued the following statement on equity indexed annuities:

Equity indexed annuities are extremely complex investment products that have often been used as instruments of fraud and abuse. For years, they have taken an especially heavy toll on our nation’s most vulnerable investors, our senior citizens for whom they are clearly unsuitable.³¹

²⁷ “Equity-Indexed Annuities: A Complex Choice” available at https://www.finra.org/investors/alerts/equity-indexed-annuities_a-complex-choice.

²⁸ *Id.*

²⁹ SEC Office of Investor Education and Advocacy Investor Bulletin: Indexed Annuities, available at <https://www.sec.gov/investor/alerts/secindexedannuities.pdf>.

³⁰ *Id.*

³¹ See NASAA Statement on SEC Equity-Indexed Annuity Rule (December 17, 2008) available at <http://www.nasaa.org/5611/statement-on-sec-equity-indexed-annuity-rule/>.

In the Department’s view, the complexity and conflicted payment structures associated with fixed indexed annuities heighten the dangers posed by conflicts of interest when Advisers recommend these products to Retirement Investors. These are complex products requiring careful consideration of their terms and risks. Assessing the prudence of a particular indexed annuity requires an understanding of surrender terms and charges; interest rate caps; the particular market index or indexes to which the annuity is linked; the scope of any downside risk; associated administrative and other charges; the insurer’s authority to revise terms and charges over the life of the investment; and the specific methodology used to compute the index-linked interest rate and any optional benefits that may be offered, such as living benefits and death benefits. In operation, the index-linked interest rate can be affected by participation rates; spread, margin or asset fees; interest rate caps; the particular method for determining the change in the relevant index over the annuity’s period (annual, high water mark, or point-to-point); and the method for calculating interest earned during the annuity’s term (e.g., simple or compounded interest). Investors can all too easily overestimate the value of these contracts, misunderstand the linkage between the contract and index performance, underestimate the costs of the contract, and overestimate the scope of their protection from downside risk (or wrongly believe they have no risk of loss). As a result, Retirement Investors are acutely dependent on sound advice that is untainted by the conflicts of interest posed by Advisers’ incentives to secure the annuity purchase, which can be quite substantial.

Accordingly, the Department has taken care to address these concerns, while preserving the beneficial and important role these products can play for retirement investors.³² As noted above, when prudently recommended, fixed indexed annuities can promote investor interests because of their combination of limited financial market exposures and minimum guaranteed values. In addition, the Department seeks additional comments on insurers’ ability to change the terms of a fixed indexed annuity contract during the life of the annuity, particularly during the period in which a surrender charge is in effect. To the extent that the insurer can change critical terms, such as the participation rate, indexing method,

³² See Regulatory Impact Analysis for the Regulation, p. 8, available at www.dol.gov/ebsa.

²³ Relief is also proposed from ERISA section 406(a)(1)(D) and Code section 4975(c)(1)(D), which prohibit transfer of plan assets to, or use of plan assets for the benefit of, a party in interest (including a fiduciary).

²⁴ See Regulatory Impact Analysis for the Regulation, p. 8, available at www.dol.gov/ebsa.

²⁵ See Best Interest Contract Exemption, 81 FR 21001, 21017 (April 8, 2016).

²⁶ See *id.* at 21067.

cap, or relevant fees and charges, it can directly affect its own compensation. And to the extent it can make such changes during the surrender period, it can place the customer in a lose-lose situation: The customer must either accept an unfavorable change to the terms of the annuity or surrender the annuity and incur a charge against the amount of the annuity. The Department asks for comment on these issues and features, with the intent of providing additional guidance on them in the final exemption, if it is granted, or potentially limiting the exemption to annuity contracts that do not permit insurers to change critical terms during periods in which the customer is subject to a surrender charge or penalty. Specifically, the Department asks parties to provide information on how commonly fixed indexed annuity contracts are structured in this manner. In practice, how commonly do insurers make such changes to critical terms during surrender periods? What constraints are imposed on such conduct by state law or otherwise? Similarly, what constraints are placed on the size of surrender charges or the methodology for calculating the charges? How are these rights and practices disclosed to consumers? How commonly do insurers give consumers advance notice of the changes coupled with a right to withdraw assets without penalty before the changes take effect? To what extent can an Adviser prudently recommend a fixed indexed annuity if it is potentially subject to changes in key terms during the surrender period? To the extent insurers can unilaterally increase their compensation by changing key terms during the surrender period, do they need a separate exemption for the exercise of that authority? Finally, to what extent should the Department be concerned about similar issues with respect to fixed rate annuities?

Definition of Fixed Annuity Contract

As stated above, the proposed exemption is limited to transactions involving Fixed Annuity Contracts. To ensure that the exemption would not be used more broadly than intended, the proposal includes a definition of Fixed Annuity Contract, which is “an annuity contract that satisfies applicable state standard nonforfeiture laws at the time of issue and the benefits of which do not vary, in whole or in part, on the basis of the investment experience of a separate account or accounts maintained by the insurer. This includes both fixed rate annuity contracts and fixed indexed annuity contracts.” The definition is intended to

include fixed immediate annuities but exclude variable annuity contracts, which the Department understands are typically sold through securities distribution channels.

If this proposed exemption is granted, therefore, relief will be available for sales of fixed rate annuities sold by insurance intermediaries and independent insurance agents under several different exemptions. Relief for all annuity sales is available under the Best Interest Contract Exemption if, as discussed above, an insurance company acts as the Financial Institution under the terms of that exemption. Alternatively, relief for fixed rate annuity contracts is available under PTE 84–24. By also proposing relief for such transactions in this exemption, the Department is not indicating that these other exemptions are unavailable. The intent is to provide flexibility to parties depending on their individual circumstances.

The Department requests comment on the proposed definition of Fixed Annuity Contract. Does the definition adequately describe fixed annuities and carve out variable annuities? Are there other attributes of fixed annuity contracts that should be identified in the definition? Finally, should the definition address group annuity contracts, which may not be required to satisfy state nonforfeiture laws? Is relief necessary in this distribution channel for group annuity contracts? If so, should the definition provide that rather than satisfying the state nonforfeiture laws, the group annuity contract must “guarantee return of principal net of reasonable compensation, and provide a guaranteed declared minimum interest rate in accordance with the rates specified in the standard nonforfeiture laws in the state that are applicable to individual annuities”?³³

Definition of Adviser

The proposed definition of Adviser in Section VIII(a) generally mirrors the definition in the Best Interest Contract Exemption, although a reference to banking law was not included in this proposed definition as the Department did not believe it was relevant. The definition states:

“Adviser” means an individual who:

(1) Is a fiduciary of the Plan or IRA by reason of the provision of investment advice described in ERISA section 3(21)(A)(ii) or Code section 4975(e)(3)(B), or both, and the applicable regulations, with respect to the assets of the Plan or IRA involved in the recommended transaction;

(2) Is an employee, independent contractor, or agent of a Financial Institution; and

(3) Satisfies the federal and state regulatory and licensing requirements of insurance laws with respect to the covered transaction, as applicable.

The Department requests comment on whether this definition accurately describes the relationship between independent insurance agents and insurance intermediaries who will serve as Financial Institutions under the exemption, and, if not, how the definition should be revised.

Definition of Financial Institution

The proposal includes a new definition of Financial Institution that would apply with respect to insurance intermediaries. See Section VIII(e). As the Department stated in the preamble to the Best Interest Contract Exemption, the definition of Financial Institution in that exemption included entities identified in the statutory exemption for investment advice under ERISA section 408(g) and Code section 4975(f)(8) and that are subject to well-established regulatory conditions and oversight.³⁴ In addition, in that preamble, the Department requested that intermediaries seeking to serve as Financial Institutions provide information as to their ability to effectively supervise Advisers’ compliance with the terms of the exemption.³⁵ The applicants described their ability to oversee Advisers and proposed a variety of safeguards that they believed would be protective of Retirement Investors engaging in these transactions.

The proposed definition of Financial Institution is based on the applicants’ representations and suggestions and the Department’s additional analysis of how best to safeguard Retirement Investors’ interests in this distribution channel. The components of the definition are intended to describe insurance intermediaries that are likely to be able to comply with the exemption and provide meaningful oversight of Advisers working in the fixed annuity marketplace. The proposal seeks to identify insurance intermediaries with the financial stability and operational capacity to implement the anti-conflict policies and procedures required by the exemption. Additionally, insurance intermediaries described in the definition are sufficiently large and established to stand behind their contractual and other commitments to Retirement Investors, and to police conflicts of interest associated with a

³³ See Final Amendment to PTE 84–24, 81 FR 21147, 21176 (April 8, 2016) (definition of “Fixed Rate Annuity Contract”).

³⁴ See 81 FR 21067.

³⁵ See *id.*

wide range of insurance products offered by a wide range of insurance companies.

As an initial matter, the proposal defines a Financial Institution as an insurance intermediary that has a direct written contract regarding the distribution of Fixed Annuity Contracts with both the insurance company issuing the annuity contract and the Adviser or another intermediary (sub-intermediary) that has a direct written contract with the Adviser. Additional exemption conditions describe the terms of the required contract, see proposed Section II(d)(6) and (7). By requiring a contractual relationship between the insurance company and the intermediary, the proposal would ensure that the insurance intermediary and the insurance company have a direct relationship that will enable the insurance intermediary to satisfy its obligations under the exemption. By also requiring a contractual relationship between the intermediary and the Adviser or sub-intermediary, the proposal would further ensure that the intermediary will have the right to implement its oversight obligations as a Financial Institution pursuant to the requirements of the exemption, if granted. The Department requests comment on whether this condition should be adjusted to allow for multiple levels of intermediaries.

In addition to the baseline contractual relationship requirement, the proposal sets forth a series of conditions that would apply to the insurance intermediary. Subsection (1) of the proposed definition would require the insurance intermediary to satisfy the applicable licensing requirements of the insurance laws of each state in which it conducts business. Accordingly, the intermediary would be required to operate in accordance with the states' requirements in this respect.

Next, the proposal seeks to confirm that the insurance intermediary has sound business practices that have been reviewed by an independent entity. Subsection (2) of the proposed definition would require that the intermediary have financial statements that are audited annually by an independent certified public accountant. This condition would utilize the definition of Independent in Section VIII(f) of the proposed exemption.³⁶ In addition, under

proposed Section III(b)(vii), the audited financial statements must be provided on the Financial Institution's Web site.

This condition was suggested in several individual applications. Some applicants believed that periodic financial audits would provide reasonable assurance of the entity's financial health. The Department agrees. The Department anticipates that requiring an annual audit of the financial statements, coupled with the Financial Institution's web disclosures, will provide an opportunity for the Department and other interested persons to be alerted to any financial weaknesses or other items of concern with respect to the stability or solvency of the Financial Institution, or its ability to stand behind its commitments to Retirement Investors.

As an alternative to an audit of financial statements, one applicant suggested that the audit should relate to the intermediary's internal controls and procedures. The applicant noted that banks and trust companies are currently required to obtain these reports under SSAE 16 (formerly SAS 70), and that the applicant could work with its auditors to prepare a similar report, but suggested that such an approach would require additional transition relief as the accounting industry would have to agree on the appropriate data points for an internal controls audit for an insurance intermediary and the resulting topics of the SSAE 16-like report.

The Department requests comment on the utility of the proposed audited financial statements requirement as a protection of Retirement Investors, and the suggested alternative audit of internal controls and procedures. The Department also requests information on the cost of these alternatives to insurance intermediaries intending to rely on the exemption.

Insurance or Assets Set Aside for Potential Liability

Subsection (3) of the proposed definition would require the Financial Institution to maintain fiduciary liability insurance, or unencumbered cash, bonds, bank certificates of deposit, U.S. Treasury Obligations, or a combination of all of these, available to satisfy potential liability under ERISA or the Code as a result of the firm's failure to meet the terms of this

exemption, or any contract entered into pursuant to Section II(a). The aggregate amount of these items must equal at least 1% of the average annual amount of premium sales of Fixed Annuity Contracts by the Financial Institution to Retirement Investors over the prior three fiscal years of the Financial Institution. To the extent this condition is satisfied by insurance, the proposal states that the insurance must apply solely to actions brought by the Department of Labor, the Department of Treasury, the Pension Benefit Guaranty Corporation, Retirement Investors or plan fiduciaries (or their representatives) relating to Fixed Annuity Contract transactions, including but not limited to, actions for failure to comply with the exemption or any contract entered into pursuant to Section II(a), and it may not contain an exclusion for Fixed Annuity Contracts sold pursuant to the exemption. Any such insurance also may not have a deductible that exceeds 5% of the policy limits and may not exclude coverage based on a self-insured retention or otherwise specify an amount that the Financial Institution must pay before a claim is covered by the fiduciary liability policy. To the extent this condition is satisfied by retaining assets, the assets must be unencumbered and not subject to security interests or other creditors.

This provision of the proposal seeks to ensure that the Financial Institution can stand behind its commitments to retirement investors and satisfy potential liabilities under the exemption. The Financial Institution's ability to back its commitments ensures that it can be held accountable when it violates its obligations and, thereby, promotes compliance. A number of the applicants specifically suggested that they would obtain insurance to cover potential liability under the exemption, although the approaches and suggested amounts varied. Additionally, as some applicants indicated uncertainty as to the current availability of insurance for liability under the exemption, the proposal would provide flexibility to the intermediaries to determine whether to acquire insurance or set aside assets to satisfy potential liability.

The Department has concluded that the condition should be included in this proposal based on the suggestion of applicants, as well as its understanding that insurance intermediaries often are not legally required to maintain, and do not maintain, significant amounts of capital. Particularly because these entities do not necessarily have the sort of history of regulatory oversight and supervisory experience that characterize Financial Institutions identified in the

³⁶ Under section VIII(f), "Independent" means a person that: (1) Is not the Adviser, the Financial Institution or any Affiliate relying on the exemption; (2) Does not have a relationship to or an interest in the Adviser, the Financial Institution or Affiliate that might affect the exercise of the person's best judgment in connection with

transactions described in this exemption; and (3) Does not receive or is not projected to receive within the current federal income tax year, compensation or other consideration for his or her own account from the Adviser, Financial Institution or Affiliate in excess of 2% of the person's annual revenues based upon its prior income tax year.

Best Interest Contract Exemption, the Department believes that this additional condition is a necessary enhancement of the protections necessary to ensure that the intermediaries maintain full responsibility for compliance with the proposed exemption's conditions.

The Department requests comment on the approach taken in proposed subsection (3) of the definition. First, do commenters agree that the exemption should specify that insurance/assets should be based on a percentage of prior sales of Fixed Annuity Contracts? Is a three-year average an appropriate method for determining the amount of premium sales? Should a different and or minimum/maximum amount be specified, or should there be no specific level at all? For example, should the exemption instead require that a "reasonable" amount of insurance be obtained or assets set aside? As an additional protection for Retirement Investors, should individual Advisers be required to carry insurance themselves?

Moreover, should the final exemption retain the proposal's approach of allowing Financial Institutions flexibility to either obtain fiduciary liability insurance or set aside assets to satisfy potential liabilities? If the Department adopts this approach, should it specify how assets should be held (*i.e.*, in an escrow account) in order to ensure they are available in the event there is a judgment against the intermediary? Further, should the condition describe with more specificity which assets are acceptable, how they are to be valued, or how they are to be insulated from the claims of creditors other than Retirement Investors? As an alternative, should the final exemption require both fiduciary liability insurance coverage and a minimum level of assets set aside? If so, how should the requirement for a minimum level of assets be defined?

Premium Threshold

Finally, subsection (4) of the proposed definition would require the insurance intermediary to have had annual Fixed Annuity Contract sales averaging at least \$1.5 billion in premiums over each of the three prior fiscal years to qualify as a Financial Institution. This proposed threshold is intended to identify insurance intermediaries that have the financial stability and operational capacity to implement the anti-conflict policies and procedures required by the exemption. The proposed condition aims to ensure that the insurance intermediary is in a position to meaningfully mitigate compensation conflicts across products and insurers, which is a critical safeguard of the

exemption, as proposed. Although this proposed threshold would limit entities that could operate as the supervisory Financial Institution to larger intermediaries, it would not prevent smaller intermediaries from working with larger intermediaries, similarly to how some of them currently operate.

The proposed \$1.5 billion threshold is based on a variety of factors. The intermediaries that approached the Department for individual exemptions and expressed their willingness and ability to function in a supervisory capacity to mitigate conflicts generally indicated sales of this amount or more in their applications, although not all applicants provided this information. Additionally, the Department believes that the \$1.5 billion dollar threshold will cover those intermediaries that are most likely to make beneficial use of the exemption because economies of scale are likely to yield advantages in efficiently carrying out compliance responsibilities under this proposed exemption, especially if they step into the role that insurance companies would otherwise serve under the Best Interest Contract Exemption. The Department is also concerned that the conditions of the exemption will not serve their purpose in protecting Retirement Investors from conflicts of interest if the insurance intermediary does not have the requisite experience and resources to be able to effectively mitigate the potential adverse impact of these incentives.

To this point, the Department questions whether intermediaries with lower levels of annual sales will be able to effectively mitigate conflicts in an environment that is so heavily dependent on commission compensation, particularly without the history of regulatory oversight and supervisory experience that characterize other Financial Institutions, such as banks, insurance companies, and broker-dealers. One of the chief reasons for extending Financial Institution status to insurance intermediaries is their ability to mitigate the conflicts of interest posed by the variable compensation that independent agents may receive from different insurance companies paying different compensation. Sufficiently large intermediaries that sell many products from a wide variety of insurance companies are in a position to control the compensation that the agent stands to receive from the various insurers and products and, thereby, minimize or eliminate the independent agents' conflicts of interest in choosing between insurance companies and products. In addition, the anti-conflict purpose of the

exemption's conditions would not be served with respect to an entity that is so small that the difference between the firm's conflicts and the individual advisers' conflicts is essentially non-existent.

The proposed requirement that the premium threshold be met using the preceding three-year average is intended, again, to identify intermediaries with an established history of significant sales. However, it is not intended as a barrier to new entities becoming Financial Institutions or for smaller intermediaries to operate under this exemption, albeit not as a Financial Institution. The Department notes that while a large intermediary would be responsible for acting as the Financial Institution under the exemption, smaller intermediaries will typically be eligible to obtain prohibited transaction relief under the proposed exemption's provisions that extend to "affiliates" and "related entities." In this regard, the Department understands that the marketplace of intermediaries that distributes fixed annuities is hierarchical. Smaller intermediaries commonly work with larger intermediaries, and receive materials and support from the larger intermediaries in exchange for a fee or a portion of the sales commission. Therefore, smaller intermediaries could obtain relief from ERISA's prohibited transaction rules as long as there is an intermediary in their distribution hierarchy that acts as the Financial Institution and provides the requisite anti-conflict and supervisory role under the exemption, including execution of the best interest contract.³⁷ Accordingly, where several intermediaries (a top-level intermediary and one or more sub-intermediaries) receive commission compensation in connection with an annuity transaction, each intermediary would be eligible for prohibited transaction relief under this proposed exemption, although only one would act as the Financial Institution and need to satisfy the premium threshold.

Importantly, in determining whether an intermediary meets the \$1.5 billion threshold, each intermediary that receives a commission for an annuity transaction could count the total premium amount involved towards the required premium threshold. This will facilitate the ability of smaller intermediaries to satisfy the premium

³⁷ If an intermediary is not an affiliate or related entity, or otherwise a party in interest or disqualified person with respect to the plan or IRA, the intermediary's receipt of payments as a result of an Adviser's advice would not be a prohibited transaction requiring compliance with an exemption.

threshold under this exemption, and act as a Financial Institution, if desired. For example, assume an Annuity Adviser contracts with IMO A, which in turn is a part of IMO B's network. IMO B is a Financial Institution under this exemption. If Annuity Adviser sells an annuity to a Retirement Investor for \$100,000, both IMO A and IMO B can count the \$100,000 towards their own \$1.5 billion threshold. If IMO A eventually reaches the \$1.5 billion threshold (averaged over three years), it could act as a Financial Institution under this exemption, but would not be required to do so, as long as IMO B or another Financial Institution acts in the requisite role.

The Department notes that applicants suggested various other methods of defining which intermediaries should qualify as Financial Institutions. The most prevalent suggestion was to limit the exemption to "top tier" intermediaries with a significant number of direct relationships with insurance carriers. The "top tier" intermediary was generally described as the entity at the top of an insurance carrier's distribution hierarchy. Some applicants stated that the exemption should focus on the "top tier" intermediaries because such entities have a closer tie with the insurance company.

The Department's proposal is not limited to intermediaries with "top tier" status. As an initial matter, the Department understands that many insurance intermediaries have direct contracts with insurance carriers regardless of the intermediary's size and it may not be clear whether a particular contractual relationship is properly characterized as a "top tier" relationship. Additionally, even assuming that "top tier" could be defined objectively, the Department is not certain that status at the top of an insurance company's distribution hierarchy is necessary to indicate that an intermediary is an established entity capable of providing effective oversight of Advisers and mitigating compensation incentives. Accordingly, the Department has tentatively concluded that the premium threshold is a better indicator that an intermediary can serve these functions based on its involvement in a significant amount of sales over its three prior fiscal years.

The Department requests comment on a variety of aspects of the proposed premium threshold condition and possible alternatives. First, the Department seeks comment on alternative approaches to identifying intermediaries that are likely to be able to comply with the exemption and

provide meaningful oversight of Advisers working in the fixed annuity marketplace. More specifically, the Department asks whether focusing on premium levels is an effective measure of compliance and conflict mitigation capability. The Department also seeks comment on the requirement that the premium condition be met by averaging premiums over the preceding three fiscal years. In particular, the Department asks the following questions:

- Is the \$1.5 billion threshold likely to identify intermediaries with the history and capability of handling supervisory and regulatory compliance of this nature? If there is a threshold, should it be set at a different level?
- If a premium threshold is adopted, should it be indexed to grow with consumer price inflation or some other reference?
- If a premium threshold is included, is basing it on an average over the prior three years an effective way to account for fluctuations in annual sales to ensure intermediaries have certainty that they will continue to qualify as a Financial Institution? Are there alternative ways to address annual sales fluctuations to provide such certainty?
- In addition to entities that have satisfied the premium threshold, should the Financial Institution definition extend to entities with a "reasonable expectation" of meeting the threshold over the next three years, to ensure that newer or growing entities can more readily become Financial Institutions? Would a subjective threshold of this type provide adequate protections to Retirement Investors? How should the exemption apply to intermediaries that fail to meet the threshold, notwithstanding their previously "reasonable expectation" that they would meet the threshold?
- If the exemption did not include a premium threshold, would smaller intermediaries nevertheless be likely to rely on larger intermediaries for exemption compliance due to cost savings, efficiency, or other reasons?
- Are there a large number of smaller intermediaries selling fixed annuities that do not work with any other intermediaries that could satisfy the \$1.5 billion or similar threshold?
- Should the premium threshold apply specifically to fixed annuity sales, or should it apply more broadly to all sales of insurance and annuity products? If it applies to insurance sales other than fixed annuities, how

should premiums for those sales be measured?

- As an alternative or in addition to a premium threshold, should the exemption have a threshold based on the number of annuity contracts sold by the intermediary annually?
- Should a "top tier" requirement replace or be added to a premium threshold requirement? If so, how would the Department define "top tier" status, and should intermediaries be required to have a certain minimum number of contractual relationships with different insurance companies to satisfy such a requirement?
- Alternatively, or in addition to, either a premium threshold or a "top tier" requirement, should the exemption require that the intermediary also have agreements to sell fixed annuities with a specified minimum number of different insurance companies? If so, what would be an appropriate minimum number and why?
- Are there other conditions (*e.g.*, minimum number of employees, annual revenue threshold, capitalization requirement) that would satisfy the Department's intent to ensure the covered Financial Institutions are able and likely to comply with the exemption and engage in meaningful oversight of Advisers working in the fixed annuity marketplace?

Conditions

Sections II through V of the proposal contain the conditions proposed for relief under the exemption. The conditions are the same as the Best Interest Contract Exemption in many respects, but some of the conditions have been revised, augmented or deleted, as discussed in this section. The Department requests comments on these revisions.

Sections II(a), (b), (c)

Section II sets forth the requirements that establish the Retirement Investor's enforceable right to adherence to the Impartial Conduct Standards and related conditions. For advice to certain Retirement Investors—specifically, advice regarding IRA investments, and plans that are not covered by Title I of ERISA (non-ERISA plans), such as plans covering only partners or sole proprietors—Section II(a) requires the Financial Institution and Retirement Investor to enter into a written contract that includes the provisions described in Section II(b)–(d) of the exemption and that also does not include any of the ineligible provisions described in

Section II(f) of the exemption. Financial Institutions additionally must provide the disclosures set forth in Section II(e).³⁸

The contract with Retirement Investors regarding IRAs and non-ERISA plans must include the Financial Institution's acknowledgment of its fiduciary status and that of its Advisers, as required by Section II(b) and the Financial Institution's agreement that it and its Advisers will adhere to the Impartial Conduct Standards as required by Section II(c). The Impartial Conduct Standards require Advisers and Financial Institutions to provide advice that is in the Retirement Investor's best interest (*i.e.*, prudent advice that is based on the investment objectives, risk tolerance, financial circumstances, and needs of the Retirement Investor, without regard to financial or other interests of the Adviser, Financial Institution, or their affiliates, related entities or other parties); charge no more than reasonable compensation; and make no misleading statements about investment transactions, compensation, and conflicts of interest. These provisions are unchanged from the Best Interest Contract Exemption.

In this regard, the Department cautions Financial Institutions and Advisers to avoid inaccurate or misleading statements regarding the risk characteristics of fixed indexed annuity contracts, particularly statements that inaccurately suggest these products have only upside potential and no risk of loss of principal. *See* Equity-Indexed Annuities: Member Responsibilities for Supervising Sales of Unregistered Equity-Indexed Annuities, available at <http://www.finra.org/industry/notices/05-50>. In particular, firms and Advisers violate the Impartial Conduct Standards if they fail to explain any limitations on the upside of the investments (*e.g.*, as imposed by caps, participation rates, and crediting practices), or if they

falsely describe fixed indexed annuities as "no risk" products or state that there can be no loss of principal with Fixed Annuity Contracts, without acknowledging the potential impact of surrender charges or other provisions that could, in fact, result in the consumer's receiving less than he or she paid for the contract. As further discussed below, this proposal includes a new proposed Section II(d)(4) that would require that, as part of the policies and procedures requirement, the Financial Institution approve marketing materials used by Advisers, to increase oversight in this area.

Section II(d)—Policies and Procedures

Under Section II(d), the Financial Institution must warrant that it has adopted, and in fact must comply with, anti-conflict policies and procedures reasonably and prudently designed to ensure that Advisers adhere to the Impartial Conduct Standards. The policies and procedures requirements generally include all the elements in the Best Interest Contract Exemption, including the requirement that the Financial Institution designate a person or persons responsible for addressing material conflicts of interest and monitoring Advisers' adherence to the Impartial Conduct Standards. *See* Section II(d)(2).

Proposed Section II(d)(3)

Proposed Section II(d)(3) specifically addresses incentives to Advisers, and provides that the Financial Institution's policies and procedures must prohibit the use of quotas, appraisals, or performance or personnel actions, bonuses, contests, special awards, differential compensation, or other actions or incentives if they are intended or would reasonably be expected to cause Advisers to make recommendations that are not in the best interest of the Retirement Investor. The condition applies regardless of the source of the incentive. Independent insurance agents distribute the products of multiple insurance companies and accordingly, may be subject to more than one company's incentives. In some cases, the agents may also work for more than one intermediary. Under the terms of the exemption, however, the intermediary would be expected to ensure that these arrangements did not incentivize the agents to make recommendations that run counter to the best interest standard.

The insurance intermediaries indicated they are well positioned to mitigate the impact of the competing financial incentives offered by multiple insurance companies. Consistent with

the intermediaries' representations, one of the key protections of this exemption is the requirement that the insurance intermediary Financial Institution manage the conflicts of interest that independent agents and other Advisers face in recommending the products of multiple insurance companies. Proposed Section II(d)(3) would tolerate differential compensation—regardless of source—only to the extent that it is not intended or reasonably expected to cause Advisers to make recommendations that are not in the best interest of the Retirement Investor. Financial Institutions can allow Advisers to receive differential compensation if it is justified by neutral factors tied to the differences in the services delivered to Retirement Investors. *See* Best Interest Contract Exemption, 81 FR at 21039–40 (preamble discussion of neutral factors analysis); *FAQs about Conflict of Interest Rules and Exemptions, Part I*, FAQ 9 (addressing compensation incentives).³⁹

The Department views this as a critical safeguard of this proposed exemption. The proposed condition is intended to ensure that an Adviser's relationship with multiple insurance companies and even multiple insurance intermediaries does not generate compensation or incentive structures that undermine the Adviser's provision of advice that is in Retirement Investors' best interest.

Proposed Section II(d)(3) retains the principles based approach of the Best Interest Contract Exemption, and does not purport to detail any single approach for compliance with the condition. A number of applicants indicated that they expect their

³⁸ Unlike the Best Interest Contract Exemption, this proposal does not contain provisions addressing relief in the event of the failure to enter into a contract. *See* Best Interest Contract Exemption, section II(a)(1)(iii). This provision was included in the Best Interest Contract Exemption to address concerns voiced generally in the context of mutual fund transactions. Commenters raised concerns that it would be possible for a Retirement Investor to receive advice from an Adviser to enter into a transaction but fail to open an account with the particular Adviser or Financial Institution, yet nevertheless follow the advice in a way that generates additional compensation for the Financial Institution or an affiliate or related entity. The Department does not anticipate that such concerns are present in the context of the annuity transactions covered in this proposal and has therefore not included provisions in this proposal to parallel section II(a)(1)(iii) of the Best Interest Contract Exemption; however, the Department requests comment on this approach.

³⁹ *See* <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/coi-rules-and-exemptions-part-1.pdf>. This is a broader requirement for the elimination or mitigation of conflicts of interest than would apply to an individual insurance company relying on section II(d)(3) of the Best Interest Contract Exemption. As discussed above (and in the Department's FAQ 22), the insurer's responsibility under the Best Interest Contract Exemption is to oversee the recommendation and sale of its products, not recommendations and transactions involving other insurers. Thus, under the Best Interest Contract Exemption, the insurance company has an obligation to ensure that it and its affiliates and related entities do not use or create inappropriate incentives, but it does not have an obligation to control the compensation incentives independently created by other insurance companies or parties. The different business model of IMOs and other intermediaries, however, enables them to broadly eliminate differential compensation that is not tied to neutral factors based upon differences in the services provided by the Adviser. This exemption requires them to eliminate such differentials and to avoid misaligned incentives with respect to all the independent agent's recommendations.

relationships with Advisers to be exclusive with respect to the sale of Fixed Annuity Contracts to Retirement Investors. In that case, the Financial Institution would have a ready means of supervising the insurers and product that the Adviser recommended and controlling associated incentive structures. The proposal does not mandate exclusivity, however; a Financial Institution could alternatively require an Adviser to provide information to the Financial Institution regarding all the compensation and incentives provided by all the other insurance companies and intermediaries through which the Adviser sells Fixed Annuity Contracts. Whatever approach is adopted by a Financial Institution, the Financial Institution will ultimately be responsible for implementing the policies and procedures across all the Advisers' incentive arrangements.

New Proposed Policies and Procedures Requirements

A new proposed Section II(d)(4) would require Financial Institutions to approve in advance all written marketing materials used by Advisers after determining that such materials provide a balanced description of the risks and features of the annuity contracts to be recommended. The condition ensures that Advisers are not using marketing materials that do not fully and fairly disclose the risks and characteristics of an annuity.

New proposed Section II(d)(5) would impose additional requirements on the person or persons designated as responsible for addressing material conflicts of interest and monitoring Advisers' adherence to the Impartial Conduct Standards. The new section would require the person to approve, in writing, recommended annuity applications involving Retirement Investors prior to transmitting the applications to the insurance company. While a specific approval requirement is not in the Best Interest Contract Exemption, a number of applicants suggested they would have internal compliance departments review recommendations prior to the transmittal of an annuity contract to an insurance company. The condition would reinforce the duty of the Financial Institution to monitor and supervise the Advisers operating within the Financial Institution's distribution chain. This may be particularly important when there are sub-intermediaries, who may be more involved in day-to-day activities, between the Adviser and the Financial Institution.

The proposal also would establish certain specific requirements for the relationship between the insurance intermediary and the Adviser. Section II(d)(6) would specify certain aspects of the written contract between the Financial Institution and the Adviser or sub-intermediary. First, the Financial Institution must require in its written contract with the Adviser or sub-intermediary that Advisers may use written marketing materials only if they are approved by the Financial Institution. As discussed above, Section II(d)(4) of this proposal would require Financial Institutions to approve in advance all written marketing materials used by Advisers after determining that such materials provide a balanced description of the risks and features of the annuity contracts to be recommended.

Second, Advisers must be required to provide the transaction disclosure required by Section III(a) of the exemption and orally review the annuity-specific information required in Section III(a)(1) with the Retirement Investor, as discussed below. These marketing and disclosure conditions address the Department's objective that Advisers and Financial Institutions relying on the exemption should describe recommended annuity contracts fully and fairly, and that the Retirement Investor must be made aware of aspects of the annuity contract that could impact the amounts ultimately paid to the Retirement Investor.

New proposed Section II(d)(7) sets forth requirements that would govern the compensation of the Adviser and sub-intermediary. The applicants described two broad approaches to paying compensation, and Section II(d)(7) permits both. Under the first approach, all compensation to be paid to the Adviser or sub-intermediary with respect to the purchase of an annuity contract pursuant to the exemption must be paid to the Adviser or sub-intermediary exclusively by the insurance intermediary. Under this approach, the intermediary would contract with insurance companies to receive the entire commission itself, and then, in turn, would pay an Adviser and/or any sub-intermediary a portion of the commission.

Under the second approach, Advisers or sub-intermediaries could receive commissions from insurance companies for the sale of annuities to Retirement Investors provided that the commission structure was approved in advance by the insurance intermediary and all forms of compensation other than commissions, whether cash or non-

monetary, are paid to the Adviser or sub-intermediary exclusively by the insurance intermediary. In this approach, insurance companies can continue the practice of paying commissions directly to agents, with an override payment going to the intermediary.

Under the proposal, the insurance intermediary may elect either compensation approach or some combination of the two. The proposal offers this flexibility because different applicants had different preferences for accomplishing the same general result, that the insurance intermediaries take responsibility for Adviser compensation and other incentives. Some applicants preferred to take in all compensation from insurance companies in order to facilitate compliance with the exemption and avoid the potential for errors. Other applicants preferred the second approach, expressing the view that it would not require the establishment of new internal accounting procedures and the engagement of additional personnel.⁴⁰

A new proposed Section II(d)(8) would also require that Financial Institutions provide, and require Advisers to attend, annual training on compliance with the exemption, conducted by a person who has appropriate technical training and proficiency with ERISA and the Code. The training must, at a minimum, cover the policies and procedures, the Impartial Conduct Standards, material conflicts of interest, ERISA and Code compliance (including applicable fiduciary duties and the prohibited

⁴⁰ Several applicants indicated an interest in offering Advisers product-neutral incentives based solely on levels of sales activity. If this exemption is granted, entities relying on it would be subject to Section II(d)(3), under which Financial Institution must prohibit the use of quotas, appraisals, performance or personnel actions, bonuses, contests, special awards, differential compensation or other actions or incentives that are intended or would reasonably be expected to cause Advisers to make recommendations that are not in the best interest of the Retirement Investor. The extent to which such incentive programs satisfy the requirements of Section II(d) of the exemption (or the Best Interest Contract Exemption) would be based on all the factors surrounding the incentive programs. The Department has provided guidance on related issues in the context of compensation grids that escalate based on sales volume. See *FAQs about Conflict of Interest Rules and Exemptions, Part I, FAQ9*, <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/coi-rules-and-exemptions-part-1.pdf>. These principles would apply equally to Financial Institutions under this proposed exemption, if granted. In particular, the Department cautions against compensation and other incentives that are disproportionate and can undermine the best interest standard and create misaligned incentives for Advisers to make recommendations based on their own financial interest, rather than the customer's interest in sound advice.

transaction provisions), ethical conduct, and the consequences for not complying with the conditions of this exemption (including any loss of exemptive relief provided herein). The Department notes that a number of the applicants emphasized the importance of training. The Department agrees and emphasizes that Advisers must be trained on important areas that are key to understanding their duty to Retirement Investors under the exemption and that are not likely covered by state insurance laws.

Sections II(e), (f) and (g)

Section II(e) requires the Financial Institution to disclose information about its services and applicable fees and compensation. Section II(e) is generally unchanged from the Best Interest Contract Exemption, although some of the provisions were revised in minor ways to reflect the fact that this proposed exemption is limited to Fixed Annuity Contracts.

Like the Best Interest Contract Exemption, Section II(e)(7) of this proposal would require the Financial Institution to disclose whether or not the Adviser and Financial Institution will monitor the Retirement Investor's annuity contract and alert the Retirement Investor to any recommended change to the contract, and, if monitoring, the frequency with which the monitoring will occur and the reasons for which the Retirement Investor will be alerted. Financial Institutions and their Advisers should not disclaim responsibility for monitoring if they will receive ongoing compensation justified in whole or in part based on the provision of such monitoring services.

Section II(f) generally provides that the exemption is unavailable if the contract includes exculpatory provisions or provisions waiving the rights and remedies of the plan, IRA or Retirement Investor, including their right to participate in a class action in court. The contract may, however, provide for binding arbitration of individual claims, and may waive contractual rights to punitive damages or rescission to the extent permitted by governing law. Pursuant to Section II(g) of the exemption, advice to Retirement Investors regarding ERISA plans does not have to be subject to a written contract, but Advisers and Financial Institutions must comply with the substantive standards established in Section II(b)–(e) to avoid liability for a non-exempt prohibited transaction. These conditions are unchanged from the Best Interest Contract Exemption.

Section II(h) of the Best Interest Contract Exemption established streamlined conditions for “level fee fiduciaries” defined in section VIII(h) of that exemption. Under that definition, a Financial Institution and Adviser can be level fee fiduciaries if the only fee received by them and their affiliates is a “level fee” that is disclosed in advance to the Retirement Investor. A “level fee” is defined as a fee or compensation that is provided as a fixed percentage of the value of the assets or a set fee that does not vary with the particular investment recommended, rather than a commission or other transaction-based fee.

This proposal, however, does not include provisions for “level fee fiduciaries.” Although some of the applicants acknowledged they would level commissions across product categories, the mere leveling of commissions would not cause these Advisers and Financial Institutions to be “level fee fiduciaries” as defined in the Best Interest Contract Exemption because each purchase of a fixed annuity by a Retirement Investor would initiate the payment of a commission based on that particular transaction. The Department seeks comment on this aspect of the proposal. Are there business models in existence for the recommendation and sale of Fixed Annuity Contracts that would satisfy the level fee provisions of the Best Interest Contract Exemption, as described above?⁴¹

Section III

Section III proposes certain disclosure requirements, in addition to the disclosures in Section II(e) of the exemption. Section III(a)'s provisions on “transaction disclosure” generally require the disclosure of material conflicts of interest and basic information relating to those conflicts and the advisory relationship. In this respect, the proposal mirrors the Best Interest Contract Exemption.

In addition, the transaction disclosure in this proposal has an annuity-specific disclosure requirement that would apply to recommendations of all Fixed Annuity Contracts. A new proposed Section III(a)(1) would require the Financial Institution to provide a transaction disclosure in accordance

with the most recent Annuity Disclosure Model Regulation published by the National Association of Insurance Commissioners (NAIC) or its successor.⁴² Broadly, the 2015 Annuity Disclosure Model Regulation requires the disclosure of information regarding the contract, including, among other items: (i) Value reductions caused by withdrawals or surrenders; (ii) the guaranteed and non-guaranteed elements of the Fixed Annuity Contract and their limitations, including, for fixed indexed annuities, the elements used to determine the index-based interest, such as the participation rates, caps or spreads, and an explanation of how they operate; (iii) an explanation of the initial crediting rate, or for fixed annuities, an explanation of how the index-based interest is determined; (iv) available periodic income options; (v) how values in the annuity contract can be accessed; (vi) the death benefit, if available; (vii) a summary of the federal tax status; (viii) the impact of any riders; and (ix) a list of charges and fees and how they apply.

Under the proposal, both the Adviser and the Retirement Investor must sign the disclosure after the Adviser orally reviews the information. The aim of this disclosure is to ensure that Retirement Investors are informed of the risks and features of annuity products prior to entering into the annuity contract. This disclosure would be required prior to the transmittal of the annuity application to the insurance company and would be required to be made in connection with any recommendations to make additional deposits into the contract. The Department understands that in some cases, insurance companies currently provide an advance disclosure document, commonly referred to as a “statement of understanding.” This condition of the exemption would be satisfied if the required information is provided in a “statement of understanding” in accordance with the applicable time frames specified in the condition. So long as the disclosure is delivered in a document that is distinct from the annuity contract, whether through a “statement of understanding” or otherwise the disclosure will satisfy the condition.

The Department requests comment on the proposed disclosure condition. Does the Annuity Disclosure Model Regulation require the information commenters believe is appropriate and necessary in transactions involving

⁴¹ Similarly, provisions applicable to “bank networking arrangements” are not included in this proposal, although they are in the Best Interest Contract Exemption. See Best Interest Contract Exemption, sections II(i) and VIII(c). Bank networking arrangements are defined to involve only banks or similar financial institutions, or savings associations and are therefore considered inapplicable to insurance intermediaries.

⁴² Annuity Disclosure Model Regulation, National Association of Insurance Commissioners (2015), available at <http://www.naic.org/store/free/MDL-245.pdf>.

Fixed Annuity Contracts sold pursuant to the exemption? Should the final exemption require disclosure of any additional information? In particular, with respect to fixed indexed annuity contracts, should the exemption require an illustration designed to convey the difference between the performance of the applicable index or indices and the amount credited to the customer's annuity, in light of the indexing features such as the participation rate; any spread, margin or asset fees; interest rate caps or floors; and the recognition of dividends. For example, should the exemption require that Financial Institutions provide a chart illustrating prior annual returns of an index for a certain number of years compared to the amounts that would have been credited annually under the terms of the indexed annuity contract? If commenters believe such a disclosure would be desirable, the Department requests comment on how it should be operationalized.

Section III(b) requires web-based disclosure that is intended to provide information about the Financial Institutions' arrangements with product manufacturers and other parties for Third Party Payments in connection with specific investments or classes of investments that are recommended to Retirement Investors, a description of the Financial Institution's business model and its compensation and incentive arrangements with Advisers and a copy of the Financial Institution's most recent audited financial statements as required pursuant to Section VIII(d)(2). Other than the disclosure of the audited financial statements, this provision is generally otherwise unchanged from the Best Interest Contract Exemption, except that certain provisions are revised in minor ways to account for the fact that the exemption will provide relief only for Fixed Annuity Contracts.

The Department requests comment on the proposed requirement to maintain a copy of the Financial Institution's most recent audited financial statements on the Web site.

Section IV

Section IV of the proposal relates to Financial Institutions that limit Advisers' investment recommendations, in whole or in part, based on whether the investments are Proprietary Products (as defined in Section VIII(j)) or to investments that generate Third Party Payments (as defined in Section VIII(n)). For purposes of this proposal, Section IV would apply to all Financial Institutions relying on the exemption because insurance intermediaries sell only investments that generate Third

Party Payments (from the insurance company). Among other things, Section IV requires Financial Institutions to document the limitations they place on their Advisers' investment recommendations, the material conflicts of interest associated with proprietary or third party arrangements, and the services that will be provided both to Retirement Investors as well as third parties in exchange for payments. Such Financial Institutions must then reasonably conclude that the limitations will not cause the Financial Institution or its Advisers to receive compensation in excess of reasonable compensation, and, after consideration of their policies and procedures, reasonably determine that the limitations and associated conflicts of interest will not cause the Financial Institution or its Advisers to recommend imprudent investments. Financial Institutions must document the bases for their conclusions in these respects and retain the documentation pursuant to the recordkeeping requirements of the exemption, for examination upon request by the Department and other parties set forth in that section.⁴³

Sections V, VI and VII

Section V of the proposed exemption would establish record retention and disclosure conditions that a Financial Institution must satisfy for the exemption to be available for compensation received in connection with recommended transactions. This provision is unchanged from the Best Interest Contract Exemption.

Sections VI and VII propose supplemental exemptions. Section VI would apply to certain prohibited transactions commonly associated with annuity purchases but which are not covered by Section I. Section I permits Advisers and Financial Institutions to receive compensation that would otherwise be prohibited by the self-dealing and conflicts of interest provisions of ERISA section 406(a)(1)(D) and 406(b), and Code section 4975(c)(1)(D)–(F). However, Section I does not extend to any other prohibited transaction sections of ERISA and the Code. ERISA section 406(a) and Code section 4975(c)(1)(A)–(D) contain additional prohibitions on certain specific transactions between plans and IRAs and “parties in interest” and “disqualified persons,” including service providers. These additional prohibited transactions include: (i) The purchase of a Fixed Annuity Contract by a plan/IRA from a party in interest/disqualified person, and (ii) the transfer

of plan/IRA assets to a party in interest/disqualified person. These prohibited transactions are subject to excise tax and personal liability for the fiduciary.

Section VII proposes an exemption for pre-existing transactions involving Fixed Annuity Contracts. The exemption permits continued receipt of compensation based on transactions involving Fixed Annuity Contracts that occurred prior to the Applicability Date, as defined in Section VII(a), as well as the receipt of compensation for recommendations to continue to adhere to a systematic purchase program established before the Applicability Date. In this case, the Department anticipates that a systematic purchase program would involve a program in which a Retirement Investor would make regular, pre-scheduled contributions to an annuity contract; however, the Department requests comment on whether such relief is necessary or appropriate. The exemption also explicitly covers compensation received as a result of a recommendation to hold an annuity contract that was purchased prior to the Applicability Date but would not cover recommendations to exchange an annuity for another annuity. In addition, a few references to securities that are found in the Best Interest Contract Exemption were deleted from this exemption because it would not provide relief for securities transactions.

This preamble discussion focused on conditions in this proposal that differ from the Best Interest Contract Exemption. The preamble to the Best Interest Contract Exemption includes a lengthy and in-depth discussion of the remaining conditions, which is incorporated into this preamble by reference. Because of the significant length of that discussion, the Department did not repeat it in this document, but rather directs parties to the Best Interest Contract Exemption preamble for a more complete description of the scope, definitional terms, and conditions of the exemption.⁴⁴

Transition Relief

Section IX of the proposal provides for a transition period, from April 10, 2017, to August 15, 2018, under which fewer conditions would apply. During the transition period, the Financial Institution and its Advisers would be required to satisfy the conditions of Section IX(d) of the proposal. Prior to receiving compensation in reliance on the exemption, Financial Institutions would be required under Section IX(d)

⁴³ See Section IV(b)(3).

⁴⁴ 81 FR 21002 (April 8, 2016).

to notify the Department of their intention to rely on the exemption and make a specific representation to the Department regarding their active engagement in creating systems and safeguards to satisfy the conditions applicable to the relief in Section I, following the transition period. The proposed required representation is: “[Name of Financial Institution] is presently taking steps to put in place the systems necessary to comply with Section I of the Best Interest Contract Exemption for Insurance Intermediaries, and fully intends to comply with all applicable conditions for such relief after the expiration of the transition period.” The Department proposed a transition period to give Financial Institutions under the proposed exemption time to comply with all the exemption’s conditions, and the Department anticipates that parties relying on the transition period should be developing an approach to full compliance during the transition period.

During the transition period, the Adviser and Financial Institution must comply with the Impartial Conduct Standards. Additionally, the Financial Institution would be required to comply with applicable disclosure obligations under state insurance law with respect to the sale of the Fixed Annuity Contract, and certain additional disclosures would be required, including an acknowledgment of the Adviser’s and Financial Institution’s fiduciary status; a description of their material conflicts of interest; and a disclosure of whether they offer proprietary products or products that generate third party payments and the extent to which they limit investment recommendations on those bases. The Financial Institution would have to approve all written marketing materials used by Advisers, as described in Section II(d)(4). The Financial Institution would have to designate a person responsible for addressing material conflicts of interest and monitoring Advisers’ adherence to the Impartial Conduct Standards, and such person would be required to approve, in writing, recommended annuity applications involving Retirement Investors prior to transmitting them to the insurance company. Finally, the Financial Institution would have to comply with the recordkeeping requirements of Section V(b) and (c).

It is proposed that, starting on August 16, 2018, parties intending to rely on the exemption must comply with all of the applicable conditions in Sections II–V.

No Relief Proposed From ERISA Section 406(a)(1)(C) or Code Section 4975(c)(1)(C) for the Provision of Services

This proposed exemption would not provide relief from a transaction prohibited by ERISA section 406(a)(1)(C), or from the taxes imposed by Code section 4975(a) and (b) by reason of Code section 4975(c)(1)(C), regarding the furnishing of goods, services or facilities between a plan and a party in interest. The provision of investment advice to a plan under a contract with a plan fiduciary is a service to the plan and compliance with this exemption will not relieve an Adviser or Financial Institution of the need to comply with ERISA section 408(b)(2), Code section 4975(d)(2), and applicable regulations thereunder.

Regulatory Impact Analysis

Executive Order 12866 and 13563 Statement

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing and streamlining rules, and of promoting flexibility. It also requires federal agencies to develop a plan under which the agencies will periodically review their existing significant regulations to make the agencies’ regulatory programs more effective or less burdensome in achieving their regulatory objectives.

Under Executive Order 12866, “significant” regulatory actions are subject to the requirements of the Executive Order and review by the OMB. Section 3(f) of Executive Order 12866, defines a “significant regulatory action” as an action that is likely to result in a rule (1) having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as “economically significant” regulatory actions); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the

rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, OMB has tentatively determined that this proposed action is economically significant within the meaning of section 3(f)(1) of the Executive Order. Accordingly, OMB has reviewed the proposed prohibited transaction class exemption and the Department provides the following assessment of its impact.

Background of Proposed Exemption

As discussed earlier in this preamble, the prohibited transaction rules of ERISA and the Code prohibit employee benefit plan and individual retirement account (IRA) fiduciaries from receiving indirect or variable compensation as a result of their investment advice to the plans and IRAs. The exemption proposed in this document would allow certain insurance intermediaries, and the insurance agents and insurance companies with whom they contract, to receive compensation in connection with certain fixed annuity transactions that may otherwise give rise to prohibited transactions as a result of the provision of investment advice to plan participants and beneficiaries, IRA owners and certain plan fiduciaries. The proposed class exemption includes protective conditions, similar to those contained in the Department’s Best Interest Contract Exemption (PTE 2016–01) granted on April 8, 2016,⁴⁵ that are designed to safeguard the interests of plans, participants and beneficiaries, and IRA investors and ensure that they receive investment advice that is in their best interest.

The Best Interest Contract Exemption is available only to certain Financial Institutions that are subject to well-established regulatory conditions and oversight, namely banks, investment advisers registered under the Investment Advisers Act of 1940 or state law, broker-dealers, and insurance companies. However, the exemption provides a mechanism that would make it more broadly available to other entities that are described in the definition of Financial Institution in an individual prohibited transaction exemption providing relief under the same conditions as in the Best Interest Contract Exemption. Thus, if an individual exemption is granted, other entities that satisfy the applicable

⁴⁵ 81 FR 21002 (April 8, 2016) as corrected at 81 FR 44773 (July 11, 2016).

conditions could rely on the Best Interest Contract Exemption.⁴⁶

In response to this provision, the Department received 22 individual exemption applications from insurance intermediaries that work with independent insurance agents to sell fixed annuity products (“applicants”). The applicants describe themselves as “independent marketing organizations,” “insurance marketing organizations” and “field marketing organizations” among other names. Collectively, the Department refers to the applicants and similar entities as “IMOs” in this analysis. The applicants sought individual exemptions under the same conditions as the Best Interest Contract Exemption, but with a new definition of “Financial Institution” incorporating insurance intermediaries.

Because of the large number and similar characteristics of the applicants, the Department decided that instead of utilizing the individual exemption process described in the Best Interest Contract Exemption, it would propose, on its own motion, a class exemption for IMOs based on the facts and representations provided in the individual exemption applications received by the Department. As discussed more fully below, the Department believes this is the most efficient way to provide relief to IMOs from the prohibited transaction rules of ERISA and the Code so long as they meet the protective conditions of the exemption that would safeguard the interests of affected plans, participants

and beneficiaries, and IRA owners. Accordingly, the Department today is proposing a class exemption that would allow IMOs and associated independent insurance agents to continue to recommend fixed annuities in the Retirement Investor marketplace and receive commissions and other variable compensation.

Background Regarding Fixed-Indexed Annuities and IMOs

*Fixed-Indexed Annuities (FIA) and Their Distribution Channel*⁴⁷

As discussed in detail in section 3.2 of the Regulatory Impact Analysis for the Regulation,⁴⁸ unlike fixed rate annuities where an insurer agrees to credit no less than a specified rate of interest during the time that the account value is growing, fixed-indexed annuities (FIAs) are annuity contracts whose return is based on the performance of a specified market index. Traditionally, common indexes used in FIAs are equity indexes such as the S&P 500 or Dow Jones Industrial Average. Although the S&P 500 is still the most often used index, various alternative indexes—including gold and a hybrid derived from one or more other indexes—have gained market share.⁴⁹

Insurers generally guarantee FIA contract holders at least a zero return. However, the actual return on a FIA is not determined until the end of the crediting period and is based on the performance of the index or other external reference.

Similar to variable annuities, the returns of fixed-indexed annuities can vary widely, which results in a risk to investors. Furthermore, insurers generally reserve rights to change participation rates, interest caps, and fees, which can limit the investor's exposure to the upside of the market and effectively transfer investment risks from insurers to investors.

In 2015, FIA sales totaled a record high \$54.5 billion, which represents a 13% increase from sales of \$48.2 billion in 2014.⁵⁰ This upward trend in FIA sales continued in 2016. In the first-half of 2016, FIA sales increased by 32% to \$31.9 billion compared to the same period in 2015.⁵¹ FIA sales are projected to exceed \$64 billion by the end of 2016 according to LIMRA Secure Retirement Institute.⁵²

Table 1 shows the shares of FIA sales by distribution channel for 2008–2015. In 2015, approximately 63% of FIAs, \$34.1 billion, were sold through the independent agent distribution channel.⁵³ FIA sales through banks and broker-dealers (BDs) have been trending upward over time. In 2008, only 4% of FIAs were sold through banks and 2% were sold through independent BDs. By 2015, FIA sales by banks had steadily grown to 16% and sales by independent BDs had also grown to 12% of total FIA sales. In contrast, the share of FIA sales by independent agents has declined. For example, in 2008, 88% of FIAs were sold by independent agents; however by 2015 their share of FIA sales had decreased to 63%.

TABLE 1—SHARE OF FIXED INDEXED ANNUITY SALES BY DISTRIBUTION CHANNEL (%) 2008–2015

| | 2008 (%) | 2009 (%) | 2010 (%) | 2011 (%) | 2012 (%) | 2013 (%) | 2014 (%) | 2015 (%) |
|-----------------------------|----------|----------|----------|----------|----------|----------|----------|----------|
| Independent Agents | 88 | 84 | 85 | 86 | 81 | 77 | 66 | 63 |
| Banks | 4 | 7 | 7 | 6 | 9 | 13 | 14 | 16 |
| Independent BD | 2 | 3 | 2 | 2 | 3 | 5 | 13 | 12 |
| Career Agents | 6 | 6 | 6 | 5 | 6 | 4 | 5 | 6 |
| Full Service National BD .. | 0 | 0 | 0 | 0 | 1 | 1 | 2 | 3 |
| Total | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 |

Source: LIMRA Individual Annuity Yearbook 2008–2015.

⁴⁶ In the preamble to the Best Interest Contract Exemption, the Department stated that “[i]f parties wish to expand the definition of Financial Institution to include marketing intermediaries or other entities, they can submit an application to the Department for an individual exemption, with information regarding their role in the distribution of financial products, the regulatory oversight of such entities, and their ability to effectively

supervise individual [a]dvisers’ compliance with the terms of this exemption. See 81 FR at 21067.

⁴⁷ The statistics presented here are for all FIAs, and not just FIAs sold to or held in IRAs.

⁴⁸ The RIA is available at www.dol.gov/ebsa.

⁴⁹ LIMRA U.S. Individual Annuity Yearbook—2015.

⁵⁰ LIMRA U.S. Individual Annuity Sales—Fixed annuity breakout, 2015 Year-end Results http://www.limra.com/uploadedFiles/limra.com/LIMRA_

Root/Posts/PR/_Media/PDFs/2015-Top-20-Fixed-Breakout.pdf.

⁵¹ LifeHealthPro Editors, August 16, 2016, “Fixed indexed annuities break quarterly sales record” Available at <http://www.lifehealthpro.com/2016/08/16/fixed-indexed-annuities-break-quarterly-sales-reco?slreturn=1476799732>.

⁵² LIMRA Individual Annuity Yearbook 2015.

⁵³ DOL’s own calculations based on LIMRA U.S. Individual Annuity Yearbook 2014.

Role of IMOs in Distributing Insurance Products and Market Structure

As discussed earlier in this preamble, the main function of IMOs is to market, distribute and wholesale various insurance products.⁵⁴ This intermediary structure is appealing to both insurance carriers (insurers) and independent insurance producers (insurance agents) because it allows insurers to reduce their overhead costs while facilitating the sale of the products by independent insurance agents, as opposed to their captive insurance agent counterparts.⁵⁵

There is no centralized database containing information identifying all existing IMOs in the U.S., because IMOs are licensed as insurance agents or agencies in each state where they operate. Therefore, it is difficult to reliably estimate how many IMOs currently exist in the U.S. Some evidence indicates that the number of IMOs could be in the hundreds,⁵⁶ or, more specifically, as many as 350.⁵⁷ Regardless of the total number, one industry observer reported that the top 20 IMOs conduct the lion's share of the business.⁵⁸ Many large IMOs, such as Annexus, Legacy Marketing Group and Market Synergy Group act as intermediaries between insurers and multiple small IMOs, and therefore, are referred to as Super-IMOs, or IMO aggregators. One media report additionally identifies M&O Marketing, InsurMark and Advisors Excel as other large IMOs.⁵⁹ In 2015, Annexus alone reported approximately \$4 billion in FIA sales representing approximately 7% of total FIA sales⁶⁰ and comprising

a network of 17 IMOs. Legacy Marketing Group, Inc. contracted with approximately 200 IMOs, and actively conducts business with 50 to 60.⁶¹ Market Synergy reported \$15 billion in fixed-indexed sales collectively and consisted of 11 sub-IMOs.⁶² This information suggests that the IMO market has a complex hierarchical structure.

*Common Characteristics of IMO Individual Exemption Applicants*⁶³

As discussed earlier in this preamble, the Department has studied the characteristics of IMOs that applied for the individual exemptions. The applications indicate that most IMOs applicants have been in business for 25 to 40 years and operate in all 50 states. For example, one IMO applicant has over 600 offices across 50 states.⁶⁴ IMO applicants tend to be large: Almost all IMO applicants were identified as Super-IMOs or larger IMOs by industry trade press. Of those applicant IMOs that disclosed their sales information, all indicated sales of more than \$1.5 billion in 2015, and two IMOs reported FIA sales of from \$4–5 billion in 2015.⁶⁵ Other IMOs reported from \$2–3 billion of annual fixed annuity sales. These data suggest that IMO applicants generate FIA sales equivalent to the FIA sales of some insurance companies. In 2015, FIA sales of the top 10 FIA issuers by sales ranged from \$8.7 billion (Allianz Life of North America) to \$1.8 billion (Security Benefit Life).⁶⁶

Most applicant IMOs partner with between 20 and 75 insurers. One IMO indicated that it conducts business with nine out of the top 10 insurers offering

FIA's.⁶⁷ Many of the applicants state that they have direct contractual relationships with the majority of the insurers for whom they distribute fixed annuities. Frequently, these direct contractual relationships include recognition that the applicants are contractually responsible for the oversight of agents and sub-IMOs. This oversight is accomplished through applying the top-level IMO's use of its compliance structure and other business and administrative tools. The applicants use their compliance structure to directly oversee agents or they use those same tools to assist sub-IMOs in the distribution of fixed annuities and the oversight of their agents.

Sub-IMOs have contractual relationships with the insurers for whom they distribute fixed annuities, and they also have contractual relationships with top-level IMOs. Top-level IMOs generally provide their related sub-IMOs with distribution and other support services. Top-level IMOs often assist these sub-IMOs in accessing a wide variety of insurance products. Sub-IMOs contract with top-level IMOs to obtain this access, and these services allow some sub-IMOs to focus on the training and support of their agents.

Some applicants, in addition to describing themselves as top-level IMOs, also represented that they are affiliated with large insurers. One of these applicants, in turn, wholly owns numerous sub-IMOs. Despite the differences in the ownership structure, these applicants represent that they, like the other top-level IMOs, assist in the distribution of fixed annuities, both for their affiliates and for other insurers, and provide valuable business and administrative assistance to sub-IMOs and agents.

The number of smaller IMOs or sub-IMOs that larger IMOs conduct business with varies widely, but most applicant IMOs that disclosed this information in their applications state that they conduct business with between 7 and 35 sub-IMOs. Two IMO applicants indicate that they work with over 100 other IMOs.⁶⁸ However, not all affiliated sub-

⁵⁴ Joe Simonds, "Warning: Why FMOs will be extinct soon," LifeHealthPro (Dec. 5, 2012); available at: <http://www.lifehealthpro.com/2012/12/05/warning-why-fmos-will-be-extinct-soon>.

⁵⁵ Ibid.

⁵⁶ Cyril Tuohy, June 10, 2016, Insurancenewsnet.com "Insurance Marketing Organizations Feel The DOL's Freezer Burn" Available at <http://insurancenewsnet.com/inarticle/wholesalers-mull-future>.

⁵⁷ Warren Hersch, August 12, 2016, LifeHealthPro.com "Unchartered waters: Why this IMO is seeking FI status under DOL rule." Available at <http://www.lifehealthpro.com/2016/08/12/unchartered-waters-why-this-imo-is-seeking-fi-stat> Arthur Postal, August 10, 2016 LifeHealthPro.com "IMOs take on enhanced sales role under the new DOL rule" available at <http://www.lifehealthpro.com/2016/08/10/imos-take-on-enhanced-sales-role-under-the-new-dol?ref=related-embedded>.

⁵⁸ Cyril Tuohy, June 10, 2016, Insurancenewsnet.com "Insurance Marketing Organizations Feel The DOL's Freezer Burn" Available at <http://insurancenewsnet.com/inarticle/wholesalers-mull-future>.

⁵⁹ Cyril Tuohy, June 10, 2016, Insurancenewsnet.com "Insurance Marketing Organizations Feel The DOL's Freezer Burn" Available at <http://insurancenewsnet.com/inarticle/wholesalers-mull-future>.

⁶⁰ Greg Iacurci, June 23, 2016, Investment News, "Indexed annuity distributors weigh launching B-

Ds due to DOL fiduciary rule" available at <http://www.investmentnews.com/article/20160623/FREE/160629957/indexed-annuity-distributors-weigh-launching-b-ds-due-to-dol>.

⁶¹ Warren Hersch, September 16, 2016, "Not ready to become a DOL compliance FI? Go partner with one" Available at <http://www.lifehealthpro.com/2016/09/16/not-ready-to-become-a-dol-compliant-fi-go-partner?t=diversity-market>.

⁶² See Market Synergy Preliminary Injunction Memo filed June 17, 2016, in the United States District Court for the District of Kansas.

⁶³ In some cases, the information presented here is supported by sources beyond the applications, but in all cases the information is consistent with information provided in the applications.

⁶⁴ Individual Exemption Application of Advisors Excel.

⁶⁵ Advisors Excel and Annexus reported \$5 billion and \$4 billion sales in FIAs respectfully according to the their individual exemption applications and Annexus reported \$4 billion sales in the article by Greg Iacurci, June 23, 2016, Investment News, "Indexed Annuity Distributors Weigh Launching B-Ds Due to DOL Fiduciary Rule" available at <http://www.investmentnews.com/article/20160623/FREE/160629957/indexed-annuity-distributors-weigh-launching-b-ds-due-to-dol>.

⁶⁶ LIMRA Individual Annuity Yearbook 2015.

⁶⁷ Individual Exemption Application submitted by Advisors Excel.

⁶⁸ Warren Hersch, September 7, 2016, LifeHealthPro, "Eye on the Future: Futurity First Readies Advisors for DOL Rule" Available at <http://www.lifehealthpro.com/2016/09/07/eye-on-the-future-futurity-first-readies-advisors>. Warren Hersch, September 16, 2016, "Not Ready to Become a DOL Compliance FI? Go partner with One" Available at <http://www.lifehealthpro.com/2016/09/16/not-ready-to-become-a-dol-compliant-fi-go-partner?t=diversity-market>.

IMOs generate sales on a regular basis.⁶⁹ Several IMO applicants indicate that they work with approximately 2,000 to 4,000 agents and others report that they have approximately 120,000 to 200,000 affiliated agents nationwide. However, according to some IMO applicants, only approximately 20% to 30% of the large number of contracted agents generates sales through them on a regular basis.⁷⁰ These independent agents can work with multiple IMOs. However, two IMOs indicated that they work with an exclusive group of affiliated agents or employee agents that are selected after undergoing a rigorous screening process.⁷¹ The applications indicate that most IMOs currently not maintaining exclusive business relationships with independent agents would require independent agents to exclusively process FIA sales through them if the proposed exemption were granted.

Several IMO applicants are affiliated with BDs and/or registered investment advisers (RIAs). Moreover, some of the IMOs that currently are not affiliated with BDs or RIAs reported that they are developing a BD,⁷² or have a subsidiary that is in the process of becoming a RIA.⁷³ One IMO stated that it has partnered with nearly 20 BDs and provided extensive training and mentoring to registered representatives regarding selling FIAs.⁷⁴ Two IMOs also stated that they have an affiliated IT firm or proprietary technology platform that will help them comply with the exemption.

The applicants represented to the Department that they have experience in

a variety of areas that will contribute to their ability to satisfy the conditions of the Best Interest Contract Exemption. Some applicants pointed to direct experience providing oversight of independent agents for insurance law compliance, while some indicated that they planned to rely on affiliated RIAs and/or BD entities in developing systems to comply with the exemption. The cost of developing a new compliance platform often represents a large share of total compliance costs. Thus, if an IMO does not have to develop a new system, it would save costs significantly for itself and the insurance industry as a whole would save significant costs if other IMOs were similarly positioned. In addition, IMOs with affiliated BDs and/or RIAs can draw from the supervisory experience of BDs and RIAs regarding properly training, monitoring, and not inappropriately incentivizing agents and even share personnel with them. They also can use disclosure forms similar to their affiliated BDs and/or RIAs.

The applicants generally indicated they would maintain internal compliance departments and adopt supervisory structures to ensure compliance with the exemption. Several applicants pointed to technology that would be used in ensuring compliance. Some applicants indicated that insurance agents would be required to use their technology to ensure clients receive disclosures and a contract, where required. Agents would also be required to use the IMO's Web site services and maintain records centrally.

Some applicants additionally described how their sales practices would ensure best interest recommendations. A number of the applicants specifically proposed to require centralized approval of agent recommendations; in some cases, the recommendations would be reviewed by salaried employees of the IMO with additional credentials, such as Certified Financial Planners. One applicant indicated that internal review would include a comparison of the proposed product to other similar fixed indexed annuity products available in the marketplace to ensure it is appropriate for the purchaser, and that the analysis would include utilizing third-party benchmarking services and industry comparisons. Another applicant indicated that it would ensure that a RIA representative would work with insurance-only agents when a recommendation would involve the liquidation of securities to ensure that both state and federal securities laws are properly followed.

Some applicants additionally stated that their contracts with insurance agents would include certain specific requirements, including: Adherence to the IMO's policies and procedures with respect to advertising, market conduct and point of sale processes, transparency and documentation; provision of advice in accordance with practices developed by the IMO; and agreement that the agents will not accept any direct or indirect compensation from an insurance company, except as specifically approved by the IMO. A number of the applicants indicated that they would perform background checks and rigorous selection processes before working with agents and would require agents to receive ongoing training regarding compliance with the exemption.

A few of the applicants addressed product selection. These applicants indicated that agents making recommendations pursuant to the exemption would be limited to certain products and insurance companies. The applicants indicated there would be ongoing due diligence with respect to insurance companies and product offerings under the exemption.

Based on information contained in the submitted applications, some qualified and willing IMOs might be able to perform compliance responsibilities more cost effectively than some insurance companies. Many IMO applicants indicate that they have affiliated BDs or RIAs, and these IMOs have several advantages in managing compliance costs: They can utilize compliance platforms already developed and implemented for BDs and/or RIAs with some necessary adjustments. This would allow large IMOs to save some large start-up fixed costs to develop a new system.

The applications also indicate that some IMOs already have many of the capacities and much of the infrastructure in place that would be necessary to carry out compliance responsibilities required by the exemption, and thus might incur only relatively small, incremental costs to comply with the exemption conditions.

The Department cautions that although its careful review of individual exemption applications reveals that many applicant IMOs share the common characteristics discussed above, the Department is uncertain regarding the extent to which these characteristics can be generalized to the overall IMO market. The Department welcomes comments regarding whether these common characteristics can be extrapolated to the broader IMO market

⁶⁹ Warren Hersch, September 16, 2016, "Not Ready to become a DOL Compliance FI? Go Partner with One" Available at <http://www.lifehealthpro.com/2016/09/16/not-ready-to-become-a-dol-compliant-fi-go-partner?t=diversity-market>.

⁷⁰ Individual Exemption Applications of M&O Financial, Application of ECA Marketing and Warren Hersch, September 16, 2016, "Not Ready to Become a DOL Compliance FI? Go Partner with One" Available at <http://www.lifehealthpro.com/2016/09/16/not-ready-to-become-a-dol-compliant-fi-go-partner?t=diversity-market>.

⁷¹ Individual Exemption Application of Saybrus Partners, Inc. and Warren Hersch, August 12, 2016, LifeHealthPro.com "Unchartered Waters: Why This IMO is Seeking FI Status under DOL Rule." Available at <http://www.lifehealthpro.com/2016/08/12/unchartered-waters-why-this-imo-is-seeking-fi-stat>.

⁷² Greg Iacurci, June 23, 2016, Investment News, "Indexed Annuity Distributors Weigh Launching B-Ds Due to DOL Fiduciary Rule" available at <http://www.investmentnews.com/article/20160623/FREE/160629957/indexed-annuity-distributors-weigh-launching-b-ds-due-to-dol>.

⁷³ Cyril Tuohy, August 9, 2016, insurancenewsnet.com "AmeriLife Files for FI Status Under DOL Fiduciary Rule" Available at <http://insurancenewsnet.com/innarticle/amerilife-files-fi-status-dol-fiduciary-rule>.

⁷⁴ Individual Exemption Application of InsurMark.

or whether they are distinctive and unique to the IMO applicants.

Impact of Proposed Class Exemption

As discussed earlier in this preamble, IMOs are not included within the Financial Institution definition under the Best Interest Contract Exemption. Instead, the exemption provides a mechanism under which the definition can be expanded if an individual exemption is granted to another type of entity. In that event, the individual exemption would provide relief to the applicants identified in the exemption, but the definition of Financial Institution in the Best Interest Contract Exemption would be expanded so that other entities that satisfy the definition in the individual exemption could rely on the Best Interest Contract Exemption. The Department received 22 applications for individual exemptions from IMOs that work with independent insurance agents to sell fixed annuity products. Because of the large number of applications, the Department determined to propose, on its own motion, a class exemption for such intermediaries based on the facts and representations in the individual applications received by the Department.

The following discussion assesses the impact of this class exemption relative to the baseline associated with the aforementioned provision of the Best Interest Contract Exemption. Under this baseline scenario, the Department would have granted individual exemptions to one of more of the applicants. The specific contours of this baseline are necessarily hypothetical, because at this time the Department has neither granted nor proposed any such individual exemptions. For purposes of this assessment, the Department assumes that any such individual exemptions would have included all of the same conditions included in this class exemption, and made available the same exemptive relief to the same market participants. This assumption is reasonable insofar as at this time the Department has not reached a tentative finding with respect to any particular applicant that an exemption with fewer or different conditions would be beneficial to IRA investors and protective of their rights as is required before the Department grants an exemption.

Given this assumption that the scope and conditions of this class exemption are substantively the same as those associated with the appropriate baseline, it follows that the impact of this class exemption relative to the baseline is likely to be limited to the

procedural differences between the class and individual exemption procedures. With the exception of these procedural differences, under both the proposed class exemption and the baseline scenario, the same market participants would chiefly pursue the same courses of action and achieve the same results. However, notwithstanding the substantive equivalence of the proposed class exemption and the baseline, it is possible that some market participants would perceive substantive differences, and make different decisions with different results. The Department invites comments these or any other potential substantive impact of this proposed class exemption relative to the baseline scenario.

This proposed class exemption would extend to IMOs that satisfy its conditions relief that is similar to that for Financial Institutions under the Best Interest Contract Exemption. The Department anticipates that, like the Best Interest Contract Exemption, this proposed exemption will deliver benefits that justify its costs.⁷⁵

In issuing the Regulation and Best Interest Contract Exemption, the Department noted that compliance might be more burdensome for some industry segments than for others, that some insurers and some independent insurance agents might be among those needing to make more significant changes, and that this could impose some costs on affected Retirement Investors.

This proposed class exemption offers affected insurers, agents, and IMOs an alternative path to compliance that in some cases is likely to prove more economically efficient than existing paths. The applications that prompted this proposal support the premise that many IMOs have, or can affordably develop, the capacity to perform the functions required of Financial Institutions. In particular, some IMOs' positions as intermediaries between multiple insurers and multiple independent agents may be advantageous for purposes of mitigating agents' conflicts and ensuring that their recommendations are loyal to their customers' interests.

Under the proposed class exemption, market forces will favor migration of these functions to the entities that can

perform them most efficiently. To the extent that IMOs take advantage of relief under this proposed exemption to shoulder these responsibilities, insurers may be relieved of what would have been greater costs to perform the same functions. This would improve the efficiency of the market in which insurers, independent agents, and IMOs operate. Meanwhile, the conditions of this exemption aim to ensure that, like Financial Institutions under the Best Interest Contract Exemption, covered IMOs can be relied on to perform their role effectively. If IMOs and related independent agents sell their services and FIAs in efficiently competitive intermediate and consumer markets, then such efficiency would accrue mostly to Retirement Investors.

The Department believes that the proposed class exemption will be more beneficial than would the individual exemption approach that is contemplated under the relevant provision of the Best Interest Contract Exemption. The Department believes that as a practical matter, the same rules could be established via either approach. That is, an individual exemption issued pursuant to the relevant provision of the Best Interest Contract Exemption could be crafted to make the intended relief available to any IMO that satisfied the same conditions as those included in this proposed class exemption. The Department believes, however, that the proposed class exemption offers the less costly route to the desired result. The cost advantage arises not from any difference in ongoing compliance costs, which generally would be the same. Rather the Department anticipates that the availability of the class exemption will obviate the need for some or all current and potential future applicants to pursue to completion an application for an individual exemption,⁷⁶ and any attendant net procedural cost savings (relative to the baseline) would constitute benefits of this proposed class exemption. The Department invites comments on these potential net cost savings. In addition, although substantively the same as the baseline, by providing a single class exemption this proposal potentially will provide greater simplicity and clearer consistency, and a more clearly even playing field, than multiple individual exemptions might. Finally, relative to one or more individual exemptions, a class exemption may encourage more IMOs to accelerate their efforts to

⁷⁵ The Department provides a detailed discussion of the cost and benefits associated with the Best Interest Contract Exemption in its regulatory impact analysis for the Regulation and exemptions, which was published on the Department's Web site at the same time that the Regulation and exemptions were published in the **Federal Register** and is available at <https://www.dol.gov/ebsa/pdf/conflict-of-interest-ria.pdf>.

⁷⁶ The Department's individual exemption procedure is described in 29 CFR 2570.30 through 2570.52.

optimize their competitive market positions.

If the conditions of the exemption are satisfied, IMOs acting as Financial Institutions, and the independent agents and insurers they contract with, would be permitted to receive indirect and variable compensation in connection with recommendations of Fixed Annuity Contracts that would otherwise be prohibited as a result of the Regulation extending fiduciary status to many investment professionals who formerly were not treated as fiduciaries.⁷⁷ This would provide IMOs with flexibility to maintain their current business model in a cost-effective way, as was contemplated under the relevant provision of the Best Interest Contract Exemption. The applicants represent that the independent insurance agent model benefits consumers, because independent agents are able to offer a wider variety of products to satisfy consumers' goals. The class exemption would allow IMOs to serve as Financial Institutions, which will allow independent insurance agents to continue to recommend fixed annuities in the Retirement Investor marketplace under a single set of policies and procedures.

The Department expects that IMOs will determine whether to seek relief under this exemption's conditions based on their long-term strategic goals and will do so only if makes economic sense. IMOs that choose not to use the exemption, or that are unable to satisfy the conditions, may still play a role in the fixed annuity distribution channel by providing valuable compliance assistance and other services to insurance companies or other insurance intermediaries who act as Financial Institutions under the Best Interest Contract Exemption, or this exemption if granted, and receive compensation for their services.

The proposed class exemption would require IMOs to structure compensation received for transactions involving Fixed Annuity Contracts in a way that mitigates conflicts of interests and does not improperly incentivize independent agents to sell one product over another.⁷⁸ Furthermore, it requires

IMOs to satisfy some additional conditions that do not apply to Financial Institutions using the Best Interest Contract Exemption such as (i) conducting annual audits of financial statements, (ii) providing an annuity-specific disclosure to Retirement Investors, and (iii) obtaining fiduciary liability insurance coverage or setting aside sufficient reserves to cover potential liability exposure.⁷⁹

The Department considered the alternative of issuing the proposed class exemption without imposing additional conditions to those contained in the Best Interest Contract Exemption, but chose to propose these additional conditions to ensure that transactions involving recommendations for Retirement Investors to purchase FIAs that are sold by independent agents through IMOs occur only when they are in their clients' best interest. These protections respond to the Department's concern that IMOs are not subject to well-established regulatory conditions and oversight like those that apply to Financial Institutions eligible to act as Financial Institutions under the Best Interest Contract Exemption and concerns expressed by the SEC, FINRA, and North American Securities Administrators Administration regarding how FIAs have been designed and marketed. The conditions would provide additional protection to consumers to ensure that Retirement Investors are adequately protected from the deleterious effects of conflicts of interest. However, these additional conditions will impose some compliance burden on IMOs relying on the exemption. Due to data limitations, the Department only was able to quantify the incremental costs associated with additional annuity disclosure. The Department discusses the impact of these additional conditions below.

Obtain Fiduciary Liability Insurance or Set Aside Reserves: One of the

Insurance Agents" Available at <http://insurancene.wsnet.com/innarticle/fmo-proposes-finra-based-supervision-structure>.

⁷⁹ There are several other additional conditions that would apply, such as: (i) The IMO must approve written marketing materials used by Advisers (Section II(d)(4)); (ii) the IMO's compliance officer designated pursuant to Section II(d)(2) must approve recommended annuity applications prior to their submission to the insurance company (Section II(d)(5)); (iii) the IMO must provide, and require Advisers to attend, annual training on compliance with the exemption (Section II(d)(8)), and IMOs must meet the requirement of Section IV, because they limit product recommendations based on third-party payments. For purposes of this analysis, the Department has focused its discussion in the regulatory impact analysis on the conditions that it believes would have the most significant impact.

additional conditions requires IMOs to maintain fiduciary liability insurance, or cash, bonds, bank certificates of deposit, U.S. Treasury Obligations, or a combination of all of these, available to satisfy potential liability under ERISA or the Code as a result of this exemption. The aggregate amount of these items must equal at least 1% of the average annual amount of premium sales of Fixed Annuity Contract sales by the Financial Institution to Retirement Investors over the prior three fiscal years of the Financial Institution. For example, an IMO with average sales of \$2 billion could satisfy this condition by setting aside \$20 million. If valued at 7 percent (3 percent) net, the attendant opportunity cost for such an IMO would amount to \$1.4 million (\$600,000) in the first year. The aggregate opportunity cost would be proportional to the total sales of all IMOs pursuing this course, assuming a uniform valuation rate.

To the extent this condition is satisfied by insurance, the proposal states that the insurance must apply solely to actions brought by the Department of Labor, the Department of Treasury, the Pension Benefit Guaranty Corporation, Retirement Investors or plan fiduciaries (or their representatives) relating to Fixed Annuity Contract transactions, including but not limited to actions for failure to comply with the exemption or any contract entered into pursuant to the exemption, and it may not contain an exclusion for Fixed Annuity Contracts sold pursuant to the exemption. Any such insurance also may not have a deductible that exceeds 5% of the policy limits nor exclude coverage based on a self-insured retention or otherwise specify an amount that the Financial Institution must pay before a claim is covered by the fiduciary liability policy. To the extent this condition is satisfied by retaining assets, the assets must be unencumbered and not subject to security interests or other creditors.

This condition provides IMOs with the flexibility to either obtain fiduciary liability insurance or set aside sufficient assets to satisfy potential liabilities. The Department expects that IMOs will choose the option that makes the best sense for them economically. If insurance markets are efficient and loss ratios are not very high, it is likely that insurance will be more attractive, unless an IMO faces particularly high fiduciary risks. In addition, an IMO with a more profitable best use for cash is more likely to find insurance more attractive than a cash set-aside. A number of the applicants specifically suggested that they would obtain insurance to cover

⁷⁷ The proposed exemption would apply to commissions and other compensation received by an insurance agent, IMO insurance intermediary, insurance companies and any other affiliates and related entities, as a result of a plan's or IRA's purchase of Fixed Annuity Contracts.

⁷⁸ Cyril Tuohy, August 9, 2016, insurancene.wsnet.com "6 IMOs Apply for 'Financial Institution' Status Under DOL Rule," Available at <http://insurancene.wsnet.com/innarticle/six-imos-apply-for-dol-fi-status> Cyril Tuohy, August 17, 2016, insurancene.wsnet.com "Allianz FMO Proposes FINRA-Style Oversight of

potential liability under the exemption, although the approaches and suggested amounts varied. However, some applicants indicated uncertainty as to the current availability of insurance for liability under the exemption.

An upper bound on the costs of this provision an estimate is obtained by looking at the costs of using the set-aside reserve option. As discussed above, in 2015, approximately \$34.1 billion in total sales FIAs were sold through the independent agent distribution channel. If all sales in the independent agent distribution channel were through an IMO utilizing the exemption then one percent, or \$341 million, would have to be set aside as a reserve. The opportunity costs of this reserve using a return of 7 percent (3 percent) would be \$23.9 million (\$10.2 million) for one year. There are at least three reasons why this estimate is too high: not all sales through the independent agent channel would be made using this exemption, the estimate of the total sales includes not just FIAs sold to IRAs, but all FIA sales, and to the extent the insurance option is cheaper IMOs will use that less expensive option and costs will be lower.⁸⁰ The Department invites comments on these cost estimates.

This condition requiring IMOs to set aside cash or maintain insurance is likely to yield benefits for consumers. Set asides or insurance premiums that are paid out to compensate consumers for losses arising from fiduciary breaches will represent one, direct such benefit. In addition, the condition may deter fiduciary breaches. Some applicants indicated that they may pass on expenses attributable to this condition to advisers, particularly to advisers whose records or observed conduct indicate high fiduciary risk, or may step up efforts to screen advisers and end relationships with those deemed most risky. These steps by IMOs in turn could reinforce advisers' motivation to maintain high fiduciary standards.

The Department considered an alternative of requiring a fixed minimum amount of fiduciary liability insurance to be purchased and requiring individual Advisers to carry the insurance themselves. The Department, however, chose the alternative of basing the insurance coverage or reserve requirement on premiums, because it views this method as the most efficient way to ensure that Financial Institutions

have sufficient financial resources to satisfy any potential liabilities. The Department solicited comments on this approach and potential alternatives to the Department's chosen alternative earlier in this preamble.

Audited Financial Statements: In order to confirm that the IMO has sound business practices, the Department chose the alternative of requiring IMOs to have financial statements that are audited annually by an independent certified public accountant. In addition, the audited financial statements must be available on the IMO's Web site. The cost of such audits will depend on the degree to which IMOs currently maintain detailed, audit-ready records, and the extent and complexity of IMOs operations and records. The Department invites comments on these costs.

The Department understands that insurance companies submit their financial statements on a quarterly basis to the NAIC, which collects these data on behalf of state insurance commissioners.⁸¹ Unlike insurance companies; however, IMOs are generally not required to submit their financial statements to any regulatory authority. The Department does not believe IMOs will incur prohibitive costs to comply with the provision, because the condition was suggested by several applicants seeking individual exemptions. Some applicants indicated that periodic financial audits would provide reasonable assurance of the entity's financial health. The Department expects that requiring IMOs to conduct an annual audit of their financial statements, coupled with its disclosure on the Web site, will provide an opportunity for the Department and other interested persons to be alerted to any financial weaknesses or other items of concern with respect to the stability or solvency of the Financial Institution, or its ability to stand behind its commitments to Retirement Investors.

As an alternative to an audit of financial statements, one applicant suggested that the audit should relate to the intermediary's internal controls and procedures. The applicant noted that banks and trust companies are currently required to obtain these reports under SSAE 16 (formerly SAS 70), and that the applicant could work with its auditors to prepare a similar report, but suggested that such an approach would require additional transition relief as the accounting industry would have to agree on the appropriate data points for an internal controls audit for an

insurance intermediary and the resulting topics of the SSAE 16-like report. The Department did not propose this alternative, because there are no clear standards for such a compliance-based audit, and the Department believes it is most critical for financial statements to be audited to ensure that the financial viability of the IMO and its ability to meet its commitment to Retirement Investors can be determined and assessed.

Mitigate Adverse Incentives: Proposed Section II(d)(3) specifically addresses incentives to Advisers, and provides that the Financial Institution's policies and procedures would be required to prohibit the use of quotas, appraisals, or performance or personnel actions, bonuses, contests, special awards, differential compensation, or other actions or incentives if they are intended or would reasonably be expected to cause Advisers to make recommendations that are not in the best interest of the Retirement Investor. The condition applies regardless of the source of the incentive. Moreover, the Department understands that some independent agents work with more than one intermediary. As noted above, the IMO applicants indicated that they have the capability to mitigate the incentives with respect to multiple insurance companies. The Department views this as a critical safeguard of this proposed exemption. The proposed condition is intended to ensure that an Adviser's relationship with multiple insurance companies (or multiple insurance intermediaries) does not generate compensation or incentive structures that undermine the Adviser's provision of advice that is in Retirement Investors' best interest.

Proposed Section II(d)(3) does not specify the precise manner by which a Financial Institution must comply with the condition. The Department considered the alternative of requiring Financial Institutions to make their relationships with their Advisers exclusive with respect to the sale of Fixed Annuity Contracts to Retirement Investors. However, in order to provide maximum flexibility the Department chose not to require exclusivity in the proposal. Accordingly, a Financial Institution may take the alternative approach of contractually requiring an Adviser to provide information to the Financial Institution regarding all of the compensation and incentives provided by all of the other insurance companies and intermediaries through which the Adviser sells Fixed Annuity Contracts in which case the Financial Institution ultimately would be responsible for implementing the policies and

⁸⁰ The Department notes that these insurance costs discussed here are not a cost of this proposal but part of the baseline reflected in the Department's Regulatory Impact Analysis of the final rule.

⁸¹ NAIC Financial Statement Filing and Step through Guidance, Available at http://www.naic.org/industry_financial_filing.htm.

procedures to mitigate adverse incentives across all of the Advisers' incentive arrangements.

Annuity Specific Disclosure: Section III(a) of the proposed class exemption requires an annuity-specific disclosure in connection with recommendations of all Fixed Annuity Contracts. As stated, the disclosure applies to all Fixed Annuity Contracts; however, the elements of the disclosure are required to be made only to the extent applicable.

The objective of this disclosure is to ensure that Retirement Investors are informed of the risks and features of annuity products prior to entering into the annuity contract. While the information required to be disclosed could be available in the annuity contract or other document, the Department chose this alternative because it believes that the consumer will be better able to make an informed choice regarding whether to invest in the product if the features of the annuity contract are specifically highlighted in advance of the purchase in a separate, stand-alone written document. This disclosure would be required prior to the transmittal of the annuity application to the insurance company and would have to be made in connection with any recommendations to make additional deposits into the contract. The Department understands that in some cases, insurance companies currently provide an advance disclosure document, often referred to as a "statement of understanding." This condition of the exemption would be satisfied if the required information is provided in a statement of understanding or similar document in accordance with the applicable time frames specified in the condition. The Department provides an estimate regarding the costs associated with the annuity-specific disclosure in the "Paperwork Reduction Act" section below.

Premium Threshold: Finally, the proposed exemption would require IMOs to have transacted annual fixed annuity sales averaging at least \$1.5 billion in premiums over each of the three prior fiscal years. As discussed above, this threshold equates approximately to the sales of the top 20 insurance companies. Relative to the top insurers, in 2014, an IMO with \$1.5 billion sales in fixed annuities would have been 18th in sales, whereas in 2015, it would have been slightly below the top 20 in fixed annuity sales.

The Department chose the alternative of imposing this condition, to ensure that IMOs using the exemption are well-established entities possessing the financial stability and operational

capacity to implement the anti-conflict policies and procedures required by the exemption. This proposed condition aims to ensure that the IMO is in the position to mitigate compensation incentives across products, which is a critical safeguard of the proposed exemption.

The proposed \$1.5 billion threshold was based on the representations in the applications. Not all applicants provided this information, but the applicants that did generally indicated sales of this amount or more. In addition, almost all IMOs that applied for individual exemptions are identified in media reports as large IMOs or super-IMOs. Some IMO applicants reported \$4 billion to \$5 billion in FIA sales alone in 2015.⁸² Putting this into context, these sales are higher than FIA sales of all but 2 insurance companies.⁸³ In 2015, the insurance company that ranked 2nd in FIA sales reported \$6.8 billion, while the insurance company ranked 3rd reported \$3.7 billion in FIA sales.⁸⁴ Other IMO applicants reported more than \$2 billion in FIA sales in 2015.⁸⁵ This suggests that four IMOs seeking exemptions generated approximately 42% of FIA sales through the independent agent channel in 2015.⁸⁶

The Department believes that this dollar threshold covers IMOs most likely to make beneficial use of the exemption, because economies of scale are likely to yield advantages in efficiently carrying out compliance responsibilities. The largest share of compliance costs often is up-front fixed costs incurred to construct a compliance infrastructure. As the IMO gets larger, the burden of fixed costs can be spread out more widely.

Because the sales threshold is based on a three-year average, some year-to-year volatility in sales would not cause

IMOs to lose their eligibility for the exemption. Smoothing sales over three years provides IMOs with the degree of certainty and continuity that are necessary for IMOs to justify up-front expenditures to update compliance systems. However, if an exempted IMO falls slightly below this threshold, it may look for a way to boost sales volume, such as by acquiring another IMO or recruiting highly productive independent agents. Thus, in certain situations, this condition may accelerate mergers and acquisitions among IMOs. One applicant has reported that it already acquired three IMOs.⁸⁷ All of these additional conditions are designed to protect the interest of consumers who purchase annuity products through the IMO distribution channel.

These additional conditions could impose additional burdens on IMOs seeking exemptive relief that are not incurred by Financial Institutions seeking relief under the Best Interest Contract Exemption. However, with the exception of the annuity-specific disclosure, the Department does not have sufficient data to quantify the incremental costs associated with these conditions. Instead, the Department solicits public comments regarding costs related to the additional conditions set forth in the proposed class exemption.

Uncertainty

While the Department received 22 individual exemption applications from IMOs, it is uncertain regarding how many applicants and/or other IMOs would use the proposed class exemption, if it is granted. The Department also is uncertain about the extent to which covered IMOs' compliance burdens, including burdens attributable to the additional conditions not required of Financial Institutions under the Best Interest Contract Exemption, would be less than the reduction in burden that otherwise would be shouldered by insurers acting as Financial Institutions. The Department invites comments regarding the uncertainties discussed above.

Paperwork Reduction Act

As part of its continuing effort to reduce paperwork and respondent burden, the Department conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance

⁸² In the application for the individual exemption, Advisors Excel disclosed its sales in FIA as \$5 billion in 2015. Annexus reported \$4 billion sales in FIA in 2015 according to Investment News article by Greg Iacurici on Jun 23, 2016.

⁸³ LIMRA Individual Annuity Report 2015.

⁸⁴ LIMRA "Individual Annuity Sales—Fixed Annuity Break-Out: 2015 Year-End Results" Available at http://www.limra.com/uploadedFiles/limra.com/LIMRA_Root/Posts/PR/_Media/PDFs/2015-Top-20-Fixed-Breakout.pdf

⁸⁵ In the application for exemption, InForce Solutions states its annual sales in FIAs exceed \$2.8 billion; Futurity First Financial reported \$2.5 billion sales in FIA in 2015 according to an article "IMOs Dance with DOL on Fiduciary Deadline" by John Hilton on October 19, 2016. Available at <http://insurancenewsnet.com/inarticle/1050689>.

⁸⁶ Total combined sales from these four IMOs are \$14.3 billion. FIA sales by independent agents are approximately \$34.1 billion in 2015. Thus \$14.3 billion FIA sales generated by these four IMOs are about 42% of \$34.1 billion FIA sales by independent agents.

⁸⁷ Kristen Beckman, July 29, 2016, LifeHealthPro, "Futurity First Financial Acquired Nationwide Annuity IMO" available at <http://www.lifehealthpro.com/2016/07/29/futurity-first-financial-acquires-nationwide-annui>.

with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This helps to ensure that the public understands the Department's collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Department can properly assess the impact of collection requirements on respondents.

Currently, the Department is soliciting comments concerning the proposed information collection request (ICR) included in the Proposed Best Interest Contract Exemption for Insurance Intermediaries (PTE). A copy of the ICR may be obtained by contacting the PRA addressee shown below or at <http://www.RegInfo.gov>.

The Department has submitted a copy of the proposed PTE to the Office of Management and Budget (OMB) in accordance with 44 U.S.C. 3507(d) for review of its information collections. The Department and OMB are particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Comments should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; Attention: Desk Officer for the Employee Benefits Security Administration. OMB requests that comments be received within 30 days of publication of the proposed PTE to ensure their consideration.

PRA Addressee: Address requests for copies of the ICR to G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW., Room N-5718, Washington, DC 20210.

Telephone (202) 693-8410; Fax: (202) 219-5333. These are not toll-free numbers. ICRs submitted to OMB also are available at <http://www.RegInfo.gov>.

As discussed in detail below, the proposed class exemption will require Financial Institutions to enter into a contractual arrangement with Retirement Investors regarding investments in IRAs and plans not subject to Title I of ERISA (non-ERISA plans), adopt written policies and procedures and make disclosures to Retirement Investors (including with respect to ERISA plans), the Department, and on a publicly accessible Web site, in order to receive relief from ERISA's and the Code's prohibited transaction rules for the receipt of compensation as a result of a Financial Institution's and its Adviser's advice (i.e., prohibited compensation). Financial Institutions will have to prepare a written documentation regarding the limitations that they place on recommendations. Financial Institutions will be required to have all transactions reviewed internally by a senior compliance official and maintain records necessary to prove that the conditions of the exemption have been met. In addition, the exemption provides a transition period from the Applicability Date to August 15, 2018. As a condition of relief during the transition period, Financial Institutions must make a disclosure (transition disclosure) to all Retirement Investors (in ERISA plans, IRAs, and non-ERISA plans) prior to or at the same time as the execution of recommended transactions. These requirements are ICRs subject to the Paperwork Reduction Act.

The Department has made the following assumptions in order to establish a reasonable estimate of the paperwork burden associated with these ICRs:

- 51.8 percent of disclosures to ERISA plans and plan participants⁸⁸

⁸⁸ According to data from the National Telecommunications and Information Agency (NTIA), 33.4 percent of individuals age 25 and over have access to the internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt out that are automatically enrolled (for a total of 28.1 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 38.9 percent of individuals age 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61 percent of internet users use online banking, which is used as the proxy for the number of internet users who will opt in for electronic disclosure (for a total of 23.7 percent receiving electronic disclosure outside of work). Combining the 28.1 percent who receive electronic disclosure at work with the 23.7 percent who receive electronic disclosure outside of

and 44.1 percent of contracts with and disclosures to IRAs and non-ERISA plans⁸⁹ will be distributed electronically via means already used by respondents in the normal course of business and the costs arising from electronic distribution will be negligible, while the remaining contracts and disclosures will be distributed on paper and mailed at a cost of \$0.05 per page for materials and \$0.47 for first class postage;

- Financial Institutions will use existing in-house resources to distribute required disclosures.
- Tasks associated with the ICRs performed by in-house personnel will be performed by clerical personnel at an hourly wage rate of \$54.74 and financial managers at an hourly wage rate of \$167.39.⁹⁰
- Financial Institutions will hire outside service providers to assist with nearly all other compliance costs;
- Outsourced legal assistance will be billed at an hourly rate of \$335.00.⁹¹
- Approximately 19 large insurance intermediary Financial Institutions will use this exemption.⁹² These Financial

work produces a total of 51.8 percent who will receive electronic disclosure overall.

⁸⁹ According to data from the NTIA, 72.4 percent of individuals age 25 and older have access to the Internet. According to a Pew Research Center survey, 61 percent of internet users use online banking, which is used as the proxy for the number of Internet users who will opt in for electronic disclosure. Combining these data produces an estimate of 44.1 percent of individuals who will receive electronic disclosures.

⁹⁰ For a description of the Department's methodology for calculating wage rates, see <http://www.dol.gov/ebsa/pdf/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-august-2016.pdf>.

⁹¹ This rate is the average of the hourly rate of an attorney with 4–7 years of experience and an attorney with 8–10 years of experience, taken from the Laffey Matrix. See http://www.justice.gov/sites/default/files/usao-dc/legacy/2014/07/14/Laffey%20Matrix_2014-2015.pdf.

⁹² The Department obtained the sales information about seven IMOs from their exemption applications and media reports. All these seven IMOs met \$1.5 billion premium threshold and altogether reported approximately total \$20.45 billion sales in 2015. Some IMOs reported sales from only FIAs, while other IMOs reported sales from FIAs and fixed-rate annuities. According to the LIMRA U.S. Individual Annuity Year book 2015, \$38.4 billion total premiums—\$34.1 billion in FIAs and \$4.3 billion in fixed-rate annuities—were sold through the independent agent distribution channel in 2015. This implies that approximately \$17.95 billion FIA and fixed-rate annuity sales (\$38.40–\$20.45) were generated by other entities/agents. Assuming that \$17.95 billion sales were generated by IMOs, not by agents without any IMO affiliation and assuming that each IMO equally generated \$1.5 billion sales, the Department estimates that twelve (\$17.95 billion/\$1.5 billion) IMOs potentially would be eligible to use the exemption. Thus, in total, 19 (12+7) IMOs would potentially use the exemption. Although the Department recognizes that exemption-eligible IMOs would have all different sales records, in

Continued

Institutions will use this exemption in conjunction with any transactions involving recommendations regarding the purchase or sale of fixed annuity contracts in the retirement market.

Compliance Costs Substantially Similar to Those in PTE 2016–01

The Department believes that nearly all Financial Institutions will contract with outside service providers to implement the various compliance requirements of this exemption. As discussed previously, the conditions in this proposed PTE are similar to the conditions in the Department's Best Interest Contract Exemption (PTE 2016–01) but with some additional requirements. The Department believes it accurately estimated the aggregate burden imposed on the insurance industry in the Best Interest Contract Exemption, and it acknowledges that most of the entity-level burden attributed to insurance companies in the Best Interest Contract Exemption will instead be incurred by IMO covered by this proposed PTE. For the conditions that are substantially similar between this PTE and PTE 2016–01, the Department estimates that IMOs will incur compliance costs identical to similarly sized insurance companies. Accordingly, for the conditions in this PTE that are substantially similar to those in PTE 2016–01, the per-firm costs are as follows:

- *Start-Up Costs for Large Insurance Intermediaries:* \$6.6 million
- *Ongoing Costs for Large Insurance Intermediaries:* \$1.7 million

In order to receive compensation covered under this exemption, Section II requires Financial Institutions to acknowledge, in writing, their fiduciary status and adopt written policies and procedures designed to ensure compliance with the Impartial Conduct Standards. Financial Institutions and Advisers must make certain disclosures to Retirement Investors. Financial Institutions must generally enter into a written contract with Retirement Investors with respect to investments in IRAs and non-ERISA plans with certain required provisions, including affirmative agreement to adhere to the Impartial Conduct Standards.

order to estimate the upper-bound number of potentially eligible IMOs, the Department assumed that IMOs equally generate \$1.5 billion sales, the minimum premium sales threshold, for \$17.95 billion sales. This approach reflects the Department's conservative approach to estimating the compliance costs associated with the proposed class exemption. The Department welcomes any comments and information about the number of IMOs meeting the minimum sales threshold condition set forth in the exemption.

Sections III and V require Financial Institutions and Advisers to make certain disclosures. These disclosures include: (1) A pre-transaction disclosure, stating the best interest standard of care, describing any Material Conflicts of Interest with respect to the transaction, disclosing the recommendation of proprietary products and products that generate third party payments (where applicable), and informing the Retirement Investor of disclosures available on the Financial Institution's Web site and informing the Retirement Investor that the investor may receive specific disclosure of the costs, fees, and other compensation associated with the transaction; (2) a disclosure, on request, describing in detail the costs, fees, and other compensation associated with the transaction; (3) a web-based disclosure; and (4) a one-time disclosure to the Department.

Under Section IV, Financial Institutions will have to prepare a written documentation regarding the limitations they place on recommendations.

Section IX requires Financial Institutions to make a transition disclosure, acknowledging their fiduciary status and that of their Advisers with respect to the advice, stating the Best Interest standard of care, and describing the Financial Institution's Material Conflicts of Interest and any limitations on product offerings, prior to or at the same time as the execution of any transactions during the transition period from the Applicability Date to August 15, 2018. The transition disclosure can cover multiple transactions, or all transactions occurring in the transition period.

Financial Institutions will also be required to maintain records necessary to prove that the conditions of the exemption have been met.

The Department is able to disaggregate an estimate of many of the legal costs from the costs above; however, it is unable to disaggregate any of the other costs.

In response to a recommendation made during the Department's August 2015 public hearing on the proposed Regulation, and in an attempt to create estimates with a clearer empirical evidentiary basis, the Department itself drafted examples of certain portions of the required disclosures, including a sample contract, the one-time disclosure to the Department, and the transition disclosure. The Department believes that the time spent updating existing contracts and disclosures in future years would be no longer than the time necessary to create the original

disclosure. The Department did not attempt to draft the complete set of required disclosures because it expects that the amount of time necessary to draft such disclosures will vary greatly among firms. For example the Department did not attempt to draft sample policies and procedures, disclosures describing in detail the costs, fees, and other compensation associated with the transaction, documentation of the limitations regarding proprietary products or investments that generate third party payments, or a sample web disclosure. The Department expects the amount of time necessary to complete these disclosures will vary significantly based on a variety of factors including the nature of a firm's compensation structure, and the extent to which a firm's policies and procedures require review and signatures by different individuals.

Considered in conjunction with the estimates provided in the proposal for PTE 2016–01, the Department estimates that outsourced legal assistance to draft standard contracts, contract disclosures, pre-transaction disclosures, the one-time disclosure to the Department, and the transition disclosures will cost an average of \$3,857 per firm for a total of \$73,000 during the first year. In subsequent years, it will cost an average of \$3,076 per firm for a total of \$58,000 annually to update the contracts, contract disclosures, and pre-transaction disclosures.

The legal costs of these disclosures were disaggregated from the total compliance costs because these disclosures are expected to be relatively uniform. Although the tested disclosures generally took less time than many of the commenters on the proposal for PTE 2016–01 said they would, the Department acknowledges that the disclosures that were not tested are those that are expected to be the most time consuming. Importantly, as explained in greater detail in section 5.3 of the regulatory impact analysis for the Regulation, the Department is primarily relying on cost data provided by the Securities Industry and Financial Markets Association (SIFMA) and the Financial Services Institute (FSI) to calculate the total cost of the legal disclosures, rather than its own internal drafting of disclosures. Accordingly, in the event that any of the Department's estimates understate the time necessary to create and update the disclosures, it does not impact the total burden estimates. The total burden estimates were derived from SIFMA and FSI's all-inclusive costs. Therefore, in the event that legal costs are understated, other

cost estimates in this analysis would be overstated in an equal manner.

In addition to legal costs for creating the contracts and disclosures, the start-up cost estimates include the costs of implementing and updating the IT infrastructure, creating the Web disclosures, gathering and maintaining the records necessary to produce the various disclosures and to prove that the conditions of the exemption have been met, developing policies and procedures, documenting limitations regarding proprietary products or investments that generate third party payments, addressing material conflicts of interest, monitoring Advisers' adherence to the Impartial Conduct Standards, and any other steps necessary to ensure compliance with the conditions of the exemption not described elsewhere. In addition to legal costs for updating the contracts and disclosures, the ongoing cost estimates include the costs of updating the IT infrastructure, updating the Web disclosures, reviewing processes for gathering and maintaining the records necessary to produce the various disclosures and to prove that the conditions of the exemption have been met, reviewing the policies and procedures, producing the detailed transaction disclosures on request, documenting limitations regarding proprietary products or investments that generate third party payments, monitoring investments as agreed upon with the Retirement Investor, addressing material conflicts of interest, monitoring Advisers' adherence to the Impartial Conduct Standards, and any other steps necessary to ensure compliance with the conditions of the exemption not described elsewhere. These costs total \$126.1 million during the first year and \$31.4 million in subsequent years. These costs do not include the costs of distributing disclosures and contracts, nor do they include the costs of the additional requirements imposed on insurance intermediary Financial Institutions in this proposed PTE, all of which are discussed below.

Distribution of Disclosures and Contracts

The Department estimates that 15,000 Retirement Investors through ERISA plans and 212,000 Retirement Investors through IRAs and non-ERISA plans will receive a three-page transition disclosure during the first year.⁹³

⁹³ These estimates are based on LIMRA data on the number of fixed indexed annuity policies sold in 2015 to ERISA covered plans and IRAs and the market share held by independent agents, who might seek exemptive relief.

Additionally, 15,000 Retirement Investors with respect to ERISA plans will receive a fifteen-page contract disclosure, and 212,000 Retirement Investors with respect to IRAs and non-ERISA plans will receive a fifteen-page contract during the first year. In subsequent years, 4,300 Retirement Investors with respect to ERISA plans⁹⁴ will receive a fifteen-page contract disclosure and 42,000 Retirement Investors with respect to IRAs and non-ERISA plans⁹⁵ will receive a fifteen-page contract.

The transition disclosure will be distributed electronically to 51.8 percent of ERISA plan investors and 44.1 percent of IRAs and non-ERISA plan investors during the first year. Paper disclosures will be mailed to the remaining 48.2 percent of ERISA plan investors and 55.9 percent of IRAs and non-ERISA plan investors. The contract disclosure will be distributed electronically to 51.8 percent of ERISA plan investors during the first year or during any subsequent year in which the plan begins a new advisory relationship. Paper contract disclosures will be mailed to the remaining 48.2 percent of ERISA plan investors. The contract will be distributed electronically to 44.1 percent of IRAs and non-ERISA plan investors during the first year or during any subsequent year in which the investor enters into a new advisory relationship. Paper contracts will be mailed to the remaining 55.9 percent of IRAs and non-ERISA plan investors. The Department estimates that electronic distribution will result in de minimis cost, while paper distribution will cost approximately \$232,000 during the first year and \$31,000 during subsequent years. Paper distribution will also require two minutes of clerical time to print and mail the disclosure or contract, resulting in 8,400 hours at an equivalent cost of \$459,000 during the first year and 900 hours at an equivalent cost of \$47,000 during subsequent years.

The Department assumes that Retirement Investors interested in engaging in the purchase or sale of fixed indexed annuities will engage in one

⁹⁴ The Department estimates that approximately 28.7 percent of advisory relationships are new each year. (According to an analysis of Form 5500 Schedule C data conducted by Brightscope, Inc. and provided to the Department, 66,962 plans reported advisers in 2012, 22,302 plans changed advisers from 2012 to 2013, and 16,196 plans changed advisers from 2013 to 2014. $[(22,302 + 16,196)/2]/66,962 = 28.7$ percent.)

⁹⁵ The Department estimates that approximately 20 percent of advisory relationships are new each year. (2012 Cerulli data show that 20 percent of households opened a new account as a result of a new contact.)

transaction per year that requires a pre-transaction disclosure. Therefore, the Department estimates that plans and IRAs will receive 227,000 three-page pre-transaction disclosures during the second year and all subsequent years. The pre-transaction disclosures will be distributed electronically for 51.8 percent of the ERISA plan investors and 44.1 percent of the IRA holders and non-ERISA plan participants. The remaining 126,000 disclosures will be mailed. The Department estimates that electronic distribution will result in de minimis cost, while paper distribution will cost approximately \$78,000. Paper distribution will also require two minutes of clerical time to print and mail the statement, resulting in 4,200 hours at an equivalent cost of \$230,000 annually.

The Department estimates that Financial Institutions will receive ten requests per year for more detailed information on the fees, costs, and compensation associated with the transaction during the second year and all subsequent years. The Department solicits comments on the number of requests for more detailed information that Financial Institutions can expect to receive. The detailed disclosures will be distributed electronically for 51.8 percent of the ERISA plan investors and 44.1 percent of the IRA holders and non-ERISA plan participants. The Department believes that requests for additional information will be proportionally likely with each Retirement Investor type. Therefore, approximately 105 detailed disclosures will be distributed on paper. The Department estimates that electronic distribution will result in de minimis cost, while paper distribution will cost approximately \$76. Paper distribution will also require two minutes of clerical time to print and mail the statement, resulting in 4 hours at an equivalent cost of \$192 annually.

Finally, the Department estimates that all 19 Financial Institutions will submit the required one-page disclosure to the Department electronically at de minimis cost during the first year.

Costs for Provisions Not Included in PTE 2016-01

In order to receive compensation covered under this proposed exemption, Section II(d)(5) requires a person designated pursuant to Section II(d)(2) as responsible for addressing Material Conflicts of Interest and monitoring Advisers' adherence to Impartial Conduct Standards to approve, in writing, recommended annuity applications involving Retirement Investors prior to transmitting the

applications to the insurance company. Section III(a) requires the Financial Institution to furnish the Retirement Investor with a pre-transaction disclosure in accordance with the most recent Annuity Disclosure Model Regulation published by the NAIC or its successor. Section VIII(e)(2) requires a Financial Institution to have financial statements that are audited annually by an Independent certified public accountant.

As discussed previously in this analysis, the Department estimates that Advisers working on behalf of Financial Institutions will make 227,000 recommendations to Retirement Investors annually. The Department estimates that, on average, it will take a financial manager fifteen minutes to review and approve recommendations. This results in 57,000 hours annually at an equivalent cost of \$9.5 million.

The Department assumes that each of the 19 Financial Institutions will hire outside service providers to create a template for the pre-transaction annuity disclosure. The Department estimates that it will take legal service providers 1.5 hours to create the template during the first year and 1.5 hours to update the template during subsequent years. Once the template has been created, the disclosure itself will be populated by the IT systems (the costs of IT updates were discussed previously). The total cost burden for the outsourced legal assistance to create and update the template for the pre-transaction annuity disclosure is estimated to be \$10,000 annually.

The Department estimates that plans and IRAs will receive 227,000 one page pre-transaction annuity disclosures annually. The pre-transaction disclosures will be distributed electronically for 51.8 percent of the ERISA plan investors and 44.1 percent of the IRA holders and non-ERISA plan participants. The remaining 126,000 disclosures will be mailed. The Department estimates that electronic distribution will result in de minimis cost, while paper distribution will cost approximately \$65,000. Paper distribution will also require two minutes of clerical time to print and mail the statement, resulting in 4,200 hours at an equivalent cost of \$230,000 annually.

The Department assumes that maintaining financial statements that are audited annually by an Independent certified public accountant is a best practice for businesses in this industry and that Financial Institutions generally engage in this practice. Therefore, no additional burden is assessed for this requirement. The Department solicits

comment on how widespread the practice of obtaining annual audits is. In the event that it is not a usual and customary business practice, the Department solicits comments regarding the costs associated with this requirement.

Overall Summary

Overall, the Department estimates that in order to meet the conditions of this class exemption, Financial Institutions and Advisers will distribute approximately 681,000 disclosures and contracts during the first year and 501,000 disclosures and contracts annually during subsequent years. Distributing these disclosures and contracts, reviewing recommendations, and maintaining records that the conditions of the exemption have been fulfilled will result in a total of 69,000 hours of burden during the first year and 66,000 hours of burden annually during subsequent years. The equivalent cost of this burden is \$10.2 million during the first year and \$10.0 million annually in subsequent years. This exemption will result in an outsourced labor, materials, and postage cost burden of \$126.4 million during the first year and \$31.6 million annually during subsequent years.

These paperwork burden estimates are summarized as follows:

Type of Review: New collection.

Agency: Employee Benefits Security Administration, Department of Labor.

Title: Proposed Best Interest Contract Exemption for Insurance Intermediaries.

OMB Control Number: 1210-NEW.

Affected Public: Businesses or other for-profits; not for profit institutions.

Estimated Number of Respondents: 19.

Estimated Number of Annual Responses: 681,449 during the first year and 501,199 annually during subsequent years.

Frequency of Response: When engaging in exempted transaction.

Estimated Total Annual Burden Hours: 69,369 during the first year and 66,037 annually in subsequent years; includes 8,389 during the first year and 5,057 annually in subsequent years of duplicative burden that will be transferred over from OMB Control Number 1210-0156 upon approval of this information collection request.

Estimated Total Annual Burden Cost: \$126,369,454 during the first year and \$31,617,550 annually during subsequent years; includes \$126,294,476 during the first year and \$31,542,571 annually in subsequent years of duplicative burden that will be transferred over from OMB Control Number 1210-0156 upon

approval of this information collection request.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and which are likely to have a significant economic impact on a substantial number of small entities. Unless an agency certifies that a rule will not have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires the agency to present an initial regulatory flexibility analysis at the time of the publication of the notice of proposed rulemaking describing the impact of the rule on small entities. Small entities include small businesses, organizations and governmental jurisdictions.

As discussed above, only IMOs that have transacted sales averaging at least \$1.5 billion in premiums per fiscal year over its prior three fiscal years are eligible to use the proposed exemption. The Small Business Administration (SBA) defines a small business in the Financial Investments and Related Activities Sector as a business with up to \$38.5 million in annual receipts. Although the Department believes that revenues of IMOs are closely related to sales volume, the Department is uncertain regarding the exact relationship between sales and revenue for these entities.

Based on the limited information disclosed by the individual exemptions applicants, the Department believes that receipts of IMOs that are eligible to use proposed class exemption are likely to exceed the SBA revenue threshold and, therefore, such entities are unlikely to be considered small entities for purposes of the RFA.⁹⁶ Small IMOs not

⁹⁶ Only two applicant IMOs disclosed both sales and revenue information in their applications. One IMO reported that \$37.7 million in revenues were generated from \$1.55 billion sales in fixed rate annuities and FIAs in 2015. Another IMO reported that revenues of \$125 million were generated from \$2.1+ billion sales in various insurance products in 2015. The IMO applicant with the largest reported revenue exceeds the SBA size threshold by three times. The Department notes that the even the IMO with the smaller revenue comes extremely close to meeting the SBA size threshold. Furthermore, it reports only the subset of its entire revenues—revenues from fixed rate annuities and FIAs only. Most IMOs sell other types of insurance products such as life insurance. If it includes the revenues from other sources, the IMO with the smaller revenue is very likely to exceed the threshold set by the SBA. Thus, the Department believes that IMOs satisfying all conditions of this exemption are likely to have revenue that meets or exceeds the SBA size threshold. However, the Department is

meeting the sales threshold would not incur any compliance costs, because they are not eligible to use the exemption. These IMOs could partner with larger IMOs using the proposed exemption insurers using the Best Interest Contract Exemption in order to conduct commission-based sales.

Accordingly, based on the foregoing, pursuant to section 605(b) of the RFA, the Assistant Secretary of the Employee Benefits Security Administration hereby proposes to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Congressional Review Act

The proposed exemption is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and, if finalized, will be transmitted to Congress and the Comptroller General for review. The proposed exemption is a “major rule” as that term is defined in 5 U.S.C. 804, because it is likely to result in (1) an annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, or Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

Federalism Statement

Executive Order 13132 outlines fundamental principles of federalism. It also requires adherence to specific criteria by federal agencies in formulating and implementing policies that have “substantial direct effects” on the states, the relationship between the national government and states, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the final regulation. The Department does not believe this proposed class exemption has federalism implications because it has

no substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under ERISA section 408(a) and Code section 4975(c)(2) does not relieve a fiduciary, or other party in interest or disqualified person with respect to a plan, from certain other provisions of ERISA and the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of ERISA section 404 which require, among other things, that a fiduciary act prudently and discharge his or her duties respecting the plan solely in the interests of the participants and beneficiaries of the plan. Additionally, the fact that a transaction is the subject of an exemption does not affect the requirement of Code section 401(a) that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before the exemption may be granted under ERISA section 408(a) and Code section 4975(c)(2), the Department must find that the exemption is administratively feasible, in the interests of plans and their participants and beneficiaries and IRA owners, and protective of the rights of participants and beneficiaries of the plan and IRA owners;

(3) If granted, the proposed exemption is applicable to a particular transaction only if the transaction satisfies the conditions specified in the exemption; and

(4) The proposed exemption, if granted, is supplemental to, and not in derogation of, any other provisions of ERISA and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

Proposed Exemption

Section I—Best Interest Contract Exemption for Insurance Intermediaries

(a) In general. ERISA and the Internal Revenue Code prohibit fiduciary advisers to employee benefit plans (Plans) and individual retirement

accounts (IRAs) from receiving compensation that varies based on their investment advice. Similarly, fiduciary advisers are prohibited from receiving compensation from third parties in connection with their advice. This exemption permits certain persons who provide investment advice to Retirement Investors, and associated Financial Institutions, Affiliates and other Related Entities, to receive such otherwise prohibited compensation as described below.

(b) Covered transactions. This exemption permits Advisers, Financial Institutions, and their Affiliates and Related Entities, to receive compensation as a result of their provision of investment advice within the meaning of ERISA section 3(21)(A)(ii) or Code section 4975(e)(3)(B) to a Retirement Investor regarding the purchase of a Fixed Annuity Contract, as defined in Section VIII(d).

As defined in Section VIII(m) of the exemption, a Retirement Investor is: (1) A participant or beneficiary of a Plan with authority to direct the investment of assets in his or her Plan account or to take a distribution; (2) the beneficial owner of an IRA acting on behalf of the IRA; or (3) a Retail Fiduciary with respect to a Plan or IRA.

As detailed below, Financial Institutions and Advisers seeking to rely on the exemption must adhere to Impartial Conduct Standards in rendering advice regarding Fixed Annuity Contracts. In addition, Financial Institutions must adopt policies and procedures designed to ensure that their individual Advisers adhere to the Impartial Conduct Standards; disclose important information relating to fees, compensation, and Material Conflicts of Interest; and retain records demonstrating compliance with the exemption. The exemption provides relief from the restrictions of ERISA section 406(a)(1)(D) and 406(b) and the sanctions imposed by Code section 4975(a) and (b), by reason of Code section 4975(c)(1)(D), (E) and (F). The Adviser and Financial Institution must comply with the applicable conditions of Sections II–V to rely on this exemption. This document also contains separate exemptions in Section VI (Exemption for Purchases of Fixed Annuity Contracts) and Section VII (Exemption for Pre-Existing Transactions).

(c) Exclusions. This exemption does not apply if:

(1) The Plan is covered by Title I of ERISA, and (i) the Adviser, Financial Institution or any Affiliate is the

uncertain regarding why two IMOs with similar sales generate quite different levels of revenues and welcomes any comments regarding how IMOs generate revenue from sales of fixed annuity products.

employer of employees covered by the Plan, or (ii) the Adviser or Financial Institution is a named fiduciary or plan administrator (as defined in ERISA section 3(16)(A)) with respect to the Plan, or an affiliate thereof, that was selected to provide advice to the Plan by a fiduciary who is not Independent;

(2) The compensation is received as a result of investment advice to a Retirement Investor generated solely by an interactive Web site in which computer software-based models or applications provide investment advice based on personal information each investor supplies through the Web site without any personal interaction or advice from an individual Adviser (*i.e.*, “robo-advice”); or

(3) The Adviser has or exercises any discretionary authority or discretionary control with respect to the recommended transaction.

Section II—Contract, Impartial Conduct, and Other Requirements

The conditions set forth in this section include certain Impartial Conduct Standards, such as a Best Interest Standard, that Advisers and Financial Institutions must satisfy to rely on the exemption. In addition, Section II(d) and (e) require Financial Institutions to adopt anti-conflict policies and procedures that are reasonably designed to ensure that Advisers adhere to the Impartial Conduct Standards, and requires disclosure of important information about the Financial Institutions’ services, applicable fees and compensation. With respect to IRAs and Plans not covered by Title I of ERISA, the Financial Institutions must agree that they and their Advisers will adhere to the exemption’s standards in a written contract that is enforceable by the Retirement Investors. To minimize compliance burdens, the exemption provides that the contract terms may be incorporated into annuity contracts or applications, and permits reliance on a negative consent process with respect to existing contract holders. Advisers and Financial Institutions need not execute the contract before they make a recommendation to the Retirement Investor. However, the contract must cover any advice given prior to the contract date in order for the exemption to apply to such advice. There is no contract requirement for recommendations to Retirement Investors about investments in Plans covered by Title I of ERISA, but the Impartial Conduct Standards and other requirements of Section II(b)–(e), including a written acknowledgment of fiduciary status, must be satisfied in

order for relief to be available under the exemption, as set forth in Section II(g). Section II imposes the following conditions on Financial Institutions and Advisers:

(a) Contracts with Respect to Investments in IRAs and Other Plans Not Covered by Title I of ERISA. If the investment advice concerns an IRA or a Plan that is not covered by Title I of ERISA, the advice is subject to an enforceable written contract on the part of the Financial Institution, which may be a master contract covering multiple recommendations, that is entered into in accordance with this Section II(a) and incorporates the terms set forth in Section II(b)–(d). The Financial Institution additionally must provide the disclosures required by Section II(e). The contract must cover advice rendered prior to the execution of the contract in order for the exemption to apply to such advice and related compensation.

(1) Contract Execution and Assent.

(i) New Contracts. Prior to or at the same time as the execution of the recommended transaction, the Financial Institution enters into a written contract with the Retirement Investor acting on behalf of the Plan, participant or beneficiary account, or IRA, incorporating the terms required by Section II(b)–(d). The terms of the contract may appear in a standalone document or they may be incorporated into an annuity contract or application, or similar document, or amendment thereto. The contract must be enforceable against the Financial Institution. The Retirement Investor’s assent to the contract may be evidenced by handwritten or electronic signatures.

(ii) Amendment of Existing Contracts by Negative Consent. As an alternative to executing a contract in the manner set forth in the preceding paragraph, the Financial Institution may amend Existing Contracts to include the terms required in Section II(b)–(d) by delivering the proposed amendment and the disclosure required by Section II(e) to the Retirement Investor prior to August 15, 2018, and considering the failure to terminate the amended contract within 30 days as assent. If the Retirement Investor does terminate the contract within that 30-day period, this exemption will provide relief for 14 days after the date on which the termination is received by the Financial Institution. An Existing Contract is an annuity contract that was executed before August 15, 2018, and remains in effect. If the Financial Institution elects to use the negative consent procedure, it may deliver the proposed amendment by mail or electronically, but it may not

impose any new contractual obligations, restrictions, or liabilities on the Retirement Investor by negative consent.

(2) Notice. The Financial Institution maintains an electronic copy of the Retirement Investor’s contract on its Web site that is accessible by the Retirement Investor.

(b) Fiduciary. The Financial Institution affirmatively states in writing that it and the Adviser(s) act as fiduciaries under ERISA or the Code, or both, with respect to any investment advice provided by the Financial Institution or the Adviser subject to the contract or, in the case of an ERISA plan, with respect to any investment recommendations regarding the Plan or participant or beneficiary account.

(c) Impartial Conduct Standards. The Financial Institution affirmatively states that it and its Advisers will adhere to the following standards and, they in fact, comply with the standards:

(1) When providing investment advice to the Retirement Investor, the Financial Institution and the Adviser(s) provide investment advice that is, at the time of the recommendation, in the Best Interest of the Retirement Investor. As further defined in Section VIII(c), such advice reflects the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent person acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims, based on the investment objectives, risk tolerance, financial circumstances, and needs of the Retirement Investor, without regard to the financial or other interests of the Adviser, Financial Institution or any Affiliate, Related Entity, or other party;

(2) The recommended transaction will not cause the Financial Institution, Adviser or their Affiliates or Related Entities to receive, directly or indirectly, compensation for their services that is in excess of reasonable compensation within the meaning of ERISA section 408(b)(2) and Code section 4975(d)(2).

(3) Statements by the Financial Institution and its Advisers to the Retirement Investor about the recommended transaction, fees and compensation, Material Conflicts of Interest, and any other matters relevant to a Retirement Investor’s investment decisions, will not be materially misleading at the time they are made.

(d) Warranties. The Financial Institution affirmatively warrants, and in fact complies with, the following:

(1) The Financial Institution has adopted and will comply with written policies and procedures reasonably and prudently designed to ensure that its Advisers adhere to the Impartial

Conduct Standards set forth in Section II(c);

(2) In formulating its policies and procedures, the Financial Institution has specifically identified and documented its Material Conflicts of Interest; adopted measures reasonably and prudently designed to prevent Material Conflicts of Interest from causing violations of the Impartial Conduct Standards set forth in Section II(c); and designated a person or persons, identified by name, title or function, responsible for addressing Material Conflicts of Interest and monitoring their Advisers' adherence to the Impartial Conduct Standards;

(3) The Financial Institution's policies and procedures prohibit the use of quotas, appraisals, performance or personnel actions, bonuses, contests, special awards, differential compensation or other actions or incentives that are intended or would reasonably be expected to cause Advisers to make recommendations that are not in the Best Interest of the Retirement Investor. Notwithstanding the foregoing, this Section II(d)(3) does not prevent the provision of differential compensation (whether in type or amount, and including, but not limited to, commissions) based on investment decisions by Plans, participant or beneficiary accounts, or IRAs, to the extent that the Financial Institution's policies and procedures and incentive practices, when viewed as a whole, are reasonably and prudently designed to avoid a misalignment of the interests of Advisers with the interests of the Retirement Investors they serve as fiduciaries (such compensation practices can include differential compensation based on neutral factors tied to the differences in the services delivered to the Retirement Investor with respect to the different types of investments, as opposed to the differences in the amounts of Third Party Payments the Financial Institution receives in connection with particular investment recommendations);

(4) The Financial Institution has approved in advance all written marketing materials used by Advisers after determining that such materials provide a balanced description of the risks and features of the Fixed Annuity Contracts to be recommended;

(5) A person designated pursuant to Section II(d)(2) as responsible for addressing Material Conflicts of Interest and monitoring Advisers' adherence to the Impartial Conduct Standards approves, in writing, recommended annuity applications involving Retirement Investors prior to

transmitting the applications to the insurance company;

(6) The Financial Institution requires in its written contract with Advisers or sub-intermediaries that Advisers must (i) use written marketing materials only if they are approved in advance by the Financial Institution as described in Section II(d)(4), and (ii) provide the disclosure required by Section III(a) and orally review the information in Section III(a)(1) with the Retirement Investor;

(7) The Financial Institution either: (i) Requires in its written contract with the insurance company and each Adviser or sub-intermediary that all compensation to be paid to the Adviser or sub-intermediary with respect to the purchase of a Fixed Annuity Contract by a Retirement Investor pursuant to this exemption must be paid to the Adviser or sub-intermediary exclusively by the Financial Institution; or (ii) requires in its written contract with the insurance company and each Adviser or sub-intermediary that with respect to the purchase of a Fixed Annuity Contract by a Retirement Investor pursuant to this exemption, (A) the Adviser or sub-intermediary may only sell annuities to Retirement Investors for which the commission structure has been approved in advance by the IMO and (B) all other forms of compensation, whether cash or non-monetary, must be paid to the Adviser or sub-intermediary exclusively by the Financial Institution; and

(8) The Financial Institution will provide, and require its Advisers to attend, annual training on compliance with the exemption that is conducted by a person who has appropriate technical training and proficiency with ERISA and the Code. The training must, at a minimum, cover the policies and procedures, the Impartial Conduct Standards, Material Conflicts of Interest, ERISA and Code compliance (including applicable fiduciary duties and the prohibited transaction provisions), ethical conduct, and the consequences of failure to comply with the conditions of this exemption (including any loss of exemptive relief provided herein).

(e) Disclosures. In the Best Interest Contract or in a separate single written disclosure provided to the Retirement Investor with the contract, or, with respect to ERISA plans, in another single written disclosure provided to the Plan prior to or at the same time as the execution of the recommended transaction, the Financial Institution clearly and prominently:

(1) States the Best Interest standard of care owed by the Adviser and Financial Institution to the Retirement Investor; informs the Retirement Investor of the

services provided by the Financial Institution and the Adviser; and describes how the Retirement Investor will pay for services, directly or through Third Party Payments. If, for example, the Retirement Investor will pay through commissions or other forms of transaction-based payments, the contract or writing must clearly disclose that fact;

(2) Describes Material Conflicts of Interest; discloses any fees or charges the Financial Institution, its Affiliates, or the Adviser imposes upon the Retirement Investor or the Retirement Investor's annuity; and states the types of compensation that the Financial Institution, its Affiliates, and the Adviser expect to receive from third parties in connection with Fixed Annuity Contracts recommended to Retirement Investors;

(3) Informs the Retirement Investor that the Retirement Investor has the right to obtain copies of the Financial Institution's written description of its policies and procedures adopted in accordance with Section II(d), as well as the specific disclosure of costs, fees, and compensation, including Third Party Payments, regarding recommended transactions, as set forth in Section III(a), below, described in dollar amounts, percentages, formulas, or other means reasonably designed to present materially accurate disclosure of their scope, magnitude, and nature in sufficient detail to permit the Retirement Investor to make an informed judgment about the costs of the transaction and about the significance and severity of the Material Conflicts of Interest, and describes how the Retirement Investor can get the information, free of charge; provided that if the Retirement Investor's request is made prior to the transaction, the information must be provided prior to the transaction, and if the request is made after the transaction, the information must be provided within 30 business days after the request;

(4) Includes a link to the Financial Institution's Web site as required by Section III(b), and informs the Retirement Investor that: (i) Model contract disclosures updated as necessary on a quarterly basis are maintained on the Web site, and (ii) the Financial Institution's written description of its policies and procedures adopted in accordance with Section II(d) are available free of charge on the Web site;

(5) Discloses to the Retirement Investor whether the Financial Institution offers Proprietary Products or receives Third Party Payments with respect to any recommended Fixed

Annuity Contracts; and to the extent the Financial Institution or Adviser limits investment recommendations, in whole or part, to Proprietary Products or annuities that generate Third Party Payments, notifies the Retirement Investor of the limitations placed on the universe of investments that the Adviser may offer for purchase, sale, exchange, or holding by the Retirement Investor. The notice is insufficient if it merely states that the Financial Institution or Adviser “may” limit investment recommendations based on whether the annuities are Proprietary Products or generate Third Party Payments, without specific disclosure of the extent to which recommendations are, in fact, limited on that basis;

(6) Provides contact information (telephone and email) for a representative of the Financial Institution that the Retirement Investor can use to contact the Financial Institution with any concerns about the advice or service they have received; and

(7) Describes whether or not the Adviser and Financial Institution will monitor the Retirement Investor’s annuity contract and alert the Retirement Investor to any recommended change to the annuity contract, and, if so monitoring, the frequency with which the monitoring will occur and the reasons for which the Retirement Investor will be alerted.

(8) The Financial Institution will not fail to satisfy this Section II(e), or violate a contractual provision based thereon, solely because it, acting in good faith and with reasonable diligence, makes an error or omission in disclosing the required information, provided the Financial Institution discloses the correct information as soon as practicable, but not later than 30 days after the date on which it discovers or reasonably should have discovered the error or omission. To the extent compliance with this Section II(e) requires Advisers and Financial Institutions to obtain information from entities that are not closely affiliated with them, they may rely in good faith on information and assurances from the other entities, as long as they do not know that the materials are incomplete or inaccurate. This good faith reliance applies unless the entity providing the information to the Adviser and Financial Institution is (1) a person directly or indirectly through one or more intermediaries, controlling, controlled by, or under common control with the Adviser or Financial Institution; or (2) any officer, director, employee, agent, registered representative, relative (as defined in

ERISA section 3(15)), member of family (as defined in Code section 4975(e)(6)) of, or partner in, the Adviser or Financial Institution.

(f) Ineligible Contractual Provisions. Relief is not available under the exemption if a Financial Institution’s contract contains the following:

(1) Exculpatory provisions disclaiming or otherwise limiting liability of the Adviser or Financial Institution for a violation of the contract’s terms;

(2) Except as provided in paragraph (f)(4) of this Section, a provision under which the Plan, IRA or Retirement Investor waives or qualifies its right to bring or participate in a class action or other representative action in court in a dispute with the Adviser or Financial Institution, or in an individual or class claim agrees to an amount representing liquidated damages for breach of the contract; provided that, the parties may knowingly agree to waive the Retirement Investor’s right to obtain punitive damages or rescission of recommended transactions to the extent such a waiver is permissible under applicable state or federal law; or

(3) Agreements to arbitrate or mediate individual claims in venues that are distant or that otherwise unreasonably limit the ability of the Retirement Investors to assert the claims safeguarded by this exemption.

(4) In the event that the provision on pre-dispute arbitration agreements for class or representative claims in paragraph (f)(2) of this Section is ruled invalid by a court of competent jurisdiction, this provision shall not be a condition of this exemption with respect to contracts subject to the court’s jurisdiction unless and until the court’s decision is reversed, but all other terms of the exemption shall remain in effect.

(g) ERISA plans. Section II(a) does not apply to recommendations to Retirement Investors regarding investments in Plans that are covered by Title I of ERISA. For such investment advice, relief under the exemption is conditioned upon the Adviser and Financial Institution complying with certain provisions of Section II, as follows:

(1) Prior to or at the same time as the execution of the recommended transaction, the Financial Institution provides the Retirement Investor with a written statement of the Financial Institution’s and its Advisers’ fiduciary status, in accordance with Section II(b).

(2) The Financial Institution and the Adviser comply with the Impartial Conduct Standards of Section II(c).

(3) The Financial Institution adopts policies and procedures incorporating

the requirements and prohibitions set forth in Section II(d), and the Financial Institution and Adviser comply with those requirements and prohibitions.

(4) The Financial Institution provides the disclosures required by Section II(e).

(5) The Financial Institution and Adviser do not in any contract, instrument, or communication: Purport to disclaim any responsibility or liability for any responsibility, obligation, or duty under Title I of ERISA to the extent the disclaimer would be prohibited by ERISA section 410; purport to waive or qualify the right of the Retirement Investor to bring or participate in a class action or other representative action in court in a dispute with the Adviser or Financial Institution, or require arbitration or mediation of individual claims in locations that are distant or that otherwise unreasonably limit the ability of the Retirement Investors to assert the claims safeguarded by this exemption.

Section III—Web and Transaction-Based Disclosures

The Financial Institution must satisfy the following conditions with respect to an investment recommendation, to be covered by this exemption:

(a) Transaction Disclosure. The Financial Institution provides the Retirement Investor, prior to the transmittal of a recommended application for a Fixed Annuity Contract to the insurance company, the following disclosure, clearly and prominently, in a single written document, that:

(1) Provides a disclosure regarding the Fixed Annuity Contract that is in accordance with the most recent Annuity Disclosure Model Regulation published by the National Association of Insurance Commissioners, or its successor, as of the time of the transaction;

(2) States the Best Interest standard of care owed by the Adviser and Financial Institution to the Retirement Investor; and describes any Material Conflicts of Interest;

(3) Informs the Retirement Investor that the Retirement Investor has the right to obtain copies of the Financial Institution’s written description of its policies and procedures adopted in accordance with Section II(d), as well as specific disclosure of costs, fees and other compensation including Third Party Payments regarding recommended transactions. The costs, fees, and other compensation may be described in dollar amounts, percentages, formulas, or other means reasonably designed to present materially accurate disclosure of their scope, magnitude, and nature in

sufficient detail to permit the Retirement Investor to make an informed judgment about the costs of the transaction and about the significance and severity of the Material Conflicts of Interest. The information required under this Section must be provided to the Retirement Investor prior to the transaction, if requested prior to the transaction, and, if the request is made after the transaction, the information must be provided within 30 business days after the request; and

(4) Includes a link to the Financial Institution's Web site as required by Section III(b) and informs the Retirement Investor that: (i) Model contract disclosures or other model notices, updated as necessary on a quarterly basis, are maintained on the Web site, and (ii) the Financial Institution's written description of its policies and procedures as required under Section III(b)(1)(iv) are available free of charge on the Web site.

(5) Following disclosure of the information in Section III(a)(1), the Adviser must orally review the information with the Retirement Investor, and both the Adviser and Retirement Investor must sign the transaction disclosure and indicate that the oral review has occurred.

(6) The disclosures in subsections (2)–(4) do not have to be repeated for subsequent recommendations by the Adviser and Financial Institution to invest in the same Fixed Annuity Contract within one year of the provision of the contract disclosure in Section II(e) or a previous disclosure pursuant to this Section III(a), unless there are material changes in the subject of the disclosure.

(b) Web Disclosure. For relief to be available under the exemption for any investment recommendation, the conditions of Section III(b) must be satisfied.

(1) The Financial Institution maintains a Web site, freely accessible to the public and updated no less than quarterly, which contains:

(i) A discussion of the Financial Institution's business model and the Material Conflicts of Interest associated with that business model;

(ii) A schedule of typical contract fees and service charges, if applicable;

(iii) A model contract or other model notice of the contractual terms (if applicable) and required disclosures described in Section II(b)–(e), which are reviewed for accuracy no less frequently than quarterly and updated within 30 days if necessary;

(iv) A written description of the Financial Institution's policies and procedures that accurately describes or

summarizes key components of the policies and procedures relating to conflict-mitigation and incentive practices in a manner that permits Retirement Investors to make an informed judgment about the stringency of the Financial Institution's protections against conflicts of interest;

(v) To the extent applicable, a list of all product manufacturers and other parties with whom the Financial Institution maintains arrangements that provide Third Party Payments to either the Adviser or the Financial Institution with respect to Fixed Annuity Contracts recommended to Retirement Investors; a description of the arrangements, including a statement on whether and how these arrangements impact Adviser compensation, and a statement on any benefits the Financial Institution provides to the product manufacturers or other parties in exchange for the Third Party Payments;

(vi) Disclosure of the Financial Institution's compensation and incentive arrangements with Advisers including, if applicable, any incentives (including both cash and non-monetary compensation or awards) to Advisers for recommending particular product manufacturers or Fixed Annuity Contracts to Retirement Investors, or for Advisers to move to the Financial Institution from another firm or to stay at the Financial Institution, and a full and fair description of any payout or compensation grids, but not including information that is specific to any individual Adviser's compensation or compensation arrangement; and

(vii) A copy of the Financial Institution's most recent audited financial statements required in accordance with Section VIII(e)(2).

(viii) The Web site may describe the above arrangements with product manufacturers, Advisers, and others by reference to dollar amounts, percentages, formulas, or other means reasonably calculated to present a materially accurate description of the arrangements. Similarly, the Web site may group disclosures based on reasonably-defined categories of Fixed Annuity Contracts, product manufacturers, Advisers, and arrangements, and it may disclose reasonable ranges of values, rather than specific values, as appropriate. But, however constructed, the Web site must fairly disclose the scope, magnitude, and nature of the compensation arrangements and Material Conflicts of Interest in sufficient detail to permit visitors to the Web site to make an informed judgment about the significance of the compensation practices and Material Conflicts of

Interest with respect to transactions recommended by the Financial Institution and its Advisers.

(2) To the extent the information required by this Section is provided in other disclosures which are made public, the Financial Institution may satisfy this Section III(b) by posting such disclosures to its Web site with an explanation that the information can be found in the disclosures and a link to where it can be found.

(3) The Financial Institution is not required to disclose information pursuant to this Section III(b) if such disclosure is otherwise prohibited by law.

(4) In addition to providing the written description of the Financial Institution's policies and procedures on its Web site, as required under Section III(b)(1)(iv), Financial Institutions must provide their complete policies and procedures adopted pursuant to Section II(d) to the Department upon request.

(5) In the event that a Financial Institution determines to group disclosures as described in subsection (1)(vii), it must retain the data and documentation supporting the group disclosure during the time that it is applicable to the disclosure on the Web site, and for six years after that, and make the data and documentation available to the Department within 90 days of the Department's request.

(c)(1) The Financial Institution will not fail to satisfy the conditions in this Section III solely because it, acting in good faith and with reasonable diligence, makes an error or omission in disclosing the required information, or if the Web site is temporarily inaccessible, provided that, (i) in the case of an error or omission on the Web site, the Financial Institution discloses the correct information as soon as practicable, but not later than seven (7) days after the date on which it discovers or reasonably should have discovered the error or omission, and (ii) in the case of an error or omission with respect to the transaction disclosure, the Financial Institution discloses the correct information as soon as practicable, but not later than 30 days after the date on which it discovers or reasonably should have discovered the error or omission.

(2) To the extent compliance with the Section III disclosures requires Advisers and Financial Institutions to obtain information from entities that are not closely affiliated with them, they may rely in good faith on information and assurances from the other entities, as long as they do not know that the materials are incomplete or inaccurate. This good faith reliance applies unless the entity providing the information to

the Adviser and Financial Institution is (i) a person directly or indirectly through one or more intermediaries, controlling, controlled by, or under common control with the Adviser or Financial Institution; or (ii) any officer, director, employee, agent, registered representative, relative (as defined in ERISA section 3(15)), member of family (as defined in Code section 4975(e)(6)) of, or partner in, the Adviser or Financial Institution.

(3) The good faith provisions of this Section apply to the requirement that the Financial Institution retain the data and documentation supporting the group disclosure during the time that it is applicable to the disclosure on the Web site and provide it to the Department upon request, as set forth in subsection (b)(1)(vii) and (b)(5) above. In addition, if such records are lost or destroyed, due to circumstances beyond the control of the Financial Institution, then no prohibited transaction will be considered to have occurred solely on the basis of the unavailability of those records; and no party, other than the Financial Institution responsible for complying with subsection (b)(1)(vii) and (b)(5) will be subject to the civil penalty that may be assessed under ERISA section 502(i) or the taxes imposed by Code section 4975(a) and (b), if applicable, if the records are not maintained or provided to the Department within the required timeframes.

Section IV—Proprietary Products and Third Party Payments

(a) General. A Financial Institution that at the time of the transaction restricts Advisers' investment recommendations, in whole or part, to Proprietary Products or to Fixed Annuity Contracts that generate Third Party Payments, may rely on this exemption provided all the applicable conditions of the exemption are satisfied.

(b) Satisfaction of the Best Interest standard. The Financial Institution satisfies the Best Interest standard of Section VIII(c) as follows:

(1) Prior to or at the same time as the execution of the recommended transaction, the Retirement Investor is clearly and prominently informed in writing that the Financial Institution offers Proprietary Products or receives Third Party Payments with respect to the purchase, sale, exchange, or holding of Fixed Annuity Contracts; and the Retirement Investor is informed in writing of the limitations placed on the universe of Fixed Annuity Contracts that the Adviser may recommend to the Retirement Investor. The notice is

insufficient if it merely states that the Financial Institution or Adviser "may" limit investment recommendations based on whether the annuities are Proprietary Products or generate Third Party Payments, without specific disclosure of the extent to which recommendations are, in fact, limited on that basis;

(2) Prior to or at the same time as the execution of the recommended transaction, the Retirement Investor is fully and fairly informed in writing of any Material Conflicts of Interest that the Financial Institution or Adviser have with respect to the recommended transaction, and the Adviser and Financial Institution comply with the disclosure requirements set forth in Section III above (providing for web and transaction-based disclosure of costs, fees, compensation, and Material Conflicts of Interest);

(3) The Financial Institution documents in writing its limitations on the universe of recommended Fixed Annuity Contracts; documents in writing the Material Conflicts of Interest associated with any contract, agreement, or arrangement providing for its receipt of Third Party Payments or associated with the sale or promotion of Proprietary Products; documents in writing any services it will provide to Retirement Investors in exchange for Third Party Payments, as well as any services or consideration it will furnish to any other party, including the payor, in exchange for the Third Party Payments; reasonably concludes that the limitations on the universe of recommended Fixed Annuity Contracts and Material Conflicts of Interest will not cause the Financial Institution or its Advisers to receive compensation in excess of reasonable compensation for Retirement Investors as set forth in Section II(c)(2); reasonably determines, after consideration of the policies and procedures established pursuant to Section II(d), that these limitations and Material Conflicts of Interest will not cause the Financial Institution or its Advisers to make imprudent investment recommendations; and documents in writing the bases for its conclusions;

(4) The Financial Institution adopts, monitors, implements, and adheres to policies and procedures and incentive practices that meet the terms of Section II(d); and, in accordance with Section II(d)(3), neither the Financial Institution nor (to the best of its knowledge) any Affiliate or Related Entity uses or relies upon quotas, appraisals, performance or personnel actions, bonuses, contests, special awards, differential compensation or other actions or incentives that are intended or would

reasonably be expected to cause the Adviser to make imprudent investment recommendations, to subordinate the interests of the Retirement Investor to the Adviser's own interests, or to make recommendations based on the Adviser's considerations of factors or interests other than the investment objectives, risk tolerance, financial circumstances, and needs of the Retirement Investor;

(5) At the time of the recommendation, the amount of compensation and other consideration reasonably anticipated to be paid, directly or indirectly, to the Adviser, Financial Institution, or their Affiliates or Related Entities for their services in connection with the recommended transaction is not in excess of reasonable compensation within the meaning of ERISA section 408(b)(2) and Code section 4975(d)(2); and

(6) The Adviser's recommendation reflects the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent person acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims, based on the investment objectives, risk tolerance, financial circumstances, and needs of the Retirement Investor; and the Adviser's recommendation is not based on the financial or other interests of the Adviser or on the Adviser's consideration of any factors or interests other than the investment objectives, risk tolerance, financial circumstances, and needs of the Retirement Investor.

Section V—Disclosure to the Department and Recordkeeping

This Section establishes record retention and disclosure conditions that a Financial Institution must satisfy for the exemption to be available for compensation received in connection with recommended transactions.

(a) EBSA Disclosure. Before receiving compensation in reliance on the exemption in Section I, the Financial Institution notifies the Department of its intention to rely on this exemption. The notice will remain in effect until revoked in writing by the Financial Institution. The notice need not identify any Plan or IRA. The notice must be provided by email to *e-BICE@dol.gov*.

(b) Recordkeeping. The Financial Institution maintains for a period of six (6) years, in a manner that is reasonably accessible for examination, the records necessary to enable the persons described in paragraph (c) of this Section to determine whether the conditions of this exemption have been

met with respect to a transaction, except that:

(1) If such records are lost or destroyed, due to circumstances beyond the control of the Financial Institution, then no prohibited transaction will be considered to have occurred solely on the basis of the unavailability of those records; and

(2) No party, other than the Financial Institution responsible for complying with this paragraph (c), will be subject to the civil penalty that may be assessed under ERISA section 502(i) or the taxes imposed by Code section 4975(a) and (b), if applicable, if the records are not maintained or are not available for examination as required by paragraph (c), below.

(c)(1) Except as provided in paragraph (c)(2) of this Section or precluded by 12 U.S.C. 484, and notwithstanding any provisions of ERISA section 504(a)(2) and (b), the records referred to in paragraph (b) of this Section are reasonably available at their customary location for examination during normal business hours by:

(i) Any authorized employee or representative of the Department or the Internal Revenue Service;

(ii) Any fiduciary of a Plan that engaged in an investment transaction pursuant to this exemption, or any authorized employee or representative of such fiduciary;

(iii) Any contributing employer and any employee organization whose members are covered by a Plan described in paragraph (c)(1)(ii), or any authorized employee or representative of these entities; or

(iv) Any participant or beneficiary of a Plan described in paragraph (c)(1)(ii), IRA owner, or the authorized representative of such participant, beneficiary or owner; and

(2) None of the persons described in paragraph (c)(1)(ii)–(iv) of this Section are authorized to examine records regarding a recommended transaction involving another Retirement Investor, privileged trade secrets or privileged commercial or financial information of the Financial Institution, or information identifying other individuals.

(3) Should the Financial Institution refuse to disclose information on the basis that the information is exempt from disclosure, the Financial Institution must, by the close of the thirtieth (30th) day following the request, provide a written notice advising the requestor of the reasons for the refusal and that the Department may request such information.

(4) Failure to maintain the required records necessary to determine whether the conditions of this exemption have

been met will result in the loss of the exemption only for the transaction or transactions for which records are missing or have not been maintained. It does not affect the relief for other transactions.

Section VI—Exemption for Purchases of Fixed Annuity Contracts

(a) In general. In addition to prohibiting fiduciaries from receiving compensation from third parties and compensation that varies based on their investment advice, ERISA and the Internal Revenue Code prohibit the purchase by a Plan, participant or beneficiary account, or IRA of a Fixed Annuity Contract from an insurance company that is a service provider to the Plan or IRA. This exemption permits a Plan, participant or beneficiary account, or IRA to engage in a purchase with a Financial Institution that is a service provider or other party in interest or disqualified person to the Plan or IRA. This exemption is provided because Fixed Annuity Contract transactions often involve prohibited purchases involving entities that have a pre-existing party in interest relationship to the Plan or IRA.

(b) Covered transactions. The restrictions of ERISA section 406(a)(1)(A) and (D), and the sanctions imposed by Code section 4975(a) and (b), by reason of Code section 4975(c)(1)(A) and (D), shall not apply to the purchase of a Fixed Annuity Contract by a Plan, participant or beneficiary account, or IRA, from a Financial Institution that is a party in interest or disqualified person.

(c) The following conditions are applicable to this exemption:

(1) The transaction is effected by the Financial Institution in the ordinary course of its business;

(2) The compensation, direct or indirect, for any services rendered by the Financial Institution and its Affiliates and Related Entities is not in excess of reasonable compensation within the meaning of ERISA section 408(b)(2) and Code section 4975(d)(2); and

(3) The terms of the transaction are at least as favorable to the Plan, participant or beneficiary account, or IRA as the terms generally available in an arm's length transaction with an unrelated party.

(d) *Exclusions:* The exemption in this Section VI does not apply if:

(1) The Plan is covered by Title I of ERISA and (i) the Adviser, Financial Institution or any Affiliate is the employer of employees covered by the Plan, or (ii) the Adviser and Financial Institution is a named fiduciary or plan

administrator (as defined in ERISA section 3(16)(A)) with respect to the Plan, or an affiliate thereof, that was selected to provide advice to the plan by a fiduciary who is not Independent.

(2) The compensation is received as a result of investment advice to a Retirement Investor generated solely by an interactive Web site in which computer software-based models or applications provide investment advice based on personal information each investor supplies through the Web site without any personal interaction or advice from an individual Adviser (*i.e.*, “robo-advice”); or

(3) The Adviser has or exercises any discretionary authority or discretionary control with respect to the recommended transaction.

Section VII—Exemption for Pre-Existing Transactions

(a) In general. ERISA and the Internal Revenue Code prohibit Advisers, Financial Institutions and their Affiliates and Related Entities from receiving compensation that varies based on their investment advice. Similarly, fiduciary advisers are prohibited from receiving compensation from third parties in connection with their advice. Some Advisers and Financial Institutions did not consider themselves fiduciaries within the meaning of 29 CFR 2510–3.21 before the applicability date of the amendment to 29 CFR 2510–3.21 (the Applicability Date). Other Advisers and Financial Institutions entered into transactions involving Plans, participant or beneficiary accounts, or IRAs before the Applicability Date, in accordance with the terms of a prohibited transaction exemption that has since been amended. This exemption permits Advisers, Financial Institutions, and their Affiliates and Related Entities, to receive compensation in connection with a Plan's, participant or beneficiary account's or IRA's purchase, exchange, or holding of a Fixed Annuity Contract that was acquired prior to the Applicability Date, as described and limited below.

(b) Covered transaction. Subject to the applicable conditions described below, the restrictions of ERISA section 406(a)(1)(A), 406(a)(1)(D) and 406(b) and the sanctions imposed by Code section 4975(a) and (b), by reason of Code section 4975(c)(1)(A), (D), (E) and (F), shall not apply to the receipt of compensation by an Adviser, Financial Institution, and any Affiliate and Related Entity, as a result of investment advice (including advice to hold) provided to a Plan, participant or beneficiary or IRA owner in connection

with the purchase, or holding of a fixed annuity (i) that was acquired before the Applicability Date, or (ii) that was acquired pursuant to a recommendation to continue to adhere to a systematic purchase program established before the Applicability Date. This Exemption for Pre-Existing Transactions is conditioned on the following:

(1) The compensation is received pursuant to an agreement, arrangement or understanding that was entered into prior to the Applicability Date and that has not expired or come up for renewal post-Applicability Date;

(2) The purchase, exchange, holding or sale of the investment property was not otherwise a non-exempt prohibited transaction pursuant to ERISA section 406 and Code section 4975 on the date it occurred;

(3) The compensation is not received in connection with the Plan's, participant or beneficiary account's or IRA's investment of additional amounts in the previously acquired investment vehicle;

(4) The amount of the compensation paid, directly or indirectly, to the Adviser, Financial Institution, or their Affiliates or Related Entities in connection with the transaction is not in excess of reasonable compensation within the meaning of ERISA section 408(b)(2) and Code section 4975(d)(2); and

(5) Any investment recommendations made after the Applicability Date by the Financial Institution or Adviser with respect to the investment property reflect the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent person acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims, based on the investment objectives, risk tolerance, financial circumstances, and needs of the Retirement Investor, and are made without regard to the financial or other interests of the Adviser, Financial Institution or any Affiliate, Related Entity, or other party.

Section VIII—Definitions

For purposes of this exemption:

(a) "Adviser" means an individual who:

(1) Is a fiduciary of the Plan or IRA by reason of the provision of investment advice described in ERISA section 3(21)(A)(ii) or Code section 4975(e)(3)(B), or both, and the applicable regulations, with respect to the assets of the Plan or IRA involved in the recommended transaction;

(2) Is an employee, independent contractor, or agent of a Financial Institution; and

(3) Satisfies the federal and state regulatory and licensing requirements of insurance laws with respect to the covered transaction, as applicable

(b) "Affiliate" of an Adviser or Financial Institution means—

(1) Any person directly or indirectly through one or more intermediaries, controlling, controlled by, or under common control with the Adviser or Financial Institution. For this purpose, "control" means the power to exercise a controlling influence over the management or policies of a person other than an individual;

(2) Any officer, director, partner, employee, or relative (as defined in ERISA section 3(15)), of the Adviser or Financial Institution; and

(3) Any corporation or partnership of which the Adviser or Financial Institution is an officer, director, or partner.

(c) Investment advice is in the "Best Interest" of the Retirement Investor when the Adviser and Financial Institution providing the advice act with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent person acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims, based on the investment objectives, risk tolerance, financial circumstances, and needs of the Retirement Investor, without regard to the financial or other interests of the Adviser, Financial Institution or any Affiliate, Related Entity, or other party.

(d) "Fixed Annuity Contract" means an annuity contract that satisfies applicable state standard nonforfeiture laws at the time of issue and the benefits of which do not vary, in whole or in part, on the basis of the investment experience of a separate account or accounts maintained by the insurer. Fixed Annuity Contracts includes fixed rate annuity contracts and fixed indexed annuity contracts.

(e) "Financial Institution" means an insurance intermediary that has a direct written contract regarding the distribution of Fixed Annuity Contracts with both (i) the insurance company issuing the Fixed Annuity Contract and (ii) the Adviser or another intermediary (sub-intermediary) that has a direct written contract with the Adviser, and that also:

(1) Satisfies the applicable licensing requirements of the insurance laws of each state in which it conducts business;

(2) Has financial statements that are audited annually by an Independent certified public accountant;

(3) Maintains, to satisfy potential liability under ERISA or the Code as a result of this exemption, or any contract entered into pursuant to Section II(a), in an aggregate amount which must be at least 1% of the average annual amount of premium sales of Fixed Annuity Contracts sold by the Financial Institution to Retirement Investors pursuant to this exemption over its prior three fiscal years:

(A) Fiduciary liability insurance that:

(i) Applies solely to actions brought by the Department of Labor, the Department of Treasury, the Pension Benefit Guaranty Corporation, Retirement Investors or plan fiduciaries (or their representatives) relating to Fixed Annuity Contract transactions, including but not limited to actions for failure to comply with the exemption or any contract entered into pursuant to Section II(a);

(ii) does not contain an exclusion of Fixed Annuity Contracts;

(iii) has a deductible that does not exceed 5% of the policy limits; and

(iv) does not exclude claims coverage based on a self-insured retention or otherwise specify an amount that the Financial Institution must pay before a claim is covered by the fiduciary liability policy;

(B) cash, bonds, bank certificates of deposit, U.S. Treasury Obligations that are unencumbered and not subject to security interests or other creditors, or

(C) a combination of (A) and (B); and

(4) Has transacted sales of Fixed Annuity Contracts averaging at least \$1.5 billion in premiums per fiscal year over its prior three fiscal years;

(f) "Independent" means a person that:

(1) Is not the Adviser, the Financial Institution or any Affiliate relying on the exemption;

(2) Does not have a relationship to or an interest in the Adviser, the Financial Institution or Affiliate that might affect the exercise of the person's best judgment in connection with transactions described in this exemption; and

(3) Does not receive or is not projected to receive within the current federal income tax year, compensation or other consideration for his or her own account from the Adviser, Financial Institution or Affiliate in excess of 2% of the person's annual revenues based upon its prior income tax year.

(g) "Individual Retirement Account" or "IRA" means any account or annuity described in Code section 4975(e)(1)(B) through (F), including, for example, an

individual retirement account described in section 408(a) of the Code and a health savings account described in Code section 223(d).

(h) A “Material Conflict of Interest” exists when an Adviser or Financial Institution has a financial interest that a reasonable person would conclude could affect the exercise of its best judgment as a fiduciary in rendering advice to a Retirement Investor.

(i) “Plan” means any employee benefit plan described in section 3(3) of ERISA and any plan described in section 4975(e)(1)(A) of the Code.

(j) “Proprietary Product” means a product that is managed, issued or sponsored by the Financial Institution or any of its Affiliates.

(k) “Related Entity” means any entity other than an Affiliate in which the Adviser or Financial Institution has an interest which may affect the exercise of its best judgment as a fiduciary.

(l) A “Retail Fiduciary” means a fiduciary of a Plan or IRA that is not described in section (c)(1)(i) of the Regulation (29 CFR 2510.3–21(c)(1)(i)).

(m) “Retirement Investor” means—

(1) A participant or beneficiary of a Plan subject to Title I of ERISA or described in section 4975(e)(1)(A) of the Code, with authority to direct the investment of assets in his or her Plan account or to take a distribution,

(2) The beneficial owner of an IRA acting on behalf of the IRA, or

(3) A Retail Fiduciary with respect to a Plan subject to Title I of ERISA or described in section 4975(e)(1)(A) of the Code or IRA.

(n) “Third-Party Payments” include sales charges and insurance commissions when not paid directly by the Plan, participant or beneficiary account, or IRA; gross dealer concessions; revenue sharing payments; distribution, solicitation or referral fees; volume-based fees; fees for seminars and educational programs; and any other compensation, consideration or financial benefit provided to the Financial Institution or an Affiliate or Related Entity by a third party as a result of a transaction involving a Plan, participant or beneficiary account, or IRA.

Section IX—Transition Period for Exemption

(a) In general. ERISA and the Internal Revenue Code prohibit fiduciary advisers to Plans and IRAs from receiving compensation that varies based on their investment advice. Similarly, fiduciary advisers are prohibited from receiving compensation from third parties in connection with their advice. This transition period

provides relief from the restrictions of ERISA section 406(a)(1)(D), and 406(b) and the sanctions imposed by Code section 4975(a) and (b) by reason of Code section 4975(c)(1) (D), (E), and (F) for the period from April 10, 2017, to August 15, 2018 (the Transition Period) for Advisers, Financial Institutions, and their Affiliates and Related Entities, to receive such otherwise prohibited compensation subject to the conditions described in Section IX(d).

(b) Covered transactions. This provision permits Advisers, Financial Institutions, and their Affiliates and Related Entities to receive compensation as a result of their provision of investment advice within the meaning of ERISA section 3(21)(A)(ii) or Code section 4975(e)(3)(B) to a Retirement Investor regarding Fixed Annuity Contracts during the Transition Period.

(c) Exclusions. This provision does not apply if:

(1) The Plan is covered by Title I of ERISA, and (i) the Adviser, Financial Institution or any Affiliate is the employer of employees covered by the Plan, or (ii) the Adviser or Financial Institution is a named fiduciary or plan administrator (as defined in ERISA section 3(16)(A)) with respect to the Plan, or an Affiliate thereof, that was selected to provide advice to the Plan by a fiduciary who is not Independent;

(2) The compensation is received as a result of investment advice to a Retirement Investor generated solely by an interactive Web site in which computer software-based models or applications provide investment advice based on personal information each investor supplies through the Web site without any personal interaction or advice from an individual Adviser (*i.e.*, “robo-advice”); or

(3) The Adviser has or exercises any discretionary authority or discretionary control with respect to the recommended transaction.

(d) Conditions. The provision is subject to the following conditions:

(1) Before receiving compensation in reliance on the exemption in this Section IX, the Financial Institution notifies the Department of its intention to rely on this exemption and makes the following representation to the Department: “[Name of Financial Institution] is presently taking steps to put in place the systems necessary to comply with Section I of the Best Interest Contract Exemption for Insurance Intermediaries, and fully intends to comply with all applicable conditions for such relief after the expiration of the transition period.” The notice will remain in effect until revoked in writing by the Financial

Institution. The notice need not identify any Plan or IRA. The notice must be provided by email to e-BICE@dol.gov.

(2) The Financial Institution and Adviser adhere to the following standards:

(i) When providing investment advice to the Retirement Investor, the Financial Institution and the Adviser(s) provide investment advice that is, at the time of the recommendation, in the Best Interest of the Retirement Investor. As further defined in Section VIII(c), such advice reflects the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent person acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims, based on the investment objectives, risk tolerance, financial circumstances, and needs of the Retirement Investor, without regard to the financial or other interests of the Adviser, Financial Institution or any Affiliate, Related Entity, or other party;

(ii) The recommended transaction does not cause the Financial Institution, Adviser or their Affiliates or Related Entities to receive, directly or indirectly, compensation for their services that is in excess of reasonable compensation within the meaning of ERISA section 408(b)(2) and Code section 4975(d)(2).

(iii) Statements by the Financial Institution and its Advisers to the Retirement Investor about the recommended transaction, fees and compensation, Material Conflicts of Interest, and any other matters relevant to a Retirement Investor’s investment decisions, are not materially misleading at the time they are made.

(3) Disclosures. The Financial Institution complies with applicable disclosure obligations under state insurance law with respect to the sale of the Fixed Annuity Contract, and provides to the Retirement Investor, prior to the transmittal of the annuity application to the insurance company, a single written disclosure that clearly and prominently:

(i) Affirmatively states that the Financial Institution and the Adviser(s) act as fiduciaries under ERISA or the Code, or both, with respect to the recommendation;

(ii) Sets forth the standards in paragraph (d)(1) of this Section and affirmatively states that it and the Adviser(s) adhered to such standards in recommending the transaction;

(iii) Describes the Financial Institution’s Material Conflicts of Interest; and

(iv) Discloses to the Retirement Investor whether the Financial Institution offers Proprietary Products or

receives Third Party Payments with respect to any Fixed Annuity Contract recommendations; and to the extent the Financial Institution or Adviser limits Fixed Annuity Contract recommendations, in whole or part, to Proprietary Products or investments that generate Third Party Payments, notifies the Retirement Investor of the limitations placed on the universe of investment recommendations. The notice is insufficient if it merely states that the Financial Institution or Adviser “may” limit investment recommendations based on whether the investments are Proprietary Products or generate Third Party Payments, without specific disclosure of the extent to which recommendations are, in fact, limited on that basis.

(v) The disclosure may be provided in person, electronically or by mail. It does not have to be repeated for any subsequent recommendations during the Transition Period.

(vi) The Financial Institution will not fail to satisfy this Section IX(d)(3) solely because it, acting in good faith and with reasonable diligence, makes an error or omission in disclosing the required

information, provided the Financial Institution discloses the correct information as soon as practicable, but not later than 30 days after the date on which it discovers or reasonably should have discovered the error or omission. To the extent compliance with this Section IX(d)(3) requires Financial Institutions to obtain information from entities that are not closely affiliated with them, they may rely in good faith on information and assurances from the other entities, as long as they do not know, or unless they should have known, that the materials are incomplete or inaccurate. This good faith reliance applies unless the entity providing the information to the Adviser and Financial Institution is (1) a person directly or indirectly through one or more intermediaries, controlling, controlled by, or under common control with the Adviser or Financial Institution; or (2) any officer, director, employee, agent, registered representative, relative (as defined in ERISA section 3(15)), member of family (as defined in Code section 4975(e)(6)) of, or partner in, the Adviser or Financial Institution.

(4) The Financial Institution approves in advance all written marketing materials used by Advisers after determining that such materials provide a balanced description of the risks and features of the annuity contracts to be recommended;

(5) The Financial Institution designates a person or persons, identified by name and title or function, responsible for addressing Material Conflicts of Interest and monitoring Advisers’ adherence to the Impartial Conduct Standards and the person approves, in writing, recommended applications for Fixed Annuity Contracts involving Retirement Investors prior to transmitting them to the insurance company; and

(6) The Financial Institution complies with the recordkeeping requirements of Section V(b) and (c).

Signed at Washington, DC, this 12th day of January, 2017.

Lyssa Hall,

*Director of Exemption Determinations,
Employee Benefits Security Administration,
U.S. Department of Labor.*

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Department of Education

2 CFR Part 3474

Open Licensing Requirement for Competitive Grant Programs; Final Rules

DEPARTMENT OF EDUCATION**2 CFR Part 3474****RIN 1894-AA07****[Docket ID ED-2015-OS-0105]****Open Licensing Requirement for Competitive Grant Programs****AGENCY:** Office of the Secretary, Department of Education.**ACTION:** Final regulations.

SUMMARY: The Secretary amends the regulations of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in order to require, subject to certain categorical exceptions and case-by-case exceptions, that Department grantees awarded competitive grant funds openly license to the public copyrightable grant deliverables created with Department grant funds.

DATES: These regulations are effective March 20, 2017.

FOR FURTHER INFORMATION CONTACT:

Sharon Leu, U.S. Department of Education, 400 Maryland Avenue SW., Room 6W224, Washington, DC 20202. Telephone: (202) 453-5646 or by email: tech@ed.gov.

If you use a telecommunications device for the deaf (TDD) or text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:**Background and Summary of This Regulatory Action**

On November 3, 2015, the Secretary published a notice of proposed rulemaking (NPRM) in the **Federal Register** (80 FR 67672) that would amend regulations regarding the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. Under the amendments proposed in the NPRM, the Department would require, with certain categorical exceptions and the ability to grant case-by-case exceptions, that entities receiving Department funds under a competitive grant program openly license all copyrightable intellectual property created with those funds. These final regulations adopt the proposed amendments with modifications that we discuss in greater detail in these final regulations.

Under the Department's current regulations, title to intellectual property, including copyright, acquired under Department grant funds vests in the grantee. At the same time, for any work

subject to copyright that was developed or for which ownership was acquired under a grant award, the Department reserves a royalty-free, non-exclusive, and irrevocable right to reproduce, publish, or otherwise use for Federal purposes, and to authorize others to do so (referred to as a "Federal purpose license"). This license allows the government the ability to authorize others to use work funded by Department grants.

Grantees under the Department's competitive grant programs create a number of copyrightable works using Department competitive grant funds that have significant benefit for students, parents, teachers, school districts, States, institutions of higher education, and the public overall. These copyrightable works are wide ranging in nature and include instructional materials, personalized learning delivery systems, assessment systems, language tools, and teacher professional development training modules, just to name a few. The Department's grantees creating these works include State educational agencies (SEAs), local educational agencies (LEAs), institutions of higher education (IHEs), and non-profit organizations and while the works are created under a specific grant program and therefore may target a specific school or group of students, the resources are such that other education stakeholders would significantly benefit from being able to access them, reuse them, and in some cases, modify them to address their needs and goals.

It is the Department's experience, however, that copyrightable works created under competitive grants made by the Department generally have not been disseminated widely to the public. This is the case despite the existence of the Federal purpose license and efforts by the Department and grantees to proactively make them available. Although the Department provides individualized technical assistance and actively works with all grantees on dissemination planning, we have found that many education stakeholders and other members of the public are generally not aware of the educational resources created as a result of the Department's competitive grant programs. We believe this is because the education resources often are created and disseminated locally or disseminated to limited audiences by grantees in presentations at research conferences, through professional associations, or by commercial mechanisms that are not easily accessed by the general public or to a wider group of stakeholders. Even when the

resources are known to exist, stakeholders and the public are not sure how to access them, what usage rights or permissions are necessary to use them, or how to obtain those rights or permissions. Accordingly, while the Department's Federal purpose license does allow for the public to obtain a copy of these works from the Department, this has rarely occurred.

We believe that the open licensing regulation we are adopting here will address these key problems. Through an open license, grantees under the Department's competitive grant programs will explicitly give permission to the public to access, reproduce, publicly perform, publicly display, and distribute the copyrightable work; prepare derivative works, as defined in the Copyright Act, 17 U.S.C. 101, and reproduce, publicly perform, publicly display and distribute those derivative works; and otherwise use the copyrightable work, created in whole or in part with competitive grant funds provided by the Department, provided that in all such instances attribution is given to the copyright holder. Copyrightable grant deliverables, or deliverables, are final versions of a work developed to carry out the purpose of the grant, as specified in the grant announcement (*i.e.*, notice inviting applications or application package). The requirement will apply both to the deliverables themselves and any final version of program support materials necessary to the use of the deliverables. We believe that this will result in significantly enhanced dissemination of deliverables created with Department competitive grant funds and provide education stakeholders and members of the public with a simpler and more transparent framework to access, use, and possibly modify these deliverables for the benefit of their education communities.

The approach the Department is taking with this rule is limited in scope. It will apply only to grantees receiving Department competitive grant funds, which constitutes approximately 10 percent of the Department's total discretionary funding. Within that category of grants, we anticipate approximately 60 percent would potentially be subject to the rule. The rule will not apply to grants that provide funding for general operating expenses; grants that provide supports to individuals (*e.g.*, scholarships, fellowships); grant deliverables that are jointly funded by the Department and another Federal agency if the other Federal agency does not require the open licensing of its grant deliverables for the relevant grant program;

copyrightable works created by the grantee or subgrantee that are not created with Department funds; any copyrightable work incorporated in the grant deliverable that is owned by a party other than the grantee or subgrantee, unless the grantee or subgrantee has acquired the right to provide such a license in that work; peer-reviewed scholarly publications that arise from any scientific research funded, either fully or partially, from grants awarded by the Department; or grants under the Department's Ready to Learn Television Program. Grantees receiving funds under the Department's formula grant programs will not be subject to the rule. Further, the rule will not apply to a grantee for which compliance with the rule would conflict with, or materially undermine the ability to protect or enforce, other intellectual property rights or obligations of the grantee or subgrantee, in existence or under development, including those rights provided under 15 U.S.C. 1051, *et seq.*, 18 U.S.C. 1831–1839, and 35 U.S.C. 200, *et seq.* Similarly, the rule does not alter any applicable rights in the grant deliverable available under 17 U.S.C. 106A, 203 or 1202, 15 U.S.C. 1051, *et seq.*, or State law.

The rule also provides for the Department to consider individual grantee requests for exception to the open licensing requirement. We note in the rule some examples of situations that may be appropriate for an exception to the open licensing requirement, such as where the Secretary has determined that the grantee or subgrantee's dissemination plan would likely achieve meaningful dissemination equivalent to or greater than the dissemination likely to be achieved through the open licensing requirement. Similarly, we provide the example of a situation in which the open licensing requirement would impede the grantee's ability to form the required partnerships necessary to carry out the purpose of the grant. The list of examples in the rule is not exhaustive and is intended to indicate the types of situations in which an exception may be appropriate depending on the specific circumstances.

In designing competitions that would not fall within any of the categorical exceptions specified in the rule, the Department will also consider whether to make an exception for a grant program for a particular year's competition. In that regard, the Department will consider whether the open licensing requirement conflicts with the statutory purpose of the program and whether harm caused to

the program by implementing the open licensing requirement would outweigh its benefit. In granting exceptions, we may consider factors such as the following: (1) Possible negative effect on the statutory purpose of the program if an open licensing requirement is applied; (2) Possible barriers to the intended benefits of broad dissemination if an open licensing requirement is applied, for example, if the broadest possible dissemination can be achieved only through exclusive private entity partnerships; (3) The public need for, or benefit from, the opportunity to access or use the copyrightable grant deliverable given the context of the particular program; and (4) Other economic considerations, such as an undue financial hardship on the grantees to implement the rule. The Secretary's designee(s) will make final decisions about whether a program-level exception is granted. In each Notice Inviting Applications for a competitive grant program, the Department will clearly communicate whether or not the program is subject to the open licensing requirement or has received an exception.

The Department recognizes that implementation of these regulations represents a change from current practice and therefore plans to take a phased approach to implementing the rule for new competitive grants announced in FY 2017 and will fully implement it for all applicable competitive grant programs across the Department in FY 2018. This approach will provide us additional opportunities to take steps such as preparing administrative procedures regarding the consideration of requests for exceptions and providing relevant staff training. In FY 2017, each new competitive grant competition announcement will clearly indicate whether this rule will apply so that eligible applicants can make informed decisions regarding their participation in the competition.

Public Comment: In the NPRM we published on November 3, 2015, we proposed to amend regulations regarding the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in order to require that all Department grantees awarded competitive grant funds openly license to the public copyrightable intellectual property created with Department grant funds. The NPRM established a December 3, 2015, deadline for the submission of written comments. To ensure that all interested parties were provided sufficient opportunity to submit comments, we published a notice in the **Federal Register** (80 FR 74715) on

November 30, 2015, which extended the public comment period to December 18, 2015.

In response to our invitation in the NPRM, 146 parties submitted comments. We group major issues according to subject and by comments submitted in response to the five additional questions we posed. Generally, we do not address technical and other minor changes or suggested changes the Secretary is not legally authorized to make under applicable statutory authority. In some cases, comments addressed issues beyond the scope of the proposed regulations. Although we appreciate commenters' concerns for broader issues affecting open access, because those comments are beyond the scope of this regulatory action, we do not discuss them here.

Analysis of Comments and Changes: An analysis of the comments and changes in the regulations since publication of the NPRM follows. We note that we have renumbered some of the paragraphs from the proposed rule in this final rule. As a result, some of the provisions in the proposed rule have different paragraph numbers in this final rule.

General Comments

Comments: The Department received many positive comments regarding the proposed regulations. These commenters praised the Department for taking steps to provide broader access for taxpayers to deliverables produced with Department grant funds.

Discussion: We appreciate the commenters' support.

Changes: None.

Request for Extension of the Comment Period

Comments: We received several comments requesting that the Department extend the public comment period for the NPRM, indicating that additional time would be helpful to analyze and respond to the Department's proposals.

Discussion: The Department agreed that additional time for public comment would be helpful and extended the comment period by an additional 15 days. We believe that 45 days provided the public a meaningful opportunity to comment on the proposed rule, and this is supported by the complex and thoughtful comments we received.

Changes: None.

Legal Issues

Comments: One commenter requested clarification regarding the basis for the determination that this regulatory action

is significant under Executive Order 12866.

Discussion: This regulatory action is economically significant under section 3(f)(1) of Executive Order 12866 as we estimate that it will have an annual effect on the economy of more than \$100 million. We explain this determination further in the *Regulatory Impact Analysis* section of these regulations.

Changes: None.

Comments: Several commenters stated that the Department has not complied with Executive Order (EO) 13563, which requires agencies to base all regulatory frameworks on the best available science. As an example, one commenter noted that the impact analysis does not cite empirical data or evidence from research and is instead based on speculative statements.

Discussion: The Department has provided further analysis of the economic impacts of the regulations in accordance with both Executive Order 13563 and Executive Order 12866 in the *Regulatory Impact Analysis* section of these regulations. However, we note that Section 1 of EO 13563 reiterates principles established by EO 12866 and asks agencies “to use the best available techniques to quantify anticipated present and future costs as accurately as possible, such as identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.” Section 1 also recognizes that in some cases, careful and accurate quantification may not be possible and allows agencies to consider values including equity, human dignity, fairness, and distributive impacts that are difficult or impossible to quantify. Section 4 requires agencies to identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. In this case, our grantees retain the ability to choose to apply to receive funding through our grant competitions.

Each year, the Department funds a wide variety of competitive grant programs that support a diverse array of grant-funded copyrightable works. Conducting an empirical analysis of the exact costs and benefits of this final rule would require data not historically collected in the course of the administration of Department grants. Consistent with Section 1 of EO 13563, in our analysis of the rule, the Department considered qualitative values, including, transparency, equity, and distributive impacts, and recognized that some benefits and costs are difficult to quantify.

Changes: None.

Comments: A few commenters asserted that the NPRM ignores the statutory mandate of the Information Quality Act (IQA) (also commonly referred to as the Data Quality Act, such as by the commenter). Specifically, one commenter stated that the NPRM lacks information indicating that the Department has taken necessary steps to ensure that the disseminated information is reliable, in accordance with the Office of Management and Budget’s (OMB) IQA guidelines. The commenter indicated that to the extent that direct competitive grant funding is a mechanism of the Department to create and disseminate information, the Department has not taken those steps.

Discussion: The Department disagrees with the commenters’ interpretation of the IQA and the assertion that the Department is not in compliance with the requirements of the IQA. Although the comment mentioned OMB’s Data Quality Act guidelines, the applicable guidelines here are the Department’s Information Quality Act (IQA) guidelines, which were issued pursuant to the direction of OMB’s IQA guidelines and the IQA. The IQA is a procedural statute that requires the Department to issue guidelines: (1) Ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency, and (2) to establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines. In addition, the IQA requires the Department to send reports to the Director of OMB periodically.

The Department has developed the guidelines required under the IQA, which are available at: <http://www2.ed.gov/policy/gen/guid/iq/infoqualguide.pdf>. Notably, those guidelines provide that an affected person who does not believe the information the Department disseminates complies with the guidelines must provide, among other things: (1) A detailed description of the information that the requester believes does not comply with the Department’s or OMB’s guidelines; and (2) an explanation of the reason(s) that the information should be corrected (*i.e.*, describe clearly and specifically the elements of the information quality guidelines that were not followed). We note that these guidelines do not govern all information of the Department, nor do they cover all information disseminated by the Department. The IQA guidelines cover information in

four categories that is disseminated by the Department and subject to the Paperwork Reduction Act (44 U.S.C. 3502(1)): (1) Information about education programs; (2) research studies and program evaluation information; (3) administrative and program data; and (4) statistical data. As a general matter, these guidelines do not cover materials created through the support of competitive grants, research findings, or other information published by grantees.

We note that the IQA guidelines do provide a procedure for the public to register complaints to the Department for applicable information covered by the IQA. According to these procedures, any member of the public may provide a detailed explanation of the specific data being sought or the specific elements of the guidelines that it believes we have not followed. If the commenter had provided this information we could have attempted to either provide this data in the final rule or explain why the data is unavailable to us. If the commenter wishes to submit another request under our IQA guidelines, in compliance with the procedures those guidelines set out, we would be happy to review such a request.

Changes: None.

Comments: Several commenters asserted that the proposed regulations conflict with the Patent and Trademark Law Amendments Act, also known as the Bayh-Dole Act (Pub. L. 96–517, 35 U.S.C. 200 *et seq.*, which covers the intellectual property rights for patentable inventions resulting from Federal funding, as well as E.O. 12591. Many of these commenters questioned whether the Department was aware that 35 U.S.C. 212 provides to institutions the rights for copyrightable intellectual property or whether the Department has the legal authority to require an open license under the provisions of that section.

Commenters citing these conflicts note specifically that computer software source code can be both patentable and copyrightable and that under the Bayh-Dole Act, inventors, rather than the Federal government, are entitled to the title of the patents. These commenters suggested that further clarification of rights is necessary in order to avoid both confusion and litigation. One commenter noted that the proposed requirement to apply an open license to computer software source code is overly broad and could potentially cover all patentable inventions, trade secrets, or other intangible rights.

Other commenters who supported the proposed regulation stated that the

proposed open licensing requirement does not present a conflict with the Bayh-Dole Act, since the Bayh-Dole Act applies only to patentable inventions and not to copyrightable works. In the case of computer software, these commenters stated that for the subset of software that is considered patentable, the open licensing requirement does not prevent the inventor from also seeking patent protection under the legal conditions established by the Bayh-Dole Act.

Discussion: We appreciate the commenters raising these issues and agree that further clarification is necessary as to the rule's scope and application. The Department notes the distinction between copyrightable works, patentable inventions, and information that may be protected as trade secrets under applicable laws. The Department further acknowledges that products such as computer software may contain elements that would be protected under copyright laws, patent laws, and trade secret laws, giving rise to commenters' concerns. The Department did not intend that this regulation would interfere with other intellectual property rights of grantees, including the rights to protect trade secrets and to obtain patent protection on inventions. Thus, we have revised the rule to clarify this issue.

Changes: We have revised § 3474.20(d)(1)(viii) to expressly provide that the rule does not apply to grantees if compliance with the rule would conflict with, or materially undermine the ability to protect or enforce, other intellectual property rights or obligations of the grantee or subgrantee, in existence or under development, including those provided under 15 U.S.C. 1051, *et seq.*, 18 U.S.C. 1831–1839, and 35 U.S.C. 200, *et seq.*

Comment: Several commenters raised concerns that the proposed regulation contradicts the purpose of the Small Business Innovation Research (SBIR) program. These commenters noted that the stated purpose of the SBIR program is to encourage domestic small businesses to commercialize research-based innovations and that loss of exclusive copyright would contradict this purpose. Similarly, commenters also note that the proposed regulation would conflict with SBIR program directives issued by the Small Business Administration. Other commenters urged the Department to provide an exemption to the SBIR and Small Business Technology Transfer (STTR) program from this requirement.

Discussion: We note that the Department's SBIR program is currently awarded through contract competition

rather than grant competition. As a result, SBIR operates under the regulations as described in the Federal Acquisition Regulations at 48 CFR parts 1–99 and Executive Order 13329 rather than 2 CFR part 3474. The Department's SBIR program, therefore, is not currently covered by 2 CFR part 3474 of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards and would not be subject to this final rule. The SBIR program is established under the Small Business Innovation Development Act of 1982 (Pub. L. 97–219) and operates according to the Small Business Administration Policy Directives found at: https://www.sbir.gov/sites/default/files/sbir_pd_with_1-8-14_amendments_2-24-14.pdf. Additional information about the regulations, legislation, and guidance for SBIR can be found at: <http://www2.ed.gov/programs/sbir/legislation.html>.

Changes: None.

Comment: Many commenters suggested that any licensing requirements should align with current requirements used by other Federal agencies. Many commenters who supported the open licensing requirement recommended that the Department consider similar requirements implemented at the U.S. Department of Labor, the U.S. Department of State, and the United States Agency for International Development (USAID). These commenters noted that at these agencies, the open licensing requirement for grant programs and contracts specifically requires Creative Commons¹ licenses. Some commenters suggested that the regulations be aligned with current practice at the National Science Foundation.

Discussion: In developing these final regulations, the Department did take into account the experiences of other Federal agencies with open licensing. Specifically, we (1) considered the Office of Management and Budget's (OMB) Open Government Directive in M–13–13 Memorandum for Heads of Executive Departments and Agencies on Open Data Policy, which describes the Administration's intent to promote use of open licenses, in consultation with Project Open Data, the online, public repository intended to promote the continual improvement of the Open Data Policy, that allow minimal restrictions on copying, publishing,

distributing, transmitting, adapting, or otherwise using the information for non-commercial or for commercial purpose; and (2) consulted with other grant-making agencies through an inter-agency working group on open education to better understand their grant-making processes and implementation best practices. These final regulations are based on our review of these issues and reflect our determination as to how best to tailor an open licensing requirement to the needs of our grant programs and grantees.

We also note that the Department regularly engages our colleagues at other Federal agencies to explore the use of openly licensed resources in advancing the goals of our programs. In June 2016, the Department, in collaboration with NSF and the Institute for Museum and Library Services (IMLS), convened an Open Educational Resources (OER) Research Meeting, attended by representatives from #GoOpen States and Districts, leading principal investigators of projects funded by NSF, IMLS, and the Department's Institute of Education Sciences (IES) programs, as well as with other knowledgeable education stakeholders and researchers. The convening was designed around articulating key OER research issues, identifying OER research infrastructure needs, and exploring potential partnerships to pursue research and development projects. A separate, more detailed discussion regarding the suggestion to use Creative Commons licenses is below.

Changes: None.

Comment: Several commenters stated that this rule is unnecessary because, under current policy, the Department can already disseminate works created through grant funds. These commenters cite the current policy in 2 CFR 200.315(b) that provides the Federal awarding agency with a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so.

Discussion: As we discuss elsewhere in these final regulations, in practice, the Department has exercised the Federal purpose license described in 2 CFR 200.315(b), and previously established in 34 CFR parts 74 and 80, only in rare cases and in those instances the license did not allow the public to access resources directly without first contacting the Department. This regulation should enable deliverables produced under our competitive grants to be more readily available to the public. As discussed earlier, we are concerned that the current policy has

¹ Creative Commons is a global non-profit organization whose mission is to promote sharing and reuse through free legal tools. The organization is most well-known for public copyright licenses known as Creative Commons licenses.

not allowed for broad or efficient dissemination of copyrightable works.

Changes: None.

Comment: One commenter noted language in the preamble to the proposed rule where the commenter thought that, in order to ensure an open license, the grantee must not be allowed to copyright works resulting from Department funding. The commenter noted that, in fact, licenses of any kind are only needed when one party has legal rights, such as those established by copyright.

Discussion: We agree that the explanation in the preamble of the NPRM could have been clearer and appreciate the opportunity to clarify these issues. The NPRM did not propose to amend the Copyright Act of 1976 (17 U.S.C. 101 *et seq.*), which would be outside of the scope of the Department's authority. The legal framework for open licenses is built on the foundation established by the Copyright Act, which automatically gives protection to original works of authorship at the moment they are fixed in any tangible medium of expression and provides certain exclusive rights to authors of these works, 17 U.S.C. 106. In addition to those exclusive rights, the Copyright Act and other provisions of federal and state law provide various elements of what are known internationally as "moral rights."² In addition, the Copyright Act provides for termination rights, *i.e.*, the right of the author or her statutorily designated successors in interest to terminate a copyright transfer or license during a five-year period beginning several decades after the date of the grant or of first publication of the work. Thus, in the final rule, we clarify that grantees will retain ownership of their respective copyrights to their original works of authorship but, by accepting Department grant funds, agree to license to the public the right to exercise their exclusive rights. We also clarify that the rule does not alter any applicable rights in the grant deliverable available under 17 U.S.C. 106A, 203 or 1202, 15 U.S.C. 1051, *et seq.*, or State law. We have revised the regulatory text to make these clarifications.

We note that the proposed rule excluded current 2 CFR 200.315(b) from

the Department's regulations. We proposed this exception to avoid any inconsistency between the proposed open licensing rule and the provision in 2 CFR 200.315(b) recognizing a copyright to material developed with grant funds. In light of the comment we received, however, we recognize that there is not an inconsistency and therefore, there is no need to exclude 2 CFR 200.315(b) from our regulations. As the commenter pointed out, a grantee must hold a copyright to any material to which it provides a copyright license. Indeed, central to the functionality of this final rule is the existence of provisions that give title for intangible property created with Federal support to the creators that is provided in 2 CFR 200.315(a) and (b).

Changes: In final 2 CFR 3474.20, we have removed the exception of § 200.315(b) from the Department's regulations. We also removed proposed § 3474.20(d), which retains the Federal government's rights to copyrighted material, because the substance of that paragraph is already contained in § 200.315(b). Additionally, we have added an exception to § 3474.20(d)(2) to expressly provide that the rule does not alter any applicable rights in the grant deliverable available under 17 U.S.C. 106A, 203 or 1202, 15 U.S.C. 1051, *et seq.*, or State law.

Scope and Definitions

Comment: None.

Discussion: For the purposes of this regulatory action, there is no substantive difference between "direct competitive discretionary grant" and "competitive grant." We have selected the shorter term for the sake of clarity and to enable better understanding in the field.

Changes: Throughout this rule, we replaced "direct competitive discretionary grant" with "competitive grant."

Comment: One commenter noted that the term "grantee" is not defined in 2 CFR part 200 and that its use in the NPRM could include both for-profit and not-for-profit entities. The commenter made several observations related to the applicability of the proposed rule for different types of grantees and suggested that the Department separately review impacts on for-profit and not-for-profit entities and specifically questioned whether the NPRM should apply to for-profit entities.

Discussion: Although the term "grantee" is not defined in 2 CFR part 200, our regulations at 34 CFR 77.1 define the term "grantee." As defined in 77.1, a "grantee" includes any entity that receives a grant, which can include both for-profit and not-for-profit

entities. Applying this rule to for-profit entities is consistent with 2 CFR 200.101(c), which provides that a Federal awarding agency may apply the Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards regulations to for-profit entities unless there is a conflict with international obligations. We note that, in general, the eligibility requirements for our programs contained in statute limit eligibility to governmental entities and not-for-profit entities and for-profit entities are only eligible for our competitive grant funds in rare instances. Thus, the suggestion to review the impact of this rule on each type of grantee (not-for-profit and for-profit entities) separately is unnecessary.

In reviewing this issue, we realized that the proposed rule was not clear on whether the open licensing requirement would apply to subgrantees. We believe that it would and have revised the rule to make clear that it applies to the subgrantees of competitive grantees that are subject to this rule.

Changes: We have added "subgrantee" to various paragraphs throughout the rule.

Comment: One commenter requested a definition of the meaning of "Federal purpose," as used in the NPRM.

Discussion: Because we removed the proposed exception to 2 CFR 200.315(b), this final rule does not use the term "Federal purpose." Therefore, there is no need to elaborate on the meaning of this term for the purposes of this final rule.

Changes: None.

Comment: One commenter requested a more precise definition of Open Education Resources (OER). This commenter stated that the broad definition provided in the NPRM of openly licensed educational resources could lead to confusion on usage rights.

Discussion: It is important to note that for the purposes of this regulation, we do not use the term OER. Instead, we are requiring that an open license be applied to all grant deliverables, including final versions of program support materials that are necessary to the use of the deliverables, developed to carry out the purpose of the grant, that are created by Department grantees or subgrantees, wholly or in part with Department competitive grant funds. A subset of the resources that may be required to be openly licensed will meet the common definition of OER, but this rule is not limited to only OER. Furthermore, we believe that the education-focused policy reflected in these final regulations establishes clearly the conditions of an open

² Moral rights include the rights "(1) to claim authorship of their works ('the right of paternity'); and (2) to object to distortion, mutilation or other modification of their works, or other derogatory action with respect thereto, that would prejudice their honor or reputation (the 'right of integrity')." S. Rep. No. 100-352 at 9 (1988); see Berne Convention for the Protection of Literary and Artistic Works, Art. 6bis. The sources for such rights under U.S. law include various provisions of the Copyright Act and Lanham Act, and various state laws. S. Rep. No. 100-352 at 9.

license. That is, the grantee or subgrantee must “grant to the public a worldwide, non-exclusive, royalty-free, perpetual, and irrevocable license to (i) access, reproduce, publicly perform, publicly display, and distribute the copyrightable work; (ii) prepare derivative works and reproduce, publicly perform, publicly display and distribute those derivative works; and (iii) otherwise use the copyrightable work, provided that in all such instances attribution is given to the copyright holder.” However, we believe that greater clarity concerning usage rights would be achieved by including a definition of “derivative works” and we have revised the rule to do so.

Changes: We have modified § 3474.20(f)(2) to provide that “[a] “derivative work” means a “derivative work” as defined in the Copyright Act, 17 U.S.C. 101.”

Comment: One commenter requested a clearer definition of the term “peer-reviewed research publications.”

Discussion: The proposed rule used the term “peer-reviewed research publications” in describing materials that will not be covered by this final rule. This is terminology that differs slightly from the terminology used in the IES Policy Regarding Public Access to Research (“public access policy”)³ that uses the term “peer-reviewed scholarly publications.” For the purposes of this final rule, we use the term “peer-reviewed scholarly publications” to refer to final peer-reviewed manuscripts accepted for publication, that arise from research funded, either fully or partially, by Federal funds awarded through a Department of Education grant, procurement contract, or other agreement. A final peer-reviewed manuscript is the author’s final manuscript of a peer-reviewed scholarly paper accepted for publication, including all modifications from the peer review process. The final peer-reviewed manuscript is not the same as the final published article, which is defined as a publisher’s authoritative copy of the paper, including all modifications from the publishing peer-review process, copyediting, stylistic edits, and formatting changes. However, the content included in both the final peer-reviewed manuscript and the final published article is identical.

We note that we have expanded the exception in § 3474.20(d)(1)(v) to include all peer-reviewed scholarly publications that arise from any scientific research funded, either fully or partially, from grants awarded by the

Department. This change is discussed further elsewhere in this preamble. Although the final rule no longer references the IES public access policy specifically, we are using the term “peer reviewed scholarly publications” because it is used by IES grantees, who represent a majority of those covered by this exception and is widely used in the field.

Changes: We have revised 2 CFR 3474.20(d)(1)(v) to use the same term defined in the IES public access policy, “peer-reviewed scholarly publications.”

Comment: Many commenters generally appreciated the conditions of the open license required in § 3473.20(a) and praised the Department for including terms that would ensure the broadest possible use by eliminating barriers while ensuring authors receive attribution for their work.

Discussion: We appreciate the commenters’ support.

Changes: None.

Comment: Many commenters that supported the conditions of the open license proposed in the NPRM suggested that these conditions be expanded to explicitly include the “right to redistribute” openly licensed materials, including adapted derivative works. These commenters note that without this explicit right, grantees may interpret the conditions to restrict downstream users from distributing any modifications or adaptations made to these materials. The commenters assert that the free distribution of modifications or adaptations makes open licenses powerful tools for innovation when any member of the public can modify or adapt grant-funded resources. Conversely, some commenters proposed additional modifications that would explicitly prohibit downstream users of the openly licensed materials, including adapted derivative works, from restricting usage or commercially distributing derivative works. These include Creative Commons licenses with Non-Commercial and Share-Alike restrictions.

Discussion: The Department agrees with the importance of having the ability to adapt and modify openly licensed materials, and to distribute those adaptations and modifications. We generally believe that where there are few restrictions on the terms of use and distribution, the Department’s grant-funded resources will be disseminated widely. To that end, we have expressly clarified that for copyrightable grant deliverables created in whole or in part with Department competitive grant funds, the grantee or subgrantee must include as a term of the

open license, the right to prepare derivative works and reproduce, publicly perform, publicly display and distribute those derivative works. At the same time, we appreciate commenters’ concerns regarding ensuring that a grantee or subgrantee has the discretion to select an open license, including a license that limits use of the grant deliverable to noncommercial purposes. Although we intended in the proposed rule that a grantee would have this discretion, we realize this was not clear and are revising the regulation to reflect the grantee’s or subgrantee’s discretion in this area.

For copyrightable works that are not funded by the Department, we have similarly left the terms under which any derivative works may be licensed to the discretion of the owner of the derivative work (e.g., if a grantee created a deliverable with grant funds and then creates a derivative work with other funding, the grantee would have the flexibility to choose how to license the derivative work, such as through commercial channels).

Finally, as discussed earlier in this section, we have defined the term “derivative work” to have the same meaning as contained in the Copyright Act.

Changes: We have modified § 3474.20(b)(1) to explicitly provide the right to prepare derivative works based upon the openly licensed works, as well as the right to reproduce, publicly perform, publicly display and distribute those derivative works. We have also revised § 3474.20(b)(2) to reflect that a grantee or subgrantee has the discretion to select a license that limits use of the grant deliverable to noncommercial purposes. In addition, we have modified § 3474.20(f)(2) to provide that “[a] “derivative work” means a “derivative work” as defined in the Copyright Act, 17 U.S.C. 101.”

Comment: In addition to comments on the conditions of open licenses, many commenters recommended that the Department specify the type of licenses that grantees should use under this rule. In particular, commenters suggested that the Department clearly reference or require the use of Creative Commons licenses. Commenters offered a number of considerations.

First, commenters noted that without a commonly understood licensing framework, lack of clarity over terms of use would impede the Department’s goals of widespread sharing and dissemination. For example, individual grantees could each create their own open licenses by following the conditions provided in the proposed rule. While their intent would be to

³ <https://ies.ed.gov/funding/researchaccess.asp>.

meet the requirements of the rule, the proliferation of novel licenses could result in confusion about usage rights or concerns about interoperability with other existing licenses. In these cases, the new or non-standardized licensing language may discourage or delay adoption or integration of resources due to the additional time and resources required to interpret the unfamiliar language and to verify legal interoperability issues and widespread sharing and dissemination could decrease, rather than increase. Directing grantees towards a licensing framework with broad familiarity would enhance the utility of the requirement and enable more immediate impact. These commenters cite Creative Commons licenses as the most commonly known, easily recognizable, and widely-used public license. To support this claim, commenters cited Web sites such as Wikipedia, Flickr, and Whitehouse.gov as well-known repositories of content that is openly licensed using Creative Commons licenses. Others note that Creative Commons recently reported that one billion works are licensed using one of their public licenses.

Second, commenters stated that the Department should adopt a Creative Commons licensing framework because it would align with frameworks already in place at other organizations. This alignment would enable entities to collaborate and share resources across these projects with fewer barriers. For example, commenters pointed to open licensing and access policies by other funders including the Bill and Melinda Gates Foundation, the William and Flora Hewlett Foundation, the Ford Foundation, the World Health Organization, and the World Bank, that require use of Creative Commons licenses. Commenters also pointed to other governments (the United Kingdom, Australia, and Poland) that have identified Creative Commons licenses as they begin to implement similar policies. Many commenters pointed to grant programs at the Department of State, including USAID, and the Department of Labor's Trade Adjustment Assistance Community College and Career Training (TAACCCT) grant program as examples of programs at other Federal agencies that have already implemented open licensing requirements using Creative Commons licenses. Commenters noted that Creative Commons licenses have been embraced by open courseware projects that have produced diverse educational materials and innovative textbook offerings currently used at hundreds of

major colleges and universities and K-12 schools throughout the country.

Third, commenters stated that individually created licenses may satisfy the conditions provided in the proposed rule, but may not have the same force or effect of law. Commenters asserted that Creative Commons licenses are legally robust, internationally recognized licenses that are enforceable and easily adopted worldwide as they were written to conform to the international treaties governing copyright.

Finally, commenters noted the practicality of a Creative Commons license. These commenters stated that while Creative Commons licenses have a three-layered design (legal, human readable, machine-readable), the process of selecting and affixing the license and license deed is simple. In addition, commenters pointed to the wide availability of tools and resources developed to support the implementation of the Creative Commons licensing framework in various contexts. By adopting the same licensing framework, the Department could also utilize these existing tools and resources in its own implementation and training activities.

Discussion: We agree that the particular terms of the Creative Commons Attribution licenses (CC BY) are an example of a permissible type of license. However, we are concerned that limiting the license to only a CC BY license would result in less flexibility for grantees and would not account for changes and developments that could occur with respect to the types of licenses commonly used. We believe an appropriate balance of these concerns is to maintain our description of an open license.

However, we have revised § 3474.20(b)(2) to provide greater specificity concerning the requirements for the open licenses that a grantee may use under this rule that ensure that licenses selected are readily identified, either visually or electronically, and to minimize confusion about licensing terms and usage rights. These include the requirement that grantees use a symbol or device that readily communicates to users the permissions granted concerning the use of the copyrightable work, machine-readable code for digital resources, readily accessed legal terms, and the statement of attribution and disclaimer specified in 34 CFR 75.620(b).

Changes: In § 3474.20(b)(2) we added provisions requiring that any license used contain the following features: (i) A symbol or device that readily communicates to users the permissions

granted concerning the use of the copyrightable work; (ii) machine-readable code for digital resources; (iii) readily accessed legal terms; and (iv) the statement of attribution and disclaimer specified in 34 CFR 75.620(b).

Comment: Many commenters suggested that the Department expand the scope of the proposed rule beyond competitive grants to include all grants funded by the Department, including those grants funded by formula. These commenters note that while the absolute amount of funding that is available through competitive grant programs is not insignificant, it is small proportionally, when compared with the total funding available through formula programs. The commenters noted that in excluding formula grant programs funded under the Elementary and Secondary Education Act of 1965 (ESEA), as amended by the Every Student Succeeds Act (ESSA), and the Individuals with Disabilities Education Act (IDEA), the Department overlooks valuable resources created as a result of these programs. A few of these commenters specifically noted that with the passage of ESSA, many programs that were previously funded as competitive grants have been converted to State block grants, further decreasing the number of programs that would be covered by the proposed rule. The commenters noted the loss of public benefit, and encouraged the Department to promote greater development of open educational resources as a critical strategy to ensuring educational equity, especially for those served by schools in less wealthy communities.

Discussion: In developing the proposed rule, we considered whether it should apply to formula grants but we believe it is most appropriate to limit the applicability of the rule to competitive grants. Based on our experience in implementing this final rule for the Department's competitive grant programs, we will explore whether it is appropriate to expand its coverage to other Department grant programs.

With respect to ESSA, we note a few provisions that may be helpful in establishing the broader context of the Department's work to increase dissemination of educational materials through the use of open educational resources and educational technology. In particular, we note that while Title IV of ESSA authorizes block grants for services that previously were provided under competitive grants under ESEA, openly licensed resources are now incorporated more broadly into all digital education interventions funded by ESSA formula programs. For example, ESSA incorporates open

educational resources into the definition of digital learning in section 4102. As a result, open educational resources may be more easily incorporated into programs authorized under section 4101 to expand digital learning opportunities to rural and remote areas or to develop courses or curricula that incorporate digital learning technologies and under section 4109, to allow LEAs receiving subgrants from States to implement similar measures in their districts. Separately, States receiving allotments under section 4104 may use them to increase access to personalized learning experiences, including “making content widely available through open educational resources.”

Change: None.

Comment: Some commenters requested that the Department explicitly communicate which of the Department’s grant programs would be impacted by the open licensing requirement. These commenters noted that the language of the NPRM leaves open to interpretation the particular grant programs covered and has resulted in confusion over whether it would be applicable to grants awarded under the SBIR program.

Discussion: We address these comments on identifying the Department’s grants that would be impacted by this rule in the *Regulatory Impact Analysis* section of these final regulations because this issue of applicability is closely tied to budgetary and regulatory impact concerns. We address the question of whether this rule applies to the SBIR program in a separate *Discussion* section above.

Changes: None.

Comment: One commenter asked whether the requirements and exemption provided in proposed § 3474.20(c)(3) applied only to peer-reviewed research publications that result from IES-funded research or whether it is applicable to publications resulting from all Department-funded research. The commenter also asked whether the proposed rule would require that the work of writing the article also be funded by the grant, in order for the requirements to apply.

Other commenters suggested that the Department eliminate the exception for peer-reviewed research publications under the proposed rule. These commenters noted that, although the IES’ public access policy makes peer-reviewed scholarly publications available for the public to access, these same publications would still be subject to copyright restrictions. These commenters expressed concern that exempting peer-reviewed research unintentionally overlooks materials that would be of value to the public and to

the scientific community and encouraged the Department to apply the rule uniformly for all grant-funded materials, including these publications. The commenters recognized that IES’ current public access policy is consistent with the requirements laid out in the 2013 Office of Science and Technology Policy (OSTP) Memorandum for Heads of Executive Departments and Agencies https://www.whitehouse.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf. However, they stated that requiring an open license, in addition to requiring public access, could provide an opportunity to accelerate scientific discovery and fuel innovation. One commenter recommended that research publications be made available under a CC BY license, aligning our rule to requirements for publications resulting from scientific research funded by other organizations, such as the Bill and Melinda Gates Foundation. Another noted the high cost of access to research publications and that removing the exception would ease financial constraints on some institutions.

Other commenters that did not support the proposed rule applauded the Department for exempting peer-reviewed research publications covered by the IES’ public access plan. These commenters noted that the 2013 OSTP Memorandum provides an example of a policy that appropriately balances policy benefits of open access while accommodating journal publisher subscription business models.

Discussion: While the majority of research and development activities at the Department are supported through competitive grants administered by the two IES research centers, commenters rightly observe that research and development investments are also supported by other offices within the Department. These include the Office of Innovation and Improvement, the Office of Special Education and Rehabilitative Services (OSERS), the Office of Postsecondary Education (OPE), and the Office of Career, Technical, and Adult Education (OCTAE).

The exception in proposed § 3474.20(c) would have applied only to IES grantees because peer reviewed scholarly publications produced under those grants are subject to the IES’ public access policy, which ensures that those publications are made available to the public through posting on the Education Resources Information Center (ERIC). In the final rule, we have broadened this exception to cover any peer-reviewed scholarly publications funded by any Department grant, not

just an IES grant. We do not believe this significantly changes the practical application of this exception; rather, we believe it makes the application of our rule more consistent. We note that the majority of research and development activities at the Department are the result of IES research grants. For IES grants that result in peer reviewed scholarly publications, the requirements of the IES public access plan will still apply. Currently, the Department is exploring the development of a rule, which would be subject to Administrative Procedures Act notice and comment requirements, which would extend the IES public access requirements for peer-reviewed scholarly publications to all Department grantees. Additionally, we have removed the reference to the IES public access plan from the exception in the corresponding final § 3474.20(d)(1)(v) because that plan is not applicable to Department grants funded outside of IES. The IES public access policy is a document that, under 20 U.S.C. 9581, could be revised without rulemaking. In light of the fact the document could continue to evolve, we do not think it is appropriate to rely on it for the scope of the exception.

One commenter also correctly noted that the work of writing publications may not always be funded by research and development grants. Regardless of whether the work of writing the article is grant-funded, if the research on which the publication is based is supported in whole or in part by grant funds, then the exception in final § 3474.20(d)(1)(v) applies.

Conversely, some grant programs may fund the authorship of articles for publication that do not arise from any scientific research funded by the Department. In these cases, the grantee would be required to apply open licenses to the new works of authorship as described in final § 3474.20(a).

In response to the comments to eliminate the exception in proposed § 3474.20(c)(3), we think that at this time, it is necessary to provide for an exception for peer-reviewed scholarly publications. The research community benefits from allowing the results of scientific research, including research funded by the Department, to be published in scientific journals and subjected to the rigors of peer-review that is a prerequisite to such publication. We note that we are not maintaining the exception in order to accommodate journal publisher subscription business models. Rather, we recognize that there are limited number of open access research journals. Requiring these grantees to

openly license the publications at this time may limit their ability to distribute rigorously reviewed scholarly publications without this exception.

Changes: We have moved this exception from proposed paragraph (c)(3) and into final paragraph (d)(1)(v) and removed the reference to the IES public access policy from the exception. We also expanded the exception to include all peer-reviewed scholarly publications resulting from research grants awarded by any office within the Department.

Comment: Many commenters expressed concern that the open licensing requirement would cause grantees to violate existing copyright or licensing restrictions if they were required to openly license materials. For example, one commenter noted that grant-funded educational resources could incorporate the use of licensed stock photos. Similarly, some commenters note that in many cases, the new modifications to existing intellectual property may require the original, copyrighted work in order for context or application. Another commenter indicated there was confusion in understanding the difference between our usage of the phrases “pre-existing content” and “existing intellectual property.” Many commenters pointed in particular to modifications of computer software, where improvements would not be useful without access to the original licensed programs.

Discussion: It is not our intent to cause any grantee to violate any existing copyrights or licensing restrictions. First, this rule covers only those grant deliverables that are created wholly or in part with Department competitive grant funds, and that constitute new copyrightable works. In instances where the grant deliverables consist of copyrightable modifications to a pre-existing work, the rule only extends to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. This rule does not impose a requirement to license pre-existing works. This rule also does not require the grantee to modify the terms of any pre-existing license or restrictions, irrespective of whether the grantee is the copyright owner. To ensure these points are clear, we are revising the rule to reflect that it does not cover copyrightable works that are not created with Department grant funds or any copyrightable work incorporated in the grant deliverable that is owned by a party other than the grantee or

subgrantee, unless the grantee or subgrantee has acquired the right to provide such a license in that work. Further, the rule does not apply to grantees or subgrantees where compliance would result in a conflict with the grantee’s or subgrantee’s other intellectual property-related obligations, such as those under the terms of a license agreement.

Similarly, this rule does not require that grantees provide access to computer programs protected under copyright or other laws. We understand that in many cases, the modifications may only be viable within the context of existing commercial software or platforms. However, we believe that these modifications, accompanied by any supporting documentation, may benefit other users of the same commercial software or platforms to the extent that these modifications can be separately identified and extracted from the underlying proprietary work and that open licensing would be permissible under the terms of any restrictions applicable to that underlying work. In light of these comments, we have revised the text of the rule to make this distinction more salient.

Finally, we agree that the references to “pre-existing content” and “existing intellectual property” required appropriate revisions in order to provide greater clarity to the public.

Changes: We have revised § 3474.20(a) to provide that the rule applies to copyrightable modifications to pre-existing works, to the extent such modifications can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works.” Additionally, § 3474.20(d)(1)(iv) and (e), now provide, respectively, that the rule does not apply to “[c]opyrightable works created by the grantee or subgrantee that are not created with grant funds,” or “any copyrightable work incorporated in the grant deliverable that is owned by a party other than the grantee or subgrantee, unless the grantee or subgrantee has acquired the right to provide such a license in that work.” Also, § 3474.20(d)(1)(vi) now provides that the rule does not apply to “[g]rantees or subgrantees for which compliance with these requirements would conflict with, or materially undermine the ability to protect or enforce, other intellectual property rights or obligations of the grantee or subgrantee, in existence or under development, including those provided under 15 U.S.C. 1051, *et seq.*, 18 U.S.C. 1831–1839, and 35 U.S.C. 200, *et seq.*”

Finally, the references to “pre-existing content” and “existing intellectual property” have been removed and the rule now refers to “pre-existing works.”

Comment: Many commenters stated that the requirement to openly license copyrightable works is overly broad. Commenters noted that the Department appears to intend to implement the regulation indiscriminately, without regard for how to distribute works for maximum benefit or without regard for whether the public would benefit from the intellectual property. Specifically, one commenter noted that emails, deliberative work product, and assessments, among other resources would be included in this requirement.

Discussion: Our intention with these regulations is to ensure broad dissemination of and access to high-quality educational resources. We recognize that, in the course of developing these resources, grantees will generate additional copyrightable materials such as email correspondence, administrative documentation, or deliberative work products. Although these materials are items that are considered copyrightable works produced through a grant project, many of them will not be considered program support materials necessary to the use of the deliverables and therefore would not need to be openly licensed. Others, however, may be considered program support materials necessary in order to understand, learn from, and replicate deliverables. For example, some outreach materials may describe grant deliverables to stakeholders, or others may document best practices in implementation for specific target populations. These program support materials that are considered necessary to the use of grant deliverables, must be openly licensed and made available to the public. Other items, such as staff training curricula, production guides or planning documents that are created as a result of implementing the grant project, may or may not provide useful information for understanding the administration of grant activities. In these cases, the Department is committed to working with grantees to determine whether these should be part of their dissemination plan. In cases where these support materials are appropriately considered records, grantees should follow record-keeping requirements in 34 CFR 75.730–732. Our goal is to ensure that the public may benefit from the sharing of those grant products that may have significant value, but not to unduly burden grantees.

We agree with the commenters that our intentions and the rule’s scope

should be clarified and are revising the final rule to narrow the scope of the copyrightable works that must be openly licensed under § 3474.20(a) to copyrightable grant deliverables. Specifically, we are including a definition of “grant deliverable” in the final regulations and specifying that the open licensing requirement only applies to grant deliverables. Under the definition, a “grant deliverable” is a final version of a work, including any final version of program support materials necessary to the use of the deliverable, developed to carry out the purpose of the grant, as specified in the grant announcement.

The Department is committed to working with grantees to develop licensing and dissemination strategies that are particular to their grant program, offer appropriate privacy protection, do not create duplicative work for the grantee, and are consistent with the goals of the grant program and this final rule. Department staff will be trained to address these items throughout the implementation period of the rule. We note that it is impossible for us to make specific determinations in advance about which resources would be of use to various stakeholders in the field and believe our goals are best accomplished when the public is given access to the broadest array of materials created to make their own determination regarding their usefulness. The Department will provide further guidance to grantees concerning grant deliverables during implementation of grant programs.

Changes: We have added § 3474.20(f) to provide a definition of “grant deliverable” to mean a final version of a work, including any final version of program support materials necessary to the use of the deliverable, developed to carry out the purpose of the grant, as specified in the grant announcement.

Comment: One commenter expressed concern over the potential negative effects of the proposed regulation on grantees of the Department’s Ready to Learn Television grant program, and recommended the Department add an exception for “grants that provide funding for public television entities.” The commenter detailed consequences of the final regulation in three broad categories.

First, the commenter indicated that under existing programmatic requirements, content and resources created by the Ready to Learn grant program are already distributed as broadly as possible. In implementing these distribution and outreach requirements, the commenter noted that grant-funded television content is

distributed over-the-air to almost every household in America and grant-funded transmedia content such as mobile applications and other digital resources are already available at no cost to teachers, parents, and children.

Second, the commenter indicated that the quality and sustainability of materials created with Ready to Learn grant funds would be undermined. The commenter noted that Ready to Learn grant funding serves as seed funding for many of the public television series and transmedia content and asserted that without non-exclusive distribution rights it would be impossible to secure additional funding through public-private partnerships. In addition, the commenter noted that it would be impossible to secure partnerships with experienced producers of top quality educational series. Similarly, the commenter noted that Ready to Learn grantees, together with experienced producers, have been able to create resources that are qualitatively different than content created by other grantees and that the open license requirement would preclude production of any further content.

Finally, the commenter stated that the impact of the open license would extend beyond loss of revenue to encompass loss of educational content that would not be produced in response to this regulation. In addition, the commenter noted that resources produced by Ready to Learn funding can be used broadly by educators in accordance with the fair use provisions of copyright law and that testing and research have shown that there is no indication of a further need for educators to create derivative works. The commenter also stated that contrary to the Department’s expectation that the proposed regulations would not have a significant economic impact on a substantial number of small entities, the proposed regulation would have a significant impact on a substantial number of small entities as it would reduce the programming available for small entity licensee stations to air, and would degrade community and foundation financial support for stations by constraining stations’ ability to engage with and serve their local communities.

Discussion: The Department values the work of our Ready to Learn grant recipients. We appreciate the commenter’s data on the broad distribution and availability of the television and digital content created by public television entities through the Ready to Learn Television grant program. We commend the Ready to Learn Television program grantees for

creating high quality, research-based transmedia content that is readily available to early learners of many diverse backgrounds.

We have added an exception in § 3474.20(d)(1)(vi) for grantees or subgrantees under the Ready to Learn Program because of two factors unique to the design and statutory mandate of the Ready to Learn program. First, one stated goal of the proposed regulation is the broad distribution of materials funded by the Department. The commenter provided evidence that the particular qualities of the Ready to Learn distribution model and transmedia strategy, and the specific programmatic and statutory requirements to broadly distribute these materials have achieved market dissemination at least equivalent to the dissemination likely to be achieved through compliance with this final rule. Second, a stated goal of the proposed regulation is to spur innovation through creative reuse of grant-funded materials. As the commenter notes, many of the resources created under the Ready to Learn program are based on pre-existing intellectual property and the intellectual property owned by the grantee in the final grant deliverable, in isolation, would provide minimal opportunity for meaningful adaptation, modification, or other re-use.

We disagree with the commenter’s recommendation that the Department adopt a categorical exception for all grants that provide funding for public television entities. Although it is apparent from the comment that the recommended exception was specifically with reference to the Ready to Learn television grant program, we note that public television entities may also be the recipient or sub-recipient of other Department grants subject to this regulation. For example, public television entities have received funding as partners in the Special Education Educational Technology, Media, and Materials for Individuals with Disabilities Program (formerly Technology and Media Services for Individuals with Disabilities). The recommended exception, as written, would apply too broadly to any grant in which a public television entity was a recipient or sub-recipient, without sufficient evidence that all public television entities would be adversely affected by this rule in a similar manner.

The reasons the commenter gave for a categorical exception are seemingly unique to grantees under the Ready to Learn grant program.

Changes: We have revised the final regulations to provide that grantees under the Ready To Learn Television

Program, as authorized in section 2431 of the ESEA, 20 U.S.C. 6775, are excepted from the rule's requirements.

Comment: A few commenters expressed concerns with the proposed rule in the context of the Department's broader #GoOpen initiative to encourage States, school districts, and educators to use openly licensed educational materials. One commenter disagreed with the Department's assertion that openly licensed materials will increase equity, suggesting that inequality of connectivity and hardware necessary to access openly licensed resources and costs of printing of digital materials instead preserves the existing inequalities between schools. This commenter also stated that rather than empowering teachers, adaptable, openly licensed resources actually impose additional burdens on already overtaxed teachers. Finally, another commenter similarly questioned whether the Department, in expressing a preference for openly licensed educational resources, might be distorting fair market competition for educational materials.

Discussion: We appreciate the comments on the #GoOpen initiative. Because the #GoOpen initiative is an activity separate from this rulemaking, many of these concerns are beyond the scope of this regulatory action. However, we believe a few clarifications will limit any confusion between these activities, and their differing scopes.

The #GoOpen movement is a specific movement where districts and states voluntarily participate in a community of practice focused on the use of openly licensed, digital resources. For these #GoOpen districts and States, openly licensed resources provide opportunities for cost savings and dissemination and innovation beyond the mere digitization and print reproduction of resources across the socioeconomic spectrum. The #GoOpen movement supports districts and States, in curating curricular materials that teachers can use or reuse or adopt based on the unique needs of their students or to suit their individual approaches to instruction. These teachers are afforded tools and professional learning resources from their district or State and from other districts and States so that they can capitalize on the opportunities provided by openly licensed and other digital resources. This is consistent with other policies, such as those reflected in the ESEA the authorization of appropriations for, among other professional development activities, training on the use of digital and openly sourced materials. Beyond individual classroom teachers, the #GoOpen

initiative encourages administrators, technology directors, parents, and students themselves to work collaboratively in order to ensure the best opportunities for success. Through the #GoOpen movement, the Department actively supports partnerships between States, districts, and educators; promoting promising models of leadership; and aligning public and private efforts.

The #GoOpen movement is one specific initiative of the Department, where the Department coordinates the community of practice for States, school districts, and educators that voluntarily use openly licensed educational materials. We believe that a consideration to move towards openly licensed textbooks must include an objective evaluation of relevance and quality, as well as cost. Those resource decisions are made at the State and local level. Our efforts through the #GoOpen movement encourage State and district leaders to give equal consideration to openly licensed resources in making the best possible decision for educators and students.

This rule does not impose requirements for teachers or any other stakeholders to use openly licensed resources or encourage them to eschew publisher textbooks.

Changes: None.

Comment: Several commenters stated that the proposed rule would conflict with patent rules, stating that the existing technology transfer mechanism established at research institutions through current regulations is the most effective means of promoting innovation and commercialization of grant funded intellectual property. The commenters assert that requiring an open license on grant-funded materials would reduce rather than increase innovation and dissemination.

These commenters note that the technology transfer infrastructure established as a result of the Bayh-Dole Act and other patent provisions has incentivized commercial entities to develop grant-funded works into successful products and services with greater reach. One commenter provided data from articles analyzing the impact of the Bayh-Dole Act which state that federally funded research has resulted in nearly 10,000 patented products and enabled the launch of 4,200 new companies with a net product sales of \$22 billion in 2013 alone. The commenter concluded from this data that the profits from these sales have incentivized partnerships with Department grantees that result in broad and relevant dissemination of products. Other commenters similarly note that

public-private partnerships are critical to enabling sustainability of grant-funded products. In cases where grantees that have created computer software source code, that code itself often requires additional investment in product development, marketing, distribution, and support services for updates and upgrades. In cases where grant-funded research has resulted in creating interventions, these partnerships can allow continuous refinement and improvement of the intervention.

Those commenters that warned the Department about the unintended effects of an open license on the incentive to innovate asserted that profit incentives are the engine of innovation. The commenters stated that, this rule would remove these incentives, which would stifle new ideas and result in fewer innovations. Similarly, some commenters stated that commercialization was the only means by which intellectual property becomes widely distributed and that open licenses would irrevocably harm product dissemination for grant funded materials.

Other commenters expressed concerns that the loss of profit incentives would cause stakeholders to pursue alternate, non-Federal funding, rather than Department grant funding.

Discussion: The Department agrees with the commenters that commercialization is an important means of promoting innovation and can result in broad dissemination of patents and other types of intellectual property. Grantees that comply with the legal requirements to openly license grant funded copyrightable works identified in the rule may still wish to seek patent protection on any invention created with grant funds. To ensure clarity about the rule's application, we are revising the rule to provide that it would not apply in instances in which compliance with the rule would conflict with or materially undermine the ability to protect or enforce other intellectual property rights or obligations of the grantee or subgrantee, in existence or under development. For example, the rule would not apply to a grantee or subgrantee in instances where the application of the rule would materially undermine the grantee's rights if the grantee or subgrantee had developed, or was in the process of developing, an invention that it wishes to patent.

Alternatives to commercialization also exist that can promote innovation in the field of education, act as an efficient means of broad dissemination of educational research or resources, and help sustain innovations after grant

periods end. As shown elsewhere in this document, there have been many examples of the broad dissemination and innovations developed from high-quality openly licensed educational content.

We again note that any derivative works created based upon grant deliverables using non-Department grant funds are not covered by this rule. Grantees may leverage works created under an open license to establish or maintain a relationship with a private entity for the purpose of commercialization.

The Department appreciates the commenters' concerns that our stakeholders may eschew Department grants in favor of other funding without these requirements. Our competitive grant programs are intended to support equal access to high-quality education for all students. By allowing others to freely use, with minimal restrictions, the educational resources created with our funding, we are providing opportunities for the global community of stakeholders to pursue solutions to their challenges. As previously mentioned, commercial incentives are not the only drivers of innovation in the field of education; similarly, we do not believe economic motive to be the sole consideration for stakeholders to participate in our grant programs. We observe that after implementing their similar policy, the Department of Labor continued to require applicants to form public-private partnerships in numerous notices inviting applicants for competitive grants. Despite the requirement that grantees make copyrightable intellectual property available under a Creative Commons Attribution (CC BY) license, the many programs covered since the enactment of their regulation have received a large pool of applicants. We recognize, however, that there may be some situations where a grantee may have difficulty forming a partnership with a private entity to create a grant deliverable. We believe that such situations are best addressed on a case-by-case basis and are revising the final regulation to include this situation as an example of where the Secretary may consider it appropriate to grant an exception to the open licensing requirement.

Changes: We have revised § 3474.20(d)(1)(viii) to provide that the open licensing requirement does not apply to “[g]rantees or subgrantees for which compliance with these requirements would conflict with, or materially undermine the ability to protect or enforce other intellectual property rights or obligations of the

grantee or subgrantee, in existence or under development, including those provided under 15 U.S.C. 1051, *et seq.*, 18 U.S.C. 1831–1839, and 35 U.S.C. 200, *et seq.*” We also have included in § 3474.20(d)(1)(vii) examples of situations in which the Secretary may consider it appropriate to grant an individual exception to the open licensing requirement. One of these examples is the situation in which the grantee's compliance with the open licensing requirement would impede the grantee's or subgrantee's ability to form the required partnership to carry out the purpose of the grant. The other example is discussed later in this section.

Comment: Commenters stated their concerns related to openly licensing research-based interventions resulting from the Department's research grants. These comments fall into three general categories. First, commenters noted that grantees often receive research funds to produce early prototype models or interventions that have not yet benefited from robust efficacy studies. Openly licensing these resources would allow the public to access them ahead of testing and could lead to adoption of ineffective or potentially harmful resources. Commenters noted that this would especially harm disadvantaged populations. Second, commenters stated that the interventions developed through research grants are complex to administer, often requiring expert training or technical support in order to maintain quality control and ensure valid outcomes. Commenters noted that quality could be diminished through uncontrolled adaptations or derivatives that deviate from the evidence base or context established by the original researchers. Similarly, commenters also stated that in some cases, individuals could deliberately ignore the original parameters or context established by the researchers and pursue inappropriate use. In all of these cases, the reputation of the researcher could be compromised and the effectiveness of the original resource dismissed.

Third, many commenters noted that research institutions exercise good stewardship over grant resources and already employ a number of strategies to broadly disseminate their findings. Many commenters also provided examples of existing initiatives that result in broad dissemination of research-based interventions. Some of these examples included use of strong partnerships with a commercial partner to allow for continued refinements to the products, reinvestment into future research, and technical support for implementation, even after the end of

the grant period. These commenters also note that many research institutions do not have the expertise or capacity to effectively scale interventions, and even if openly licensed resources were available, wide dissemination would not occur without these partnerships. Additionally, some commenters stated that the existing IES goal structure was the most effective model of ensuring research-based interventions are scaled and disseminated widely, and recommended that IES maintain this goal structure.

Discussion: We appreciate the concern that many IES grantees and education researchers have expressed related to implementation of the rule. In general, we note that this rule is intended to apply across competitive grant programs, not only to IES grantees.

We agree with commenters that rigorous efficacy testing is necessary to ensure high quality resources, including interventions, products, and assessments, benefit students. We note that in addition to the early prototype models or interventions themselves, any final versions of program support materials necessary to the use of the prototype model or intervention, including professional development and training materials, research findings, and documentation of the context and efficacy of the resources created with grant funds would also be made available through an open license. Additionally, any materials created as part of IES research grants would also include rigorous peer-reviewed scholarly publications that would be available through ERIC. The availability of these supporting materials will allow the public to readily discern which resources could be appropriately used and which resources have not yet reached maturity. In some cases, these materials will prescribe the appropriate context and correct implementation methodology of the resource. We believe that practitioners should not be denied access to materials because of the possibility that they will misunderstand or misuse them. By openly licensing the supporting materials, data, and other program support materials, grantees can ensure that practitioners have the tools necessary to understand, learn from, and replicate deliverables, and to consult with researchers as appropriate.

In response to the commenters' concerns, we make three observations. First, even before product maturity, prototypes and early stage research, including supporting documentation, can greatly benefit other researchers, allowing them to also test and refine the resource, potentially creating prototypes for different applications. We believe

this will result in developing resources at a rapid speed and encouraging innovation in the educational research field. We note that although peer-reviewed scholarly publications are excepted from this rule, those publications that are supported by IES grant funds are subject to the requirements of the IES' Policy Regarding Public Access to Research. As noted earlier, the Department is exploring other administrative means for expanding the requirements currently followed by for IES grant-supported peer-reviewed scholarly publications to all Department grants. We believe that the combination of the open access to publications and data with the openly licensed resources will enable the community of education and scientific stakeholders to use the early research effectively and responsibly.

Second, we share in the concerns related to the misapplication of scientific research and misuse of educational tools. Nevertheless, we note that these issues may occur regardless of whether the research or tools are under copyright or available through an open license. We also note that members of the public, policymakers, educational practitioners, and other stakeholders, often incorrectly attribute their assertions to researchers, resulting in loss of reputation to the researcher. We do not believe that the root cause of these unfortunate circumstances is the availability of resources through an open license. In fact, a machine-readable license format on digital resources may actually facilitate the discovery of the original research and underlying frameworks for implementation. We also note that separate from the IES Policy Regarding Public Access to Research, many research institutions have already established faculty open access policies that enable public access to research and data.⁴

Third, we acknowledge that in many cases, research entities lack expertise and capacity to scale the adoption of new resources and that in many cases, private entities play an important role in the iterative improvement of resources, often contributing funding in the process. For the purposes of this rule, the Department believes that the primary barrier to broad dissemination is not the lack of capacity; rather it is the lack of access to resources. Even if one research entity does not have the capacity to scale a resource, an open license enables other entities, some with greater expertise and resources, to disseminate them. We note that this

regulation does not cover derivative works, funded privately through these partnerships.

Finally, we note that this regulation does not alter the structure or statutory requirements for any existing grant program, including the goal structure of IES-funded grant programs. As discussed elsewhere in this regulation, peer-reviewed scholarly publications that arise from scientific research funded, either fully or partially, from grants awarded by the Department are excepted from this regulation. This plan provides access both to research findings and the scientific data, encouraging researchers, practitioners, and the general public to test and improve findings and resources and otherwise enhance value for all stakeholders.

Changes: None.

Additional Questions

In the NPRM we posed five questions that requested comments on whether the proposed regulations should include certain additional implementation requirements. The responses provided to the five questions are summarized below.

Question 1: Should the Department require that copyrightable works be openly licensed prior to the end of the grant period as opposed to after the grant period is over? If yes, what impact would this have on the quality of the final product?

Comments: Commenters that responded to this question were divided over whether it would be best to require that the open licenses be applied prior to the end of the grant or after the grant is over. In general, all commenters that opposed the requirements of the NPRM did not believe that open licenses should be applied prior to the end of the grant period. These commenters noted that this would result in a number of negative public consequences. For example, prior to the end of the grant period, products or interventions may not yet be complete or useful and may harm the public if disseminated too early or without proper training on their implementation. In addition, openly licensing and distributing non-final versions could create confusion for the public about which version to adopt or hinder the peer review process.

Conversely, some commenters stated that applying open licenses and distributing materials prior to completion will give opportunity for more feedback and review and give the grantee additional time to make adjustments or refinements prior to the end of the grant period leading to a better final product. In addition, by

making their work known, duplicative efforts can be avoided.

Other commenters stated that the decision of whether the license is applied prior to the end of the grant period should be made based on the goals and circumstances of the grant program.

Discussion: We considered the variety of viewpoints reflected in the comments and the variety of grant programs funded by the Department. We believe that it would be difficult to prescribe a single timing requirement appropriate for all programs. Depending on the goals of the particular grant program or the individual project proposal, the grantee may elect to openly license the intellectual property created through the grant before the grant period has ended, though that is not a requirement. The final rule does not specify whether copyrightable grant deliverables should be openly licensed prior to the end of the grant period or after the grant period is over, thereby leaving it to each grant program to decide.

Changes: None.

Question 2: Should the Department include a requirement that grantees distribute copyrightable works created under a direct competitive grant program? If yes, what suggestions do you have on how the Department should implement such a requirement?

Comments: Commenters were divided in their response to the proposed requirement for grantees to distribute Department-funded works. Many commenters supported an additional requirement to distribute Department-funded works. Of these, some commenters proposed that the Department be nonspecific about the method of distribution. One commenter expressed concerns that specificity would drive away institutions currently implementing other distribution methods. Others suggested more specific methods, including the use of a CC BY license or dissemination of works through online platforms. Some of these commenters accompanied their suggestions with proposals for additional Federal requirements, such as a sustainability plan in the grant application or a final report containing a link to the location of the work in an online repository.

Other commenters disagreed with requiring distribution by grantees. These commenters suggested that the responsibility of distribution resides with the Department, such as through the use of the ERIC, an online library of education research and information, sponsored by IES. Similarly, others suggested partnership with existing repositories or the creation of another

⁴ <http://sparcopen.org/coapi-members/>.

online repository. Commenters also noted that the Department should make funding or other resources available to grantees if it establishes distribution requirements or allow grantees to monetize modifications to the grant-funded materials.

Discussion: We note the variety of suggestions that reflect the experience of the diversity of our grant recipients. In reading the suggestions, we believe that the specific mode of dissemination enabled by open licenses should remain at the discretion of the program in order to be appropriate to the needs of the grantees and align with the statutory goals of that program. However, we believe that our goals would be best achieved by including a requirement that grantees provide information about the resources that have been created with support of Department grant funds. As a result, we have added a requirement for grantees to submit a plan for dissemination of their openly licensed resources. We would encourage grantees to provide links to public Web sites of their works if that is appropriate based on the nature of their resource. We note that for a grantee that does not have its own Web site, there are a number of free methods to distribute digital openly licensed materials through publicly available Web sites, learning resource, and metadata repositories.

We also recognize that a grantee may develop a robust dissemination plan that could demonstrate meaningful dissemination that is equivalent to or greater than the dissemination likely to be achieved by compliance with the open licensing requirements. Accordingly, we are revising the regulation to provide this situation as an example of a scenario in which the Secretary would consider granting an exception to the open licensing requirement.

Changes: We have added final § 3474.20(c) to state that a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate the openly licensed grant deliverables that were created in whole, or in part, with Department grant funds. In final § 3474.20(d)(1)(vii), we have also provided an example of a basis for providing an exception under 2 CFR 3474.5 and 200.102 where the Secretary has determined that the grantee's dissemination plan would likely achieve meaningful dissemination equivalent to or greater than the dissemination likely to be achieved through compliance with paragraph (a) or (b) of this final rule.

Question 3: What further activities would increase public knowledge about

the materials and resources that are created using the Department's grant funds and broaden their dissemination?

Comments: The Department thanks commenters for the numerous recommendations regarding activities that would broaden the dissemination of materials and resources created using the Department's grant funds. Several commenters suggested the adoption of an existing online, open platform, such as OER Commons, GitHub, and OpenStax CNX. Others stated the need to create and enforce an entirely new repository of works and related reports or an index containing links to pages where the specific resource can be located.

Aside from online platforms, commenters suggested the launch of a large advertising campaign of Department-funded works including the use of media such as emails, newsletters, and speeches where the Department highlights openly licensed materials and resources. Finally, a few commenters stated the need for the Department to communicate with grantees directly to discuss what exactly open licensing entails and how dissemination practices can be funded.

Discussion: We appreciate the variety of suggestions provided by commenters. In addition, we appreciate the concern for public awareness. We will consider these recommendations as we work to increase the public's knowledge of materials that are openly licensed pursuant to this final rule. It is our intention to also provide robust training to grantees on how to satisfy this requirement. We note that at this time, the Department does not have the funding to support the development of an online repository solution.

Changes: None.

Question 4: What technical assistance should the Department provide to grantees to promote broad dissemination of their grant-funded intellectual property?

Comments: Commenters suggested that the Department provide guidance for grantees for a variety of topics, such as licensing standards, metadata, formatting, information on how to access openly licensed resources to incorporate them into original works, and creating accessible materials. The commenters suggested that this guidance be provided through formal workshops and training. Other commenters suggested that the Department promote dissemination by creating a user-friendly central repository of works and related reports, developing a directory of funded materials, or establishing a funding mechanism specific to distribution.

One commenter suggested that grantees should continue to work with technology transfer offices at their institutions.

Discussion: We thank the commenters for the numerous suggestions provided. The Department has taken these into account and will incorporate these into future training for grant recipients. At this time, we will not be providing funding for the creation of a central repository of works or reports, nor is there any additional funding available specific to distribution.

Changes: None.

Question 5: What experiences do you have implementing requirements of open licensing policy with other Federal agencies? Please share your experiences with these different approaches, including lessons learned and recommendations that might be related to this document.

Comments: We thank the commenters who responded to this question and had a wide breadth of experience implementing other open licensing requirements. Only one commenter had direct experience as a Department grantee. Though open licensing was not a requirement of their grant project, the grantee elected to use an open license to ensure that grant-funded resources would be made available to as many individuals as possible. This grantee reported positive experience running a grant-funded education center that provides services to individuals with disabilities. In addition to distribution, the grantee reported that with equal availability as a foundation, "openness" enabled cooperation between multiple organizations to address the common challenge of STEM accessibility. The grantee made several recommendations, including use of Creative Commons licenses, that materials be released under an open license at time of completion or wide distribution during the grant period, that materials be made available on the internet without obstructions, and that metadata be listed on a resource site such as the Learning Registry. The grantee also recommended that the Department host all grant funded materials on a resource site.

A few commenters had direct experience implementing open licensing policies of other Federal agencies, including the Departments of Labor and the National Science Foundation. Based on their experience these commenters recommended that the Department direct grantees to use licenses that are interoperable that allow a broad range of reuse, including specifically, Creative Commons licenses. One commenter had experience leading open repository

development and technical assistance on numerous projects including establishing the Department of Labor's repository for the TAACCCT grant program, the National Science Foundation National Digital Library of Science, and the California Affordable Learning Solutions initiative. This commenter noted the importance of providing an online library of all grant-funded resources to enable quality and continuous improvement. In addition, the commenter noted the importance of providing support to institutional leaders in developing and implementing a change management strategy for their institution to locally design and implement culturally aligned, locally supported, and collectively valued ecosystems of intellectual property strategies, recognition, and incentives for openly sharing intellectual property, and an institutional mission for improving society through quality education.

One commenter stated that they did not know of any other Federal funding agencies that would make this regulation a grant requirement, as it would require forfeiture of intellectual property.

Discussion: We thank these commenters for sharing their experiences. All of the suggestions have been discussed elsewhere in this regulation, except for the suggestion to list metadata on a resource site such as Learning Registry. The Department believes that Learning Registry is a valuable metadata repository for open educational resources. Grantees of the Department are encouraged to consider using Learning Registry or other public, freely available platforms to enable sharing of resources.

In reviewing these comments, we noted that our proposed rule did not account for situations in which a grant deliverable is jointly funded by both the Department and another Federal agency where the other Federal agency does not require the open licensing of its grant deliverables for that program. In these instances, we recognize that complying with the Department's open licensing requirement may cause confusion regarding a grantee's ability to comply with the requirements of that other Federal agency regarding the grant deliverable, so we are revising the regulation to provide that the rule would not apply to these types of grant deliverables.

Changes: We have revised § 3474.30(d)(1)(iii) to provide that the open licensing requirement does not apply to grant deliverables that are jointly funded by the Department and another Federal agency if the other

Federal agency does not require the open licensing of its grant deliverables for the relevant grant program.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is "significant" and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of \$100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities in a material way (also referred to as an "economically significant" rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This final regulatory action will have an annual effect on the economy of more than \$100 million because of the benefits that will be realized as a result of the dissemination of openly licensed resources required under this rule. Although the costs associated with this rule are relatively low, we believe the benefits from the resources that will be readily available to the public through broad dissemination will reach more than \$100 million. We explain these costs and benefits in more detail in the *Costs and Benefits* section of this *Regulatory Impact Analysis*. Therefore, this final action is "economically significant" and subject to review by OMB under section 3(f)(1) of Executive Order 12866. We have also reviewed these regulations under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency "to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible." The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include "identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes."

We are issuing these final regulations only on a reasoned determination that their benefits would justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that these final regulations are consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action would not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

Need for Regulatory Action, Potential Impacts, and Costs and Benefits

Need for Regulatory Action

Grantees under the Department's competitive grant programs create a number of copyrightable grant deliverables using Department grant funds that may have significant benefit for students, parents, teachers, school districts, States, institutions of higher education, and the public overall. These copyrightable works are wide ranging in nature and include instructional materials, personalized learning delivery systems, assessment systems,

language tools, and teacher professional development training modules, just to name a few. The Department's grantees creating these works include SEAs, LEAs, IHEs, and non-profit organizations and while the works are created under a specific grant program and therefore may target a specific school or group of students, the resources are such that other education stakeholders would significantly benefit from being able to readily and freely access them, use them, and in some cases, modify them to address their needs and goals.

As we note earlier, wide dissemination of these types of copyrightable works has not occurred under the Department's current regulations. We found very few instances in the last decade where program offices received a request to make grant-funded resources available under the Federal purpose license. However, we do have evidence of the impacts of open licensing in those competitive grant programs where open licensing was required or where the grantee voluntarily openly licensed its copyrightable works.

For example, the Department's First in the World (FITW) program has an existing open licensing requirement and thus provides a basis for estimating the potential benefit of these final regulations. In FY 2015, the Department awarded approximately \$60 million in FITW funds to 18 institutions of higher education, research organizations, and education agencies. This total included 16 FITW development grants intended to seed and evaluate early stage innovations, where new intellectual property would be created, and two validation grants to test at a broad scale existing interventions supported by significant evidence.

We estimate that the 16 development grantees will produce at least 1,400 new resources that would be openly licensed, approximately 90 resources per grantee. This estimate is based on work that the FY 2015 grantees project they will do over a four-year period and we generally anticipate that most resources would be available for dissemination and licensing in the last two years of the grant period. We also note that the total number of resources to be created across the 16 grantees varies widely as a result of the different activities and innovative approaches proposed in their projects. For example, CSU-Los Angeles is proposing to redesign every first year science course, resulting in the largest estimate of resources created, while Delaware State is proposing to develop an analytics framework and tool for matching

student interests to programs, which we believe would result in the creation of fewer resources. These two projects would impact approximately the same number of students, but one approach involves the creation of a large number of resources while another invests resources towards creation of a platform tool and a smaller number of resources associated with that tool.

Moreover, we believe that our estimates for the FITW grantees are likely to be higher than what we would expect for most other Department competitive grant programs, including those at the higher education level and those focused on elementary and secondary education. For example, in the higher education space, the Federal TRIO programs, which accounted for nearly half of all competitive awards to IHEs in FY 2015, have a more narrowly focused statutory purpose to provide basic services (e.g., tutoring, counseling, mentoring) to needy students using strategies and generally are less likely to produce copyrightable resources.

On the other hand, the Department also funds a number of activities that, under the final regulations, would be likely to produce significantly higher numbers of copyrightable resources than FITW grantees. For example, our National Language Resource Centers (LRC) program funds IHEs to research and develop resources for Less Commonly Taught Languages (LCTL), http://www.nflrc.org/lrc_broc_full.pdf. In the FY 2014–FY 2017 grant cycle, we awarded approximately \$2.8 million to 16 IHEs to support National Language Resource Centers (LRC) for research and development of resources for LCTL. There was no requirement for the grantees to openly license their resources, but one grantee did so of its own volition. Specifically, the University of Texas at Austin received approximately \$200,000 in FY 2015 to fund the Center for Open Educational Resources and Language Learning (COERLL), which creates fully openly licensed language and pedagogical materials for 16 languages, in addition to an open platform for discovery, remix, and repurposing of these language resources, and open research. The Department estimates that there are approximately 500 educational resources, including curricula, lessons, worksheets, assessments, textbooks, videos, podcasts, research studies, open apps for student learning, and interactive platform, materials, openly licensed on the COERLL Web site (<https://www.coerll.utexas.edu/coerll/>).

Based on the experience with UT-Austin, we believe that if an open license requirement were in place at the

time these awards were made to the 15 other grantees, we could assume that 15 times more language learning materials would be made available, or an additional 7,500 pieces of openly licensed content across the different language areas. Moreover, the enhanced availability of these materials potentially would have increased the impact of each of the individual centers by encouraging and supporting vibrant communities of practice focused on language instruction and learning at institutions that do not have the resources themselves. For example, this would have enabled discovery and use of resources created by the University of Indiana National African Resource Center, whose lack of broad dissemination leaves the public without information about what resources are available, where to access any materials, or how to seek permission to use any resources found. Since this is the only African language program in this cohort, the result is also the loss of resources for this entire language family.

Analysis of Potential Impacts

In FY 2016, the Department made new and continuation awards under roughly 110 unique discretionary competitive and non-competitive grant programs that totaled \$44.155 billion (excluding Pell). Of this total we estimate that 66 programs would be subject to the open licensing requirements of the final regulations. In addition to the Ready to Learn program, of the 43 programs (roughly \$39.932 billion in FY 2016) that we estimate would be exempt from open licensing, approximately 30 are non-competitive programs that allocate funds on the basis of a formula, and approximately 13 support competitive grants in which program funds are only used to support activities that clearly fit within one or more of the categorical exemptions in this rule (e.g., approximately 7 are competitive programs that only support fellowships or scholarship awards to individuals, and the other 6 provide support for general operating expenses).

Within the group of 66 competitive grant programs (which received \$4.223 billion in FY 2016) subject to the rule, not all grantees will produce intellectual property. For example, in the IDEA Personnel Development to Improve Services and Results for Children with Disabilities Program, many cohorts of grantees do not produce intellectual property at all and, therefore, this rule would not apply to those specific grantee cohorts. We note that the required activities in grant competitions often change over time, so the impact of

the rule may vary from one competition and cohort to the next.

In addition, in some cases, only a portion of activities and funding would result in the creation of resources that would be required to be openly licensed under the final regulations. For example, in the case of IES's Education Research, Development, and Dissemination program, grants are awarded competitively to support research programs that both create interventions and resources and peer-reviewed publications that arise from scientific research (receiving an exception). The Department also has developed an agency-level exceptions process where any program could ultimately be granted either partial or complete exception to the requirements of the final regulations. For all of these reasons, we estimate that the potential impact of these final regulations will be limited to a relatively small but important subset of the programs and projects funded by the Department in any given year. The final regulations will ensure that those programs and projects that do produce copyrightable educational materials and resources, including materials and resources proven effective through rigorous evaluation, make such resources freely and widely available to the public for the potential benefit of students, teachers, and schools across the nation.

Potential Costs and Benefits

The final regulations will not impose significant costs on entities that receive assistance through the Department's competitive grant programs. We note that annual variation in the total volume of new and continuing discretionary grant awards, as well as in the purposes and priorities associated with such grants, limits the precision of our estimates, but we estimate that the upper bound total cost of these regulations, over ten years, will be approximately \$22.6 million in labor fees, at an annualized rate of \$3.2 million per year, with no additional costs to support technology infrastructure. This estimate assumes a discount rate of three to seven percent.

Analysis of Technology Infrastructure Costs

While the benefits of the final regulations depend on the broad, accessible dissemination of copyrightable educational materials and resources, we estimate that such dissemination will result in no additional technology infrastructure costs to grantees subject to the open licensing requirements, for two reasons. First, the near-universal adoption of

digital tools and devices means that grantees will be creating and refining grant deliverables in digital formats that facilitate dissemination at no additional technology cost. Second, grantees may readily access and use a number of free methods to distribute digital openly licensed materials, including publicly available Web sites, content, or metadata repositories at no cost. Thus, we expect that grantees generally will be able to meet the dissemination requirements of the final regulations without incurring additional technology infrastructure costs.

Analysis of Technology Labor Costs

Even though there will generally be no additional costs associated with technology infrastructure, we estimate that over a period of 10 years there may be a likely high-end labor cost of \$22.6 million. This cost represents an upper bound estimate of the labor necessary to disseminate copyrightable products expected to be generated by all new ED grantees over a period of 10 years. To develop this upper bound estimate, we started by analyzing the volume of ED grantees that could potentially be impacted by the rule. In 2016, the most recent year preceding this final rule, the Department made approximately 5,470 new competitive grant awards. We know not all of these grantees will generate copyrightable products requiring dissemination under this final rule, so for purposes of this upper bound estimate we estimate that the Department will continue to make 5,470 new competitive grants each year, and that 30 percent of these awards will produce copyrightable content and consequently will be affected by the final rule. Further, we assume that for each year the rule is in effect after year one, every cohort of continuation awards will also be affected by the final rule. So, based on past data, we estimate that in the first year the final rule takes effect 1,641 grants will generate copyrightable products (30 percent of 5,470 total new grant awards made), and that by year four a total of 6,564 new and continuation awards would be impacted by the rule. Likewise, from years 4 through 10 this number plateaus and remains stable at 6,564.

Next, consistent with the estimates in the *Need for Regulatory Action* section, we estimate that each grantee will generate an average of approximately 90 copyrightable products requiring dissemination over the duration of their grant award (typically ED grantees have 4 or 5 year grant performance periods). As stated previously, we know that many non-exempt programs have a narrowly focused statutory purpose that

often involves provision of services (e.g., tutoring, counseling, mentoring), and that grantees under such programs are much less likely to produce copyrightable resources. But, again, for purposes of developing an upper bound estimate we analyzed a handful of grantees for which dissemination of products or content is a core purpose of their grant. Since dissemination is a core activity for grantees included in this sample, we know these grantees are likely to generate significantly more products requiring dissemination each year than grantees focusing on other activities such as service provision. Further, since it generally takes grantees some time to scale up their projects we assume, taking into account the past production rate of grantees, the following "outlay" rate (over an assumed project length of 4 years) for all grantees affected by the rule: Year One 5 copyrightable products produced and disseminated; Year Two 15 copyrightable products produced and disseminated; Year Three 20 copyrightable products produced and disseminated; and Year Four 50 copyrightable products produced and disseminated.

Assuming a total of 1,641 new competitive grantees would generate copyrightable product during the first year the rule is in effect, with each new grantee producing 5 total deliverables in the first year, the overall volume of resources requiring dissemination would be 8,205 (1,641 grantees producing an average of 5 copyrightable products each). In the second year, with new grantees expected to produce 15 total deliverables on average, the overall volume of copyrightable products would be 49,230 (3,282 grantees producing an average of 15 copyrightable products). In year three the overall volume would increase to 98,460 (4,923 grantees producing and average of 20 copyrightable products), and by year 4 this number would be 328,200 (6,564 grantees producing an average of 50 copyrightable products).

Finally, we estimate the likely time and salary that would be required for individual grantees to complete these requirements. As an example of the specific steps that might be necessary for an individual grantee to complete dissemination requirements envisioned in the final rule, the grantee would:

1. Use the Creative Commons License tool to select and apply the symbol to the work and generate the machine readable code and affix to the work (<http://www.creativecommons.org/chooser>)
2. Upload the resource and metadata, including the name, description,

license, publisher, and URL of the resource, to a shared learning resource repository or educator Web site:

We estimate the time for completion of Steps 1 and 2 to be approximately 30 minutes total per resource. We also recognize that the actual time for completion may be substantially shorter in the case of automated or bulk resource uploads. Assuming a pay rate of \$15/hour for data entry,⁵ new grantees generating 5 products in the first year would require approximately 2.5 hours per year in total labor to complete these steps at an annualized cost of approximately \$38 per grantee. By year four of implementation these estimates would plateau at approximately 45 hours required per year in total labor costs at an annualized cost of approximately \$675 per grantee.

Taking into account these assumptions, we estimate that a reasonable upper bound estimate of the maximum likely labor costs for all expected grantees to implement this final rule over a period of 10 years to be \$22.6 million, at an average total annual cost of \$2.26 million.

Other Potential Costs

Under current regulations, title to intellectual property acquired under Department grant funds, including copyright, vests in the grantee. With respect to copyrighted works, under 2 CFR 200.315(b), the Department also reserves a royalty-free, non-exclusive, and irrevocable right to reproduce, publish, or otherwise use for Federal purposes, and to authorize others to do so. No further action is necessary to designate these rights. Grantees may establish terms and conditions that permit use of their works to any member of the public, for each instance of use or for each created work. That the Department does not frequently exercise its Federal purpose license may create the false impression that any grantee can use the copyrighted works it creates with Federal grant funds for revenue generating purposes without any concern that third parties will have free access to those materials for Federal purposes.

This final rule requires that grantees openly license copyrightable grant deliverables created with Department funds to enable the public to use the work without restriction, so long as the public provides attribution to the copyright holder. While the type of

license will differ depending on the type of work created, applying an open license to a grant product typically involves the addition of a brief license identification statement or insertion of a license symbol or device. This could occur following the development of the product, at the same time that the disclaimer currently required under 34 CFR 75.620 is applied.

In this context, the regulations could reduce commercial incentives for an eligible entity to apply to participate in a competitive grant program. For example, we believe that under some competitive grant programs, grant recipients may produce materials that will be subsequently sold or licensed to third parties, such as publishing companies or others in the field. Although an open license does not preclude the grantee or any individual from developing commercial products and derivatives from the grant funded material, it could diminish certain competitive advantages that these grantees currently possess as the copyright holder. In addition, publishers and other third parties may incur loss of revenue since their commercial product will potentially compete with freely available versions of a similar product or may hesitate to enter into licensing agreements with grantees.

In response to these concerns, we note that derivative works built upon the Department funded copyrightable works using non-Department funds are considered new works to the extent of the modifications and are not covered by this regulation. As long as the grantee or subgrantee does not elect an open license with a noncommercial use requirement, using non-Department funds, any other entity can improve upon the grant-funded copyrightable works resulting in a derivative work that can be commercialized for financial gain or as part of a sustainability plan. For purposes of clarity, noncommercial licenses would not limit the ability of grantees to commercialize their own derivative works. It is the underlying Department grant-funded copyrightable works that will be freely available to the public. This allows multiple entities to enter into a commercial market for derivative works, potentially resulting in multiple derivative products. In the event that a grantee or subgrantee selects an open license with a noncommercial use requirement, members of the public would likely need to contact the grantee or subgrantee directly in order to obtain broader usage rights.

Nothing in this regulation prevents the grantee itself from entering this

marketplace, or from entering into private, commercial relationships with select commercial entities to distribute derivative works based upon the openly licensed works. In this case, the grantee's expertise as the original creator could allow it to retain market leverage, if its commercial product demonstrated market value that outcompeted other commercial derivatives. We believe that the grantee may be best positioned to create derivative works with the most economic value since it best understands both the present utility and future potential of the product and can anticipate the enhancements that would need to be taken to address unmet market needs.

Third, based on the Department's past grant making experiences, relatively few grantees have developed and marketed copyrighted works paid for with Department funds. In those cases, the open license requirement would not preclude their ability to continuously iterate and improve their product through copyrighted commercial derivatives.

We further note that in the competitions in which we required that grant-funded copyrightable works be openly licensed, it was not our experience that the requirement deterred grantees from applying or attracting partners. The two rounds of FITW grant competitions attracted over 500 applications in FY 2014 for 24 awards and over 300 applicants in FY 2015 for 18 awards. We have not heard from grantees that attracting partners has been or would be problematic. In addition, one of the considerations for granting a program level exception will be whether the open licensing requirement would impede the grantee's ability to form the required partnerships necessary to carry out the purpose of the grant. Thus, we believe we can address this concern through our exceptions process.

Benefits

We believe that the benefits of the open licensing requirement in the education field will significantly outweigh the costs our grantees might incur. The education sector has had considerable recent experience with successful implementation of open licenses as a mechanism that enables dissemination, broad access, and use. Open licenses have enabled the Department's own grantees, including the New York State Department of Education (NYSED) to have broad reaching impacts and enabled collaboration that has resulted in significant cost savings for SEAs, LEAs,

⁵ Unless otherwise noted, all hourly wages are non-loaded wage rates and are based on median hourly earnings as reported in the May 2014 National Occupational Employment and Wage Estimates from the Bureau of Labor Statistics (see www.bls.gov/oes/current/999201.htm).

and other stakeholders. In the case of NYSED, in 2010, the Department awarded New York State Department of Education (NYSED) approximately \$700 million in funding through the Race to the Top (RTT) grant program. NYSED invested \$12.9 million of that award in the creation of openly licensed curriculum in math and English Language Arts called “EngageNY” that was made freely available to the public under a Creative Commons Non-Commercial Share-Alike (CC-SA-NC) license.⁶ The EngageNY curriculum created by NYSED has been implemented statewide in New York. Because this curriculum is openly licensed, California, Louisiana, and Washington have adapted and used these materials statewide as a foundation for their standards aligned curriculum. Additionally, teachers at schools across the nation have been freely accessing, using, and adapting the EngageNY content.⁷

The open license has also enabled other organizations to create derivative works that enhance the original curriculum. For example, Unbounded, a non-profit educational organization, has adapted the original materials created by the grant, developed supplemental digital content, English language learner support, and is offering curated sets of these materials to the public at no cost. In addition to the content, Unbounded has developed new teacher professional development materials and offers paid teacher training on using these and other open resources. Thus, the open license has enabled a single investment to result in broad, national dissemination and stimulated a derivative marketplace of services and supplemental content. Since the EngageNY content is freely available, other teachers, SEAs, and LEAs do not have to duplicate investments in curricula in these same content areas, resulting in a more efficient use of resources.

In addition, between 2012 and 2015, the Office of Career Technical and Adult Education (OCTAE) invested national activities funds in accelerating the teaching and learning of STEM competencies through high-quality OERs and high-quality adult education instruction of STEM by funding adult educators who located, used, evaluated, and shared science and math OER that are appropriate for adult education classes. The project also developed

online professional development courses for teachers on how to use OER for math and science instruction in their adult education classrooms that are freely available in multiple repositories.⁸ Adult educators, working in Teacher User Groups located, used, evaluated, and shared science and math OERs that are appropriate for adult education classes. The reviews are posted within www.OERCommons.org, part of a newly formed “adult education” category with over 2,400 resources that can now be searched and accessed freely through this repository. The project also developed online professional development courses for teachers on how to use OER that are freely available in multiple national repositories for math and science instruction in their adult education classrooms. The Department’s investment of funding has resulted in a valuable resource that is searchable on public repositories and widely available to members of the public that would not have been otherwise reached by the Department’s National Activity Activities funds.

Under the National Language Resource Centers (LRC) grant program, the Department awarded funds to IHEs for research and development of resources for Less Commonly Taught Languages (LCTL). Though there was no specific requirement for the grantees to openly license their resources, one grantee did choose to do so. As previously discussed, the University of Texas at Austin created the Center for Open Educational Resources and Language Learning (COERLL), which creates fully openly licensed language and pedagogical materials for 16 languages, in addition to an open platform for discovery, remixing, and repurposing of these language resources, and open research. There are hundreds of different and diverse open materials, including curricula, lessons, worksheets, assessments, textbooks, videos, podcasts, research studies, open apps for student learning, and interactive platform, materials openly licensed on their Web site available under an open license and publically available on their Web site. These resources include language learning materials such as OER for K’ichee’ Maya, an indigenous language spoken in Guatemala; software that allows a group of users to annotate the same text together; a series of native speaker

surveys; a teacher professional development digital badge system; research on the perception and use of foreign language OER; and a Web site supporting a community of practice on Open Education in language learning.

Finally, the Department’s FITW grant program has required grantees to openly license intellectual property.⁹ The online remediation tool created by the Southern New Hampshire University under this grant program will help underprepared, underrepresented, and low-income working adults obtain a postsecondary credential and reduce the time to degree completion. Under the terms of the grant, the open license will allow any other IHE or adult education provider to use this tool to serve the working adults in its service areas, without incurring costs or duplicating efforts of development.

Elsewhere in the Federal government, as noted previously, the Department of Labor was the earliest user of open copyright licenses. The Department of Labor first piloted the open license requirement in FY 2011, through the \$2 billion TAACCCT grant program, which required all new resources created with TAACCCT funding to be made available under CC BY license.¹⁰ With this requirement, TAACCCT grantees have created thousands of openly licensed learning resources that have been downloaded and reused hundreds of thousands of times, including courses, curriculum, modules, and assessments that are freely available at <https://www.skillscommons.org>.¹¹ The open resources have enabled partnerships and collaborations between colleges, with other Federal agencies, State agencies, and even international education systems and expanded the investment beyond one single grantee to a broad range of stakeholders. For example, an openly licensed basic computer skills training online course (BITS)¹² created by the Wisconsin Technical College system is being used by the Ohio Workforce Investment board to provide computer training to adults at 89 American Job Centers statewide, has been used across the 15 community colleges in the Iowa Community College System, and is being customized by the Technical College System of Georgia. Competency based training along aerospace and energy career pathways developed by

⁹ <http://www2.ed.gov/programs/fitw/index.html> and <https://www.federalregister.gov/d/2014-11463/p-188>.

¹⁰ <https://creativecommons.org/licenses/by/4.0>.

¹¹ https://wdr.doleta.gov/directives/corr_doc.cfm?docn=4109.

¹² <https://www.skillscommons.org/handle/taaccct/6799>.

⁶ <https://creativecommons.org/licenses/by-nc-sa/3.0/>.

⁷ http://www.rand.org/content/dam/rand/pubs/research_reports/RR1500/RR1529/RAND_RR1529.pdf.

⁸ <https://lincs.ed.gov/programs/oerstem> and <http://www2.ed.gov/rschstat/eval/sectech/factsheet/open-education-resources-stem-teaching.html> <https://lincs.ed.gov/programs/oerstem> and <http://www2.ed.gov/rschstat/eval/sectech/factsheet/open-education-resources-stem-teaching.html>.

consortia of community colleges in Washington State and Arizona and major employers and industry partners were adapted through Rutas (Routes), a USAID-funded workforce development program operating along Mexico's northern border. Relying on the open license, USAID grantees were able to translate the curricula into Spanish, rather than using funds to create their own materials from scratch, and created additional educational pathways suitable for the Mexican technical high school system.¹³ In each of these examples, an open license allowed uses that would have otherwise involved separate and duplicative investments, either by the same or separate Federal agency, by a State agency, or through other public funding, and has resulted in significant discount to the public. Because of these early successes, the Department of Labor expanded the requirement across the agency through regulation¹⁴ and is the first Federal Agency to require grantees to apply Creative Commons Attribution licenses to all grant funded materials.

Privately funded openly licensed projects also have a long history of creating educational resources with significant benefit to the public. For example, organizations such as Rice University's OpenStax and California State University's Multimedia Educational Resource for Learning and Online Teaching (MERLOT)¹⁵ have over 20 years of experience creating and curating OER and developing national

communities of practice for teaching and learning with digital resources. In public comments submitted by OpenStax, it was noted that its openly licensed college textbooks, first introduced in 2012, are currently used by more than 650,000 students in 1,600 educational institutions in the United States alone, saving those students \$66,000,000 in that short span of time.¹⁶ Despite not expending any resources on marketing activities, their textbooks have been downloaded by three million users worldwide. More than the broad dissemination of the textbooks, the open licenses have enabled an ecosystem of more than 38 different for-profit and not for-profit organizations to develop content in interactive and adaptive learning systems and through other ancillary products, providing greater reach than OpenStax could have achieved on its own. Similarly the Washington State Board for Community and Technical Colleges (SBCTC), the State agency that instituted the nation's first open licensing policy, did so to address issues of educational access. Since its inception in 2010,¹⁷ the policy has been implemented for competitive awards funded or managed by SBCTC totaling more than \$25,000,000. The end products from these projects have been widely distributed with a CC BY license benefiting faculty members and the students across the country. For example, a textbook developed during one of the competitive grant projects has been downloaded 127,000 times and

students have purchased over 5,000 copies of the book for approximately \$15. These regulations build on the lessons learned through these efforts and seek to scale the benefits of these early successes across multiple Department competitive grant programs and education stakeholder groups.

In sum, we believe that these regulations will help to ensure the broader and more effective dissemination of Department grant-funded works to the public. Department stakeholders, such as LEAs, SEAs, IHEs, students, and others beyond direct grant recipients would be able to freely use and access the technology and high-quality materials. The framework established by these regulations will also result in greater transparency and efficiencies in how these stakeholders and other members of the public can access these valuable educational resources.

Accounting Statement

As required by OMB Circular A-4 (available at www.whitehouse.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf) in the following table we have prepared an accounting statement showing the classification of the expenditures associated with provisions of these final regulations. This table provides our best estimate of the changes in annual monetized costs, benefits, and transfers as a result of the final regulations.

| Category | Benefits | |
|---|----------------|-------------|
| Broader and more effective dissemination of Department grant-funded works to the public | Not quantified | |
| Category | Cost | |
| | 7% | 3% |
| Labor Costs (dissemination activities) | \$3,181,331 | \$3,218,633 |

Alternatives Considered

In determining whether to pursue regulatory action, we first considered other options that might accomplish our goals of enhancing dissemination and transparency. First, we considered whether we should establish an open licensing requirement as a supplemental priority, creating an authority for the Department to require open licensing in any appropriate grant program for fiscal year 2017 and future years. Although

supplemental priorities provide opportunities for program offices to select or exempt certain grant programs from this requirement as appropriate, it would only lead to change program-by-program. We believe that it will be far more efficient to establish the requirement as a general rule for our competitive grant programs, while also building in the program-level and grantee exceptions process when an exception is appropriate.

We also considered whether we could instead license all copyrightable material to the public using our Federal purpose license. This approach would allow for access to and dissemination of grant-funded resources. However, as previously discussed, the Federal purpose license requires significantly increased administrative capacity at the Department. From an administrative perspective, use of the Federal purpose license places the burden on the

¹³ http://blogs.iadb.org/energia_es/2016/02/17/how-to-build-a-renewable-energy-future-in-mexico/; <http://www.iyfnet.org/blog/poised-take-mexican-youth-prepare-aerospace-careers>.

¹⁴ www.federalregister.gov/articles/2015/12/30/2016-32725/uniform-administrative-requirements-

[cost-principles-and-audit-requirements-for-federal-awards](http://www.federalregister.gov/articles/2015/12/30/2016-32725/uniform-administrative-requirements-cost-principles-and-audit-requirements-for-federal-awards).

¹⁵ <https://www.merlot.org>.

¹⁶ <https://openstax.org/impact>.

¹⁷ www.sbctc.edu/resources/documents/colleges-staff/programs-services/elearning-open-education/open-licensing-policy-board-resolution.pdf.

Authorizing legislation: RCW 28A.300.803 created the Open Education Resources project to create openly licensed K-12 resources aligned to Common Core standards: <http://app.leg.wa.gov/rcw/default.aspx?cite=28A.300.803>. See also: <http://www.k12.wa.us/Communications/PressReleases2016/GoOpen.aspx>.

Department to exercise the license for each program and grantee and copyrightable work, and is therefore not an efficient approach. Each grantee already has direct control over its work, can use Department grant funds to implement the open licensing requirement, and is in a far better position than the Department to make the work publicly available directly. Therefore, we believe this final rule will greatly expand the scope of dissemination compared with what the Department could achieve.

The Department recognizes that the variety of our programs require grantees to adopt a wide range of strategies for implementation. As previously discussed, we believe this final rule advances our goals of broad dissemination by requiring an open license that does not restrict the distribution of derivative works, such as through commercial channels, or create additional restrictions on future licensing of derivative works not created with Department grant funds. We recognize that in some instances, placing limitations on the license (e.g. non-commercial licenses) or restricting the ability to use/reuse materials may be appropriate and we are committed to working with grantees to develop licensing strategies that are aligned to their grant projects and that are consistent with the goals of the final rule.

We also recognize that there will be cases where implementation of the requirements of this regulation would be inconsistent with statutory requirements of the grant programs or the Department's general goals. In cases such as those, the Secretary retains the ability to make exceptions to the open licensing requirement for those programs on a case-by-case basis under 2 CFR 3474.5(a)¹⁸ and 2 CFR 200.102(b) and (c).

Paperwork Reduction Act of 1995

Section 3474.20(c) contains an information collection requirement. Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3507(d)), the Department has submitted a copy of this section as part of a change request to OMB for its review under OMB Control Number(s) 1894-0006, and 1894-0009 to reflect this new requirement. There will be no increase or decrease in

burden. This change request has been approved by OMB.

A Federal agency may not conduct or sponsor a collection of information unless OMB approves the collection under the PRA and the corresponding information collection instrument displays a currently valid OMB control number. Notwithstanding any other provision of law, no person is required to comply with, or is subject to penalty for failure to comply with, a collection of information if the collection instrument does not display a currently valid OMB control number.

Intergovernmental Review: These final regulations affect direct grant programs of the Department that are subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for these programs.

Assessment of Educational Impact

In the NPRM we requested comments on whether the proposed regulations would require transmission of information that any other agency or authority of the United States gathers or makes available. We received no comments.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotope, or compact disc) on request to the person listed under **FOR FURTHER INFORMATION CONTACT**.

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You may also access documents of the Department published in the **Federal Register** by using the article search feature at: www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

List of Subjects in 2 CFR Part 3474

Accounting, Administrative practice and procedure, Adult education, Aged, Agriculture, American Samoa, Bilingual education, Blind, Business and industry, Civil rights, Colleges and universities, Communications, Community development, Community facilities, Copyright, Credit, Cultural exchange programs, Educational facilities, Educational research, Education, Education of disadvantaged, Education of individuals with disabilities, Educational study programs, Electric power, Electric power rates, Electric utilities, Elementary and secondary education, Energy conservation, Equal educational opportunity, Federally affected areas, Government contracts, Grant programs, Grant programs-agriculture, Grant programs-business and industry, Grant programs-communications, Grant programs-education, Grant programs-energy, Grant programs-health, Grant programs-housing and community development, Grant programs-social programs, Grant administration, Guam, Home improvement, Homeless, Hospitals, Housing, Human research subjects, Indians, Indians-education, Infants and children, Insurance, Intergovernmental relations, International organizations, Inventions and patents, Loan programs, Loan programs social programs, Loan programs-agriculture, Loan programs-business and industry, Loan programs-communications, Loan programs-energy, Loan programs-health, Loan programs-housing and community development, Manpower training programs, Migrant labor, Mortgage insurance, Nonprofit organizations, Northern Mariana Islands, Pacific Islands Trust Territories, Privacy, Renewable Energy, Reporting and recordkeeping requirements, Rural areas, Scholarships and fellowships, School construction, Schools, Science and technology, Securities, Small businesses, State and local governments, Student aid, Teachers, Telecommunications, Telephone, Urban areas, Veterans, Virgin Islands, Vocational education, Vocational rehabilitation, Waste treatment and disposal, Water pollution control, Water resources, Water supply, Watersheds, Women.

Dated: January 11, 2017.

John B. King, Jr.,

Secretary of Education.

For the reasons discussed in the preamble, the Secretary amends part 3474 of title 2 of the Code of Federal Regulations as follows:

¹⁸ 2 CFR 3474.5(a), “. . . the Secretary of Education, after consultation with OMB, may allow exceptions for classes of Federal awards or non-Federal entities subject to the requirements of this part when exceptions are not prohibited by statute. However, in the interest of maximum uniformity, exceptions from the requirements of this part will be permitted only in unusual circumstances.”

**PART 3474—UNIFORM
ADMINISTRATIVE REQUIREMENTS,
COST PRINCIPLES, AND AUDIT
REQUIREMENTS FOR FEDERAL
AWARDS**

■ 1. The authority citation for part 3474 continues to read as follows:

Authority: 20 U.S.C. 1221e–3 and 3474 unless otherwise noted.

■ 2. Add § 3474.20 to read as follows:

§ 3474.20 Open licensing requirement for competitive grant programs.

For competitive grants awarded in competitions announced after February 21, 2017:

(a) A grantee or subgrantee must openly license to the public the rights set out in paragraph (b)(1) of this section in any grant deliverable that is created wholly or in part with Department competitive grant funds, and that constitutes a new copyrightable work; provided, however, that when the deliverable consists of modifications to pre-existing works, the license shall extend only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works.

(b)(1) With respect to copyrightable work identified in paragraph (a) of this section, the grantee or subgrantee must grant to the public a worldwide, non-exclusive, royalty-free, perpetual, and irrevocable license to—

(i) Access, reproduce, publicly perform, publicly display, and distribute the copyrightable work;

(ii) Prepare derivative works and reproduce, publicly perform, publicly display and distribute those derivative works; and

(iii) Otherwise use the copyrightable work, provided that in all such instances attribution is given to the copyright holder.

(2) Grantees and subgrantees may select any open licenses that comply

with the requirements of this section, including, at the grantee's or subgrantee's discretion, a license that limits use to noncommercial purposes. The open license also must contain—

(i) A symbol or device that readily communicates to users the permissions granted concerning the use of the copyrightable work;

(ii) Machine-readable code for digital resources;

(iii) Readily accessed legal terms; and

(iv) The statement of attribution and disclaimer specified in 34 CFR 75.620(b).

(c) A grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate the openly licensed copyrightable works identified in paragraph (a) of this section.

(d)(1) The requirements of paragraphs (a), (b), and (c) of this section do not apply to—

(i) Grants that provide funding for general operating expenses;

(ii) Grants that provide support to individuals (e.g., scholarships, fellowships);

(iii) Grant deliverables that are jointly funded by the Department and another Federal agency if the other Federal agency does not require the open licensing of its grant deliverables for the relevant grant program;

(iv) Copyrightable works created by the grantee or subgrantee that are not created with Department grant funds;

(v) Peer-reviewed scholarly publications that arise from any scientific research funded, either fully or partially, from grants awarded by the Department;

(vi) Grantees or subgrantees under the Ready To Learn Television Program, as defined in the Elementary and Secondary Education Act of 1965, as amended, Title II, Subpart 3, Sec. 2431, 20 U.S.C. 6775;

(vii) A grantee or subgrantee that has received an exception from the Secretary under 2 CFR 3474.5 and 2 CFR 200.102 (e.g., where the Secretary

has determined that the grantee's dissemination plan would likely achieve meaningful dissemination equivalent to or greater than the dissemination likely to be achieved through compliance with paragraph (a) or (b) of this section, or compliance with paragraph (a) or (b) of this section would impede the grantee's ability to form the required partnerships necessary to carry out the purpose of the grant); and

(viii) Grantees or subgrantees for which compliance with these requirements would conflict with, or materially undermine the ability to protect or enforce, other intellectual property rights or obligations of the grantee or subgrantee, in existence or under development, including those provided under 15 U.S.C. 1051, *et seq.*, 18 U.S.C. 1831–1839, and 35 U.S.C. 200, *et seq.*

(2) The requirements of paragraphs (a), (b), and (c) of this section do not alter any applicable rights in the grant deliverable available under 17 U.S.C. 106A, 203 or 1202, 15 U.S.C. 1051, *et seq.*, or State law.

(e) The license set out in paragraph (b)(1) of this section shall not extend to any copyrightable work incorporated in the grant deliverable that is owned by a party other than the grantee or subgrantee, unless the grantee or subgrantee has acquired the right to provide such a license in that work.

(f) *Definition.* For purposes of this section,

(1) A *grant deliverable* is a final version of a work, including any final version of program support materials necessary to the use of the deliverable, developed to carry out the purpose of the grant, as specified in the grant announcement.

(2) A *derivative work* means a derivative work as defined in the Copyright Act, 17 U.S.C. 101.

[FR Doc. 2017–00910 Filed 1–18–17; 8:45 am]

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Part XIII

Environmental Protection Agency

40 CFR Part 192

Health and Environmental Protection Standards for Uranium and Thorium
Mill Tailings; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 192

[EPA-HQ-OAR-2012-0788; FRL-9958-12-OAR]

RIN 2060-AP43

Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is proposing new health and environmental protection standards under the Uranium Mill Tailings Radiation Control Act (UMTRCA) of 1978. The standards proposed in this action would be applicable to byproduct materials produced by uranium in-situ recovery (ISR) and would be implemented by the U.S. Nuclear Regulatory Commission (NRC) and NRC Agreement States. The EPA initially proposed new health and environmental protection standards for ISR facilities on January 26, 2015; however, the EPA has decided to re-propose the rule and seek additional public to comment on changes to the original proposal, including changes in the regulatory framework and approach, based on public comment and new information received from stakeholders.

The first standards for uranium recovery were issued by the EPA in 1983 when conventional mining and milling were the predominant methods of uranium extraction, and were last amended in 1995. Since the early 1990s, ISR has mostly replaced conventional milling. This proposed rule would strengthen the existing regulations for uranium recovery by adopting new standards addressing groundwater hazards specific to ISR facilities. As with the original proposal, the primary focus of this proposal is groundwater protection, restoration and long-term stability.

The most significant changes from the original proposal include: Removing the default 30-year long-term monitoring provision and shifting to a Resource Conservation and Recovery Act (RCRA) Subtitle C corrective action framework as a model rather than a RCRA Subtitle C landfill framework; adding specific criteria and procedures for approving termination of long-term stability monitoring; deleting gross alpha particle activity from proposed Table 1 to subpart F of 40 CFR part 192, and

allowing more flexibility for the NRC or Agreement States to determine on a site-specific basis the constituents for which concentration based standards are set. The EPA has also sought to clarify how these standards under UMTRCA complement, and do not overlap with, the requirements of the Safe Drinking Water Act (SDWA).

This action also proposes amendments to certain provisions of the existing rule to address a ruling of the Tenth Circuit Court of Appeals, to update a cross-reference to another environmental standard and to correct certain technical and typographical errors. The proposed rule has been informed by input from the NRC, the U.S. Department of Energy (DOE), states, tribes, industry, environmental groups and other stakeholders, and would promote public health and protect groundwater by reducing the potential for groundwater contamination after production has ceased, and in aquifers adjacent to ISR facilities during uranium recovery.

DATES: Comments must be received on or before July 18, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2012-0788, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email:* a-and-r-docket@epa.gov.
- *Fax:* (202) 566-9744.
- *Mail:* Air and Radiation Docket, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.
- *Hand Delivery:* EPA West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC 20004. Such deliveries are only accepted during the Docket's normal hours of operation; special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-HQ-OAR-2012-0788. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or *email*. The *www.regulations.gov* Web site is an "anonymous access" system, which means the EPA will not know

your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *www.regulations.gov*, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA's public docket visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Office of Air and Radiation Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Air and Radiation Docket is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT:

Ingrid Rosencrantz, Office of Radiation and Indoor Air, Radiation Protection Division, Mailcode 6608T, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 343-9286; fax number: (202) 343-2304; email address: Rosencrantz.ingrid@epa.gov.

SUPPLEMENTARY INFORMATION:

A. Does this action apply to me?

The regulated categories and entities potentially affected by the proposed standards include:

| Category | NAICS code ¹ | Examples of regulated entities |
|--|-------------------------|--|
| Industry: Uranium Ores Mining and/or Beneficiating. | 212291 | Facilities that extract or concentrate uranium from any ore processed primarily for its source material content. |
| Leaching of Uranium, Radium or Vanadium Ores. | 212291 | Facilities that extract or concentrate uranium from any ore processed primarily for its source material content. |

¹ North American Industry Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this proposed action.

B. What should I consider as I prepare my comments to EPA?

Submitting CBI. Do not submit CBI information to the EPA through www.regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information contained on a disk or CD ROM that you mail to the EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

Tips for preparing your comments. When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Submit your comments by the comment period deadline.

C. When would a public hearing occur?

If anyone contacts the EPA requesting to speak at a public hearing concerning this proposed rule by February 21, 2017, the EPA will hold a public hearing. If you are interested in attending a public hearing, contact Mr. Anthony Nesky at (202) 343–9597. If a public hearing is held, the Agency will announce the date, time and venue on the EPA Web site at <http://www.epa.gov/radiation/tenorm/40CFR192.html>.

D. What documents are referenced in today's proposal?

The EPA refers to a number of documents that provide supporting information for the Agency's proposed uranium and thorium mill tailings standards. All documents relied upon by the EPA in regulatory decision making may be found in the EPA docket (EPA–HQ–OAR–2012–0788) accessible via <http://www.regulations.gov/>. Other documents (e.g., statutes, regulations, and proposed rules) are readily available from public sources. The EPA documents listed below are referenced most frequently in today's proposal.

EPA 402/D–14–001, “Considerations Related to Post Closure Monitoring of Uranium In-Situ Leach/In-Situ Recovery (ISL/ISR) Sites,” EPA, 2014.

EPA 402/R–14–003, “Economic Analysis: Proposed Revisions to the Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings Rule (40 CFR part 192),” EPA, 2016.

EPA 530/R–09–007, “Statistical Analysis of Groundwater Monitoring Data at RCRA Facilities—Unified Guidance,” EPA, 2009.

E. Preamble Abbreviations

The following abbreviations are used in this preamble:

ACL Alternate concentration limit
AEA Atomic Energy Act
BID Background information document
CFR Code of Federal Regulations
COOs Civilian owners and operators
DOE Department of Energy
EPA U.S. Environmental Protection Agency
FR Federal Register
ISR In-situ recovery, also known as in-situ leaching (ISL)
MCL Maximum contaminant level
NRC U.S. Nuclear Regulatory Commission

NUREG U.S. Nuclear Regulatory Commission Guides
OMB Office of Management and Budget
RAC Radiation Advisory Committee
RCRA Resource Conservation and Recovery Act
RFA Regulatory Flexibility Act
SAB Science Advisory Board
SDWA Safe Drinking Water Act
UCL Upper control limit
UIC Underground injection control
U.S. United States
UMRA Unfunded Mandates Reform Act of 1995
UMTRCA Uranium Mill Tailings Radiation Control Act of 1978
U.S.C. United States Code
USDW Underground source of drinking water

F. Organization of This Document

The information presented in this preamble is organized as follows:

- I. Executive Summary
 - A. Background
 - B. Purpose of the Regulatory Action
 - C. Summary of the Major Provisions
 - D. Summary of the Costs and Benefits
 - E. Statutory Authority for This Action
- II. Summary of the Proposed Rule
 - A. Proposed Standards for Uranium ISR Operations
 - B. Amendments to 40 CFR Part 192, Subparts C and D
- III. Summary of Changes Made to the Original Proposal and Rationale for Those Changes
 - A. Incorporation of the Initial and Long-Term Stability Standards in Proposed 40 CFR 192.52
 - B. Groundwater Protection Standards
 - C. Preoperational Monitoring Requirements
 - D. Exempted Aquifers
 - E. Excursions
 - F. Initial and Long-Term Stability
 - G. Corrective Action Program
 - H. Costs and Economic Impacts
 - I. Other Miscellaneous Changes
- IV. Responses to Other Significant Comments That Did Not Result in Changes to the Original Proposal
 - A. Authority To Set and Enforce Standards
 - B. Need for New Standards for Uranium ISR Facilities
 - C. Applicability
 - D. The 95 Percent Confidence Level
- V. Summary of Environmental, Cost and Economic Impacts
 - A. Environmental Impacts of the Proposed Rule on Groundwater Quality
 - B. Incremental Costs of Complying With the Proposed Rule
 - C. Economic Impacts of the Proposed Rule on the Market for Uranium and the Uranium Industry

- D. Benefits of the Proposed Rule
- VI. Statutory and Executive Order Reviews
 - A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
 - B. Paperwork Reduction Act
 - C. Regulatory Flexibility Act
 - D. Unfunded Mandates Reform Act
 - E. Executive Order 13132: Federalism
 - F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
 - G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks
 - H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use
 - I. National Technology Transfer Advancement Act
 - J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

I. Executive Summary

A. Background

ISR is a method by which uranium is leached from underground ore bodies by the introduction of a solvent solution, called a lixiviant, through injection wells drilled into the ore zone. The process does not require excavation to extract the ore body from the ground or conventional milling to extract the uranium from the mined ore. After the lixiviant is injected underground, it passes through the ore zone and mobilizes the uranium. The uranium-bearing solution is then pumped to the surface via extraction wells, and the solution is processed to extract the uranium. During uranium production, the fluids injected to mobilize uranium change the chemistry of the aquifer from its original state, thereby mobilizing uranium and many other minerals and metals. Groundwater from the ISR production zone can migrate from the production zone and contaminate nearby groundwater with arsenic, barium, cadmium, chromium, lead, mercury, selenium, silver, nitrate, molybdenum, radium and uranium and other constituents. The standards proposed in this action would minimize the risk of undetected groundwater degradation and constituent migration during and after ISR operations have ceased.

The EPA initially proposed new health and environmental protection standards for ISR facilities on January 26, 2015 (hereinafter “original proposal”), with the intention of finalizing the new standards in 2016.¹ During the public comment period, the

Agency received over 5,380 public comment letters from a wide range of stakeholders, with comments covering more than 80 different topics. In addition, during interagency review, more than 15 groups of stakeholders met with Office of Management and Budget (OMB) to voice comments on the original proposal. Commenters were particularly concerned about the default 30-year long-term monitoring requirement, felt that the optional method by which a licensee could request permission to cease long-term stability monitoring lacked sufficient specificity and believed the number of constituents required to be monitored was unreasonably burdensome. Several commenters thought the economic analysis underestimated the compliance costs and identified several additional categories of costs related to the long-term monitoring requirements they felt had been omitted from the analysis or were not representative of the actual costs incurred. Other commenters felt that several additional types of benefits should be included in the benefits analysis. After consulting with the NRC and other agencies and collecting additional information from industry, including participation in stakeholder meetings during interagency review with OMB, the EPA decided to make several changes to the original proposal and solicit additional public comment rather than finalize the rule with the changes. These changes are described in detail in section III of this preamble. The most significant changes include removing the default 30-year long-term monitoring provision and shifting to more of a RCRA Subtitle C corrective action framework as a model rather than a RCRA Subtitle C landfill framework, adding specific criteria and procedures for approving termination of long-term stability monitoring, deleting gross alpha particle activity from proposed Table 1 to subpart F, and allowing more flexibility for the NRC and Agreement States (hereinafter “regulatory agency”) to determine on a site-specific basis the constituents for which concentration-based standards are set. The EPA has also sought to clarify how these standards under UMTRCA complement, and do not overlap with, the requirements of the SDWA. In addition to these more significant changes, the EPA has also made minor changes to the original proposal, such as moving the initial and long-term monitoring standards to the proposed § 192.52 and moving the requirements for alternate concentration limits (ACLs) to a separate section (see proposed § 192.54). In addition to making changes to the

rule text, the EPA also re-calculated the incremental compliance costs to incorporate estimated non-monitoring costs (e.g., licensing, leasing fees, continued surety, maintenance) and incorporated additional cost information provided by industry. The EPA re-evaluated the economic and energy impacts to both address the concerns raised by commenters and to incorporate the changes the Agency made to the standards since the original proposal was published. The revised costs and economic analysis for this proposal are discussed in section V of this preamble. While the majority of the changes to the original proposal are relatively minor, the EPA decided it was appropriate to re-propose the rule due to the high level of public interest in this rulemaking. This action provides the public an opportunity to review and provide comment on the changes made to the original proposal and allows the EPA to consider and make any additional changes based on those comments before finalizing the rule. The EPA is requesting comment on all aspects of this proposed action. Because this is a re-proposal, and the EPA wishes to consider comments in context, please re-submit any relevant comments that may have been submitted on the original proposal.

Several commenters also voiced concerns about information and data collection, including review of Agreement State regulatory programs that address ISRs. Although the EPA requested and collected data and information as outlined in section IV.B of this preamble, the Agency understands stakeholders concerns and are inviting stakeholders to submit additional data and analyses to further clarify the ISR process, including any additional monitoring results and analyses. The EPA will be collecting additional information on state regulatory programs, as recommended by several states.

B. Purpose of the Regulatory Action

The EPA is proposing to add new health and environmental protection standards to regulations promulgated under UMTRCA. The proposed standards would regulate byproduct materials produced by ISR, including both surface and groundwater standards, with a primary focus on groundwater protection, restoration and stability. By explicitly addressing the most significant environmental and public health hazards presented by ISR activities, these proposed standards would address the shift toward ISR as the dominant form of uranium recovery that has occurred since the standards for

¹ See 80 FR 4156, January 26, 2015.

uranium and thorium mill tailings were promulgated in 1983.

This rule would provide the necessary framework for consistent and sustainable protection of groundwater at ISR sites that will continue to have beneficial uses even if the aquifer has been exempted from protection under the SDWA.

Groundwater is a scarce resource that is under increasing pressure, particularly in the arid West where groundwater has multiple uses, including for livestock production, crop irrigation, wildlife support, and human consumption. As groundwater resources are depleted, it becomes even more important to preserve those resources for future uses. Stakeholders in these areas are already finding a need to use groundwater that is of lower quality than desired.² Groundwater that contains mineral resources, such as uranium, is not necessarily of such poor quality that it cannot be used for these purposes. By altering the chemical composition of groundwater, ISR creates reasons to be concerned about impacts to groundwater, which may be used for human drinking water, as well as for other purposes, such as livestock watering, crop irrigation and wildlife support.

While an aquifer or portions of an aquifer may have been exempted from the protections of the SDWA, the aquifer may be needed in the future for human drinking water or other purposes. The standards proposed in this action do not require licensees to improve groundwater quality, only to provide confidence that: (1) In the area mined, the applicable constituent concentration standards (set at either background or health-based levels, whichever is higher), are met and remain stable; and (2) that uranium recovery operations will not endanger adjacent aquifers. EPA requests comment on whether groundwater, once it meets the constituent concentration standards, could or would potentially be used for drinking water or other purposes.

UMTRCA directs the EPA to establish standards of general application, while the NRC is vested with implementing the EPA's standards under its licensing and enforcement authority. The EPA has previously promulgated general standards under UMTRCA for surface disposal of mill tailings from

conventional uranium mining and milling, but ISR has become the dominant form of uranium extraction since the 1990s. In 2006, an NRC commissioner observed that ISR-specific rules were needed to provide a national approach to bring predictability to the industry and state regulators. This view was not predicated on specific documented instances of groundwater contamination outside of the ISR production zone. The scope and level of protection of the SDWA differs from the UMTRCA. The purpose of the SDWA UIC program is to prevent endangerment of underground sources of drinking water. In determining whether an aquifer may be exempted from the protection of the SDWA, the EPA does not consider its use for purposes other than human drinking water (e.g., agriculture and other uses).

As the highlighted portions of the SDWA regulations below show, there is no requirement to demonstrate poor water quality prior to issuing an aquifer exemption if the aquifer is or could be mineral producing. Under the SDWA's UIC regulations, aquifer exemptions are used to allow for mineral recovery in aquifers that would otherwise be protected as sources of drinking water when certain criteria are met. In the SDWA regulations, § 146.4 provides that: "An aquifer or a portion thereof which meets the criteria for an "underground source of drinking water" in § 146.3 may be determined under § 144.7 of this chapter to be an "exempted aquifer" for Class I–V wells if it meets the criteria in paragraphs (a) through (c) of this section. Class VI wells must meet the criteria under paragraph (d) of this section: (a) It does not currently serve as a source of drinking water; and (b) It cannot now and will not in the future serve as a source of drinking water because: (1) It is mineral, hydrocarbon or geothermal energy producing, or can be demonstrated by a permit applicant as part of a permit application for a Class II or III operation to contain minerals or hydrocarbons that considering their quantity and location are expected to be commercially producible; or (2) It is situated at a depth or location which makes recovery of water for drinking water purposes economically or technologically impractical; or (3) It is so contaminated that it would be economically or technologically impractical to render that water fit for human consumption; or (4) It is located over a Class III well mining area subject to subsidence or catastrophic collapse; or (5) The total dissolved solids content of the ground water is more than 3,000

and less than 10,000 mg/l and it is not reasonably expected to supply a public water system . . .".

In addition, although a portion of an aquifer may be exempted from the protections of the SDWA, there are no federal requirements preventing recovery and use of the water within exempted aquifers (including where ISR operations were previously conducted) for private drinking water supply, public water supply, or other uses.

UMTRCA provides authority that can be used to protect aquifers during and after uranium recovery operations, regardless of whether the aquifer meets the definition of an underground source of drinking water (USDW) as defined in the EPA's UIC regulations or is exempted from the protections of the SDWA because it meets the existing regulatory criteria for exemption. UMTRCA directs the Administrator to promulgate "standards of general application for the protection of public health, safety, and the environment from radiological and non-radiological hazards associated with the processing, and possession, transfer, and disposal of byproduct material".³ The statute further provides that "[i]n establishing such standards, the Administrator shall consider the risk to the public health, safety, and the environment, the economic costs of applying such standards, and such other factors as the administrator determines to be appropriate".⁴

In areas being mined for uranium, the SDWA does not require operators or regulators to collect the level of data needed to definitively confirm or disprove drinking water contamination or contamination of water for other purposes that may also impact humans, such as livestock watering and crop irrigation. Additionally, data that the EPA's UIC Program have received and evaluated at or near at least one ISR facility are consistent with an excursion beyond the boundary of the exempt aquifer (i.e., leading to elevated uranium levels outside the ISR facility area).

The proposed 40 CFR part 192, subpart F would afford protections that do not currently exist under federal UIC regulations and would be complementary to existing regulations (e.g., UIC regulations) at uranium ISR facilities. For example, these new provisions proposed under the authority of UMTRCA would address corrective action, broad baseline development, monitoring well placement and aquifer restoration. The proposed provisions would also provide assurance that once

² Application for Amendment of USNRC Source Materials License SUA-1601, Ross ISR Project, Kendrick Expansion Area, Crook County, Wyoming Docket #40-9091, 2015, pp. 3-100; USGS National Brackish Groundwater Information Sheet 2013; Advanced Treatment for Groundwater, Treating Low Quality Groundwater for Municipal Use, Water Engineering and Management, Nov. 2001.

³ See 42 U.S.C. 2022(b)(1).

⁴ *Ibid.*

a facility decommissions a site, the water will meet the applicable constituent concentration standards in 40 CFR 192.52(c)(1) and will remain stable over time.

The proposed 40 CFR part 192, subpart F also would ensure that industry maintains responsibility for protection of public health and the environment at uranium ISR facilities during and after uranium recovery operations.

Since ISR alters the chemical composition of groundwater, it creates reasons to be concerned about risk to public health, safety and the environment from radiological and non-radiological hazards associated with the processing and disposal of byproduct material. Industry commenters and others say that there is no need for this rule because the EPA has not identified an instance in which an ISR operation has contaminated a source of drinking water. First, the Agency notes that this proposal addresses groundwater protection at ISR facilities both in and around the production zone and in surrounding aquifers. Focusing on the area of surrounding or adjacent aquifers, the EPA acknowledges that the Agency does not have sufficient information to document a specific instance of contamination of a public source of drinking water caused by an ISR. The Agency remains concerned, however, that the available data may not be capturing some instances of contamination that this proposed rule seeks to prevent. In other words, the Agency remains concerned that the lack of data does not demonstrate that no contamination is occurring, as industry commenters assert, but instead merely demonstrates the lack of data available to be able to make such a determination, especially where there has been limited post-restoration monitoring. The monitoring requirements in this proposal address the issue of lack of data.

As explained in this preamble, in documents supporting this proposal, and as included in the docket for this proposal, there is ample evidence of excursions occurring as the result of ISR facilities. For example, data that the EPA's UIC Program have received and evaluated at or near at least one ISR facility are consistent with an excursion beyond the boundary of the exempt aquifer, leading to elevated uranium levels outside the ISR facility. In addition, there is data in the proposal's Background Information Document (BID) describing numerous excursions from several ISR facilities. Moreover, data in attachment 5 of the BID shows that several ISR facilities have not met

background or health-based levels after restoration of the production zone. This data, when considered with the understanding that groundwater flow is often extremely slow, raises concerns that there has been insufficient monitoring conducted by these ISR facilities to identify the actual contamination that may be occurring or may occur in the future beyond the production zone and in sources of drinking water. The EPA solicits comment on industry's assertion that in no case have any excursions from ISR facilities resulted in contamination in aquifers being used as public sources of drinking water or for other uses. In addition, the EPA also requests comment on the kinds of data that would be needed to clearly link ISR operations with off-site contamination or that would support claims that there is no contamination of concern.

The EPA notes that several NRC-regulated ISR facilities are continuing to work toward restoring groundwater, with restoration and monitoring being conducted for as long as 10 years after ceasing production. The Agency understands that restoration does not always meet original background levels as evidenced by the number of restoration goals exceeding background or the levels proposed in Table 1 to subpart F. Additionally, the NRC acknowledges that efficiency could be gained by codifying its longstanding effective regulatory regime into regulations specific to ISR facilities. Historically, restoration and monitoring at ISR facilities are typically conducted for only a short period, and a longer period would provide more confidence to demonstrate that restoration of the affected groundwater is complete and that long-term stability is established with confidence before license termination. The initial and long-term stability monitoring and corrective action program included in this proposal would ensure that both of these requirements are met before ISR facilities can be decommissioned.

At ISR facilities, the groundwater is directly impacted by the injection of lixiviant into the aquifer, which alters the geochemistry of the ore-bearing formation and increases the concentration of radionuclides and other metals in the water. Restoration activities attempt to restore the water quality for specific constituents to the applicable constituent concentration standards inside the production zone. Although subpart D to 40 CFR part 192 (hereinafter "subpart D") addresses contamination of aquifers, it explicitly addresses only contamination resulting from releases from uranium mill tailings

impoundments used to store uranium byproduct material (e.g., conventional tailings impoundments, evaporation or holding ponds). Under the proposed subpart F, the licensee is required to restore groundwater in the production zone and surrounding aquifers to the applicable constituent concentration standards, to the extent possible, and to show some level of stability in the production zone prior to terminating the license. Because ISR changes the geochemistry of the groundwater, more rigorous stability-based standards together with corrective action programs are necessary to ensure that the production zone is restored and the applicable constituent concentration standards will continue to be met in the future.

As described in the preamble to the 2015 proposal, the EPA solicited technical advice on key issues related to groundwater protection at ISR sites from the Radiation Advisory Committee (RAC) of the Agency's Science Advisory Board (SAB) (80 FR 156). The final report of the SAB/RAC, along with the EPA's response, can be found at: <https://yosemite.epa.gov/sab/sabproduct.nsf/c91996cd39a82f648525742400690127/0314cef928df63cc8525775200482fa3!OpenDocument&TableRow=2.4#2>.

The SAB/RAC further considered this issue in 2015, and the Agency provided a detailed cross-walk to the 2015 proposed rule to show how the RAC's advice had been addressed. The SAB determined that no further action was needed on its part. See [https://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/8DA59AB1BE0EA14B85257E660071F2EF/\\$File/EPA-SAB-15-009+unsigned.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/02ad90b136fc21ef85256eba00436459/8DA59AB1BE0EA14B85257E660071F2EF/$File/EPA-SAB-15-009+unsigned.pdf). In general, the BID addresses topics specifically addressed by the RAC as follows:

The EPA has evaluated available data for all phases of ISR activities to address the SAB recommendations. Section 5 of the BID analyzes data and examines specific case studies for baseline and restoration, with particular attention given to establishment of baseline at the Dewey-Burdock site in South Dakota (Attachment A). Sections 6 and 7.8 and Attachment F provide extensive analysis of post-restoration monitoring at the Crow Butte, Christensen, Highland, and Irigaray ISR sites, including regression analysis and statistical testing, and cumulative complementary distribution functions (CCDF). Results are presented by analyte, mine unit, and well.

Section 6 addresses in detail SAB recommendations related to influences on groundwater chemistry and their effects on time frames for stability

monitoring, in particular fate and transport processes (speciation, including a case study of the Crow Butte facility, and solubility) and natural attenuation processes (adsorption, presence of secondary minerals, and biological mechanisms).

This action also proposes amendments to certain provisions in the current rule, located at 40 CFR part 192. Specifically, this action addresses a ruling of the Tenth Circuit Court of Appeals, updates a cross-reference to another environmental standard and corrects other technical and typographical errors.

C. Summary of the Major Provisions

The proposed rule includes a new subpart, subpart F, within 40 CFR part 192, which sets standards to protect groundwater at uranium ISR operations. Specifically, subpart F would set standards of general application to protect groundwater beyond the production zone during ISR operational and restoration phases and to ensure, once the wellfield is restored, that the restoration is complete and stable. The proposed rule includes three types of groundwater protection standards: (1) Constituent concentration standards, (2) initial stability standards, and (3) long-term stability standards. The proposed rule also includes monitoring requirements to establish statistically valid background water quality levels, excursion monitoring (for the operational and restoration phases), and monitoring to meet the initial and long-term stability standards. The proposed rule also includes a requirement to establish a corrective action program. Once finalized, these standards will be implemented by the regulatory agency. Once the regulatory agency incorporates the new standards into its regulations, or takes other appropriate steps to implement the new standards, this will provide a nationally consistent approach for the licensing process for ISR facilities.⁵

D. Summary of the Costs and Benefits

The costs and benefits of this rulemaking are described briefly in Table 2 of this preamble. The costs reflect the difference in costs that would be incurred by ISR licensees under the

proposed rule and costs that would be incurred by those facilities in the absence of the proposed rule. These incremental costs include added costs associated with monitoring and non-monitoring compliance actions under the proposed rule. For additional details on the incremental costs of the proposed rule, see section V.B of this preamble and section 3 of the document titled, "Economic Analysis: Revisions to the Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings Rule (40 CFR part 192)," available in Docket ID No. EPA-HQ-OAR-2012-0788.

Complying with the proposed standards may require some existing ISR facilities to monitor groundwater for additional constituents that they are not currently monitoring. It would also require all ISR facilities to continue monitoring for a period of at least three years after the initial stability standard is met, and to conduct geochemical modeling and other analysis to demonstrate that the applicable constituent concentration standards will continue to be met in the future. The additional monitoring, modeling and analysis that would be required under this proposed rule could increase costs to ISR facilities. The additional years during which ISR facilities' license, surety, insurance, maintenance and other non-monitoring activities would have to be maintained would also increase costs. The EPA estimates the rule imposes annualized incremental costs on the ISR industry of approximately \$11.9 million, including incremental monitoring costs and other non-monitoring costs.

In its economic analysis, the EPA analyzed potential economic impacts of the rule on small entities (7 companies) using a range of assumptions about revenues of firms that own ISR facilities and costs of complying with the rule. The "average revenue" assumption is based on a market price of \$55 per pound of U₃O₈e and production that is 25% of facility capacity. The "low revenue" assumption reflects revenues 10% lower, and the high revenue assumption reflects revenues that would be 20% higher. With average costs, cost-to-sales ratios for small firms range from 0.7% to 3.1% for the low revenue scenario and from 0.5% to 2.3% under the higher revenue scenario. These assumptions are intended to reflect the range of possible market conditions at the time when the rule would take effect (likely 2022 to 2025). Uranium market projections for the longer term are generally optimistic, reflecting growth in nuclear power in China and India and other countries; 57 new reactors are

currently under construction with 65% of those projected to come online by 2020, and world-wide electricity consumption is projected to increase by 50% between 2013 and 2035 (only part of the increase is estimated to be met by nuclear energy) (Cameco, 2016).

Outlook for the near term, however, is less positive, and the rate of recovery is uncertain.

The EPA acknowledges that current uranium market conditions reflect depressed demand for uranium (due to lingering effects of the Fukushima incident, slow recovery of demand for electricity since the recession and low prices of substitute sources of energy) and some reliance on alternative (non-mine) sources of uranium. As a result, both the price and production of uranium have fallen. The long-term contract price of uranium has declined from around \$60 per pound of U₃O₈e in 2012 to around \$40 per pound in 2016. Spot prices have generally been 20% lower than contract prices. While market forces have driven the market price for uranium down by \$20 to \$30 dollars over the past 5 years, the rule is estimated to increase the cost of producing uranium using ISR methods by between \$1.27 per pound U₃O₈e and \$2.45 per pound of U₃O₈e, depending on the cost scenario.

Because of these market conditions, several ISR facilities that are fully licensed and permitted are not currently producing uranium (including previously operational facilities that have been placed on standby and licensed and permitted facilities that have never gone into production), and development of new ISR facilities has largely been put on hold. Further, several ISR facilities have changed ownership in the past few years, as companies have been forced by market conditions to sell assets. In other words, some ISR firms currently are unable to profitably operate their facilities even in the absence of the rule. Several of the small firms report little or no revenue from sales of uranium. Even the relatively small incremental costs required to comply with the rule's provisions would not currently be affordable for such firms. This is not due to the magnitude of the rule's costs; it is due to current conditions in the world's economy generally and in the market for uranium in particular. The EPA considers that when the market for uranium recovers, as it is projected to do, ISR uranium production and price will increase; under those conditions, facilities that are currently unprofitable without the rule would likely be profitable with the rule's costs included. However, the EPA solicits public

⁵ Currently, the process used by the NRC for licensing ISR facilities is based on a combination of NRC regulations, site-specific license conditions, and guidance. The process used by the Agreement States is based on regulations that vary by state for Agreement States that regulate ISR facilities. The NRC and many of the Agreement States have an established hearing process that allows for interested parties to request a hearing on the merits for the issuance and amendment of ISR facility licenses.

comment on this rule’s expected impact on the domestic ISR industry.

The EPA compared these costs to the potential financial, ecological and human health benefits that would result from the proposed rule. Although the EPA is unable to quantify all the potential benefits, the EPA has identified several categories of benefits that can be attributable to the rule. The proposed rule would require groundwater at ISR facilities to be restored to the constituent concentration standards. Licensees would have to demonstrate stability of groundwater at those constituent concentration standards by completing at least 6 years of monitoring (3 years to meet the initial stability standards plus 3 years to meet the long-term stability standards), and conduct modeling and analysis to demonstrate there is a reasonable assurance that the applicable constituent concentration standards will continue to be met in the future. This provision would minimize the risk of degradation of valuable groundwater resources and the potential exposure of human, domestic livestock or ecological receptors to radiological or other constituents. The proposed rule would also minimize the potential contamination of surface water and potential adverse health impacts resulting from such contamination. In addition, the proposed rule would avoid the potential costs associated with remediating contaminated aquifers; the cost of remediating a single plume of contamination could exceed the nationwide incremental costs associated with the proposed rule. The EPA estimated the cost savings due to avoided pump and treat remediation for hypothetical contaminant migration examples using the Conceptual Mine Unit, under three plume scenarios. For each scenario, the EPA computed the estimated cost savings by computing the difference in the cost of remediating a large plume (which might result if the plume were not detected for many years) and the cost of remediating a small plume discovered through monitoring prior to facility closure. The total estimated avoided costs over the entire remediation episode in this illustration, remediating three different sized plumes, ranged from \$23.7 million to \$608 million, depending on the scenario. Annualized, these avoided costs range from \$1.5 million to \$11.1 million per year. To reflect the recognition that the proposed rule would reduce the likelihood of contamination relative to existing regulatory requirements, but not eliminate it entirely, the EPA further assumed a range of probability that the illustrative example contamination episode would be prevented by the proposed rule, but not identified under current requirements. The EPA assumed that the likelihood that the proposed rule would prevent the contamination, but current requirements would not, would range from 20% to 80%. Thus, the values shown in the table are 20% of the lower bound value (\$0.3 million) to 80% of the upper bound value (\$8.9 million). However, because the EPA is unable to quantify the number or characteristics of contamination episodes that could occur in the absence of the proposed rule, the EPA is unable to estimate nationwide cost savings. Thus, the EPA has not compared these illustrative costs savings with the estimated national costs of the proposed rule or computed the net benefits.

TABLE 2—CHARACTERIZATION OF THE COSTS AND BENEFITS OF 40 CFR PART 192, SUBPART F

| Incremental costs (2015 dollars) | Benefits |
|--|--|
| Annualized costs of monitoring, modeling and analysis ranging from \$0.2 to \$7.3 million. Annual non-monitoring costs, including license, surety, lease, maintenance: \$7.6 million. | Protection of groundwater quality. Possible protection of surface water quality. Potentially reduced risk of exposure of human or ecological receptors to radiological pollutants. Potentially reduced human health impacts, including cancer. Annualized avoided cost of single remediation effort would be between \$0.3 million and \$8.9 million. ¹ |

¹ The costs presented are not an estimate of the nationwide remediation cost savings. They are the estimated cost of remediation for a simplified example of a single wellfield, for three contaminant plume scenarios.

E. Statutory Authority for This Action

The EPA is proposing the new standards and amendments under its authority in section 275 of the Atomic Energy Act (AEA), as added by section 206 of UMTRCA.⁶ Section 206 of UMTRCA authorizes the EPA to promulgate standards of general application for the protection of public health, safety, and the environment from radiological and non-radiological hazards associated with (a) residual radioactive materials located at specifically listed inactive uranium milling sites, nearby contaminated “vicinity properties,” and depository sites for such materials selected by the Secretary of Energy (commonly referred

to as Title I sites); and (b) the processing and the possession, transfer and disposal of byproduct material at sites that process ores primarily for their uranium and thorium source material content⁷ or disposal of such byproduct material (commonly known as Title II sites). See 42 U.S.C. 2022.⁸ These public health, safety and environmental standards are contained in 40 CFR part 192 and are implemented by the NRC

⁷ “Source material” is defined as “(1) Uranium or thorium or any combination of uranium or thorium in any chemical or physical form; or (2) Ores that contain, by weight, one-twentieth of one percent (0.05 percent), or more, of uranium or thorium, or any combination of uranium or thorium.” See 42 U.S.C. 2014(z), 10 CFR 20.1003.

⁸ Although the statute covers both uranium and thorium mill tailings sites, there are no existing thorium mill tailings sites.

and its Agreement States, as well as the DOE.

Title I of UMTRCA covers inactive uranium milling sites, nearby contaminated “vicinity properties” and depository sites. The EPA was directed to set general standards that are consistent with the requirements of the Solid Waste Disposal Act (later amended as the Resource Conservation and Recovery Act, or RCRA) to the maximum extent practicable. The Title I standards are located in EPA regulations at 40 CFR part 192, subparts A–C.

This proposed rule is based on Title II of the Act, which covers operating uranium processing or disposal facilities licensed by the NRC or NRC Agreement States. The EPA has authority to promulgate standards of general

⁶ See 42 U.S.C. 2022.

application to protect public health, safety and the environment from hazards associated with processing, possession, transfer and disposal of byproduct material at such facilities. Such standards must address both radiological and non-radiological hazards; further, standards applicable to non-radiological hazards must be consistent with the standards required under Subtitle C of the Solid Waste Disposal Act (*i.e.*, RCRA).⁹ The NRC is required to implement these standards at Title II sites. See 42 U.S.C. 2022(b), (d).

II. Summary of the Proposed Rule

A. Proposed Standards for Uranium ISR Operations

In today's action, the EPA is proposing to add a new subpart, subpart F, to the EPA's existing regulations for uranium and thorium mill tailings in 40 CFR part 192. The proposed standards would apply only to ISR facilities and are designed to protect public health, safety and the environment from contamination associated with their uranium recovery operations. The proposed standards are summarized in the following sections.

1. Who is subject to the proposed standards?

Subpart F would apply to new and existing ISR facilities, including facilities that have temporarily ceased uranium production (*i.e.*, ISR facilities in standby). Subpart F would not apply to Title I sites, facilities that use only conventional or heap leach uranium production methods, or Title II ISR wellfields that have already begun or completed restoration within three years of the rule's effective date. The NRC and NRC Agreement States would develop regulations or take other appropriate steps to implement the new subpart F standards, once they are finalized.

2. What are the proposed surface and groundwater standards for ISR facilities?

In the proposed new subpart, the EPA has cross-referenced subpart D to indicate that the existing standards for protecting surface waters and groundwater also apply to ISR facilities. The subpart D standards were initially written to address the handling, storing and disposal of byproduct material produced from the processing of uranium ore.

⁹ With the restriction that the EPA not require any RCRA permit for the processing, possession, transfer or disposal of byproduct material at such facilities.

3. What are the proposed groundwater protection standards for ISR facilities?

Consistent with the original proposal, this proposed rule includes the following three types of groundwater protection standards for ISR facilities: (1) Constituent concentration standards (including provisions for Alternate Concentration Limits (ACLs)); (2) initial stability standards; and (3) long-term stability standards.¹⁰ These standards of general application would apply to all ISR facilities and are intended to prevent the mobilization of uranium and other constituents beyond the production zone during the operational and restoration phases and to ensure, once the wellfield is restored, that the restoration is complete and stable, both immediately after restoration and into the foreseeable future.

Constituent Concentration Standards. The constituent concentration standards are numerical concentration limits for a set of groundwater constituents that are present in or affected by ISR operations. When corrective action is necessary after an excursion has occurred, the licensee would have to clean-up the groundwater to meet these proposed constituent concentration standards. In addition, during the restoration and stability monitoring phases, these proposed constituent concentration standards would be the levels to which restoration must be achieved and maintained.

In this proposal, the appropriate constituent concentration standards for an ISR facility would be determined by the regulatory agency for each licensee. The constituent concentration standard for each constituent would be the highest level of the following values: (1) The lowest regulatory standard for that constituent found in 40 CFR 141.62, 141.66, 141.80, 143.3, 264.94, and Table 1 to subpart A of 40 CFR part 192; (2) that constituent's preoperational background level in the wellfield; or (3) an ACL for that constituent as approved by the regulatory agency. When setting the constituent concentration standards for a licensee, the regulatory agency would consider a minimum of 12 constituents. The regulatory agency would not be required to set standards for all 12 constituents, but the regulatory agency would have to set a

¹⁰ The initial stability standards and the long-term stability standards were originally included in the proposed monitoring programs section of the rule. The initial stability standards (called "short-term stability" in the proposal) was proposed in 40 CFR 192.53(d)(2)(i) and the long-term stability standards were proposed in 40 CFR 192.53(e)(1)(iii). To improve clarity, the initial and long-term stability standards have been moved to 40 CFR 192.52(c)(2) and (c)(3), respectively.

constituent concentration standard for each of the listed constituents that is present in or could be affected by the ISR operation. The regulatory agency would have to identify the constituents during the preoperational monitoring phase. The regulatory agency would need to consider the following 12 constituents when setting the constituent concentration standards for an ISR operation: Arsenic, barium, cadmium, chromium, lead, mercury, selenium, silver, nitrate (as N), molybdenum, combined radium-226 and radium-228, and uranium (total). The original proposal included gross alpha particle activity (excluding radon and uranium), however, this constituent was not included in this proposal for the reasons explained in section III.3.2. The EPA is specifically requesting comment on the deletion of gross alpha particle activity (excluding radon and uranium) from the list of constituents. The regulatory agency may also set constituent concentration standards for additional constituents beyond these 12 constituents for situations where the regulatory agency considers concentration standards for other constituents necessary due to facility-specific conditions.

Once these proposed standards are finalized and the regulatory agency implements the subpart F standards, the constituent concentration standards would have to be established in accordance with the provisions in § 192.52 for all new wellfields and expansions to existing wellfields, and for all existing wellfields that are already operating, excluding those that are in and remain in the restoration and stability monitoring phases, as of the date three years after the effective date of this rule. Wellfields that begin and remain in restoration, initial stability monitoring or long-term stability monitoring at a licensed facility prior to the date three years after the effective date of the rule would need to meet the standards established when their license was issued or as otherwise specified by the regulatory agency.

Alternate Concentration Limits. Consistent with the original proposal, this proposal would allow licensees the flexibility to request ACLs when the best practicable active restoration has taken place, as determined by the regulatory agency, and the licensee demonstrates one or more of the constituent concentration standards cannot be met through further groundwater restoration. The best practicable active restoration must be used before the licensee can apply to the regulatory agency for a provisional ACL. Under this proposal, once the regulatory

agency establishes a provisional ACL, and the licensee can demonstrate the ACL has been met for three consecutive years, the regulatory agency can consider finalizing the ACL.

It must be understood that granting an ACL is an indication that restoration has not returned the affected groundwater to either preoperational background levels or other health-based levels. However, there are some overarching principles that must be considered when establishing ACLs. In general, as described in § 192.54, any provisional or final ACL should not pose a substantial present or potential hazard to human health and the environment, as determined by the regulatory agency. Points of exposure are defined in the proposal as locations identified by the regulatory agency that represent possible future areas of exposure where the receptor can come into contact with groundwater (e.g., areas of recoverable groundwater). The groundwater at the point of exposure should be protective of the receptor. The EPA specifically requests comment on this approach, especially with regard to the overall regulatory model of how ACL application would work, the definition of points of exposure and the use of this term, and the overall environmental, human health and safety protection goals for setting and using ACLs. Commenters, including interagency commenters, raised questions concerning the integration of an aquifer exemption under the SDWA and point of exposure as it was defined in the EPA's original proposal and the differing jurisdictions of the SDWA and UMTRCA.

Under this proposal, when considering setting an ACL, the regulatory agency would consider a list of factors, including potential adverse effects on groundwater quality, physical and chemical characteristics of the constituent, including the potential for migration, hydrogeological characteristics of the area, proximity and withdrawal rates of local groundwater users, current and anticipated future uses of the groundwater, existing quality of the groundwater, potential for health risks, potential to damage wildlife, crops, vegetation and physical structures, the persistence and permanence of the potential effects, adverse impacts on hydraulically connected surface water (including several factors) and the presence of any USDW.

The EPA expects that setting a provisional and final ACL will require consideration of the hydrologic and other characteristics of the wellfield and surrounding area, any potential areas of

groundwater withdrawal or discharge and be protective of human health into the foreseeable future.

Consistent with UMTRCA, the Tenth Circuit Court of Appeals in the *Environmental Defense Fund v. NRC* decision,¹¹ and current practice, the regulatory agency would be responsible for reviewing and approving ACL requests. Although not a proposed provision, the EPA considers it good practice for the regulatory agency to make public the information used for determining whether a provisional ACL is warranted and at what concentration before approving a provisional ACL. Although the NRC has not issued an ACL to date for an ISR wellfield, the NRC current practice would result in making such information publicly available and would support the EPA's effort to increase the effectiveness of the rule.

Stability Standards. In addition to the constituent concentration standards discussed above, licensees would also need to meet initial and long-term stability standards. The initial stability standards would require three consecutive years of quarterly monitoring results showing no statistically significant increasing trends exceeding the ISR facility's constituent concentration standards at the 95 percent confidence level. The long-term stability standards would require an additional three consecutive years of quarterly monitoring results showing no statistically significant increasing trends exceeding the ISR facility's constituent concentration standards at the 95 percent confidence level and also would require the licensee to demonstrate through geochemical modeling and other analysis that the applicable constituent concentration standards will continue to be met in the future. Consistent with the original proposal, the regulatory agency issuing the license would be responsible for determining whether there is reasonable assurance that the applicable constituent concentration standards will continue to be met at the ISR facility in the future.

4. What are the proposed general and preoperational monitoring requirements?

In order to understand the hydrogeology and geochemistry of the production zone and surrounding area and to set the preoperational background for the constituent concentration standards, licensees would develop a preoperational monitoring plan for the wellfield. The preoperational monitoring plan would

characterize the hydrogeology and geochemistry of the area, support identification of any potential future excursions from the production zone during the operational and restoration phases, and support the monitoring, modeling and other analysis as determined by the regulatory agency to be necessary to meet the proposed initial and long-term stability standards.

The preoperational monitoring determines the groundwater flow regime and the background groundwater concentrations of the 12 listed constituents and any additional constituents required by the regulatory agency. The data collected during this period would be used to select the indicator parameters and set the upper control limits (UCLs) for these parameters. The indicator parameters would be monitored during the operational and restoration phases and, when the UCL is exceeded, indicate that lixiviant or other constituents are migrating beyond the production zone. The preoperational monitoring would be conducted at wells within the production zone and in areas surrounding the production zone, including aquifers immediately above and below the production zone, and in areas laterally adjacent to the production zone, both up and down gradient. A sufficient number of wells would have to be installed and monitored so that the sampling data collected could be used to statistically determine appropriate background levels and support statistical tests, modeling and other analysis determined by the regulatory agency to be necessary during the operational, restoration, initial stability and long-term stability phases. The licensee would collect a sufficient number of sample sets per well over a time period sufficient to indicate a statistically valid background concentration that is not affected by well installation or temporal variations. In areas where temporal (e.g., seasonal) variation could occur (e.g., ore zones in unconfined aquifers), the preoperational monitoring would be conducted for at least one year in a sufficient number of wells to adequately represent the hydrologic system.

In addition to monitoring the concentrations of the constituents required by the regulatory agency, the licensee would collect any other data necessary to establish background conditions to support future modeling and other analysis in preparation to meet the proposed long-term stability standards in § 192.52(c)(3).

¹¹ 866 F.2d 1263 (10th Cir. 1989).

5. What are the proposed monitoring requirements for the operational and restoration phases?

To ensure that no lixiviant, uranium or other constituents are migrating outside of the production zone, the licensee would monitor groundwater for specified indicator parameters at a set of monitoring wells surrounding the production zone. These excursion monitoring wells would be located around the perimeter of the production zone and in any aquifers immediately above or below the production zone that may be impacted by ISR activities. That is, the excursion monitoring wells need to surround the production zone in three dimensions. The excursion monitoring wells would be of sufficient number, density, and placement to detect the possibility of an excursion from the production zone. The regulatory agency would be responsible for reviewing and, when appropriate, approving well placement and installation, indicator parameters, the UCLs for the indicator parameters, as well as background levels for constituents for which constituent concentration standards are set.

Typical indicator parameters used to identify possible excursions include chloride, conductivity and total alkalinity. Other parameters may be appropriate as well. In the proposed rule, an excursion has occurred when either (1) two indicator parameters exceed their respective UCLs in any excursion monitoring well; or (2) as determined by the regulatory agency, one indicator parameter significantly exceeds its UCL in any excursion monitoring well. The EPA specifically requests comment on this proposed definition of an excursion and suggestions for other approaches for determining when an excursion has occurred. If an excursion occurs, the licensee would need to initiate corrective action in accordance with its facility-specific corrective action program and would be required to test for all constituents for which a constituent concentration standard was established. At a minimum, the constituents from Table 1 that are typically present and that warrant monitoring during an excursion are uranium, radium, arsenic and selenium. The regulatory agency would be allowed to identify additional constituents that are present in the groundwater and need to be monitored on a facility-specific basis.

In some cases, a licensee may have temporarily stopped recovering uranium and the facility may be in a phase commonly called "standby" by the

industry. In such instances, the EPA considers the facility to be in the operational phase and the licensee would be required under the proposed rule to continue monitoring and taking actions, such as maintaining an inward hydraulic gradient, to prevent excursions.

6. What monitoring is proposed for the initial stability standards?

Once the licensee believes restoration is near completion and believes they can, over time, demonstrate that the proposed initial stability standards in § 192.52(c)(2) can be met, the EPA expects that the licensee would begin monitoring the groundwater constituent concentrations throughout the wellfield to determine when the initial stability standards have been met. To meet the proposed initial stability standards, the licensee would need to demonstrate stability by providing three consecutive years of quarterly monitoring results showing no statistically significant increasing trend exceeding each established constituent concentration standard. For all monitored constituents, this trend would need to be demonstrated at the 95 percent confidence level. The licensee would be required to develop and implement a compliance monitoring program approved by the regulatory agency that identifies compliance points encompassing the entire affected area of the wellfield.

The purpose of the proposed stability monitoring is to determine whether constituent levels in the entire affected area of the wellfield, including the production zone, have returned to levels below the established constituent concentration standards and stable conditions are established. Hence, compliance wells must include wells previously used as excursion monitoring wells and those previously used as production related wells. The location of the compliance wells used to determine compliance with the initial stability standards would need to be approved by the regulatory agency and would need to be located in areas likely to be affected by ISR operations. Therefore, compliance well would be located within the production zone, adjacent to the production zone and in aquifers located immediately above and below the production zone, as approved by the regulatory agency. The number and location of compliance wells will vary depending on the size and characteristics of the wellfield, but should encompass the entire affected area of the wellfield.

To meet the proposed initial stability standards of § 192.52(c)(2),

measurements would need to be taken quarterly at each well. If one or more constituents exceed a constituent concentration standard during the initial stability monitoring, then the licensee would follow the corrective action program approved by the regulatory agency. When monitoring to assess whether the initial stability standards have been met, constituent concentrations may fluctuate above the respective standard. The corrective action program should address the possibility of and the regulatory agency should consider potential responses to an exceedance of the constituent concentration standards while the licensee is establishing a statistically adequate trend. The regulatory agency may allow continued monitoring, if appropriate, or require the licensee to undertake a remedy. Regardless of the action taken, the licensee would be required by the proposed standards to achieve three consecutive years of stable measurements. Furthermore, as in all phases, if lixiviant or other constituents escape the production zone, the licensee would be required to take the necessary actions to return the aquifer to below the constituent concentration standards.

When the licensee demonstrates three consecutive years of quarterly monitoring results showing no statistically significant increasing trends exceeding the established constituent concentration standards at the 95 percent confidence level, then the facility has met the proposed initial stability standards and the licensee may, upon the determination of the regulating agency that the initial stability standards have been satisfied, begin long-term stability monitoring.

7. What are the proposed requirements for the long-term stability standards?

During the proposed long-term stability monitoring, the licensee continues quarterly monitoring to demonstrate compliance with the constituent concentration standards using the compliance wells established for monitoring during the initial stability phase. To meet the proposed long-term stability standards in § 192.52(c)(3), the licensee would need to first demonstrate quarterly monitoring results for a minimum of three consecutive years showing no statistically significant increasing trends exceeding the established constituent concentration standards (including any approved ACLs) at the 95 percent confidence level.

To approve cessation of long-term stability monitoring, the regulatory agency would be responsible for determining whether there is reasonable

assurance that the applicable constituent concentration standards will continue to be met at the ISR facility in the future. To make this determination, an analysis of geochemical hydrologic and other conditions within and around the production zone should be prepared by the licensee and reviewed by the regulatory agency. The EPA requests comment on the specificity of the regulatory language for this final determination of stability and the elements to be considered. In general, the EPA expects that the review should examine various features within the production zone and use a combination of sample collection and analysis of the restored production zone, data review, geochemical modeling and analysis to integrate the various types of data and to assess groundwater conditions. Various types of geochemical models may be employed from saturation index calculations to reactive transport models that can evaluate changing hydrologic and geochemical conditions within the wellfield. The EPA believes the licensee's long-term stability assessment should include the following elements:

- (i) Conceptual hydrogeochemical modeling for the mine unit/production zone;
- (ii) Ground water and solid (core) data used for geochemical model(s), including field parameters;
- (iii) Incorporation of ground water data in an initial geochemical model (*i.e.*, saturation indices calculations and assessment);
- (iv) Demonstration that stability (mainly reduction-oxidation or redox) conditions can be maintained in the production zone;
- (v) Demonstration that ground water migrating into the production zone will not significantly change the geochemical stability within the production zone;
- (vi) Demonstration of alternative geochemical conditions that demonstrate stability (uranium and other elements); and

(vii) Inter-relationships and contradictory claims (unintended consequences) for these various elements need to be identified and assessed in the context of the conceptual hydrogeochemical model.

The EPA requests comment on whether these seven elements should be required at all sites and thus included in the standards in 40 CFR part 192, subpart F.

The regulatory agency has the responsibility to establish the timeframe for long-term stability monitoring, based on facility-specific conditions at the wellfield and the results of long-term stability monitoring, modeling and analysis. If one or more constituents exceed their concentration standard (or approved ACL) or show a statistically significant increasing trend during the long-term stability phase, the regulatory agency may require the licensee to take corrective action as specified in the facility's corrective action program.

8. What are the proposed corrective action requirements?

Each licensee would be required to develop a corrective action program that addresses the actions it will take when an excursion is detected during the operational and restoration phases, or when monitoring during the stability phases shows a concentration higher than the established constituent concentration standard or a statistically significant increasing trend. Corrective action, as identified in the corrective action program and approved by the regulatory agency, would be initiated as soon as practicable and would begin within 60 days of the date the excursion or exceedance of a constituent concentration standard is detected. The corrective action program would consider a range of possibilities for action from the operational phase through the long-term stability monitoring phase. Corrective action may include removing or treating in place any constituents that exceed the constituent concentration standards (or

approved ACL). If the concentration of one or more constituents exceeds the constituent concentration standard (or approved ACL) during long-term stability monitoring, the licensee would be required to take corrective action to restore the groundwater to comply with the proposed constituent concentration standards; once restoration is complete, the licensee would begin again with initial stability monitoring.

B. Proposed Amendments to 40 CFR Part 192, Subparts C and D

As part of this rulemaking, the EPA is also proposing several minor amendments to the provisions in 40 CFR part 192, subparts C and D. These amendments are described in this section and are not related to the new standards for ISR facilities added in 40 CFR part 192, subpart F.

1. What are the proposed revisions to § 192.32(a)(2)(v)?

This proposed rule deletes the requirement in § 192.32(a)(2)(v) for the NRC to obtain concurrence from the EPA before the NRC may approve alternative requirements or proposals under AEA section 84(c).¹² As the EPA stated in the proposal, this portion of § 192.32(a)(2)(v) was effectively struck down by the Tenth Circuit Court of Appeals in *Environmental Defense Fund vs. U.S. Nuclear Regulatory Commission*, 866 F.2d 1263 (10th Cir. 1989). In its decision, the Court ruled that the NRC has authority under AEA section 84(c) to independently make these facility-specific determinations, and that the NRC has no duty to obtain the EPA's concurrence.

2. What are the proposed miscellaneous updates and corrections?

The EPA is also proposing several minor amendments to subparts C and D to correct cross-references, typographical and punctuation errors. These amendments include the following:

| Section | Description of proposed technical correction | Rationale for correction |
|----------------------------|---|--|
| 40 CFR part 192, subpart C | | |
| 192.20(b)(3) | Delete reference to “Pub. L. 92–314 (10 CFR part 712)” .. | The Grand Junction Remedial Action Criteria to which this reference applied no longer exist in the CFR. Methods were found to be ineffective and are no longer recommended as remedial options for radon mitigation. |
| 192.20(b)(3) | Delete language referencing sealants and filtration | |
| 40 CFR part 192, subpart D | | |
| § 192.31(a) | Replace “Uranium Mill Tailings Radiation Control Act” with “Uranium Mill Tailings Radiation Control Act”. | Corrects a typographical error. |

¹² See 42 U.S.C. 2114(c).

| Section | Description of proposed technical correction | Rationale for correction |
|-------------------------|--|---------------------------------|
| § 192.31(f) | Replace “pile containing uranium by product materials” with “pile containing uranium byproduct materials”. | Corrects a typographical error. |
| § 192.32(a)(2)(v) | Replace “laser fusion, of soils, etc.” with “laser fusion of soils, etc.”. | Corrects a punctuation error. |

III. Summary of Changes Made to the Original Proposal and Rationale for Those Changes

As previously indicated, the standards proposed in today's action differ from those standards proposed on January 26, 2015 (80 FR 4156). This section of the preamble describes the most significant changes made to the original proposal and the rationale for those changes. Many of the changes were made in response to public comments and additional information provided by stakeholders. In response to the original proposal, the EPA received over 5,380 public comment letters on the proposed amendments, of which 5,192 were duplicate letters. The comments covered more than 80 different topics and were submitted by a wide range of stakeholders, including private citizens, public interest groups, industry, Indian tribes, state agencies and other federal agencies. For the original proposal, the EPA also held public hearings in Corpus Christi, TX (April 14, 2015); Washington, DC (March 10, 2015); Casper, WY (May 13 and 14, 2015); and Chadron, NE (May 12, 2015), where 114 stakeholders provided comments.

In addition to describing the changes made to the original proposal, this section also discusses and responds to the significant comments that resulted in many of those changes. The significant comments received that did not result in changes to the original proposal are discussed in section IV of the preamble.

A. Incorporation of the Initial and Long-Term Stability Standards in Proposed 40 CFR 192.52

For clarity, the EPA has restructured the proposed rule to move the initial and long-term stability standards that were originally included with the monitoring requirements in § 192.53 to the standards in § 192.52. The initial stability standards (called “stability” or “short-term stability” in the original proposal) were proposed in § 192.53(d)(2)(i), and the long-term stability standards were proposed in § 192.53(e)(1)(iii). In this proposal, the initial and long-term stability standards have been moved to § 192.52(c)(2) and (c)(3), respectively.

B. Groundwater Protection Standards

1. Clarifications to Terminology

The original January 2015 proposal listed 13 constituents for which a facility-specific concentration limit must be set for each constituent that is present in the groundwater. In the original proposal, the EPA referred to these facility-specific concentration limits as “groundwater protection standards” and “restoration goals” (see § 192.52(c) of the original proposed rule). Since the use of these two terms may lead to confusion, the EPA is no longer using the term “restoration goals” but is instead using the term “constituent concentration standards” throughout the proposed rule to refer to these facility-specific concentration limits.

In the original proposed rule, the EPA also used the phrase “identified in the groundwater” when referring to constituents for which constituent concentration standards should be established (see § 192.52(c) of the original proposed rule). The EPA intended concentration standards to be set for any constituent that is present in groundwater before or after ISR activities have begun. Some constituents may not be initially present in the groundwater but may become soluble only after lixiviant is injected and groundwater chemistry has been altered. However, the phrase “identified in the groundwater” could be misinterpreted to mean only those that are present during preoperational monitoring. For clarification, the EPA has revised the original proposal to specify that constituent concentration standards must be established for all constituents that are “identified as present or affected by operations in the groundwater.”

2. Gross Alpha Particle Activity

In the original proposal, the list of constituents in Table 1 of subpart F included gross alpha particle activity.¹³ Several commenters opposed listing gross alpha particle activity, stating that it provided no useful information that could not be otherwise obtained from the required measurement of

¹³ The SDWA MCL of 15 pCi/L for gross alpha particle activity excludes alpha particle activity contributions from radon and uranium.

radionuclides, such as radium 226. In addition, commenters noted the wide uncertainty range for the radiochemistry analytical methodology currently used to measure gross alpha activity.

The EPA tends to agree with commenters who suggested that gross alpha measurements are likely to be of limited value when other radionuclides of concern are also being sampled. The Agency also recognizes that the uncertainty associated with gross alpha measurements may be greater than those for other constituents, which may make the application of statistical tests especially complicated. However, gross alpha is specified as a constituent to be sampled in other subparts of 40 CFR part 192, and it does have a maximum contaminant level (MCL), which cannot be overlooked. Further, there may be instances where gross alpha measurements provide information regarding the presence of decay products such as lead and polonium. The EPA is specifically requesting comment on the deletion of gross alpha particle activity as one of the original proposal's 13 constituents, whether it provides useful information, and how measurement uncertainty might be addressed.

C. Preoperational Monitoring Requirements

In the original proposal, the EPA included provisions for preoperational monitoring that were designed to characterize the groundwater flow regime, geology and geochemistry. The EPA originally proposed that preoperational monitoring would measure the background concentrations of radiological and non-radiological constituents, including all the constituents listed in Table 1 of subpart F, and any additional constituents or parameters specified by the regulatory agency or needed for calculations or groundwater modeling. The original proposal required preoperational monitoring be continued for a minimum of one year in order to account for any temporal changes occurring in the aquifer. The EPA also proposed some requirements for the location of the wells, requiring monitoring wells to be located in overlying aquifers, underlying aquifers, inside the exempted aquifer and outside the exempted aquifer, including areas that

are up- and downgradient from the future production zone. The original proposal specified standards for installing the monitoring wells, including requirements for casings and for sealing the wells to prevent contamination.

1. Duration of Preoperational Monitoring

The EPA received a number of comments on the duration of the proposed preoperational monitoring requirements. Some commenters supported the one-year timeframe, while others recommended the time period be extended to up to two years. Many commenters cited the NRC Criterion 7 from 10 CFR part 40, Appendix A, which requires uranium mills to complete one or more years of preoperational monitoring before a company can submit a license application. Two commenters noted that some aquifers do not experience seasonal variations in groundwater constituents. For example, commenters asserted there may be no seasonally influenced fluctuation in the concentrations of groundwater constituents in deeper target ore production aquifers.

Based on all of these comments, the EPA has refined the approach to preoperational monitoring. Instead, the Agency is proposing that preoperational monitoring of wells screened in areas where temporal variations are not expected to occur, such as in deep ore zones in confined aquifers, would be allowed to monitor for periods of less than one year. However, the licensee would collect several sets of samples over a time period sufficient to demonstrate seasonal variability does not occur. For example, in some cases, four sets of samples collected over several months would be adequate to determine the background for systems that do not exhibit seasonal changes. In this proposal, sample sets collected over a period of at least one year would still be necessary for facilities that operate in areas where constituent concentrations are expected to exhibit seasonal fluctuations. The regulatory agency would determine whether the licensee's preoperational monitoring is of sufficient duration and that sampling occurs at appropriate intervals to establish the background concentrations for all 12 constituents, as well other constituents identified by the regulatory agency and all indicator parameters. To provide flexibility where appropriate, the EPA did not propose an across-the-board two-year monitoring requirement, although the regulatory agency would be allowed to do what is necessary to

reflect seasonal or other variation in background constituent concentrations or flow.

2. Changes to the Well Completion Requirements

The Agency received several comments on the original proposed requirements for well completions. A general concern expressed by the commenters is that true baseline conditions of the groundwater constituents cannot be established if the well drilling and development methods introduce oxygen into the groundwater. The commenters explained that since oxygen may increase the solubility of uranium, elevated baseline concentrations will lead to artificially high restoration goals. Commenters suggested several methods to alleviate this concern, including air-rotary drilling with recirculated nitrogen gas instead of air and a foam surfactant that contains organic constituents to eliminate oxygen.

After considering these comments, the EPA believes sufficient monitoring should be completed to ensure all perturbations associated with well construction are resolved prior to establishing the background concentrations. To achieve this goal, under this proposed action, the licensee would collect several sets of samples over a time period sufficient to demonstrate baseline conditions that are unaffected by monitoring well construction. In the proposal, the EPA requires the sampling frequency to be sufficient to ensure statistically valid background levels that are not influenced by well construction. The samples used for this purpose may be the same as those used for the temporal variability analyses, if technically feasible. The regulatory agency would determine whether the licensee's well construction follows appropriate protocols and that sampling occurs at appropriate intervals to establish accurate background concentrations.

D. Exempted Aquifers

The EPA originally proposed that preoperational monitoring wells, excursion monitoring wells used during the operational and restoration phases, and compliance wells used during the initial and long-term stability monitoring phases (referred to as "point(s) of compliance") be located inside and outside of "exempted aquifers" (see the proposed definition for "point(s) of compliance" at 80 FR 4184). In the original proposal, the EPA also defined the term "point(s) of exposure" as the "intersection of a vertical plane with the boundary of the

exempted aquifer" and the term "adjacent aquifer" as an aquifer or portion of an aquifer that "shares a border or end point with the exempted aquifer or the exempted portion of an aquifer" (see 80 FR 4183–4184). As the EPA explained in the original proposal, the term "exempted aquifer" refers to aquifers that are exempted from the protections afforded by the SDWA (see 80 FR 4160).

Under the SDWA, the EPA sets health-based standards for drinking water to protect against naturally occurring and anthropogenic contaminants that may be found in surface and groundwater sources of drinking water. Additionally, under SDWA authority, the EPA promulgated Underground Injection Control (UIC) Program regulations to ensure protection of USDWs,¹⁴ which may be consumed now or in the future, where injection activities are occurring. The UIC regulations at 40 CFR 144.12 prohibit any injection activity that allows the movement of fluid containing any contaminant into USDWs if the presence of that contaminant may cause a violation of any primary drinking water standard or otherwise adversely affect the health of persons. Under UIC Program regulations, an aquifer or a portion of an aquifer may be exempted from the protections afforded USDWs, under the SDWA, if (a) it does not currently serve as a source of drinking water; and (b) it cannot now and will not in the future serve as a source of drinking water because one of four specified conditions is met, or (c) the total dissolved solids content of the groundwater is more than 3,000 mg/L and less than 10,000 mg/L and it is not reasonably expected to supply a public water system (see § 146.4). The four conditions referenced above for the aquifer exemption criteria at 40 CFR 146.4(b) are:

(1) It is mineral, hydrocarbon or geothermal energy producing, or can be demonstrated by a permit applicant as part of a permit application for a Class II or III operation to contain minerals or hydrocarbons that considering their quantity and location are expected to be commercially producible.

(2) It is situated at a depth or location which makes recovery of water for drinking water purposes economically or technologically impractical;

¹⁴ USDWs are defined, by regulation at 40 CFR 144.3, as: "An aquifer or its portion: (a)(1) Which supplies any public water system; or (2) Which contains a sufficient quantity of ground water to supply a public water system; and (i) Currently supplies drinking water for human consumption; or (ii) Contains fewer than 10,000 mg/l total dissolved solids; and (b) Which is not an exempted aquifer."

(3) It is so contaminated that it would be economically or technologically impractical to render that water fit for human consumption; or

(4) It is located over a Class III well mining area subject to subsidence or catastrophic collapse.

1. Removal of References to “Exempted Aquifer”

In this proposal, the EPA has removed references to “exempted aquifers”, deleted the definitions of “adjacent aquifer” and “exempted aquifer” from § 192.51, and removed the phrase “exempted aquifer” from the definition of “background” in § 192.51 and from the requirements specifying where monitoring wells must be located. This change to the original proposal was made to help clarify that these standards under UMTRCA complement, and do not overlap with, the requirements of the SDWA. As discussed in section I.B., the scope and level of protection of the SDWA differs from the UMTRCA as groundwater at uranium ISR sites could have beneficial uses even if the aquifer has been exempted from protection under the SDWA. Since UMTRCA provides authority that can be used to protect aquifers during and after uranium recovery operations, regardless of whether the aquifer meets the definition of an USDW as defined in EPA’s UIC regulations or is exempted from the protections of the SDWA, the scope of UMTRCA’s protection should be reflected in the regulatory text of these standards rather than relying on the SDWA UIC exemption regulations. Thus, the regulatory text proposed in this action does not depend on or use the term exempt aquifer. Also, although a remote possibility, because ISR facilities may be located in aquifers that are not designated as “exempted aquifers” under the SDWA, under the original proposal there would have been a lack of clarity on how a facility located in a non-exempt aquifer would comply with a rule using “exempt aquifer” boundaries in the regulatory text.

Aquifer Exemptions at ISR facilities. The EPA recognizes that almost all ISR facilities may be considering Class III injection into a formation that meets the UIC regulatory definition of a USDW and is afforded SDWA protection. In such scenarios, in addition to applying for a Class III permit, a Class III owner or operator must (1) apply to the appropriate UIC Program for an aquifer exemption pursuant to requirements at 40 CFR 144.7 and 146.4 (or applicable state requirements), or (2) ensure that the boundaries of an existing exemption are appropriately delineated for the proposed injection activity. While

aquifer exemptions facilitate commercial production of minerals and hydrocarbons under specific conditions, the UIC Program requirements are intended to ensure protection of non-exempted portions of a formation which meet the definition of a USDW even where ACLs may be established at an ISR site located within an exempted portion of that aquifer.

As stated above, this proposed rule is established under the UMTRCA and not under the SDWA; however, both the UMTRCA and the SDWA requirements may apply to ISR facilities. As discussed above and in section I.A., the requirements of these statutes are complementary and not overlapping or duplicative. The SDWA requirements provide for permits to inject lixiviant and recover uranium and possible exemption of the production zone from SDWA requirements. The proposed UMTRCA requirements protect adjacent aquifers that are not exempt from SDWA by requiring monitoring and corrective action, if necessary, during the operational and restoration phases in and around the ore zone after production ceases. The SDWA does not prevent recovery and use of the water within exempted aquifers (including where ISR operations were previously conducted) for private drinking water supply, public water supply, or other uses.

2. Changes to the Definition of “Point(s) of Exposure”

Points of exposure are defined in the proposal as locations identified by the regulatory agency that represent possible future areas of exposure where the receptor can come into contact with groundwater (e.g., areas of recoverable groundwater). The groundwater at the point of exposure should be protective of the receptor. As noted earlier in this preamble, commenters, including interagency commenters, raised questions concerning the integration of an aquifer exemption under the SDWA and point of exposure as it was defined in the EPA’s original proposal and the differing jurisdictions of the SDWA and UMTRCA. The EPA specifically requests comment on this approach, especially with regard to the overall regulatory model of how ACL application would work, the definition of points of exposure and the use of this term, and the overall environmental, human health and safety protection goals for setting and using ACLs.

E. Excursions

In the original proposal, the EPA defined an excursion as “the movement of fluids containing uranium byproduct

materials from an ISR production zone into surrounding groundwater” and specified that an excursion has occurred when “. . . any two indicator parameters . . . exceed their respective upper control limits” (see 80 FR 4184).

1. Changes to the Definition

Although the EPA generally considers that an excursion has occurred when any two parameters are above the UCL, in this proposal, the EPA provides flexibility for the regulatory agency to determine that an excursion has occurred when any single indicator parameter significantly exceeds its UCL. The EPA made this change to the proposed definition because in some situations a single parameter may be sufficiently high to indicate a possible excursion. The EPA emphasizes that this would be a judgement of the regulatory agency, and the Agency’s understanding is that it is consistent with current NRC practice.

In this proposal, the EPA also revised the definition of excursion to indicate that an excursion includes the movement of fluids containing lixiviant, as well as any fluids containing uranium byproduct material, because these fluids may migrate outside of the ISR production zone. The EPA replaced the reference to “the ISR production zone” with “ISR wellfield” to indicate a broader scope of consideration is necessary in order to ensure that background is appropriately addressed and to ensure that areas within and surrounding the production zone are stable.

2. Changes to the Constituents Required To Be Monitored During the Different Phases of Operation

The EPA originally proposed that licensees would be required to monitor for all constituents listed in Table 1 of 40 CFR part 192, subpart F, during the different phases of operation at an ISR facility. In this proposal, the EPA changed this requirement such that facilities would be required only to monitor for those constituents that are expected to be present (e.g., uranium, radium, selenium and arsenic) based on the preoperational monitoring and any other constituents identified by the regulatory agency. The EPA made this change to the monitoring parameters to ensure monitoring requirements are established based on data indicating the expected contaminants. This change reduces the monitoring burden for ISR facilities compared to the original proposal. This proposed change also provides the regulatory agency flexibility to specify any other constituents not listed in Table 1 of 40

CFR part 192, subpart F, that are expected to be present. Under this proposal, the EPA considers it unnecessary to monitor for constituents that are not present. Hence, facilities would be required to monitor only for those constituents that are likely to be present.

F. Initial and Long-Term Stability

After restoration ends, ISR facilities must demonstrate compliance with the proposed constituent concentration standards, and also demonstrate those levels will persist and remain stable in the future. In the original proposal, to demonstrate stability, the EPA proposed three consecutive years of stability monitoring with stability demonstrated at the 95 percent confidence level followed by long-term monitoring for an additional period of 30-years. The originally proposed long-term stability monitoring would have allowed facilities to cease monitoring once they had completed monitoring for 30 years. However, the original proposal also allowed a licensee to shorten the 30-year long-term stability monitoring period by demonstrating geochemical stability through monitoring and geochemical modeling.

1. Statutory Authority and 30-Year Long-Term Monitoring

The EPA derived the 30-year long-term stability monitoring period in the original proposal based on consideration of the Agency's statutory mandate to be consistent with the requirements applied to managing hazardous waste under RCRA.

Numerous commenters thought the proposed 30 years of long-term monitoring was not justified, and was excessive and unnecessary. The general positions of these commenters were that these very specific monitoring time frames were outside the EPA's statutory authority under the UMTRCA to promulgate "standards of general application" and that there is no evidence that ISR facilities have impacted offsite underground sources of drinking water. Commenters also thought the requirement would have a significant economic impact, including impacts on leasing and surety costs that would place a number of ISR companies out of business. Other commenters noted that ISR facilities are not equivalent to RCRA hazardous waste facilities and should not be similarly regulated. Some commenters were concerned the long-term monitoring requirements would increase radiologic dose to employees maintaining the processing plant and well fields, which would be inconsistent with the NRC's

ALARA (As Low As Reasonably Achievable) regulations found in 10 CFR part 20. However, other commenters strongly supported the 30-year monitoring time frame or recommended a longer time frame. These commenters felt that 30 or more years of monitoring would provide sufficient time to detect instability and potential migration of constituents.

2. Proposed Requirements for Initial and Long-Term Stability

Under UMTRCA, the EPA has authority to promulgate "standards of general application" for the protection of public health, safety and the environment from the radiological and non-radiological hazards associated with the processing and the possession, transfer and disposal of byproduct material at uranium ISR facilities. 42 U.S.C. 2022(b). The Tenth Circuit Court of Appeals has clearly recognized that this authority encompasses the ability for the EPA to include monitoring as part of its "standards of general application." *American Mining Congress et al. v. Thomas*, 772 F.2d 640, 644, 647–649 (10th Cir. 1985) ("The regulations necessitate monitoring programs."). In the proposal, the EPA has retained the initial and long-term stability monitoring requirements but has removed the default requirement for 30 years of long-term monitoring. The initial stability monitoring period remains the same as in the original proposed rule (*i.e.*, at least three years). Under this proposal, the duration of the long-term stability monitoring must be at least three years, and the regulatory agency would determine the appropriate length of any additional long-term stability monitoring based on criteria that will enable the licensee to demonstrate, as appropriate, that there is reasonable assurance that the applicable constituent concentration standards will continue to be met in the future. Similar performance criteria were part of the standards in the original proposed rule, where the EPA had proposed that licensees would be required to demonstrate three consecutive years of initial stability monitoring and then maintain long-term stability monitoring for an additional period of 30 years. The original proposal included an option that allowed a licensee to shorten the 30-year timeframe by demonstrating long-term geochemical stability through modeling. Under this proposal, modeling would no longer be optional. Consistent with the original proposal, the EPA is proposing that the regulatory agency would be responsible for reviewing the licensee's data and analysis, and making

the determination of when the licensee could discontinue long-term stability monitoring and initiate decommissioning.

While many commenters supported the 30-year monitoring requirement, and some even preferred a longer period, the proposal maintains the same performance-based standards for the long-term stability phase as the original proposal and hence ensures the same level of protection the EPA anticipated in the original proposal. The Agency emphasizes the role of modeling in achieving that objective. As explained in the original proposal, the Agency expected that licensees would make extensive efforts to develop robust models that would significantly shorten the long-term monitoring period. In fact, as presented in the proposal, it would have been possible for a licensee to submit modeling such that no (or minimal) long-term monitoring would be necessary. However, should licensees be unable to provide such modeling, or choose not to, the additional monitoring would have provided the level of confidence necessary for the regulatory agency to determine that long-term stability had been demonstrated. This revised proposal relies on modeling and analysis to as an essential element in concluding that groundwater will continue to meet the applicable constituent concentration standards into the foreseeable future, leading to the Agency's judgment that the revised approach is comparable in protectiveness to the original proposal.

As noted above, other commenters stated that 30 years of monitoring would not add value and would put many companies out of business. ISR facilities that disturb groundwater and mobilize constituents of concern are responsible for restoring disturbed groundwater to background or health-based conditions regardless of the time required to achieve this goal. However, the EPA also agrees with commenters who noted the time period necessary to establish stability at an ISR facility is variable due to differences in geology, hydrology and geochemistry. As reflected by one of the commenters, after 10 years of monitoring at the Kingsville Dome ISR facility, it appears that reducing conditions have not been re-established in the production zone. Restoration at Christensen Ranch has not been approved by the NRC because the NRC found that restoration was not complete and water quality was not stable after completion of uranium recovery in 2005.¹⁵ Uranium concentrations also

¹⁵ NRC (2012), "Technical Evaluation Report: Christensen Ranch Mine Units 2 through 6

increased in a production monitoring well at Smith Highlands Ranch after restoration was completed.

This proposal defines the initial stability standards as “three consecutive years of quarterly monitoring results with no statistically significant increasing trends exceeding the constituent concentration standards at the 95 percent confidence level.” These performance-based standards would apply after the licensee completes restoration and, once met, would demonstrate that restoration was initially successful. The EPA requests comment on this approach and the wording of the regulatory text. Alternative language the EPA considered for this proposal for both initial and long term stability, included requiring the licensee to show “. . . three consecutive years of quarterly monitoring results demonstrating a statistically significant non-increasing trend at the 95 percent confidence level remaining below each constituent concentration standard.” This alternative approach, which would require the licensee to demonstrate that the trend line is either horizontal or decreasing (“non-increasing”), has been applied in the Superfund program. It has the clear advantage of accepting only trend lines that are not increasing, which can provide some additional confidence that the trend is not in a direction that could (eventually) threaten to exceed the constituent concentration standards.

However, based on discussions with the NRC, the agency responsible for implementing this rule after promulgation, it is clear that licensees may see increasing, but not statistically significant trends in constituent concentrations during stability monitoring. Consequently, the EPA opted to change the language to “no statistically significant increasing trend” to provide the NRC flexibility in addressing this specific scenario. Further, the EPA is concerned that specifying a non-increasing trend may introduce complications in applying statistical techniques, particularly when working from the hypothesis that there is no slope to the trend line. The level of natural variation present may itself forestall the ability to determine a non-increasing slope with the level of confidence the EPA believes necessary. The level of statistical significance associated with an increasing trend that would be unacceptable is left to the

regulatory agency to determine based on site-specific conditions.

The EPA requests public comment on the proposed approach as well as the alternatives. Specifically, the EPA would like to know whether this language is sufficiently protective and whether there are any other practical approaches the Agency should consider as possible alternatives.

In this proposal, the EPA has defined the long-term stability standards as a two-part test, with the following elements: (1) The licensee must provide an additional three consecutive years of quarterly monitoring data demonstrating no statistically significant increasing trend exceeding the constituent concentration standard for each applicable constituent at the 95 percent confidence level; and (2) the licensee must provide geochemical modeling and other analysis to demonstrate that constituent concentrations within the production zone will be met in the future. The regulatory agency would evaluate the modeling and other analysis and make a determination as to whether there is reasonable assurance that the applicable constituent concentration standards will continue to be met in the future. In this proposal, only after this determination has been made by the regulatory agency would the licensee cease long-term monitoring.

The three-year long-term monitoring period represents a different application of the RCRA paradigm than the 30-year post-closure monitoring. The three-year monitoring period is consistent with RCRA corrective action requirements, which can be seen as analogous with groundwater restoration at ISR sites. The Agency believes the three-year performance standard for the long term is appropriate to provide additional confidence in restoration of these sites and provides sufficient time to conduct a trend analysis, as well as being consistent with RCRA requirements of three years of monitoring to demonstrate no exceedance associated with corrective action. The EPA finds that this alternative approach will provide the necessary protectiveness and is particularly responsive to industry comments regarding the potential costs associated with a 30-year monitoring period.

G. Corrective Action Program

The EPA originally proposed that facilities be required to take corrective action as soon as practicable but no later than 90 days after an excursion or exceedance is detected. The original proposal also required that the concentrations of constituents be returned to the constituent

concentration standards “within the production zone and the maximum constituent level in adjacent aquifers” (see § 192.54(a) of the proposed rule). Groundwater monitoring for a period of at least three years after corrective action had been terminated was proposed with reference to the proposed monitoring requirements for the initial and long-term stability phases.

A few commenters supported the requirement to take corrective action as soon as practicable. However, most commenters disagreed with the original proposed requirement to require ISR facilities to implement a corrective action program within 90 days. One commenter was concerned the compliance costs would be high because the wellfield and associated equipment would have to be maintained at the ISR facility for many years in order for corrective action to be started within the required 90 days. Another commenter thought a longer time period was justified due to the low velocity of groundwater at ISR facilities. This commenter asserted that additional time may be needed for drilling wells and installing pump and treat equipment, particularly during the long-term stability period when equipment has been removed. This commenter recommended a period of two years be allowed for implementing a corrective action program and stated that groundwater may move only 10 to 20 feet over this time period. Another commenter noted that the NRC already has regulations covering corrective action in 10 CFR part 40, Appendix A, Criterion 5D, which specify that a licensee has up to 18 months to implement a corrective action program. One commenter found the proposed requirements for groundwater monitoring confusing and questioned why the proposed rule referenced the initial and long-term stability monitoring requirements. This commenter thought the groundwater monitoring applied to excursions and questioned why additional monitoring was necessary for excursions occurring during the operational phase.

The EPA has made several changes to the corrective action requirements in this proposal. First, the EPA would require ISR facilities to *begin* (but not necessarily complete) corrective action no later than 60 days after an excursion or exceedance is detected. The EPA made this change to be consistent with the NRC’s current practice for excursions.¹⁶ Full implementation may

Restoration Report, Uranium One USA, Inc. Willow Creek ISR Project.” Available at <http://www.nrc.gov/docs/ML1217/ML1217A048.pdf>.

¹⁶ NRC (2003), “Standard Review Plan for In-Situ Leach Uranium Extraction License Applications

take additional time, as recognized by the NRC in 10 CFR Appendix A, Criterion 5D. The time for the initiation and completion of the corrective action in all phases of operation would be addressed in the corrective action program and approved by the regulatory agency.

Second, the EPA is acknowledging that corrective action in the initial stability phase may be different than in the long-term stability phase, as during the initial stability phase data are being collected to show the initial trend and may be more subject to fluctuation. One exceedance may be acceptable during the initial stability phase, but not for the long-term stability phase, without taking corrective action. The EPA is proposing the regulatory agency would have the authority to determine whether an exceedance truly warrants action or continued monitoring while the licensee is trying to establish the data trend during the initial stability phase. The need for action or monitoring during each phase of operation would be anticipated and addressed in the corrective action program. Whether or not the regulatory agency has determined that corrective action is necessary does not negate or affect the proposed initial stability standards requiring three consecutive years of quarterly monitoring results with no statistically significant increasing trends exceeding the constituent concentration standards at the 95 percent confidence level. The corrective action program would have to return the constituent concentrations to levels below the constituent concentration standards established by the regulatory agency.

Finally, the EPA is proposing to change the groundwater monitoring provisions proposed for § 192.54(c) (80 FR 4187) to better reflect the requirements applicable to ISR facilities that experience exceedances of constituent concentration standards during the long-term stability phase. The EPA agrees with a commenter who stated that the proposed rule language for the groundwater monitoring requirements in § 192.54(c) could easily be misinterpreted. The change to the original proposed rule makes it explicit that corrective action is followed by another round of initial stability monitoring followed by long-term stability monitoring. Under this proposal, the ISR facility would need to first meet the three-year initial stability standards, and then meet the long-term stability standards of § 192.53(c)(3)(i) and (ii), before it is eligible to apply to

the regulatory agency for approval to cease long-term stability monitoring. These changes to § 192.54(c) would not add any new requirements but simply clarify the requirements that were originally proposed.

H. Costs and Economic Impacts

1. Compliance Costs

Commenters expressed concern that the EPA had not considered the entire spectrum of legal, regulatory and other costs required to hold and preserve the ISR facility, lands and wellfields during the stability monitoring periods. The EPA reviewed and updated the economic analysis to incorporate estimated non-monitoring costs (e.g., licensing, leasing fees, continued surety, maintenance) identified in the comments. Commenters also recommended that the EPA consult the ISR industry to better characterize costs, and the EPA requested additional information from some of the uranium recovery companies that had provided cost data during the public comment period to clarify the information provided. The additional cost information received from the uranium recovery companies was incorporated into the economic analysis. A listing of the non-monitoring costs that were identified in the comments and added to the revised analysis, along with a comparison of non-monitoring costs provided by industry and the average values used in the economic model, can be found in the economic analysis report (see sections 3.2 and 3.3). The addition of non-monitoring costs added \$2,300 per acre to the modeled average facility costs excluding license and surety. The estimated total annualized incremental non-monitoring costs projected to be incurred by firms owning existing ISR facilities ranged between \$0.1 million and \$4.1 million, with total national non-monitoring costs of \$7.6 million for all firms. All costs in the economic analysis have been adjusted from 2011 to 2015 dollars, as suggested by commenters.

Another concern expressed by commenters was that the EPA had not considered additional costs to self-funded regulatory programs, and that these costs would be passed along to the uranium recovery companies. The revised standards reflect the practices that have become more common between the NRC and ISR facilities; therefore, this proposal is not expected to add significant burden to regulatory programs.

Compliance for existing ISR facilities also concerned commenters. As in the proposal, § 192.52(a) of this proposal

makes clear that these standards would not apply to wellfields that are currently in and remaining in restoration or stability monitoring.

Commenters also expressed concern that the costs of monitoring were not adequately reflected due to inaccurate assumptions for current monitoring requirements. The EPA adjusted the monitoring costs in the economic analysis based on guidance received from the NRC regarding current monitoring practices and requirements, as opposed to historical practices that were noted by some commenters as common to more developed ISR facilities. Also, a commenter noted that the rule discussion in the proposal preamble at 80 CFR 4186 (§ 192.53(a)(3) of the original proposal) required monitoring well locations outside of the monitoring well ring and that these costs were not included in the economic analysis. The proposal maintains the requirement in the original proposal for down-gradient monitoring wells outside the monitoring well ring where needed, and at the discretion of the regulating agency, especially when an adjacent aquifer is present. Initially, the EPA's proposal required monitoring at locations down-gradient from the wellfield in exempted aquifers. However, placement of down-gradient monitoring wells outside the well ring was not found to be common practice at existing sites and the EPA removed these wells from the cost model. The EPA also assumed in the proposal that monitoring and hydrogeologic and geochemical modeling requirements would allow most sites to demonstrate that groundwater conditions down-gradient of the wellfield would trap any mobilized constituents, thus ensuring that groundwater quality is protected. Reference to the "exempted aquifer" has also been removed from this proposal, as discussed in section III.D of this preamble.

Comments were also received on the methodology used to extrapolate a cost per acre for operating ISR facilities based on a conceptual ISR unit, and while it was acknowledged that the method may be appropriate for fully developed ISR facilities, the commenters were concerned that this methodology may not capture the full costs of implementation for facilities in earlier stages of development. The EPA further reviewed and used available information from facility surety and license reports to estimate and account for the proposed and anticipated number of ISR units at each ISR facility that was included in the cost model.

In light of the adjustments described above, the EPA considers the estimated

monitoring costs for existing ISR facilities that it developed for purposes of the proposal to be reasonable; however, the Agency continues to recognize that there are uncertainties inherent to the process used to extrapolate the monitoring costs associated with these standards as compared to actual costs to ISR facilities.

2. Energy Impacts Summary

Several commenters noted the importance of nuclear power to shift the nation's reliance away from carbon-based energy resources and expressed concern that the proposed standards would reduce the viability of uranium recovery and continued development of nuclear energy. In response to these comments, the EPA reevaluated the incremental costs of the selected option to existing and planned ISR facilities, which further substantiated that this action is not a "significant energy action" as defined in Executive Order 13211 (66 FR 28355, May 22, 2001). The proposed standards, in large part, codify groundwater monitoring practices and requirements already being implemented at permitted operations; further, domestic uranium has historically provided less than 10 percent of total uranium supplied to civilian owners and operators (COOs) of nuclear power stations. Because the proposal would increase the costs of facilities that produce a relatively small share of uranium traded in U.S. markets, the EPA estimate that a \$1.96 increase per pound in the cost of ISR uranium production would increase the price of uranium paid by COOs by only \$0.11 per pound. Because nuclear generation provides a relatively small share of total domestic electricity, the \$0.11 increase in the price of uranium would increase the price of electricity very little (less than 0.1 percent). Although the proposal would slightly increase the costs of domestic uranium production relative to international sources, this rule is not expected to directly and adversely affect productivity, competition or prices in the energy sector. For more information, please see section VI.H of this preamble and sections 5.3 and 6.9 of the document titled, "Economic Analysis: Revisions to the Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings Rule (40 CFR part 192)," available in Docket ID No. EPA-HQ-OAR-2012-0788.

3. Groundwater Resource Impacts of Restoration

Several commenters expressed concern that the proposed rule would

cause an unnecessary waste of groundwater resources beyond diminishing returns, due to prolonged additional restoration to satisfy the proposed requirement for 95 percent statistical confidence of groundwater stability. The EPA disagrees and believes that the 95 percent statistical confidence level is widely accepted and used in other environmental standards. For more information on the 95 percent confidence level, see section IV.D of the preamble.

One commenter stated that the EPA ignored its authority under CERCLA that allows the Agency to require former operators and their successors to clean up post-license termination, thereby unnecessarily increasing monitoring costs for ISR facilities. The EPA does not believe it is appropriate to rely upon expectations of future cleanup rather than make reasonable efforts to prevent groundwater contamination in the first place. The intent of this rule is to protect groundwater and prevent its degradation, thereby eliminating the need for remedial actions under CERCLA that, by the time discovered, could be far costlier. This approach is fully consistent with the EPA's Groundwater Protection Strategy, which emphasizes pollution prevention over remediation. Also, commenters asserted that the groundwater modeling was inadequate, and flawed inputs were used to estimate the duration of remediation to clean up a plume after facility closure. The EPA understands that the contaminant transport models used to estimate costs of remediating a contaminant plume are simplistic, the inputs used are based on limited ISR facility data, and selected parameterizations are based on assumptions. Nevertheless, the flow model provides a reasonable estimate for the duration of an illustrative general pump and treat remediation scenario, based on the EPA's extensive pump and treat remediation experience under CERCLA and other remedial programs, and, upon review, the models and inputs were determined to be adequate to illustrate potential cost savings for purposes of the economic analysis.

I. Other Miscellaneous Changes

1. Clarification of "Operational Phase"

In the original proposal, the EPA defined the operational phase of an ISR facility as "the time period during which uranium extraction by in-situ recovery occurs" and noted that "operations end when the operator permanently ceases injection of lixiviant and recovery of uranium-bearing solution for processing" (see 80 FR

4160). However, the EPA notes there are periods when the ISR facility is not actively recovering uranium for various reasons (e.g., market conditions), but production is intended to resume when conditions are more favorable. These periods are sometimes referred to as "standby" by operators. In the original proposal, the EPA expressed the view that it would not be appropriate to allow a standby period for ISR facilities if the gradient within the wellfield is not being maintained, and that stopping the extraction cycle should require the operator to enter the restoration phase. Commenters acknowledged that ISR facilities can experience extended periods of standby and noted that active pumping during these periods is necessary to prevent contamination of groundwater in areas outside the production zone. One commenter recommended the EPA minimize the amount of time during which an ISR facility in standby is not pumping. Other commenters thought ISR facilities entering standby should be required to initiate restoration and recommended that the EPA require ISR facilities to commence restoration within a specified time period after ceasing active uranium recovery.

The EPA agrees with the commenters who said ISR facilities must be responsible for ensuring that lixiviant and constituents do not migrate outside of the production zone during standby periods. The EPA disagrees with the commenter who suggested ISR facilities that temporarily cease operations should be required to commence restoration. The EPA agrees, however, that during standby periods the migration of constituents mobilized by the prior injection of lixiviant may continue even if the decision is made to stop extracting uranium. Excursions beyond the production zone are more likely to occur if the hydraulic gradient within the wellfield is not maintained. For this reason, the EPA considers standby to be part of the operational phase, and facilities should not cease pumping during standby periods since it is important that an inward hydraulic gradient is maintained during these periods. For this reason, the EPA is proposing that all requirements applicable to the operational phase remain in effect during these standby periods. Provided the licensee complies with the operational phase monitoring and corrective action requirements in the proposed rule, ISR facilities in standby would not need to enter restoration because groundwater in areas surrounding the production zone will be afforded the same level of

protection as required during restoration. In this proposal, the EPA has revised the definition of “operational phase” in original proposal to clarify that standby mode is considered part of the operational phase and that ISR facilities in standby must maintain appropriate groundwater controls to prevent constituents from leaving the production zone.

2. Changes to the Definition of “Point(s) of Compliance”

As stated in the original proposal, during the restoration phase, the definition of “point(s) of compliance” may include “monitoring, injection, and extraction wells in the production zone” (see 80 FR 4184). Points of compliance during the initial stability and long-term stability phases should include locations within the former production zone, including existing monitoring, injection and extraction wells. To clarify these requirements, in this proposal, the EPA revised the definition of “point(s) of compliance” to indicate that excursion monitoring wells are considered points of compliance during all phases of ISR operation and that during the initial and long-term stability monitoring phases, points of compliance should also include locations, identified by the regulatory agency, where a potential receptor can come into contact with contaminated groundwater. The EPA is specifically requesting comment on the definition of “point(s) of compliance” and how it is applied. Again, the EPA is requesting comment on the definition of point of exposure and conceptual framework for establishing ACLs.

IV. Responses to Other Significant Comments That Did Not Result in Changes to the Original Proposal

The EPA carefully reviewed and considered comments from a wide range of different groups in preparing this proposal. As discussed in section III of this preamble, the EPA modified and clarified various aspects of the proposed rule based on the information and views provided, including comments on the original proposal. However, not all comments resulted in modifications to the proposed rule. Those significant comments that did not result in changes, together with the EPA’s responses, are summarized in this section of the preamble.

A. Authority To Set Generally Applicable Standards

Some commenters thought the proposed rules were legally invalid and felt the EPA was overreaching its authority under UMTRCA by proposing

standards that are too detailed and prescriptive. The commenters argued the EPA was redefining what UMTRCA established as the EPA’s role to set general standards while making the NRC responsible for implementing those standards through its licensing process. These commenters believe that UMTRCA limits the EPA’s authority to setting general standards that do not include any prescriptive implementation requirements. Some of these commenters cited a statement from the legislative history of UMTRCA in which a House Committee advised that “[t]he EPA standards and criteria should not interject any detailed or site-specific requirements for management, technology, or engineering methods on licensees or the Department of Energy.”

However, other commenters thought the proposal was an appropriate exercise of the EPA’s authority under the UMTRCA because the proposed rule would not supplant the NRC’s jurisdiction or impede its licensing authority. They cited the statutory provisions that assign the authority to set standards to the EPA and the authority to implement and enforce the standards to the NRC (See 42 U.S.C. 2022(b), (d)). The commenters thought the proposed standards were an appropriate application of the EPA’s authority under the UMTRCA and felt that the EPA had correctly left implementation of the new standards to the NRC and Agreement States.

The Agency disagrees with those commenters who believe the EPA has redefined its role or overreached its authority in developing the new standards for ISR facilities. Section 206 of the UMTRCA clearly authorizes the EPA to promulgate standards of general application for the protection of public health, safety and the environment from radiological and non-radiological hazards associated with the processing and the possession, transfer and disposal of byproduct material at uranium ISR facilities. See 42 U.S.C. 2022(b). The Tenth Circuit Court of Appeals affirmed EPA’s authority to set such standards under UMTRCA in two companion cases challenging the original part 192 rules. See *American Mining Congress et al. v. Thomas*, 772 F.2d 617 (10th Cir. 1985) (“*AMC I*”); *American Mining Congress et al. v. Thomas*, 772 F.2d 640 (10th Cir. 1985) (“*AMC II*”). Consistent with the reasoning of these opinions, the new standards proposed in this action would apply the same requirements to all ISR facilities and would establish general requirements to (1) meet constituent concentration standards and demonstrate groundwater conditions are

stable with 95 percent confidence; (2) conduct monitoring; and (3) develop and implement a corrective action program. Within the framework of these generally applicable standards, the regulatory agency would be responsible for implementing the proposed new standards on a site-specific basis through the licensing process and would retain the authority to determine when an ISR license can be terminated. *AMC II*, 772 F.2d at 647–648 (“General application standards that allow the Nuclear Regulatory Commission (NRC) to choose the means of implementation are consistent with the authority Congress vested in the EPA.”).

The first of these three components of the proposed standards has two integral parts—numerical constituent concentration standards and groundwater stability standards. This proposal sets forth minimum requirements for the constituent concentration standards, but implementation of those standards on a site-specific basis remains the responsibility of the regulatory agency. However, a numerical concentration standard by itself is not sufficient to address “the risk to public health, safety, and the environment” that the EPA is required by statute to consider when setting general standards. 42 U.S.C. 2022(b)(1). Since ISR facilities alter the natural groundwater flow, this risk includes the risk that constituent concentrations in the groundwater will not remain the same over time if the groundwater remains unstable. Thus, to address this risk, the proposed rule contains a general requirement to demonstrate that groundwater conditions are stable after production ends at a site. For example, to satisfy the proposed initial stability standards, ISR facilities would provide three consecutive years of quarterly monitoring results demonstrating no statistically significant increasing trends exceeding the constituent concentration standards at the 95 percent confidence level. This proposed requirement to demonstrate groundwater stability is an integral part of the standard. The proposed general standard for stability is defined by a level of statistical confidence that is applicable to all sites. EPA believes this level of statistical confidence is necessary at all sites to ensure that the stability standards are sufficiently stringent to address the risk that groundwater exceeding the applicable constituent concentration standards poses to public health, safety and the environment from ISR facilities that have ceased operation. Contrary to some commenters’ remarks (see Section

IV.D below), the proposal does not include any “detailed or site-specific requirements” regarding how an ISR facility must satisfy the 95 percent confidence level. Hence, these proposed standards lack any “management, technology or engineering methods” pertaining to this confidence level. The proposed stability standards do not prescribe what specific statistical methods, sampling methods, or monitoring equipment should be used to show 95 percent confidence. Such decisions are left to the regulatory agency through its licensing of each facility. The Tenth Circuit has recognized that other provisions with these characteristics are within EPA’s standard-setting authority under UMTRCA. *AMC I*, 772 F.2d at 630 (“Furthermore, because the standards are general in nature—they apply to all sites—we do not view them as site-specific ‘management, technology or engineering methods.’”); *AMC II*, 772 F.2d at 645–646 (“Most of the arguments by the various petitioners are substantially identical to those in the consolidated *Inactive Sites Case* decided this day. On the basis of the analysis in that opinion, we again hold . . . that the EPA’s standards do not unlawfully impose management, design, and engineering requirements. . . .”).

Some commenters argued the long-term monitoring requirements in the original proposal were too prescriptive and that the EPA would be effectively dictating when a license could be terminated. As noted above, the Tenth Circuit has clearly recognized that the EPA’s standard-setting authority under UMTRCA enables the EPA to include monitoring as part of its “standards of general application.” *AMC II*, 772 F.2d at 644 (“The regulations necessitate monitoring programs.”). In affirming the monitoring provisions in the original part 192 rule (monitoring provisions that are very similar to those in this proposal), the Court in *AMC II* readily distinguished between monitoring that is properly included as part of a standard the EPA promulgates and more prescriptive monitoring requirements that should be left to the regulatory agency. *AMC II*, 772 F.2d at 647–648 (“The regulations require the industry to satisfy SWDA drinking water concentration standards at specified distances from the pile, but they do not dictate the kind of monitoring system that must be used or the method by which purity levels must be achieved. These decisions are left to the implementing agency, the NRC.”). The EPA has not included detailed

monitoring requirements in these proposed standards (e.g. what kind of monitors to use), but has instead left those details up to the review and approval of the NRC or the Agreement State.

Several comments were also critical of the EPA’s authority to require corrective action programs. While the term “standard” includes numerical limitations, such as the concentration-based limits for the listed constituents in groundwater, the EPA has long interpreted this term to also encompass the actions a source must take to reduce, remediate or otherwise avoid release of pollutants. The EPA notes that the existing rule, in subpart D, includes similar non-numerical standards to those included in this proposed rule. For example, 40 CFR 192.32(a)(2)(iii) requires affected sources to implement detection monitoring programs, while 40 CFR 192.32(a)(3)(i) requires uranium mill tailings piles or impoundments to have a permanent barrier.

In sum, the regulatory agency must determine the constituent concentration standards applicable to each site, approve the number, location, and installation of all wells used for monitoring, and determine when the initial and long-term stability standards are satisfied. See *AMC II*, 772 F.2d at 647–648 (Court affirms standards because “they do not dictate the kind of monitoring system that must be used or the method by which purity levels must be achieved. These decisions are left to the implementing agency, the NRC.”) The regulatory agency is also responsible for approving the licensee’s corrective action program and, when an excursion has occurred, determining when corrective action should begin and when it can cease. The regulatory agency may also bring enforcement actions against any non-compliant ISR facility. Thus, as required by UMTRCA, and consistent with the case law affirming the EPA’s previous part 192 rulemakings, the implementation and enforcement of the proposed new standards remain with the regulatory agency.

B. Need for New Standards for Uranium ISR Facilities

Several commenters concurred with the EPA’s assessment that new standards are necessary for ISR facilities. These commenters noted that environmental impacts from ISR are significantly different from the impacts of conventional mining and milling. Commenters supported the EPA’s conclusion that a more rigorous approach is warranted for determining background groundwater

concentrations. They considered the preoperational monitoring requirements as necessary to establish appropriate concentration-based standards for each ISR facility. They also supported the stability-phase monitoring, which they considered important for demonstrating groundwater stability after restoration and for providing assurance groundwater quality will not degrade over time and that constituent migration will not occur in the future. One commenter felt that more rigorous standards with detailed restoration and long-term stability demonstrations were necessary to bring “coherency and accountability” to ISR facilities. However, other commenters thought the rule was unnecessary and provided a variety of reasons to support their contentions. Most commenters felt the standards were not justified because the industry was already regulated, arguing that the EPA had failed to provide or quantify sufficient evidence that ISR poses a risk, or had failed to consider relevant data. A number of commenters asserted that EPA had not adequately addressed recommendations of the Agency’s SAB. Many commenters noted that ISR facilities are already regulated by the EPA, the NRC, and states, and that the success of the existing regulatory oversight over the last 40 years proved that further regulation was not needed. In support of their statements, these commenters stated that there were no documented cases of off-site contamination of drinking water supplies from ISR activities in the United States. Other commenters noted that the new standards were unnecessary because ISR facilities are located in exempted aquifers under the SDWA in 40 CFR 146.4 and cannot serve as sources of drinking water because the EPA has already determined the water is unsafe for human consumption. One commenter stated that the SDWA UIC program has requirements prohibiting injection of fluids where production fluids could migrate into non-exempt aquifers and stated that these existing requirements were sufficient to protect groundwater. Other commenters argued the regulations were unnecessary because ISR facilities already collect background water quality data, restore groundwater impacted during recovery, and monitor for stabilization after restoration under the existing regulations. Some commenters felt the migration of uranium from ISR facilities was unproven. These commenters cited papers they said showed uranium had

not migrated from ISR facilities.¹⁷ A few commenters recommended the EPA postpone promulgation of the rule until additional research could be completed and the health and environmental risks better understood.

The EPA disagrees with commenters who contend that new standards are unnecessary. First, it is in the national interest to protect groundwater resources. Water is becoming a scarce resource, particularly in the arid regions where most ISR currently operate. Groundwater in this region is not exclusively used for human consumption, and has other uses such as livestock production, crop irrigation, and wildlife support. The best way to preserve groundwater for all such uses is to prevent contamination by addressing the source of contamination. The SDWA UIC program plays an important role in protecting underground sources of drinking water. However, as discussed in section I.A. above, the scope and level of protection of the SDWA differs from the UMTRCA. The SDWA does not prevent recovery and use of the water within exempted aquifers (including where ISR operations were previously conducted) for private drinking water supply, public water supply, or other uses. UMTRCA provides authority that can be used to require restoration of the groundwater in the production zone and to protect the groundwater outside the production zone aquifer, during and after uranium recovery operations, regardless of whether the aquifer has been exempted from the protections of the SDWA.

Thus, this proposed rule under UMTRCA is needed to establish generally-applicable groundwater standards for ISR facility restoration and require more extensive monitoring, modeling and analysis to ensure that groundwater restoration will endure. ISR alters the chemical composition of groundwater and creates reasons to be concerned about risk of mobilization of constituents. The EPA notes that several NRC-regulated sites are continuing to work toward restoring groundwater with restoration and monitoring being conducted for as long as 10 years after

ceasing production.¹⁸ In addition, restoration does not always meet original background levels as evidenced by the number of restoration goals above background or Table 1 levels.¹⁹ In addition, the NRC acknowledges that efficiency could be gained by codifying its longstanding effective regulatory regime into regulations specific to ISRs. As described in the original proposal, this rulemaking was initially prompted by the NRC's conclusion that ISR-specific rules are needed to create a more workable and sustainable regulatory framework for this activity, and is not based on any specific instances of identified contamination.²⁰ The EPA considers the approach to protecting groundwater in this proposal to be reasonable and responsible. The EPA further notes that remediation of contaminated groundwater is more expensive and difficult to achieve than for surface waters because it is not easily accessible. It is more cost-effective to prevent contamination by ISR facilities than to clean it up after wide-spread contamination occurs.

Second, the information the EPA has reviewed indicates that current industry practices for restoration and monitoring of the affected aquifer may not be adequate to prevent degradation of water quality at ISR facilities or the more widespread contamination of surrounding groundwater that is suitable for human consumption. Historically, once restoration is halted, stability demonstrations at ISR facilities are typically conducted for only a short period, which may not be adequate to determine that restoration is complete and long-term stability established. Several instances are noted in section III.F.2 where facilities have monitored for lengthy periods after restoration was deemed to be complete, but have not been able to demonstrate stability for even the more limited times typically required under current practice. The initial and long-term stability monitoring and corrective action program included in the new proposed rule would provide greater confidence that both of these requirements are met before ISR facilities can be decommissioned.

Finally, the EPA considers the existing regulations at 40 CFR part 192

to be inadequate for addressing groundwater contamination from ISR facilities. Subparts A, B and C of 40 CFR part 192 apply to inactive uranium milling facilities, vicinity properties, and depository sites (*i.e.*, Title I sites). Only subpart D is applicable to active uranium processing and disposal sites; however, subpart D primarily targets conventional milling as it contains provisions for managing uranium byproduct materials during and following the processing of uranium ore and for the restoration of disposal sites. Although the standards in subpart D applied to ISR facilities, ISR was not the predominant uranium extraction method at the time the standards were promulgated. ISR differs significantly from conventional mining and milling and consequently presents different environmental concerns from those of conventional mining and milling operations. For example, ISR does not generate large volumes of solid waste materials or require permanent tailings impoundments as does conventional mining and milling. At ISR facilities, the groundwater is directly impacted by the injection of lixiviant into the aquifer, which alters the geochemistry of the ore-bearing formation and increases the concentration of radionuclides and other metals in the water. The purpose of restoration activities is to restore the groundwater to the applicable constituent concentration standards. Although subpart D addresses contamination of aquifers, it explicitly addresses only contamination resulting from releases from uranium mill tailings impoundments used to store uranium byproduct material (*e.g.*, conventional tailings impoundments, evaporation or holding ponds). Under subpart F, the operator would be required to restore the groundwater in the production zone aquifer and surrounding aquifers to the applicable constituent concentration standards, to the extent possible, and to show some level of stability in the production zone prior to terminating the license. Because ISR changes the geochemistry of the groundwater, more rigorous stability-based standards together with corrective action programs are necessary to ensure that the production zone is restored and that restoration will persist in the future.

Regarding comments that the EPA did not request or collect data from industry, the Agency disagrees. The EPA has appropriately considered available data to support its proposed rules and requested additional data from industry. During the SAB's public teleconferences in 2011, industry stakeholders stated that additional data

¹⁷ The commenter cited the following two papers: (1) Basu, Anirban, et al., "Isotopic and Geochemical Tracers for U(VI) Reduction and U Mobility at an In Situ Recovery U Mine", *Environmental Science Technology*, April 24, 2015, 49(10), pages 5939–5947; and (2) Reimus, Paul, "Field Evaluation of the Restorative Capacity of the Aquifer Down Gradient of a Uranium In Situ Recovery Mining Site" presented at the "2015 In situ Recovery of Uranium Research Symposium" held at the University of Wyoming, Laramie, Wyoming, April 21, 2015.

¹⁸ EPA (2016), "Considerations Related to Post Closure Monitoring of Uranium In-Situ Leach/In-Situ Recovery Sites", available in Docket ID No. EPA-HQ-OAR-2012-0788.

¹⁹ *Ibid.*

²⁰ NRC (2006), "Regulation of Groundwater Protection at In-Situ Leach Uranium Extraction Facilities," COMJSM-06-001, January 17, 2006; <http://www.nrc.gov/reading-rm/doc-collections/commission/comm-secy/2006/2006-0001comjasm.pdf>.

was available beyond that contained in EPA's draft report. The EPA requested this information from the National Mining Association in January 2012; however, the EPA found that the data provided by NMA had already been considered by the EPA. The EPA also provided an additional 60 days for public comment on the original proposal for industry stakeholders to provide additional data. While the data did in some cases appear to involve longer-term monitoring at some sites, the information was largely piecemeal and lacking in context. Consequently, the EPA did not find this information useful.

The EPA further believes the commenters have misinterpreted the SAB recommendation to constructing a database to support modeling and build an evidence base for EPA's rulemaking. In section 3.2, page 8, the SAB discusses the development of such a database. However, in section 3.3, the SAB goes on to recommend that "for the near term, *until the needed large evidence base is accumulated and systematized*, that the EPA [should] articulate a set of guiding principles and assumptions on which to base regulations. The proposed standards *can be based on these assumptions during the next several years*, and superseded if evidence of their unsuitability becomes available." (emphases added). The SAB clearly did not intend for EPA's rulemaking to be held in abeyance until all available data had been collected, systematized, and analyzed. Rather, the SAB viewed this as a longer-term effort in which EPA's standards could be modified should the underlying assumptions not be supported by additional data. Further, because of the limited long-term data available for sites once they have been deemed "stable," which the SAB members recognized during the July 2011 meetings, in EPA's view this necessarily involved a period during which EPA's standards would be effective and require collection of such longer-term data.

However, as mentioned earlier, given the concern about data collection and the comments concerning lack of state data, the EPA will consider additional data collection and analysis, including review of affected state regulatory programs. The Agency also takes issue with some comments characterizing the UIC program requirements. An aquifer exemption is not a judgment that the water is unsafe for human consumption. In most, if not all, cases, an ISR facility is provided with an aquifer exemption solely because of the presence of uranium that is economically producible. Further, while the UIC

program objective is to prevent endangerment of USDWs, it is the responsibility of the permittee to operate in a manner that does not allow production fluids to migrate into non-exempt aquifers. 40 CFR 144.12(a).

C. Applicability

Consistent with the original proposal, this proposed rule does not apply to licensed ISR facilities that are engaged in restoration, initial stability monitoring, or long-term stability monitoring. However, some commenters stated that the original proposed rule should not apply to existing ISR facilities that are currently operating. These commenters noted that it was not clear how an existing ISR facility would comply with the proposed rule for ISR wellfields that are already in the operational, restoration or stability monitoring phase. Commenters stated that preoperational background water quality would have already been established for operational wellfields, but the methods used to establish the background concentrations may not be consistent with the requirements in the proposed rule. They noted that it would not be possible to resample for background water quality for operating wellfields since the aquifers have already been changed by uranium recovery operations.

The EPA sees no need to omit existing ISR facilities from this rule due to preoperational considerations. The NRC already requires ISR facilities to establish background conditions prior to beginning operation under 10 CFR part 40, Appendix A, Criterion A. Under this NRC guideline, an ISR facility must implement a preoperational monitoring program that provides complete baseline data on the facility and its surrounding area. In addition to the NRC guidelines, ISR facilities conduct studies of the ore zone prior to beginning production to collect data necessary for designing the ISR facility. Although the most appropriate monitoring would consist of a statistically representative sample of wells spatially distributed throughout the wellfield, the EPA recognizes that operating facilities cannot collect unaffected background samples at ISR facilities that are already operating. However, facilities that are already operating, but have not yet entered the restoration phase, can use the background data they collected prior to operation to set their constituent concentration standards. Even with limited data, existing ISR facilities can analyze the preoperational data they collected and develop a statistically meaningful data set to use as the basis

for the constituent concentration standards and also define other aspects of the system, such as the flow regime, that are necessary to develop site models. Selecting high or the highest values of the chemical monitoring data would not be considered an appropriate basis for establishing background conditions. Further the collection of data to demonstrate stability would be essentially the same for all facilities.

D. The 95 Percent Confidence Level

The original proposed rule contained a requirement to gather monitoring data sufficient to demonstrate the stability of groundwater with 95 percent confidence. Some commenters thought the 95 percent confidence level was too restrictive. These commenters stated that the EPA did not address properly the cost, both in dollars and water resources, required to achieve a 95 percent confidence level. Some of these commenters misinterpreted the 95 percent confidence requirement as a restoration goal requiring the constituent concentrations to be reduced by 95 percent, rather than a level of confidence in the statistical tests used to assess stability. Most commenters thought the 95 percent confidence level was too high, while a few thought it was too low. A few comments addressed the general requirements to demonstrate that the hydrogeological and geochemical properties have been returned to preoperational condition and expressed concern the 95 percent confidence level would be required for the statistical tests. Many of these comments indicated a concern with the high variability of these properties at ISR facilities. Concerns were raised that many of the ionic species are reported in the parts per billion and parts per million concentrations and duplication of analysis on the same sample can vary a few parts per million when samples are rerun.

Some commenters thought that the original proposed rule was not sufficiently prescriptive. Several commenters expressed concern with the statistical tests recommended for detecting trends and for the comparison with baseline values. These commenters noted that important details required to implement the statistical tests are not provided in the proposed rule, including whether the statistical analysis is conducted for the well field as a whole, within clusters or well-by-well; what parameter should be tested; and what requirements there are for the tests, particularly for the trend test.

This proposal retains a 95 percent confidence level but makes it clear that

this is part of the generally applicable stability standard in both the initial and long-term stability phases. The 95 percent confidence level is used to define stability, and EPA considers a confidence level a measure of stringency of the standard. This is one approach for defining stability, but not necessarily the only approach. However, the EPA is concerned that a stability standard that lacks any statistical criterion would provide insufficient assurances that full restoration has been achieved and allow stringency of the standard to vary from site-to-site, thus failing to fulfill EPA's obligation to produce standards of general application. See *AMC I*, 772 F.2d at 638–639 (finding the EPA failed to specify generally applicable standards by directing the regulatory agency to determine standards that could vary on site-specific basis). The EPA requests comment on alternative approaches that would present a rigorous benchmark against which to measure and ensure stability.

The 95 percent confidence criterion would apply for all constituents. The proposed standards to demonstrate initial and long-term stability with 95 percent confidence would be applied after restoration has been completed to confirm that the restoration was successful and likely to persist. Again, the EPA requests that commenters share examples where the 95 percent confidence level cannot be used or met and the limitations of these examples and the Agency invites commenters to propose other options that would clearly represent a valid and explicit groundwater stability standard that includes a measure of stringency.

The EPA understands that NRC staff has attempted to use the 95 percent confidence level for at least one facility (see the NRC presentation in the BID) but has concerns about its use in every case. The Agency considered changing the level of confidence, however the 95 percent confidence level is the standard used under other regulatory programs, including the EPA's hazardous waste program. It is a widely accepted standard used across many industries that must monitor groundwater. Again, the EPA requests comment on the use of the 95 percent confidence level as part of the stability standard and whether there are better or more practical ways to word the standards such that they present a clear level of stringency.

The costs of conducting the statistical tests are related largely to the number of wells monitored and the duration and frequency of baseline and post-restoration monitoring. These costs are not related to the dollar and resource costs of restoration. The EPA recognizes

there is a trade-off between the cost of additional monitoring and the level of confidence achieved in the confirmatory statistical tests. Due to the high variability in hydrogeological and geochemical properties it may be necessary to do more monitoring to compensate for the higher variability.

While the proposed initial and long-term stability standards define stability as attaining 95 percent confidence, the methods to be used to demonstrate compliance would be determined by the regulatory agency. The BID²¹ provides suggested sampling plans for stability monitoring that include instructions for applying the parametric and nonparametric statistical tests to detect trends and for comparing with baseline values. Each statistical test has its own set of parameters, null and alternative hypotheses, decision rules and underlying assumptions about the data. However, it was not the intention of the EPA to provide detailed instructions for conducting the statistical tests in the rule. The licensee would be responsible for selecting the specific statistical test to be used for stability monitoring and comparisons with the baseline values. EPA expects that the regulatory agency would provide additional guidance regarding the statistical analysis required and the reasons for using the statistical test, the concepts of Type 1 and Type 2 errors, the calculations required to perform the test, and how test results are interpreted. Information about what parameter is tested, the null and alternative hypotheses, requirements for implementing the statistical tests and tables for interpreting test results is included in the BID. Decisions concerning whether the statistical analyses are conducted for the well field as a whole, within clusters, or well-by-well would remain a responsibility of the regulatory agency.

V. Summary of Environmental, Cost and Economic Impacts

A. Environmental Impacts of the Proposed Rule on Groundwater Quality

This proposed action reduces the risk of undetected contamination of groundwater resources surrounding ISR facilities both during uranium production and after production has ceased. During uranium production, the fluids injected to mobilize uranium change the chemistry of the aquifer from its original state, thereby mobilizing uranium and many other minerals and metals. Groundwater from the ISR

production zone can migrate from the production zone and contaminate nearby groundwater with arsenic, barium, cadmium, chromium, lead, mercury, selenium, silver, nitrate, molybdenum, radium and uranium and other constituents. The new standards proposed in this action would reduce the risk of groundwater degradation both during the ISR operational phase and after an ISR operator's license is terminated and the facility is closed. This would be achieved through provisions requiring characterization of groundwater prior to uranium recovery and standards set to protect groundwater from excursions during the operational phase and standards for restoration to pre-operating conditions and stability after the operational phase ends. These proposed requirements would significantly reduce the probability that groundwater down-gradient from an ISR facility will become contaminated by radiological and non-radiological constituents. Through monitoring and corrective action programs, the new proposed standards would ensure potential excursions are detected and remedied in a timely manner. The proposed initial and long-term stability standards would ensure the ISR aquifer is stable prior to closure, reducing the potential for contamination to occur after uranium recovery has ceased and the ISR facility's operating license has been terminated following closure.

B. Incremental Costs of Complying With the Proposed Rule

Using information on the uranium extraction industry, the EPA estimated incremental costs resulting from this proposal. Under this proposal, ISR facilities would be required to complete the following additional activities: (1) A comprehensive preoperational characterization of the area (including characterization of geochemical conditions); (2) monitoring for excursions during the operational and restoration phases; (3) three years of initial stability monitoring; and (4) long-term stability assessment, with a minimum of three years of additional monitoring, with the total duration of the long-term stability monitoring determined by the regulatory agency based on modeling and monitoring of geochemical conditions.

Incremental costs attributable to the proposal are costs that would be higher under the proposal than they would be if 40 CFR part 192 was not revised. If no revisions were made to 40 CFR part 192, ISR facilities would be required by the NRC or agreement states to characterize preoperational conditions,

²¹ EPA (2016), "Considerations Related to Post Closure Monitoring of Uranium In-Situ Leach/In-Situ Recovery Sites", available in in Docket ID No. EPA-HQ-OAR-2012-0788.

monitor for excursions during operational and restoration phases, and monitor after restoration to show that conditions are stable. The EPA consulted with the NRC to ensure that its characterization of compliance requirements in the absence of the rule accurately reflected current trends in the NRC's permit requirements. To estimate incremental costs of complying with the proposed rule, the EPA estimated the costs of complying with the proposal and then subtracted the costs of complying with the NRC's requirements in the absence of the rule. EPA requests comment on this approach.

Under the proposal, the EPA estimates that ISR facilities would incur higher costs, for several reasons: (1) More monitoring wells would be required under the proposal; (2) more constituents would be monitored under the proposal; and/or (3) monitoring during the preoperational and stability phases would be required to continue for a longer period of time under the proposal. In addition, because the overall duration of monitoring prior to closure and license termination would be longer under the proposal, other non-monitoring costs would be incurred for several additional years, compared to requirements in the absence of the proposal.

To estimate the incremental costs for complying with these additional proposed requirements, the EPA used ISR operations listed by the U.S. Energy Information Administration as likely affected ISR operations and a projected 2017 ISR uranium production of 3.3 million pounds. From this analysis, the EPA estimated low, average and high incremental costs of complying with the proposal; average incremental costs of complying with the proposal at approximately \$1.96 per pound of uranium and an annual cost of \$181,000 to \$6.4 million for firms owning ISR facilities, depending on the number and scale of the ISR facilities they own. Nationally, the EPA estimates the incremental total annual cost of the proposal to be approximately \$11.9 million, including incremental annualized capital costs and monitoring costs (\$4.3 million) and incremental annual non-monitoring costs (\$7.6 million). The EPA's estimated national incremental annualized costs for the original proposed rule totaled \$13.5 million for monitoring and capital costs alone. Since the original proposal, the EPA learned from discussions with the NRC that many of the monitoring requirements of the proposed rule (and also those of the proposal) would already be embodied in expected NRC

license requirements in the absence of the proposal. In addition, the EPA revised some of the rule's requirements to increase flexibility and reduce burden. For these reasons, the difference between the monitoring requirements and costs for the proposal and those for current practice (the incremental monitoring costs of the proposal) are estimated to be considerably lower than the estimates for the proposed rule. This reduction in incremental monitoring costs is largely offset by including, in response to public comment, estimated incremental non-monitoring costs). Overall, the EPA's estimate of incremental annualized costs of complying with the proposed rule is slightly lower than the costs estimated for the original proposal. For additional information regarding the methodology used to estimate the costs, see the technical document titled, "Economic Analysis: Revisions to the Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings Rule (40 CFR part 192)" available in Docket ID No. EPA-HQ-OAR-2012-0788.

C. Economic Impacts of the Proposed Rule on the Market for Uranium and the Uranium Industry

The EPA estimated the impact of the proposal on the market for uranium using a simplified model of the U.S. market for uranium in 2017, using 2015 market quantities as a proxy for market quantities in 2017. EPA requests comment on this approach. The partial equilibrium model of the U.S. uranium market estimated market impacts and revealed the following: (a) Changes in the quantity of uranium purchased by U.S. COOs of nuclear power plants; (b) changes in the sales of domestically produced uranium and imports; and (c) changes in the market price for uranium. Based on average incremental costs of complying with the proposal, the EPA found that the market quantity of uranium purchased for use in electric generation is expected to decline by less than 0.01 percent and the market price to increase by approximately 0.2 percent. Domestic ISR facilities are projected to decrease their production by approximately 6.7 percent, and imports of uranium are expected to increase by 0.4 percent. Because the cost of uranium is a very small share of the cost of electricity, the EPA estimates that the cost of generating electricity will likely increase by less than 0.1 percent due to this action. Although the national total annual cost of the proposal (approximately \$11.9 million, based on average costs) is well below the \$100 million threshold that is one of

the criteria used to identify a significant regulatory action, the industry has only a small number of companies operating a small number of ISR facilities.

The EPA used existing and planned ISR operations and the companies that own them as models for the types of facilities and companies affected by the proposal. This proposal would affect approximately 15 ISR facilities that are currently operating or may operate in the near future. The 15 ISR facilities are owned by 9 firms. This action would apply to the following ISR facilities identified by the Energy Information Administration in 2015 as either operating, permitted and licensed, developing, or partially permitted and licensed: (1) Crow Butte (Nebraska) and (2) Smith Ranch-Highland (Wyoming), both owned by Cameco Resources; (3) Alta Mesa (Texas), and (4) Nichols Ranch (Wyoming) both owned by Energy Fuels; (5) Willow Creek, (6) Jab and Antelope, and (7) Moore Ranch (Wyoming), all owned by Uranium One/Rosatom; (8) Hobson-La Palangana and (9) Goliad (Texas), both owned by Uranium Energy Corp.; (10) Lost Creek (Wyoming), owned by Ur-Energy Inc.; (11) Church Rock and (12) Crownpoint (New Mexico), both owned by Laramide; (13) Reno Creek (Wyoming), owned by Bayswater; (14) Dewey Burdock (South Dakota), owned by Azarga Uranium Corp.; and (15) Ross (Wyoming), owned by Peninsula Energy. Three other ISR projects (Kingsville Dome, Rosita, and Vasquez, owned by Uranium Resources, Inc.) are out of scope for the analysis because they are undergoing restoration or reclamation as of 2015. Using the Small Business Administration size standard for NAICS code 212291 (*i.e.*, fewer than 250 employees) all the parent company firms except Cameco Resources and Rosatom/Uranium One Americas, Inc. qualify as small businesses. Thus, the majority of the firms in NAICS 212291 are small firms.

To evaluate the magnitude of the economic impacts of the proposed revisions to 40 CFR part 192 on firms owning ISR facilities, the EPA estimated the incremental costs that would be incurred by affected facilities including both monitoring and non-monitoring costs, summed costs to the firm-level, and compared each firm's estimated costs to estimated or reported firm revenues. EPA requests comment on this approach.

Compiling these estimated costs at the parent company level and comparing them to estimated sales or reported sales for the parent company, average estimated annualized costs would range from 0.66 percent to 2.78 percent of

average company sales for the seven small businesses, and 0.2 percent and 2.6 percent for the two large businesses. Of the seven small businesses, one firm has cost-to-sales ratio below 1 percent, three firms have cost-to-sales ratios between 1 percent and 2 percent, and three have cost-to-sales ratios between 2 percent and 3 percent. The EPA's estimated costs may overstate actual annual costs, especially for ISR facilities with large acreage, because the cost estimates are scaled based on the entire wellfield acreage, while ISR facilities typically have some wellfields in the operational phase and others in various stages of development and restoration or reclamation. Average costs based on total acreage may overstate costs incurred at some times during the life of the project. Further, the EPA included costs associated with all phases of operation for all ISR facilities; this would overstate costs for all wellfields currently operating, because it includes costs for preoperational monitoring and assessment. In addition, the EPA assumed that all ISR facilities would monitor for all Table 1 constituents during all phases of monitoring; in fact, the regulatory agency may specify monitoring for only those constituents expected to be present based on preoperational monitoring, which would reduce costs. While some costs may have been over-estimated, the EPA considers that values for firm revenues may be under-estimated. For facilities for which the EPA estimated sales revenues, the EPA assumed that production equaled 25 percent of capacity (based on average levels of capacity utilization over the period 2011 to 2015, which is a period with relatively low production). The EPA multiplied these relatively low estimated production values times market price to estimate revenue. For firms for which the EPA used 2015 reported revenues, these revenues similarly represent a time period when both production and price are lower than usual. Thus, the EPA may have underestimated the revenues ISR firms may earn in the future. Because no small firms incur costs exceeding 3 percent of sales, and because the costs may be overestimated while the future revenues underestimated, the EPA concludes that the proposal will not result in a significant impact to a substantial number of small entities. In addition to the direct economic impacts on ISR producers, the proposal may have indirect impacts on businesses that supply inputs to ISR producers (supply chain impacts), businesses located in areas near ISR facilities (consumption

impacts), and local governments in those areas (revenue impacts). Some businesses and governments potentially indirectly affected by the proposal may be small entities. EPA's analysis projects that the costs of the proposal and direct impacts on ISR producers will generally be small; indirect impacts are typically smaller than direct impacts. Thus, the EPA projects that indirect impacts of the proposal would generally be small. Details of the economic analysis are presented in the technical document titled, "Economic Analysis: Revisions to the Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings Rule (40 CFR part 192)" available in the docket for this action. EPA requests comment on the economic analysis.

D. Benefits of the Proposed Rule

The EPA has conducted a qualitative assessment of the benefits of the proposal and has identified three principal benefits. First, the proposed rule would reduce the potential human health risks associated with human exposure to radionuclides, metals and other constituents in well water used for drinking and agriculture. The EPA considers water contaminated with radionuclides to be a potential pathway for exposure to radiation that can cause cancer and other health effects (*e.g.*, kidney damage). Likewise, heavy metals and other contaminants can cause cancer and/or non-cancer health effects. By reducing the potential for contaminants to migrate into aquifers adjacent to ISR facilities, the proposal would reduce the potential human exposure to radionuclides, heavy metals and other groundwater contaminants from ISR operations and thus reduces the potential human health risks from these contaminants.

Second, the proposal would protect valuable groundwater resources for future generations. Groundwater provides a valuable resource that is increasingly threatened by population growth and technological advances that have significantly increased groundwater extraction. Declining groundwater resources, especially in arid regions where ISR operations are mostly located, are a growing concern. Although the EPA is unable to quantify the value of the groundwater resources that would be protected by the proposal, groundwater resources are likely to become more valuable over time. By reducing the potential for groundwater contamination and ensuring that any migration of constituents from ISR operations is detected early, the proposal would help protect groundwater from contamination. Rapid

detection of constituent migration from an ISR operation reduces the overall amount of contamination that must be remediated; early detection can trigger corrective action before a contaminated plume migrates into overlying and underlying aquifers and in areas located down-gradient from ISR facilities, thus reducing the risk of exposure to hazardous constituents. Reducing the risk of contamination of groundwater also protects the surface water bodies to which affected aquifers discharge. By combining sufficient duration of stability monitoring with hydrogeological and geochemical modeling and other analyses to demonstrate that groundwater constituent concentration standards will continue to be met, the proposal would reduce the risk that such migration of constituents above constituent concentration standards might occur after the ISR site is decommissioned and its license terminated.

Finally, the proposed standards would reduce or avoid the costs of remediating contaminated groundwater by reducing the potential for groundwater contamination to occur and by causing any contamination that does occur to be discovered and remedied sooner than would be the case if the new standards were not issued. The costs incurred for cleaning up a plume of contamination may be significant. To illustrate the potential magnitude of the benefits associated with reduced or avoided remediation costs, the EPA compared remediation costs for a model facility under two scenarios: One without the proposed rule and one with the proposed rule. The difference in the total pump and treat remediation under the two scenarios illustrates the cost savings that could result from the rule for this hypothetical contamination episode. Using this approach, the EPA was able to illustrate the benefits of the proposed rule to be between \$23.7 million and \$608 million in avoided remediation costs over the entire remediation period for a single plume, including capital/well development costs and annual costs. The EPA was unable to estimate the potential avoided costs of remediation that would result from the proposed rule on a national scale because the EPA could not predict the number of incidents of groundwater contamination that would require remediation with and without the rule, or how long it would take for the groundwater contamination to be detected. However, the avoided remediation costs of this rule at the national level could be substantial based

on the estimated avoided remediation costs for a single model plume. The EPA requests comment on this approach. For additional information regarding the methodology used to estimate avoided costs, see section 4.2.3 in the document titled, "Economic Analysis: Revisions to the Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings Rule (40 CFR part 192)," available in Docket ID No. EPA-HQ-OAR-2012-0788.

VI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the OMB for review. This action is considered a significant regulatory action because it may "raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order." Accordingly, the EPA has described the need for the proposal, prepared an economic analysis of the potential costs and benefits associated with this action, considered non-regulatory approaches, and submitted the rule to OMB for review. The economic and benefits analysis is contained in the document "Economic Analysis: Final Revisions to the Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings Rule (40 CFR part 192)," December 2016, available in the docket for this action. Any changes made in response to OMB recommendations have been documented in the docket.

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the provisions of the PRA because it does not impose any reporting requirements on affected facilities.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are small businesses with fewer than 250 employees that are primarily engaged in leaching or beneficiation of uranium, radium or vanadium ores as defined by NAICS code 212291. No small organizations or small governmental entities have been identified that would be impacted by this proposed rulemaking.

The Agency has determined that the seven small firms owning ISR facilities may experience an impact to average estimated annualized costs of between 0.66 percent and 2.78 percent of average company sales, with one firm expected to have a cost-to-sales ratio of below 1 percent, three firms between 1 percent and 2 percent, and three between 2 percent and 3 percent. Details of this analysis are presented in the technical document titled, "Economic Analysis: Revisions to the Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings Rule (40 CFR part 192)," December 2016, available in the docket for this action.

D. Unfunded Mandates Reform Act (UMRA)

This proposed action does not contain an unfunded mandate of \$100 million or more as described in the UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector. This action contains no regulatory requirements or obligations that apply to small governments.

E. Executive Order 13132: Federalism

This proposed action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This proposed action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). The action imposes requirements on licensees of ISR facilities and not on tribal governments. Thus, Executive Order 13175 does not apply to this action.

Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, the EPA solicited and considered information submitted by tribal officials during the development of this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This proposed action is not subject to Executive Order 13045 because it is not an economically significant regulatory action as defined by Executive Order 12866. This action's health and risk

assessments are contained in the document titled "Ground Water Modeling Studies at In-Situ Leaching Facilities and Evaluation of Doses and Risks to Off-Site Receptors from Contaminated Ground Water" available in Docket EPA-HQ-OAR-2012-0788. The EPA evaluated several regulatory strategies for assuring groundwater restoration and stability at ISR facilities and selected the option providing greatest assurance that groundwater systems will remain in a chemically reduced state. By setting new groundwater standards, which include improved monitoring and requirements to plan for and implement corrective measures for excursions and exceedances, this proposed rule reduces children's risk of exposure to contaminated groundwater.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This proposed action is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. This action proposes standards applicable for uranium ISR facilities that do not directly impact energy supply, distribution or use. The proposed rule would increase the costs of domestic uranium producers relative to foreign producers; however, because domestic-source uranium generally constitutes between 10 percent and 15 percent of total uranium purchased by COOs of nuclear power plants, the EPA does not expect the proposed rule to have a significant impact on uranium quantities or prices available to nuclear power generators, and essentially no impact on the quantity or price of electricity. Thus, the EPA has concluded that this proposed action is not likely to have any adverse effects on productivity, competition, or prices in the energy sector.

I. National Technology Transfer and Advancement Act

This proposed rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this proposed action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).

The documentation for this decision is contained in the document titled “Ground Water Modeling Studies at In-Situ Leaching Facilities and Evaluation of Doses and Risks to Off-Site Receptors from Contaminated Ground Water” available in Docket EPA–HQ–OAR–2012–0788. The proposed rule will reduce exposure to all populations by setting new groundwater standards, which include improved monitoring and requirements for planning for and implementing corrective measures when excursions and exceedances occur at ISR facilities. By increasing the level of environmental protection for all affected populations, including minority and low-income populations, this action will have a positive impact on human health and the environment.

List of Subjects in 40 CFR Part 192

Environmental protection, Hazardous substances, Radiation protection, Radioactive materials, Reclamation, Uranium, Waste treatment and disposal, Water resources.

Dated: January 3, 2017.

Gina McCarthy,
Administrator.

For the reasons stated in the preamble, title 40, Chapter I of the Code of Federal Regulations is proposed to be amended as set forth below:

PART 192—HEALTH AND ENVIRONMENTAL PROTECTION STANDARDS FOR URANIUM AND THORIUM MILL TAILINGS

■ 1. The authority citation for 40 CFR part 192 continues to read as follows:

Authority: Sec. 275 of the Atomic Energy Act of 1954, 42 U.S.C. 2022, as added by the Uranium Mill Tailings Radiation Control Act of 1978, Pub. L. 95–604, as amended.

Subpart C—Implementation

■ 2. Section 192.20 is amended by revising paragraph (b)(3) as follows:

§ 192.20 Guidance for implementation.

* * * * *

(b) * * *

(3) Compliance with § 192.12(b) may be demonstrated by methods that the Department of Energy has approved for use or methods that the implementing agencies determine are adequate. Residual radioactive materials should be removed from buildings exceeding 0.03 WL so that future replacement buildings will not pose a hazard [unless removal is not practical, see § 192.21(c)]. However, ventilation devices and other radon mitigation methods recommended by the EPA may provide reasonable assurance of reductions from

0.03 WL to below 0.02 WL. In unusual cases, indoor radiation may exceed the levels specified in § 192.12(b) due to sources other than residual radioactive materials. Remedial actions are not required in order to comply with the standard when there is reasonable assurance that residual radioactive materials are not the cause of such an excess.

* * * * *

Subpart D [Amended]

■ 3. The heading for Subpart D is revised to read as set forth below.

■ 4. Section 192.31 is amended by revising paragraphs (a), (f), and the second sentence of paragraph (m).

The revisions read as follows:

Subpart D—Standards for the Management of Uranium Byproduct Materials

* * * * *

§ 192.31 Definitions and cross-references.

(a) Unless otherwise indicated in this subpart, all terms shall have the same meaning as in Title II of the Uranium Mill Tailings Radiation Control Act of 1978, subparts A and B of this part, or parts 190, 260, 261, and 264 of this chapter. For the purposes of this subpart, the terms “waste,” “hazardous waste” and related terms, as used in parts 260, 261, and 264 of this chapter, shall apply to byproduct material.

* * * * *

(f) *Disposal area* means the region within the perimeter of an impoundment or pile containing uranium byproduct materials to which the post-closure requirements of § 192.32(b)(1) apply.

* * * * *

(m) * * * This term shall not be construed to include extraordinary measures or techniques that would impose costs that are grossly excessive as measured by practice within the industry or one that is reasonably analogous (such as, by way of illustration only, unreasonable overtime, staffing or transportation requirements, etc., considering normal practice in the industry; laser fusion of soils, etc.), provided there is reasonable progress toward emplacement of a permanent radon barrier. * * *

* * * * *

■ 5. Section 192.32 is amended by revising paragraph (a)(2)(v) as follows:

§ 192.32 Standards.

(a) * * *

(2) * * *

(v) The functions and responsibilities designated in part 264 of this chapter as

those of the “Regional Administrator” with respect to “facility permits” shall be carried out by the regulatory agency.

* * * * *

■ 6. Part 192 is amended by adding subpart F to read as follows:

Subpart F—Public Health, Safety and Environmental Protection Standards for Byproduct Materials Produced by Uranium In-Situ Recovery

Sec.

192.50 Purpose and applicability.

192.51 Definitions and cross-references.

192.52 Standards.

192.53 Monitoring programs, modeling and other analysis.

192.54 Alternate concentration limits.

192.55 Corrective action program.

192.56 Effective date.

Subpart F—Public Health, Safety and Environmental Protection Standards for Byproduct Materials Produced by Uranium In-Situ Recovery

§ 192.50 Purpose and applicability.

(a) This rule contains standards of general application that the regulatory agency will implement and enforce to protect groundwater at in-situ uranium recovery facilities.

(b) This subpart applies to the management of uranium byproduct materials prior to, during and following the processing of uranium ores utilizing uranium in-situ recovery methods, and to the protection of groundwater at such facilities. Within three years of the effective date of this rule, the regulatory agency shall apply these standards of general application to ISR facilities licensed to process uranium byproduct material.

§ 192.51 Definitions and cross-references.

(a) Unless otherwise indicated in this subpart, all terms shall have the same meaning as in Title II of the Uranium Mill Tailings Radiation Control Act of 1978, subparts A, B, and D of this part, or parts 190, 260, 261, and 264 of this chapter.

(b) *Agreement State*. Any State with which the Nuclear Regulatory Commission (NRC) or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act.

(c) *Alternate Concentration Limit (ACL)*. An alternate concentration limit approved by the regulatory agency for a groundwater constituent after the regulatory agency determines that best practicable restoration activities have been completed and that concentrations of the constituent cannot be restored to the applicable standards in 40 CFR 192.52(c)(1)(i) or (c)(1)(ii), following the process prescribed in § 192.54.

(d) *Aquifer*. A geological formation, group of formations, or part of a formation that is capable of yielding a significant amount of water to a well or spring. See 40 CFR 144.3.

(e) *Background*. The condition of groundwater, including the radiological and non-radiological constituent concentrations, prior to the beginning of ISR operations.

(f) *Constituent*. A detectable component within the groundwater.

(g) *Constituent concentration standard*. A concentration limit for a constituent in groundwater set according to § 192.52(c)(1).

(h) *Exceedance of a constituent concentration standard*. An exceedance has occurred when, during stability monitoring, a constituent concentration standard is exceeded at any point of compliance well, as determined by the regulatory agency.

(i) *Excursion*. The movement of fluids containing lixiviant or uranium byproduct materials from the production zone into surrounding groundwater. An excursion is considered to have occurred when two indicator parameters (e.g., chloride, conductivity, total alkalinity) exceed their respective upper control limits in any excursion monitoring well, or, as determined by the regulatory agency, when one indicator parameter significantly exceeds its upper control limit in any excursion monitoring well.

(j) *Excursion Monitoring Wells*. Wells located around the perimeter of the production zone, including in overlying and underlying aquifers, which are used to detect any excursions from the production zone. These wells may also be used to demonstrate compliance with stability standards once restoration has been completed.

(k) *Extraction Well*. Well used to extract uranium enriched solutions from the ore-bearing aquifer; also known as a production well. Extraction and injection wells may be converted from one use to the other.

(l) *Indicator Parameter*. A constituent, such as chloride, conductivity or total alkalinity, whose upper control limit is used to identify an excursion. Indicator parameters are not necessarily contaminants, but relate to geochemical conditions in groundwater.

(m) *Initial Stability Phase*. The period immediately following the restoration phase when the wellfield is monitored to determine if and when the initial stability standards are met. This is the period in which provisional alternate concentration limits may be established and implemented, if necessary.

(n) *Injection Well*. A well into which fluids are being injected. See 40 CFR 144.3.

(o) *In-Situ Recovery (ISR)*. A method by which uranium is leached from underground ore bodies by the introduction of a solvent solution, called a lixiviant, through injection wells drilled into the ore body. The process does not require the extraction of ore from the ground. The lixiviant is injected, passes through the ore body, and mobilizes the uranium; the uranium-bearing solution is pumped to the surface via extraction wells. The pregnant leach solution is processed to extract the uranium.

(p) *Listed Constituent*. One of the twelve groundwater constituents specified in Table 1 to this subpart.

(q) *Lixiviant*. A liquid medium used to recover uranium from underground ore bodies through in-situ recovery. This liquid medium typically contains native groundwater and an added oxidant, such as oxygen or hydrogen peroxide, as well as sodium carbonate, sodium bicarbonate or carbon dioxide.

(r) *Long-Term Stability Phase*. The period after the constituent concentration standards have been met and initial stability has been demonstrated according to § 192.52(c)(2), as determined by the regulatory agency. The regulatory agency sets the extent of time the facility remains in the long-term stability phase.

(s) *Maximum Constituent Concentration*. The maximum permissible level of a constituent in groundwater, as established under § 192.52(c)(1).

(t) *Maximum Contaminant Level (MCL)*. The maximum permissible level of a contaminant in water delivered to any user of a community water system. See 40 CFR 141.2.

(u) *Monitoring Wells*. Wells used to obtain groundwater levels and water samples for the purpose of determining the hydrogeological regime and the amounts, types and distribution of constituents in the groundwater. Wells are located in the production zone, around the perimeter of the production zone and in overlying and underlying aquifers.

(v) *Operational Phase*. The time period during which uranium recovery occurs. Operation begins when extraction begins and lixiviant is injected. Operation ends when the operator permanently ceases injection of lixiviant and recovery of uranium-bearing solution for processing purposes. The operational phase includes periods during which the ISR temporarily ceases uranium recovery

(i.e., when the ISR is in “stand-by” mode) but the ISR still needs to maintain appropriate groundwater controls to prevent contaminants from leaving the production zone.

(w) *Overlying Aquifer*. An aquifer that is immediately vertically shallower than (i.e., directly above) the production zone aquifer.

(x) *Point(s) of Compliance*. Locations where groundwater protection standards are generally applied. The regulatory agency reviews and approves the location of points of compliance for the wellfield. During all phases of ISR, points of compliance should include excursion monitoring well locations; during the initial and long-term stability phases, points of compliance should also include wells in the production zone.

(y) *Point(s) of Exposure*. Used in setting ACLs, points of exposure are locations identified by the regulatory agency that represent possible future areas of exposure where the receptor can come into contact with groundwater (e.g., areas of recoverable groundwater). The groundwater at that point of exposure must be protective of the receptor.

(z) *Preoperational Monitoring*. Measurement of groundwater conditions in the production zone, up and down gradient of the production zone and in overlying and underlying aquifers, when present. Preoperational monitoring plans are subject to approval by the regulatory agency prior to the operational phase.

(aa) *Production Zone*. The portion of the aquifer in which in-situ recovery occurs. The production zone lies within the wellfield.

(bb) *Regulatory Agency*. The NRC or an Agreement State.

(cc) *Restoration (Act of)*. The process of remediating groundwater to a state where it meets the constituent concentration standards listed in 40 CFR 192.52(c)(1).

(dd) *Restoration Phase*. The period immediately after lixiviant injection permanently ceases, during which restoration activities occur.

(ee) *Underlying Aquifer*. An aquifer that is immediately vertically deeper (i.e., directly below) than the production zone aquifer.

(ff) *Upper Control Limit (UCL)*. Upper control limits are maximum concentrations for excursion indicator parameters that, when exceeded, indicate lixiviant or other constituents are migrating beyond the production zone.

(gg) *Uranium Recovery Facility*. A facility licensed to process uranium ores primarily for the purpose of recovering

uranium (and/or thorium) and to manage uranium (and/or thorium) byproduct materials that result from processing of ores. Common names for these facilities include, but are not limited to, the following: A conventional uranium mill, an in-situ recovery (or leach) facility, and a heap leach facility or pile.

(hh) *Wellfield*. The area of an ISR operation that encompasses the array of injection, extraction and monitoring wells, ancillary equipment and interconnected piping employed in the uranium in-situ recovery process. The area of the wellfield exceeds that of the production zone.

§ 192.52 Standards.

(a) No later than three years after the effective date of this rule, all operating wellfields, new wellfields and expansions of wellfields at ISR facilities must meet the standards in this section. These standards do not apply to those wellfields at licensed ISR facilities that, within three years of the effective date of this rule, are in and remain in the restoration, initial stability monitoring or long-term stability monitoring phases.

(b) *Surface impoundments*. (1) Surface impoundments associated with ISR activities shall conform to the standards of § 192.32.

(2) Disposal of solid uranium byproduct materials produced by ISR activities shall conform to the standards in § 192.32.

(c) *Groundwater protection standards*. The constituent concentration standards, in paragraph (c)(1) of this section, must be met after restoration or corrective action and are also incorporated into the initial and long-term stability standards. The initial stability standards, in paragraph (c)(2) of this section, are a measure of the effectiveness of restoration and must be met prior to meeting the long-term stability standards. The long-term stability standards, in paragraph (c)(3) of this section, must be met prior to decommissioning and termination of the ISR facility's license.

(1) *Constituent concentration standards*. The licensee shall propose and the regulatory agency shall review and approve constituent concentration standards for each of the constituents listed in Table 1 to this subpart that are identified by the licensee and approved by the regulatory agency as being

present or affected by operations in the production zone. The limit for each constituent is the highest level of the following values:

(i) That constituent's preoperational background level in and around the wellfield, as determined by preoperational monitoring conducted under § 192.53(a); or

(ii) the lowest regulatory standard for that constituent found in 40 CFR 141.61, 141.62, 141.66, 141.80, 143.3, 264.94, or Table 1 of subpart A of this part. For any constituent not listed in Table 1 to this subpart, but designated by the regulatory agency for monitoring, a constituent concentration standard at or above the background level should be established from the values in 40 CFR parts 141, 143 or 264, if such values exist. For a constituent not found in 40 CFR parts 141, 143 or 264, the constituent concentration standard above the background level should be established at a concentration level that represents a cumulative excess lifetime risk no greater than 10^{-4} to an average individual;

(iii) an alternate concentration limit for that constituent as approved by the regulatory agency under § 192.54.

TABLE 1 TO SUBPART F—MAXIMUM CONCENTRATION OF CONSTITUENTS FOR GROUNDWATER PROTECTION AT ISR FACILITY SITES

| Constituent | Maximum concentration |
|---|---|
| Arsenic, Barium, Cadmium, Chromium, Lead, Mercury, Selenium, Silver, Nitrate (as N), Molybdenum, Radium-226 and radium-228 (combined), Uranium (uranium-234, uranium-235 and uranium-238 combined). | The constituent concentration standard is the primary or secondary MCL listed in 40 CFR 141.61, 141.62, 141.66, 141.80, and 143.3, the maximum concentration of hazardous constituents for groundwater protection under 40 CFR 264.94, or the maximum constituent concentration specified in Table 1 to subpart A of this part, whichever value is the lowest. Where a background concentration is determined to be higher than the lowest value in the applicable regulations, the background concentration will serve as the constituent concentration standard. |

(2) *Initial Stability Standards*. The licensee must demonstrate to the satisfaction of the regulatory agency that groundwater conditions are stable by showing three consecutive years of quarterly monitoring results with no statistically significant increasing trends that would exceed the constituent concentration standards at the 95 percent confidence level. This showing shall be based on monitoring data collected in accordance with § 192.53(c).

(3) *Long-term Stability Standards*. After meeting the initial stability standards in paragraph (c)(2) of this section, the licensee must demonstrate to the satisfaction of the regulatory agency that groundwater conditions will

remain stable into the future by showing:

(i) Three consecutive years of quarterly monitoring results demonstrating no statistically significant increasing trends that would exceed the constituent concentration standards at the 95 percent confidence level. This showing shall be based on monitoring data collected in accordance with the § 192.53(d); and

(ii) the applicable constituent concentration standards will continue to be met into the future. This showing shall be based on the information collected under § 192.53(d), including monitoring data, geochemical modeling, and other analysis required by the regulatory agency.

§ 192.53 Monitoring programs, modeling and other analysis.

Licensees subject to this subpart must conduct a groundwater monitoring program, subject to review and approval by the regulatory agency, at prospective and licensed ISR wellfields. The components of the program include preoperational monitoring to determine statistically valid background levels, excursion monitoring to identify and correct excursions, and initial and long-term stability monitoring. This program shall address all phases of the uranium recovery activities and must be conducted as follows:

(a) *General monitoring program requirements and preoperational monitoring*.

(1) A sufficient number of wells, at appropriate locations and depths, shall

be installed in such a manner as to yield representative samples in order to define the groundwater flow regime and measure preoperational conditions and water quality during background determination, operations, restoration, initial stability and long-term stability.

(2) All monitoring wells must be installed and developed as directed by the regulatory agency to maintain well integrity, allow for accurate sample collection and prevent contamination of samples.

(3) The preoperational monitoring shall include the production zone and areas immediately surrounding the production zone, as identified by the regulatory agency, including up- and down-gradient areas outside of the production zone.

(4) During the preoperational monitoring effort, relevant data documenting geology, hydrology and geochemistry for radiological and non-radiological constituents shall be collected as required by the regulatory agency, both in the production zone and in surrounding areas that may be affected by the ISR operations.

(i) The monitoring effort shall be of sufficient scope and duration to adequately characterize temporal (e.g., no less than one year where seasonal variation is expected) and spatial variations in groundwater, using statistically valid approaches to evaluate groundwater quality trends and ensure adequate background characterization of the wellfield and adjacent areas. If monitoring is to be conducted for less than one year, it must be sufficient to demonstrate that the measured constituents do not reflect impacts associated with well construction.

(ii) Preoperational monitoring shall be focused on determining background concentrations of constituents and indicator parameters in the following locations:

(A) Points of compliance within the proposed production zone; and

(B) Points of compliance outside the production zone including point of compliance screened in potentially affected overlying and underlying aquifers (when present); and points of compliance screened in upgradient and downgradient aquifers (when present).

(5) The licensee shall employ appropriate statistical techniques to analyze background concentrations measured in individual wells within the wellfield and in any other wells identified by the regulatory agency for the purpose of determining constituent concentration standards. Background concentrations used to establish the constituent concentration standards may be representative of individual

wells, multiple wells, or all wells within the proposed production zone and are subject to review and approval by the regulatory agency.

(6) Radiological and non-radiological constituents to be monitored during the preoperational phase shall include:

(i) All constituents listed in Table 1 of this subpart;

(ii) Constituents and parameters as determined by the regulatory agency to be necessary to characterize the geochemistry of the groundwater and to demonstrate that the applicable constituent concentration standards have been met and will continue to be met into the future; and

(iii) Any additional constituents or parameters required by the regulatory agency, such as metals potentially mobilized by the recovery process.

(b) *Excursion Monitoring.*

(1) Indicator parameters, as established by the regulatory agency, shall be monitored in excursion monitoring wells surrounding the production zone, including aquifers above and below the production zone, at a minimum throughout the operational and restoration phases of ISR activities.

(2) If an excursion is detected as evidenced by indicator parameters exceeding established upper control limits, as determined by the regulatory agency, corrective action under § 192.55 must be initiated and constituents listed in Table 1 of this subpart expected to be present (e.g., uranium, radium, arsenic, and selenium) and any other constituent identified by the regulating agency shall be monitored until the excursion is controlled.

(c) *Initial Stability Monitoring.*

(1) Once the regulatory agency determines restoration is complete, the licensee shall begin its initial stability monitoring as described in paragraphs (c)(2), (3), and (4) of this section to meet its initial stability standards as described in § 192.52(c)(2).

(2) The constituents to be monitored at the points of compliance shall include:

(i) All constituents having a constituent concentration standard and expected to be present, as determined by the regulatory agency under § 192.52(c)(1);

(ii) Any additional constituents required by the regulatory agency, such as:

(A) Constituents and parameters necessary to characterize the geochemistry of the groundwater and other analysis to demonstrate that the applicable constituent concentration standards have been met and will continue to be met into the future;

(B) Components of the lixiviant fluids injected during uranium recovery and any fluids injected during restoration; or

(C) Metals potentially mobilized by the uranium recovery process that could reasonably be expected to be found in the groundwater.

(3) If the licensee finds that the initial stability standard in § 192.52(c)(2) cannot be demonstrated for one or more constituents, the regulatory agency may:

(i) Require the licensee to resume active restoration efforts; or

(ii) After all best practicable active restoration activities have been completed, establish a provisional alternate concentration limit according to the requirements of § 192.54. Once initial stability according to the standard in § 192.52(c)(2) at the provisional alternate concentration limit has been documented, the regulatory agency may establish a final alternate concentration limit according to the requirements of § 192.54.

(4) If the regulatory agency determines that a constituent exceeds a constituent concentration standard in § 192.52(c)(1) at a point of compliance, the licensee, as directed by the regulatory agency, must undertake corrective action under § 192.55 until the regulatory agency determines that the exceedance of the constituent concentration standard is adequately remedied.

(d) *Long-term stability monitoring, modeling and other analysis.*

(1) Once the regulatory agency determines the initial stability standards have been met, the licensee shall begin conducting long-term stability monitoring as described in paragraph (d)(2) of this section to demonstrate it meets its long-term stability standards, established under § 192.52(c)(3).

(2) The constituents to be monitored at the points of compliance shall include:

(i) All constituents having a constituent concentration standard expected to be present, as determined by the regulatory agency under § 192.52(c)(1);

(ii) Any additional constituents required by the regulatory agency, such as:

(A) Constituents and parameters necessary to characterize the geochemistry of the groundwater and modeling and other analysis to demonstrate that the applicable constituent concentration standards have been met and will continue to be met into the future;

(B) Components of the lixiviant fluids injected during uranium recovery and any fluids injected during restoration; or

(C) Metals potentially mobilized by the uranium recovery process that could

reasonably be expected to be found in the groundwater.

(3) If the regulatory agency finds that one or more constituents at a point of compliance within the wellfield exceeds a constituent concentration standard as defined in § 192.52(c)(1) then, as directed by the regulatory agency, the licensee must undertake corrective action under § 192.55 until the regulatory agency determines that the exceedance of the constituent concentration standard(s) is adequately remedied.

(4) If the licensee finds that the long-term stability standard in § 192.52(c)(3) cannot be demonstrated for one or more constituents, the regulatory agency may:

(i) Require the licensee to resume active restoration efforts; or

(ii) After all best practicable active restoration activities have been completed, establish an alternate concentration limit according to the requirements of § 192.54.

(5) In addition to the long-term stability monitoring requirements described in paragraph (d)(2) of this section, the licensee must provide to the regulatory agency geochemical modeling and other analysis sufficient to demonstrate that the long-term stability standard in § 192.52(c)(3) has been met.

(6) The licensee must continue its long-term stability monitoring until the regulatory agency determines that the long-term stability standard in § 192.52(c)(3) has been met and releases the facility from monitoring.

§ 192.54 Alternate Concentration Limits.

(a) *Provisional Alternate Concentration Limits.* The regulatory agency may establish a provisional alternate concentration limit within the production zone for any constituent that meets the following conditions:

(1) The regulatory agency determines that all best practicable active restoration activities have been completed in accordance with the license, and that the previously approved constituent concentration standard under § 192.52(c)(1)(i) or (ii) are not reasonably achievable; and

(2) The constituent will not pose a substantial present or potential hazard to human health or the environment as long as the provisional alternate concentration limit is not exceeded; and

(3) The constituent concentration standard, as determined under paragraph (c)(1) of this section, is satisfied at all points of exposure in the wellfield and in surrounding aquifers.

(b) *Final Alternate Concentration Limits.* The regulatory agency may approve a final alternate concentration

limit provided that the following conditions are met:

(1) The licensee has demonstrated initial groundwater stability as defined in § 192.52(c)(2); and (2) The constituent will not pose a substantial present or potential future hazard to human health or the environment as long as the final alternate concentration limit is not exceeded.

(c) In deciding whether to approve a provisional or a final alternate concentration limit, the regulatory agency shall consider, at a minimum, the following factors:

(1) Potential adverse effects on groundwater quality, considering:

(i) The physical and chemical characteristics of constituents in the groundwater at the site, including their potential for migration;

(ii) The hydrogeological characteristics (e.g., groundwater velocity) of the site and surrounding land;

(iii) The quantity of groundwater and the direction of groundwater flow;

(iv) The proximity and withdrawal rates of local groundwater users;

(v) The current and anticipated future uses of groundwater in the region surrounding the site;

(vi) The existing quality of groundwater, including other sources of contamination and their cumulative impact on groundwater quality;

(vii) The potential for health risks caused by human exposure to constituents;

(viii) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to constituents; and

(ix) The persistence and permanence of the potential adverse effects.

(2) Potential adverse effects on hydraulically-connected surface-water quality, considering:

(i) The volume and physical and chemical characteristics of the groundwater at the site;

(ii) The hydrogeological characteristics of the site and surrounding land;

(iii) The quantity and quality of groundwater, and the direction of groundwater flow;

(iv) The patterns of rainfall in the region;

(v) The proximity of the site to surface waters;

(vi) The current and future uses of surface waters in the region surrounding the site and any water quality standards established for those surface waters;

(vii) The existing quality of hydraulically-connected surface water, including other sources of contamination and their cumulative impact on surface water quality;

(viii) The potential for health risks caused by human exposure to constituents;

(ix) The potential damage to wildlife, crops, vegetation, and physical structures caused by exposure to constituents; and

(x) The persistence and permanence of the potential adverse effects.

(3) The presence of any underground source of drinking water.

§ 192.55 Corrective action program.

(a) A corrective action program shall be developed by the licensee and approved by the regulatory agency for each ISR site at the time of licensing. The plan shall address a range of possible scenarios (e.g., types and routes of potential excursions) and list options for corrective action for operational through long-term stability phases. If an excursion is detected at a licensed ISR facility at any time, a constituent concentration standard is exceeded during the initial or long-term stability phases, or the regulatory agency is concerned about an increasing trend in stability monitoring results, the applicable portions of the corrective action program shall be initiated as soon as is practicable, and in no event later than 60 days after such an occurrence. With the objective of returning constituent concentration levels in groundwater to the constituent concentration standards established under § 192.52(c)(1), the corrective action program shall address removing constituents at the point of compliance or treating them in place.

(b) The licensee shall continue corrective action measures to the extent necessary to achieve and maintain compliance with the constituent concentration standards in § 192.52(c)(1). The regulatory agency will determine when the licensee may terminate corrective action measures based on data from the groundwater monitoring program and other information that provides reasonable assurance that the constituent concentration standards in § 192.52(c)(1) will not be exceeded.

(c) Upon termination of any corrective action initiated during long-term stability monitoring, the licensee shall then be subject to the initial and long-term stability standards specified in § 192.53(c)(2) and (3).

§ 192.56 Effective date.

Subpart F shall be effective on [60 DAYS AFTER DATE OF PUBLICATION OF FINAL RULE IN **FEDERAL REGISTER**].

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Environmental Protection Agency

40 CFR Part 751

Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing Under
TSCA Section 6(a); Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 751

[EPA-HQ-OPPT-2016-0387; FRL-9950-08]

RIN 2070-AK11

Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing Under TSCA Section 6(a)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Trichloroethylene (TCE) is a volatile organic compound widely used in industrial and commercial processes and has some limited uses in consumer and commercial products. EPA identified significant health risks associated with TCE use in vapor degreasing and EPA's proposed determination is that these risks are unreasonable risks. To address these unreasonable risks, EPA is proposing under section 6 of the Toxic Substances Control Act (TSCA) to prohibit the manufacture (including import), processing, and distribution in commerce of TCE for use in vapor degreasing; to prohibit commercial use of TCE in vapor degreasing; to require manufacturers, processors, and distributors, except for retailers of TCE for any use, to provide downstream notification of these prohibitions throughout the supply chain; and to require limited recordkeeping.

DATES: Comments must be received on or before March 20, 2017.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2016-0387, at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the Web, cloud, or other file sharing system). For additional submission methods (*e.g.*, mail or hand delivery), the full EPA public comment policy, information about CBI or multimedia submissions,

and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

Docket. Docket ID No. EPA-HQ-OPPT-2016-0387 contains supporting information used in developing the proposed rule, comments on the proposed rule, and additional supporting information. In addition to being available online at <http://www.regulations.gov>, the docket is available for inspection and copying between 8:30 a.m. and 4:30 p.m., Monday through Friday, excluding federal holidays, at the U.S. Environmental Protection Agency, EPA Docket Center Reading Room, WJC West Building, Room 3334, 1301 Constitution Avenue NW., Washington, DC 20004. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Cindy Wheeler, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 566-0484; email address: wheeler.cindy@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this proposed action if you manufacture (defined under TSCA to include import), process, or distribute in commerce TCE or commercially use TCE in vapor degreasers. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Petroleum Refineries (NAICS code 324110).
- Petroleum Lubricating Oil and Grease Manufacturing (NAICS code 324191).
- Petrochemical Manufacturing (NAICS code 325110).
- Industrial Gas Manufacturing (NAICS code 325120).
- Other Basic Inorganic Chemical Manufacturing (NAICS code 325180).
- All Other Basic Organic Chemical Manufacturing (NAICS code 325199).

- Plastics Material and Resin Manufacturing (NAICS code 325211).
- Synthetic Rubber Manufacturing (NAICS code 325212).
- Paint and Coating Manufacturing (NAICS code 325510).
- Adhesive Manufacturing (NAICS code 325520).
- Soap and Other Detergent Manufacturing (NAICS code 325611).
- Polish and Other Sanitation Good Manufacturing (NAICS code 325612).
- All Other Miscellaneous Chemical Product and Preparation Manufacturing (NAICS code 325998).
- Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing (NAICS code 326113).
- All Other Plastics Product Manufacturing (NAICS code 326199).
- Rubber and Plastics Hoses and Belting Manufacturing (NAICS code 326220).
- All Other Rubber Product Manufacturing (NAICS code 326299).
- Cement Manufacturing (NAICS code 327310).
- Ground or Treated Mineral and Earth Manufacturing (NAICS code 327992).
- Iron and Steel Pipe and Tube Manufacturing from Purchased Steel (NAICS code 331210).
- Steel Wire Drawing (NAICS code 331222).
- Copper Rolling, Drawing, Extruding, and Alloying (NAICS code 331420).
- Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing, and Extruding (NAICS code 331491).
- Nonferrous Metal Die-Casting Foundries (NAICS code 331523).
- Powder Metallurgy Part Manufacturing (NAICS code 332117).
- Metal Crown, Closure, and Other Metal Stamping (except Automotive) (NAICS code 332119).
- Saw Blade and Hand Tool Manufacturing (NAICS code 332216).
- Metal Window and Door Manufacturing (NAICS code 332321).
- Power Boiler and Heat Exchanger Manufacturing (NAICS code 332410).
- Other Fabricated Wire Product Manufacturing (NAICS code 332618).
- Machine Shops (NAICS code 332710).
- Precision Turned Product Manufacturing (NAICS code 332721).
- Bolt, Nut, Screw, Rivet, and Washer Manufacturing (NAICS code 332722).
- Metal Heat Treating (NAICS code 332811).
- Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers (NAICS code 332812).

- Electroplating, Plating, Polishing, Anodizing, and Coloring (NAICS code 332813).
- Oil and Gas Field Machinery and Equipment Manufacturing (NAICS code 333132).
- Cutting Tool and Machine Tool Accessory Manufacturing (NAICS code 333515).
- Small Arms, Ordnance, and Ordnance Accessories Manufacturing (NAICS code 332994).
- Fluid Power Pump and Motor Manufacturing (NAICS code 333996).
- All Other Miscellaneous Fabricated Metal Product Manufacturing (NAICS code 332999).
- Oil and Gas Field Machinery and Equipment Manufacturing (NAICS code 333132).
- Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing (NAICS code 333413).
- Cutting Tool and Machine Tool Accessory Manufacturing (NAICS code 333515).
- Pump and Pumping Equipment Manufacturing (NAICS code 333911).
- Fluid Power Pump and Motor Manufacturing (NAICS code 333996).
- Search, Detection, Navigation, Guidance, Aeronautical, and Nautical System and Instrument Manufacturing (NAICS code 334511).
- Automatic Environmental Control Manufacturing for Residential, Commercial, and Appliance Use (NAICS code 334512).
- Motor and Generator Manufacturing (NAICS code 335312).
- Primary Battery Manufacturing (NAICS code 335912).
- Carbon and Graphite Product Manufacturing (NAICS code 335991).
- Motor Vehicle Brake System Manufacturing (NAICS code 336340).
- Aircraft Manufacturing (NAICS code 336411).
- Other Aircraft Parts and Auxiliary Equipment Manufacturing (NAICS code 336413).
- Guided Missile and Space Vehicle Manufacturing (NAICS code 336414).
- Ship Building and Repairing (NAICS code 336611).
- Dental Equipment and Supplies Manufacturing (NAICS code 339114).
- Other Chemical and Allied Products Merchant Wholesalers (NAICS code 424690).
- Petroleum Bulk Stations and Terminals (NAICS code 424710).
- Hazardous Waste Treatment and Disposal (NAICS code 562211).
- Solid Waste Combustors and Incinerators (NAICS code 562213).

This action may also affect certain entities through pre-existing import certification and export notification

rules under TSCA. Persons who import any chemical substance governed by a final TSCA section 6(a) rule are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines after risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk.

For a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which a completed risk assessment was published prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, TSCA section 26(l)(4) expressly authorizes EPA to issue rules under TSCA section 6(a) that are consistent with the scope of the completed risk assessment and consistent with the other applicable requirements of TSCA section 6. TCE is such a chemical substance. It is listed in the 2014 update to the TSCA Work Plan and the completed risk assessment was published on June 25, 2014. The scope of the completed risk assessment includes vapor degreasing.

C. What action is the Agency taking?

EPA's proposed determination is that the use of TCE in vapor degreasing presents an unreasonable risk of injury

to health. Accordingly, EPA is proposing under TSCA section 6 to prohibit the manufacture (including import), processing, and distribution in commerce of TCE for use in vapor degreasing; to prohibit commercial use of TCE in vapor degreasing; and to require manufacturers, processors, and distributors, except for retailers, to provide downstream notification of this prohibition throughout the supply chain (e.g., via a Safety Data Sheet (SDS)), and to keep records. The application of this supply chain approach is necessary so that TCE no longer presents the identified unreasonable risks. EPA is requesting public comment on this proposal.

This proposal is related to the proposed rule on TCE aerosol degreasing and spot cleaning in dry cleaning facilities that published in the **Federal Register** on December 16, 2016 (81 FR 91592) (FRL-9949-86) (Ref. 1). This proposal and the earlier proposal together address risks for workers and consumers associated with exposure to TCE through inhalation that were identified in the 2014 TCE risk assessment and EPA intends to finalize both actions together.

D. Why is the Agency taking this action?

Based on EPA's analysis of worker exposures to TCE, EPA's proposed determination is that the use of TCE in vapor degreasing presents an unreasonable risk to human health. More specifically, this use results in significant non-cancer risks under both acute and chronic exposure scenarios and significant cancer risks from chronic exposures. These adverse health effects include those resulting from developmental toxicity (e.g., cardiac malformations, developmental immunotoxicity, developmental neurotoxicity, fetal death), toxicity to the kidney (kidney damage and kidney cancer), immunotoxicity (such as systemic autoimmune diseases, e.g., scleroderma, and severe hypersensitivity skin disorder), non-Hodgkin's lymphoma, reproductive and endocrine effects (e.g., decreased libido and potency), neurotoxicity (e.g., trigeminal neuralgia), and toxicity to the liver (impaired functioning and liver cancer) (Ref. 2). TCE may cause fetal cardiac malformations that begin in utero. Cardiac malformations can be irreversible and impact a person's health for a lifetime. In addition, fetal death, possibly resulting from cardiac malformation, can be caused by exposure to TCE. In utero exposure to TCE may cause other effects, such as damage to the developing immune system, which manifest later in adult

life and can have long-lasting health impacts. Certain effects that follow adult exposures, such as kidney and liver cancer, may develop many years after initial exposure.

As discussed in Unit I.C., EPA is not proposing to prohibit all manufacturing, processing, distribution in commerce, and use of TCE. As such, the application of this proposal's supply chain approach tailored to specific uses that present unreasonable risks to human health is necessary so that the chemical substance no longer presents the identified unreasonable risks.

E. What are the estimated incremental impacts of this action?

EPA has evaluated the potential costs of multiple regulatory options, including the proposed approach of prohibiting the manufacture (including import), processing, and distribution in commerce of TCE for use in vapor degreasing; prohibiting the commercial use of TCE in vapor degreasing; and requiring manufacturers, processors, and distributors, except for retailers, to provide downstream notification of these prohibitions throughout the supply chain as well as associated recordkeeping requirements. This analysis (Ref. 3), which is available in the docket, is discussed in Unit VI., and is briefly summarized here.

Alternatives to TCE with similar performance characteristics are readily available. Most of the costs of the rule would be borne by commercial users of TCE in vapor degreasing equipment, because they would have to switch solvents and likely equipment as well. EPA has estimated that the costs to users range from \$30M to \$45M when annualized over 20 years at a 3% discount rate, and from \$32M to \$46M over 20 years at a 7% discount rate. These are the total estimated costs of this proposal. The costs of the downstream notification and recordkeeping requirements to manufacturers, processors, and distributors of TCE, estimated to be approximately \$3,200 and \$4,400 annualized over 20 years using 3% and 7% discount rates respectively. For additional information see Unit 5.1.3 of the Economic Analysis. (Ref. 3) However, because these notification and recordkeeping costs were already accounted for in the economic analysis accompanying the earlier TCE proposal (Ref. 1), they are not included in the total costs for this proposal. EPA accounted for these costs in the prior proposal because it believes the universe of entities distributing TCE for both sets of uses are the same. EPA is taking comment on whether the same

firms distribute TCE for these two sets of uses.

Although TCE causes a wide range of non-cancer adverse effects and cancer, monetized benefits included only benefits associated with reducing cancer risks. The Agency does not have sufficient information to include a quantification or valuation estimate for non-cancer benefits in the overall benefits at this time. The monetized benefits for the proposed approach range from approximately \$65 to \$443 million on an annualized basis over 20 years at 3% and \$31 million to \$225 million at 7% (Ref. 3). The non-monetized benefits resulting from the prevention of the non-cancer adverse effects associated with TCE exposure from use in vapor degreasers include developmental toxicity, toxicity to the kidney, immunotoxicity, reproductive and endocrine effects, neurotoxicity, and toxicity to the liver (Ref. 2). Some of the effects that can be caused by exposure to TCE, such as cardiac malformations and fetal death, occur in utero and can impact a person for a lifetime; other effects, such as damage to the developing immune system, may first manifest when a person is an adult and can have long lasting impacts. Also see Unit VI.D.

F. Children's Environmental Health

This action is consistent with the 1995 EPA Policy on Evaluating Health Risks to Children (<http://www.epa.gov/children/epas-policy-evaluating-risk-children>). EPA has identified women of childbearing age and the developing fetus as a susceptible subpopulation relevant to its risk assessment for TCE. After evaluating the developmental toxicity literature for TCE, the Integrated Risk Information System (IRIS) TCE assessment concluded that fetal heart malformations are the most sensitive developmental toxicity endpoint associated with TCE inhalation exposure (Ref. 4). In its TSCA Chemical Work Plan Risk Assessment for TCE, EPA identified developmental toxicity as the most sensitive endpoint for TCE inhalation exposure (*i.e.*, fetal heart malformations) for the most sensitive human life stage (*i.e.*, women of childbearing age between the ages of 16 and 49 years and the developing fetus) (Ref. 2). EPA used developmental toxicity endpoints for both the acute and chronic non-cancer risk assessments based on its developmental toxicity risk assessment policy that a single exposure of a chemical within a critical window of fetal development may produce adverse developmental effects (Ref. 5). For the identified susceptible subpopulations, the

proposed regulatory action is protective of the fetal heart malformation endpoint and, for the exposed population as a whole, the proposal is also protective of cancer risk. In addition, the supporting non-cancer risk analysis of children and women of childbearing age conducted in the TSCA Chemical Work Plan Risk Assessment for TCE (Ref. 2) also meets the 1995 EPA Policy on Evaluating Health Risks to Children (Ref. 6). Supporting information on TCE exposures and the health effects of TCE exposure on children are also available in the IRIS Toxicological Review of Trichloroethylene (Ref. 4) and the TSCA Chemical Work Plan Risk Assessment on Trichloroethylene (Ref. 2), as well as Unit VI of this preamble.

II. Overview of TCE and the Use Subject to This Proposed Rule

A. What chemical is included in the proposed rule?

This proposed rule applies to TCE (Chemical Abstract Services Registry Number 79-01-6) for use in vapor degreasing.

B. What are the uses of TCE?

In 2011, global consumption of TCE was 945 million pounds and consumption in the United States was 255 million pounds. TCE is produced within and imported into the United States. Nine companies, including domestic manufacturers and importers, reported a total production and import of 225 million pounds of TCE in 2011 to EPA pursuant to the Chemical Data Reporting (CDR) rule (Ref. 2).

The majority (about 83.6%) of TCE is used as an intermediate chemical for manufacturing refrigerant HFC-134a. This use occurs in a closed system that has low potential for human exposure (Ref. 2). EPA did not assess this use and is not proposing to regulate this use of TCE under TSCA at this time. However, this does not mean that EPA found that this use or other uses not included in the TCE risk assessment present low risk. Much of the remainder, about 14.7%, is used as a solvent for degreasing of metals. A relatively small percentage, about 1.7%, accounts for all other uses, including TCE use in products, such as aerosol degreasers.

Based on the Toxics Release Inventory (TRI) data for 2012, 38 companies used TCE as a formulation component, 33 companies processed TCE by repackaging the chemical, 28 companies used TCE as a manufacturing aid, and 1,113 companies used TCE for ancillary uses, such as degreasing (Ref. 2). Based on the latest TRI data from 2014, the number of users of TCE has significantly

decreased since 2012: 24 companies use TCE as a formulation component, 20 companies process TCE by repackaging the chemical, 20 companies use TCE as a manufacturing aid, and 97 companies use TCE for ancillary uses, such as degreasing. The TRI data does not represent all of the facilities manufacturing, processing, and/or using TCE because only certain industries and types of facilities are required to report. EPA estimates that there are 2,632 to 6,232 firms using TCE for vapor degreasing in the U.S. (Ref. 3).

The use assessed by EPA that is the subject of this proposal, commercial use of TCE in vapor degreasing, is estimated to represent up to 14.7% of total use of TCE. This use is discussed in detail in Unit VI.

C. What are the potential health effects of TCE?

A broad set of relevant studies including epidemiologic studies, animal bioassays, metabolism studies, and mechanistic studies show that TCE exposure is associated with an array of adverse health effects. TCE has the potential to induce developmental toxicity, immunotoxicity, kidney toxicity, reproductive and endocrine effects, neurotoxicity, liver toxicity, and several forms of cancer (Ref. 2).

TCE is fat soluble (lipophilic) and easily crosses biological membranes. TCE has been found in human maternal and fetal blood and in the breast milk of lactating women (Ref. 2). EPA's IRIS assessment (Ref. 4) concluded that TCE poses a potential health hazard for non-cancer toxicity including fetal heart malformations and other developmental effects, immunotoxicity, kidney toxicity, reproductive and endocrine effects, neurotoxicity, and liver effects. The IRIS assessment also evaluated TCE and its metabolites. Based on the results of *in vitro* and *in vivo* tests, TCE metabolites have the potential to bind or induce damage to the structure of deoxyribonucleic acid (DNA) or chromosomes (Ref. 4).

An evaluation of the overall weight of the evidence of the human and animal developmental toxicity data suggests an association between pre- and/or post-natal TCE exposures and potential adverse developmental outcomes. TCE-induced heart malformations and immunotoxicity in animals have been identified as the most sensitive developmental toxicity endpoints for TCE. Human studies examined the possible association of TCE with various prenatal effects. These adverse effects of developmental TCE exposure may include: Death (spontaneous abortion, perinatal death, pre- or post-

implantation loss, resorptions); decreased growth (low birth weight, small for gestational age); congenital malformations, in particular heart defects; and postnatal effects such as reduced growth, decreased survival, developmental neurotoxicity, developmental immunotoxicity, and childhood cancers. Some epidemiological studies reported an increased incidence of birth defects in TCE-exposed populations from exposure to contaminated water. As for human developmental neurotoxicity, studies collectively suggest that the developing brain is susceptible to TCE toxicity. These studies have reported an association with TCE exposure and central nervous system birth defects and postnatal effects such as delayed newborn reflexes, impaired learning or memory, aggressive behavior, hearing impairment, speech impairment, encephalopathy, impaired executive and motor function and attention deficit disorder (Ref. 2).

Immune-related effects following TCE exposures have been observed in adult animal and human studies. In general, these effects were associated with enhanced immune response as opposed to immunosuppressive effects. Human studies have reported a relationship between systemic autoimmune diseases, such as scleroderma, with occupational exposure to TCE. There have also been a large number of case reports in TCE-exposed workers developing a severe hypersensitivity skin disorder, often accompanied by systemic effects to the lymph nodes and other organs, such as hepatitis (Ref. 2).

Studies in both humans and animals have shown changes in the proximal tubules of the kidney following exposure to TCE (Ref. 2). The IRIS TCE assessment concluded that TCE is carcinogenic to humans based on convincing evidence of a causal relationship between TCE exposure in humans and kidney cancer (Ref. 4). A recent review of TCE by the International Agency for Research on Cancer (IARC) also supported this conclusion (Ref. 7). The 12th report on carcinogens (RoC) by the National Toxicology Program also concluded that TCE is reasonably anticipated to be a human carcinogen 2015 (Ref. 8). These additional recent peer reviews are consistent with EPA's classification that TCE is carcinogenic to humans by all routes of exposures based upon strong epidemiological and animal evidence (Refs. 2, 4).

TCE metabolites appear to be the causative agents that induce renal toxicity, including cancer. S-dichlorovinyl-L-cysteine (DCVC), and

to a lesser extent other metabolites, appears to be responsible for kidney damage and kidney cancer following TCE exposure. Toxicokinetic data suggest that the TCE metabolites derived from glutathione conjugation (in particular DCVC) can be systemically delivered or formed in the kidney. Moreover, DCVC-treated animals showed the same type of kidney damage as those treated with TCE (Ref. 2). The toxicokinetic data and the genotoxicity of DCVC further suggest that a mutagenic mode of action is involved in TCE-induced kidney tumors, although cytotoxicity followed by compensatory cellular proliferation cannot be ruled out. As for the mutagenic mode of action, both genetic polymorphisms (Glutathione transferase (GST) pathway) and mutations to tumor suppressor genes have been hypothesized as possible mechanistic key events in the formation of kidney cancers in humans (Ref. 2).

The toxicological literature provides support for male and female reproductive effects following TCE exposure. Both the epidemiological and animal studies provide evidence of adverse effects to female reproductive outcomes. However, more extensive evidence exists in support of an association between TCE exposures and male reproductive toxicity. There is evidence that metabolism of TCE in male reproductive tract tissues is associated with adverse effects on sperm measures in both humans and animals. Furthermore, human studies support an association between TCE exposure and alterations in sperm density and quality, as well as changes in sexual drive or function and altered serum endocrine levels (Ref. 2).

Neurotoxicity has been demonstrated in animal and human studies under both acute and chronic exposure conditions. Evaluation of multiple human studies revealed TCE-induced neurotoxic effects including alterations in trigeminal nerve and vestibular function, auditory effects, changes in vision, alterations in cognitive function, changes in psychomotor effects, and neurodevelopmental outcomes. These studies in different populations have consistently reported vestibular system-related symptoms such as headaches, dizziness, and nausea following TCE exposure (Ref. 2).

Animals and humans exposed to TCE consistently experience liver toxicity. Specific effects include the following structural changes: Increased liver weight, increased DNA synthesis (transient), enlarged hepatocytes, enlarged nuclei, and peroxisome proliferation. Several human studies

reported an association between TCE exposure and significant changes in serum liver function tests used in diagnosing liver disease, or changes in plasma or serum bile acids. There was also human evidence for hepatitis accompanying immune-related generalized skin diseases, jaundice, hepatomegaly, hepatosplenomegaly, and liver failure in TCE-exposed workers (Ref. 2).

TCE is characterized as carcinogenic to humans by all routes of exposure as documented in EPA's IRIS TCE assessment (Ref. 4). This conclusion is based on strong cancer epidemiological data that reported an association between TCE exposure and the onset of various cancers, primarily in the kidney, liver, and the immune system, *i.e.*, non-Hodgkin's lymphoma (NHL). Further support for TCE's characterization as a carcinogen comes from positive results in multiple rodent cancer bioassays in rats and mice of both sexes, similar toxicokinetics between rodents and humans, mechanistic data supporting a mutagenic mode of action for kidney tumors, and the lack of mechanistic data supporting the conclusion that any of the mode(s) of action for TCE-induced rodent tumors are irrelevant to humans. Additional support comes from the 2014 evaluation of TCE's carcinogenic effects by IARC, which classifies TCE as carcinogenic to humans (Ref. 7). The 12th NTP RoC also concluded that TCE exposure is reasonably anticipated to be a human carcinogen (Ref. 8). These additional recent peer reviewed documents are consistent with EPA's classification that TCE is carcinogenic to humans by all routes of exposures based upon strong epidemiological and animal evidence (Refs. 2, 4).

D. What are the environmental impacts of TCE?

Pursuant to TSCA section 6(c), this unit describes the effects of TCE on the environment and the magnitude of the exposure of the environment to TCE. The unreasonable risk determination of this proposal is based solely on risks to human health since those risks are the most serious consequence of use of TCE and are sufficient to support this proposed action. The following is a discussion of the environmental impacts of TCE.

1. Environmental effects and impacts. TCE enters the environment as a result of emissions from metal degreasing facilities, and spills or accidental releases, and historic waste disposal activities. Because of its high vapor pressure and low affinity for organic matter in soil, TCE evaporates fairly

rapidly when released to soil; however, where it is released onto land surface or directly into the subsurface, TCE can migrate from soil to groundwater. Based on TCE's moderate persistence, low bioaccumulation, and low hazard for aquatic toxicity, the magnitude of potential environmental impacts on ecological receptors is judged to be low for the environmental releases associated with the use of TCE for vapor degreasing. This should not be misinterpreted to mean that the fate and transport properties of TCE suggest that water and soil contamination is likely low or does not pose an environmental concern. EPA is addressing TCE contamination in groundwater, drinking water, and contaminated soils at a large number of sites. While the primary concern with this contamination has been human health, there is potential for TCE exposures to ecological receptors in some cases (Ref. 2).

2. What is the global warming potential of TCE? Global warming potential (GWP) measures the potency of a greenhouse gas over a specific period of time, relative to carbon dioxide, which has a high GWP of 1 regardless of the time period used. Due to high variability in the atmospheric lifetime of greenhouse gases, the 100-year scale (GWP100) is typically used. TCE has relatively low global warming potential at a GWP100 of 140 and thus the impact is low (Ref. 2).

3. What is the ozone depletion potential of TCE? TCE is not an ozone-depleting substance and is listed as acceptable under the Significant New Alternatives Policy (SNAP) program for degreasing and aerosols. In 2007, TCE was identified as a substitute for two ozone depleting chemicals, methyl chloroform and CFC-113, for metals, electronics, and precision cleaning (72 FR 30142, May 30, 2007) (FRL-8316-8) (Ref. 9).

4. Is TCE a volatile organic compound (VOC)? TCE is a VOC as defined at 40 CFR 51.100(c). A VOC is any compound of carbon, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, which participates in atmospheric photochemical reactions.

5. Does TCE persist in the environment and bioaccumulate? TCE may be persistent, but it is not bioaccumulative. TCE is slowly degraded by sunlight and reactants when released to the atmosphere. Volatilization and microbial biodegradation influence the fate of TCE when released to water, sediment or soil. The biodegradation of TCE in the environment is dependent on a variety of factors and so a wide range of

degradation rates have been reported (ranging from days to years). TCE is not expected to bioconcentrate in aquatic organisms based on measured bioconcentration factors of less than 1000 (Ref. 2).

III. Regulatory Actions Pertaining to TCE

Because of its potential health effects, TCE is subject to state, federal, and international regulations restricting and regulating its use, which are summarized in this unit. None of these actions addresses the unreasonable risks under TSCA that EPA is seeking to address in this proposed rule.

A. Federal Actions Pertaining to TCE

Since 1979, EPA has issued numerous rules and notices pertaining to TCE under its various authorities.

- **Toxic Substances Control Act:** On December 16, 2016, EPA issued a proposed rule under TSCA section 6 to prohibit the manufacture (including import), processing, distribution in commerce and commercial use of TCE in aerosol degreasers and as a spot removal agent in dry cleaning facilities (Ref. 1). In addition, EPA published a final Significant New Use Rule (SNUR) that would require manufacturers (including importers) and processors of TCE to notify the Agency before starting or resuming any significant new uses of TCE in certain consumer products, including in spray fixatives used to finish arts and crafts (81 FR 20535, April 8, 2016) (Ref. 10).

- **Safe Drinking Water Act:** EPA has issued drinking water standards for TCE pursuant to section 1412 of the Safe Drinking Water Act. EPA promulgated the National Primary Drinking Water Regulation (NPDWR) for TCE in 1987 (52 FR 25690, July 8, 1987). The NPDWR established a non-enforceable maximum contaminant level (MCL) goal of zero milligrams per liter (mg/L) based on classification as a probable human carcinogen. The NPDWR also established an enforceable MCL of 0.005 mg/L. EPA is evaluating revising the TCE drinking water standard as part of a group of carcinogenic volatile organic compounds.

- **Clean Water Act:** EPA identified TCE as a toxic pollutant under section 307(a)(1) of the Clean Water Act (33 U.S.C. 1317(a)(1)) in 1979 (44 FR 44502, July 30, 1979) (FRL-1260-5). In addition, EPA developed recommended TCE ambient water quality criteria for the protection of human health pursuant to section 304(a) of the Clean Water Act.

- **Clean Air Act:** TCE is a hazardous air pollutant (HAP) under the Clean Air Act (42 U.S.C. 7412(b)(1)). EPA

promulgated National Emission Standards for Hazardous Air Pollutants (NESHAPs) for TCE for several industrial source categories, including halogenated solvent cleaning, fabric printing, coating, and dyeing, and synthetic organic chemical manufacturing. The halogenated solvent cleaning NESHAP, controls emissions of several halogenated solvents, including TCE, from halogenated solvent cleaning machines (40 CFR subpart T). The NESHAP includes multiple compliance alternatives to allow maximum compliance flexibility. In 2007, EPA promulgated the Halogenated Solvent Cleaning NESHAP RTR (Risk and Technology Review) Rule (72 FR 25138, May 3, 2007) (FRL-8303-6), in which EPA evaluated the health and environmental risks remaining after promulgation of the original NESHAP and established revised standards that further limit emissions of TCE (and other solvents) in halogenated solvent cleaning. Specifically, EPA promulgated a facility-wide emission limit of 60,000 kilograms per year (kg/year) methylene chloride equivalent, a unit which combines emissions of methylene chloride, trichloroethylene, and perchloroethylene. The facility-wide emission limit applied to all halogenated solvent cleaning machines with the exception of halogenated solvent cleaning machines used by the following industries: Facilities that manufacture narrow tubing, facilities that use continuous web cleaning machines, aerospace manufacturing and maintenance facilities, and military maintenance and depot facilities. EPA also promulgated a facility-wide emission limit of 100,000 kg/year methylene chloride equivalent for halogenated solvent cleaning machines used at military maintenance and depot facilities. TCE is also regulated under the NESHAP rule for synthetic organic chemical manufacturing. This rule consists of four subparts in 40 CFR part 63. In 2003, EPA issued a final NESHAP rule to reduce toxic air pollutant emissions from fabric and other textile coating, printing, and dyeing facilities. The final rule applied to new and existing facilities that emit 10 tons per year or more of a single toxic air pollutant listed in the Clean Air Act or 25 tons per year or more of a combination of those pollutants, including TCE. In addition, EPA has established VOC standards for consumer products under section 183(e) of the Clean Air Act.

• *Resource Conservation and Recovery Act (RCRA)*: EPA classifies certain wastes containing TCE as

hazardous waste subject to Subtitle C of RCRA pursuant to the toxicity characteristics or as a listed waste. RCRA also provides authority to require cleanup of hazardous wastes containing TCE at RCRA facilities.

• *Comprehensive Environmental Response, Compensation and Liability Act (CERCLA)*: EPA designated TCE as a hazardous substance with a reportable quantity pursuant to section 102(a) of CERCLA and EPA is actively overseeing cleanup of sites contaminated with TCE pursuant to the National Contingency Plan (NCP). While many of the statutes that EPA is charged with administering provide statutory authority to address specific sources and routes of TCE exposure, none of these can address the serious human health risks from TCE exposure that EPA is proposing to address under TSCA section 6(a) with this proposed rule.

The Occupational Safety and Health Administration (OSHA) established a permissible exposure limit (PEL) for TCE in 1971. The PEL is an 8-hour time-weighted average (TWA) TCE concentration of 100 ppm. In addition, the TCE PEL requires that exposure to TCE not exceed 200 ppm (ceiling) at any time during an eight hour work shift with the following exception: Exposures may exceed 200 ppm, but not more than 300 ppm (peak), for a single time period up to 5 minutes in any 2 hours (Ref. 11). OSHA acknowledges that many of its PELs are not sufficiently protective of worker health. OSHA has noted that “with few exceptions, OSHA’s PELs, which specify the amount of a particular chemical substance allowed in workplace air, have not been updated since they were established in 1971 under expedited procedures available in the short period after the OSH Act’s adoption . . . Yet, in many instances, scientific evidence has accumulated suggesting that the current limits are not sufficiently protective” (Ref. 12 at p. 61386), including the PEL for TCE.

To provide employers, workers, and other interested parties with a list of alternate occupational exposure limits that may serve to better protect workers, OSHA’s Web page highlights selected occupational exposure limits derived by other organizations. For example, the National Institute for Occupational Safety and Health considers TCE a potential occupational carcinogen and recommended an exposure limit of 25 ppm as a 10-hour TWA in 2003 (Ref. 13). The American Conference of Governmental Industrial Hygienists recommended an 8-hour TWA of 10 ppm and an acute, or short term, exposure limit of 25 ppm in 2004 (Ref. 14).

B. State Actions Pertaining to TCE

Many states have taken actions to reduce risks from TCE use. TCE is listed on California’s Safer Consumer Products regulations candidate list of chemicals that exhibit a hazard trait and are on an authoritative list and is also listed on California’s Proposition 65 list of chemicals known to cause cancer or birth defects or other reproductive harm. In addition, the California Code of Regulations, Title 17, Section 94509(a) lists standards for VOCs for consumer products sold, supplied, offered for sale, or manufactured for use in California (Ref. 15). As part of that regulation, use of consumer general purpose degreaser products that contain TCE are banned in California and safer substitutes are in use.

In Massachusetts, TCE is a designated high hazard substance, with an annual reporting threshold of 1,000 pounds (Ref. 16). Minnesota classifies TCE as a chemical of high concern (Ref. 17). Many other states have considered TCE for similar chemical listings (Ref. 18). Several additional states have various TCE regulations that range from reporting requirements to product contamination limits to use reduction efforts aimed at limiting or prohibiting TCE content in products.

Most states have set PELs identical to the OSHA 100 ppm 8-hour TWA PEL (Ref. 18). Nine states have PELs of 50 ppm (Ref. 18). California’s PEL of 25 ppm is the most stringent (Ref. 15). All of these PELs are significantly higher than the exposure levels at which EPA identified unreasonable risks for TCE use for vapor degreasing and would not be protective.

C. International Actions Pertaining to TCE

TCE is also regulated internationally and the international industrial and commercial sectors have moved to alternatives. TCE was added to the EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) restriction of substances classified as a carcinogen category 1B under the EU Classification and Labeling regulation in 2009 (Ref. 19). The restriction prohibits the placing on the market or use of TCE as a substance, as a constituent of other substances, or in mixtures for supply to the general public when the individual concentration of TCE in the substance or mixture is equal to or greater than 0.1% by weight (Ref. 19). In 2010, TCE was added to the Candidate List of substances for inclusion in Annex XIV of REACH, or the Authorisation List. Annex XIV includes substances of very high concern that are subject to use

authorization due to their hazardous properties. TCE meets the criteria for classification as a carcinogen. In 2011, TCE was recommended for inclusion in Annex XIV of REACH due to the very high volumes allocated to uses in the scope of authorization and because at least some of the described uses appeared to result in significant exposure of workers and professionals, and could be considered widely dispersive uses.

In 2013, the Commission added TCE to Annex XIV of REACH, making it subject to authorization. As such, entities that wanted to use TCE were required to apply for authorization by October 2014, and those entities without an authorization were required to stop using TCE by April 2016. The European Chemicals Agency (ECHA) received 19 applications for authorization from entities interested in using TCE beyond April 2016. Two of those were for vapor degreasing applications (Refs. 20, 21). In each case, the opinion of the Committee for Risk Assessment was that it was not possible to determine a derived no-effect level (DNEL) for the carcinogenicity properties of the substance in accordance with REACH and that the operational conditions and risk management measures in the applications appeared not to limit the risk. Those measures included use in a specific type of closed vapor degreasing system with personal protective equipment (PPE). Final decisions have not yet been made on the applications.

Canada conducted a hazard assessment of TCE in 1993 and concluded that “trichloroethylene occurs at concentrations that may be harmful to the environment, and that may constitute a danger in Canada to human life or health. It has been concluded that trichloroethylene occurs at concentrations that do not constitute a danger to the environment on which human life depends” (Ref. 22). In 2003, Canada issued the Solvent Degreasing Regulations (SOR/2003–283) to reduce releases of TCE into the environment from solvent degreasing facilities using more than 1,000 kilograms of TCE per year (Ref. 23). In 2013, Canada added TCE to the Toxic Substances List—Schedule 1 because TCE “is entering or may enter the environment in a quantity or concentration or under conditions that: (a) Have or may have an immediate or chronic harmful effect on the environment or its biological diversity, and (c) constitute or may constitute a danger in Canada to human life or health.” (Ref. 23).

In Japan, the Chemical Substances Control Law considers TCE a Class II substance (substances that may pose a

risk of long-term toxicity to humans or to flora and fauna in the human living environment, and that have been, or in the near future are reasonably likely to be, found in considerable amounts over a substantially extensive area of the environment) (Ref. 24). Japan also controls air emissions and water discharges containing TCE, as well as aerosol products for household use and household cleaners containing TCE.

TCE is listed in the Australian National Pollutant Inventory, a program run cooperatively by the Australian, State and Territory governments to monitor common pollutants and their levels of release to the environment. Australia classifies TCE as a health, physicochemical and/or ecotoxicological hazard, according to the Australian National Occupational Health and Safety Commission (Ref. 25).

IV. TCE Risk Assessment

In 2013, EPA identified TCE use as a solvent degreaser (aerosol degreasing and vapor degreasing) and spot remover in dry cleaning operations as a priority for risk assessment under the TSCA Work Plan. This Unit describes the development of the TCE risk assessment and supporting analysis and expert input on vapor degreasing, the use that is the subject of this proposed rule. A more detailed discussion of the risks associated with TCE use in vapor degreasing can be found in Unit VI.

A. TSCA Work Plan for Chemical Assessments

In 2012, EPA released the TSCA Work Plan Chemicals: Methods Document in which EPA described the process the Agency intended to use to identify potential candidate chemicals for near-term review and assessment under TSCA (Ref. 26). EPA also released the initial list of TSCA Work Plan chemicals identified for further assessment under TSCA as part of its chemical safety program (Ref. 27).

The process for identifying these chemicals for further assessment under TSCA was based on a combination of hazard, exposure, and persistence and bioaccumulation characteristics, and is described in the TSCA Work Plan Chemicals Methods Document (Ref. 26). Using the TSCA Work Plan chemical prioritization criteria, TCE ranked high for health hazards and exposure potential and was included on the initial list of TSCA Work Plan chemicals for assessment.

B. TCE Risk Assessment

EPA finalized a TSCA Work Plan Chemical Risk Assessment for TCE (TCE risk assessment) in June 2014, following

the July 2013 peer review of the December 2012 draft TCE risk assessment. All documents from the July 2013 peer review of the draft TCE risk assessment are available in EPA Docket Number EPA–HQ–OPPT–2012–0723. TCE appears in the 2014 update of the TSCA Work Plan for Chemical Assessments and the completed risk assessment is noted therein. The TCE risk assessment evaluated commercial and consumer use of TCE as a solvent degreaser (aerosol degreasing and vapor degreasing), commercial use of TCE as a spotting agent at dry cleaning facilities, and consumer use of TCE as a spray-applied protective coating for arts and crafts (Ref. 2).

The uses selected for the TCE risk assessment were chosen because they were expected to involve frequent or routine use of TCE in high concentrations and/or have high potential for human exposure (Ref. 2). However, this does not mean that EPA found that other uses not included in the TCE risk assessment present low risk.

As described in the TCE risk assessment, solvent cleaning or degreasing is widely used to remove grease, oils, waxes, carbon deposits, fluxes, and tars from metal, glass, or plastic surfaces. With respect to vapor degreasing, there are two general types of degreasing machines: Batch and in-line. Batch cleaning machines are the most common type, while in-line cleaners are typically used in large-scale industrial operations. There are a number of variations of each general type of machine. Emissions from degreasing machines typically result from:

- Evaporation of the solvent from the interface between the solvent and the air,
- “Carry out” of excess solvent on cleaned parts, and
- Evaporative losses of the solvent during filling and draining of the degreasing machine.

In its assessment of vapor degreasing, the TCE risk assessment concentrated on open top vapor degreasing machines because they are the most prevalent, particularly for smaller operations. The risk assessment identified acute and chronic non-cancer risks for workers who conduct TCE-based solvent vapor degreasing at small degreasing facilities, as well as occupational bystanders to those activities. More specifically, the TCE risk assessment identified risks for non-cancer developmental effects resulting from acute exposure. The risk assessment also identified risks for a range of non-cancer health effects resulting from chronic exposure. Within

this range of effects, the greatest risk is for developmental effects (*i.e.*, fetal cardiac defects), although there also are risks for kidney effects and immunotoxicity. In addition, there are risks for adverse reproductive effects, neurotoxicity, and liver toxicity associated with chronic exposures (Ref. 2).

Margins of exposure (MOEs) were used in this assessment to estimate non-cancer risks for acute and chronic exposures. The MOE is the health point of departure (an approximation of the no-observed adverse effect level) for a specific endpoint divided by the exposure concentration for the specific scenario of concern. The benchmark MOE accounts for the total uncertainty factor based on the following uncertainty factors: Intraspecies, interspecies, subchronic to chronic, and lowest observed adverse effect level (LOAEL) to no-observed adverse effect level (NOAEL). Uncertainty factors are intended to account for (1) the variation in sensitivity among the members of the human population (*i.e.*, interhuman or intraspecies variability); (2) the uncertainty in extrapolating animal data to humans (*i.e.*, interspecies variability); (3) the uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure (*i.e.*, extrapolating from subchronic to chronic exposure); and (4) the uncertainty in extrapolating from a LOAEL rather than from a NOAEL (Ref. 28). MOEs provide a non-cancer risk profile by presenting a range of estimates for different non-cancer health effects for different exposure scenarios, and are a widely recognized method for evaluating a range of potential non-cancer health risks from exposure to a chemical.

The acute inhalation risk assessment used developmental toxicity data to evaluate the acute risks for the TCE use scenarios. As indicated in the TCE risk assessment, EPA's policy supports the use of developmental studies to evaluate the risks of acute exposures. This science-based policy presumes that a single exposure of a chemical at a critical window of fetal development may produce adverse developmental effects (Ref. 5). This is the case with cardiac malformation. EPA reviewed multiple studies for suitability for acute risk estimation including a number of developmental studies of TCE exposure and additional developmental studies of TCE metabolites (Appendix N) (Ref. 2). EPA based its acute risk assessment on the most sensitive health endpoint (*i.e.*, fetal heart malformations) representing the most sensitive human life stage (*i.e.*, the developing fetus) (Ref. 2). The acute

risk assessment used the physiologically-based pharmacokinetic (PBPK)-derived hazard values (HEC50, HEC95, or HEC99; HECXX is the Human Equivalent Concentration at a particular percentile) from the Johnson et al. (2003) (Ref. 29) developmental toxicity study for each vapor degreaser use scenario. Note that the differences among these hazard values is small and no greater than 3-fold (*i.e.*, 2-fold for HEC50/HEC95 ratios; 3-fold for HEC50/HEC99 ratios; 1.4-fold for HEC95/HEC99 ratios). The IRIS TCE assessment used the HEC99 for the non-cancer dose-response derivations because the HEC99 was interpreted to be protective for a sensitive individual in the population (Ref. 4). While the HEC99 was used to find the level of risk to be used in making the proposed TSCA section 6(a) determination, the small variation among HEC50, HEC95 and HEC99 would not result in a different risk determination.

For non-cancer effects, EPA estimated exposures that are significantly greater than the point of departure. The baseline cancer risk is estimated to be 3.66×10^{-1} for users of open top vapor degreasing systems.

The levels of acute and chronic exposures estimated to present low risk for non-cancer effects also result in low risk for cancer.

Given these identified risks, EPA conducted an additional analysis consistent with the scope of the TCE risk assessment to better characterize the risk to workers and occupational bystanders from the use of TCE in batch vapor degreasing machines as well as in two different types of in-line systems (conveyor and continuous web cleaning machines) (Ref. 30). This analysis also evaluated the exposure reductions that would result from switching from an open-top vapor degreasing system to a closed-loop vapor degreasing system. More information on the different types of vapor degreasing machines can be found in Unit VI.A.1. In the supplemental analysis, EPA identified short-term and long-term non-cancer and cancer risks for all types of vapor degreasing machines, although the risks for closed-loop machines are estimated to be lower than for any of the other types (Ref. 30).

C. Stakeholder Input on TCE and Vapor Degreasing

On July 29, 2014, EPA held a 2-day public workshop on TCE degreasing (Ref. 31). The purpose of the workshop was to collect information from users, academics, and other stakeholders on the use of TCE as a degreaser in various applications, *e.g.*, in degreasing metal

parts, availability and efficacy of safer alternatives, safer engineering practices and technologies to reduce exposure to TCE, and to discuss possible risk reduction approaches. The workshop included presentations by experts, breakout sessions with case studies, and public comment opportunities (Ref. 31) and informed EPA's assessment of the alternatives to TCE considered in this proposed rule. All documents from the public workshop are available in EPA Docket Number EPA-HQ-OPPT-2014-0327. Informed in part by the workshop and other analysis, including discussion with the Toxics Use Reduction Institute at the University of Massachusetts Lowell, EPA has concluded that TCE alternatives are available for all applications subject to this proposed rule as well as EPA's earlier proposal (Ref. 1). The discussions at the public workshop demonstrated that alternatives are available for the vapor degreasing uses that are being addressed in this proposed rulemaking.

On June 1, 2016, EPA convened a Small Business Advocacy Review (SBAR) Panel on TCE in vapor degreasing. The Panel solicited input from eighteen Small Entity Representatives (SERs) and made several recommendations on aspects of this rulemaking. The Panel process, including the final report of the Panel (Ref. 32), is discussed in Unit XII.

V. Regulatory Approach

A. TSCA Section 6 Unreasonable Risk Analysis

Under TSCA section 6(a), if the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the Agency's risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance no longer presents such risk.

The TSCA section 6(a) requirements can include one or more, or a combination of, the following actions:

- Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of such substances (§ 6(a)(1)).
- Prohibit or otherwise restrict manufacturing, processing, or distribution in commerce of such substances for particular uses or for uses in excess of a specified concentration (§ 6(a)(2)).

- Require minimum warning labels and instructions (§ 6(a)(3)).
- Require record keeping or testing (§ 6(a)(4)).
- Prohibit or regulate any manner or method of commercial use (§ 6(a)(5)).
- Prohibit or otherwise regulate any manner or method of disposal (§ 6(a)(6)).
- Direct manufacturers and processors to give notice of the determination to distributors and the public and replace or repurchase substances (§ 6(a)(7)).

EPA analyzed a wide range of regulatory options under TSCA section 6(a) in order to select the proposed regulatory approach. EPA considered whether a regulatory option (or combination of options) would address the identified unreasonable risks so that the chemical substance no longer presents such risks. To do so, EPA initially analyzed whether the regulatory options could reduce risks (non-cancer and cancer) to levels below those of concern, based on EPA's technical analysis of exposure scenarios. For the non-cancer risks, EPA found an option could be protective against the risk if it could achieve the benchmark MOE for the most sensitive non-cancer endpoint. EPA's assessments for these uses indicate that when exposures meet the benchmark MOE for the most sensitive endpoint, they also result in low risk for cancer.

After the technical analysis, which represents EPA's assessment of the potential for the regulatory options to achieve risk benchmarks based on analysis of exposure scenarios, EPA then considered how reliably the regulatory options would actually reach these benchmarks. For the purposes of this proposal, EPA found that an option addressed the risk so that it was no longer unreasonable if the option could achieve the benchmark MOE or cancer benchmark for the most sensitive endpoint. In evaluating whether a regulatory option would ensure that the chemical substance no longer presents the identified unreasonable risks, the Agency considered whether the option could be realistically implemented or whether there were practical limitations on how well the option would mitigate the risks in relation to the benchmarks, as well as whether the option's protectiveness was impacted by environmental justice or children's health concerns.

B. TSCA Section 6(c)(2) Considerations

TSCA section 6(c)(2) requires EPA to consider and publish a statement based on reasonably available information with respect to the:

- Health effects of the chemical substance or mixture (in this case, TCE) and the magnitude of human exposure to TCE;
- Environmental effects of TCE and the magnitude of exposure of the environment to TCE;
- Benefits of TCE for various uses;
- Reasonably ascertainable economic consequences of the rule, including: The likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; the costs and benefits of the proposed and final rule and of the one or more primary alternatives that EPA considered; and the cost effectiveness of the proposed rule and of the one or more primary alternatives that EPA considered.

In addition, in selecting among prohibitions and other restrictions available under TSCA section 6(a), EPA must factor in, to the extent practicable, these considerations. Further, in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, EPA must also consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

EPA's analysis of the health effects of and magnitude of exposure to TCE can be found in Units IV and VI, which discuss the TCE risk assessment and EPA's regulatory assessment of the use of TCE in vapor degreasing. A discussion of the environmental effects of TCE can be found in Unit II.D.

With respect to the costs and benefits of this proposal and the alternatives EPA considered, as well as the impacts on small businesses, the full analysis is presented in the economic analysis document (Ref. 3) To the extent information was available, EPA considered the benefits realized from risk reductions (including monetized benefits, non-monetized quantified benefits, and qualitative benefits), offsets to benefits from countervailing risks (e.g., risks from chemical substitutions and alternative practices), the relative risk for environmental justice populations and children and other potentially exposed or susceptible subpopulations (as compared to the general population), and the cost of regulatory requirements for the various options. A discussion of the benefits EPA considered can be found in Units VI.C. and VII.

EPA considered the estimated costs to regulated entities as well as the cost to administer and enforce the options. For example, an option that includes use of a respirator would include inspections to evaluate compliance with all elements of a respiratory protection program. EPA took into account reasonably available information about the functionality and performance efficacy of the regulatory options and the ability to implement the use of chemical substitutes or other alternatives (e.g., PPE). Reasonably available information included the existence of other Federal, state, or international regulatory requirements associated with each of the regulatory options as well as the commercial history for the options. A discussion of the costs EPA considered can be found in Units VI.E. and VII, along with a discussion of the cost effectiveness of the proposal and the alternatives that EPA considered. In addition, a discussion of the impacts on small businesses can be found in Unit XII.C.

With respect to the anticipated effects of this proposal on the national economy, EPA considered the number of businesses and workers that would be affected and the costs and benefits to those businesses and workers. In addition, EPA considered the employment impacts of this proposal, as discussed in the economic analysis for this proposal (Ref. 3). EPA found that the direction of change in employment is uncertain, but the expected short term and longer term employment effects are expected to be small.

The benefits of TCE in vapor degreasing are discussed in Unit VI.D., along with the availability of alternatives. The dates that the proposed restrictions would take effect are discussed in Unit X.D., as is the availability of alternatives to TCE vapor degreasing on those dates.

Finally, with respect to this proposal's effect on technological innovation, EPA expects this action to spur innovation, not hinder it. (Ref. 3) An impending ban on the use of TCE in vapor degreasing is likely to increase demand for alternatives, which would be expected to result in the development of new alternatives.

C. Regulatory Options Receiving Limited Evaluation

As discussed previously, EPA analyzed a wide range of regulatory options under TSCA section 6(a). One of the options EPA evaluated involved a TSCA section 6(a)(3) requirement for warning labels or instructions on containers of TCE or on vapor degreasing equipment. However, EPA

reasoned that warning labels and instructions alone could not mitigate the identified unreasonable risks presented by TCE to workers operating vapor degreasing equipment. In making this finding, EPA considered several factors including the fact that, in many cases, the workers being exposed are not in a position to influence their employer's decisions about the type of solvent or the type of degreasing equipment that will be used, or ensure that their employer provides appropriate PPE and an adequate respiratory protection program. EPA also considered the analysis of relevant studies that was discussed in the prior proposal on TCE (Ref. 33). This analysis found that even professional users do not consistently pay attention to labels; they often do not understand label information; and they often base a decision to follow label information on previous experience and perceptions of risk (Ref. 33).

EPA found that presenting information about TCE on a label would not adequately address the identified unreasonable risks because the nature of the information the user or owner would need to read, understand, act upon, convey, and ensure adherence to is extremely complex. It would be challenging to most users or owners to follow or convey the complex product label instructions required to explain how to reduce exposures to the extremely low levels needed to minimize the risk from TCE. Rather than a simple message, the label would need to explain a variety of inter-related factors, including but not limited to the use of local exhaust ventilation, respirators and assigned protection factor for the user and bystanders, and time periods during pregnancy with susceptibility of the developing fetus to acute developmental effects, as well as effects to bystanders. It is unlikely that label language changes for this use will result in widespread, consistent, and successful adoption of risk reduction measures by users and owners.

While labeling alone would not address the identified unreasonable risks so that TCE used in vapor degreasing no longer presents such risks, EPA recognizes that the TSCA section 6(a)(3) warnings and instruction requirement can be an important component of an approach that addresses identified unreasonable risks with a specific use prohibition. EPA has included a simple downstream notification requirement as part of this proposed rule to ensure that users would be made aware of the ban on the use of TCE in vapor degreasing.

In addition, early in the process, EPA identified two regulatory options under

TSCA section 6(a) that do not pertain to this action and were therefore not evaluated for this proposed rulemaking. First, EPA reasoned that the TSCA section 6(a)(1) regulatory option to prohibit the manufacture (including import), processing or distribution in commerce of TCE or limit the amount of TCE which may be manufactured (including imports), processed or distributed in commerce is not germane because the Agency is not proposing to ban or limit the manufacture (including import), processing or distribution in commerce of TCE for uses other than in vapor degreasing, aerosol degreasing or for spot cleaning in dry cleaning facilities at this time. In addition, EPA reasoned that the TSCA section 6(a)(6) regulatory option to prohibit or otherwise regulate any manner or method of disposal of the chemical is not applicable since EPA did not evaluate the risks associated with ongoing TCE disposal.

VI. Regulatory Assessment of TCE Use in Vapor Degreasing

This Unit describes the current use of TCE in vapor degreasing, the unreasonable risks presented by this use, and how EPA identified which regulatory options address those unreasonable risks so that TCE in vapor degreasing no longer presents such unreasonable risks.

A. Description of the Current Use

Vapor degreasing is a cleaning process that uses a solvent vapor to remove contaminants such as grease, oils, dust, and dirt from fabricated parts. Solvents such as TCE are boiled in a degreasing unit to produce a hot vapor. When parts are placed into the degreaser, the hot vapor within the unit condenses onto the parts, causing beading and dripping. The dripping action carries the contaminants away from the fabricated part, leaving behind a clean surface. After vapor degreasing, the parts are suspended on a rack in order to drain the solvent (Ref. 30). Vapor degreasing is used in a variety of occupational settings such as metal plating, electronics assembly, metal or composite part fabrication, and repair shops.

Vapor degreasing may take place in batches or as part of an in-line (*i.e.*, continuous) system. In batch machines, each load (parts or baskets of parts) is loaded into the machine after the previous load is completed. With in-line systems, parts are continuously loaded into and through the vapor degreasing equipment as well as the subsequent drying steps.

The five basic types of batch vapor degreasers are described in the following paragraphs (Ref. 30):

As the name suggests, open-top vapor degreasers are open at the top to allow introduction of the parts to be cleaned. Heating elements at the bottom of the cleaner heat the liquid solvent to above its boiling point. Solvent vapor rises in the machine to the height of chilled condensing coils on the inside walls of the cleaner. The condensing coils cool the vapor, causing it to condense and return to the bottom of the cleaner. Cleaning occurs in the vapor zone above the liquid solvent and below the condensing coils, as the hot vapor solvent condenses on the cooler work surface. The workload or a parts basket is lowered into the heated vapor zone with a mechanical hoist. While the condensing coils reduce the amount of solvent that escapes the vapor zone, they do not eliminate emissions, and throughout the degreasing process, significant vapor emissions of the solvent can occur. These vapor emissions are hazardous to workers operating the machine, as well as nearby workers. In addition, replacing solvent lost to emissions can be costly. In assessing the use of TCE in vapor degreasers, the TCE risk assessment focused on the use of open top vapor degreasing systems.

Vapor emissions of solvent can be reduced by enclosing the vapor degreasing machine. Open top vapor degreasing systems with enclosures operate in the same manner as standard open top vapor degreasing systems, except that the machine is enclosed on all sides during degreasing. The enclosure is opened and closed when adding or removing parts, and solvent is exposed to the air when the cover is open. Nearly all open top vapor degreasing systems regulated by the NESHAP have a cover because that is a more common compliance strategy than complying with the overall emission limit. A variety of additional controls may be needed to comply with the NESHAP, including two-part covers, extended freeboard (the area above the vapor zone), freeboard refrigeration devices, and holding cleaned parts in the freeboard to allow draining. Enclosed vapor degreasing systems may be vented directly to the atmosphere or first vented to an external carbon filter and then to the atmosphere.

Solvent emissions can be further reduced by using a sealed, closed-loop degreasing system. In airtight closed-loop systems, parts are placed into a basket, which is then placed into an airtight work chamber. The door is closed and solvent vapors are sprayed

onto the parts. When cleaning is complete, vapors are exhausted from the work chamber and circulated over a cooling coil to condense and recover the solvent. The parts are dried by forced hot air. Air is circulated through the chamber and residual solvent vapors are captured by carbon adsorption. The door is opened when the residual solvent vapor concentration has reached a specified level.

A refinement of the airtight closed-loop degreasing system is the airless degreasing system. An airless system removes air at some point during the degreasing process. Typically, this takes the form of drawing vacuum, but some machines purge the air with nitrogen. In airless degreasing systems with vacuum drying, a vacuum is generated, typically below 5 torr, which dries the parts. A vapor recovery system recovers the solvent.

The greatest solvent emission reductions are achieved with the airless vacuum-to-vacuum degreasing system. These systems are referred to as airless because the entire cycle is operated under vacuum. Typically, parts are placed into the chamber, the chamber sealed, and then vacuum drawn within the chamber. The parts are then sprayed with hot solvent vapor, which raises the pressure in the chamber. The parts are dried by again drawing vacuum in the chamber. Solvent vapors are recovered through compression and cooling. An air purge then removes residual vapors which can be routed to an optional carbon adsorber and then out a vent. Finally, air is introduced to return the chamber to atmospheric pressure so that the chamber can be opened. These systems have the added benefit of generating vapor at a much lower temperature than open-top degreasing systems because the boiling point of TCE is lower at the lower pressure of these systems.

In contrast to batch degreasers, in-line vapor degreasing systems use an automated parts handling system, often a conveyor, to automatically provide a continuous supply of parts to be cleaned (Ref. 30). Conveyorized vapor degreasing systems are usually fully enclosed except for the conveyor inlet and outlet portals. Conveyorized degreasers are likely used in the same applications as batch vapor degreasers, except that they would be used in larger operations, where the number of parts being cleaned is large enough to warrant the use of a conveyorized system. Conveyorized degreasers use different methods for transporting the parts through the cleaning zone. For example, monorail degreasers use a straight-line conveyor to transport parts into and out

of the cleaning zone; these systems are typically used when parts are already being transported through manufacturing areas by a conveyor. Cross-rod degreasers use two parallel chains connected by a rod to support the parts, which are typically loaded manually into perforated baskets or cylinders. Ferris wheel degreasing systems, generally the smallest of the conveyorized degreasers, rotate manually-loaded baskets or cylinders of parts vertically through the cleaning zone and back out. Belt degreasers are used for simple and rapid loading and unloading of parts; the parts are loaded onto a mesh conveyor belt that transports them through the cleaning zone and out the other side.

There are also continuous web cleaning machines (Ref. 30). These in-line degreasers differ from typical conveyorized degreasers in that they are specifically designed for cleaning parts that are coiled or on spools such as films, wires, metal strips, and metal sheets. In continuous web degreasers, parts are uncoiled and loaded onto rollers that transport the parts through the cleaning and drying zones at speeds typically greater than 11 feet per minute. The parts are then recoiled or cut after exiting the machine.

B. Analysis of Regulatory Options

In this unit, EPA explains how it evaluated whether the regulatory options considered would address the unreasonable risks presented by the current use so that TCE in vapor degreasing no longer presents such unreasonable risks. First, EPA characterizes the unreasonable risks associated with the current use of TCE in vapor degreasers. Then, the Agency describes its initial analysis of which regulatory options have the potential to reach the protective non-cancer and cancer benchmarks. The levels of acute and chronic exposures estimated to present low risk for non-cancer effects also result in low risk for cancer. Lastly, this unit evaluates how well those regulatory options would address the identified unreasonable risks in practice.

1. Risks associated with the current use. a. General impacts. The TCE risk assessment identified cancer and non-cancer risks from acute and chronic exposure for workers operating vapor degreasers and for occupational bystanders, nearby workers who have the potential to be exposed to TCE but are not directly involved with degreasing operations (Ref. 2). Because the TCE risk assessment focused on open top vapor degreasing systems, EPA performed supplemental analysis

consistent with the methodology used in the risk assessment for closed-loop, conveyorized, and continuous web degreasers and identified cancer and non-cancer risks from acute and chronic exposure for each of the scenarios (Ref. 30). EPA estimates that there are approximately 2,600 to 6,000 open top vapor degreasing systems currently using TCE, 120 closed-loop systems currently using TCE, and 150 in-line (either conveyorized or continuous web) systems currently using TCE, with an estimated 17 workers and occupational bystanders per machine (Ref. 3). This means that there are an estimated 40,800 to 102,000 persons exposed to TCE from open top vapor degreasing systems, 2,040 persons exposed to TCE from closed-loop systems, and 2,550 persons exposed to TCE from in-line systems.

b. Impacts on minority and low income populations. There is no known disproportionate representation of minority or low income populations in these occupations.

c. Impacts on children. EPA has concerns for effects on the developing fetus from acute and chronic worker and occupational bystander exposures to TCE used in vapor degreasers. The risk estimates are focused on pregnant women because one of the most sensitive health effects associated with TCE exposure from vapor degreasing is adverse effects on the developing fetus. The potential risk due to exposure during pregnancy is significant. Approximately half of all pregnancies are unintended. If a pregnancy is not planned before conception, a woman may not be in optimal health for childbearing (Ref. 34). More specifically, in this case, a woman who is not planning a pregnancy may not take steps to avoid exposure to TCE in vapor degreasing. EPA estimates that there are over 1,000 pregnant women exposed to TCE as a result of vapor degreasers.

d. Specific vapor degreaser exposure information. In the supplemental analysis (Ref. 30), EPA estimated baseline exposures for all batch vapor degreasing machines, regardless of facility size, and for in-line vapor degreasing machines (both conveyorized and continuous web). Baseline exposures for in-line machines were not specifically calculated in the TCE risk assessment. For the supplemental analysis, estimating the baseline exposures involved using a near-field/far-field modeling approach to estimate airborne concentrations of TCE and Monte Carlo simulation to establish the range and likelihood of exposures. The near-field/far-field model estimates airborne concentrations in a near field (a

zone close to the source of exposure) and a far field (a zone farther from the source of exposure but within the occupational building). Controls required by the 2007 NESHAP were accounted for in the estimations. (Ref. 30) EPA used these estimated airborne concentrations to estimate 8-hour time weighted average (TWA) exposures for workers (*i.e.*, in the near field) and occupational bystanders (*i.e.*, in the far field). Details of the modeling and estimation method for calculating exposure levels during vapor degreasing are available in the supplemental analysis document (Ref. 30). This analysis is based on the methodology used in the peer reviewed TCE risk assessment (Ref. 2). Prior to promulgation of the final rule, EPA will peer review the "supplemental Occupational Exposure and Risk Reduction Technical Report in Support of Risk Management Options for Trichloroethylene (TCE) Use in Vapor Degreasing" (Ref. 30).

The estimated 8-hour TWA exposure levels for open top vapor degreasing systems ranged from 2.74 ppm to 491.36 ppm for workers, with the 50th percentile at 55.16 ppm and the 99th percentile at 190.17 ppm. For occupational bystanders, the exposure levels ranged from 0.33 ppm to 440.61 ppm, with the 50th percentile at 20.45 ppm and the 99th percentile at 144.93 ppm. The estimated 8-hour TWA exposure levels for conveyorized degreasers were even higher, ranging from 5.14 ppm to 32,722 ppm for workers, with the 50th percentile and 99th percentile being 180.74 ppm and 1162.6 ppm, respectively. For bystanders, the levels ranged from 0.63 ppm to 29,410 ppm, with the 50th percentile and 99th percentile being 80.93 ppm and 745.11 ppm, respectively. The estimated 8-hour TWA exposure levels for continuous web degreasers were lower overall than for open top vapor degreasing systems or conveyorized degreasers. These estimates ranged from 4.18 ppm to 50.61 ppm for workers, with the 50th percentile and 99th percentile being 8.18 ppm and 22.42 ppm, respectively. For bystanders, the levels ranged from 0.52 ppm to 45.49 ppm, with the 50th percentile and 99th percentile being 3.70 ppm and 17.49 ppm, respectively.

As part of this supplemental analysis, EPA also evaluated the exposure reductions that would result from switching from an open top vapor degreasing system to a closed-loop vapor degreasing system. The data available on TCE emissions from closed-loop systems was not sufficient to enable EPA to distinguish between the

three types of closed-loop systems (airtight, airless, and airless vacuum-to-vacuum) with respect to employee exposures. As a result, for the purpose of assessing exposure, EPA assumed that all of the closed-loop systems achieve a 98% reduction in exposure compared to open top vapor degreasing systems (Ref. 30). This assumption leads to exposure estimates of 0.05 ppm to 9.8 ppm for workers.

However, the assumption of a 98% reduction in exposures compared to open top vapor degreasing systems may be an overestimate for airtight systems, and an underestimate for airless vacuum-to-vacuum systems. EPA requests information and data on TCE emissions from all vapor degreasing systems, particularly information and data that would enable EPA to better distinguish between the different types of closed-loop systems.

The SBAR Panel convened in support of this action heard from several SERs who disagreed with EPA's exposure estimates. These SERs indicated that fewer employees were involved in the degreasing operation, or that the machines were operated for fewer hours per day than EPA estimated. However, another SER stated that his degreasing machines run ten hours a day during the week and six hours on Saturdays, which exceeds EPA's estimate. In addition, most SERs thought that EPA's estimated TWAs were too high, and EPA received some monitoring data indicating lower exposures, but several SERs stated that they complied with the recommended exposure limit of the American Conference of Governmental Industrial Hygienists (ACGIH) of 10 ppm, which is within the exposure ranges estimated by EPA. However, EPA specifically requests exposure data, especially data involving employee exposure monitoring.

e. Specific risks for TCE use in vapor degreasers. Inhalation risks were estimated for all acute exposure scenarios and risks were identified for all types of machines, regardless of the type of exposure (typical vs. reasonable worst case scenario). For acute exposures associated with open top vapor degreasing systems, the MOE is 0.00006 for fetal heart malformations. This equates to exposures that are many times greater than the benchmark MOE of 10. The MOE for fetal heart malformations from acute exposures associated with conveyorized systems is 0.00001, while for continuous web systems, the MOE is 0.0005. Even for acute exposures with closed-loop systems, which we assume reduce TCE emissions as much as 98% from open top vapor degreasing systems, the MOE

for fetal heart malformations is 0.003. The MOEs for every vapor degreasing scenario are below the benchmark MOE. Based on this assessment, EPA's proposed determination is that acute TCE exposures from vapor degreasing present unreasonable risks.

Chronic exposures from TCE use in vapor degreasing also present risks. For non-cancer effects, the most sensitive of which are developmental, the benchmark MOE is also 10. For chronic exposures associated with open top vapor degreasing systems, conveyorized systems, continuous web systems, and closed-loop systems, the MOEs are 0.00008, 0.00001, 0.00007, and 0.004, respectively. With respect to cancer, the risk posed to workers ranges from 5.16×10^{-1} for open top vapor degreasing systems to 1×10^{-2} for closed-loop systems, exceeding common cancer benchmarks of 10^{-6} to 10^{-4} (Refs. 2, 30). Therefore, EPA's proposed determination is that chronic TCE exposures due to vapor degreasing also present unreasonable risks.

The SBAR Panel convened in support of this action heard from several SERs who expressed concerns about the underlying TCE risk assessment. Many of the concerns expressed by these SERs were already expressed in the public comments and the peer review comments on the risk assessment. The Summary of External Peer Review and Public Comments and Disposition document explains how EPA responded to the comments received (Ref. 35).

2. Initial analysis of potential regulatory options. Having identified unreasonable risks from the use of TCE in vapor degreasing, EPA evaluated whether regulatory options under TSCA section 6(a) could reach the risk (non-cancer and cancer) benchmarks.

EPA assessed a number of exposure scenarios associated with risk reduction options in order to find variations in TCE exposure from vapor degreasing, including: Reducing the amount of TCE in the degreasing formulation, with concentrations varying from 5% to 95% by weight in the product, engineering controls, equipment substitution, and use of PPE. EPA also assessed combinations of these options.

For the engineering controls risk reduction option exposure scenarios, EPA evaluated using local exhaust ventilation to improve ventilation near the vapor degreaser, with an assumed 90% reduction in exposure over baseline levels. The equipment substitution risk reduction option was only evaluated with respect to open top vapor degreasing systems, the evaluation assumed substitution of a closed-loop system for the open top

vapor degreasing system. EPA did not identify any equipment substitution options for either conveyorized or continuous web systems; it is likely that a closed-loop system, being a batch-process system, would not meet the specialized production requirements of facilities currently using conveyorized or continuous web systems. EPA requests comment, information, and data on potential equipment substitution options for these systems, including both emissions and cost information. The PPE risk reduction option exposure scenarios evaluated workers and occupational bystanders wearing respirators with an assigned protection factor (APF) varying from 10 to 10,000. Additionally, EPA evaluated various combinations of these options, including PPE with each of the other three options and reducing the amount of TCE in the solvent solution with each of the other three options. The way that closed-loop systems operate may render local exhaust ventilation redundant, because ventilation is being done as part of the closed system, so EPA did not evaluate local exhaust ventilation and equipment substitution together. EPA requests comment on the accuracy of EPA's assumption that these control options are mutually exclusive.

EPA has estimated that, in order to avoid cancer and non-cancer unreasonable risks, the 8-hour TWA exposure should be approximately 1 ppb (Ref. 36). However, EPA's inhalation exposure level estimates for all types of vapor degreasing machines exceed that figure by several orders of magnitude.

Of the control options evaluated by EPA in its supplemental analysis (Ref. 30), which did not include a ban on the use of TCE in vapor degreasing, the only control options that achieved the necessary exposure reductions for workers operating the degreaser involved PPE in addition to other measures. Even switching from an open top vapor degreasing system to a closed-loop system did not achieve the necessary reductions without the addition of PPE with an APF of 10,000. For that control option, equipment substitution plus PPE, EPA estimated that worker exposure levels would be 0.4 ppb. Other combinations of control options, such as reducing the amount of TCE in the solvent solution and PPE with an APF of 10,000, or reducing the amount of TCE in the solvent solution and engineering controls and PPE, achieved exposure reductions of approximately the same magnitude. However, EPA found that these combinations are unlikely to be practical for users because the exposure

reductions needed would only be achieved by a reduction in the concentration of TCE in the degreasing solution to 5%. At 5% TCE, the effectiveness of the solution would be greatly reduced. Additional exposure level estimates for various scenarios are available in the supplemental analysis document, which also documents options that did not meet the risk benchmarks and which do not, for purposes of this proposal, address the identified unreasonable risks (Ref. 30).

3. *Assessment of whether regulatory options address the identified unreasonable risks to the extent necessary so that TCE no longer presents such unreasonable risks.* After excluding the unrealistic options involving reductions in the amount of TCE in the solvent solution, only two options were left that had the potential to address the identified unreasonable risks. These options were: (a) Prohibiting under TSCA section 6(a)(2) the manufacturing (including import), processing, and distribution in commerce of TCE for use in vapor degreasing, prohibiting the commercial use of TCE in vapor degreasing under TSCA section 6(a)(5), and requiring downstream notification under TSCA section 6(a)(3) when distributing TCE; and (b) prohibiting under TSCA section 6(a)(2) the manufacturing (including import), processing, and distribution in commerce of TCE for use in vapor degreasing except in closed-loop vapor degreasing machines, prohibiting under TSCA section 6(a)(5) the commercial use of TCE in vapor degreasing except in closed-loop vapor degreasing machines, requiring downstream notification under TSCA section 6(a)(3) when distributing TCE, and requiring, under TSCA section 6(a)(5), appropriate PPE (or an exposure limit alternative) for both workers operating closed-loop vapor degreasing machines containing TCE and for occupational bystanders.

a. *Proposed approach to prohibit manufacturing (including import), processing, distribution in commerce, and use of TCE for vapor degreasing and require downstream notification.* As noted previously, the proposed regulatory approach is to prohibit the manufacturing (including import), processing, and distribution in commerce of TCE for vapor degreasing under TSCA section 6(a)(2), prohibit the commercial use of TCE in vapor degreasing under TSCA section 6(a)(5), and require manufacturers, processors, and distributors, except for retailers, to provide downstream notification, e.g., via a Safety Data Sheet (SDS), of the prohibition under TSCA section 6(a)(3).

As discussed in Unit IV, the baseline risk for exposure to workers and occupational bystanders for vapor degreasing does not achieve the non-cancer MOE benchmarks for all non-cancer effects (e.g., developmental effects, kidney toxicity, and immunotoxicity) or the common cancer benchmarks. Under this proposed approach, exposures to TCE from use in vapor degreasing would be completely eliminated. As a result, both non-cancer and cancer risks from this use of TCE would be eliminated.

The proposed approach would ensure that employees are no longer at risk from TCE exposure associated with vapor degreasing. Prohibiting the manufacturing (including import), processing and distribution in commerce of TCE for use in vapor degreasing would minimize the availability of TCE for vapor degreasing. The downstream notification of these restrictions ensures that processors, distributors, and other purchasers are aware of the manufacturing (including import), processing, distribution in commerce and use restrictions for TCE in vapor degreasing, and helps to ensure that the rule is effectively implemented by discouraging off-label use of TCE manufactured for other uses. Downstream notification is important because EPA is not proposing to prohibit manufacturing, processing and all uses of TCE, just those activities associated with vapor degreasing. This integrated supply chain approach is necessary to address the identified unreasonable risks presented by the use of TCE in vapor degreasing. In addition, the proposed approach would provide staggered compliance dates for implementing the prohibition on manufacturing (including import), processing, distribution in commerce, and commercial use in order to avoid undue impacts on the businesses involved.

b. *Variation of the proposed approach that would allow the use of TCE in closed-loop vapor degreasing systems and require under TSCA section 6(a)(5) the use of personal protective equipment in vapor degreasing operations in which TCE is used.* Another regulatory option that EPA considered was to allow the use of TCE in closed-loop vapor degreasing systems and require respiratory protection equipment for workers operating the equipment in the form of a full face piece self-contained breathing apparatus (SCBA) in pressure demand mode or other positive pressure mode with an APF of 10,000 with an alternative to the specified APF respirator of an air exposure limit. EPA's analysis found

that use of a SCBA with an APF of 10,000 for workers operating closed-loop vapor degreasing systems that contain TCE could control TCE air concentration to levels that ensure that TCE no longer presents the identified unreasonable risks. Depending on air concentrations and proximity to the vapor degreasing equipment, other employees in the area would also need to wear respiratory protection equipment.

Although respirators could reduce exposures to levels that are protective of non-cancer and cancer risks, there are many documented limitations to successful implementation of respirators with an APF of 10,000. Not all workers can wear respirators. Individuals with impaired lung function, due to asthma, emphysema, or chronic obstructive pulmonary disease, for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for a tight fitting full-facepiece respirator to provide the required protection. Also, difficulties associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the assigned capabilities of the respirator. Individuals who cannot get a good facepiece fit, including those individuals whose beards or sideburns interfere with the facepiece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems and vision problems, increase worker fatigue, and reduce work efficiency (Ref. 37). According to OSHA, “improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer’s safety or health.” (Ref. 37, at 1189–1190). Nonetheless, it is sometimes necessary to use respiratory protection to control exposure. The OSHA respiratory protection standard requires employers to establish and implement a respiratory protection program to protect their respirator-wearing employees (Ref. 38). This OSHA standard contains a number of implementation requirements, *e.g.*, for program administration; worksite-specific procedures; respirator selection; employee training; fit testing; medical evaluation; respirator use; respirator cleaning, maintenance, and repair; and other provisions that would be difficult to fully implement in some small

business settings where they are not already using respirators.

In addition, OSHA adopted a hierarchy of controls established by the industrial hygiene community used to protect employees from hazardous airborne contaminants, such as TCE (see, *e.g.*, 29 CFR 1910.134(a)(1), 29 CFR 1910.1000(e), and OSHA’s substance specific standards in 29 CFR 1910 subpart Z). According to the hierarchy, substitution of less toxic substances, engineering controls, administrative controls, and work practice controls are the preferred method of compliance for protecting employees from airborne contaminants and are to be implemented first, before respiratory protection is used. OSHA permits respirators to be used where engineering controls are not feasible or during an interim period while such controls are being implemented.

Under this approach, a company could choose to use a closed-loop system coupled with an air exposure limit. In order to reach the health benchmarks, the air exposure limit would have to be 1 ppb as an 8-hour TWA. Based on EPA’s analysis, the only way to achieve an air exposure limit of 1 ppb is with a combination of a closed-loop vapor degreaser and a respirator with an APF of 10,000. However, as previously discussed, EPA acknowledges that available data is limited, particularly with respect to the different types of closed-loop vapor degreasers. It is possible that the more sophisticated airless vacuum-to-vacuum closed-loop systems have lower emissions than EPA estimated, and, therefore, respiratory protection with an APF of 10,000 may not be necessary for operators. As part of this approach, EPA believes it would be necessary to establish employee exposure monitoring requirements to ensure that employee exposures are measured accurately and that employees are not exposed to the identified unreasonable risks associated with TCE use in vapor degreasing. EPA would require upfront monitoring representative of each exposed employee’s exposures and would model the requirements on comparable OSHA requirements as well as on the New Chemical Exposure Limit (NCEL) requirements that EPA has long used in addressing employee exposure to chemicals undergoing review under TSCA section 5 (Refs. 38–39). The requirements would specify how and when sampling must be performed and how the samples would have to be analyzed.

EPA is not proposing this option because substitutes for TCE are commercially available and

implementation of a respiratory protection program is likely to be difficult for many vapor degreasing facilities. In addition, EPA’s economic analysis indicates that this option is more expensive than switching to a different solvent or cleaning system. However, EPA requests comment, information, and data on the utility and feasibility of this option and whether, if it were adopted, it should be implemented by specifying the vapor degreasing technology and either requiring specific PPE or compliance with an air exposure limit. If EPA were to specify both the vapor degreasing technology and the required PPE with the alternative air exposure limit in the final rule, EPA would require the vapor degreasing system to be an airless vacuum-to-vacuum closed-loop system and the PPE to have an APF of 10,000 or otherwise meet the air exposure limit of 1 ppb as an 8-hour TWA. As previously discussed, EPA’s assessment of worker exposure from closed-loop systems relies on an assumption that emissions from each closed-loop system are 98% less than the emissions from an open top vapor degreasing system. EPA is requesting information on whether releases from the use of TCE in an airless vacuum-to-vacuum closed-loop system would result in air levels that are at or below the air exposure limit of 1 ppb. To the extent that EPA receives information that indicates that this is the case, EPA would consider finalizing this rule to exclude airless vacuum-to-vacuum closed-loop systems. In contrast, this assumption of a 98% reduction may be overly generous for the most basic of the closed-loop systems, and operators of such systems, even when wearing PPE with an APF of 10,000, would continue to be exposed to the identified unreasonable risks. Under the optional approach, companies choosing to keep using TCE would have to comply with all of OSHA’s requirements for respiratory protection programs, including fit-testing and medical monitoring.

C. Adverse Health Effects and Related Impacts That Would Be Prevented by the Proposed Option

The proposed option would prevent exposure to TCE from vapor degreasing and thus would prevent the risks of adverse effects and associated impacts. As discussed in Unit IV., TCE exposure is associated with a wide array of adverse health effects. These health effects include those resulting from developmental toxicity (*e.g.*, cardiac malformations, developmental immunotoxicity, developmental neurotoxicity, fetal death), toxicity to

the kidney (kidney damage and kidney cancer), immunotoxicity (systemic autoimmune diseases such as scleroderma) and severe hypersensitivity skin disorder, non-Hodgkin's lymphoma, endocrine and reproductive effects (e.g., decreased libido and potency), neurotoxicity (e.g., trigeminal neuralgia), and toxicity to the liver (impaired functioning and liver cancer) (Ref. 2). These health effects associated with exposure to TCE are serious and can have impacts throughout a lifetime. The following is a discussion of the impacts of significant acute, chronic non-cancer, and cancer effects associated with TCE exposure during vapor degreasing, including the severity of the effect, the manifestation of the effect, and how the effect impacts a person during their lifetime.

1. *Developmental effects.* The TCE risk assessment (and EPA's 2011 IRIS Assessment) identified developmental effects as the critical effect of greatest concern for both acute and chronic non-cancer risks. There are increased health risks for developmental effects to the estimated 454 to 1,066 pregnant women exposed to TCE during the use of vapor degreasers (Ref. 3). Specifically, these assessments identified fetal cardiac malformations in the offspring of mothers exposed to TCE during gestation as the critical effect. Although fetal cardiac defects are the effect of greatest concern and are the focus of the discussion in this Unit, TCE exposures can result in other adverse developmental outcomes, including prenatal (e.g., spontaneous abortion and perinatal death, decreased birth weight, and congenital malformations) and postnatal (e.g., reduced growth, decreased survival, developmental neurotoxicity, developmental immunotoxicity, and childhood cancers) effects. TCE exposure during development results in qualitatively different immunotoxic effects than when exposure occurs during adulthood. TCE exposure during development can influence the development of the immune system and result in impairment of the immune system's ability to respond to infection, whereas TCE exposures during adulthood result in a more pronounced immune effect related to autoimmune responses.

Cardiac defects, which can result from low-level exposure to TCE, affect the structural development of a baby's heart and how it works. The defects impact how blood flows through the heart and out to the rest of the body. The impact can be mild (such as a small hole in the heart) or severe (such as missing or

poorly formed septal wall and valves of the heart). While diagnosis for some cardiac defects can occur during pregnancy, for other cardiac defects, detection may not occur until after birth or later in life, during childhood or adulthood. These cardiac defects can be occult or life-threatening with the most severe cases causing early mortality and morbidity. While the incidences in the following paragraphs reflect adverse health outcomes beyond just exposure to TCE, the general population numbers provide a context for understanding the impact of the adverse health effects TCE can cause.

Nearly 1% or about 40,000 births per year in the United States are affected by cardiac defects (Ref. 40). About 25% of those infants with a cardiac defect have a critical defect. Infants with critical cardiac defects generally need surgery or other procedures in their first year of life. Some estimates put the total number of individuals (infants, children, adolescents, and adults) living with cardiac defects at 2 million (Ref. 40). Cardiac defects can be caused by genetics, environmental exposure, or an unknown cause.

Infant deaths resulting from cardiac defects often occur during the neonatal period. One study indicated that cardiac defects accounted for 4.2% of all neonatal deaths. Of infants born with a non-critical cardiac defect, 97% are expected to survive to the age of one, with 95% expected to survive to 18 years of age. Of infants born with a critical cardiac defect, 75% are expected to survive to one year of age, with 69% expected to survive to 18 years of age (Ref. 41). A child with a cardiac defect is 50% more likely to receive special education services compared to a child without birth defects (Ref. 40).

Treatments for cardiac defects vary. Some affected infants and children might need one or more surgeries to repair the heart or blood vessels. In other instances, a heart defect cannot be fully repaired, although treatments have advanced such that infants are living longer and healthier lives. Many children are living into adulthood and lead independent lives with little or no difficulty. Others, however, may develop disability over time, making it difficult to predict and quantify impacts.

Even though a person's heart defect may be repaired, for many people this is not a cure. They can still develop other health problems over time, depending on their specific heart defect, the number of heart defects they have, and the severity of their heart defect. For example, some related health problems that might develop include

irregular heart beat (arrhythmias), increased risk of infection in the heart muscle (infective endocarditis), or weakness in the heart (cardiomyopathy). In order to stay healthy, a person needs regular checkups with a cardiologist. They also might need further operations after initial childhood surgeries (Ref. 40).

Depending upon the severity of the defect, the costs for surgeries, hospital stays, and doctor's appointments to address a baby's cardiac defect can be significant. The costs for the defects may also continue throughout a person's lifetime. In 2004, hospital costs in the United States for individuals with a cardiac defect were approximately \$1.4 billion (Ref. 40).

Beyond the monetary cost, the emotional and mental toll on parents who discover that their child has a heart defect while *in utero* or after birth will be high (Ref. 41). They may experience anxiety and worry over whether their child will have a normal life of playing with friends and participating in sports and other physical activities, or whether their child may be more susceptible to illness and be limited in the type of work and experiences they can have. In addition, parents can be expected to experience concerns over potential unknown medical costs that may be looming in the future, lifestyle changes, and being unable to return to work in order to care for their child.

The emotional and mental toll on a person throughout childhood and into adolescence with a heart defect also should be considered (Ref. 41). Cardiac patients who are children may feel excluded from activities and feel limited in making friends if they have to miss school due to additional surgeries, or may not be able to fully participate in sports or other physical exercise. Children may feel self-conscious of the scars left by multiple surgeries. This, in turn, adds emotional and mental stress to the parents as they observe their child's struggles.

As a person with a heart defect enters adulthood, the emotional or mental toll of a cardiac defect may continue or in other instances the problem may only surface as an adult. If a cardiac defect impacts a person's ability to enter certain careers, this could take a monetary as well as emotional toll on that person and on their parents or families who may need to provide some form of financial support. The monetary, emotional, and mental costs of heart defects can be considerable, and even though neither the precise reduction in individual risk of developing a cardiac defect from reducing TCE exposure or the total

number of cases avoided can be estimated, their impact should be considered.

2. *Kidney toxicity. a. Non-cancer chronic effects.* The TCE risk assessment identified kidney toxicity as a significant concern from TCE exposure with the risk from this non-cancer effect being from chronic exposure. There are increased health risks for kidney toxicity to the approximately 2,670 to 6,270 workers and 42,720 to 100,320 occupational bystanders in facilities that use TCE for vapor degreasing, where exposure to TCE is a result of vapor degreasing operations (Ref. 3).

Exposure to TCE can lead to changes in the proximate tubules of the kidney. This damage may result in signs and symptoms of acute kidney failure that include; decreased urine output, although occasionally urine output remains normal; fluid retention, causing swelling in the legs, ankles or feet; drowsiness; shortness of breath, fatigue, confusion, nausea, seizures or coma in severe cases; and chest pain or pressure. Sometimes acute kidney failure causes no signs or symptoms and is detected through lab tests done for another reason.

Kidney toxicity means the kidney(s) has suffered damage that can result in a person being unable to rid their body of excess urine and wastes. In extreme cases where the kidney(s) is impaired over a long period of time, the kidney(s) could be damaged to the point that it no longer functions. When a kidney(s) no longer functions, a person needs dialysis and ideally a kidney transplant. In some cases, a non-functioning kidney(s) can result in death. Kidney dialysis and kidney transplantation are expensive and incur long-term health costs if kidney function fails (Ref. 42).

Approximately 31 million people, or 10% of the adult population, in the United States have chronic kidney disease. In the United States, it is the ninth leading cause of death. About 93% of chronic kidney disease is from known causes, including 44% from diabetes and 28.4% from high blood pressure. Unknown or missing causes account for about 6.5% of cases, or about 2 million people (Ref. 43).

The monetary cost of kidney toxicity varies depending on the severity of the damage to the kidney. In less severe cases, doctor visits may be limited and hospital stays unnecessary. In more severe cases, a person may need serious medical interventions, such as dialysis or a kidney transplant if a donor is available, which can result in high medical expenses due to numerous hospital and doctor visits for regular dialysis and surgery if a transplant

occurs. The costs for hemodialysis, as charged by hospitals, can be upwards of \$100,000 per month (Ref. 44).

Depending on the severity of the kidney damage, kidney disease can impact a person's ability to work and live a normal life, which in turn takes a mental and emotional toll on the patient. In less severe cases, the impact on a person's quality of life may be limited, while in instances where kidney damage is severe, a person's quality of life and ability to work would be affected. While neither the precise reduction in individual risk of developing kidney toxicity from reducing TCE exposure or the total number of cases avoided can be estimated, these costs must still be considered because they can significantly impact those exposed to TCE.

b. *Cancer effects.* Chronic exposure to TCE can also lead to kidney cancer. The estimated value of the annualized benefit is \$12 million to \$108 million at 3% and \$6 million to \$57 million at 7% over 20 years. Kidney cancer rarely shows signs or symptoms in its early stages. As kidney cancer progresses, the cancer may grow beyond the kidney, spreading to lymph nodes or distant sites like the liver, lung or bladder, increasing the impacts on a person and the costs to treat it. This metastasis is highly correlated with fatal outcomes. Impacts of kidney cancer that are not monetized include the emotional, psychological and treatment impacts of the cancer on the well-being of the person.

3. *Immunotoxicity. a. Non-cancer chronic effects.* The TCE risk assessment identified immunotoxicity as a chronic non-cancer effect that is associated with TCE exposure. There are increased health risks for immunotoxicity to the approximately 2,670 to 6,270 workers and 42,720 to 100,320 bystanders exposed to TCE as a result of vapor degreasing operations (Ref. 3).

Human studies have demonstrated that TCE exposed workers can suffer from systemic autoimmune diseases (e.g., scleroderma) and severe hypersensitivity skin disorders. Scleroderma is a chronic connective tissue disease with autoimmune origins. The annual incidence is estimated to be 10 to 20 cases per 1 million persons (Ref. 45), and the prevalence is four to 253 cases per 1 million persons (Ref. 46). About 300,000 Americans are estimated to have scleroderma. About one third of those people have the systemic form of scleroderma. Since scleroderma presents with symptoms similar to other autoimmune diseases, diagnosis is difficult. There may be

many misdiagnosed or undiagnosed cases (Ref. 46).

Localized scleroderma is more common in children, whereas systemic scleroderma is more common in adults. Overall, female patients outnumber male patients about 4-to-1. Factors other than a person's gender, such as race and ethnic background, may influence the risk of getting scleroderma, the age of onset, and the pattern or severity of internal organ involvement. The reasons for this susceptibility are not clear. Although scleroderma is not directly inherited, some scientists believe there is a slight predisposition to it in families with a history of rheumatic diseases (Ref. 46).

The symptoms of scleroderma vary greatly from person to person with the effects ranging from very mild to life threatening. If not properly treated, a mild case can become much more serious. Relatively mild symptoms are localized scleroderma, which results in hardened waxy patches on the skin of varying sizes, shapes and color. The more life threatening symptoms are from systemic scleroderma, which can involve the skin, esophagus, gastrointestinal tract (stomach and bowels), lungs, kidneys, heart and other internal organs. It can also affect blood vessels, muscles and joints. The tissues of involved organs become hard and fibrous, causing them to function less efficiently.

Severe hypersensitivity skin disorders include exfoliative dermatitis, mucous membrane erosions, eosinophilia, and hepatitis. Exfoliative dermatitis is a scaly dermatitis involving most, if not all, of the skin. Eosinophilia, on the other hand, is a chronic disorder resulting from excessive production of a particular type of white blood cells. If diagnosed and treated early, a person can lead a relatively normal life (Ref. 45).

The monetary costs for treating these various immunotoxicity disorders will vary depending upon whether the symptoms lead to early diagnosis and this early diagnosis can then influence whether symptoms progress to mild or life-threatening outcomes. For mild symptoms, doctors' visits and outpatient treatment could be sufficient, while more severe immunotoxicity disorders, may require hospital visits. Treatments for these conditions with immune modulating drugs also have countervailing risks.

These disorders also take an emotional and mental toll on the person as well as on their families. Their quality of life may be impacted because they no longer have the ability to do certain activities that may affect or

highlight their skin disorder, such as swimming. Concerns over doctor and hospital bills, particularly if a person's ability to work is impacted, may further contribute to a person's emotional and mental stress. While neither the precise reduction in individual risk of developing this disorder from TCE exposure or the total number of cases avoided can be estimated, this should be considered.

b. Cancer effects: Non-Hodgkin's Lymphoma. EPA's 2011 IRIS assessment for TCE found that TCE is carcinogenic. Chronic exposure to TCE, by all routes of exposure, can result in non-Hodgkin's lymphoma (NHL), one of the three cancers for which the EPA IRIS TCE assessment based its cancer findings. There are increased health risks for NHL for the approximately 2,670 to 6,270 workers and 42,720 to 100,320 occupational bystanders exposed to TCE as a result of vapor degreasing operations (Ref. 3).

NHL is a form of cancer that originates in a person's lymphatic system. For NHL, there are approximately 19.7 new cases per 100,000 men and women per year with 6.2 deaths per 100,000 men and women per year. NHL is the seventh most common form of cancer (Ref. 47). Some studies suggest that exposure to chemicals may be linked to an increased risk of NHL. Other factors that may increase the risk of NHL are medications that suppress a person's immune system, infection with certain viruses and bacteria, or older age (Ref. 48).

Symptoms are painless, swollen lymph nodes in the neck, armpits or groin, abdominal pain or swelling, chest pain, coughing or trouble breathing, fatigue, fever, night sweats, and weight loss. Depending on the rate at which the NHL is advancing, the approach may be to monitor the condition, while more aggressive NHL could require chemotherapy, radiation, stem cell transplant, medications that enhance a person's immune system's ability to fight cancer, or medications that deliver radiation directly to cancer cells.

Treatment for NHL will result in substantial costs for hospital and doctors' visits in order to treat the cancer. The treatments for NHL can also have countervailing risks and can lead to higher susceptibility of patients to secondary malignancies (Ref. 49). The emotional and mental toll from wondering whether a treatment will be successful, going through the actual treatment, and inability to do normal activities or work will most likely be high. This emotional and mental toll will extend to the person's family and friends as they struggle with the

diagnosis and success and failure of a treatment regime. If a person has children, this could affect their mental and emotional well-being and may impact their success in school. The estimated value of the monetized benefit is \$32 million to \$201 million at 3% and \$15 million to \$98 million at 7% annualized over 20 years.

4. Reproductive and endocrine effects. The TCE risk assessment identified risks of chronic non-cancer reproductive effects for workers and bystanders exposed to TCE. There are increased health risks for reproductive effects for the approximately 2,670 to 6,270 workers and 42,720 to 100,320 occupational bystanders exposed to TCE as a result of vapor degreasing operations (Ref. 3).

The reproductive effect for both females and males can be altered libido. The prevalence of infertility is estimated at about 10–15% of couples with a decreased libido among the factors of infertility (Ref. 50). For females, there can be reduced incidence of fecundability (6.7 million women ages 15 to 44 or 10.9% affected) (Ref. 51), increase in abnormal menstrual cycles, and amenorrhea (the absence of menstruation). Reproductive effects on males can be decreased potency, gynaecomastia, impotence, and decreased testosterone levels, or low T levels. Approximately 2.4 million men age 40 to 49 have low T levels, with a new diagnosis of about 481,000 androgen deficiency cases a year. Other estimates propose a hypogonadism prevalence of about 13 million American men (Ref. 52). Low T levels are associated with aging; an estimated 39% of men 45 or older have hypogonadism, resulting in low T levels (Ref. 53). Hormone therapy and endocrine monitoring may be required in the most severe cases.

The monetary costs of these potential reproductive effects involve doctor's visits in order to try to determine a diagnosis. In some instances, a person or couple may need to visit a fertility doctor.

The impact of a reduced sex drive can take an emotional and mental toll on single people as well as couples. For people trying to get pregnant, decreased fertility can add stress to a relationship as the cause is determined and avenues explored to try to resolve the difficulties in conceiving. A person or couples' quality of life can also be affected as they struggle with a reduced sex drive. Similar to other non-cancer effects discussed previously, while neither the precise reduction in individual risk of developing this disorder from reducing TCE exposure or the total number of

cases avoided can be estimated, the Agency still must consider their impact.

5. Neurotoxicity. The TCE risk assessment identified neurotoxicity risks for workers and bystanders from chronic TCE exposures. There are increased health risks of neurotoxicity for the approximately 2,670 to 6,270 workers and 42,720 to 100,320 occupational bystanders exposed to TCE as a result of vapor degreasing operations (Ref. 3).

Studies have also demonstrated neurotoxicity from acute exposures. Neurotoxic effects observed include alterations in trigeminal nerve and vestibular function, auditory effects, changes in vision, alterations in cognitive function, changes in psychomotor effects, and neurodevelopmental outcomes. Developmental neurotoxicity effects include delayed newborn reflexes, impaired learning or memory, aggressive behavior, hearing impairment, speech impairment, encephalopathy, impaired executive and motor function and attention deficit (Ref. 4).

The impacts of neurotoxic effects due to TCE exposure can last a person's entire lifetime. Changes in vision may impact a person's ability to drive, which can create difficulties for daily life. Impaired learning or memory, aggressive behavior, hearing impairment, speech impairment, encephalopathy, impaired executive and motor function and attention deficit can impact a child's educational progression and an adolescent's schooling and ability to make friends, which in turn can impact the type of work or ability to get work later in life.

Neurotoxicity in adults can affect the trigeminal nerve, the largest and most complex of the 12 cranial nerves, which supplies sensations to the face, mucous membranes, and other structures of the head. Onset of trigeminal neuralgia generally occurs in mid-life and known causes include multiple sclerosis, sarcoidosis and Lyme disease. There is also a co-morbidity with scleroderma and systemic lupus. Some data show that the prevalence of trigeminal neuralgia could be between 0.01% and 0.3% (Ref. 54). Alterations to this nerve function might cause sporadic and sudden burning or shock-like facial pain to a person. One way to relieve the burning or shock-like facial pain is to undergo a procedure where the nerve fibers are damaged in order to block the pain. This treatment can have lasting impact on sensation which may also be deleterious for normal pain sensation. The potential side effects of this

procedure includes facial numbness and some sensory loss.

The monetary health costs can range from doctor's visits and medication to surgeries and hospital stays. Depending upon when the neurotoxic effect occurred, the monetary costs may encompass a person's entire lifetime or just a portion.

The personal costs (emotional, mental, and impacts to a person's quality of life) cannot be discounted. Parents of a child with impaired learning, memory, or some other developmental neurotoxic effect may suffer emotional and mental stress related to worries about the child's performance in school, ability to make friends, and quality of the child's life because early disabilities can have compounding effects as they grow into adulthood. The parent may need to take off work unexpectedly and have the additional cost of doctor visits and/or medication.

For a person whose trigeminal nerve is affected, there is an emotional and mental toll as they wonder what is wrong and visit doctors in order to determine a diagnosis. Depending on the severity of the impact to the nerve, they may be unable to work. Doctor visits and any inability to work will have a monetary impact to the person. There are varying costs (emotional, monetary, and impacts to a person's quality of life) from the neurotoxic effects due to TCE exposure. However, while neither the precise reduction in individual risk of developing this disorder from reducing TCE exposure or the total number of cases avoided can be estimated, this is not a reason to disregard their impact.

6. Liver toxicity. The TCE risk assessment identified liver toxicity as an adverse effect of chronic TCE exposure. There are increased health risks for liver toxicity to the approximately 2,670 to 6,270 workers and 42,720 to 100,320 occupational bystanders exposed to TCE as a result of vapor degreasing operations (Ref. 2).

Specific effects to the liver can include increased liver weight, increase in DNA synthesis (transient), enlarged hepatocytes, enlarged nuclei, and peroxisome proliferation (Ref. 2). In addition, workers exposed to TCE have shown hepatitis accompanying immune-related generalized skin diseases, jaundice, hepatomegaly, hepatosplenomegaly, and liver failure (Ref. 2).

Some form of liver disease impacts at least 30 million people, or 1 in 10 Americans (Ref. 55). Included in this number is at least 20% of those with nonalcoholic fatty liver disease

(NAFLD) (Ref. 55). NAFLD tends to impact people who are overweight/obese or have diabetes. However, an estimated 25% do not have any risk factors (Ref. 55). The danger of NAFLD is that it can cause the liver to swell, which may result in cirrhosis over time and could even lead to liver cancer or failure (Ref. 55). The most common known causes to this disease burden are attributable to alcoholism and viral infections, such as hepatitis A, B, and C. In 2013, there were 1,781 reported acute cases of viral hepatitis A and the estimated actual cases were 3,500 (Ref. 56). For hepatitis B in 2013 there were 3,050 reported acute cases, while the estimated actual incidence was 19,800, and the estimated chronic cases in the United States is between 700,000 to 1.4 million (Ref. 56). For hepatitis C, in 2013 there were 2,138 reported cases; however, the estimated incidence was 29,700 and the estimated number of chronic cases is between 2.7 to 3.9 million (Ref. 56). These known environmental risk factors of hepatitis infection may result in increased susceptibility of individuals exposed to organic chemicals. While the incidences in this paragraph reflect adverse health outcomes beyond just exposure to TCE, the general population numbers provide a context for understanding the impact of the adverse health effects that TCE can cause.

Effects from TCE exposure to the liver can occur quickly. Liver weight increase has occurred in mice after as little as 2 days of inhalation exposure (Ref. 4). Human case reports from eight countries indicated symptoms of hepatitis, hepatomegaly and elevated liver function enzymes, and in rare cases, acute liver failure developed within as little as 2–5 weeks of initial exposure to TCE (Ref. 4).

Chronic exposure to TCE can also lead to liver cancer. There is strong epidemiological data that reported an association between TCE exposure and the onset of various cancers, including liver cancer. The estimated value of the annualized benefit is estimated to be \$21 million to \$133 million at 3% and \$11 million to \$71 million at 7% over 20 years.

Additional medical and emotional costs are associated with non-cancer liver toxicity from TCE exposure, although they cannot be quantified. These costs include doctor and hospital visits and medication costs. In some cases, the ability to work can be affected, which in turn impacts the ability to get proper ongoing medical care. Liver toxicity can lead to jaundice, weakness, fatigue, weight loss, nausea, vomiting, abdominal pain, impaired

metabolism, and liver disease.

Symptoms of jaundice include yellow or itchy skin and a yellowing of the whites of the eye, and a pale stool and dark urine. These symptoms can create a heightened emotional state as a person tries to determine what is wrong with them.

Depending upon the severity of the jaundice, treatments can range significantly. Simple treatment may involve avoiding exposure to the TCE; however, this may impact a person's ability to continue to work. In severe cases, the liver toxicity can lead to liver failure, which can result in the need for a liver transplant, if a donor is available. Liver transplantation is expensive (with an estimated cost of \$575,000) and there are countervailing risks for this type of treatment (Ref. 57). The mental and emotional toll on an individual and their family as they try to determine the cause of sickness and possibly experience an inability to work, as well as the potential monetary cost of medical treatment required to regain health are significant.

D. Availability of Alternatives

TCE is commonly used in vapor degreasing systems for a variety of reasons. It is able to dissolve the greases, fats, oils, waxes, resins, gums and rosin fluxes generally used in metalworking operations and it is compatible with most metal substrates. TCE is non-flammable and it has a relatively low boiling point. It is also available at a relatively low cost. Several SERs providing input to the SBAR Panel convened in support of this rulemaking noted that TCE is particularly well-suited for use in vapor degreasing in the narrow tube, razor blade, and aerospace industries (Ref. 32).

Nevertheless, EPA identified a wide variety of technically and economically feasible alternatives for vapor degreasing with TCE. See Unit 4 of the Economic Analysis for a complete discussion of the technically and economically feasible alternatives to TCE. (Ref. 3). While some substitutes, such as methylene chloride or 1–BP, also present risks to workers, there are numerous other solvents available. These include designer solvents such as hydrofluorocarbon (HFC) and hydrofluoroether (HFE) solvent blends and hydrofluoroolefin (HFO), as well as other alternative solvents and cleaning systems, such as terpene-based cleaners, volatile methyl siloxanes, soy-based cleaners, and water-based cleaners.

Alternatives to TCE fall within several broad categories: Drop-in solvent alternatives, non-drop-in solvent alternatives (designer solvents, such as

hydrofluorocarbons, hydrofluoroolefins, and hydrofluoroethers), aqueous cleaning systems, other cleaning solvents (such as glycol ethers, siloxanes, terpenes, soy-based cleaners), and cold cleaning with TCE (Ref. 58).

EPA considered a solvent to be a drop-in alternative if it could be used in an existing vapor degreasing system with only minor modifications. One important consideration for many vapor degreasing machines is the flammability of the solvent. Heating a flammable solvent up to its boiling point increases the likelihood that, if there is a source of ignition or if the vapor concentration exceeds certain limits, the solvent will ignite or explode. Halogens (fluorine, chlorine and bromine) suppress flammability, hence their common use as fire extinguishants. For this reason, halogenated solvents are commonly used in vapor degreasing, although solvent flammability is less of a concern in closed-loop systems operated under vacuum. Depending on the type of vapor degreasing system, the drop-in solvent alternatives identified by EPA include methylene chloride, 1-bromopropane (1-BP or n-propyl bromide), and perchloroethylene. Like TCE, methylene chloride and perchloroethylene are hazardous air pollutants (HAPs) under the Clean Air Act and their use is regulated under the Halogenated Solvent NESHAP (40 CFR part 63, subpart T). Therefore, facilities that switch from TCE to methylene chloride or perchloroethylene will still be regulated by the NESHAP. In addition, although 1-BP is not currently listed as a HAP, EPA is currently considering a petition to list this chemical (Ref. 59).

There are significant hazards associated with all three of these drop-in replacements for TCE in vapor degreasing systems. However, based on EPA's analysis, the adverse effects associated with TCE exposure occur at exposure levels below the levels at which the adverse effects associated with the replacement chemicals occur (Ref. 58). With respect to methylene chloride, in August 2014, EPA issued a risk assessment of its use for paint and coating removal and EPA intends to issue a proposal to regulate this use of methylene chloride. While EPA has not specifically assessed the risks associated with using methylene chloride in vapor degreasing applications for this rulemaking, there are a number of hazard concerns associated with this chemical. The potential effects of methylene chloride exposure include death, liver toxicity, kidney toxicity, reproductive toxicity, specific cognitive impacts, and cancer (Ref. 60). Some of

these effects result from a very short, acute exposure; others follow years of occupational exposure. Acute exposures may cause confusion and respiratory suppression in humans and there have been a number of deaths associated with worker exposures in homes and other job sites due to the buildup of carbon monoxide in the blood. Methylene chloride is likely to be carcinogenic in humans, so chronic exposures may increase cancer risk. Chronic exposures to methylene chloride may also lead to liver effects. However, these adverse effects are generally seen at higher exposure levels than those associated with TCE toxicity.

With respect to environmental effects, methylene chloride is volatile and releases of methylene chloride are likely to evaporate to the atmosphere, or if released to soil, migrate to groundwater (Ref. 59). It has a global warming potential (GWP) of 8.7 relative to carbon dioxide and thus can act as a greenhouse gas. Methylene chloride has been shown to biodegrade over a range of rates and conditions and is considered to be moderately persistent in the environment. Measured bioconcentration factors suggest that its bioconcentration potential is low.

EPA also has concerns for 1-BP. In May of 2016, a peer review meeting was held on EPA's draft TSCA Work Plan Chemical Risk Assessment for 1-BP. This draft assessment specifically evaluated the risks associated with the use of 1-BP in vapor degreasing (Ref. 61). According to the peer review draft, most acute exposure scenarios for vapor degreasing identified risks for adverse developmental effects that may occur as a result of a single exposure to 1-BP during a critical window of susceptibility. Likewise, chronic exposure risks for adverse neurological and developmental effects were identified in the draft risk assessment for all uses evaluated without engineering controls. In addition, the draft weight-of-evidence analysis for the cancer endpoint is sufficient to support a probable mutagenic mode of action for 1-BP carcinogenesis. However, these adverse effects are generally seen at higher exposure levels than those associated with TCE toxicity.

1-BP is a volatile liquid with high vapor pressure, moderate water solubility, and high mobility in soil (Ref. 61). It is expected to exhibit low adsorption to soil and thus can migrate rapidly through soil to groundwater. 1-BP is slowly degraded by sunlight and reactants when released to the atmosphere. Based on the estimated half-life of nine to twelve days, long range transport via the atmosphere is

possible. Biotic and abiotic degradation studies have not shown this substance to be persistent (overall environmental half-life less than two months). While no measured bioconcentration studies for 1-BP are available, an estimated bioaccumulation factor of 12 suggests that bioconcentration and bioaccumulation in aquatic organisms are low.

EPA is also concerned about the adverse health effects associated with perchloroethylene (tetrachloroethylene) exposure. Based on the available human epidemiologic data and experimental and mechanistic studies, EPA has concluded that it poses a potential human health hazard for noncancer toxicity to the central nervous system, kidney, liver, immune and hematologic system, and on development and reproduction. (Ref. 62) Neurotoxicity has been identified as a sensitive endpoint following either oral or inhalation exposure. In addition, EPA has determined that perchloroethylene (tetrachloroethylene) is likely to be carcinogenic to humans by all routes of exposure (Ref. 62). As with methylene chloride and 1-BP, the adverse health effects associated with perchloroethylene (tetrachloroethylene) are generally seen at higher exposure levels than those associated with TCE toxicity. Perchloroethylene presents low to moderate risk to aquatic organisms (Ref. 62). It is moderately persistent, with a low bioaccumulation potential.

In contrast, aqueous cleaning systems present less risk to workers. Water-based cleaners have been used for many years in applications where users originally used TCE or other chlorinated solvents in vapor degreasing. In these systems, water-based cleaners are used to clean grease or oil from parts, the parts are rinsed, sometimes with deionized water if a spot free part is required for the next process, and dried. The cleaner concentrate, typically made up of boric acid or gluconic acid and other constituents, is generally diluted to between about 5% and 20% in a heated wash bath, depending on the cleaning task and the agitation in the equipment. The rinse is generally heated as well. Often driers composed of air knives that drive the water from the part are used.

Depending on the circumstances, several different types of equipment capable of using water-based cleaners can replace vapor degreasing machines that use TCE. Ultrasonic cleaning systems have transducers for generating the ultrasonic action in a bath. There are some immersion systems where the parts are placed on a platform and moved up and down in the cleaning

agent. In certain circumstances parts can be sprayed at pressures of about 60 psi and greater in spray cabinets. Conveyorized spray systems, where the parts go through high pressure spray at between about 80 and 120 psi, are also used in some cases. These systems often have wash, rinse and dry sections.

Water-based cleaners have a few characteristics to consider when evaluating replacements for TCE vapor degreasing (Ref. 63). Since TCE is used primarily to clean metal parts, the water cleaners often contain rust or corrosion inhibitors, which typically are present at very low concentrations, to protect the metals (Ref. 61). In addition, in order to be used in spray equipment, water-based cleaners must be formulated with a non-foaming surfactant. However, there are numerous water-based cleaners available on the market that have been formulated for these purposes (Ref. 64). In addition, the SBAR Panel convened in support of this rulemaking heard from several SERs about the increased water use associated with aqueous cleaning systems (more than 10,000 gallons a day). While this water can be reused in the degreasing system, any effluent is considered industrial wastewater for which a permit may be required under the Clean Water Act (Ref. 32).

SERs providing input to the SBAR Panel noted that, in general the use of TCE in vapor degreasing is declining very rapidly in certain sectors, but is still the method of choice for some, especially for small, intricate parts and substrates (e.g., small tubes). Several SERs contended that none of the currently available chemical alternatives are good substitutes for TCE because of the health hazards associated with the substitutes, potential upcoming regulations and use restrictions on substitutes, compliance with the NESHAP limitations, and cost. In addition, some degreasing applications require highly efficient cleaning, such as electronics and glass to metal seals, which must be absolutely free of soil. A SER stated that no substitutes for critical glass to metal seals have been identified. Several SERs stated that substitutes with lower boiling points are not viable alternatives because they volatilize during processes involving elevated temperatures and because they cannot be shipped in standard drums. Most SERs indicated that replacing their open-top vapor degreasing systems with more sophisticated systems or alternative systems using aqueous cleaners would be very expensive, estimates ranged from \$350,000 to \$650,000. In contrast, one SER noted that water-based, or aqueous cleaning

systems can be developed to replace most TCE-based vapor degreasing systems (Ref. 32). This same SER also stated that potential drawbacks to aqueous cleaning systems are the increased water use and the need for additional facility space. According to this SER, aqueous systems are typically much larger than vapor degreasing systems and aqueous operations often require multiple stages to reach the same cleaning efficiency as vapor degreasers.

Based on this input from the SERs, EPA is specifically requesting additional comments, information, and data to assist EPA in evaluating the availability of alternatives to TCE in vapor degreasing applications, including information on the costs to achieve TCE exposure reductions or to transition to alternative chemicals or processes. In addition, EPA will consider granting a time-limited exemption, under the authority of TSCA section 6(g), for a specific condition of use for which EPA can obtain documentation: That the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; that compliance with the proposed ban would significantly disrupt the national economy, national security, or critical infrastructure; or that TCE vapor degreasing in a specific application, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety. To this end, EPA requests comment on a process for receiving and evaluating petitions and requesting EPA promulgate critical use exemption rules. Under this process, entities who believe that their specific condition of use is a critical or essential use under TSCA section 6(g) would submit a petition for an exemption rulemaking with supporting documentation that they believe demonstrates that the use meets the statutory criteria. EPA would review the petition for completeness and, if the documentation warrants further action, respond to the petition by publishing a proposal in the **Federal Register** inviting comment on a proposed exemption. EPA would consider the comments received, along with any additional information reasonably available, and then take final action on the proposed exemption. EPA requests comment on the specific kinds of documentation that should be required from entities seeking an exemption rulemaking in order to facilitate EPA's and later, the public's review. EPA also requests comment on the appropriate

timeframes for EPA action, given that the documentation for any given use could be technical and extensive, and that EPA may also need to develop additional information, such as economic estimates, in order to promulgate an exemption rule under TSCA section 6(g). Finally, members of the potentially regulated community who believe that their operation is a critical or essential use should provide as much detail as possible to EPA about their operation during this comment period, including information on any evaluations of alternatives, the costs to transition to another chemical or process, and any other relevant information. This would assist EPA in reviewing the specific condition of use, as well as in establishing provisions for future exemption petitions.

EPA urges vapor degreasing facilities to think strategically about their choices should TCE be banned for their use or if they are in the market to replace or upgrade vapor degreasing equipment for other reasons. To the extent that a process currently using TCE in a vapor degreasing system can be converted to a significantly less toxic alternative, such as an aqueous cleaning system, it will avoid significant risks to workers and also reduce the likelihood that further actions on toxic solvents by EPA or other regulatory authorities will spur another process change.

E. Impacts of the Proposed and Alternative Regulatory Options

This unit describes the estimated costs of the proposed and alternative regulatory actions that EPA considered.

1. Proposed approach to prohibit manufacturing (including import), processing, distribution in commerce, and use of TCE for vapor degreasing and require downstream notification. The costs of the proposed approach are estimated to include equipment modification costs, product costs, electricity, disposal, and other costs associated with using alternative solvents or systems. Although the proposal imposes costs resulting from downstream notification and recordkeeping requirements, these actions required under this proposed rule are identical in requirement and coverage to those included as part of the earlier proposed rule on TCE use in aerosol degreasing and spot cleaning at dry cleaning facilities (Ref. 1) that is a companion to this proposed rule. These notification and recordkeeping costs were accounted for as part of that proposal and are not included in the costs for this rule. Overall, EPA estimates that 50% of users will switch to drop-in alternatives, 25% will

convert to aqueous cleaning systems, and 25% will convert to other alternatives. The total costs for switching from TCE-based vapor degreasing to a substitute are estimated to be approximately \$30 million to \$45 million per year (annualized at 3% over 20 years) and \$32 million to \$46 million (annualized at 7% over 20 years).

2. *Option that bans manufacturing (including import), processing, distribution in commerce, and use of TCE for vapor degreasing except in airless vacuum-to-vacuum closed-loop systems where proper PPE is used and a requirement for downstream notification.* Given equipment costs and the burden of establishing a respiratory protection program which involves training, respirator fit testing and the establishment of a medical monitoring program, EPA anticipates that companies not currently using airless vacuum-to-vacuum systems would choose to switch to substitutes instead of purchasing an airless system and adopting a program for PPE because substitutes are readily available and are more technically and economic feasible. EPA also assumes that this would be the case even if this alternative were expressed as a performance-based air exposure limit for TCE. The estimated annualized costs of switching to a respiratory protection program requiring PPE of APF 10,000 are \$30,000 at 3% and \$32,000 at 7% per vapor degreasing machine over 20 years. In addition, there would be higher EPA administration and enforcement costs with respiratory protection program than there would be with an enforcement program under the proposed approach. Further, even if cost were not an impediment, there are many limitations to the successful implementation of respirators with an APF of 10,000 in a workplace.

3. *Options that exclude downstream notification.* For those options that exclude downstream notification, the options are less cost effective and more burdensome to enforce. This is even though EPA assumes monetized enforcement costs to be the same under all options for the purpose of this proposed rulemaking because EPA was unable to monetize the extent to which enforcement costs would vary by regulatory option. The proposed approach to prohibit manufacturing (including import), processing, distribution in commerce, and use of TCE for vapor degreasing and require downstream notification is relatively easy to enforce because key requirements are directly placed on a small number of suppliers and because the supply chain approach minimizes to

the greatest extent the potential for TCE products to be intentionally or unintentionally misdirected into the prohibited uses. Enforcement under the other options would be more difficult since the key requirements are directly placed on the larger number of product users. Under these other options, enforcement activities must target firms that might perform the activity where a TCE use is restricted or prohibited. Therefore, EPA considers downstream notification to be a critical component of this proposal and EPA also finds that incorporating downstream notification reduces the burden on society by easing implementation, compliance, and enforcement.

VII. Monetized Benefits and Costs of the Proposed Rule, the Alternatives EPA Considered, and Comparison of Benefits and Costs

The health endpoints associated with TCE exposure are serious. The following is a discussion of the impacts of the most significant cancer and non-cancer effects associated with TCE exposure, including the severity of the effect, the manifestation of the effect, and how the effect impacts a person during their lifetime.

A. Benefits of the Proposed Rule and the Alternatives That EPA Considered

The risk reduction from preventing TCE exposure cannot be comprehensively quantified or monetized even though the adverse effects are well-documented, the TCE risk assessment estimating these risks has been peer-reviewed, and the benefits of reducing the risk of these health endpoints can be described. It is relatively straightforward to monetize the benefits of reducing the risk of the costs of the effects of cancer (kidney cancer, liver cancer, non-Hodgkin's lymphoma) due to TCE exposure. The estimated value of the annualized benefit is estimated to be \$65 million to \$447 million at 3% and \$32 million to \$227 million at 7% over 20 years. It is currently not possible to monetize the benefits of reducing the risks of the costs of non-cancer effects (all developmental toxicity, kidney toxicity, immunotoxicity, reproductive toxicity, neurotoxicity, and liver toxicity) of TCE exposure. There are two reasons for this. First, dose response information and concentration response functions in humans are not available. This information would allow EPA to estimate the number of population-level non-cancer cases that would be avoided by reducing exposures to levels corresponding with MOE benchmarks. Second, even it were possible to

calculate the number of cases avoided, EPA may not be able to monetize the benefits of these avoided cases due to limitations in data needed to apply established economic methodologies. However, being unable to quantitatively assess individual risk and population-level non-cancer cases avoided from TCE exposure does not negate the impact of these effects. Similarly, the inability to monetize an adverse effect does not reflect the severity of the effect, the lifetime nature of the impact, or the magnitude of the benefit in preventing the adverse impact from TCE exposure, such as a cardiac malformation, on a person. In considering the benefits of preventing TCE exposure, EPA considered the type of effect, the severity of the effect, the duration of the effect, and costs and other monetary impacts of the health endpoint.

The alternative options that EPA considered are unlikely to result in the same health benefits as the proposed rule for the reasons discussed in Unit VI. However, EPA was unable to quantify the differences in benefits that would result from the alternatives.

B. Costs of the Proposed Rule and the Alternatives That EPA Considered

The details of the costs of the proposed approach for use of TCE in vapor degreasing are discussed in Unit VI.C. Under the proposed option, costs to users of TCE in vapor degreasing applications range from \$30 million to \$45 million (annualized at 3% over 20 years) and \$32 million to \$46 million (annualized at 7% over 20 years). Costs of downstream notification and recordkeeping for manufacturers, processors, and distributors on an annualized basis over 20 years are \$3,200 and \$4,400 using 3% and 7% discount rates respectively. However, the costs of the downstream notification and recordkeeping requirements were already accounted for in the prior proposal on TCE use in aerosol degreasing and as a spotting agent in dry-cleaning facilities, and thus are not included in the total costs for this proposal.

The primary alternative that EPA considered is a requirement that TCE be used for vapor degreasing only in certain closed systems and that workers operating the systems and in the immediate area wear PPE with an APF of 10,000. The estimated annualized costs of this option are \$32 million to \$46 million annualized over 20 years at 3% and \$34 million to \$47 million annualized over 20 years at 7%.

C. Comparison of Benefits and Costs

The monetized benefits for preventing the risks resulting from TCE exposure from this use significantly outweigh the estimated costs. Simply comparing the costs and monetized benefits of prohibiting the manufacture (including import), processing, and distribution in commerce of TCE for use in vapor degreasing, prohibiting commercial use of TCE in vapor degreasing, and requiring downstream notification demonstrates that the monetized benefits of this proposed action outweigh the costs. However, EPA believes that the balance of costs and benefits cannot be fairly described without considering the additional, non-monetized benefits of mitigating the non-cancer adverse effects as well as cancer. As discussed previously, the multitude of potential adverse effects associated with TCE exposure can profoundly impact an individual's quality of life. Some of the adverse effects associated with TCE exposure can be immediately experienced and can affect a person from childhood throughout a lifetime (e.g., cardiac malformations, developmental neurotoxicity, and developmental immunotoxicity). Others (e.g., adult immunotoxicity, kidney and liver failure or cancers) can have impacts that are experienced for a shorter portion of life, but are nevertheless significant in nature.

While the risk of non-cancer health effects associated with TCE exposure cannot be quantitatively estimated, the qualitative discussion in this Unit highlights how some of these non-cancer effects occurring much earlier in life from TCE exposure may be as severe as cancer's mortality and morbidity and thus just as life-altering. These effects include not only medical costs but also personal costs such as emotional and mental stress that are impossible to accurately measure.

While the impacts of non-cancer effects cannot be monetized, EPA considered the impacts of these effects in deciding how best to address the unreasonable risks presented by TCE use in vapor degreasing. Considering only monetized benefits would significantly underestimate the impacts of TCE-induced non-cancer adverse outcomes on a person's quality of life to perform basic skills of daily living, including the ability to earn a living, the ability to participate in sports and other activities, and the impacts on a person's family and relationships.

Thus, considering costs, benefits that can be monetized (risk of cancer), and benefits that cannot be quantified and

subsequently monetized (risk of developmental toxicity, kidney toxicity, immunotoxicity, reproductive toxicity, neurotoxicity, and liver toxicity), including benefits related to the severity of the effects and the impacts on a person throughout her/his lifetime in terms of medical costs, effects on earning power and personal costs, and the emotional and psychological costs, the benefits of preventing exposures to TCE emissions from vapor degreasing systems outweigh the costs. Further, if EPA were to consider only the benefits that can be monetized in comparison to the cost, the monetized benefits from preventing kidney and liver cancer and non-Hodgkin's lymphoma from the use of TCE in vapor degreasing (the annualized monetized benefits on a 20 year basis range from approximately \$65 million to \$447 million at 3% and \$32 million to \$227 million at 7%) far outweigh the costs of the proposal to ban the use of TCE in vapor degreasing (the annualized costs on a 20 year basis range from approximately \$30 million to \$45 million at 3% and \$32 million to \$46 million at 7%). Considering the costs and benefits of the proposed and alternative options, while both address the unreasonable risks from TCE exposure, the proposed approach is more cost effective because it achieves the same or greater benefits at lower costs. For more information, see Section 7 in the Economic Analysis.

VIII. Overview of Uncertainties

A discussion of the uncertainties associated with this proposed rule can be found in the TCE risk assessment (Ref. 2) and in the supplemental analysis (Ref. 30) for use of TCE in vapor degreasing. A summary of these uncertainties follows.

EPA used a number of assumptions in the TCE risk assessment and supporting analysis to develop estimates for occupational exposure scenarios and to develop the hazard/dose-response and risk characterization. EPA recognizes that the uncertainties may underestimate or overestimate actual risks. These uncertainties include the possibility that releases of and exposures to TCE vary from one vapor degreasing machine to the next. EPA attempted to quantify this uncertainty by evaluating multiple scenarios to establish a range of releases and exposures. In estimating the risk from vapor degreasing, there are uncertainties in the number of workers exposed to TCE and in the inputs and algorithms of the models used to estimate exposures.

In addition to the uncertainties in the risks, there are uncertainties in the cost and benefits. The uncertainties in the

benefits are most pronounced in estimating the benefits from preventing the non-cancer adverse effects because these benefits generally cannot be monetized due to the lack of concentration-response functions in humans leading to the ability to estimate the number of population-level non-cancer cases and limitations in established economic methodologies. Additional uncertainties in benefit calculations include the potential risks for adverse health effects that the alternatives may pose and the estimates of the alternatives that users might choose to adopt. While there are some products that have comparable risks, there are a number of alternatives that are likely to be of lower risk, although EPA is unable to estimate the incremental change in the risk. To account for this uncertainty, EPA includes a lower and a higher estimate for the benefits from eliminating exposure to TCE. The lower benefits estimate assumes no benefits for TCE users that keep the same vapor degreasing machines and switch to methylene chloride, perchloroethylene, 1-BP, or designer solvent alternatives, assumes that TCE users switching to any other alternative suffer no adverse health effects associated with the alternatives (i.e., accrue the full benefits from eliminating TCE exposure), and applies a lowering factor to cancer risk estimates. The higher benefits estimate includes the benefit from entirely eliminating TCE exposure for all alternative compliance strategies, assumes that no risks are introduced by alternatives, and does not apply a lowering factor to cancer risk estimates. This inability to adequately account for adverse health effects of alternatives in the benefits analysis is expected to contribute most to the uncertainty in the estimates.

In addition, under certain assumptions EPA's economic analysis estimates that some TCE users will see a cost savings when switching to aqueous systems and certain other solvents. Standard economic theory suggests that financially rational companies would choose technologies that maximize profits so that regulatory outcomes would not typically result in a cost savings for the regulated facilities. There could be several reasons that cost savings might occur in the real world. Potential reasons include lack of complete information or barriers to obtaining information on the cost savings associated with alternatives as well as investment barriers or higher interest rates faced by firms. Additionally, there may be costs

associated with these alternatives that are not adequately accounted for in the analysis. To evaluate the effect of this uncertainty, EPA has included a sensitivity analysis that sets the cost savings to zero for these compliance alternatives (Ref. 3 at section 8.2). EPA also recognizes that these firms might experience positive costs of compliance rather than zero costs, so that the actual total costs could be higher than those in the sensitivity analysis. However, EPA has no current basis to estimate these potentially higher costs, since the available data appear to show that there are lower cost substitutes available. EPA requests comment and/or data on any hidden costs that may be missing from the analysis, or any other information that may help explain why some firms appear to be missing current opportunity for cost-savings substitutes.

There are also uncertainties in the estimates of the number of affected vapor degreasing machines, and for numbers of processors and distributors of TCE-containing products not prohibited by the proposed rule who are required to provide downstream notification and/or maintain records. The estimate for number of facilities using TCE-containing vapor degreasing machines is based upon available industry information and an industry expert (Ref. 3). To estimate the number of processors, EPA relied on public 2012 CDR data. The number of sites is reported in the CDR data as a range. The midpoint of the reported ranges was used to estimate the total number of sites using the chemical. Furthermore, the CDR data only includes processors immediately downstream of those reporting to CDR. Finally, EPA estimated the number of wholesaler firms distributing products containing TCE by taking a ratio of the number of Chemical and Allied Products Merchant Wholesaler firms to Basic Chemical Manufacturing firms and applying it to the estimated number of manufacturers and processors of TCE (Ref. 3).

EPA will consider additional information received during the public comment period. This includes public comments, scientific publications, and other input submitted to EPA during the comment period.

IX. Analysis Under TSCA Section 9 and TSCA Section 26(h) Considerations

A. TSCA Section 9(a) Analysis

Section 9(a) of TSCA provides that, if the Administrator determines in her discretion that an unreasonable risk may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA,

the Administrator must submit a report to the agency administering that other law that describes the risk and the activities that present such risk. If the other agency responds by declaring that the activities described do not present an unreasonable risk or if that agency initiates action under its own law to protect against the risk within the timeframes specified by TSCA section 9(a), EPA is precluded from acting against the risk under sections 6(a) or 7 of TSCA.

TSCA section 9(d) instructs the Administrator to consult and coordinate TSCA activities with other Federal agencies for the purpose of achieving the maximum enforcement of TSCA while imposing the least burden of duplicative requirements. For this proposed rule, EPA has consulted with OSHA.

OSHA assures safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance. OSHA adopted an eight-hour time weighted average PEL of 100 ppm along with a ceiling limit in 1971 shortly after the agency was formed. It was based on the ACGIH recommended occupational exposure limit that was in place at that time. OSHA recognizes that the TCE PEL and many other PELs issued shortly after adoption of the OSHA Act in 1970 are outdated and inadequate for ensuring protection of worker health. OSHA recently published a Request for Information on approaches to updating PELs and other strategies to managing chemicals in the workplace (Ref. 12). OSHA's current regulatory agenda does not include revision to the TCE PEL or other regulations addressing the risks EPA has identified when TCE is used in vapor degreasing or the uses identified in a prior proposal (Ref. 1), aerosol degreasing or for spot cleaning in dry cleaning facilities (Ref. 12).

This proposed rule and the related proposal (Ref. 1), which EPA intends to finalize together, address risks in both workplace (both private- and public-sector) and consumer settings from exposure to TCE in vapor degreasers, aerosol spray degreasers, and as a spot cleaner at dry cleaning facilities. With the exception of TSCA, there is no Federal law that provides authority to prevent or sufficiently reduce these cross-cutting exposures. No other Federal regulatory authority, when considering the exposures to the populations and within the situations in its purview, can evaluate and address the totality of the risk that EPA is addressing in this proposal and the prior proposal on TCE uses (Ref. 1). For

example, OSHA may set exposure limits for workers but its authority is limited to the workplace and does not extend to consumer uses of hazardous chemicals. Further, OSHA does not have direct authority over state and local employees, and it has no authority at all over the working conditions of state and local employees in states that have no OSHA-approved State Plan under 29 U.S.C. 667. Other Federal regulatory authorities, such as CPSC, have the authority to only regulate pieces of the risks posed by TCE, such as when used in consumer products.

Moreover, recent amendments to TSCA, Public Law 114-182, alter both the manner of identifying unreasonable risk under TSCA and EPA's authority to address unreasonable risk under TSCA, such that risk management under TSCA is increasingly distinct from analogous provisions of the Consumer Product Safety Act (CPSA), the Federal Hazardous Substances Act, or the OSH Act. These changes to TSCA reduce the likelihood that an action under the CPSA, FHSA, or the OSH Act would reduce the risk of TCE from these uses to a sufficient extent under TSCA. Whereas (in a TSCA section 6 rule) an unreasonable risk determination sets the objective of the rule in a manner that excludes cost considerations, 15 U.S.C. 2605(b)(4)(A), subject to time-limited conditional exemptions for critical chemical uses and the like, 15 U.S.C. 2605(g), a consumer product safety rule under the CPSA must include a finding that "the benefits expected from the rule bear a reasonable relationship to its costs." 15 U.S.C. 2058(f)(3)(E). Additionally, recent amendments to TSCA reflect Congressional intent to "delete[] the paralyzing 'least burdensome' requirement," 162 Cong. Rec. S3517 (June 7, 2016). However, a consumer product safety rule under the CPSA must impose "the least burdensome requirement which prevents or adequately reduces the risk of injury for which the rule is being promulgated." 15 U.S.C. 2058(f)(3)(F). Analogous requirements, also at variance with recent revisions to TSCA, affect the availability of action under the FHSA relative to action under TSCA. 15 U.S.C. 1262. Gaps also exist between OSHA's authority to set workplace standards under the OSH Act and EPA's amended obligations to sufficiently address chemical risks under TSCA. To set PELs for chemical exposure, OSHA must first establish that the new standards are economically feasible and technologically feasible. 79 FR 61387 (2014). But under TSCA, EPA's substantive burden under TSCA § 6(a) is

to demonstrate that, as regulated, the chemical substance no longer presents an unreasonable risk, with unreasonable risk being determined without consideration of cost or other nonrisk factors.

TSCA is the only regulatory authority able to prevent or reduce risks from these uses of TCE to a sufficient extent across the range of uses and exposures of concern. In addition, these risks can be addressed in a more coordinated, efficient and effective manner under TSCA than under two or more different laws implemented by different agencies. Furthermore, there are key differences between the newly amended finding requirements of TSCA and those of the OSH Act, CPSA, and the FHSA. For these reasons, in her discretion, the Administrator does not determine that unreasonable risks from the use of TCE in vapor degreasers, aerosol spray degreasers, and as a spot cleaner at dry cleaning facilities may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA.

B. TSCA Section 9(b) Analysis

If EPA determines that actions under other Federal laws administered in whole or in part by EPA could eliminate or sufficiently reduce an unreasonable risk, section 9(b) of TSCA instructs EPA to use these other authorities unless the Administrator determines in the Administrator's discretion that it is in the public interest to protect against such risk under TSCA. In making such a public interest finding, TSCA section 9(b)(2) states: "the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk . . . and a comparison of the estimated costs and efficiencies of the action to be taken under this title and an action to be taken under such other law to protect against such risk."

Although several EPA statutes have been used to limit TCE exposure, as discussed in Unit III.A., regulations under these EPA statutes have limitations because they largely regulate releases to the environment, rather than direct human exposure. SDWA only applies to drinking water. CAA does not apply directly to worker exposures or consumer settings where TCE is used. Under RCRA, TCE that is discarded may be considered a hazardous waste and subject to requirements designed to reduce exposure from the disposal of TCE to air, land and water. RCRA does not address exposures during use of products containing TCE. Only TSCA provides EPA the authority to regulate the manufacture (including import),

processing, and distribution in commerce, and use of chemical substances.

For these reasons, the Administrator does not determine that unreasonable risks from the use of TCE in vapor degreasers, aerosol spray degreasers, and as a spot cleaner at dry cleaning facilities could be eliminated or reduced to a sufficient extent by actions taken under other Federal laws administered in whole or in part by EPA.

C. Section 26(h) Considerations

EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the best available science. For example, EPA based its proposed determination of unreasonable risk presented by the use of TCE in vapor degreasing systems on the completed risk assessment, which followed a peer review and public comment process, as well as using the best available science and methods (Ref. 2). A supplemental analysis was performed to better characterize the exposed populations and estimate the effects of various control options. This supplemental analysis was performed consistent with the methods and models used in the risk assessment. These analyses were developed for the purpose of determining whether the particular risks are unreasonable. They were also developed to support risk reduction by regulation under section 6 of TSCA, to the extent risks were determined to be unreasonable. It is reasonable and consistent to consider these analysis in this rulemaking for such relevant purposes.

The extent to which the various information, procedures, measures, methods, protocols, methodologies or models, as applicable, used in EPA's decision have been subject to independent verification or peer review is adequate to justify their use, collectively, in the record for this rule. Additional information on the peer review and public comment process, such as the peer review plan, the peer review report, and the Agency's response to comments, can be found on EPA's Assessments for TSCA Work Plan Chemicals Web page at <https://www.epa.gov/assessing-and-managing-chemicals-under-tasca/assessments-tsca-work-plan-chemicals>.

X. Major Provisions and Enforcement of the Proposed Rule

This proposal relies on general provisions in the proposed Part 751, Subpart A, which can be found at 81 FR 91592 (December 16, 2016).

A. Prohibitions on TCE Manufacturing (Including Import), Processing, Distribution in Commerce, and Commercial Use

This proposal would prohibit the manufacture (including import), processing, distribution in commerce, and commercial use of TCE in vapor degreasing.

B. Downstream Notification

EPA has authority under TSCA section 6 to require that a substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. Many TCE manufacturers and processors are likely to manufacture or process TCE or TCE containing products for other uses that would not be regulated under this proposal. Other companies may be strictly engaged in distribution in commerce of TCE, without any manufacturing or processing activities, to customers for uses that are not regulated. As discussed in the prior proposal on TCE use in aerosol degreasers and as a spot remover agent in dry cleaning facilities, EPA is proposing a requirement for downstream notification by manufacturers (including importers), processors, and distributors of TCE for any use to ensure compliance with the proposed prohibitions on the manufacture, processing, distribution in commerce, and commercial use of TCE. Downstream notification is necessary for effective enforcement of the rule because it provides a record, in writing, of notification on use restrictions throughout the supply chain, likely via modifications to the Safety Data Sheet. Downstream notification also increases awareness of restrictions on use, which is likely to decrease unintentional uses of TCE. Downstream notification represents minimal burden and is necessary for effective enforcement of the rule. The specific requirement, that persons who manufacture (including import), process, or distribute in commerce TCE for any use would have to provide written notification of the restrictions to persons to whom TCE is shipped, was included in an earlier proposal on TCE use (Ref. 1). The specific recordkeeping requirements were also contained in the prior proposal (Ref. 1). Those provisions would require manufacturers (including importers), processors, and distributors of TCE for any use to retain documentation of the identity and

contact information for persons to whom TCE was shipped as well as the amount of TCE shipped, and a copy of the notification that was provided. This documentation would have to be retained for 3 years from the date of shipment.

As presented in the prior proposal (Ref. 1), the estimated costs of downstream notification and recordkeeping on an annualized basis over 20 years are \$3,200 and \$4,400 using 3% and 7% discount rates respectively.

C. Enforcement

TSCA section 15 makes it unlawful to fail or refuse to comply with any provision of a rule promulgated under TSCA section 6. Therefore, any failure to comply with this proposed rule when it becomes effective would be a violation of TSCA section 15. In addition, TSCA section 15 makes it unlawful for any person to: (1) Fail or refuse to establish and maintain records as required by this rule; (2) fail or refuse to permit access to or copying of records, as required by TSCA; or (3) fail or refuse to permit entry or inspection as required by TSCA section 11.

Violators may be subject to both civil and criminal liability. Under the penalty provision of TSCA section 16, any person who violates TSCA section 15 could be subject to a civil penalty for each violation. Each day of operation in violation of this proposed rule when it becomes effective could constitute a separate violation. Knowing or willful violations of this proposed rule when it becomes effective could lead to the imposition of criminal penalties and imprisonment. In addition, other remedies are available to EPA under TSCA sections 7 and 17.

Individuals, as well as corporations, could be subject to enforcement actions. TSCA sections 15 and 16 apply to "any person" who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies. In particular, EPA may proceed against individuals who report false information or cause it to be reported.

D. Implementation Dates and Incentives

As proposed in the prior action on TCE use (Ref. 1), the downstream notification requirements and the recordkeeping requirements applicable to manufacturers (including importers) and processors of TCE for any use and persons who distribute TCE in commerce for any use (other than retailers) would take effect 45 days after the final rule is issued. EPA is proposing to make the ban on

manufacturing (including importing), processing, or distributing in commerce TCE for vapor degreasing uses, the downstream notification requirements, and the recordkeeping requirements effective 18 months after publication of the final rule. The ban on the use of TCE in vapor degreasing systems would take effect six months after that, or two years after publication of the final rule. EPA heard from the SERs who provided input to the SBAR Panel that converting from a vapor degreasing system that uses TCE to one that does not is often a time-intensive process (Ref. 32). SERs had different ideas on how long it would take for the conversion process. One SER observed that many users do not know exactly how clean their products must be, or how clean their existing system gets them. According to this SER, testing is needed to determine the required cleaning efficiency, and it can take six months for the testing. Changing to a new system could take an additional twelve to eighteen months. Another SER agreed with the estimate of two years for a changeover, while still another SER thought it could take anywhere from six months to four years. In light of this input, EPA believes that it is reasonable to establish the compliance date for the prohibition on TCE in vapor degreasing at two years from the date the final rule is promulgated. EPA believes that, in most cases, the transition can be made within this time, but EPA requests comment on whether there are special situations which may require more time.

EPA would like to encourage as many companies as possible to adopt less hazardous technologies, such as aqueous cleaning systems, instead of switching to an alternative that also presents health risks for workers, albeit of a lower magnitude than TCE. EPA's analysis indicates that the best answer for many vapor degreasing operations may be a switch to water-based cleaners, even though there are higher upfront costs. An effective system that works for a given application and that is acceptable to customers must be researched and designed, new equipment and cleaning solutions must be purchased, new permits may be required, operating and safety procedures must be updated, and affected employees must learn to operate the new equipment. However, once the system is up and running properly, operation of the system on an annual basis is likely to be less expensive and much less hazardous to employees than a vapor degreasing system using TCE.

EPA requests comment on its analysis of the alternatives and the impacts of

switching to less hazardous cleaners. EPA is particularly interested in comments and information on water and energy use associated with water-based cleaners and other less-toxic solvents, as well as on the costs of conversion from a system that uses TCE and the length of time such a conversion would take.

EPA is also requesting comment on potential incentives for vapor degreasing facilities to switch to less toxic alternatives. TSCA does not provide the authority for EPA to offer incentives such as tax credits, so there are a limited number of regulatory incentives available to EPA. One potential incentive would be a delayed implementation date for a ban on TCE use in vapor degreasing. This incentive would allow vapor degreasing facilities that intend to convert to aqueous cleaning systems a longer period of time to make the conversion. One way to administer this incentive would be to require vapor degreasing facilities to specifically request an extension for a certain length of time. Of course, in order to limit misuse of this extension opportunity, EPA would have to also require documentation of the facility's clear intention to convert to an aqueous cleaning system. This might include a description of the steps the company has already taken to implement a change to aqueous substitutes, or a description of the specific plan for implementing the change within the extension period requested, with some sort of documentation, such as a contract to purchase equipment. EPA also notes that TSCA section 6(d) generally provides that compliance dates for the start of a ban or phase-out promulgated under section 6(a) must be as soon as practicable, but not later than five years after the rule is promulgated, except for those critical or essential uses exempted under TSCA section 6(g). EPA requests comments on all aspects of this potential incentive, including comments on the length of time that should be allowed for an extension, what documentation should be required, and which technologies or solvents should be eligible for an extension and how to define them. EPA also requests comments on other potential incentives or regulatory flexibilities that EPA could incorporate to encourage the adoption of safer degreasing technologies. Finally, in keeping with the SBAR Panel recommendation regarding flexibility for small businesses, EPA requests comment on whether there are flexibilities other than delayed implementation dates that would be particularly advantageous for small

businesses while still ensuring that they address the unreasonable risks to which their workers may be exposed.

XI. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Trichloroethylene; Regulation of Certain Uses under TSCA § 6(a). Proposed Rule. **Federal Register**. (81 FR 91592, December 16, 2016) (FRL-9949-86).
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21. European Chemicals Association. Opinion on an Application for Authorisation for Trichloroethylene: Use of Trichloroethylene in Industrial Parts Cleaning by Vapour Degreasing in Closed Systems where specific requirements (system of use-parameters) exist (11 September 2015).
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 67. EPA. Section 6(a) Rulemakings under the Toxic Substances Control Act (TSCA) Paint Removers & TCE Rulemakings E.O. 13132: Federalism Consultation. May 13, 2015.
 68. EPA. Notification of Consultation and Coordination on Proposed Rulemakings under the Toxic Substances Control Act for (1) Methylene Chloride and n-Methylpyrrolidone in Paint Removers and (2) Trichloroethylene in Certain Uses. April 8, 2015.

XII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is an economically significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket. EPA prepared an economic analysis of the potential costs and benefits associated with this action, which is available in the docket and summarized in Unit VII. (Ref. 3).

B. Paperwork Reduction Act (PRA)

The information collection requirements in this proposed rule have been submitted to OMB for review and comment under the PRA, 44 U.S.C. 3501 *et seq*. The Information Collection Request (ICR) document prepared by the Agency has been assigned EPA ICR No. 2541.02. You can find a copy of the ICR in the docket for this proposed rule (Ref. 65), and it is briefly summarized here.

The information collection activities required under the proposed rule include a downstream notification requirement and a recordkeeping requirement. The downstream notification would require companies that ship TCE to notify companies downstream in the supply chain of the prohibitions of TCE in the proposed rule. The proposed rule does not require the regulated entities to submit information to EPA. The proposed rule also does not require confidential or sensitive information to be submitted to EPA or downstream companies. The recordkeeping requirement mandates companies that ship TCE to retain certain information at the company headquarters for three years from the date of shipment. These information

collection activities are necessary in order to enhance the prohibitions under the proposed rule by ensuring awareness of the prohibitions throughout the TCE supply chain, and to provide EPA with information upon inspection of companies downstream who purchased TCE. EPA believes that these information collection activities would not significantly impact the regulated entities.

Respondents/Affected Entities: TCE manufacturers, processors, and distributors.

Respondent's Obligation to Respond: Mandatory.

Estimated Number of Respondents: 697.

Frequency of Response: On occasion.

Total Estimated Burden: 348.5 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total Estimated Cost: \$16,848 (per year).

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this proposed rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to oira_submission@omb.eop.gov. Attention: Desk Officer for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than February 21, 2017. EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 603 of the RFA, 5 U.S.C. 601 *et seq.*, EPA prepared an initial regulatory flexibility analysis (IRFA) that examines the impact of the proposed rule on small entities along with regulatory alternatives that could minimize that impact. The complete IRFA is available for review in the docket and is summarized here (Ref. 66).

1. Need for the rule. Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines after risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a

potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk. Based on EPA's risk assessment of TCE (Ref. 2), EPA's proposed determination is that the use of TCE in vapor degreasing presents an unreasonable risk of injury to health and that the provisions of this proposal are necessary to address the unreasonable risk.

2. Objectives and legal basis. The legal basis for this proposal is TSCA section 6(a), which provides authority for the Administrator to apply requirements to the extent necessary so that a chemical substance or mixture no longer presents an unreasonable risk of injury to health or the environment. Additionally, for a chemical substance, such as TCE, which is listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which a completed risk assessment was published prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, TSCA section 26(l)(4) expressly authorizes EPA to issue rules under TSCA section 6(a) that are consistent with the scope of the completed risk assessment and consistent with the other applicable requirements of TSCA section 6.

3. Small entities covered by this proposal. EPA estimates that the proposal would affect approximately 2,500 to 6,000 small entities. The majority of these entities are commercial users of TCE in vapor degreasing machines in a variety of occupational settings such as metal plating, electronics assembly, metal or composite part fabrication, and repair shops.

4. Compliance requirements and the professional skills needed. To address the unreasonable risks that EPA has identified, this proposal would prohibit the manufacture (including import), processing, and distribution in commerce of TCE for use in vapor degreasing; prohibit commercial use of TCE in vapor degreasing; and require manufacturers, processors, and distributors, except for retailers, to provide downstream notification of this prohibition throughout the supply chain (e.g., via a Safety Data Sheet (SDS)), and to keep records. Complying with the prohibitions, the downstream notification, and the recordkeeping requirements involve no special skills. However, design and implementation of an alternative to vapor degreasing with

TCE may involve special skills, such as engineering experience.

5. Other Federal regulations. Other Federal regulations that affect the use of TCE in vapor degreasing are discussed in Unit III.A. of this preamble. Because the NESHAP regulates only emissions from vapor degreasing facilities, not worker exposures, and because the 1971 OSHA PEL is not sufficiently protective, EPA's proposal is not duplicative of other Federal rules nor does it conflict with other Federal rules.

6. Regulatory alternatives considered. EPA considered a wide variety of control measures and the Economic Analysis (Ref. 3) examined several alternative analytical options. However, EPA determined that most of the alternatives did not effectively address the unreasonable risk presented by TCE in vapor degreasing. The primary alternative considered by EPA was to allow the use of TCE in closed-loop vapor degreasing systems and require respiratory protection equipment for workers operating the equipment in the form of a full face piece self-contained breathing apparatus (SCBA) in pressure demand mode or other positive pressure mode with an APF of 10,000 with an alternative to the specified APF respirator of an air exposure limit. Depending on air concentrations and proximity to the vapor degreasing equipment, other employees in the area would also need to wear respiratory protection equipment. While this option would address the unreasonable risks presented by TCE in vapor degreasing, EPA's Economic Analysis indicates that this option is more expensive and, thus less cost effective than switching to a different solvent or cleaning system.

As required by section 609(b) of the RFA, EPA also convened a Small Business Advocacy Review (SBAR) Panel to obtain advice and recommendations from small entity representatives that potentially would be subject to the rule's requirements. The SBAR Panel evaluated the assembled materials and small-entity comments on issues related to elements of an IRFA. A copy of the full SBAR Panel Report is available in the rulemaking docket. The Panel recommended that EPA seek additional information on critical uses; availability, effectiveness, and costs of alternatives; implementation timelines; and exposure information to provide flexibility to lessen impacts to small entities, as appropriate. Throughout this preamble, EPA has requested information with respect to these and other topics. The Panel made the following specific recommendations:

a. *Critical uses.* The Panel recommended that EPA provide exemption, in accordance with TSCA section 6(g), for those critical uses for which EPA can obtain adequate documentation that:

- No technically and economically feasible safer alternative is available;
- Compliance with the ban would significantly disrupt the national economy, national security, or critical infrastructure; or
- The specific condition of use, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

To that end, the Panel recommended that EPA include in its proposal specific targeted requests for comment directed towards identifying critical uses (such as the aeronautics industry and national security) and obtaining information to justify exemptions. The Panel also recommended that EPA request public comment on allowing the use of TCE in closed-top vapor degreasing systems with the use of appropriate PPE.

b. *Alternatives.* The Panel recommended that EPA ensure that its analysis of the available alternatives to TCE in vapor degreasing complies with the requirements of section 6(c)(2)(C) and includes consideration, to the extent legally permissible and practicable, of whether technically and economically feasible alternatives that benefit health or the environment, compared to the use being prohibited or restricted, will be reasonably available as a substitute when the proposed requirements would take effect. Specifically, the Panel recommended that EPA:

- Evaluate the feasibility of using alternatives, including the cost, relative safety, and other barriers (such as space constraints, cleaning efficiency, increased energy use, cycle time, boiling points, and water use restrictions); and
- Take into consideration the current and future planned regulation of compounds the Agency has listed as alternatives.

c. *Implementation timelines.* The Panel recommended that EPA provide regulatory flexibility, as applicable, based on additional information, such as delayed compliance or a phase-out option, for small businesses that may be affected by the rule and in its proposal specifically request additional information regarding timelines for transitioning to alternative chemicals or technologies.

d. *Cost information.* The Panel also recommended that EPA specifically evaluate the cost to small business degreasing services without a viable

alternative to TCE (*i.e.*, the cost of going out of business). The Panel recommended that EPA request additional information on the cost to achieve reduced exposures in the workplace or to transition to alternative chemicals or technologies.

e. *Exposure information.* The Panel recommended that EPA include in its proposal specific requests for additional pertinent exposure data that may be available.

f. *Risk assessment.* The Panel recommended that EPA recognize the concerns that the SERs had on the risk assessment by referring readers to the risk assessment and the Agency's Summary of External Peer Review and Public Comments and Disposition document, which addresses those concerns, in the preamble of the proposed rulemaking.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The requirements of this action would primarily affect persons who commercially use TCE in vapor degreasing equipment. The total estimated annualized cost of the proposed rule is approximately \$30 million to \$45 million at 3% and \$32 million to \$46 million at 7% (Ref. 3).

E. Executive Order 13132: Federalism

EPA has concluded that this action has federalism implications, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because regulation under TSCA section 6(a) may preempt state law. EPA provides the following preliminary federalism summary impact statement. The Agency consulted with state and local officials early in the process of developing the proposed action to permit them to have meaningful and timely input into its development. EPA invited the following national organizations representing state and local elected officials to a meeting on May 13, 2015, in Washington DC: National Governors Association; National Conference of State Legislatures, Council of State Governments, National League of Cities, U.S. Conference of Mayors, National Association of Counties, International City/County Management Association, National Association of Towns and Townships, County Executives of America, and Environmental Council of States. A summary of the meeting with these organizations, including the views that they expressed, is available in the

docket (Ref. 67). Although EPA provided these organizations an opportunity to provide follow-up comments in writing, no written follow-up was received by the Agency.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This rulemaking would not have substantial direct effects on tribal government because TCE is not manufactured, processed, or distributed in commerce by tribes. TCE is not regulated by tribes, and this rulemaking would not impose substantial direct compliance costs on tribal governments. Thus, EO 13175 does not apply to this action. EPA nevertheless consulted with tribal officials during the development of this action, consistent with the EPA Policy on Consultation and Coordination with Indian Tribes.

EPA met with tribal officials in a national informational webinar held on May 12, 2015 concerning the prospective regulation of TCE under TSCA section 6, and in another teleconference with tribal officials on May 27, 2015 (Ref. 68). EPA also met with the National Tribal Toxics Council (NTTC) in Washington, DC and via teleconference on April 22, 2015 (Ref. 68). In those meetings, EPA provided background information on the proposed rule and a summary of issues being explored by the Agency. These officials expressed concern for TCE contamination on tribal lands and supported additional regulation of TCE.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is an economically significant regulatory action as defined by Executive Order 12866, and EPA believes that the environmental health or safety risk addressed by this action has a disproportionate effect on children, specifically on the developing fetus. Accordingly, we have evaluated the environmental health or safety effects of TCE used in vapor degreasing on children. The results of this evaluation are discussed in Units I.F., II.C., IV., and VI.C. of this preamble and in the economic analysis (Ref. 3).

Supporting information on the exposures and health effects of TCE exposure on children is also available in the Toxicological Review of Trichloroethylene (Ref. 4) and the TCE risk assessment (Ref. 2).

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution in Commerce, or Use

This proposed rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution in commerce, or use. This rulemaking is intended to protect against risks from TCE, and does not affect the use of oil, coal, or electricity.

I. National Technology Transfer and Advancement Act (NTTAA)

This proposed rulemaking does not involve technical standards, and is therefore not subject to considerations under NTTAA section 12(d), 15 U.S.C. 272 note.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing,

as appropriate, disproportionately high and adverse health or environmental effects of their programs, policies and activities on minority populations and low-income populations in the U.S. Units IV. and VI. of this preamble address public health impacts from TCE. EPA has determined that there would not be a disproportionately high and adverse health or environmental effects on minority, low income, or indigenous populations from this proposed rule.

List of Subjects in 40 CFR Part 751

Environmental protection, Chemicals, Export certification, Hazardous substances, Import certification, Recordkeeping.

Dated: January 11, 2017.

Gina McCarthy,
Administrator.

Therefore, 40 CFR part 751, as proposed to be added at 81 FR 91592 (December 16, 2016), is proposed to be further amended to read as follows:

PART 751—REGULATION OF CERTAIN CHEMICAL SUBSTANCES AND MIXTURES UNDER SECTION 6 OF THE TOXIC SUBSTANCES CONTROL ACT

■ 1. The authority citation for part 751 continues to read as follows:

Authority: 15 U.S.C. 2605.

■ 2. In § 751.303, add the definition “Vapor” in alphabetical order to read as follows:

§ 751.303 Definitions.

* * * * *

Vapor degreasing means a cleaning process involving heating a solvent to produce a hot vapor which is then used to remove contaminants such as grease, oils, dust, and dirt from fabricated parts and other materials.

■ 3. Add § 751.309 to read as follows:

§ 751.309 Vapor degreasing.

(a) After [*date 18 months after the date of publication of the final rule*], all persons are prohibited from manufacturing (including import), processing, and distributing in commerce TCE and mixtures containing TCE for use in vapor degreasing.

(b) After [*date 2 years after the date of publication of the final rule*], all persons are prohibited from commercial use of TCE and mixtures containing TCE in vapor degreasing.

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Environmental Protection Agency

40 CFR Part 751

Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses
Under TSCA Section 6(a); Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 751**

[EPA-HQ-OPPT-2016-0231; FRL-9958-57]

RIN 2070-AK07

Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a)**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule.

SUMMARY: Methylene chloride, also called dichloromethane, is a volatile chemical that has a variety of uses, including paint and coating removal. N-methylpyrrolidone (NMP) is a solvent used in a variety of applications, including paint and coating removal. For each of these chemicals, EPA has identified risks of concern associated with their use in paint and coating removal. EPA proposes a determination that these are unreasonable risks. EPA is proposing to prohibit the manufacture (including import), processing, and distribution in commerce of methylene chloride for consumer and most types of commercial paint and coating removal under section 6 of the Toxic Substances Control Act (TSCA). EPA is also proposing to prohibit the use of methylene chloride in these commercial uses; to require manufacturers (including importers), processors, and distributors, except for retailers, of methylene chloride for any use to provide downstream notification of these prohibitions throughout the supply chain; and to require recordkeeping. EPA is proposing an initial ten-year time-limited exemption from these proposed regulations on methylene chloride for coating removal uses critical for national security. First, EPA is proposing to prohibit the manufacture (including import), processing, and distribution in commerce of NMP for all consumer and commercial paint and coating removal; to prohibit the use of NMP for all commercial paint and coating removal; to require, consistent with methylene chloride restrictions, downstream notification of these prohibitions throughout the supply chain; to require recordkeeping; and to provide a time-limited exemption from these proposed regulations on NMP for coating removal uses critical for national security. For NMP, as an alternate proposal, EPA is proposing that (1) commercial users of NMP for paint and coating removal establish a worker protection program for dermal and respiratory protection

and not use paint and coating removal products that contain greater than 35 percent NMP by weight (except for product formulations destined to be used by DoD or its contractors performing work only for DOD projects); and (2) processors of products containing NMP for paint and coating removal reformulate products such that these products do not exceed a maximum of 35 percent NMP by weight, identify gloves that provide effective protection for the formulation, and provide warning and instruction labels on the products.

DATES: Comments must be received on or before April 19, 2017.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2016-0231, at <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods (*e.g.*, mail or hand delivery), the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

Docket. Docket number EPA-HQ-OPPT-2016-0231 contains supporting information used in developing the proposed rule, comments on the proposed rule, and additional supporting information. A public version of the docket is available for inspection and copying between 8:30 a.m. and 4:30 p.m., Monday through Friday, excluding federal holidays, at the U.S. Environmental Protection Agency, EPA Docket Center Reading Room, WJC West Building, Room 3334, 1301 Constitution Avenue NW., Washington, DC 20004. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Ana Corado, Chemical Control Division, Office of Pollution Prevention and

Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number 202-564-0140; email address: corado.ana@epa.gov. For other information contact: Niva Kramek, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: 202-564-4830; email address: kramek.niva@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:**I. Executive Summary***A. Does this action apply to me?*

You may potentially be affected by this proposed action if you manufacture (defined under Toxic Substances Control Act (TSCA) to include import), process, distribute in commerce, or use methylene chloride or NMP for paint and coating removal. Paint and coating removal, also referred to as paint stripping, is the process of removing paint or other coatings from a surface. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Chemical and Allied Products Manufacturers (NAICS code 32411).
- Ship building and repairing (NAICS code 336611)
- Aircraft manufacturing (NAICS code 336411)
- Museums (NAICS code 712110)
- Independent Artists, Writers, and Performers (NAICS code 711510)
- Reupholster and furniture repair (NAICS code 811420)
- Automotive body, paint, and interior repair and maintenance (NAICS code 81121)
- Flooring contractors (NAICS code 238330)
- Painting and wall covering contractors (NAICS code 238320)

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance governed by a final TSCA section 6(a) rule are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR

12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA determines after risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk.

With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which a completed risk assessment was published prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, TSCA section 26(l)(4) (15 U.S.C. 2625(l)(4)) expressly authorizes EPA to issue rules under TSCA section 6(a) that are consistent with the scope of the completed risk assessment and consistent with the other applicable requirements of TSCA section 6. Methylene chloride and NMP are such chemical substances (Ref. 1). They are listed in the 2014 update to the TSCA Work Plan and the completed risk assessments were published in 2014 and 2015, respectively. The scope of each completed risk assessment includes consumer and commercial paint and coating removal.

C. What action is the Agency taking?

EPA proposes a determination that the uses of methylene chloride or NMP in paint and coating removal present an unreasonable risk of injury to health. Accordingly, for methylene chloride,

EPA is proposing under section 6 of TSCA to prohibit the manufacture (including import), processing, and distribution in commerce of methylene chloride for all consumer and for most types of commercial paint and coating removal uses. EPA is also proposing under TSCA section 6 to prohibit the use of methylene chloride for commercial paint and coating removal in the specified sectors, which include painting and decorating, floor refinishing, automotive refinishing, civilian aircraft refinishing, graffiti removal, renovations and contracting, bridge repair and repainting, and marine craft refinishing and repair. EPA is not proposing at this time to regulate the use of methylene chloride in commercial furniture refinishing, also referred to as furniture stripping or refinishing conducted by professionals or commercial workers. EPA is also proposing to exempt certain uses of methylene chloride for coating removal that EPA proposes are critical for national security.

EPA is also proposing to require that any paint or coating removal products containing methylene chloride that continue to be distributed be packaged in containers with a volume no less than 55 gallons, except for formulations specifically manufactured for the Department of Defense, which may be distributed in containers with volumes no less than 5 gallons. EPA is also proposing to require manufacturers (including importers), processors, and distributors, except for retailers, of methylene chloride for any use to provide downstream notification of these requirements and prohibitions throughout the supply chain; and to require limited recordkeeping. More details on this supply chain approach are in Unit VI.C.3.

EPA intends to issue a separate proposal on methylene chloride in paint and coating removal in commercial furniture refinishing, but plans to issue one final rule covering both this proposal and the future proposed rule on methylene chloride in paint and coating removal in commercial furniture refinishing. More information on such a future proposal that would directly address methylene chloride in paint and coating removal in furniture refinishing is in Unit XI.

For NMP, EPA is co-proposing two different options to reduce the unreasonable risks presented by NMP in paint and coating removal for consumers and commercial users. EPA is co-proposing these two options because the Agency is interested in public consideration of these approaches, and is soliciting comments

regarding the extent to which these approaches could reduce the unreasonable risks the Agency has identified.

Under the first approach co-proposed for NMP (option 1), EPA is proposing to prohibit the manufacture (including import), processing, and distribution in commerce of NMP for all consumer and commercial paint and coating removal, with exemptions for certain coating removal uses that EPA proposes are critical to national security. EPA is also proposing to prohibit the commercial use of NMP for paint and coating removal, with exemptions for certain coating removal uses that EPA proposes are critical to national security. These exemptions include the condition that any exempt paint and coating removal products containing NMP be packaged in containers with a volume no less than 5 gallons. Unlike the option proposed for methylene chloride, these exemptions do not include the use of NMP in furniture refinishing. EPA is also proposing to require manufacturers (including importers), processors, and distributors, except for retailers, of NMP for any use to provide downstream notification of these prohibitions throughout the supply chain; and to require limited recordkeeping.

Under the second approach proposed for NMP, EPA is proposing a reformulation, PPE, and labeling approach. This would require product reformulation to limit the concentration of NMP in paint and coating removal products; testing of product formulations to identify specialized gloves that provide protection; relabeling of products to provide additional information to consumers; an occupational dermal and respiratory protection program for commercial use of NMP in paint and coating removal, downstream notification when distributing NMP for other uses, and limited recordkeeping. Under this approach, no exemption is proposed for coating removal identified as critical for national security because paint and coating removal products containing NMP would continue to be available for these national security uses under this option, even without establishing a national security exemption.

EPA is requesting public comment on these proposals.

D. Why is the Agency taking this action?

Based on EPA's analysis of worker and consumer populations' exposures to methylene chloride and NMP in paint and coating removal, EPA proposes a determination that methylene chloride and NMP in paint and coating removal present an unreasonable risk to human

health. For methylene chloride, the health impacts of its use in paint and coating removal include death (due to asphyxiation), liver toxicity, kidney toxicity, reproductive toxicity, specific cognitive impacts, and cancers such as brain cancer, liver cancer, certain lung cancers, non-Hodgkin's lymphoma, and multiple myeloma (Ref. 2). Some of these effects result from a very short, acute exposure; others follow years of occupational exposure. For NMP, these health effects include developmental toxicity (e.g., fetal death or decreased infant birth weight), neurotoxicity, immunotoxicity, liver and kidney toxicity, and reproductive toxicity (Ref. 3).

It is important to note that while both methylene chloride and NMP are used in paint and coating removal, products containing NMP have in recent years become increasingly popular substitutes for users interested in avoiding the health effects or odors known to be associated with products containing methylene chloride. While exposures to these chemicals have been assessed using different health endpoints, EPA proposes a determination that the use of either methylene chloride or NMP in paint and coating removal presents unreasonable risks. For this reason, EPA proposes to address the unreasonable risks presented by both chemicals in one rule.

Although EPA proposes to determine that the identified risks to workers exposed to methylene chloride in commercial furniture refinishing are unreasonable, EPA is not proposing to regulate these risks at this time. EPA intends to issue a separate proposal addressing the use of methylene chloride in paint and coating removal in commercial furniture refinishing. See Unit XI.

As discussed in Unit V.C., EPA is not proposing to prohibit all manufacturing, processing, distribution in commerce, and use of methylene chloride or NMP, of which paint and coating removal is estimated to comprise 25% and 9% of the use of each chemical, respectively (Refs. 2 and 3).

E. What are the estimated incremental impacts of this action?

EPA proposes to determine that the identified risks from methylene chloride and NMP in paint and coating removal are unreasonable. Apart from that proposed determination, EPA has evaluated the potential costs of the proposed approach of (1) prohibiting the manufacture (including import), processing, and distribution in commerce of methylene chloride for all consumer paint and coating removal in

the sectors specified in section I.C of this preamble, exempting specific uses critical to national security; (2) prohibiting the commercial use of methylene chloride for paint and coating removal in the specified sectors; (3) requiring any paint and coating removal products containing methylene chloride to be packaged for distribution in commerce in containers with volumes no less than 55 gallons so as to reduce diversion to restricted uses, except for formulations specifically manufactured for the Department of Defense; (4) requiring manufacturers (including importers), processors, and distributors, except for retailers, to provide downstream notification of these prohibitions throughout the supply chain; and (5) requiring associated recordkeeping requirements. EPA has also evaluated the costs of the two co-proposed options for NMP.

Under the first option, this includes (1) prohibiting the manufacture (including import), processing, and distribution in commerce of NMP for all paint and coating removal, exempting specific uses critical to national security; (2) prohibiting the commercial use of NMP for paint and coating removal exempting specific uses critical to national security; (3) requiring any paint and coating removal products containing NMP to be packaged for distribution in commerce in containers with a volume no less than 5 gallons; (4) requiring manufacturers (including importers), processors, and distributors of NMP for any use, except for retailers, to provide downstream notification of these prohibitions throughout the supply chain; and (5) requiring associated recordkeeping requirements. Under the second option, this includes: (1) Prohibiting the manufacture, processing, and distribution in commerce of paint and coating removal products containing more than 35 percent NMP by weight except for products used for critical national security uses; (2) Requiring product formulators to test gloves for the product formulations being processed and distributed in commerce for other than exempt critical national security uses to identify specialized gloves that provide protection for users and keep records relevant to these tests; (3) Requiring product formulators to label products with information for consumers about the risks presented by the products and how to reduce these risks during use, including identifying which specialized gloves provide protection against the specific formulation; (4) Requiring product formulators to provide information for commercial users about

reducing risks when using the product, via product labels, SDS, and other methods of hazard communication, and to keep records; (5) Prohibiting the commercial use of paint and coating removal products that contain more than 35 percent by weight of NMP, except for critical national security uses; and (6) Requiring commercial users to establish worker protection programs for dermal and respiratory protection, including hazard communication and training, and to require their employees to wear specialized gloves, impervious clothing that covers most of the body, and a respirator with an assigned protection factor (APF) of 10 or compliance with an alternative air exposure limit.

This analysis, which is available in the docket, is discussed in Units VII.A. and XVII.A., and is briefly summarized here.

Costs of the proposed approach and relevant alternate approaches for each chemical are discussed in Units VII.A. for methylene chloride and XVII.A. for NMP. Costs for the whole proposal follow. Costs to users of methylene chloride or NMP for paint and coating removal under the first co-proposed approach for NMP are \$2,517,000 to \$50,801,000 annualized for 20 years at a discount rate of 3% and \$3,114,000 to \$50,916,000 at a discount rate of 7%. Costs to users of methylene chloride or NMP for paint and coating removal under the second co-proposed approach for NMP are \$114,164,860 to \$124,893,000 annualized for 20 years at a discount rate of 3% and \$114,658,000 to \$125,438,000 at a discount rate of 7%. As described in more detail in the Economic Analysis (Ref. 4) and supplement to the Economic Analysis (Ref. 127), there are estimated to be approximately 13,000 commercial firms and 2,002,000 consumers who use methylene chloride or NMP in paint and coating removal that would be affected; costs per firm and for each household are estimated to include costs of alternative formulations of paint removal products, additional time spent applying or removing paint with alternative methods or substitute products, and other cost factors. For product processors and formulators, the costs of paint and coating removal product reformulations for methylene chloride and NMP under the first co-proposed approach for NMP are estimated to be approximately \$17,000 to \$34,000 per year (annualized at 3% over 20 years) and \$23,000 to \$43,000 (annualized at 7% over 20 years). For product processors and formulators, the costs of paint and coating removal product reformulations for methylene

chloride and NMP under the second co-proposed approach for NMP are estimated to be approximately \$25,140 to \$41,140 per year (annualized at 3% over 20 years) and \$34,160 to \$55,160 (annualized at 7% over 20 years). Only 17 firms are estimated to be affected. For manufacturers, processors, and distributors of methylene chloride or NMP under the first co-proposed approach for NMP, the costs of downstream notification and recordkeeping on an annualized basis over 20 years are \$140 and \$160 using 3% and 7% discount rates respectively. For manufacturers, processors, and distributors of methylene chloride or NMP under the second co-proposed approach for NMP, the costs of downstream notification and recordkeeping on an annualized basis over 20 years are \$140 and \$160 using 3% and 7% discount rates respectively (the same as under the first co-proposed approach). Approximately 30 firms are estimated to be affected. Agency costs for enforcement for each chemical, under the first co-proposed approach for NMP, are estimated to be approximately \$114,401 and \$111,718 annualized over 20 years at 3% and 7%, respectively (Ref. 4). Total Agency costs for enforcement, for both chemicals together under the first co-proposed approach for NMP, are estimated to be approximately \$228,802 and \$223,436 annualized over 20 years at 3% and 7%. Agency costs for enforcement for each chemical, under the second co-proposed approach for NMP, are estimated to be approximately \$114,401 and \$111,718 annualized over 20 years at 3% and 7%, respectively for methylene chloride and \$1,024,144 and \$998,711 annualized over 20 years at 3% and 7% respectively for NMP (Ref. 127). Total Agency costs for enforcement, for both chemicals together under the second co-proposed approach for NMP, are estimated to be approximately \$1,138,545 and \$1,110,429 annualized over 20 years at 3% and 7%.

In summary, total costs of the proposed rule under the first co-proposed approach for NMP are estimated to be \$2,763,000 to \$51,070,000 annualized over 20 years at 3% and \$3,361,000 to \$51,163,000 annualized over 20 years at 7% (Ref. 4). Total costs of the proposed rule under the second co-proposed approach for NMP are estimated to be \$114,196,000 to \$124,893,000 annualized over 20 years at 3% and \$114,658,000 to \$125,438,000 annualized over 20 years at 7% (Ref. 127).

Although methylene chloride in paint and coating removal can cause a wide range of non-cancer adverse effects,

cancer, and death and NMP can cause a variety of developmental non-cancer adverse effects, monetized benefits included only the subset of benefits associated with reducing cancer risks or deaths that occur at a known rate among users or bystanders. Methodological limitations prevent EPA from being able to include a quantification or monetary valuation estimate of the other non-cancer benefits at this time, and thus there is not a quantification or monetary valuation estimate for the overall total benefits. Based on the costs and benefits that EPA can estimate, the monetized benefits for the proposed approach range from approximately \$14,354,000 to \$14,558,000 on an annualized basis over 20 years at 3% and \$13,791,000 to \$13,919,000 at 7% (Ref. 4). EPA also considered non-monetized benefits that would result from the prevention of non-cancer adverse effects associated with methylene chloride or NMP in paint and coating removal, including nervous system effects, liver toxicity, kidney toxicity, and reproductive effects from exposure to methylene chloride in paint and coating removal; and developmental toxicity, fetal death, fetal body weight reductions, kidney toxicity, liver toxicity, immunotoxicity, and reproductive toxicity from exposure to NMP in paint and coating removal (Refs. 2 and 3).

F. Children's Environmental Health

This action is consistent with the 1995 EPA Policy on Evaluating Health Risks to Children (<http://www.epa.gov/children/epas-policy-evaluating-risk-children>). In its risk assessments for methylene chloride and NMP, EPA identified risks to children from exposure to methylene chloride and NMP used in paint and coating removal. EPA has also identified women of childbearing age as a potentially exposed or susceptible subpopulation who may be at greater risk than the general population of adverse health effects from exposure to NMP. EPA has identified this subpopulation as relevant to EPA's risk assessment for NMP due to NMP's effects on the developing fetus. Therefore, the risk management standard under Section 6 of TSCA, with respect to NMP, is to reduce the risk posed by NMP so that it no longer presents an unreasonable risk (either to users in the general population or to users who are women of childbearing age). In its TSCA Work Plan Risk Assessment for methylene chloride, EPA identified risks from inhalation exposure to children who may be present as bystanders in homes where paint removal occurs. These risks include neurological effects such as

cognitive impairment, sensory impairment, dizziness, incapacitation, and loss of consciousness (leading to risks of falls, concussion, and other injuries). The supporting non-cancer risk analysis of children as bystanders conducted in the TSCA Work Plan Risk Assessment for methylene chloride meets the 1995 EPA Policy on Evaluating Health Risks to Children. Supporting information on the health effects of methylene chloride exposure to children is available in the Toxicological Review of Methylene Chloride (Ref. 5) and the Final Risk Assessment on Methylene Chloride (Ref. 2), as well as Units VI.C.1. and VI.D.

In the TSCA Work Plan Risk Assessment for NMP, EPA identified developmental toxicity as the most sensitive endpoint for NMP exposure (*i.e.*, fetal death and decreased fetal birth weight) for the most sensitive human life stages (*i.e.*, women of childbearing age between the ages of 16 and 49 years and the fetus) (Ref. 3). The supporting non-cancer risk analysis of children and women of childbearing age conducted in the TSCA Work Plan Risk Assessment for NMP meets the 1995 EPA Policy on Evaluating Health Risks to Children.

II. Overview of Methylene Chloride and Uses Subject to This Proposed Rule

A. What chemical is included in the proposed rule?

This proposed rule would apply to methylene chloride (CASRN 75-09-2) when used in paint and coating removal except for several specified uses, including as part of commercial furniture refinishing and uses critical to national security.

B. What are the uses of methylene chloride?

Methylene chloride is a solvent used in a variety of industrial, commercial and consumer use applications, including (Ref. 2):

- Paint remover
 - Adhesive
 - Aerosol propellant
 - Metal cleaner and degreaser
 - Chemical processor for polycarbonate resins and cellulose triacetate (photographic film)
 - Feedstock in the production of the refrigerant hydrofluorocarbon-32
- Minor uses of methylene chloride include (Ref. 2):

- Extraction solvent for oils, waxes, fats, spices, and hops
- Tablet coating for pharmaceuticals

According to the 2012 Chemical Data Reporting (CDR) information, approximately 260 million pounds of

methylene chloride were produced or imported into the United States that year, with between 80% to 96% produced in the United States (Ref. 2). In terms of environmental releases, 277 facilities reported a total of 3.2 million pounds of releases of methylene chloride to the 2014 Toxics Release Inventory (Ref. 6).

Individuals, including workers, consumers, and the general population, are exposed to methylene chloride from industrial/commercial and consumer sources in different settings such as homes and workplaces, and through multiple routes (inhalation, dermal, and ingestion).

The use assessed by EPA that is the subject of this proposal, methylene chloride in paint and coating removal, represents about 25% of total use of methylene chloride. This is a decrease from the 1980s, when approximately 50% of the total methylene chloride market was composed of paint removal use (Ref. 2). Paint and coating removal is the application of a chemical or use of another method to remove, loosen, or deteriorate any paint, varnish, lacquer, graffiti, surface protectants, or other coatings from a substrate. Substrates can include objects, vehicles, architectural features, or structures. This use is discussed in detail in Unit VI.B.

Although the TSCA Work Plan Chemical risk assessment for methylene chloride focused on the chemical's use in paint and coating removal, EPA announced in December 2016 its designation of methylene chloride as one of the ten chemical substances that will undergo risk evaluation pursuant to section 6(b)(2)(A) of TSCA (81 FR 91927). The Agency is proceeding with this proposed rule addressing methylene chloride in paint and coating removal in accordance with TSCA section 26(l) and asks for comment on its decision to pursue risk management for specific conditions of use of methylene chloride while preparing to conduct a risk evaluation of remaining conditions of use of methylene chloride under TSCA section 6(b).

C. What are the potential health effects of methylene chloride?

Methylene chloride is a likely human carcinogen, a neurotoxicant, and acutely lethal. Acute and chronic exposures to methylene chloride are primarily associated with neurological and hepatic effects. The primary target organ of methylene chloride acute toxicity is the brain, and neurological effects result from either direct narcosis or the formation of carbon monoxide. Carbon monoxide is one of the metabolic byproducts of methylene chloride, and

reversibly binds to hemoglobin as carboxyhemoglobin. Part of the effect of methylene chloride on the central nervous system comes from the accumulation of carboxyhemoglobin in the blood, which can lead to sensory impairment, dizziness, incapacitation, loss of consciousness, heart failure, and death (Ref. 2). Hemoglobin in the fetus has a higher affinity for carbon monoxide than does adult hemoglobin. Thus, the neurotoxic and cardiovascular effects may be exacerbated in fetuses and in infants with higher residual levels of fetal hemoglobin when exposed to high concentrations of methylene chloride (Ref. 2).

During acute exposures, methylene chloride primarily affects the brain, though effects on lung, liver, and kidney have also been reported in humans following acute exposures. Acute exposures to methylene chloride can be fatal; acute lethality in humans following inhalation exposure is related to central nervous system depressant effects. Effects include loss of consciousness and respiratory depression, resulting in irreversible coma, hypoxia, and eventual death. Acute non-lethal effects in humans are similarly related to the central nervous system and can include incapacitation, loss of consciousness, heart failure, and coma. Other acute non-lethal effects in humans include neurobehavioral deficits measured in psychomotor tasks, such as tests of hand-eye coordination, visual evoked response changes, and auditory vigilance (Ref. 2).

Since 1976, more than 40 deaths have been attributed to methylene chloride when used in paint and coating removal (Ref. 7); in some cases, two or more individuals have died during a single job when air concentrations quickly reached lethal levels, potentially in less than 10 minutes. In other situations, individuals have died when entering rooms or facilities in which paint or coating removal was previously conducted and air concentrations of methylene chloride remained dangerously high (Ref. 7).

Chronic exposures to methylene chloride are associated with cancer and non-cancer hepatic effects. Methylene chloride is likely to be carcinogenic in humans with a mutagenic mode of action. This mutagenic mode of action is supported by the weight of evidence from multiple *in vivo* and *in vitro* studies. There is a risk for some specific cancers, including brain cancer, liver cancer, non-Hodgkin lymphoma, and multiple myeloma. Additionally, several cancer bioassays in animals have identified the liver and lung as the most sensitive target organs for tumor

development induced by methylene chloride (Ref. 2).

Non-cancer effects of chronic exposure to methylene chloride are primarily hepatic; the liver is the most sensitive target for non-cancer toxicity. Lifetime exposure in rats dosed with different concentrations is associated with hepatic vacuolation, degeneration, or liver necrosis. Other non-cancer effects of chronic methylene chloride exposure include renal tubular degeneration in rats and mice, testicular atrophy in mice, and ovarian atrophy in mice (Ref. 2).

D. What are the environmental impacts of methylene chloride?

Pursuant to TSCA section 6(c), EPA in this unit describes the effects of methylene chloride on the environment and the magnitude of the exposure of the environment to methylene chloride. The proposed unreasonable risk determination, however, is based solely on risks to human health since these risks are the most serious consequence of use of methylene chloride and are sufficient to support this proposed action.

1. *Environmental effects and impacts.* Methylene chloride is mainly released to the environment in air, and to a lesser extent in water and soil, due to industrial and consumer uses as a solvent, in aerosol products, and in paint and coating removal. Many chemical waste sites contain methylene chloride and these might act as additional sources of environmental contamination through spills, leaks, or evaporation. Because methylene chloride evaporates readily, most releases enter the air. In the air, it is broken down by sunlight and by reaction with other chemicals present in the air. In the air, methylene chloride's half-life is between 53 to 127 days (Ref. 8).

Ecotoxicity studies for methylene chloride have been conducted in fish, aquatic invertebrates, and aquatic plants. Based on available data, in the methylene chloride risk assessment EPA concluded that methylene chloride has low aquatic toxicity for fish, aquatic invertebrates, and aquatic plants (Ref. 2).

While methylene chloride is moderately persistent, given its low bioaccumulation and low hazard for aquatic toxicity, the magnitude of potential environmental impacts on ecological receptors is judged to be low for the environmental releases associated with methylene chloride in paint removal. This should not be misinterpreted to mean that methylene chloride does not pose environmental

concerns. Through other regulations, EPA is addressing methylene chloride releases to air and contamination of groundwater, drinking water, and contaminated soils. While the primary concern with this contamination has been human health, there is potential for methylene chloride exposures to ecological receptors in some cases (Ref. 2). More information about regulations to reduce environmental impacts of methylene chloride is in Unit III.

2. *What is the global warming potential of methylene chloride?* Global warming potential (GWP) measures the potency of a greenhouse gas over a specific period of time, relative to carbon dioxide, which has a high GWP of 1 regardless of the time period used. Due to its volatility, methylene chloride enters the atmosphere where it reacts slowly enough to undergo atmospheric transport and act as a greenhouse gas. Methylene chloride has been reported to the Intergovernmental Panel on Climate Change as a global warming potential chemical with a value of 8.7 GWP, or approximately 8.7 times more heat absorptive than carbon dioxide (Ref. 2).

3. *What is the ozone depletion potential of methylene chloride?* Methylene chloride is not an ozone-depleting substance and is listed as acceptable under the Significant New Alternatives Policy program for metal and electronic cleaning (degreasing), aerosol solvents, foam blowing agents, and other uses (59 FR 13044, March 18, 1994).

4. *Is methylene chloride a volatile organic compound (VOC)?* Though volatile, methylene chloride is exempt from being classified as a VOC as defined at 40 CFR 51.100(c). A VOC is any compound of carbon, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, which participates in atmospheric photochemical reactions. Because methylene chloride has negligible atmospheric photochemical reactions, it is not classified as a VOC (40 CFR 51.100(s)(1)).

5. *Does methylene chloride persist in the environment and bioaccumulate?* Due to its volatility, methylene chloride does not significantly partition to solid phases. Therefore, releases of methylene chloride to the environment are likely to evaporate to the atmosphere, or if released to soil, migrate to groundwater. Methylene chloride has been shown to biodegrade over a range of rates and environmental conditions. Measured bioconcentration factors for methylene chloride suggest its bioconcentration potential is low (Ref. 2).

III. Regulatory Actions Pertaining to Methylene Chloride

This section summarizes current state, federal, and international regulations and restrictions on methylene chloride, with a focus on its use in paint and coating removal. None of these actions imposes requirements to the extent necessary so that methylene chloride does not present the unreasonable risk described in this proposed rule.

A. Federal Actions Pertaining to Methylene Chloride

Methylene chloride has been the subject of U.S. federal regulations by EPA, the Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA). EPA and other agencies have taken actions (see below) to address the serious human health risks from specific sources and routes of methylene chloride exposure, but none of these actions sufficiently mitigate the risks that EPA is proposing to address under TSCA section 6(a).

EPA has issued several final rules and notices pertaining to methylene chloride under EPA's various authorities.

- *Clean Air Act:* Methylene chloride is designated as a hazardous air pollutant (HAP) under the Clean Air Act (42 U.S.C. 7412(b)(1))CAA). EPA issued a final rule in January 2008 that promulgated National Emission Standards for Hazardous Air Pollutants (NESHAP) for area sources engaged in paint stripping, surface coating of motor vehicles and mobile equipment, and miscellaneous surface coating operations. In this NESHAP, EPA listed "Paint Stripping," "Plastic Parts and Products (Surface Coating)," and "Autobody Refinishing Paint Shops" as area sources of HAPs that contribute to the risk to public health in urban areas. The final rule included emissions standards that reflect the generally available control technology or management practices in each of these area source categories, and applies to paint stripping operations using methylene chloride (73 FR 1738, January 9, 2008). In 2014, EPA issued a final rule for Flexible Polyurethane Foam Manufacturing that banned the use of methylene chloride as a foam-blowing agent (79 FR 48073, August 15, 2014). In 2015, EPA issued a final rule for Aerospace Manufacturing and Rework Facilities, which updated a NESHAP from 1995 by adding limitations to reduce organic and inorganic emissions HAPs, including methylene chloride, from specialty coating application operations; and

removed exemptions for periods of startup, shutdown and malfunction so that affected units would be subject to the emission standards at all times (80 FR 76152, December 7, 2015).

- *Solid Waste Disposal Act:* Methylene chloride is listed as a hazardous waste under the Resource Conservation and Recovery Act (RCRA) (Code U080) (Ref. 2).

- *Emergency Planning and Community Right-to-Know Act:* Methylene chloride is listed on the Toxics Release Inventory (TRI) pursuant to section 313 of the Emergency Planning and Community Right-to-Know Act (Ref. 2).

- *Safe Drinking Water Act:* The Safe Drinking Water Act (SDWA) requires EPA to determine the level of contaminants in drinking water at which no adverse health effects are likely to occur. EPA has set a maximum contaminant level goal of zero and an enforceable maximum contaminant level for methylene chloride at 0.005 mg/L or 5 parts per billion (57 FR 31776, July 17, 1992).

Regulation of methylene chloride by other agencies includes:

- In 1987, CPSC issued a statement of policy explaining that CPSC considers household products containing methylene chloride to be hazardous substances and providing guidance on labeling of such products. Labels of products containing methylene chloride are required to state that inhalation of methylene chloride vapor has caused cancer in certain laboratory animals, and the labels must specify precautions to be taken during use by consumers (52 FR 34698, September 14, 1987). In 2016, CPSC was petitioned by the Halogenated Solvents Industry Alliance to amend the statement of interpretation and enforcement policy regarding labeling of household products containing methylene chloride; CPSC published that petition for public comments (81 FR 60298, September 1, 2016).

- In 1989, FDA banned methylene chloride as an ingredient in all cosmetic products because of its animal carcinogenicity and likely hazard to human health (21 CFR 700.19). Before 1989, methylene chloride had been used in aerosol cosmetic products, such as hairspray (54 FR 27328 (June 29, 1989)).

- OSHA has taken steps to reduce exposure to methylene chloride in occupational settings. In 1997, OSHA lowered the permissible exposure limit (PEL) for methylene chloride from an eight-hour time-weighted average (TWA) of 500 parts per million (ppm) to an eight-hour TWA of 25 ppm and a 15-minute short-term exposure limit

(STEL) of 125 ppm. This standard also includes provisions for initial exposure monitoring, engineering controls, work practice controls, medical monitoring, employee training, personal protective equipment, and recordkeeping (29 CFR 1910.1052).

- The Department of Housing and Urban Development (HUD) has prohibited methylene chloride and other hazardous chemicals for use in removing lead-based paint by HUD contractors and anyone receiving grants or engaging in the HOME Program, which was created by the National Affordable Housing Act of 1990 (Ref. 9).

- The National Institute for Occupational Safety and Health (NIOSH) considers methylene chloride a potential occupational carcinogen and currently recommends an exposure limit of the “lowest feasible concentration” of methylene chloride (Ref. 10). NIOSH and OSHA in 2013 issued a hazard alert for bathtub refinishing with methylene chloride, warning that methylene-chloride based products are extremely dangerous and that the best way to prevent exposure is to use products that do not contain methylene chloride (Ref. 11).

B. State Actions Pertaining to Methylene Chloride

Several states have taken actions to reduce or make the public aware of risks from methylene chloride. For example, since 2011 methylene chloride has been prohibited from use in graffiti removal in the District of Columbia and 11 states (California, Connecticut, Delaware, Illinois, Indiana, Maine, Maryland, Michigan, New Jersey, New York, and Rhode Island) (Ref. 12). Iowa, Indiana, South Carolina, and other states have established detection monitoring regulations for methylene chloride (567 IAC 113.15, 329 IAC 10–21–15, S.C. Code Regs. 16–107.198, Appx. III). In Alaska, methylene chloride is listed as a carcinogenic hazardous substance (18 AAC 75.341). Methylene chloride is listed on California’s Safer Consumer Products regulations candidate list of chemicals that exhibit a hazard trait and are on an authoritative list of either chemical hazard traits or potential exposure concerns (Ref. 13). Methylene chloride is also listed on California’s Proposition 65 list of chemicals known to cause cancer, birth defects, or reproductive harm (Ref. 13). In Minnesota, it has been found that methylene chloride may negatively affect the nervous system and cause cancer (Minn. R. 4717.8200, Minn. R. 4717.8100). The state of Washington has listed methylene chloride as a human carcinogen and a chemical of high

concern to children (WAC 296–62–07473, WAC 173–334–130). In Pennsylvania, it is listed as an environmental and special hazardous substance (34 Pa. Code XIII, Ch. 323.2(a)).

All states have set PELs identical to the OSHA 25 ppm eight-hour time weighted average (TWA) PEL (79 FR 61384, October 10, 2014), however it is worth noting that California, Oregon, and Washington, which have a state PEL identical to the OSHA PEL, have slightly different requirements than OSHA for medical evaluation, fit testing for respirators, and implementation timelines related to methylene chloride (8 CCR 5502, OAR 437–002–1052, WAC 296–62–07470). The OSHA PEL is considerably higher than the levels at which EPA identified risks of concern for methylene chloride in paint and coating removal and would not be protective for the unreasonable risks identified.

C. International Actions Pertaining to Methylene Chloride

Methylene chloride is also regulated internationally and industrial and commercial sectors in certain other countries have moved to alternatives.

In Canada, the Canadian Minister of the Environment published in 2003 a Notice under Part 4 of the “Canadian Environmental Protection Act, 1999” requiring the preparation and implementation of pollution prevention plans for methylene chloride (Ref. 14). This Notice targets persons involved in the use of methylene chloride for the following activities: Aircraft paint stripping; flexible polyurethane foam blowing; pharmaceuticals and chemical intermediates manufacturing and tablet coating; industrial cleaning; and adhesive formulations. Also in 2003, Environment Canada published a Code of Practice for the reduction of methylene chloride emissions from the use of paint and coating removal products in commercial furniture refinishing and other stripping applications (Ref. 14). This Code of Practice was developed by a multi-stakeholder technical working committee, which consisted of industry representatives (*i.e.*, furniture refinishers, auto body shops, formulators of paint and coating removal products, solvent recovery firms), government personnel, and environmental non-governmental organizations.

In the European Union, the European Commission amended its Registration, Evaluation, Authorization, and Restriction of Chemical substances in 2010 to incorporate restrictions for the

use of methylene chloride in paint removers. Methylene chloride is banned in the European Union from: (1) Placement on the market in a new product for consumers/professionals after December 2010; (2) placement on the market in any product for consumers/professionals after December 2011; and (3) use by professionals after June 2012. Member States could allow the use of methylene chloride if they have a program to license and train professionals in the following: Awareness; evaluation and management of risks; use of adequate ventilation; and use of appropriate personal protective equipment (Ref. 15). The United Kingdom has issued a derogation to allow professional use of methylene chloride (Ref. 16). In addition, industrial installations using methylene chloride must have effective ventilation, minimize evaporation from tanks, and have measures for safe handling of methylene chloride in tanks, adequate personal protective equipment, and adequate information and training for operators. Paint and coating removers containing methylene chloride in a concentration equal to or greater than 0.1% by weight must include a label: “Restricted to industrial use and to professionals approved in certain EU Member States—verify where use is allowed” (Ref. 15).

IV. Methylene Chloride Risk Assessment and Outreach

In 2013, EPA identified methylene chloride in paint and coating removal as a priority for risk assessment under the TSCA Work Plan. This unit describes the development of the methylene chloride risk assessment and supporting analysis and expert input on the uses that are the subject of this proposed rule. A more detailed discussion of the risks associated with methylene chloride in paint and coating removal can be found in Unit VI.C.1.

A. TSCA Work Plan for Chemical Assessments

In 2012, EPA released the “TSCA Work Plan Chemicals: Methods Document” in which EPA described the process the Agency intended to use to identify potential candidate chemicals for near-term review and assessment under TSCA (Ref. 17). EPA also released the initial list of TSCA Work Plan chemicals identified for further assessment under TSCA as part of its chemical safety program (Ref. 1).

The process for identifying these chemicals for further assessment under TSCA was based on a combination of hazard, exposure, and persistence and bioaccumulation characteristics, and is

described in the TSCA Work Plan Chemicals Methods Document (Ref. 17). Using the TSCA Work Plan chemical prioritization criteria, methylene chloride ranked high for health hazards and exposure potential and was included on the initial list of TSCA Work Plan chemicals for assessment. Methylene chloride appeared in the 2012 TSCA Work Plan for Chemical Assessments and in the 2014 update of the TSCA Work Plan for Chemical Assessments.

B. Methylene Chloride Risk Assessment

EPA finalized a TSCA Work Plan Chemical Risk Assessment for methylene chloride (methylene chloride risk assessment) in August 2014, following the 2013 peer review of the 2012 draft methylene chloride risk assessment. All documents from the 2013 peer review of the draft methylene chloride risk assessment are available in EPA Docket Number EPA-HQ-OPPT-2012-0725. The completed risk assessment is included in that docket.

The methylene chloride risk assessment evaluated health risks to consumers, workers, and bystanders from inhalation exposures to methylene chloride when used in paint and coating removal (Ref. 2). EPA assumes workers and consumers would be adults of both sexes 16 and older, including pregnant women. EPA assumes bystanders in commercial or occupational settings would be worker non-users or adjacent workers, while bystanders in residential settings would be individuals of any age group (*e.g.*, children, adults, the elderly) nearby during product application. During scoping and problem formulation for the risk assessment, EPA focused on paint and coating removal because it was expected to involve frequent or routine use of methylene chloride in high concentrations and/or have high potential for human exposure (Ref. 2). However, this does not mean that EPA found that other uses not included in the methylene chloride risk assessment present low risk.

The methylene chloride risk assessment characterized human health effects associated with paint removal with methylene chloride. Based on the physical-chemical properties of methylene chloride and the paint and coating removal use scenarios described in the assessment, EPA assessed inhalation as the predominant route of exposure to methylene chloride during paint removal. Though highly volatile compounds such as methylene chloride may also be absorbed through the skin, EPA does not have the data nor the methodology to assess methylene chloride dermal exposure during paint

removal. As a result, the assessment may underestimate total exposures to methylene chloride during paint removal due to this inability to evaluate dermal exposure (Ref. 2).

The methylene chloride risk assessment identified risks of concern following acute (short-term) and chronic exposures for workers and consumers conducting paint removal with methylene chloride, as well as for exposed bystanders, including residents of homes in which paint removal is conducted and worker non-users adjacent to other workers conducting paint removal. The acute risks identified include death; neurological impacts such as coma, incapacitation, loss of consciousness, and dizziness; and liver effects. The chronic risks identified include brain, liver, lung, and hematopoietic cancers and liver damage (Ref. 2).

Margins of exposure (MOEs) were used in this assessment to estimate non-cancer risks for acute exposures (for consumers and workers) and chronic exposures (for workers). The MOE is the point of departure (an approximation of the no-observed adverse effect level (NOAEL)) for a specific health endpoint divided by the exposure concentration for the specific scenario of concern. The benchmark MOE accounts for the total uncertainty in a point of departure, including: (1) The variation in sensitivity among the members of the human population (*i.e.*, interhuman or intraspecies variability); (2) the uncertainty in extrapolating animal data to humans (*i.e.*, interspecies variability); (3) the uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure (*i.e.*, extrapolating from subchronic to chronic exposure); and (4) the uncertainty in extrapolating from a lowest observed adverse effect level rather than from a NOAEL (Ref. 18). MOEs provide a non-cancer risk profile by presenting a range of estimates for different non-cancer health effects for different exposure scenarios, and are a widely recognized method for evaluating a range of potential non-cancer health risks from exposure to a chemical. For non-cancer effects EPA estimated exposures that are significantly larger than the point of departure, thus resulting in MOEs that are significantly less than the benchmark MOE (Ref. 2). For methylene chloride, EPA identified acute or chronic non-cancer risks of concern if the MOE estimates were less than the benchmark MOE of 10 (Ref. 2). The health endpoint used for the benchmark MOE for acute exposure to methylene chloride is central nervous system

effects, such as dizziness or incapacitation; the health endpoint used for the benchmark MOE for chronic exposure to methylene chloride is liver toxicity. These are the most sensitive adverse health effects from exposure to methylene chloride.

Methylene chloride is a likely human carcinogen; cancer risks determine the estimated incremental increased probability of an individual in an exposed population developing cancer over a lifetime following exposure to the chemical under specified use scenarios. Standard cancer benchmarks used by EPA and other regulatory agencies are an increased cancer risk of 1 in 1,000,000 ranging to 1 in 10,000 (*i.e.*, 1×10^{-6} to 1×10^{-4}). For cancer effects, EPA estimated that workers and occupational bystanders exposed to methylene chloride in paint and coating removal have an increase in cancer risk that ranged from 10 times to almost 1,000 times greater than a cancer benchmark of 1 in 1,000,000, depending on the specific way paint or coating removal was conducted with methylene chloride (Ref. 2).

The levels of acute and chronic exposures estimated to present low risk for non-cancer effects also result in low risk for cancer.

The assessment identified the following risks from acute exposures to methylene chloride when used in paint and coating removal (Ref. 2):

- Acute risks of incapacitation, coma, or death in workers exposed to methylene chloride in paint removers when no respiratory protection is used. In some industries with high exposure scenarios, these risks of incapacitation or death are present even when respiratory protection is used.

- Acute risks of neurological effects for most workers. These risks are present even when respiratory protection is used.

- Acute risks of neurological effects for consumer users of methylene chloride as a paint remover.

- Acute risks of neurological effects for bystanders (including children and worker non-users) in the location in which paint removers containing methylene are used by either residents or commercial users. These risks are also present for exposures to methylene chloride in a location after the paint removal work is complete, because methylene chloride can remain in the air in spaces that are enclosed, confined, or lacking ventilation.

Based on the risk assessment scenarios, EPA identified the following non-cancer risks from chronic exposures to methylene chloride in paint and coating removal (Ref. 2):

- Non-cancer risks for liver effects for most workers (including worker non-users, or adjacent workers) in industries conducting paint removal.

- Non-cancer risks occur for most workers (including adjacent workers) when exposed to paint removers containing methylene chloride even when wearing respiratory protection in the exposure scenarios that predominantly demonstrate variations in exposure conditions (*i.e.*, exposure frequency and working years) in facilities reporting central tendency or high-end air levels of methylene chloride. Among all the occupational scenarios, the greatest risk of concern is for workers engaging in long-term use of or exposure to methylene chloride as a paint remover (*i.e.*, 250 days/year for 40 years) with no respiratory protection.

The assessment identified the following cancer risks from chronic exposures to methylene chloride when used in paint removal (Ref. 2):

- Cancer risks for workers (including adjacent workers) exposed to methylene chloride as a paint remover in various industries. These cancer risks include liver cancer, lung cancer, brain cancer, non-Hodgkin lymphoma, and multiple myeloma.

- The greatest cancer risks occur for workers exposed to methylene chloride when used as a paint remover who have no respiratory protection and are exposed for an extended period.

C. Supplemental Analysis Consistent With the Methylene Chloride Risk Assessment

Following the methylene chloride risk assessment, EPA conducted supplemental analyses to inform risk management. These analyses are consistent with the scope of the methylene chloride risk assessment and were based on the peer-reviewed methodology used in the methylene chloride risk assessment. They included identification of baseline and central tendency exposure scenarios, impacts of reduced methylene chloride content in paint removers, addition of local exhaust ventilation (LEV), use of personal protective equipment (PPE), additional consumer exposure scenarios, and methods of monitoring to determine workplace exposures. The results of EPA's analyses are available in this rulemaking docket (Refs. 19, 20, and 21). Prior to promulgation of the final rule, EPA will peer review the "Respirator and Glove Specifications for Workers Exposed to Methylene Chloride in Paint and Coating Removal," "Supplemental Consumer Exposure and Risk Estimation Technical Report for Methylene Chloride in Paint and

Coating Removal", and "Recommendation for an Existing Chemical Exposure Concentration Limit (ECEL) for Occupational Use of Methylene Chloride and Workplace Air Monitoring Methods for Methylene Chloride" (Refs. 19, 20, 21).

D. Outreach

In addition to the consultations described in Unit XXIII.C., EPA engaged in discussions with experts on and users of paint removers (Ref. 22). The purpose of these discussions was to hear from users, academics, manufacturers, and members of the public health community about practices related to paint removal in various industries and by consumers; the importance of methylene chloride and NMP in paint removal; frequently-used substitute chemicals or alternative paint removal methods; engineering control measures and personal protective equipment currently in use or feasibly adoptable for paint removal; and other risk reduction approaches that may have already been adopted or considered for commercial or consumer paint removal. Informed by these discussions and by industry and other governmental research, EPA has concluded that alternatives to methylene chloride and NMP are available for nearly all paint removal uses.

EPA is continuing to gather information, to the extent practicable, regarding the availability of alternatives to methylene chloride for furniture refinishing. EPA plans to continue to engage stakeholders to identify what methods may be available as alternatives to methylene chloride. After collecting the information, EPA expects to address this use of methylene chloride so that the substance no longer poses an unreasonable risk and intends to issue separately a proposal in the future. Also see Unit XI.

V. Regulatory Approach for Methylene Chloride in Paint and Coating Removal

A. TSCA Section 6(a) Unreasonable Risk Analysis

Under TSCA section 6(a), if the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the Agency's risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance no longer presents such risk.

TSCA section 6(a) requirements can include one or more, or a combination of, the following actions:

- Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of such substances (§ 6(a)(1)).
- Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of such substances for particular uses or for uses in excess of a specified concentration (§ 6(a)(2)).
- Require minimum warning labels and instructions (§ 6(a)(3)).
- Require recordkeeping or testing (§ 6(a)(4)).
- Prohibit or regulate any manner or method of commercial use (§ 6(a)(5)).
- Prohibit or otherwise regulate any manner or method of disposal (§ 6(a)(6)).
- Direct manufacturers and processors to give notice of the determination to distributors and the public and replace or repurchase substances (§ 6(a)(7)).

EPA analyzed a wide range of regulatory options under section 6(a) for each use in order to select the proposed regulatory approach (Refs. 23 and 24). For each use, EPA considered whether a regulatory option (or combination of options) would address the identified unreasonable risks so that the chemical substance no longer presents such risks. EPA found that an option that could reduce exposures such that they would achieve the benchmark MOE for the most sensitive non-cancer endpoint would address the risk of concern for other non-cancer endpoints. Additionally, EPA's assessments for methylene chloride in paint and coating removal found that exposures that meet the benchmark MOE for the most sensitive non-cancer endpoint would also not result in cancer risks of concern.

After the technical analysis, which represents EPA's assessment of the potential for the regulatory options to achieve risk benchmarks based on analysis of exposure scenarios, EPA then considered how reliably the regulatory options would actually reach these benchmarks. For the purposes of this proposal, EPA found that an option addressed the risk so that it was no longer unreasonable if the option could achieve the benchmark MOE or cancer benchmark for the most sensitive endpoint. In considering whether a regulatory option would ensure the chemical no longer presents the unreasonable risk, the Agency considered whether the option could be realistically implemented or whether there were practical limitations on how well the option would mitigate the risks

in relation to the benchmarks, as well as whether the option's protectiveness was influenced by concerns related to environmental justice, children's health, and potentially exposed or susceptible subpopulations identified as relevant to the Agency's risk evaluation.

B. TSCA Section 6(c)(2) Considerations

TSCA section 6(c)(2) requires EPA to consider and publish a statement based on reasonably available information with respect to the:

- Health effects of the chemical substance or mixture (in this case, methylene chloride) and the magnitude of human exposure to methylene chloride;
- Environmental effects of methylene chloride and the magnitude of exposure of the environment to methylene chloride;
- Benefits of methylene chloride for various uses;
- Reasonably ascertainable economic consequences of the rule, including: The likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; the costs and benefits of the proposed and final rule and of the one or more primary alternatives that EPA considered; and the cost-effectiveness of the proposed rule and of the one or more primary alternatives that EPA considered.

In addition, in selecting among prohibitions and other restrictions available under TSCA section 6(a), EPA must factor in, to the extent practicable, these considerations. Further, in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, EPA must also consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

EPA's analysis of the health effects and magnitude of exposure to methylene chloride can be found in Units IV.B., VI.C.1. and VI.D., which discuss the methylene chloride risk assessment and EPA's regulatory assessment of methylene chloride in paint and coating removal. A discussion of the environmental effects of methylene chloride is in Unit II.D.

With respect to the costs and benefits of this proposal and the alternatives EPA considered, as well as the impacts on small businesses, the full analysis is presented in the Economic Analysis

(Ref. 4). To the extent information was reasonably available, EPA considered the benefits realized from risk reductions (including monetized benefits, non-monetized quantified benefits, and qualitative benefits), offsets to benefits from countervailing risks (e.g., risks from chemical substitutions and alternative practices), the relative risk for environmental justice populations and children and other potentially exposed or susceptible subpopulations (as compared to the general population), the cost of regulatory requirements for the various options, and the cost effectiveness of the proposed action and the one or more primary alternate regulatory options. A discussion of the benefits EPA considered can be found in Units VI.D. and VII.B. as well as in the Economic Analysis (Ref. 4).

EPA considered the estimated costs to regulated entities as well as the cost to administer and enforce the options. For example, an option that includes use of a respirator would include inspections to evaluate compliance with all elements of a respiratory protection program (Ref. 25). In understanding the burden, EPA took into account reasonably available information about the functionality and performance efficacy of the regulatory options and the ability to implement the use of chemical substitutes or other alternatives. Reasonably available information included the existence of other Federal, state, or international regulatory requirements associated with each of the regulatory options as well as the commercial history for the options. A discussion of the costs EPA considered and a discussion of the cost-effectiveness of the proposal and the primary alternate regulatory options that EPA considered is in Units VI.F. and VII.A. In addition, a discussion of the impacts on small businesses is in Unit XXIII. and in the Initial Regulatory Flexibility Analysis and Report from the Small Business Advocacy Review Panel (Refs. 26 and 27).

With respect to the anticipated effects of this proposal on the national economy, EPA considered the number of businesses and workers that would be affected and the costs and benefits to those businesses and workers. In addition, EPA considered the employment impacts of this proposal, as discussed in section 9.2 of the Economic Analysis (Ref. 4). EPA found that the direction of change in employment is uncertain, but EPA expects the short term and longer-term employment effects to be small.

The benefits of methylene chloride in paint and coating removal are discussed

in Unit VI.B., along with the availability of alternatives. The dates that the proposed restrictions would take effect are discussed in Unit X. The availability of alternatives to methylene chloride in paint and coating removal on those dates is discussed in Unit VI.E.

Finally, with respect to this proposal's effect on technological innovation, EPA expects this action to spur innovation, not hinder it. An impending prohibition on this use of methylene chloride is likely to increase demand for alternatives, which EPA expects would result in the development of new alternatives. See also section 9.3 in the Economic Analysis (Ref. 4).

C. Regulatory Options Receiving Limited Evaluation

EPA analyzed a wide range of regulatory options under TSCA section 6(a). There are a range of regulatory options under TSCA; only those pertaining to these risks were evaluated in detail. An overview of the regulatory options not evaluated in detail follows.

First, EPA reasoned that the TSCA section 6(a)(1) regulatory option to prohibit the manufacture, processing or distribution in commerce of methylene chloride or limit the amount of methylene chloride which may be manufactured, processed or distributed in commerce is not germane because EPA is not proposing to ban or limit the manufacture, processing or distribution in commerce of methylene chloride for uses other than paint and coating removal.

In addition, EPA determined that the TSCA section 6(a)(6) regulatory option to prohibit or otherwise regulate any manner or method of disposal of the chemical is not applicable since EPA did not assess risks associated with methylene chloride disposal.

Another option EPA evaluated would require warning labels and instructions on paint and coating removal products containing methylene chloride, pursuant to TSCA section 6(a)(3) (Ref. 28). However, EPA reasoned that warning labels and instructions alone could not significantly mitigate the unreasonable risks presented by methylene chloride in paint and coating removal. EPA based its reasoning on an analysis of 48 relevant studies or meta-analyses, which found that consumers and professionals do not consistently pay attention to labels for hazardous substances; consumers, particularly those with lower literacy levels, often do not understand label information; consumers and professional users often base a decision to follow label information on previous experience and perceptions of risk; even if consumers

and professional users have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings; and consumers and professional users have varying behavioral responses to warning labels, as shown by mixed results in studies (Ref. 28). Additionally, workers being exposed may not be in a position to influence their employer's decisions about the type of paint removal method, or ensure that their employer provides appropriate PPE and an adequate respiratory protection program.

These conclusions are based on the weight-of-evidence analysis that EPA conducted of the available literature on the efficacy of labeling and warnings. This analysis indicates that a label's effectiveness at changing user behavior to comply with instructions and warnings depends on the attributes of the label and the user, and how those interact during multiple human information processing stages, including attention, comprehension, judgement, and action (Ref. 28).

Numerous studies have found that product labels and warnings are effective to some degree. However, the extent of the effectiveness has varied considerably across studies and some of the perceived effectiveness may not reflect real-world situations. This is because interactions among labels, users, the environment, and other factors greatly influence the degree of a label's effectiveness at changing user behavior (Ref. 28). In addition, while some studies have shown that certain components of labels and warnings tend to have some influence, it is less clear how effective labels and warnings are likely to be over time, as users become habituated to both the labels and the products.

Presenting information about methylene chloride on a product label would not adequately address the unreasonable risk presented by this use of this chemical because the nature of the information the user would need to read, understand, and act upon is extremely complex. When the precaution or information is simple or uncomplicated (e.g., do not mix this cleaner with bleach or do not mix this cleaner with ammonia), it is more likely the user will successfully understand and follow the direction. In contrast, it would be challenging to most users to follow the complex product label instructions required to explain how to reduce exposures to the extremely low levels needed to minimize the risk from methylene chloride. Rather than a

simple message, the label would need to explain a variety of inter-related factors, including but not limited to the use of local exhaust ventilation, respirators and assigned protection factor, and effects to bystanders. Currently, though some paint removers containing methylene chloride are labeled with information about its fatal effects if used without "adequate ventilation" (Ref. 28) and this information appears on the product safety data sheet, deaths continue to occur. It is unlikely that label language changes for this use of methylene chloride will result in widespread, consistent, and successful adoption of risk reduction measures by users.

Any use of labels to promote or regulate safe product use should be considered in the context of other potential risk reduction techniques. As highlighted by a 2014 expert report for the Consumer Product Safety Commission (CPSC), "safety and warnings literature consistently identify warnings as a less effective hazard-control measure than either designing out a hazard or guarding the consumer from a hazard. Warnings are less effective primarily because they do not prevent consumer exposure to the hazard. Instead, they rely on persuading consumers to alter their behavior in some way to avoid the hazard" (Ref. 29). Specifically regarding methylene chloride, effective personal protection resulting in risk reduction would require this altered behavior to include the appropriate use of a supplied-air respirator. Consumer users are particularly unlikely to acquire and correctly use such an apparatus in response to reading a warning label (Ref. 19). Any labeling aiming to reduce risks to consumer or commercial users of these products would need to sufficiently and clearly explain the importance of the supplied-air respirator, and would still leave the user with the problem of obtaining and properly using the supplied-air respirator, which is a particularly expensive piece of equipment (Ref. 4). Further, for the effective use of a respirator, particularly an air-supplied respirator, there would need to be fit-testing of the respirator and training in its use.

While EPA reasons that revised labeling will not address the unreasonable risk presented by methylene chloride in paint and coating removal, as a result of recommendations from the Small Business Advocacy Review (SBAR) Panel to solicit information from the public about the potential efficacy of labeling, following advice from the small entity

representatives who participated in the SBAR process (Ref. 27), EPA requests public comments on enhanced labeling requirements for consumer paint and coating removal products containing methylene chloride as a method for reducing exposure to methylene chloride in these products. More information about the SBAR process, the Panel recommendations, and advice from small businesses related to this proposal are in Unit XXIII. and in the Panel Report (Ref. 27).

While this regulatory option alone would not adequately address the unreasonable risks, EPA recognizes that the TSCA section 6(a)(3) warnings and instruction requirement can be an important component of an approach that addresses unreasonable risks associated with a specific use prohibition. EPA has included a downstream notification requirement as part of the proposed rule to ensure that users would be made aware of the prohibition on the use of methylene chloride in paint and coating removal.

An additional regulatory option receiving limited evaluation was a training and certification program for commercial paint and coating removers, similar to the certification process required under EPA's Lead-Based Paint Renovation, Repair, and Painting Rule (73 FR 21692, April 22, 2008). This option was recommended by the small entity representatives as part of the SBAR process (Ref. 27). EPA considered this option as an approach to reducing risks from methylene chloride in paint and coating removal. However, unlike the process for training and certification of commercial workers required under the Lead-Based Paint Renovation, Repair, and Painting Rule, effective risk reduction from commercial use of methylene chloride for paint and coating removal would require additional regulation of distributors of these products. When considering this approach, given the Agency's experience with the training and certification program under the Lead-Based Paint Renovation, Repair, and Painting Rule, EPA viewed the costs and challenges involved in regulating distributors and ensuring that only trained and certified commercial users are able to access these paint and coating removal products as a significant limitation for this approach. EPA seeks public comment on the feasibility of such a program and its potential to reduce risks of exposure to methylene chloride for workers and bystanders so that those risks are no longer unreasonable.

VI. Regulatory Assessment of Methylene Chloride in Paint and Coating Removal

This unit describes the current use of methylene chloride in paint and coating removal, the unreasonable risks presented by this use, and how EPA identified which regulatory options reduce the risks so that they are no longer unreasonable.

A. Methylene Chloride Uses That Are the Focus of This Regulation

The methylene chloride uses that are the focus of this action are:

1. Any consumer use of methylene chloride for paint and coating removal, and
2. Any commercial use of methylene chloride for paint and coating removal except for commercial furniture refinishing, which EPA intends to address in a separate proposal, as described in Unit XI. While EPA proposes to determine that the identified risks from methylene chloride in commercial furniture refinishing are unreasonable, EPA plans to continue public engagement before proposing regulations for methylene chloride in this industry. Additional information is in Unit XI. This is one of the recommendations from SBAR Panel (Ref. 27),

EPA proposes to exempt specific paint and coating removal with methylene chloride from critical corrosion-sensitive components of military aviation and vessels, which the Department of Defense identified as critical for national security purposes. The details of this national security use are in Unit VIII.

B. Methylene Chloride in Paint and Coating Removal

Methylene chloride has been used for decades in paint and coating removal in products intended for both commercial and consumer uses. Paint and coating removal, also referred to as paint stripping, is the process of removing paint or other coatings from a surface. Coatings can include paint, varnish, lacquer, graffiti, polyurethane, or other coatings sometimes referred to as high-performance or specialty coatings; surfaces may be the interior or exterior of buildings, structures, vehicles, aircraft, marine craft, furniture, or other objects. Paint and coating removal can be conducted in occupational or consumer settings. These surfaces, or substrates, include a variety of materials, such as wood, metals, plastics, concrete, and fiberglass. A variety of industries include paint and coating removal in their business

activities, including professionals involved in renovations, bathtub refinishing, automotive refinishing, furniture refinishing, art restoration and conservation, aircraft repair, marine craft repair, and graffiti removers (Ref. 3).

Paint and coatings can be removed by chemical, mechanical, or thermal means. Chemical paint removers can include solvents, such as methylene chloride or NMP, caustic chemicals, or other categories of chemicals. Solvents aid in removing paints and coatings by permeating the top of the coating and dissolving the bond between the coating and the substrate (Ref. 30). Following the application of the chemical paint remover, the coating can be more easily peeled, scraped, or mechanically removed from the substrate. Techniques for applying the paint remover chemical include manual coating or brushing, tank dipping, flow-over systems, and spray applications (manually or through automation). Pouring, wiping and rolling are also possible application techniques and application can be manual or automated (Ref. 3).

In the construction trades, methylene chloride is used to remove paint and coatings from walls, trim, architectural features, patios or decks, ceilings, bathtubs, floors, etc. to prepare them for new coatings during residential and commercial building renovation. Methylene chloride is typically applied to the surface using a hand-held brush. It is then left on to soften the old coating (Ref. 4). Once curing has occurred, the old coating is scraped or brushed off and the surface is cleaned. For bathtub refinishing, methylene chloride is poured and brushed onto a bathtub using a paintbrush and then scraped from the bathtub after leaving the remover to cure for 20 to 30 minutes (Ref. 4). Consumers use methylene chloride in similar ways.

Commercially, methylene chloride is also used to remove paint and coatings from civilian aircraft, marine craft, cars, trucks, railcars, tankers, storage vessels, and other vehicles or their component parts to prepare for new coatings. Similar to the construction trades, applications in the transportation industry tend to be brushed on and scraped off. More information on specific techniques for commercial paint removal and by consumers are in the methylene chloride risk assessment and supplemental materials (Refs. 2, 19, 20, 21, and 31).

Though many users are switching to substitutes and alternative methods, methylene chloride use persists because it is readily available and works quickly on nearly all coatings without damaging

most substrates. In addition, some users may prefer methylene chloride because it is less flammable than some other solvents. However, it is extremely volatile, has strong fumes, and evaporates quickly so that it must be reapplied for each layer of paint or coating to be removed. Additionally, paint and coating removal products formulated with methylene chloride tend to contain high concentrations of co-solvents that are flammable, reducing one perceived advantage of methylene chloride products.

Chemical products for paint and coating removal are used across several industries as well as by consumers or hobbyists, and products intended for one type of use—such as aircraft renovation—have been used in other situations, such as bathtub refinishing (Refs. 11, 32, and 33). Products intended for one specific type of paint removal project can be easily used in a different setting. Additionally, consumers can easily use products intended for or marketed to professional users since paint removal products are readily available at big box and local hardware stores, as well as paint specialty stores.

EPA has identified 59 different products for paint and coating removal that contain methylene chloride, formulated by 10 different firms. This is approximately 54% of the total number of paint and coating removal products EPA identified (109 products) (Ref. 34). Commercial uses of these products include automotive refinishing, furniture refinishing, art conservation and restoration, pleasure craft building and repair, aircraft paint removal, graffiti removal, bathtub refinishing, and renovations in residences or other buildings. Though the number of workers and consumers exposed to methylene chloride during paint and coating removal is uncertain, EPA has several estimates based on industry data and information gathered for rulemakings promulgated previously under other statutes, such as the Clean Air Act, intended to address different risks. As described in more detail in the Economic Analysis, EPA estimates that 32,600 workers annually are exposed to methylene chloride during paint and coating removal activities (Ref. 4). Of them, 15,000 are estimated to be exposed during furniture refinishing; 17,600 are estimated to be exposed during other commercial paint and coating removal processes (Ref. 4).

Consumer use of methylene chloride in paint and coating removal is similar to commercial use but is carried out by do-it-yourself (DIY) consumers and occurs in consumer settings, such as homes, workshops, basements, garages,

and outdoors. Paint and coating removal products containing methylene chloride are the same as those used in many commercial settings, and the process consumers use is similar to commercial methods of brushing or spraying on the paint and coating removal product, allowing time to pass for the product to penetrate the coating, and then scraping the loosened coating from the surface. Manufacturers and retailers of paint and coating removal products containing methylene chloride frequently sell them to consumers in small containers with marketing language or labeling that state they are easy to use and work on a variety of paints, coatings, and surfaces (Ref. 35). Products intended for consumers containing methylene chloride must meet minimum labeling requirements prescribed by CPSC that the product contains methylene chloride and that it may cause cancer (52 FR 34698, September 14, 1987). Information about risks of death as a result of acute exposure or methods to reduce exposure through personal protective equipment or ventilation are not required and frequently are not present on products containing methylene chloride (Refs. 35 and 36). Paint and coating removers containing methylene chloride are frequently sold at home improvement retailers or automotive supply stores that sell products to consumers as well as professional users. Additionally, due to the wide availability of products available on the Internet and through various additional suppliers that serve commercial and consumer customers, consumers may foreseeably purchase a variety of paint and coating removal products containing methylene chloride. EPA estimates that a large percentage of users of paint and coating removal products containing methylene chloride are consumers, rather than occupational users. EPA estimates that approximately 1.3 million consumers annually use paint removal products containing methylene chloride (Ref. 4).

C. Analysis of Regulatory Options

In this unit, EPA explains how it evaluated whether the regulatory options considered would address the risks presented by this use as necessary so that the risks are no longer unreasonable. First, EPA characterizes the unreasonable risks associated with the current use of methylene chloride in paint and coating removal. Then, EPA describes its initial analysis of which regulatory options have the potential to achieve standard non-cancer and cancer benchmarks. The levels of acute and chronic exposures estimated to present no risks of concern for non-cancer

effects also result in no risks of concern for cancer. Lastly, this section evaluates how well those regulatory options would address the unreasonable risk in practice.

1. *Risks associated with the current use.*

a. General impacts. The methylene chloride risk assessment and supplemental analyses identified acute and chronic risks from inhalation of methylene chloride during paint and coating removal by consumers and bystanders in residences; and commercial users and occupational bystanders in workplaces (individuals not using the paint and coating remover but nearby a user) (Refs. 2 and 19). EPA estimates, having refined the numbers since the risk assessment, that, annually, there are approximately 17,600 direct users at 8,600 commercial operations conducting paint and coating removal with methylene chloride for the uses proposed for regulation that will potentially benefit from the risk reduction resulting from this proposed regulation. EPA estimates that approximately 1.3 million consumers who use paint and coating removal products containing methylene chloride each year that will also potentially benefit from risk reduction resulting from this proposal (Ref. 4).

b. Impacts on minority and other populations. While all consumers and workers using paint and coating removal products containing methylene chloride would benefit from risk reduction, some populations are currently at disproportionate risk for the health effects associated with use of methylene chloride in paint and coating removal. In the construction trades, Hispanic workers (of all races) and foreign-born workers are over-represented (Ref. 4). In the U.S. population, 16% of adults are Hispanic, whereas in the construction trades, 35% of workers are Hispanic (Ref. 4). Due to their overrepresentation in the construction trades, Hispanic workers are disproportionately at risk of exposure to methylene chloride when used in paint and coating removal.

Similarly, foreign-born workers are overrepresented in the construction trades. In the U.S. population overall, 17% of workers in all industries are foreign-born, whereas in the construction trades, 28% of workers are foreign-born (Ref. 4). As a result, they may primarily speak a language other than English and could be characterized as having limited English proficiency. Under Executive Order 13166, EPA and other agencies are charged with examining and identifying the needs of individuals with limited English

proficiency (65 FR 50121, August 11, 2000). Like Hispanic workers, foreign-born workers are disproportionately at risk of exposure to methylene chloride when used in paint and coating removal in the construction trades.

EPA's identification of the current disproportionate risks of methylene chloride exposure faced by Hispanic and foreign-born workers in the construction trades is part of the analysis conducted as part of EPA's efforts towards environmental justice. Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice; EPA's compliance with this executive order is detailed in Unit XXIII.

c. Impacts on children. In the methylene chloride risk assessment, EPA examined acute risks for bystanders to consumer use of methylene chloride in paint and coating removal in residential settings. Although EPA expects that users of methylene chloride in paint and coating removal would be adult individuals (16 years old and older), bystanders could be individuals of any age group (*e.g.*, children, adults, and the elderly) who are elsewhere in the house during product application and in the hours following application (Ref. 2). In most scenarios, EPA found acute risks of concern for central nervous system effects for other residents of the house, including children, in which paint and coating removal with methylene chloride was conducted (Ref. 2). EPA found risks of concern not only during the application of the product, but also for several hours following (Ref. 2).

Although EPA anticipates that most consumers conducting paint and coating removal with methylene chloride would likely exclude children from the room in which the project was being carried out, it is unclear if they would exclude them from the house overall during and after the product application. Additionally, if the project involved removing the coating from a bathtub, households with only one bathroom would present challenges for bystander exclusion for several hours. As a result, children present in homes where paint and coating removal is being conducted, by family members or by professionals, face acute risks of central nervous system impacts.

EPA was not able to model scenarios in which paint and coating removal was conducted in an apartment building, hotel, or other residence or place in which children may be present other than single-family homes. However, the findings related to bystander exposure suggest risks for children and other

residents of apartments or hotel rooms adjacent to units in which paint and coating removal is being conducted. In these situations, it is even less likely that children would be excluded from all affected areas in order to protect them from acute risks. As a result, methylene chloride is likely to present acute risks to children as bystanders to paint and coating removal with methylene chloride, even if they are excluded from the areas in which work is conducted (Ref. 2).

d. Exposures for this use. Exposures assessed for this use include acute exposures to methylene chloride in paint and coating removal by consumers and residential bystanders, and acute and chronic exposures by commercial workers and occupational bystanders, as described in the methylene chloride risk assessment (Ref. 2). In some cases where commercial paint and coating removal is conducted, such as in workshops or facilities that are within residences (for example, in the case of some small businesses) (Ref. 27), exposed bystanders may include family members, such as children. The exposures assessed included some commercial furniture refinishing, which is not proposed for regulation. Different exposure scenarios were evaluated for workers, occupational bystanders, consumers, and residential bystanders (Ref. 2).

For exposures in commercial settings, EPA assessed acute risks and chronic risks, including cancer risks. For acute risks, EPA assessed four occupational scenarios based on eight-hour TWA exposure concentrations and different variations in exposure conditions, such as presence or absence of respirators and the protection factor of any respirator used. For each commercial use evaluated in the assessment, EPA modeled scenarios using assumed parameters similar to typical use conditions within those industries, such as whether work was conducted indoors or outdoors and what quantity of methylene chloride was estimated to be used. For these acute workplace estimates, the acute methylene chloride exposure concentration evaluated for risk was the eight-hour TWA air concentration in milligrams per cubic meter reported for the various relevant industries. In the risk assessment, EPA assumed that some workers could be rotating tasks and not necessarily carrying out paint and coating removal tasks using methylene chloride on a daily basis. This type of exposure was characterized as acute in this assessment because the worker's body was estimated to have sufficient time to remove methylene chloride and its

metabolites before the next encounter with methylene chloride during paint and coating removal (Ref. 2).

For chronic exposure scenarios, EPA varied not only the parameters described above, but also the number of working days exposed to methylene chloride during paint and coating removal (ranging from 125 to 250 days per year) and exposed working years (varying the number of years the worker was assumed to be exposed) (Ref. 2). Overall, EPA evaluated cancer and chronic non-cancer risks for 16 occupational scenarios.

Worker inhalation exposure data were taken from peer-reviewed literature sources, as cited in the risk assessment (Ref. 2). These data sources often did not indicate whether monitored exposure concentrations were for occupational users or bystanders. Therefore, EPA assumed that these exposure concentrations were for a combination of users and bystanders. EPA evaluated scenarios both with and without respirator use and a range of respirator assigned protection factors (APFs), but did not estimate the overall frequency of respirator use because supporting data on the prevalence of respirator use for these commercial uses was unavailable. Similarly, EPA made assumptions about the exposure frequencies and working years because data were not found to characterize these parameters, and estimated various exposure frequencies (125 and 250 days per year) and working years (20 and 40 years). Thus, EPA evaluated occupational risks by developing hypothetical scenarios under the varying exposure conditions described previously (Ref. 2).

It is important to note that EPA relied on monitoring data for these occupational exposure estimates. Many air concentrations reported and used in the risk assessment exceeded the current OSHA PEL of 25 ppm; in some industries where paint and coating removal was conducted by immersion in tanks or vats of methylene chloride, air concentrations were measured at above 7,000 milligrams per cubic meter, or 2,016 ppm. Even in industries with lower expected exposures, air concentrations frequently were reported in excess of 250 milligrams per cubic meter, or 72 ppm, such as during graffiti removal and automotive refinishing (Ref. 2). The risks associated with these dramatically high air concentrations are discussed in Unit VI.C.1.e.

For consumer and residential bystander exposures, EPA assessed exposure scenarios under which the individual user was presumed to work on one of several types of paint and

coating removal projects (coffee table, chest of drawers, or bathtub). These scenarios take into account that consumers do not reliably use personal protective equipment (respirators) or have access to engineering controls (e.g., exhaust ventilation), since these methods are costly, technically challenging, and not easily available to consumers (Ref. 2). EPA used product label information to establish the time durations (in minutes) that the user would require to complete each step of the paint or coating removal process. User breaks during wait periods were assumed; the scenarios varied the location of where the user rested (in the work space or elsewhere). In addition, back-to-back projects were modeled because it is likely that the user would take breaks during the wait periods specified on product labels. It was further assumed that the paint scrapings were removed from the house as soon as scraping was completed. In each scenario, the bystander was assumed to be somewhere else in the house, and exposed via inhalation to some of the methylene chloride from the workspace (Ref. 2).

EPA developed seven consumer exposure scenarios for the assessment. Similar to the worker exposure assessment, the following factors were considered in developing the exposure scenarios (Ref. 2):

- The type of application (*i.e.*, brush-on or spray-on), weight fraction of methylene chloride in the paint and coating removal product, application rate by the user, surface area of object from which the paint or coating was being removed, and emission rate of the chemical, which can affect the amount of methylene chloride that ultimately is released to the indoor environment;
- The location where the product is applied, which relates to exposure factors such as the room volume and its air exchange rate with outdoor air;
- The house volume and air exchange rate, for reasons similar to those for the product use location; and
- Precautionary behaviors such as opening windows in the application room, the user leaving the application room during the wait period, related changes to the air exchange rates, and the proximity of the user to the source of methylene chloride emissions.

In the absence of representative air monitoring data for consumer users and residential bystanders using paint and coating removal products containing methylene chloride, EPA used the Multi-Chamber Concentration and Exposure Model to estimate consumer and bystander inhalation exposure concentrations (Ref. 2).

EPA's estimates of the exposures during paint and coating removal with methylene chloride experienced by commercial users and bystanders and consumer users and bystanders were used to assess the risks of this use of methylene chloride. The full exposure estimates and risk findings are described in the methylene chloride risk assessment; risk findings are also summarized in Unit VI.C.1.e.

In addition to estimating likely exposures under current use patterns (baseline exposures), for both commercial and consumer users, EPA assessed a number of exposure scenarios associated with risk reduction options in order to identify variations in methylene chloride exposure during paint and coating removal. All variations in the scenarios were applied to industry-specific exposure inputs and evaluated with exposure parameters that were modified to reflect either a reasonable worst-case scenario (also called the baseline) or a scenario in which exposures were moderated by several factors (also called the central tendency scenario). The risk reduction options that varied between scenarios included engineering controls, use of PPE, and well as combinations of these options (Ref. 19).

- Under the PPE risk reduction option exposure scenarios, EPA evaluated respirators with APF 10 to 10,000 for acute and chronic risks, including cancer risks.

- For the engineering controls risk reduction option exposure scenarios, EPA evaluated exposures using local exhaust ventilation (LEV) to improve ventilation near the activity of workers (using furniture refinishing operations as a model), with an assumed 90% reduction in exposure levels.

Overall, EPA evaluated dozens of distinct exposure scenarios for commercial paint and coating removal with methylene chloride; exposure reductions for consumer users are expected to be similar to the acute risk evaluations for professional contractors or workers in furniture refinishing operations, since these commercial activities are most similar to the types of projects in which consumers would engage (Refs. 19 and 20).

e. Specific risks for this use. The acute inhalation risk assessment used central nervous system effects to evaluate the acute risks for occupational, consumer, and bystander exposure during paint and coating removal with methylene chloride. In the risk assessment, a risk of concern was identified if the MOE estimate was less than the benchmark MOE of 10 for acute central nervous system effects (Ref. 2).

EPA assessed acute risks for central nervous system effects from inhalation for all consumer, occupational, and bystander exposure scenarios of paint and coating removal with methylene chloride. For consumers, EPA identified risks of concern for all scenarios, with some consumer scenarios demonstrating risks within the first hour of product use when paint and coating removal was conducted indoors (such as in a workshop or bathroom), regardless of whether the product formulation was brush or spray. Risks for incapacitating nervous system effects were found in some indoor scenarios (such as in a bathroom) within four hours of product use. MOEs for consumer acute risks from exposures of one hour or less ranged from 1.6 to 0.2; this equates to estimated exposures that are between six and 50 times greater than those that are expected to produce no risks of concern (Ref. 2).

For residential bystanders, EPA identified risks of concern for all scenarios, even assuming that any bystander in the house was not in the room where the paint and coating removal occurred. Depending on the parameters of the scenario, MOEs for acute risks ranged from 2.9 to 0.5, or between three and 20 times greater than those that are expected to produce no risks of concern (Ref. 2).

For commercial users, the occupational scenarios in which acute risks for central nervous system effects were identified included nearly all occupational scenarios, irrespective of the absence or presence of respirators, and in both the central-tendency and worst-case assumed air concentrations of methylene chloride. Additionally, EPA found acute risks for incapacitating central nervous system effects for workers who had no respiratory protection in most industries, or with respirators with APFs of 10 or 25 in the industries with highest likely exposures, such as professional contractors, aircraft refinishers, and workers using immersion methods for paint and coating removal in several industries. MOEs for acute risks ranged from an average of 0.11 (automotive refinishing) to 0.037 (graffiti removal), with a lowest end of 0.0063 (workplaces engaged in paint and coating removal using immersion methods). In general, these workplaces are estimated to present exposure levels between 100 times to greater than 1,000 times more than those that are of concern. Not only workers, but also occupational bystanders, or workers engaged in tasks other than paint and coating removal, would be at acute risk for central nervous system effects (Ref. 2). Therefore, EPA's

proposed determination is that acute methylene chloride exposures during paint and coating removal present unreasonable risks.

In the risk assessment, EPA also assessed risks of chronic exposure to methylene chloride during paint and coating removal by commercial users and occupational bystanders (Ref. 2). The methylene chloride risk assessment used liver toxicity as the critical endpoint for chronic exposure. EPA assessed risks for liver toxicity for occupational and bystander exposure scenarios of paint and coating removal with methylene chloride.

Workers and occupational bystanders in most industries evaluated were identified as at risk for non-cancer liver toxicity as a result of chronic exposure to methylene chloride during paint and coating removal under typical exposure scenarios. When workers were exposed repeatedly at facilities they were at risk, even for scenarios evaluated with workers wearing respiratory protection with APF 50 (Ref. 2). The concern is for workers engaging in long-term use of the product (*i.e.*, 250 days/year for 40 years) with no respiratory protection.

For commercial users and bystanders, EPA also assessed cancer risks as a result of chronic exposure to methylene chloride in paint and coating removal. Workers and occupational bystanders showed were estimated to have an excess cancer risk greater than 1 in 1,000,000 for all of the commercial scenarios evaluated if exposed to paint and coating removal with methylene chloride for 250 days per year for 40 years with no respiratory protection. Depending on industry, cancer risks ranged from 6 in 10,000 (graffiti removal) to 2.5 in 1,000 (aircraft refinishing), with a maximum of 4 in 1,000 (workplaces using immersion methods, such as dip tanks for miscellaneous metal items). Workers in all industries showed a relative reduction in cancer risks when estimated to be working for 125 days per year for 20 years with a respirator with APF 50, with cancer risks in some industries estimated to be below benchmark levels in these scenarios. Therefore, EPA's proposed determination is that chronic methylene chloride exposures during paint and coating removal present unreasonable risks.

The SBAR Panel convened in support of this action heard from several SERs who expressed concerns about the underlying methylene chloride risk assessment (Ref. 27). Many of the concerns expressed by these SERs were already expressed in the public comments and the peer review

comments on the methylene chloride risk assessment. The Summary of External Peer Review and Public Comments and Disposition document in the risk assessment docket (EPA-HQ-OPPT-2012-0725) explains how EPA responded to the comments received.

2. *Initial analysis of potential regulatory options.* Having determined that the risks from methylene chloride in paint and coating removal were unreasonable, EPA evaluated whether regulatory options under section 6(a) could reduce the risk (non-cancer and cancer) so that it is no longer unreasonable.

The results of EPA's assessment of consumer uses, exposures, and risks indicate that regulatory options for consumer uses such as reducing the concentration of methylene chloride or advising the use of respirators could not achieve the target MOE benchmarks for acute exposures (benchmark MOE is 10). Similarly, the results of EPA's evaluation indicate that regulatory options for occupational exposures such as reducing the concentration of methylene chloride in products used for paint and coating removal and using local exhaust ventilation to improve ventilation, in the absence of PPE, could not achieve the target MOE benchmarks (benchmark MOE is 10) for non-cancer endpoints for acute and chronic exposures and common cancer risk benchmarks for chronic exposures (Refs. 19 and 20). The results also demonstrate that all risk reduction options meeting the benchmark MOEs and common cancer benchmarks for methylene chloride in paint and coating removal require the use of a respirator, whether used alone or in conjunction with additional levels of protection or the use of an air exposure limit. Therefore, EPA found the options of setting a maximum concentration of methylene chloride in products under TSCA section 6(a)(2) unable to reduce exposures to the risk benchmarks. Options found not to meet the risk benchmarks and, for the purposes of this proposal, found unable to address the unreasonable risk, are documented in EPA's supplemental technical reports on methylene chloride in paint and coating removal (Refs. 19 and 20).

3. *Assessment of whether regulatory options address the identified unreasonable risk so that methylene chloride in paint and coating removal no longer presents such risk.* As discussed earlier, EPA considered a number of regulatory options under TSCA section 6(a) for methylene chloride in paint and coating removal for the uses proposed for regulation. In assessing these options, EPA considered

a wide range of exposure scenarios (Refs. 19, 20, and 38). These include both baseline and risk reduction scenarios involving varying factors such as exposure concentration percentiles, LEV use, respirator use, working lifetimes, etc. As part of this analysis, EPA considered the impacts of regulatory options on consumer users and commercial users separately.

However, EPA is proposing to address paint and coating removal with methylene chloride for consumer uses together with many commercial uses, rather than as separate consumer and commercial uses. As described earlier, in Unit VI.B., paint and coating removal products containing methylene chloride frequently are available in the same distribution channels to consumers and professional users. Products are marketed for a variety of projects, and cannot be straightforwardly restricted to a single type of project or user. As highlighted in the investigation into recent deaths among bathtub refinishers using methylene chloride, "ten different products were associated with the 13 deaths [from 2000–2011]. Six of the products were marketed for use in the aircraft industry, the rest for use on wood, metal, glass, and masonry. None of the product labels mentioned bathtub refinishing" (Ref. 33).

The options that had the potential to address the unreasonable risks presented by methylene chloride when used for paint and coating removal by consumers, or within the commercial uses proposed for regulation, or for both consumer and these commercial uses included:

a. A supply-chain approach, which would include prohibiting the manufacturing (including import), processing, and distribution in commerce of methylene chloride for paint and coating removal under TSCA section 6(a)(2) for the consumer and commercial uses proposed for regulation; prohibiting the commercial use of methylene chloride in paint and coating removal under TSCA section 6(a)(5) for the commercial uses proposed for regulation; requiring that all paint and coating removers containing methylene chloride be distributed in volumes no less than 55-gallon containers under TSCA section 6(a)(2); requiring downstream notification when distributing methylene chloride under TSCA section 6(a)(3); and limited recordkeeping under TSCA section 6(a)(4);

b. Variations on such an approach, such as just prohibiting the manufacturing, processing, and distribution in commerce of methylene chloride for paint and coating removal

under TSCA section 6(a)(2) for consumer use and for the commercial uses proposed for regulation or just prohibiting the commercial use of methylene chloride for paint and coating removal under TSCA section 6(a)(5) for the commercial uses proposed for regulation;

c. Additional variations on such an approach, such as prohibiting the manufacturing, processing, and distribution in commerce of methylene chloride for paint and coating removal under TSCA section 6(a)(2) for the consumer and commercial uses proposed for regulation and requiring downstream notification (e.g., via a Safety Data Sheet (SDS)) when distributing methylene chloride for other uses under TSCA section 6(a)(3); and

d. Requiring a respiratory protection program, including PPE (a supplied-air respirator with APF 1,000 or 10,000) with an alternative air exposure limit of 1 part per million (ppm) achieved through engineering controls or ventilation alone or in combination with a supplied-air respirator at a lower APF, in commercial facilities where methylene chloride is used for paint and coating removal under TSCA section 6(a)(5) for the commercial uses proposed for regulation.

A discussion of the regulatory options that could potentially reach the risk benchmarks for consumer use, commercial uses proposed for regulation, or both is in this unit, along with EPA's evaluation of how well those regulatory options would address the unreasonable risks in practice.

a. *Proposed approach.* The proposed regulatory approach for methylene chloride in paint and coating removal for the uses proposed for regulation would prohibit the manufacturing, processing, and distribution in commerce of methylene chloride for paint and coating removal under TSCA section 6(a)(2) for consumer uses and for the commercial uses proposed for regulation; would prohibit the commercial use of methylene chloride for paint and coating removal under TSCA section 6(a)(5) for the uses proposed for regulation; would require any remaining paint and coating removal products containing methylene chloride to be distributed in packaged volumes no less than 55-gallon containers, under TSCA section 6(a)(2); would require manufacturers, processors, and distributors to provide downstream notification of the prohibitions under TSCA section 6(a)(3), and would require recordkeeping relevant to these

prohibitions under TSCA section 6(a)(4).

As discussed in Unit VI.C.1., the risks for exposure to consumers, workers, and bystanders for methylene chloride in paint and coating removal vary. The MOEs for non-cancer endpoints range from 50 to 1,000 times below the benchmark MOEs for central nervous system effects (the acute health impact) or liver toxicity (the chronic health impact). Similarly, the increased risk of cancer (including brain, liver, and lung cancer) in some industries is 100 to nearly 1,000 times greater than common cancer benchmarks (Ref. 2). Under this proposed option, exposures to methylene chloride during paint and coating removal would be completely eliminated. As a result, non-cancer and cancer risks would be eliminated.

The proposed approach would reduce the risks to workers, consumers, and bystanders from methylene chloride in paint and coating removal for the uses proposed for regulation so that those risks are no longer unreasonable. Prohibiting the manufacturing, processing and distribution in commerce of methylene chloride for paint and coating removal for the uses proposed for regulation would minimize the overall availability of methylene chloride for paint and coating removal for these uses. Importantly, this proposed regulation is protective of consumer users. EPA cannot regulate consumer use under TSCA section 6(a)(5). The prohibition of the commercial use of methylene chloride for paint and coating removal in the uses proposed for regulation would reduce commercial demand for methylene chloride paint and coating removal products, reduce the likelihood that other types of products formulated with methylene chloride would be used for paint and coating removal, and significantly reduce the potential for consumer use of commercial paint and coating removal products containing methylene chloride. Workers and occupational bystanders would not be exposed to methylene chloride for paint and coating removal in the uses proposed for regulation, and the risk to consumers and residential bystanders would be minimized because commercial paint and coating removal products containing methylene chloride would not be available in volumes smaller than 55-gallon containers. This large volume requirement would ensure that consumers, who typically buy products in much smaller volumes, would not be able to easily divert products from the supply chain intended for commercial furniture refinishing or uses proposed to be

critical to national security. EPA seeks comment on the impact to commercial furniture refinishers of a requirement that paint and coating removal products containing methylene chloride be sold only in 55-gallon containers for commercial paint and coating removal. This request for comment is one of the recommendations of the SBAR Panel, described earlier in Unit V.C. and in more detail in Unit XXIII.C. (Ref. 27). Based on the recommendations from the SBAR Panel, EPA is requesting comment on whether the rule should allow paint and coating removal products containing methylene chloride to be sold in 30-gallon containers, rather than limiting the volume to 55-gallon containers. EPA is also requesting comment on the feasibility of implementing appropriate industrial hygiene controls associated with 30- or 55-gallon containers in order to minimize potential disruptive impacts to those industrial processes where technically feasible substitutes are currently unavailable. The downstream notification of these restrictions ensures that processors and distributors are aware of the manufacturing, processing, distribution in commerce and use restrictions for methylene chloride in paint and coating removal, and enhances the likelihood that the risks associated with this use of methylene chloride are addressed throughout the supply chain. Downstream notification also streamlines compliance and enhances enforcement, since compliance is improved when rules are clearly and simply communicated (Ref. 39). This integrated supply chain proposed approach mitigates the risk to consumers and commercial workers and occupational bystanders in the uses proposed for regulation from methylene chloride in paint and coating removal.

b. Options that are variations of elements of the proposed approach. One variation of the proposed approach would be to prohibit manufacture, processing, and distribution in commerce of methylene chloride for consumer and commercial paint removal for the uses proposed for regulation without the prohibition on commercial use of methylene chloride for paint and coating removal and without the downstream notification of any prohibitions. Without the accompanying prohibition on commercial use and downstream notification that is included in the proposed supply chain approach, this option would leave open the likelihood that commercial users falling within the scope of this proposed rule and consumer users could obtain methylene

chloride (which would continue to be available for other uses, such as degreasing or solvent purposes) and use it for paint and coating removal.

Without downstream notification, unsophisticated purchasers in particular are likely to be unfamiliar with the prohibitions regarding this use and mistakenly use methylene chloride for paint and coating removal, thereby exposing themselves and bystanders to unreasonable risks. Thus, under these variations, EPA anticipates that many users would not actually realize the risk benchmarks. Therefore, these variations fail to protect against the unreasonable risks.

Another regulatory option that EPA considered was to prohibit only the commercial use of methylene chloride for paint and coating removal in the uses proposed for regulation. This approach would reduce both non-cancer and cancer risks for commercial settings, but it would not reduce risks to consumers so that they are no longer unreasonable. By prohibiting use in the commercial sector alone, without a prohibition on the manufacture, processing, and distribution in commerce of paint and coating removal products containing methylene chloride for consumer and commercial use in the uses proposed for regulation, this approach would not address consumer risks as distributors of paint and coating removal products containing methylene chloride could continue to distribute to consumers methylene chloride marked as a paint and coating remover, including products labeled and marketed as “professional strength” or “commercial grade” products. Since it is foreseeable that consumers would continue to purchase products labeled and marketed in this fashion, and consumers would continue to be exposed far above the health benchmarks, they would not be protected from the unreasonable risks posed by methylene chloride.

c. Prohibit the manufacturing, processing, and distribution in commerce of methylene chloride for consumer paint and coating removal under TSCA section 6(a)(2) or prohibit the manufacturing, processing, and distribution in commerce of methylene chloride for consumer paint and coating removal under TSCA section 6(a)(2) and require downstream notification when distributing methylene chloride for other uses under TSCA section 6(a)(3). EPA considered prohibiting the manufacturing, processing, and distribution in commerce of methylene chloride for consumer paint and coating removal including an option with a requirement for downstream

notification of such prohibition. If such a prohibition were effective, this option would mitigate the risks to consumers from methylene chloride in paint and coating removal. However, EPA recognizes that consumers can easily obtain products labeled for commercial use. Indeed, for many consumers, identifying a product as being for commercial use may imply greater efficacy. Coupled with the fact that many products identified as commercial or professional are readily obtainable in a variety of venues (e.g., the Internet, general retailers, and specialty stores, such as automotive stores), EPA does not find that this option would protect consumers. In addition, this option alone would not address the risks to workers from methylene chloride in paint and coating removal.

d. Requiring a respiratory protection program, including PPE, air monitoring, and either a supplied-air respirator of APF 1,000 or 10,000 or an air exposure limit of 1 part per million (ppm) achieved through engineering controls or ventilation, in commercial facilities where methylene chloride is used for paint and coating removal under TSCA section 6(a)(5) for the commercial uses proposed for regulation. Another regulatory option that EPA considered for the commercial uses of methylene chloride for paint and coating removal proposed for regulation was to require risk reduction through an occupational respiratory protection program, which would include air monitoring, medical monitoring, and respiratory protection through use of a supplied-air respirator with an APF of 1,000 or 10,000, depending on the methods used for paint and coating removal with methylene chloride and other workplace characteristics, with a performance-based alternative of meeting an air concentration level of 1 ppm as an exposure limit for methylene chloride. A full-facepiece (or helmet/hood) self-contained breathing apparatus (SCBA) when used in the pressure demand mode or other positive pressure mode has an APF of 10,000. EPA's analysis showed that use of a SCBA with an APF of 10,000 would, in all scenarios evaluated, control the exposure of methylene chloride to levels that allow for meeting the benchmarks for non-cancer and cancer risks. Exposures in most workplaces proposed for regulation could be reduced with an APF of 1,000 to exposure levels that reduce risks to benchmark levels (Ref. 19). It is important to note that current OSHA requirements for dermal and eye protection when using methylene chloride in any way would be

maintained under this approach, in addition to other requirements for work practices, training, and hazard communication put forth in OSHA's Methylene Chloride Standard (29 CFR 1910.1052). It is also important to note that any respirator used would need to be a supplied-air respirator, since methylene chloride can clog or damage filters or cartridges for air-purifying respirators, rendering them non-protective (Ref. 19).

Although respirators, specifically SCBAs, could reduce exposures to levels that are protective of non-cancer and cancer risks, not all workers may be able to wear respirators. Individuals with impaired lung function due to asthma, emphysema, or chronic obstructive pulmonary disease, for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for tight fitting full-face piece respirators to provide the required protection. Individuals with facial hair, like beards or sideburns that interfere with a proper face-to-respirator seal, cannot wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue, and reduced work efficiency (63 FR 1152, January 8, 1998). According to OSHA, "improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health." (63 FR 1189–1190). Nonetheless, OSHA views respiratory protection as a backup method which is used to protect employees from toxic materials in those situations where feasible engineering controls and work practices are not available or are insufficient to protect employee health (63 FR 1156–1157). The OSHA respiratory protection standard (29 CFR 1910.134) requires employers to establish and implement a respiratory protection program to protect their respirator-wearing employees. This OSHA standard contains several requirements, e.g., for program administration; worksite-specific procedures; respirator selection; employee training; fit testing; medical evaluation; respirator use; respirator cleaning, maintenance, and repair; and other provisions.

In addition, OSHA adopted a hierarchy of controls established by the industrial hygiene community and used to protect employees from hazardous airborne contaminants, such as methylene chloride (29 CFR 1910.1052).

According to this hierarchy, substitution of less toxic substances, engineering controls, administrative controls, and work practice controls are the preferred method of compliance for protecting employees from airborne contaminants and are to be implemented first, before respiratory protection is used. OSHA permits respirators to be used where engineering controls are not feasible or during an interim period while such controls are being implemented.

Given equipment costs and the costs of establishing a respiratory protection program, which involves training, respirator fit testing, and the establishment of a medical monitoring program, EPA anticipates that most companies would choose to switch to substitutes instead of adopting a program for this type of PPE to continue using methylene chloride for paint and coating removal because this type of PPE program is not cost-effective. Further, even if cost were not an impediment, there are many limitations to the successful implementation of respirators with an APF of 1,000 or 10,000 in a workplace. As recommended by the SBAR panel, EPA is requesting comment on and information about workplace experience with respiratory protection programs and air monitoring for methylene chloride (Ref. 27). Specifically, EPA seeks comment on whether companies would opt to substitute an alternate chemical or process instead of implementing a worker protection program for PPE. EPA also requests comment on the scientific and technical support used for development of the 1 ppm air exposure limit (Ref. 21) for methylene chloride and the feasibility of implementing and enforcing this performance-based approach. Additionally, EPA is requesting comment on the cost to achieve reduced exposures in the workplace or to transition to alternative chemicals or technologies.

EPA also considered requiring a combination of local exhaust ventilation and supplied-air respirators with APF of 1,000 or 50, with a performance-based alternative to the respirator of an air exposure limit of 1 ppm as an eight-hour TWA. When properly executed, this option would reduce risks to the health benchmarks for workers and bystanders (Refs. 19, 21, and 38). However, while this option has the benefit of incorporating engineering controls and the use of respirators with a lower APF, the limitations to successful implementation of the use of supplied-air respirators in the workplace discussed previously are still present. EPA is requesting comment on

whether this alternate option of allowing industrial use at specified exposure levels and with appropriate personal protective equipment should be adopted. Specifically, EPA seeks information on whether this alternative approach would incentivize industry to eliminate methylene chloride use in paint and coating removal wherever technically feasible while minimizing disruptive impacts to those processes where technically feasible substitutes are currently unavailable.

Furthermore, neither of the variations of relying upon respiratory protection for commercial paint and coating removal with methylene chloride addresses consumer risks. EPA does not have the authority to require that consumers change use practices or wear PPE. Even if this approach were coupled with a TSCA section 6(a)(2) prohibition on the manufacture, processing and distribution in commerce of methylene chloride for consumer use in paint and coating removal, this would not protect consumers because they would foreseeably continue to buy and use paint and coating removal products containing methylene chloride intended for commercial users, e.g., via the Internet or home improvement or automotive supply retailers. Consumers would continue to be exposed far above the established health benchmarks when using methylene chloride for paint and coating removal (Ref. 20).

Therefore, considering the increased complexity of a respiratory protection program involving supplied-air respirators as well as the general inability to require that consumers adhere to a respiratory protection program resulting in little mitigation of risks to consumers, an option focusing on respiratory protection would not address the unreasonable risks presented by these uses.

D. Adverse Health Effects and Related Impacts That Would Be Prevented by the Proposed Option

The proposed option would prevent exposure to methylene chloride from paint and coating removal and thus would prevent the risks of adverse effects and associated impacts. As discussed in Unit II.C., the range of adverse health effects includes effects on the nervous system, liver, respiratory system, kidneys, and reproductive systems (Ref. 2). These health effects associated with exposure to methylene chloride are serious and can have impacts throughout a lifetime. The following is a discussion of the impacts of significant acute, chronic non-cancer, and cancer effects associated with methylene chloride exposure during

paint and coating removal, including the severity of the effect, the manifestation of the effect, and how the effect impacts a person during their lifetime.

1. Nervous system effects—acute exposures. The methylene chloride risk assessment and EPA's 2011 IRIS assessment identified nervous system effects as the critical effect of greatest concern for acute exposure to methylene chloride. Specifically, these assessments identified sensory impairment and incapacitation (loss of consciousness) as the critical effect of acute exposures (Refs. 2 and 5). Exposure to methylene chloride can rapidly cause death as a result of nervous system depression, but even exposures that may in some cases result only in dizziness or fainting can be fatal if the individual who is disoriented or has fainted is alone. Several individuals have died after becoming incapacitated during paint and coating removal with methylene chloride; after losing consciousness, their nervous system is overcome by the continued accumulation of volatile fumes. As described in a recent report on deaths caused by methylene chloride, “. . . the danger posed by methylene chloride is its one-two punch when fumes accumulate. Because it turns into carbon monoxide in the body, it can starve the heart of oxygen and prompt an attack. The chemical also acts as an anesthetic at high doses: Its victims slump over, no longer breathing, because the respiratory centers of their brains switch off.” (Ref. 7).

There are increased risks of death and nervous system effects for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated, as well as for the estimated 1.3 million consumers and residential bystanders who use or are exposed to paint and coating removers containing methylene chloride each year (Ref. 4).

Although the fact that deaths occur as a result of exposure to methylene chloride is well documented, the exact number of deaths specifically attributable to methylene exposure is unclear. In 2012, the Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report (MMWR) published results of an investigation into deaths among bathtub refinishers using methylene chloride. The authors of the investigation and the MMWR editors emphasized that the reported number of deaths due to methylene chloride is an underestimate and subject to at least three limitations: A lack of reporting to the OSHA incident database

by self-employed individuals, no equivalent database to track consumer incidents and fatalities, and the likelihood that deaths due to methylene chloride exposures are misattributed to heart disease, since the pathology is similar (Ref. 33).

Based on data from OSHA, CPSC, state records, and publicly reported information, EPA has identified 49 fatalities since 1976 resulting from consumer or commercial worker exposure to methylene chloride during paint and coating removal, including for uses not proposed for regulation. However, as described earlier, this is likely an underestimate of the deaths that have occurred. As highlighted in the MMWR report from 2012 and OSHA alert from 2016, health effects from methylene chloride exposure are often misattributed to other causes (Refs. 32 and 33). For example, in several cases, workers were seen in hospital emergency rooms with symptoms of solvent exposure, were not properly diagnosed, and were sent back to the same work that ultimately killed them (Ref. 32).

Thus, EPA is unable to quantify the precise number or frequency of deaths that occur as a result of exposure to methylene chloride during paint and coating removal. However, the sporadically-occurring deaths outside of bathtub refinishing that have been documented as caused by methylene chloride, and the undocumented deaths that have been misattributed to heart disease should not be ignored merely because they cannot be monetized. Death following exposure to methylene chloride during paint and coating removal are characterized by family members as suddenly tragic, particularly when the deceased is young. In 1986 in Colorado, a worker died two hours into his first day on the job using methylene chloride to remove coatings from furniture (Ref. 40). In 2014 in New York, a 20-year old worker died while helping his father with a job refinishing a hotel bathtub (Ref. 41).

Fatalities have also occurred among more experienced workers. In 1990 in Georgia, a worker died while repairing a plastic-coated metal rack; he was found to have fainted and fallen into the tank of methylene chloride the company used to strip rack coatings (Ref. 7). In several instances, pairs of workers were killed while working on the same paint removal project with methylene chloride, such as renovating a squash court or the floor tile of a bathroom in a federal office building (Ref. 40).

In other cases, workers died when helping co-workers in distress. In South Carolina, in 1986, several workers were

killed or hospitalized in one incident: Two workers went to check on a colleague in a basement using a paint remover with methylene chloride; all three died. Five emergency responders arrived at the scene, and three were hospitalized due to inhalation of fumes (Ref. 7).

These sudden, unexpected deaths are not limited to commercial users or occupational bystanders exposed to methylene chloride during paint and coating removal. Consumer fatalities have been recorded, such as the woman who died in her house in 1990 in Ohio after removing paint from furniture with methylene chloride, as reported to the American Association of Poison Control Centers (Ref. 7). Consistent with the underreporting of commercial deaths, EPA estimates there are unreported consumer deaths due to exposure to methylene chloride during paint and coating removal.

These deaths clearly have a significant impact on families, workplaces, and communities, and yet not all of them can be monetized. Similarly, the serious health effects and lifetime impacts on workers who do not die but who are hospitalized with heart failure, coma, or other effects also cannot be quantified or monetized. However, the impacts of these effects should not be ignored. One example is a case in 2012 in California, where one man attempted to save a co-worker who had collapsed while cleaning a paint-mixing tank. The collapsed worker died, and the man attempting to rescue him was incapacitated within several seconds and lost consciousness. Though he survived, he required resuscitation, hospitalization for four days, and lengthy follow-up treatments (Ref. 7). The impacts on workers with severe but non-fatal nervous system impacts include monetary, personal health, and emotional suffering costs that cannot be quantified or monetized, but again, should not be ignored. These severe nervous system impacts can include coma and heart failure (Ref. 2).

Even when less severe, the nervous system effects of acute exposure to methylene chloride can have considerable adverse consequences on an individual, particularly if one is exposed as a bystander who is unaware of why these nervous system effects are occurring. Commercial and consumer users as well as bystanders in workplaces and residences are at risk of dizziness and sensory impairment during most uses of methylene chloride for paint and coating removal. Similarly, chronic exposure to methylene chloride presents risks to the nervous system of commercial users, consumer users, and

bystanders exposed to methylene chloride in paint and coating removal.

2. Nervous system effects—chronic exposures. The methylene chloride risk assessment identified nervous system effects as adverse effects of chronic exposure to methylene chloride exposure in paint and coating removal. There are increased health risks for nervous system effects for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated (Ref. 4).

Chronic exposures in occupational settings put users and bystanders at risk of cognitive impairment (affecting eye-hand coordination, tracking tasks, auditory vigilance); adverse effects on autonomic, neuromuscular, and sensorimotor functions (Ref. 2); and long-term effects on specific cognitive-neurological measures (*i.e.*, attention and reaction time) (Ref. 5).

3. Liver toxicity. The methylene chloride risk assessment identified liver toxicity and liver cancer as adverse effects of chronic exposure to methylene chloride exposure in paint and coating removal. There are increased health risks for liver toxicity and liver cancer for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated (Ref. 4).

Specific effects to the liver include hepatic vacuolation and non-alcoholic fatty liver disease (NAFLD) (Ref. 2). Some form of liver disease impacts at least 30 million people, or 1 in 10 Americans. Included in this number is at least 20% of those with NAFLD. NAFLD tends to impact people who are overweight/obese or have diabetes. However, an estimated 25% do not have any risk factors. The danger of NAFLD is that it can cause the liver to swell, which may result in cirrhosis over time and could even lead to liver cancer or failure (Ref. 42). The most common known causes to this disease burden are attributable to alcoholism and viral infections, such as hepatitis A, B, and C. These known environmental risk factors of hepatitis infection may result in increased susceptibility of individuals exposed to organic chemicals such as methylene chloride.

Chronic exposure to methylene chloride can also lead to liver cancers including hepatocellular carcinomas (HCC), hepatocellular adenomas, and biliary tract cancer (Ref. 2). The monetizable benefits associated with reducing the risk of liver cancers associated with methylene chloride

exposure are discussed in Unit VII.B. However, the impacts of these cancers should not be measured only as dollar valuations. For example, because HCC is frequently diagnosed only after an individual's health has deteriorated, survival is usually measured in months. As a result, "HCC is responsible for a large proportion of cancer deaths worldwide . . . HCC classically arises and grows in silent fashion, making its discovery challenging prior to the development of later stage disease" (Ref. 43). Recommended treatments are aggressive interventions such as the removal of the tumors or sections of the liver; the life expectancy of patients with HCC is a mean survival rate of 6 to 20 months. Advanced cases can metastasize to any organ system, and tends to spread to bones and lungs. Bone pain related to metastasis is frequently the initial presenting symptom of HCC (Ref. 43).

Additional medical and emotional costs are associated with cancer and non-cancer liver toxicity following chronic exposure to methylene chloride in paint and coating removal, although these costs cannot be quantified. These costs include medical visits and medication costs. In some cases, the ability to work can be affected, which in turn impacts the ability to get proper medical care. Liver toxicity can lead to jaundice, weakness, fatigue, weight loss, nausea, vomiting, abdominal pain, impaired metabolism, and liver disease.

Depending upon the severity of the jaundice, treatments can range significantly. Simple treatment may involve avoiding exposure to methylene chloride and other solvents; however, this may impact an individual's ability to continue to work. In severe cases, liver toxicity can lead to liver failure, which can result in the need for a liver transplant. Even if a donor is available, liver transplantation is expensive (with an estimated cost of \$575,000) and there are countervailing risks for this type of treatment (Ref. 44). The mental and emotional toll on an individual and their family as they try to identify the cause of sickness and possibly experience an inability to work, as well as the potential monetary cost of medical treatment required to regain health, are significant.

4. Hematopoietic cancers. EPA's 2011 IRIS assessment for methylene chloride found that it is a likely human carcinogen. Chronic inhalation exposure to methylene chloride such as during paint and coating removal has been shown to result in increased risk for non-Hodgkin's lymphoma (NHL) or multiple myeloma in workers (Ref. 5). There are increased risks for NHL or

multiple myeloma for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated (Ref. 4).

NHL is a form of cancer that originates in the lymphatic system. Approximately 19 new cases per 100,000 adults per year are diagnosed, with approximately 6.2 deaths per 100,000 adults annually (Ref. 45). NHL is the seventh most common form of cancer (Ref. 46). Other factors that may increase the risk of NHL are medications that suppress a person's immune system, infection with certain viruses and bacteria, or older age (Ref. 47).

Symptoms of NHL are swollen lymph nodes in the neck, armpits or groin, abdominal pain or swelling, chest pain, coughing or trouble breathing, fatigue, fever, night sweats, and weight loss. Depending on the rate at which the NHL advances, treatment may consist of monitoring, chemotherapy, radiation, stem cell transplant, medications that enhance the immune system's ability to fight cancer, or medications that deliver radiation directly to cancer cells (Ref. 47).

Multiple myeloma is a related hematopoietic cancer, formed by malignant plasma cells. Multiple myeloma is characterized by low blood counts, bone and calcium problems, infections, kidney problems, light chain amyloidosis, and various forms of abnormal plasma cell growth. Often, multiple myeloma has no clinical symptoms until it reaches an advanced stage (Ref. 48).

Treatments for NHL or multiple myeloma result in substantial costs for hospital and doctors' visits in order to treat the cancer. Treatments for NHL or multiple myeloma can also have countervailing risks and can lead to patients' higher susceptibility for secondary malignancies (Refs. 47 and 48). The emotional and mental toll from wondering whether a treatment will be successful, going through the actual treatment, and inability to do normal activities, or work will most likely be high (Ref. 49). This emotional and mental toll could extend to the person's family and friends as they struggle with the diagnosis and success and failure of a treatment regime.

5. Brain cancer. EPA's 2011 IRIS assessment for methylene chloride found that it is a likely human carcinogen. Chronic inhalation exposure to methylene chloride has been shown to result in brain cancer (Ref. 5). There are increased risks for brain cancer for many of the approximately 17,600 workers in 8,600 commercial facilities

or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated (Ref. 4).

Researchers at the National Cancer Institute found that "associations of astrocytic brain cancer were observed with likely exposure to carbon tetrachloride, methylene chloride, trichloroethylene, and were strongest for methylene chloride. . . . Risk of astrocytic brain tumors increased with probability and average intensity of exposure, and with duration of employment in jobs considered exposed to methylene chloride. . . . These trends could not be explained by exposures to the other solvents" (Ref. 50).

Cancers that originate in the brain, which include astrocytic brain cancers, are relatively rare. Astrocytic brain cancers are estimated to have an incidence of approximately 10 cases per 1 million people per year, depending on how these types of cancers are defined (Ref. 51). Astrocytic tumors are characterized by varying degrees of growth potential and infiltration into nearby tissues. They include tumors that can spread quickly through the brain stem (brain stem gliomas); affect the pineal gland, which controls the sleeping and waking cycle (pineal astrocytic tumors); grow slowly and can be relatively easily cured (pilocytic astrocytoma); grow slowly but often spread into nearby tissues (diffuse astrocytoma); grow quickly and spread into nearby tissues (anaplastic astrocytoma); and grow quickly, spread quickly into nearby tissues, and usually cannot be cured (glioblastoma) (Ref. 51).

For astrocytic brain cancers, like other primary malignant brain tumors, initial clinical symptoms are frequently headaches and seizures. Lower-grade tumors may persist undetected for years, whereas the faster-growing or faster-spreading tumors may rapidly provoke neurological decline. Other symptoms may include nausea, vomiting, headache, and confusion as a result of increased intracranial pressure (Ref. 51).

Treatment for astrocytic brain cancers varies by the type and stage of the tumor; it can include pharmacological treatment (for many patients, this includes steroids and anti-convulsants if they are experiencing seizures), surgery (depending on location of the tumor, they may be removed or separated from the brain), chemotherapy, hormone modulation, or combinations of these treatments (Ref. 51). Like most cancer treatments, these can have countervailing risks. Additionally, the emotional and mental tolls described in

earlier sections are relevant to these cancer treatments as well (Ref. 49).

6. Lung cancer. EPA's 2011 IRIS assessment for methylene chloride found that it is a likely human carcinogen. Chronic inhalation exposure to methylene chloride has been shown to result in bronchoalveolar carcinomas (BAC) or bronchoalveolar adenomas, which are forms of lung cancer (Ref. 5). There are increased risks for these lung cancers for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated (Ref. 4).

BAC is a small percent of lung cancers (between 2% to 4%) and has unique characteristics. It is notable for its weak relationship with cigarette smoking; about one-third of patients in the United States with BAC were never smokers. Additionally, because it rarely spreads outside the lungs, it is often initially diagnosed as pneumonia or other lung inflammations (Ref. 52). Most patients do not present clinical symptoms (Ref. 52) and are only diagnosed following radiography or biopsy. Treatment requires surgery (Ref. 52). This has clear countervailing risks, and even if successful in removing any tumors present, the BAC may return.

7. Mammary tumors. Exposure to methylene has been shown to result in significant increases in the incidence of adenomas, fibroadenomas, or fibromas in or near the mammary gland (Refs. 2 and 5). These are largely benign tumors (Ref. 2). Though many benign tumors do not require invasive procedures, doctors recommend removing fibroadenomas. Patients need to undergo a biopsy to identify the carcinogenic risk of the tumor, and have the tumors removed if they continue to grow, change the shape of the breast, or are carcinogenic (Ref. 53). If removal is necessary, the procedure may also require the removal of nearby healthy mammary tissue, resulting in scarring and changed shape and texture of the breast (Ref. 53). Women with fibroadenomas and adenomas also have an increased risk of breast cancer, estimated to be approximately 1.5 to 2.0 times the risk of women with no breast changes (Ref. 54).

8. Reproductive effects. EPA's 2011 IRIS assessment for methylene chloride found that exposure can have reproductive effects that include testicular and ovarian atrophy (Ref. 5). At very high exposures, chronic inhalation of methylene chloride during paint and coating removal can result in these reproductive effects, which are related to decreased fertility (Ref. 55).

There are increased risks for these reproductive effects for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated (Ref. 4). Similar to effects discussed previously, while neither the precise reduction in individual risk of developing this disorder from reducing exposure to methylene chloride or the total number of cases avoided can be estimated, EPA still considers their impact.

9. *Kidney toxicity.* EPA's 2011 IRIS assessment for methylene chloride identified kidney effects from exposure to methylene chloride; these effects include renal tubular degeneration (Ref. 5). At very high exposures, chronic inhalation exposure to methylene chloride during paint and coating removal can result in kidney toxicity. There are increased risks for these kidney effects for many of the approximately 17,600 workers in 8,600 commercial facilities or companies that use methylene chloride for paint and coating removal for the commercial uses proposed to be regulated (Ref. 4).

Exposure to methylene chloride can lead to changes in the proximal tubules of the kidney. This damage may result in signs and symptoms of acute kidney failure that include; decreased urine output, although occasionally urine output remains normal; fluid retention, causing swelling in the legs, ankles or feet; drowsiness; shortness of breath; fatigue; confusion; nausea; seizures or coma in severe cases; and chest pain or pressure. Sometimes acute kidney failure causes no signs or symptoms and is detected through lab tests done for another reason.

Kidney toxicity means the kidney has suffered damage that can result in a person being unable to rid their body of excess urine and wastes. In extreme cases where the kidney is impaired over a long period of time, the kidney could be damaged to the point that it no longer functions. When a kidney no longer functions, a person needs dialysis and ideally a kidney transplant. In some cases, a non-functioning kidney can result in death. Kidney dialysis and kidney transplantation are expensive and incur long-term health costs if kidney function fails (Ref. 56).

The monetary cost of kidney toxicity varies depending on the severity of the damage to the kidney. In less severe cases, doctor visits may be limited and hospital stays unnecessary. In more severe cases, a person may need serious medical interventions, such as dialysis or a kidney transplant if a donor is available, which can result in high

medical expenses due to numerous hospital and doctor visits for regular dialysis and surgery if a transplant occurs. The costs for hemodialysis, as charged by hospitals, can be upwards of \$100,000 per month (Ref. 57).

Depending on the severity of the kidney damage, kidney disease can impact a person's ability to work and live a normal life, which in turn takes a mental and emotional toll on the patient. In less severe cases, the impact on a person's quality of life may be limited while in instances where kidney damage is severe, a person's quality of life and ability to work would be affected. While neither the precise reduction in individual risk of developing kidney toxicity from reducing exposure to methylene chloride during paint or coating removal or the total number of cases avoided can be estimated, these costs must still be considered because they can significantly impact those exposed to methylene chloride.

10. *Disproportionate impacts on environmental justice communities.* An additional factor that cannot be monetized is the disproportionate impact on environmental justice communities. As described in Unit VI.C.1.b., Hispanic and foreign-born workers, who may have limited English proficiency, are disproportionately over-represented in construction trades (Ref. 4), in which methylene chloride is used for paint and coating removal. Because they are disproportionately over-represented in this industry, these populations are disproportionately exposed to methylene chloride during paint and coating removal, and are disproportionately at risk to the range of adverse health effects described in this unit.

E. Availability of Alternatives

For almost every situation in which methylene chloride is used to remove paints or coatings, EPA is aware of technically and economically feasible chemical substitutes or alternative methods that are reasonably available. The two situations for which EPA does not know of technically and economically feasible alternatives are the uses that EPA proposes are critical for national security, described in more detail in Unit VIII., and commercial furniture refinishing, discussed in more depth in Unit XI. With respect to the specific coating removal uses that EPA proposes are critical for national security, described in Unit VIII., EPA does not believe that technically and economically feasible alternatives are reasonably available at this time. With respect to the furniture refinishing uses

described in Unit XI., EPA is still investigating whether economically feasible alternatives are reasonably available.

EPA considered chemical substitutes and alternative methods consistent with the requirements of TSCA section 6(c)(2)(C) and as similarly recommended by the SBAR panel (Ref. 27). A full industry profile characterizing manufacturers, processors and end users of methylene chloride for paint and coating removal and a use and substitutes analysis are included in sections 2 and 3 of EPA's economic assessment (Ref. 4). As described below, EPA proposes that alternatives are technologically feasible, economically feasible, reasonably available, and present fewer hazards to human health than methylene chloride in paint and coating removal. EPA requests comment on whether its conclusion that substitutes for methylene chloride identified are available and technically and economically feasible is accurate and whether its consideration of alternatives was sufficient to satisfy the requirements of TSCA section 6(c)(2)(C).

Research into the efficacy of chemical substitutes has identified products currently available for commercial and consumer users of methylene chloride for paint and coating removal, for a variety of coatings on numerous substrates (Refs. 58 and 59). Research by the European Association for Safer Coating Removal in 2006 found that for every use that was studied of methylene chloride in paint and coating removal, there was a suitable substitute (Ref. 60). Other non-chemical methods of paint removal are also available (Ref. 31). Additionally, in most commercial sectors, users have voluntarily adopted substitute chemicals or methods, either due to financial considerations, customer requests, concern for worker or individual health and safety, decreased discharges to air and water, reduced clean-up costs, or reduced cost of protective equipment and respiratory protection programs (Ref. 22).

Many producers of paint and coating removal products containing methylene chloride also produce paint and coating removal products with substitute chemicals (Ref. 4). This was emphasized by a small business who makes such products (Ref. 22); other small businesses separately described the limitations of many alternatives (Ref. 27). Thus, there is already precedent for producers reformulating products to meet demand from commercial or individual customers. Additionally, methylene chloride is prohibited from use in graffiti removal in California,

Connecticut, Delaware, the District of Columbia, Illinois, Indiana, Maine, Maryland, Massachusetts, Michigan, New York, and Rhode Island (Ref. 12). The fact that 11 states and the District of Columbia have specifically prohibited the use of methylene chloride in graffiti removal supports a finding that it is not critical for this use and that there are efficacious substitutes.

Based on the frequent use of substitute chemicals or alternative methods for paint and coating removal in all industries discussed here, and the formulation and distribution of substitute chemicals for paint and coating removal by all formulators of products containing methylene chloride (Ref. 4), EPA finds that technically and economically feasible alternatives to methylene chloride are reasonably available for all uses proposed for regulation.

Primary chemical substitutes for methylene chloride in paint and coating removal include products formulated with benzyl alcohol; dibasic esters; acetone, toluene, and methanol (collectively ATM); and caustic chemicals. EPA evaluated these products for efficacy, toxicity, relative hazards compared to methylene chloride, and other hazards that might be introduced by use of these products (such as environmental toxicity, increased global warming potential, and increased flammability or other hazards to users). Overall, while the efficacies of the substitutes are comparable to the efficacy of methylene chloride, none of the substitute chemicals already available has the level of toxicity associated with methylene chloride.

Products based on benzyl alcohol formulations have been identified as efficacious paint and coating removers in various industry sectors (Refs. 22 and 27). Consumer products containing benzyl alcohol are available for sale (Refs. 22, 27, 35, 58, 59, and 61). There are fewer hazard concerns compared to methylene chloride-based products, and the levels at which benzyl alcohol causes toxicity are higher than for methylene chloride, suggesting lower toxicity (Ref. 34). The relative inhalation exposure potential is lower for benzyl alcohol than for methylene chloride. The relative dermal exposure potential of benzyl alcohol is similar to methylene chloride (Ref. 34). Benzyl alcohol-based paint removers are expected to result in lower risks than methylene chloride products, primarily due to lower toxicity (Ref. 29).

Dibasic ester products can include dimethyl succinate, dimethyl glutarate and dimethyl adipate. They are

generally viewed as efficacious products by commercial users in several sectors, though, because they evaporate slowly, they require a longer dwell time than methylene chloride (Ref. 22, 27). In general, the hazards associated with dibasic esters are less severe and occur at concentrations higher than methylene chloride (Ref. 34). Regarding differential exposures between dibasic esters and methylene chloride, the relative inhalation exposure potential is lower for dibasic esters than for methylene chloride (Ref. 34). The relative dermal exposure potentials of dibasic esters are similar to methylene chloride. Taken together, dibasic ester-based paint removers are expected to result in lower risks than methylene chloride products, primarily due to lower toxicity (Ref. 34).

ATM products contain acetone, toluene, and methanol. Products containing these chemicals may remove coatings very quickly, but may not be effective on every type of coating (Refs. 22 and 27). Acetone, toluene, and methanol evaporate quickly and are very flammable (Ref. 62). However, it is important to note that acetone, toluene, and/or methanol are present in most paint removers that contain methylene chloride, as co-solvents (Ref. 34). As a result, the main difference between paint removers that contain methylene chloride (and typically also contain acetone, toluene, and/or methanol) and ATM products is the absence of methylene chloride. Acetone is readily absorbed via inhalation and the relative inhalation exposure potential is similar to methylene chloride (Ref. 34). Acetone in particular is significantly less toxic than methylene chloride. Toluene and methanol are readily absorbed via inhalation, but the relative inhalation exposure potential is lower than for methylene chloride (Ref. 34). Dermal exposure to acetone, toluene and methanol is slightly less than for methylene chloride (Ref. 34). Taken together, ATM-based paint removers are expected to result in lower cancer risks (Ref. 36).

Products with caustic chemicals typically include calcium hydroxide or magnesium hydroxide. In many uses, they can be effective products, particularly when multiple coatings are being removed from a substrate. Caustic products have been reported to remove up to 30 coats in 24 hours, and in some cases, they have no increased dwell time compared to methylene chloride (Ref. 23). In contrast to methylene chloride-based products, there are no cancer or other repeat dose endpoints of concern associated with caustic products (Ref. 34). Caustic products pose acute concerns due to their

physical chemical properties and can cause chemical burns (Ref. 36). It is important to note that products containing methylene chloride may also cause chemical burns. Additionally, the risks associated with caustic-based products are entirely acute, and can be mitigated by appropriate protective equipment more easily than the acute and chronic risks presented by methylene chloride.

In summary, when NMP is excluded from consideration, the most likely chemical substitutes for methylene chloride in paint and coating removal do not pose a risk of cancer to users, generally have lower exposure potential than methylene chloride, and when acute risks are present, as in the case of caustic chemicals, those risks are self-limiting by the nature of the adverse effects (since a user experiencing those effects is likely to take immediate action to mitigate or cease the effect of the caustic chemical). The chemical formulations that seem to present some risks of concern are ATM products, since they contain toluene and methanol. However, these chemicals are also present in most paint removers that contain methylene chloride, as co-solvents. As a result, no additional risks would be introduced were users to substitute a typical methylene chloride product (which would likely contain acetone, toluene, and/or methanol as co-solvents) with ATM products.

In addition to examining toxicity to humans, EPA reviewed available data on the chemicals in the baseline and alternative products for aquatic toxicity, persistence and bioaccumulation data, as a basis for examining potential environmental toxicity. Only one chemical evaluated (citrus terpenes) may have significant impacts on aquatic toxicity, with concern for environmental persistence and/or bioaccumulation. This chemical is contained in NMP-based paint removal products (Ref. 34).

EPA is also mindful of the risks that may be introduced by substitute chemicals or methods to increase global warming, and has examined the global warming potential of the chemical components of likely chemical substitutes for methylene chloride in paint and coating removal. Methylene chloride presents concerns for global warming; it has a GWP of 8.7 (see Unit II.D.2.). The GWP values of likely substitute chemicals in paint and coating removal are: 0 GWP (benzyl alcohol, ATM) or not assessed (caustics, dibasic esters) (Ref. 23). As such, EPA has not identified any increased risk of global warming that would be introduced by use of chemical products

as substitutes for methylene chloride in paint and coating removal.

In addition to human and environmental toxicity, other hazards associated with chemical methods for paint and coating removal are risks of fire due to flammability of the chemical product, and poisoning or acute injury. Risks of fire are serious when using solvents such as paint and coating removal chemicals. The flammability of methylene chloride is lower than some of the substitute organic solvents. However, many paint and coating removal products containing methylene chloride also contain more flammable chemicals as part of the formulation (Ref. 34). Paint and coating removal products sold to consumers that contain methylene chloride frequently have flammability warnings prominently on them (Ref. 35). Other chemical paint and coating removal products, such as those based on benzyl alcohol and dibasic esters, have low flammability and do not present an increased risk of fire from products containing methylene chloride (Ref. 23). Even among products that fall within the same general product composition category, there is meaningful variability in the specific formulations of paint remover products, and thus in their flammability. Furthermore, it is impracticable for EPA to predict the specific product formulations for which use will increase as a result of prohibitions on methylene chloride in paint and coating removal. It is therefore impracticable for EPA to forecast whether the flammability of popular paint and coating removers would generally increase or decrease as a result of the proposed rule.

In addition to using substitute chemical products, non-chemical methods for paint and coating removal are frequently used. These include thermal removal, sanding, hydroblasting, abrasive blasting, and laser removal (Refs. 22 and 31). Acute and chronic physical hazards (e.g., burns, injuries to bodily parts) to workers and consumers can occur, in addition to any lead-related risks that should be considered when using these methods with lead-based paint.

In this overview, when considering alternatives to methylene chloride that would be available, NMP generally was not considered because, under the first co-proposed option for NMP in this proposed rule, this chemical would also be prohibited from use in paint and coating removal. However, under the second co-proposed approach for reducing the risks of NMP in paint and coating removal, products containing NMP would be available for commercial and consumer paint and coating

removal, with restrictions. Details of the two co-proposed options are in Unit XVI.3. EPA identified developmental risks following acute exposures for consumers and acute and chronic exposures for commercial users of paint and coating removal products containing NMP following exposure through dermal contact, inhalation, and vapor-through-skin. More information on the risks EPA identified related to NMP are in Unit XVI.B.1.

F. Impacts of the Proposed and Alternative Regulatory Options

This unit describes the estimated costs of the proposed and alternative regulatory actions that EPA considered for methylene chloride in paint and coating removal. More information on the benefits and costs of this proposal as a whole can be found in Unit XXIII.

1. Proposed approach for methylene chloride in paint and coating removal. The costs of the proposed approach are estimated to include product reformulation costs, downstream notification costs, recordkeeping costs, and Agency costs. The costs of paint and coating removal product reformulations are estimated to be approximately \$10,000 to \$20,000 per year (annualized at 3% over 20 years) and \$14,000 to \$24,000 (annualized at 7% over 20 years). The cost for reformulation includes a variety of factors such as identifying the appropriate substitute chemical for methylene chloride in the formulation, assessing the efficacy of the new formulation and determining shelf-life. Under the first co-proposed approach for NMP, where the manufacturing, processing, distribution, and commercial use of paint and coating removal products containing NMP would be prohibited, the costs to users of paint and coating removers containing methylene chloride are \$4,217,000 to \$23,436,000 using a 3% discount rate and \$4,592,000 to \$23,485,000 at the 7% discount rate (both rates annualized over 20 years). The costs of downstream notification and recordkeeping on an annualized basis over 20 years are \$40 and \$60 using 3% and 7% discount rates respectively (Ref. 4). Agency costs for enforcement are estimated to be approximately \$114,401 and \$111,718 annualized over 20 years at 3% and 7%, respectively. The total cost of the proposed approach for paint and coating removers containing methylene chloride under the first co-proposed approach for NMP is estimated to be \$4,247,000 to \$23,446,000 and \$4,612,000 to \$23,495,000 annualized over 20 years at 3% and 7%, respectively (Ref. 4). Under

the second co-proposed approach for NMP, where paint and coating removal products containing NMP would be available with some restrictions, the costs to users of paint and coating removers containing methylene chloride are \$67,087,960 to \$68,726,960 using a 3% discount rate and \$67,369,940 to \$69,006,940 at the 7% discount rate (both rates annualized over 20 years). The costs of downstream notification and recordkeeping on an annualized basis over 20 years are the same as under the first co-proposed approach for NMP. Agency costs for enforcement are estimated to be the same as under the first co-proposed approach for NMP. The total cost of the proposed approach for paint and coating removers containing methylene chloride under the second co-proposed approach for NMP is estimated to be \$67,098,000 to \$68,747,000 and \$67,384,000 to \$69,034,000 annualized over 20 years at 3% and 7%, respectively (Refs. 4 and 127).

2. Options that require personal protective equipment for methylene chloride in paint and coating removal. Given equipment costs and the requirements associated with establishing a respiratory protection program which involves training, respirator fit testing and the establishment and maintenance of a medical monitoring program, EPA considers the proposed approach more cost-effective than options that require person protective equipment. This is because EPA anticipates that companies would choose to switch to substitute chemicals instead of adopting a program for PPE, including with a performance-based option of meeting an air concentration level of 1 ppm as an exposure limit for methylene chloride in paint and coating removal. The estimated annualized costs of switching to a respiratory protection program requiring PPE of APF 1,000 are \$13,775,000 to \$26,535,000 at 3% and \$14,202,000 to \$26,708,000 at 7% over 20 years (Ref. 4). In addition, there would be higher EPA administration and enforcement costs with a respiratory protection program under the proposed approach.

3. Options that exclude downstream notification. For those options that exclude downstream notification, the options are less effective and more to challenging to implement. The downstream notification (e.g., via SDS) provides additional information on the prohibitions under the proposed option for processors and distributors of methylene chloride or products containing methylene chloride other than paint and coating removers, and

provides an efficient way for those entities to recognize themselves as affected by the regulation, which contributes to a more effective regulation (Ref. 63). In this way, the downstream notification component of the supply chain approach contributes to the use no longer presenting an unreasonable risk because it streamlines and aids in compliance and implementation (Ref. 64).

G. Summary

The proposed approach is necessary so that methylene chloride in paint and coating removal no longer presents an unreasonable risk. It is also more cost effective than other regulatory options the Agency identified as potentially reducing risks so that they are no longer unreasonable, because it achieves the benefits of reducing the unreasonable risks so they are no longer unreasonable for a lower cost than the primary alternative option. For more information, see section 6 in the Economic Analysis (Ref. 4).

As stated previously in this notice, the proposed approach includes:

- Prohibiting manufacturing (including import), processing, and distribution in commerce of methylene chloride for consumer paint and coating removal and commercial paint and coating removal for the uses proposed for regulation;
- Prohibiting commercial use of methylene chloride for paint and coating removal for the uses proposed for regulation;
- Requiring that any products containing methylene chloride intended or used for paint and coating removal be distributed in volumes no less than 55-gallon containers;
- Requiring downstream notification of the prohibition on manufacturing (including import) processing, and distribution of methylene chloride for paint and coating removal for the prohibited uses; and
- Requiring limited recordkeeping.

Technically and economically feasible substitutes to methylene chloride for paint and coating removal are reasonably available for the uses proposed to be regulated. The supply chain approach ensures protection of consumers from the unreasonable risk by precluding the off-label purchase of commercial products by consumers.

The proposed approach is relatively easy to enforce because key requirements are directly placed on a small number of suppliers and because the supply chain approach minimizes to the greatest extent the potential for methylene chloride products to be intentionally or unintentionally

misdirected into the prohibited uses. Enforcement under the other options would be much more difficult since the key requirements are directly placed on the large number of product users. As described in a recent article on designing more effective rules and permits, “the government can implement rules more effectively and efficiently when the universes of regulated sources are smaller and better-defined. This is because, other factors being equal, governments can more easily identify, monitor, and enforce against fewer, rather than more, entities” (Ref. 63). Under other options, enforcement activities must target firms that might perform the activity where a use of methylene chloride is restricted or prohibited. Identifying which establishments might use paint and coating removers is difficult because paint and coating removal is not strictly specific to any industry (Ref. 4).

VII. Costs and Monetized Benefits of the Methylene Chloride Component of the Proposed Rule, the Alternatives EPA Considered, and Comparison of Costs and Benefits

EPA proposes that the identified risks from methylene chloride and in paint and coating removal are unreasonable risks. Apart from that proposed determination, EPA has evaluated the potential costs and benefits of the proposed approach and alternative approaches.

A. Costs

The details of the costs of the proposed approach for use of methylene chloride in paint and coating removal by consumers and in commercial uses proposed for regulation are discussed in Unit I.E. and in the Economic Analysis (Ref. 4). Under the proposed option for methylene chloride and the first co-proposed option for NMP, costs to users of paint and coating removal products containing methylene chloride are \$4,217,000 to \$23,436,000 annualized for 20 years at a discount rate of 3% and \$4,592,000 to \$23,485,000 at a discount rate of 7%. Costs of paint and coating removal product reformulations are estimated to be approximately \$10,000 to \$20,000 per year (annualized at 3% over 20 years) and \$14,000 to \$24,000 (annualized at 7% over 20 years). Costs of downstream notification and recordkeeping on an annualized basis over 20 years are \$40 and \$60 using 3% and 7% discount rates respectively. Agency costs for enforcement are estimated to be approximately \$114,401 and \$111,718 annualized over 20 years at 3% and 7%, respectively (Ref. 4).

Total costs of the proposed rule relevant to methylene chloride in paint and coating removal under the first co-proposed option for NMP are estimated to be \$4,247,000 to \$23,446,000 annualized over 20 years at 3% and \$4,612,000 to \$23,495,000 annualized over 20 years at 7% (Ref. 4).

Under the proposed option for methylene chloride and the second co-proposed option for NMP, costs to users of paint and coating removal products containing methylene chloride are \$67,087,960 to \$68,726,960 annualized for 20 years at a discount rate of 3% and \$67,369,940 to \$69,006,940 at a discount rate of 7%. Costs of paint and coating removal product reformulations, costs of downstream notification, and Agency costs for enforcement are estimated to be the same as under the first co-proposed option for NMP (Refs. 4 and 127).

Total costs of the proposed rule relevant to methylene chloride in paint and coating removal under the second co-proposed option for NMP are estimated to be \$67,098,000 to \$68,747,000 annualized over 20 years at 3% and \$67,384,000 to \$69,034,000 annualized over 20 years at 7% (Refs. 4 and 127).

Alternatives that EPA considered include the use of PPE as well as an option that would prohibit the use of methylene chloride in paint and coating removal for consumers and for the commercial uses proposed for regulation without the companion prohibition on manufacture, processing, or distribution in commerce for these uses or the downstream notification requirements. As discussed in Unit VI.C.3., EPA found that PPE options did not address the risks presented by methylene chloride in paint and coating removal so that the risks would no longer be unreasonable. This is because consumers could not be required to adopt PPE, resulting in a significant gap in protection for consumers. In addition, EPA also assumed that no commercial users would adopt PPE because the per-facility costs were prohibitively expensive.

EPA also found that a use prohibition alone without downstream notification requirements would not address the unreasonable risks. EPA estimated the costs of this option to be \$4,239,000 to \$23,442,000 annualized over 20 years at 3% and \$4,604,000 to \$23,491,000 annualized over 20 years at 7% (Ref. 4).

B. Benefits

EPA is not fully able to quantify the full monetary benefits that would accrue from preventing all deaths due to methylene chloride in paint and coating

removal. Similarly, EPA is not able to monetize the benefits that would accrue from preventing non-fatal and non-cancer effects from exposure to methylene chloride in paint and coating removal. The subset of benefits that can be monetized from mitigating the risks from methylene chloride in paint and coating removal for consumer uses and for the commercial uses proposed for regulation are estimated to be \$14,363,000 to \$14,565,000 (annualized at 3% over 20 years) and \$13,796,000 to \$13,921,000 (annualized at 7% over 20 years) (Ref. 4). Although the alternatives considered are unlikely to result in the same health benefits as the proposed option, EPA was unable to quantify the differences.

C. Comparison of Benefits and Costs

The monetized subset of benefits for preventing the risks resulting from methylene chloride in paint and coating removal by consumers and by commercial workers for the uses proposed for regulation do not outweigh the estimated monetary costs. EPA believes that the balance of costs and benefits cannot be fairly described without considering the additional, non-monetized benefits of mitigating the non-cancer adverse effects as well as cancer. As discussed previously, the multitude of potential adverse effects associated with methylene chloride in paint and coating removal can profoundly impact an individual's quality of life. Some of the adverse effects associated with methylene chloride exposure can be immediately experienced and can result in sudden death; others can have impacts that are experienced for a shorter portion of life, but are nevertheless significant in nature. While the risk of non-cancer health effects associated with methylene chloride exposure during paint and coating removal cannot all be quantitatively estimated, the qualitative discussion highlights how some of these non-cancer effects may be as severe as cancer and thus just as life altering. These effects include not only medical costs but also personal costs such as emotional and mental stress that are impossible to accurately measure. Considering only monetized benefits would significantly underestimate the impacts of methylene chloride-induced non-cancer adverse outcomes on a person's quality of life.

Thus, considering costs; the subset of benefits that can be monetized (risk of cancer and risk of death in some sectors); and the remaining benefits that cannot be quantified and subsequently monetized (risk of nervous system effects, liver toxicity, reproductive

effects, and kidney toxicity), including benefits related to the severity of the effects and the impacts on a person throughout a lifetime in terms of medical costs, effects on earning power and personal costs, emotional and psychological costs, and the disproportionate impacts on Hispanic communities and individuals with limited English proficiency; the benefits of preventing exposure to methylene chloride in paint and coating removal by an estimated 1.3 million consumers and estimated 17,600 commercial workers for the uses proposed for regulation outweigh the costs.

D. Impacts on the National Economy, Small Businesses, Technological Innovation, the Environment, and Public Health

As described in Unit V.B. and in the Economic Analysis, EPA considered the anticipated effects of this proposal on the national economy. While the impacts of this rule as a whole are described in Unit XXIII.C. and the impacts of the methylene chloride component of this proposal are described in more detail in Unit VII.A. and in Section 9.3 of the Economic Analysis (Ref. 4), EPA does not anticipate these impacts having an effect on the overall national economy. EPA anticipates that a majority of small businesses will have cost impacts of less than one percent of the annual revenue, and the majority of small business bathtub refinishing facilities and professional contractors will have cost impacts greater than one percent of annual revenue.

The proposed approach is anticipated to drive technological innovation by formulators of paint and coating removal products containing methylene chloride, as they continue to develop substitute products, and refine such products already available. It is also anticipated to drive technological innovation by formulators of chemical paint and coating removal products with different chemistries as well as manufacturers and retailers of alternative methods of paint and coating removal. See also section 9.3 in the Economic Analysis (Ref. 4).

The proposed approach is anticipated to have a positive impact on public health, as described in Unit VI.D. There is anticipated to be a positive impact on the environment, as a result of decreased use of methylene chloride, which is a hazardous air pollutant, as described in Unit III.A.

VIII. Uses of Methylene Chloride for Paint and Coating Removal Critical for National Security

As part of interagency collaboration with the Department of Defense (DOD) on this proposed rule, EPA is aware that there are specific military uses for which methylene chloride is essential for paint and coating removal and for which there are no technically feasible alternatives currently available. The military readiness of DOD's warfighting capability is paramount to ensuring national security, which includes ensuring the maintenance and preservation of DOD's warfighting assets. DOD has identified mission-critical uses for methylene chloride for ensuring military aviation and vessel readiness. These mission-critical items require the use of methylene chloride for the removal of coatings from mission-critical corrosion-sensitive components on military aviation and vessels, including safety-critical components made of specialty metallic, nonmetallic, and composite materials. As described in this section, EPA proposes to exempt these uses from the regulations proposed on methylene chloride in paint and coating removal. This exemption is proposed for an initial ten-year period from the publication date of a final rule. EPA will engage with DOD to identify any potential extension that may need to be granted, by further rulemaking, after those ten years.

DOD has actively sought to reduce its use of methylene chloride in paint and coating removal since 1990. DOD has replaced most of its usage of methylene chloride for paint and coating removal with mechanical methods, benzyl alcohol products, other solvents, and laser ablation. For instance, the Navy's Fleet Readiness Center Southwest has undertaken a successful 20-year effort and eliminated all but a single use on safety-critical components. In an effort to reduce the use of all HAPs such as methylene chloride, the Army has conducted tests to identify and test the effectiveness of HAP-free paint and coating removers on military high-performance coatings (Ref. 61). In another example, the Air Force in December 2015 significantly reduced the use of methylene chloride for removing coatings on flight control parts and is now using substitute chemical products, primarily those with benzyl alcohol formulations (Ref. 65). This phase-out was driven by worker safety concerns and the destructive impact the methylene chloride product had on the installation's industrial wastewater treatment processes. The Air Force

sought alternatives for this use of methylene chloride for paint and coating removal in this industrial process and was successful at qualifying an alternative that met technical requirements (Ref. 65).

In light of these efforts to identify and adopt alternative chemicals or methods, it is unlikely that DOD has overlooked potential substitutes. DOD continues and will continue to pursue potential substitutes. However, for mission-critical corrosion-sensitive components on military aviation and vessels, including safety-critical components, DOD has found that currently available substitute chemicals for paint and coating removal have one or more technical limitations. In these critical and essential applications, currently available substitute chemicals cannot completely remove specific military high performance or chemical resistant coatings, resulting in improperly applied, incompletely adhering replacement coatings. The impacts of this are early coating failure, corrosion of underlying critical parts, shortened service life for critical components (some of which are no longer manufactured), and reduced availability and mission readiness of military aircraft and vessels.

Substitute chemicals currently available are also incompatible with underlying metallic, nonmetallic and composite materials, resulting in material damage to critical components (e.g. hydrogen embrittlement) creating immediate damage or longer-term susceptibility to stress fracturing and corrosion. The impacts of this are shortened service life for critical components (some of which are no longer manufactured), reduced availability and mission readiness of military aircraft and vessels, and an increased risk of catastrophic failure of safety critical parts.

Additionally, substitute chemicals or methods currently available do not support the coating removal requirements of safety inspection, non-destructive inspection, material assessment, or field repair processes. This results in an inability to properly perform safety inspections for critical components, leading to undetected fractures and defects. The impacts of this are increased risk of catastrophic failure of safety critical parts.

Under TSCA section 6(g)(1)(B), EPA may grant an exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use of a chemical substance or mixture if compliance with the requirement would significantly disrupt the national economy, national security, or critical

infrastructure. Based on discussions and information provided by DOD, EPA has analyzed the need for the exemption and concurs with DOD that compliance with the proposed regulations on the use of methylene chloride in paint and coating removal would significantly impact national security. DOD has demonstrated that the reduced mission availability of aircraft and vessels for military missions or, in the worst case, the loss of individual military aircraft and vessels, are potential impacts to military readiness that could result from the proposed prohibition of methylene chloride in paint and coating removal. Due to the importance of these military systems for national security, EPA has determined that these uses of methylene chloride for removal of specialized coatings from military aviation and vessel mission-critical corrosion-sensitive components, including safety-critical components, is critical for national security and the safety of personnel and assets. EPA includes in this exemption corrosion-sensitive military aviation and vessel mission-critical components such as landing gear, gear boxes, turbine engine parts, and other military aircraft and vessel components composed of metallic materials (specifically high-strength steel, aluminum, titanium, and magnesium) and composite materials that not only require their coatings be removed for inspection and maintenance but also would be so negatively affected by the use of technically incompatible, substitute paint removal chemicals or methods that the safe performance of the vessel or aircraft could be compromised.

EPA proposes to grant this exemption for a period of 10 years from the date of promulgation of a final rule, with a potential for extension, by further rulemaking, after review by EPA in consultation with DOD. The conditions for this exemption would be: (1) The use of methylene chloride for coating removal by DOD or its contractors performing this work only for DOD projects is limited to the mission-critical corrosion-sensitive components on military aviation and vessels, including safety-critical components; and (2) this paint and coating removal must be conducted at DOD installations, at Federal industrial facilities, or at DOD contractor facilities performing this work only for DOD projects. This exemption granted under TSCA(6)(g)(1)(B) does not impact or lessen any requirements for compliance with other statutes under which the use, disposal, or emissions of methylene chloride is regulated.

As described in Unit VI.C.3., under the proposed approach, any paint and coating removal products containing methylene chloride would be required to be distributed in packaged volumes no less than 55-gallon containers. As part of the exemption for uses identified as critical for national security, for those formulations specifically manufactured for DOD, suppliers may provide paint and coating removal products containing methylene chloride to DOD in containers with a volume no less than 5 gallons. Allowing selective use for national security purposes does not disrupt the efficacy of the supply chain approach described in Unit VI.C.3.

In addition to the exemption described in this unit, EPA will consider granting additional time-limited exemptions, under the authority of TSCA section 6(g), for a specific condition of use for which EPA can obtain documentation: that the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; that compliance with the proposed rule would significantly disrupt the national economy, national security, or critical infrastructure. To this end, EPA requests comment on a process for receiving and evaluating petitions and requesting EPA promulgate critical-use exemption rules. Under this process, entities who believe that their specific condition of use is a critical or essential use under TSCA section 6(g) would submit a petition for an exemption rulemaking with supporting documentation that they believe demonstrates that the use meets the statutory criteria. EPA would review the petition for completeness and, if the documentation warrants further action, respond to the petition by publishing a proposal in the **Federal Register** inviting comment on a proposed exemption. EPA would consider the comments received, along with any additional information reasonably available, and then take final action on the proposed exemption. EPA requests comment on the specific kinds of documentation that should be required from entities seeking an exemption rulemaking in order to facilitate EPA's and later, the public's review. EPA also requests comment on the appropriate timeframes for EPA action, given that the documentation for any given use could be technical and extensive, and that EPA may also need to develop additional information, such as economic estimates, in order to promulgate an exemption rule under TSCA section 6(g). Finally, members of

the potentially regulated community who believe that their operation is a critical or essential use should provide as much detail as possible to EPA about their operation during this comment period, including information on any evaluations of alternatives, the costs to transition to another chemical or process, and any other relevant information. This would assist EPA in reviewing the specific condition of use, as well as in establishing provisions for future exemption petitions.

IX. Overview of Uncertainties for Methylene Chloride in Paint and Coating Removal

A discussion of the uncertainties associated with this proposed rule can be found in the methylene chloride risk assessment (Ref. 2) and in the additional analyses for methylene chloride in commercial and consumer paint and coating removal (Refs. 19, 20, and 38). A summary of these uncertainties follows.

EPA used a number of assumptions in the methylene chloride risk assessment and supporting analysis to develop estimates for occupational and consumer exposure scenarios and to develop the hazard/dose-response and risk characterization. EPA recognizes that the uncertainties may underestimate or overestimate actual risks. These uncertainties include the likelihood that releases of and exposures to methylene chloride vary from one paint and coating removal project to the next. EPA attempted to quantify this uncertainty by evaluating multiple scenarios to establish a range of releases and exposures. In estimating the risk from methylene chloride in paint and coating removal, there are uncertainties in the number of workers, bystanders, and consumers exposed to methylene chloride and in the inputs to the models used to estimate exposures.

In addition to the uncertainties in the risks, there are uncertainties in the cost and benefits. The uncertainties in the benefits are most pronounced in estimating the benefits from preventing deaths due to methylene chloride that have been underreported in most commercial sectors. Additional significant uncertainties in benefits include the entirety of prevention of the non-cancer adverse effects, including underreported deaths (described in Unit VI.E.), because these benefits generally cannot be monetized due to the lack of concentration response functions in humans leading to the ability to estimate the number of population-level non-cancer cases and limitations in established economic methodologies. Additional uncertainties in benefit

calculations arose from EPA's use of a forecast from an industry expert to estimate the categories of alternatives that users might choose to adopt and the potential risks for adverse health effects that the alternatives may pose. While there are no products or methods that have comparable cancer or lethal risks, these substitute products and alternative methods do present hazards. Without information on what alternative methods or chemicals users of methylene chloride for paint and coating removal are likely to switch to, and estimates of the exposures for those alternatives, EPA is unable to quantitatively estimate any change in non-cancer risks due to use of substitute chemicals or alternative methods instead of using methylene chloride for commercial or consumer paint and coating removal.

Additional uncertainties include any benefits accrued by commercial users of methylene chloride for paint and coating removal who would benefit from using substitute chemicals and alternative processes. These users would be able to reduce or eliminate costs incurred for emissions control, hazardous waste disposal, or wastewater treatment, which are all required for commercial users of methylene chloride for any purpose.

In addition to these uncertainties related to benefits, there are uncertainties related to the cost estimates. As noted earlier, there is uncertainty in EPA's estimates of which chemical substitutes or alternative methods users may adopt instead of methylene chloride for paint and coating removal, which in turn produces uncertainty as to the cost of those substitutes or methods. EPA has estimated the cost of substitute chemicals, and, in some sectors, some increase in costs due to increased labor required by some substitute methods, but is not able to fully characterize the total costs to all sectors for using substitute chemicals or alternative products. It is possible that some users with paint removal projects that require removing multiple layers of coatings may ultimately save time by switching to a substitute chemical that is more effective than methylene chloride for this particular use. However, changes in time gained or lost during paint and coating removal projects cannot be estimated for all users potentially affected by this proposed rule. In addition, under certain assumptions EPA's economic analysis estimates that some users of methylene chloride for paint and coating removal will see a cost savings when switching to substitutes. Standard economic theory

suggests that financially rational companies would choose technologies that maximize profits so that regulatory outcomes would not typically result in a cost savings for the regulated facilities. There could be several reasons that cost savings might occur in the real world. Potential reasons include lack of complete information or barriers to obtaining information on the cost savings associated with alternatives as well as investment barriers or higher interest rates faced by firms. Additionally, there may be costs associated with these alternatives that are not adequately accounted for in the analysis. To evaluate the effect of this uncertainty, EPA has included a sensitivity analysis that sets the cost savings to zero for these compliance alternatives (Ref. 4 at Section 7). EPA also recognizes that these firms might experience positive costs of compliance rather than zero costs, so that the actual total costs could be higher than those in the sensitivity analysis. However, EPA has no current basis to estimate these potentially higher costs, since the available data appear to show that there are lower cost substitutes available. EPA requests comments on these assumptions.

Additionally, there are uncertainties due to the estimates of the number of affected commercial and consumer users, and for numbers of processors and distributors of methylene chloride-containing products not prohibited by the proposed rule who are required to provide downstream notification and/or maintain records.

EPA will consider additional information received during the public comment period. This includes scientific publications and other input submitted to EPA during the comment period.

X. Major Provisions and Enforcement of the Proposed Rule for Methylene Chloride in Paint and Coating Removal

This proposal relies on general provisions in the proposed Part 751, Subpart A, which can be found at 81 FR 91592 (December 16, 2016).

A. Prohibitions and Requirements

The rule, when final, would (1) prohibit the manufacturing, processing, and distribution in commerce of methylene chloride for paint and coating removal for consumer uses and for all commercial uses excluding for commercial furniture refinishing (see Unit XI.) and exempting those defined as critical for national security (see Unit VIII.); (2) prohibit commercial use of methylene chloride for paint and coating removal except for commercial

furniture refinishing and for uses defined as critical for national security; (3) require any paint and coating removal products containing methylene chloride to be distributed in containers with a volume no less than 55-gallons, except for formulations manufactured specifically for the Department of Defense; (4) require manufacturers, processors, and distributors of methylene chloride and all products containing methylene chloride, excluding retailers, to provide downstream notification of the prohibitions; and (5) require recordkeeping relevant to these prohibitions. As described in Unit XI., EPA intends to issue separately a proposal to regulate the risks presented by methylene chloride in commercial furniture refinishing so that those risks are no longer unreasonable; EPA intends to finalize that separate proposal and this proposal together.

The prohibition on manufacturing, processing, and distributing in commerce methylene chloride for consumer paint and coating removal would take effect 180 days after publication of a final rule. Similarly, the prohibition on manufacturing, processing, and distributing in commerce methylene chloride for any non-prohibited paint and coating removal commercial uses in containers with volumes less than 55 gallons would take effect 180 days after publication of a final rule. The prohibition on commercial use of methylene chloride for paint and coating removal except in furniture refinishing or for critical national security uses would take effect 270 days after publication of a final rule. These are reasonable transition periods because, as noted in Unit VI.E. and by the small businesses participating in the SBAR process, many formulators of paint and coating removers containing methylene chloride also manufacture products for this use that do not contain methylene chloride (Ref. 27). In addition, alternative paint removal products exist at comparable expense for users to purchase. Six months from publication of the final rule is sufficient time to allow for existing stocks to move through the market place and to allow manufacturers, processors and distributors and users to plan for and implement product substitution strategies.

B. Downstream Notification

EPA has authority under TSCA section 6 to require that a substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate

minimum warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. Many manufacturers and processors of methylene chloride are likely to manufacture or process methylene chloride or products containing methylene chloride for other uses that would not be regulated under this proposed rule. Other companies may be strictly engaged in distribution in commerce of methylene chloride, without any manufacturing or processing activities, to customers for uses that are not regulated. EPA is proposing a requirement for downstream notification by manufacturers, processors, and distributors of methylene chloride for any use to ensure compliance with the prohibition on manufacture, processing, distribution in commerce, and commercial use of methylene chloride for the uses proposed for regulation. Downstream notification is necessary for effective enforcement of the rule because it provides a record, in writing, of notification on use restrictions throughout the supply chain, likely via modifications to the Safety Data Sheet. Downstream notification also increases awareness of restrictions on the use of methylene chloride for paint and coating removal, which is likely to decrease unintentional uses of methylene chloride by these entities. Downstream notification represents minimal burden and is necessary for effective enforcement of the rule. The estimated cost of downstream notification on an annualized basis over 20 years is \$40 and \$60 using 3% and 7% discount rates respectively (Ref. 4).

The effective date of the requirement for this notification would be 45 days after publication of the final rule. This is a reasonable transition period because regulated entities would only need to provide additional information on their SDS, which are routinely produced and updated.

C. Enforcement

Section 15 of TSCA makes it unlawful to fail or refuse to comply with any provision of a rule promulgated under TSCA section 6. Therefore, any failure to comply with this proposed rule when it becomes effective would be a violation of section 15 of TSCA. In addition, section 15 of TSCA makes it unlawful for any person to: (1) Fail or refuse to establish and maintain records as required by this rule; (2) fail or refuse to permit access to or copying of records, as required by TSCA; or (3) fail or refuse to permit entry or inspection as required by section 11 of TSCA.

Violators may be subject to both civil and criminal liability. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty for each violation. Each day in violation of this proposed rule when it becomes effective could constitute a separate violation. Knowing or willful violations of this proposed rule when it becomes effective could lead to the imposition of criminal penalties for each day of violation and imprisonment. In addition, other remedies are available to EPA under TSCA.

Individuals, as well as corporations, could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to “any person” who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies. In particular, EPA may proceed against individuals who report false information or cause it to be reported.

XI. Furniture Refinishing (Methylene Chloride)

At this time, following input from small entity representatives received during the SBAR process, and based on the SBAR panel recommendations, EPA is not proposing to regulate methylene chloride when used in paint and coating removal in commercial furniture refinishing, also referred to as professional furniture refinishing (Ref. 27). Although EPA proposes to determine that risks to workers using methylene chloride for commercial furniture refinishing are unreasonable, EPA is seeking additional information about this industry to inform development of future proposed restrictions on methylene chloride in commercial furniture refinishing.

A. Description of Commercial Furniture Refinishing

Commercial furniture refinishing consists of several processes, including but not limited to repair, reupholstery, repainting, and depainting or removing paints and coatings, sometimes referred to as furniture stripping. EPA has defined furniture stripping as paint and coating removal from furniture; it includes application of a chemical or use of another method to remove, loosen, or deteriorate any paint, varnish, lacquer, graffiti, surface protectants, or other coating from wood, metal, or other types of furniture, doors, radiators, or cabinets. Furniture stripping can be conducted separately or as a part of furniture refinishing. EPA has defined commercial furniture stripping as furniture stripping conducted in a commercial facility performed by an

individual, government entity, or company for which an individual, government entity, or company receives remuneration or other form of payment.

As described in the methylene chloride risk assessment, to carry out furniture stripping, or to remove paint, lacquer, varnish, or other coatings from wood or metal furniture (or similar items such as doors, radiators, and cabinets), chemical paint and coating removal products may be applied to the furniture by either dipping the furniture in an open tank containing the chemicals, brushing or spraying the product onto the furniture surface, or manually applying the chemical product with a brush, rag, or aerosol spray. Larger furniture refinishing facilities conducting furniture stripping may pump the chemical product through a brush. The application method depends on the size and structure of the furniture as well as the capabilities of the facility (Ref. 2). Some firms may use alternative methods of paint and coating removal, such as sanding or heat/thermal guns, but EPA's information to date indicates that paint and coating removal on furniture is primarily conducted with chemical removers (Refs. 22, 27, 31, 66 and 27).

The area where furniture refinishing workers conducting furniture stripping apply paint and coating removal chemicals typically has a sloped surface to allow for collection and recycling of unused chemical product. Larger facilities use a flow tray to apply the paint and coating removal product or chemical to parts. The flow tray is a sloped, shallow tank with a drain at the lower end. Some facilities may use a dip tank to immerse whole pieces or parts of furniture in the chemical product (Refs. 2 and 22).

After a worker applies the chemical product or immerses the piece of furniture in it, the paint and coating remover is left to soak, or "dwell," on the furniture surface to soften the paint, coating, or varnish. Once soaking is complete, a worker manually scrapes or brushes the unwanted coating from the furniture surface. The worker then transfers the furniture to a washing area where they wash the waste chemical and paint or coating sludge from the furniture. Workers can wash the treated furniture with low-pressure washing operations or high-pressure water jets or high-pressure wands. Wash water may contain oxalic acid to brighten the wood surface. Wash water is collected and either recycled or disposed of as waste. After washing, the worker transfers the furniture to a drying area where it is allowed to dry before being transferred

to other refinishing processes (e.g., sanding, painting, reupholstery) (Ref. 2).

Based on industry research and discussions with stakeholders, EPA is aware that most commercial furniture refinishing firms primarily use chemical methods for paint and coating removal, and that methylene chloride or methylene chloride-based products are the types of chemical paint removers primarily and, in some firms, exclusively, used. Some commercial furniture refinishers, including some small businesses participating in the SBAR process, have said that although they make limited use of acetone for some types of furniture, they have not found any workable substitutes for methylene chloride as a primary paint and coating removal method (Refs. 22 and 27). More information on the potential use of substitutes for furniture refinishing is provided in Unit XI.E.

B. Risks Associated With Furniture Refinishing

The methylene chloride risk assessment and additional supplemental analyses identified acute and chronic risks from inhalation of methylene chloride during paint and coating removal by consumers, commercial users, and bystanders in residences or workplaces (individuals not using the paint and coating remover but nearby a user) (Refs. 2, 19, 20, and 38). This includes an assessment of the risks from methylene chloride when used in commercial furniture refinishing. EPA estimates that, annually, there are approximately 15,000 workers at 4,900 commercial refinishing operations conducting paint and coating removal with methylene chloride (Ref. 4).

1. Exposures assessed to methylene chloride during commercial furniture refinishing and immersion stripping. Exposures assessed for workers in commercial furniture refinishing include acute and chronic exposures to methylene chloride for paint and coating removal, as described in the methylene chloride risk assessment (Ref. 2). The exposure pathways of interest included dermal contact and inhalation, but, due to limitations described in the risk assessment, the assessment was based only on the inhalation route of exposure. Different exposure scenarios were evaluated for workers, occupational bystanders, consumers, and residential bystanders (Ref. 2). Not included in the assessment but important to note are bystanders in commercial refinishing operations that are located in workshops or other parts of residences; here, the bystanders may include not only workers but also children and occupants of the home.

In addition to estimating likely exposures under current use patterns, for both commercial and consumer users, EPA assessed a number of exposure scenarios associated with risk reduction options in order to identify variations in methylene chloride exposure during paint and coating removal. All variations in the scenarios were applied to industry-specific exposure inputs and evaluated with exposure parameters that were modified to reflect either a reasonable worst-case scenario (also called the baseline) or a scenario in which exposures were moderated by several factors (also called the central tendency scenario). The risk reduction options varied between scenarios and included engineering controls and use of personal protective equipment (PPE), as well as combinations of these options (Ref. 19).

- Under the PPE risk reduction option exposure scenarios, EPA evaluated respirators with APF 10 to 10,000 for acute and chronic risks, including cancer risks.

- For the engineering controls risk reduction option exposure scenarios, EPA evaluated using local exhaust ventilation (LEV) to improve ventilation near the activity of workers in furniture refinishing operations, with an assumed 90% reduction in exposure levels.

Overall, EPA evaluated several distinct exposure scenarios for paint and coating removal with methylene chloride for commercial furniture refinishing. Additionally, EPA evaluated several distinct exposure scenarios for miscellaneous paint and coating removal conducted by immersion of the object in vats or tanks of methylene chloride (dip methods), since this has been reported as a method of paint and coating removal during furniture refinishing (Refs. 19 and 27).

The results of these evaluations of exposure scenarios demonstrate that the scenarios meeting all relevant health benchmarks for all scenarios of methylene chloride in paint and coating removal in commercial furniture refinishing requires: (1) A respiratory protection program using a supplied-air respirator with APF of 1,000 or 10,000, depending on type of method used for applying methylene chloride or workplace characteristics, such as the size of the facility; (2) reducing exposures with LEV that can achieve 90% efficiency in air flow plus worker respiratory protection with APF 1,000; or (3) elimination of exposure to methylene chloride by using an alternative method of paint and coating removal (Ref. 19). Although non-cancer risks and cancer risks were estimated using separate measures, exposure

reduction that is protective against non-cancer risks from methylene chloride is also protective against cancer risks.

2. *Risks assessed from methylene chloride during commercial furniture refinishing and immersion methods.* Exposure to methylene chloride is associated with death, neurotoxicity, liver toxicity, and cancer in humans and animals. To estimate non-cancer risks for acute and chronic exposures, the methylene chloride risk assessment used MOEs. Exposure scenarios with MOEs below the benchmark MOE have risks of concern, as explained in detail in the methylene chloride risk assessment. For acute and chronic exposure scenarios, the benchmark MOE is 10 (Ref. 2). The benchmark MOE identifies a risk of concern for a given endpoint; it is obtained by multiplying the total uncertainty factors associated with each health endpoint's point of departure. For more information on uncertainty factors, see Unit IV.B.

The acute inhalation risk assessment used central nervous system effects to evaluate the acute risks for occupational, consumer, and bystander exposure during paint and coating removal with methylene chloride. A risk of concern was identified if the MOE estimate was less than the benchmark MOE of 10 (Ref. 2).

EPA assessed acute risks for central nervous system effects from inhalation for workers using methylene chloride for commercial furniture refinishing and for immersion methods of paint and coating removal for various objects, including furniture. Acute risks were estimated in this sector, even in the presence of respirators with APF 10 or APF 25. MOEs for acute risks in commercial furniture refinishing ranged from a central tendency of 0.08 to 0.035, with a high end of 0.0063 (workplaces engaged in paint and coating removal using immersion methods). In general, these workplaces are estimated to present exposure levels between 125 times to greater than 1,500 times more than those that are expected to produce no risks of concern. Not only workers, but also occupational bystanders, or workers engaged in tasks other than paint and coating removal, would be at acute risk for central nervous system effects.

EPA also assessed risks of chronic exposure to workers using methylene chloride for commercial furniture refinishing. The methylene chloride risk assessment used liver toxicity as the critical endpoint for chronic exposure. The selected exposure scenarios represented inhalation exposures with a range of conservative assumptions. As described earlier, the assumptions were

then varied, such as use of PPE (supplied-air or other respirator) and duration of time spent in contact with the product (days and years). EPA assessed risks for liver toxicity (with effects that include vacuolation and fatty liver) for occupational and bystander exposure scenarios of paint and coating removal with methylene chloride.

Workers and occupational bystanders in this industry were estimated to be at risk of non-cancer liver toxicity as a result of chronic exposure to methylene chloride during paint and coating removal under typical exposure scenarios. When workers' exposures were estimated at facilities repeatedly reporting moderate or high methylene chloride air concentration levels, EPA estimated that there were risks of concern for these workers, even for scenarios evaluated with workers wearing respiratory protection with APF 50. Among all of the occupational scenarios, the greatest risk of concern is for workers engaging in long-term use of the product (*i.e.*, 250 days/year for 40 years) with no respiratory protection. For those workers, MOEs for chronic exposures were 0.025, or reflective of risks 400 times greater than the benchmark. Even for workers assumed to have lower exposure, MOEs did not reach 10. In most workplaces engaged in commercial furniture refinishing, MOEs for chronic exposure ranged from a central tendency of 0.60 to 0.3. Additionally, in EPA's risk assessment scenarios, which are not necessarily reflective of industry-wide work practices, for workers and bystanders assumed to have the lowest exposure (respirator APF 50, limited exposure duration, and moderate air concentration), MOEs for chronic exposure were 5, or one-half of the benchmark (Ref. 2).

For commercial users and bystanders, EPA also assessed cancer risks as a result of chronic exposure to methylene chloride in paint and coating removal in commercial furniture refinishing. Methylene chloride is a likely human carcinogen; cancer risks determine the incremental increased probability of an individual in an exposed population developing cancer over a lifetime following exposure to the chemical under specified use scenarios. Common cancer benchmarks used by EPA and other regulatory agencies are an increased cancer risk of one in one million or one in ten thousand (*i.e.*, 1×10^{-6} or 1×10^{-4}). Estimates of cancer risk should be interpreted as the incremental increased probability of an individual in an exposed population developing cancer over a lifetime as a

result of exposure to the potential carcinogen (*i.e.*, incremental or excess individual lifetime cancer risk) (Ref. 2).

In the methylene chloride risk assessment, when exposure for workers and occupational bystanders was estimated in facilities conducting commercial furniture refinishing, EPA identified excess cancer risks if these workers and bystanders were exposed to paint and coating removal with methylene chloride for 250 days per year for 40 years with no respiratory protection. Cancer risks ranged from 2 in 10,000 to 8 in 10,000, with a maximum of 5 in 1,000 (workplaces using immersion methods) (Ref. 2).

For commercial users and occupational bystanders in commercial furniture refinishing, acute and chronic risks were assessed based on the typical occupational exposure parameters, which may include several hours per day of exposure over several years of work. For these reasons, any risk mitigation measures must address not only acute risks, but also chronic risks, including both cancer and non-cancer effects. For these reasons, the most sensitive endpoint for risk mitigation must be considered, whether it derives from acute or chronic exposure.

3. *Impacts of the exposures.* As discussed for other commercial uses in Unit VI.E., exposure to methylene chloride in paint and coating removal, when conducted in commercial furniture refinishing and for other purposes, is associated with a range of adverse health effects, which include impacts on the nervous system, liver, respiratory system, kidneys, and reproductive systems. In some instances, these effects may appear relatively mild, such as dizziness, which occurs early in exposure and at low exposure levels. However, with increasing levels of exposure or increasing duration, these effects can take the form of generally irreversible health effects such as cognitive impairment, sensory impairment, coma, heart failure, liver toxicity, brain cancer, liver cancer, non-Hodgkin lymphoma, and multiple myeloma.

Acute exposure to methylene chloride during paint and coating removal can be fatal; since 1980, at least seven workers have died while using methylene chloride for commercial furniture refinishing. Data from OSHA indicate that the circumstances of death vary. For example, some workers collapse while conducting paint and coating removal over or near dip tanks, frequently falling into the tanks and subsequently dying. This was the case in 1985 in Pennsylvania, 1986 in Colorado, 1990 in Connecticut, and

2000 in Pennsylvania (Ref. 7). The worker in Connecticut earlier complained that the vapors were making him dizzy, and shortly after slumped into the dip tank and died; the worker in 2000 in Pennsylvania was found face-down in the dip tank next to the shutters from which he was attempting to remove paint (Ref. 7). Other workers in commercial furniture refinishing facilities lose consciousness at their workplace, but die sometime later, such as a worker in 1991 in Colorado, and in 1999 in Tennessee (Ref. 68).

These are likely not the only deaths in commercial furniture refinishing due to methylene chloride; as discussed in Unit VI.E., many deaths due to methylene chloride have not been recorded due to a lack of reporting to the OSHA incident database by self-employed individuals and the likelihood that deaths due to methylene chloride exposures are misattributed to heart disease, since the pathology is similar (Ref. 33).

In addition to fatalities, methylene chloride exposure during commercial wood refinishing has caused acute effects, such as the 1996 case of a cabinet manufacturer employee who experienced chronic headaches found to be due to methylene chloride exposure when the doors at his facility were closed in the winter months (Ref. 69).

In most commercial furniture refinishing facilities using methylene chloride for paint and coating removal, worker and occupational bystander exposure concentrations are orders of magnitude above what would be necessary to achieve the benchmark MOE of 10 for acute and chronic non-cancer effects. For acute health effects such as nervous system impacts, EPA estimated an MOE of 0.08 for workers in commercial furniture refinishing. For chronic non-cancer health effects such as liver toxicity, workers in this industry have an MOE of 0.6 to 0.3 (Ref. 2). For a description of MOEs and their use in risk assessment, see Unit IV.B.

In each case, workers in commercial furniture refinishing using methylene chloride for paint and coating removal are exposed at a level that is generally 125 to 1,500 times higher than what EPA has found to be a level that would not present acute or chronic non-cancer risks of concern. These risks of concern are for effects such as death, multiple adverse chronic health effects, and the subsequent lifetime impacts from these effects. Additionally, individuals occupationally exposed to methylene chloride in paint and coating removal may also be impacted by an increased risk for several types of cancer. The

cancer risks to workers in commercial furniture refinishing using methylene chloride for paint and coating removal range from 8 cases in 10,000 people to 5 cases in 1,000 people (workplaces using immersion methods) (Ref. 2).

EPA's risk estimates are corroborated by research conducted independently investigating working conditions at commercial furniture refinishing and OSHA enforcement of their methylene chloride standard. In 1990, as a result of several cases of methylene chloride poisoning during paint and coating removal in commercial furniture refinishing in Colorado, occupational medicine specialists from the University of Colorado surveyed the 21 small shops in the Denver area engaged in commercial furniture refinishing. These researchers found that of the 21 shops, no workers wore respirators at all in seven shops, and in 14 facilities, workers occasionally wore half-face respirators with organic vapor cartridges (which do not provide respiratory or eye protection from methylene chloride). In ten of the 21 shops, workers experienced acute nervous system effects, such as dizziness or nausea while working to remove coatings from furniture. The researchers concluded that "current safety practices in small-scale furniture-stripping shops may be inadequate to keep methylene chloride exposure levels in compliance with latest recommendations, and serious or fatal overexposure can occur" (Ref. 70).

When considering the benefits of preventing exposure to methylene chloride in paint and coating removal in commercial furniture refinishing, EPA considered the type of effect, the severity of the effect, the duration of the effect, and costs and other impacts of the health endpoint. The health endpoints associated with exposure to methylene chloride are serious. Unit VI.E. presents a detailed discussion of the impacts of the most significant acute, chronic non-cancer, and cancer effects associated with methylene chloride exposure during paint and coating removal, including the severity of the effect, the manifestation of the effect, and how the effect impacts a person during their lifetime. These effects include nervous system effects resulting from acute exposures, such as sensory impairment, incapacitation (loss of consciousness), and death; and effects resulting from chronic, occupational exposures including liver toxicity and liver cancer, hematopoietic cancers, brain cancer, lung cancer, reproductive effects, and kidney toxicity.

There are increased risks of death, nervous system effects, and liver, lung, brain, reproductive, and kidney effects

for the approximately 15,000 workers in 4,900 commercial facilities or companies that use methylene chloride for paint and coating removal during commercial furniture refinishing each year (Ref. 4).

C. Approaches That Could Reduce the Risks of Methylene Chloride Used in Furniture Refinishing to Benchmark Levels

Although EPA is not proposing to regulate the use of methylene chloride in paint and coating removal for commercial furniture refinishing, EPA has identified potential requirements for methylene chloride in paint and coating removal for commercial furniture refinishing that could reduce exposures so that the risks presented would no longer be unreasonable. EPA is providing advanced notice of these potential approaches and is seeking comment on them.

1. *Prohibition on manufacturing, processing, distribution, and use of methylene chloride in commercial furniture refinishing.* Similar to the approach proposed for regulation of methylene chloride in other commercial paint and coating removal (see Unit V.), EPA has identified a prohibition on manufacturing, processing, distribution, and use of methylene chloride in commercial furniture refinishing as an option for reducing risks in this industry to benchmark levels, under TSCA sections 6(a)(2) and 6(a)(5). This approach could also require manufacturers, processors, and distributors to provide downstream notification of the prohibitions under TSCA section 6(a)(3), and could require recordkeeping relevant to these prohibitions under TSCA section 6(a)(4).

Under this approach, exposures to methylene chloride during paint and coating removal in commercial furniture refinishing would be completely eliminated. As a result, not only non-cancer risks, but also cancer risks would be eliminated.

2. *Requiring a respiratory protection program, including PPE, air monitoring, and either a supplied-air respirator of APF 1,000 or 10,000 or an air exposure limit of 1 part per million (ppm) achieved through engineering controls or ventilation, in commercial facilities for furniture refinishing using methylene chloride for paint and coating removal under TSCA section 6(a)(5).* Another regulatory approach that EPA has considered for the use of methylene chloride for paint and coating removal in commercial furniture refinishing would be to require risk reduction through an occupational respiratory

protection program, which would include air monitoring, medical monitoring, and respiratory protection through use of a supplied-air respirator with an APF of 1,000 or 10,000, depending on the methods used for paint and coating removal with methylene chloride and other workplace characteristics, with a performance-based option of meeting an air concentration level of 1 ppm as an exposure limit for methylene chloride.

A full-face (or helmet/hood) self-contained breathing apparatus (SCBA) when used in the pressure demand mode or other positive pressure mode has an APF of 10,000. EPA's analysis found that use of a SCBA with an APF of 10,000 would, in all scenarios evaluated, control the methylene chloride exposure to levels that allow for meeting the benchmarks for non-cancer and cancer risks. In some commercial furniture refinishing facilities using methylene chloride for paint and coating removal, workers with a supplied-air respirator with an APF of 1,000 would experience reduced exposures to methylene chloride such that their risks would be reduced to benchmark levels (Ref. 19). It is important to note that current OSHA requirements for dermal and eye protection when using methylene chloride in any way would be maintained under this approach, in addition to other requirements for work practices, training, and hazard communication put forth in OSHA's Methylene Chloride Standard (29 CFR 1910.1052).

EPA seeks comment on whether commercial furniture refinishing operations have these types of respiratory protection programs in place, any experiences in complying with the current OSHA methylene chloride standard, methods of reducing costs associated with these programs, and recommended approaches for small businesses considering a respiratory protection program that would include supplied-air respirators.

EPA also considered requiring a combination of local exhaust ventilation and respirators with APF of 1,000 or 50, with a performance-based option of an air exposure limit of 1 ppm as an eight-hour TWA. When properly executed, this option would reduce risks to the health benchmarks for workers and bystanders (Refs. 19 and 38). However, while this option has the benefit of incorporating engineering controls and the use of respirators with a lower APF, the limitations to successful implementation of the use of supplied-air respirators in the workplace discussed previously are still present.

Further, this option would also require the use of prescriptive and expensive engineering controls to ensure that the exposures are below the benchmark cancer risks (Ref. 19). In an examination of the impacts of its methylene chloride standard, OSHA in 2010 found that furniture refinishing facilities in particular have not installed ventilation systems that would lower worker exposures to methylene chloride (Ref. 68). OSHA's assessment found that this is largely due the fact that most of these facilities are part of small businesses, and they tend to be less able to have sufficient capital to purchase the ventilation systems. Additionally, this type of ventilation requires make-up air systems, which have an additional cost and which, in cold climates, would need to heat the air and thus increase energy costs (Ref. 68).

Even if these engineering controls were installed, research conducted by the National Institutes of Occupational Safety and Health (NIOSH), as well as independent researchers, has indicated that ventilation alone is generally not able to reduce methylene chloride exposures below 25 ppm (Refs. 68 and 71), and there is no indication that a level close to 1 ppm (an acceptable exposure limit) could be reached.

3. *Approaches that do not mitigate the risks of methylene chloride in commercial furniture refinishing to benchmark levels.* As described in Units IV.B. and IV.C., EPA evaluated dozens of distinct exposure scenarios across consumer and commercial uses of methylene chloride for paint and coating removal, including in commercial furniture refinishing. The results of EPA's evaluation indicate that regulatory approaches for occupational exposures in commercial furniture refinishing such as reducing the concentration of methylene chloride in products used for paint and coating removal and using local exhaust ventilation to improve ventilation, in the absence of PPE, could not achieve the target MOE benchmarks for non-cancer endpoints for acute and chronic exposures and standard cancer risk benchmarks for chronic exposures (Refs. 26 and 29). The results also demonstrate that all risk reduction options meeting the benchmark MOEs and cancer benchmarks for methylene chloride in paint and coating removal in commercial furniture refinishing require the use of a supplied-air respirator, whether used alone or in conjunction with additional levels of protection. Therefore, EPA found that setting a maximum concentration of methylene chloride in products under section 6(a)(2) could not reduce exposures so

that risks from paint and coating removal with methylene chloride in commercial furniture refinishing would be reduced to benchmark levels. Options found not to meet the risk benchmarks are documented in EPA's supplemental technical reports on methylene chloride in paint and coating removal (Refs. 19, 20, 21, and 38).

D. Costs of EPA's Potential Approach for Regulation

EPA is at this time seeking additional information to inform its consideration of the reasonably ascertainable economic consequences of an action that would address the risks of commercial furniture refinishing so that they are no longer unreasonable, as required under TSCA section 6(c)(2)(A)(iv). This section presents the information EPA currently has and identifies the information that EPA is seeking. While the costs of potential risk management actions are not a legally permissible basis for EPA to reassess its proposed unreasonable risk determination, see TSCA section 6(b)(4)(A), costs are relevant to deciding among alternative risk management approaches that reduce risk so that a chemical substance no longer presents unreasonable risk and in establishing compliance dates for a risk management approach that is ultimately selected.

1. Information available to EPA.

Based on industry research and information provided by stakeholders, including during informal discussions and more formally from small entity representatives participating in the SBAR process (described in more detail in Unit XXIII.), EPA has learned that there may not be any substitute chemicals or alternative practices frequently in use for paint and coating removal in commercial furniture refinishing other than chemical paint and coating removal with methylene chloride (Refs. 22 and 27).

Primary chemical substitutes for methylene chloride in commercial paint and coating removal more generally include products formulated with benzyl alcohol; dibasic esters; acetone, toluene, and methanol (ATM); and caustic chemicals. These substitute chemicals, their hazards, and their environmental impacts are described in more detail in Unit VI.E. EPA has learned that these chemicals are generally not suitable for paint and coating removal in furniture refinishing since they either are ineffective at removing particular coatings frequently found on furniture (such as varnish, lacquer, or older paint formulations in multiple layers); are formulated to include large amounts of water and thus

incompatible with wood objects that can become saturated and damaged (as is the case with many products containing benzyl alcohol); or are chemically incompatible with wood and can result in damage or raising the grain on the object (as is the case with caustic paint and coating removal products) (Refs. 22 and 27). Products that may be chemically compatible with wood substrates or the paints, varnishes, or lacquers to be removed were described by stakeholders as requiring too long a dwell time to be efficacious for their business and thus are not used (Refs. 22 and 27). Other than two commercial furniture refinishers who remove paints and coatings on some solid wood objects with either immersion in 100% acetone or an acetone-toluene-methanol blend, no commercial wood finishing firms reported using substitute chemicals routinely for paint and coating removal, and none felt they were able to completely eliminate use of methylene chloride, despite being aware of the worker health and environmental impacts (Refs. 22 and 27).

In addition to substitute chemical products, EPA has identified non-chemical methods for commercial paint and coating removal that can be used more generally as alternatives to methylene chloride. Frequently-used alternative methods to chemical paint and coating removal include thermal removal, sanding, hydroblasting, abrasive blasting, and laser removal (Refs. 22 and 27). These methods are already frequently in use in various industries for paint and coating removal (Refs. 22, 27, and 31); they and their acute and chronic hazards to workers are described in more detail in Unit VI.E.

For commercial furniture refinishing, EPA has learned that all firms engage in varying amounts of mechanical or hand-sanding but do not consider it a primary method of paint and coating removal (Refs. 22 and 27). Additionally, despite the hand scraping or brushing that is required to remove waste paint from furniture and other objects for which methylene chloride has been used to remove paint or coatings, most stakeholders described sanding as too time consuming or labor intensive to use routinely as a primary method of paint and coating removal. Additionally, though many other commercial sectors have adopted various soft media blasting techniques for delicate substrates, such as using soda blasting on fiberglass vehicle parts, EPA has not found this to be a practice used in commercial furniture refinishing (Refs. 22 and 27).

EPA is seeking additional information to inform its consideration of the impacts on commercial furniture refinishing if use of methylene chloride as a paint and coating remover were prohibited or restricted.

2. Information sought. To aid in identifying the economic impacts on commercial furniture refinishers of any potential prohibition or restriction on methylene chloride for paint and coating removal, EPA is seeking the following information related to the approach that would prohibit the use of methylene chloride for paint and coating removal in furniture refinishing:

- What percent of business for firms in this sector is paint and coating removal, versus furniture repair, reupholstery, or other furniture refinishing functions?
- How likely is it that firms in this sector would close if methylene chloride were prohibited from use in paint and coating removal in this sector?
- What would the impact be on this sector if all firms were prohibited from using methylene chloride for paint and coating removal, and thus any changes in work processes or dwell time would be universally experienced?
- Have firms had any success with substitute chemicals or alternative methods of paint and coating removal? If not, which aspects of the chemical or method renders the substitute or alternative ineffective?

Related to the approach that would require a respiratory protection program, including either a supplied-air respirator with either APF 1,000 or APF 10,000, or engineering controls or ventilation to reach an exposure limit of 1 ppm:

- What is the current experience of firms in this sector with supplied-air respirators and/or engineering controls?
- What is the current experience of firms in this sector with ventilation systems, makeup-air systems, and other engineering controls?
- What types of exposures do workers in firms in these sectors currently experience?

EPA has found that commercial furniture refinishing primarily uses methylene chloride for paint and coating removal and that no current chemical substitutes are seen as useful alternatives. However, in recent decades, substitute products have been developed for other types of paint and coating removal, and it is possible that new substitute chemicals or products could be developed to address the special coatings or substrates involved in commercial furniture refinishing. Several formulators and research organizations are exploring possibilities

for efficacious and cost-effective substitute chemicals.

Additionally, outside of the United States, commercial furniture refinishers have adopted methods that are alternatives to chemical paint and coating removal. For example, most paint and coating removal in Sweden is conducted by thermal methods, such as heat guns or heat lamps, including for commercial furniture refinishing (Ref. 72). In Denmark, firms engaging in commercial furniture refinishing are reported to use large microwave furnaces, which can hold large pieces of furniture (Ref. 73).

These alternative methods and the research into substitute chemicals indicate that it is now and in the future may increasingly be possible to remove paint and coatings from furniture without methylene chloride. If that were the case, EPA would be able to more straightforwardly identify the costs and impacts of any proposed regulation of methylene chloride for paint and coating removal in commercial furniture refinishing. EPA is seeking additional information on the use and development of substitute chemicals and alternative methods that would be useful in commercial paint and coating removal on furniture, including information on:

- What are the current considerations when selecting a paint and coating removal chemical for furniture refinishing or refinishing of other wood objects or surfaces?
- What are the current considerations when selecting a paint and coating removal method for furniture refinishing or refinishing of other wood objects or surfaces?
- Are there substitute chemicals or alternative methods in use beyond what EPA has identified in this notice?
- Are any new paint and coating removal product formulations or chemistries under development?
- Are any new paint and coating removal methods in development for furniture refinishing, or refinishing of other wood objects or surfaces?

E. Public Engagement To Identify Impacts and Alternatives

To learn more about paint and coating removal in furniture refinishing, foreseeable impacts of any proposed regulations, and alternatives to methylene chloride, EPA plans to hold a series of stakeholder meetings. These meetings will focus on current practices related to methylene chloride for paint and coating removal in commercial furniture refinishing; any substitute chemicals or alternative methods currently in use or under development;

and current and best practices related to respiratory protection programs and exposure reduction.

EPA will announce dates and locations of these meetings in a future notice in the **Federal Register** as well as on EPA's Web site. EPA will provide some of these meetings electronically by Webinar to maximize public participation.

F. Next Steps

EPA views this section as an Advanced Notice of Proposed Rulemaking, and intends to issue a Notice of Proposed Rulemaking following the series of stakeholder meetings and further analysis on the cost impacts of regulatory action on this industry. Following that proposal and public comment period, EPA intends to finalize together the regulations proposed and the future proposal related methylene chloride in commercial furniture refinishing.

XII. Overview of NMP and Uses Subject to This Proposed Rule

A. What chemical is included in the proposed rule?

This proposed rule would apply to N-methylpyrrolidone (Chemical Abstract Services Registry Number (CASRN) 872-50-4) when used in paint and coating removal.

B. What are the uses of NMP and how can people be exposed?

NMP is a solvent used in a variety of industrial, commercial and consumer use applications, including (Ref. 3):

- Petrochemical processing, acetylene recovery from cracked gas, extraction of aromatics and butadiene, gas purification, lube oil extraction;
- Plastics engineering, as a reaction medium for the production of high-temperature polymers such as polyethersulfones, polyamideimides and polyaramids;
- Use in coatings, as a solvent for acrylic and epoxy resins, polyurethane paints, waterborne paints or finishes, printing inks, synthesis/diluent of wire enamels, coalescing agent;
- Production of agricultural chemicals: Solvent and/or co-solvent for liquid formulations;
- Electronics cleaning: Cleaning agent for silicon wafers, photoresist stripper, auxiliary in printed circuit board technology; and
- Industrial and domestic cleaning, including as a component in degreasers and paint removers.

According to the 2012 CDR information, approximately 180 million pounds of NMP were produced or imported into the U.S. that year (Ref. 3).

Individuals, including workers, consumers, and the general population are exposed to NMP from industrial/commercial and consumer sources, in different settings such as homes and workplaces, and through multiple routes (inhalation, dermal, and vapor-through-skin).

According to data in the 2014 TRI, 386 facilities reported releases or transfers of NMP and the top 100 facilities disposed of or released a total of 10.2 million pounds of NMP (Ref. 6).

The use assessed by EPA that is the subject of this proposal, NMP in paint and coating removal, represents about 9% of total use of NMP (Ref. 3). Paint and coating removal is the application of a chemical or use of another method to remove, loosen, or deteriorate any paint, varnish, lacquer, graffiti, surface protectants, or other coating from a substrate. Substrates can include objects, vehicles, architectural features, or structures. This use is discussed in detail in Unit XVI.A.

Although the TSCA Work Plan Chemical risk assessment for NMP focused on the chemical's use in paint and coating removal, EPA announced in December 2016 its designation of NMP as one of the ten chemical substances that will undergo risk evaluation pursuant to TSCA section 6(b)(2)(A) (81 FR 91927). The Agency is proceeding with this proposed rule addressing NMP in paint and coating removal in accordance with TSCA section 26(l) and asks for comment on its decision to pursue risk management for specific conditions of use of NMP while preparing to conduct a risk evaluation of remaining NMP conditions of use under TSCA section 6(b).

C. What are the potential health effects of NMP?

NMP is a developmental toxicant (Ref. 3). A broad set of relevant studies including animal bioassays in rats, mice, and rabbits show that maternal NMP exposure is associated with dose-dependent adverse developmental impacts on the fetus (including body weight reductions and fetal death). Developmental toxicity is the most sensitive endpoint. Other adverse impacts resulting from NMP exposure include effects on maternal body weight; alterations in blood cell counts; liver, kidney, splenic, thymus, and testicular effects; and neurotoxicity.

Nearly every study that evaluated developmental toxicity of NMP exposure identified some type of adverse effect depending on the route of exposure and the internal dose achieved. Moreover, a review of effect levels reveals that these effects are

observed within a comparable dose range when administered doses are converted to internal doses for a series of gestational exposure studies in rats. The NOAELs for these comparable developmental studies typically ranged from 100 to 200 mg/kg/day for oral exposure, 237 mg/kg/day for dermal exposure, and 479 to 612 mg/m³ for inhalation exposure. EPA applied a physiologically-based pharmacokinetic model to derive internal doses for these exposure scenarios to compare across routes and aggregate exposures. Specifically, EPA identified a number of biologically relevant, consistent, and sensitive effects, representing a continuum of reproductive and developmental effects for consideration in assessing human health risks, including decreased fetal and postnatal body weight, delayed ossification, skeletal malformations, and increased fetal and postnatal mortality. EPA identified a point of departure for decreased fetal body weight based on the average blood concentration of 411 mg/L. Studies have shown acute effects of NMP exposure to include fetal mortality and indications of fetal resorptions in rodents and a point of departure based on maximum blood concentration of 216 mg/L. Fetal and postnatal mortality have also been observed in oral and dermal studies (Ref. 3).

Chronic effects of NMP exposure include fetal body weight decreases. These effects were consistent among multiple studies with different dosing regimens and across exposure routes. Reduced fetal body weight is a sensitive endpoint that is considered a marker for fetal growth restriction, which is often assumed to be representative of chronic exposures. Decreases in fetal and postnatal body weights occur at similar dose levels (Ref. 3).

There is one case report of the fetus of a pregnant woman dying in utero at week 31 of pregnancy. The worker was exposed throughout pregnancy to NMP by inhalation and dermal exposure, but the exposure levels were unknown. The worker's tasks involved other chemicals, including acetone and methanol. During week 16 of the pregnancy, the worker cleaned up a spill of NMP using latex gloves that dissolved in the NMP. She was ill for the next 4 days and experienced malaise, headache, nausea and vomiting. While this study provides some evidence that NMP may be fetotoxic, the lack of quantitative exposure data precluded its use in the TSCA Work Plan Chemical Risk Assessment for NMP (Ref. 3).

Chronic effects of NMP exposure include systemic effects following

maternal exposure, which include body weight reductions, alterations in clinical chemistry and blood cell counts, liver and kidney toxicity, neurotoxicity and thymic atrophy, with highly variable dose levels where no observed adverse effects occurred (Ref. 3).

An additional effect of chronic NMP exposure is reproductive toxicity, though these findings are significantly less frequent or consistent than the occurrence of developmental effects. When observed, reproductive effects were variable in occurrence and dose effect range. Several rat studies identified some type of testicular effect, including testicular lesions, atrophy or smaller testes. Similarly, a small number of rat studies noted some effects related to developmental neurotoxicity in postnatal development and behavior following maternal exposure (Ref. 3).

In addition to developmental toxicity, exposure to NMP presents other acute and chronic toxicity concerns. Acute effects include skin, eye, and possible respiratory irritation. Human volunteer chamber studies revealed some discomfort during exposure. Prolonged exposures to neat (*i.e.*, pure) NMP increases the permeability of the skin (Ref. 3).

D. What are the environmental impacts of NMP?

Section 6(c) of TSCA requires that EPA state the effects of NMP on the environment and the magnitude of the exposure of the environment to NMP. The proposed unreasonable risk determination, however, is based solely on risks to human health since these risks are the most serious consequence of use of NMP and are sufficient to support this proposed action.

1. *Environmental effects and impacts.* Ecotoxicity studies for NMP have been conducted in fish, aquatic invertebrates, aquatic plants and birds. There were no acceptable studies identified for sediment or soil dwelling organisms. Based on available data in the NMP risk assessment, EPA concluded that NMP has low acute and chronic toxicity to aquatic organisms (including plants) and birds (Ref. 3). Based on NMP's low persistence, low bioaccumulation, and low hazard for environmental toxicity, the magnitude of potential environmental impacts on ecological receptors are judged to be low for the environmental releases associated with the use of NMP in paint and coating removal.

2. *What is the global warming potential of NMP?* Global warming potential (GWP) measures the potency of a greenhouse gas over a specific period of time, relative to carbon

dioxide, which has a GWP of 1 regardless of the time period used. No GWP has been developed for NMP because of its very short atmospheric lifetime. Based on its very short half-life, its GWP is expected to be very low (Ref. 3).

3. *What is the ozone depletion potential of NMP?* NMP is not an ozone-depleting substance and is listed as acceptable under the Significant New Alternatives Policy (SNAP) program for degreasing and aerosols (Ref. 9).

4. *Is NMP a volatile organic compound (VOC)?* NMP is not a VOC as defined at 40 CFR 51.100(c). A VOC is any compound of carbon, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, and ammonium carbonate, which participates in atmospheric photochemical reactions.

5. *Does NMP persist in the environment and bioaccumulate?* NMP is not persistent or bioaccumulative. Biodegradation studies have consistently shown NMP to be readily biodegradable. Based on its vapor pressure, NMP released to the atmosphere is expected to exist solely in the vapor-phase. Vapor-phase NMP is degraded in air by reaction with photochemically-produced hydroxyl radicals. The half-life of this reaction is approximately 5.8 hours, assuming a hydroxyl radical concentration of 1.5×10^6 hydroxyl radicals/cm³ air over a 12-hr day. NMP in the atmosphere can be expected to dissolve into water droplets, where it will be removed by condensation or further reactions with hydroxyl radicals (Ref. 3).

When released to water, NMP is not expected to adsorb to suspended solids or sediment in the water column based upon its Koc value. Based on its low soil organic carbon partitioning coefficient ($\log K_{oc} = 0.9$), NMP is expected to possess high mobility in soil; releases of NMP to soil may volatilize from soil surfaces or migrate through soil and contaminate groundwater (Ref. 3).

EPA was not able to locate measured bioconcentration studies for NMP; however, the estimated bioaccumulation factor of 0.9 and estimated bioconcentration factor of 3.16 suggest that bioaccumulation and bioconcentration in aquatic organisms is low. Based on the available environmental fate data, NMP is expected to have low bioaccumulation potential and low persistence (Ref. 3).

XIII. Regulatory Actions Pertaining to NMP

This section summarizes current state, federal, and international regulations and restrictions on NMP, with a focus

on its use in paint and coating removal. None of these actions imposes requirements to the extent necessary so that NMP does not present the unreasonable risk described in this proposed rule.

A. Federal Actions Pertaining to NMP

While many of the statutes that EPA is charged with administering provide statutory authority to address specific sources and routes of NMP exposure, none of these can address the serious human health risks from NMP exposure that EPA is proposing to address under TSCA section 6(a).

- NMP is listed on the Toxics Release Inventory (TRI) and is therefore subject to reporting pursuant to Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) (Ref. 6).

- NMP is on The Clean Air Act (CAA) Section 111, Standards of Performance for New Stationary Sources of Air Pollutants—Equipment Leaks Chemical List (40 CFR 68.130)

- NMP is currently approved for use by EPA as a solvent and co-solvent inert ingredient in pesticide formulations for both food and non-food uses and is exempt from the requirements of a tolerance limit (Ref. 74).

In 2013, the Consumer Product Safety Commission issued a fact sheet warning the public about hazards of paint and coating removal products, including those containing NMP, and included recommendations for PPE when using products containing this chemical (Ref. 62).

B. State Actions Pertaining to NMP

Several states have taken actions to reduce or make the public aware of risks from NMP. California has set worker protection regulations that require workers to wear gloves when using NMP, and workplace to meet a permissible exposure limit of 1 ppm as an eight-hour time-weighted average (TWA) (Ref. 3). Additionally, NMP is listed as an informational candidate on California's Safer Consumer Products regulations candidate list of chemicals that exhibit a hazard trait and are on an authoritative list and is also listed on California's Proposition 65 list of chemicals known to cause cancer or birth defects or other reproductive harm (Ref. 3).

In Washington, NMP is listed as a chemical of high concern under the Children's Safe Product Act (Ref. 3). Minnesota classifies NMP as a chemical of high concern and several other states have placed NMP on similar chemical listings. Additional states have

recognized NMP as an air pollutant (Ref. 3).

C. International Actions Pertaining to NMP

NMP is currently on the candidate list of substances of very high concern for authorization in the European Union. In August 2013, the Dutch National Institute for Public Health and the Environment submitted a proposal for the restriction of NMP to the European Chemicals Agency under the Registration, Evaluation, Authorisation and Restriction regulation. The Risk Assessment Committee modified the restriction proposal and the combined opinion will be sent to the European Commission for final decision. The Risk Assessment Committee recommended using long-term exposure Derived No Effect Levels for pregnant workers (the most sensitive population) for both inhalation and dermal exposure (Ref. 3).

Other countries have also recognized the risks of NMP. When Canada conducted a categorization of the Domestic Substances List for its Chemicals Management Plan in 2006, NMP met Canada's human health categorization criteria. NMP has been the subject of a Tier II health risk assessment in Australia under that country's Inventory Multi-tiered Assessment and Prioritisation. It is currently subject to labeling and related requirements based on concern for skin, eye and respiratory irritation and for reproductive toxicity. These government assessments consider NMP to be of low environmental concern (Ref. 3). Australia concluded that further risk management is required and additional assessment (Tier III) is needed to determine if current exposure controls are adequate to protect workers and the public when NMP is used in domestic products (Ref. 3).

XIV. NMP Risk Assessment and Outreach

In 2013, EPA identified NMP in paint and coating removal as a priority for risk assessment under the TSCA Work Plan. This unit describes the development of the NMP risk assessment and supporting analysis and expert input on the uses that are the subject of this proposed rule. A more detailed discussion of the risks associated with NMP in paint and coating removal can be found in Units XVI.B.1. and XVI.D.

A. TSCA Work Plan for Chemical Assessments

Using the TSCA Work Plan chemical prioritization criteria, discussed in Unit IV.A., NMP ranked high for health hazards and exposure potential and was

included on the initial list of TSCA Work Plan chemicals for assessment. NMP appeared in the 2012 TSCA Work Plan for Chemical Assessments and in the 2014 update of the TSCA Work Plan for Chemical Assessments.

B. NMP Risk Assessment

EPA finalized a TSCA Work Plan Chemical Risk Assessment for NMP (NMP risk assessment) in 2015, following the 2013 peer review of the 2012 draft NMP risk assessment. All documents from the 2013 peer review of the draft NMP risk assessment are available in EPA Docket Number EPA-HQ-OPPT-2012-0725. The completed risk assessment is included in that docket.

The NMP risk assessment evaluated health risks to consumers, workers, and bystanders from dermal and inhalation exposures to NMP when used in paint and coating removal (Ref. 3). EPA assumes workers and consumers would be adults of both sexes 16 years and older, including pregnant women. EPA assumes bystanders in residential settings would be individuals of any age group (e.g., children, adults, and the elderly) nearby during product application. During scoping and problem formulation for the risk assessment, EPA focused on occupational and consumer paint and coating removal because of high NMP content in products and potential high exposure to workers and consumers. EPA selected these uses for the NMP risk assessment because they were expected to involve frequent or routine use of NMP in high concentrations and/or have high potential for human exposure (Ref. 3). However, this does not mean that EPA determined that other uses not included in the NMP risk assessment present low risk.

The NMP risk assessment characterized human health effects associated with paint removal with NMP. Based on the physical-chemical properties of NMP and the paint stripping use scenarios described in the assessment, EPA views dermal exposure as the predominant route of exposure to NMP during paint removal, including absorption of vapor-through-skin.

The NMP risk assessment identified developmental risks of concern following acute (short-term) and chronic (repeated) exposures for workers conducting paint removal with NMP. Specifically, these developmental effects include increased fetal resorptions (fetal death) from acute exposures and decreased fetal body weight from chronic exposures (Ref. 3). EPA identified acute risks of concern for consumers using NMP for paint and

coating removal in the more complete array of scenarios described in the supplemental analyses, which used the same modeling methods as the risk assessment (Refs. 75 and 76).

Margins of exposure (MOEs) were used in the risk assessment and supplemental analyses to estimate non-cancer risks for acute and chronic exposures. For an explanation of MOEs, see Unit IV.B. For NMP, EPA identified acute or chronic non-cancer risks of concern if the MOE estimates were less than the benchmark MOE of 30 (Ref. 3). The health endpoint used for the benchmark MOE for acute exposure to NMP is fetal death; the health endpoint used for the benchmark MOE for chronic exposure to NMP is decreased infant birth weight. These are the most sensitive adverse health effects from exposure to NMP.

The NMP risk assessment and supplemental analyses estimated acute risks of fetal death for consumers from the use of paint and coating removers containing NMP, and acute and chronic non-cancer risks of decreased infant birth weight for workers from the use of paint and coating removers containing NMP. Exposure scenarios with MOEs below the benchmark MOE present risks of concern. Typically, non-cancer adverse effects are more likely to result from exposure scenarios with MOEs multiple orders of magnitude below the benchmark MOE. For non-cancer effects, EPA estimated exposures that are significantly larger than the point of departure (Ref. 3). Specifically, the assessment identified risks of fetal death from acute exposures of:

- Four or fewer hours per day, when gloves were not used.
- Greater than 4 hours per day, and risks were not mitigated by personal protective equipment such as respirators or gloves.

The assessment identified risks of decreased infant birth weight from chronic (repeated) exposures of:

- Four or fewer hours per day, when gloves were not used.
- Greater than 4 hours per day, and risks were not mitigated by personal protective equipment such as respirators or gloves.
- Over the course of a work-week (5 days)

Given the risks identified in the NMP risk assessment, the agency undertook further analysis to consider whether that use of NMP in paint and coating removal poses an unreasonable risk.

C. Supplemental Analysis Consistent With the NMP Risk Assessment

Following the NMP risk assessment, EPA conducted supplemental analyses

to inform risk management and to expand on the consumer exposure scenarios. These analyses are consistent with the scope of the NMP risk assessment and were based on the peer-reviewed methodology used in the NMP risk assessment. They included identification of baseline and central tendency exposure scenarios, impacts of reduced NMP content in paint removers, addition of local exhaust ventilation (LEV), use of personally protective equipment (PPE), and methods of monitoring to ascertain workplace exposures. The results of EPA's analyses are available in this rulemaking docket (Refs. 37, 75, and 76). Prior to promulgation of the final rule, EPA will peer review the "Recommendation for an Existing Chemical Exposure Limit (ECEL) for Occupational Use of NMP and Workplace Air Monitoring Methods for NMP," "Respirator and Glove Specifications for Workers and Consumers Exposed to N-methylpyrrolidone (NMP) in Paint and Coating Removal and Estimated Fractions of Worker Population Vulnerable to the Acute Health Effect," and "Supplemental Consumer Exposure and Risk Estimation Technical Report for NMP in Paint and Coating Removal" (Refs. 37, 75, and 76).

D. Outreach

In addition to the consultations described in Unit XXIII., EPA initiated discussions with experts on and users of paint removers (Ref. 22). For more information on these discussions, see Unit IV.D.

XV. Regulatory Approach for NMP in Paint and Coating Removal

A. TSCA Section 6(a) Unreasonable Risk Analysis

Under TSCA section 6(a), if the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to EPA's risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance no longer presents such risk.

The TSCA section 6(a) requirements can include one or more, or a combination of, the following actions:

- Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of such substances (§ 6(a)(1)).

- Prohibit or otherwise restrict the manufacturing, processing, or distribution in commerce of such substances for particular uses or for uses in excess of a specified concentration (§ 6(a)(2)).

- Require minimum warning labels and instructions (§ 6(a)(3)).
- Require recordkeeping or testing (§ 6(a)(4)).
- Prohibit or regulate any manner or method of commercial use (§ 6(a)(5)).
- Prohibit or otherwise regulate any manner or method of disposal (§ 6(a)(6)).
- Direct manufacturers and processors to give notice of the determination to distributors and the public and replace or repurchase substances (§ 6(a)(7)).

EPA analyzed a wide range of regulatory options under section 6(a) for each use in order to select the proposed regulatory approach (Refs. 23 and 24). For each use, EPA considered whether a regulatory option (or combination of options) would address the unreasonable risk so that it no longer presents such risk. To do so, EPA initially analyzed whether the regulatory options could reduce risks to levels below those of concern, based on EPA's technical analysis of exposure scenarios.

After the technical analysis, which represents EPA's assessment of the potential for the regulatory options to achieve risk benchmarks based on analysis of exposure scenarios, EPA then considered how reliably the regulatory options would actually reach these benchmarks. For the purposes of this proposal, EPA found that an option addressed the risk so that it was no longer unreasonable if the option could achieve the benchmark MOE or cancer benchmark for the most sensitive endpoint. In considering whether a regulatory option would ensure the chemical no longer presents the unreasonable risk, EPA considered whether the option could be realistically implemented or whether there were practical limitations on how well the option would mitigate the risks in relation to the benchmarks, as well as whether the option's protectiveness was impacted by environmental justice or children's health concerns.

B. TSCA Section 6(c)(2) Considerations

As noted previously, TSCA section 6(c)(2) requires EPA to consider and publish a statement based on reasonably available information with respect to the:

- Health effects of the chemical substance or mixture (in this case, NMP) and the magnitude of human exposure to NMP;

- Environmental effects of NMP and the magnitude of exposure of the environment to NMP;

- Benefits of NMP for various uses;
- Reasonably ascertainable economic consequences of the rule, including: The likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; the costs and benefits of the proposed and final rule and of the one or more primary alternatives that EPA considered; and the cost-effectiveness of the proposed rule and of the one or more primary alternatives that EPA considered.

In addition, in selecting among prohibitions and other restrictions available under TSCA section 6(a), EPA must factor in, to the extent practicable, these considerations. Further, in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, EPA must also consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

EPA's analysis of health effects and magnitude of exposure to NMP can be found in Units XIV.B., XVI.B. and XVI.C., which discuss the NMP risk assessment and EPA's regulatory assessment of the use of NMP in paint and coating removal. A discussion of the environmental effects of NMP is in Unit XII.D.

With respect to the costs and benefits of this proposal and the alternatives EPA considered, as well as the impacts on small businesses, the full analysis is presented in the Economic Analysis (Ref. 4). The regulatory options and consideration of TSCA section 6(c)(2) factors are discussed in more detail in Unit V for methylene chloride in paint and coating removal and in Unit XV. for NMP in paint and coating removal.

To the extent information was reasonably available, EPA considered the benefits realized from risk reductions (including monetized benefits, non-monetized quantified benefits, and qualitative benefits), offsets to benefits from countervailing risks (e.g., residual risk risks from chemical substitutions and alternative practices), the relative risk for environmental justice populations and children and other potentially exposed or susceptible subpopulations (as compared to the general population), the cost of regulatory requirements for

the various options, and the cost effectiveness of the proposed action and the one or more primary alternate regulatory options. A discussion of the benefits EPA considered can be found in Units XVI.C. and XVII.B. as well as in the Economic Analysis (Ref. 4).

EPA considered the estimated costs to regulated entities as well as the cost to administer and enforce the options. For example, an option that includes use of a respirator would include inspections to evaluate compliance with all elements of a respiratory protection program (Ref. 25). In understanding the burden, EPA took into account the reasonably available information about the functionality and performance efficacy of the regulatory options and the ability to implement the use of chemical substitutes or other alternatives. Reasonably available information included the existence of other Federal, state, or international regulatory requirements associated with each of the regulatory options as well as the commercial history for the options. A discussion of the costs EPA considered and a discussion of the cost-effectiveness of the proposal and the primary alternate regulatory options that EPA considered is in Units XVI.E. and XVII.A. In addition, a discussion of the impacts on small businesses is in Unit XXIII. and in the Initial Regulatory Flexibility Analysis and Report from the Small Business Advocacy Review Panel (Refs. 26 and 27).

With respect to the anticipated effects of this proposal on the national economy, EPA considered the number of businesses and workers that would be affected and the costs and benefits to those businesses and workers. In addition, EPA considered the employment impacts of this proposal, as discussed in the Economic Analysis (Ref. 4). EPA found that the direction of change in employment is uncertain, but EPA expects the short term and longer-term employment effects to be small.

The benefits of NMP in paint and coating removal are discussed in Unit XVI.A., along with the availability of alternatives. The dates that the proposed restrictions would take effect are discussed in Unit XX. The availability of alternatives to methylene chloride in paint and coating removal on those dates is discussed in Unit XVI.D.

Finally, with respect to this proposal's effect on technological innovation, EPA expects this action to spur innovation, not hinder it. An impending prohibition on this use of NMP is likely to increase demand for alternatives, which EPA expects would result in the development of new alternatives. See

section 9.3 in the Economic Analysis (Ref. 4).

C. Regulatory Options Receiving Limited Evaluation

EPA analyzed a wide range of regulatory options under TSCA section 6(a). There are a range of regulatory options under TSCA; only those pertaining to these risks were evaluated in detail. An overview of the regulatory options not evaluated in detail follows.

First, EPA reasoned that the TSCA section 6(a)(1) regulatory option to prohibit the manufacture, processing or distribution in commerce of NMP or limit the amount of NMP which may be manufactured, processed or distributed in commerce is not applicable because EPA is not proposing to ban or limit the manufacture, processing or distribution in commerce of NMP for uses other than paint and coating removal.

In addition, EPA reasoned that the TSCA section 6(a)(6) regulatory option to prohibit or otherwise regulate any manner or method of disposal of the chemical is not applicable since EPA did not assess risks associated with NMP disposal.

Another option EPA evaluated would be to only require warning labels and instructions on paint and coating removal products containing NMP, pursuant to section 6(a)(3) (Ref. 30). EPA reasoned that warning labels and instructions alone could not mitigate the risks as necessary so that NMP no longer presents an unreasonable risk (either to users in the general population or to users who are women of childbearing age). For a further discussion of why EPA believes that labeling alone will not effectively mitigate the unreasonable risks, see Unit V.C. EPA's general observations about labeling, described in that unit, are also applicable in the case of NMP. Specifically regarding NMP, effective personal protection resulting in risk reduction would require not only the appropriate donning and doffing of specialized gloves that are not easily available to consumers, but also identification of which type of glove is protective against particular formulations of paint and coating removal products containing NMP (Ref. 75). Any labeling aiming to reduce risks to consumer or commercial users of these products would need to sufficiently and clearly explain this, and would still leave the user with the problem of obtaining and properly using the appropriate gloves and (in the case of commercial users or consumers using the product for several days at a time) the appropriate respirator. With respect to consumer risks in particular, a label on a product that is easily available to

consumers, that directs the user to obtain and use safety equipment that is not easily available to consumers, is especially unlikely to be correctly followed.

A regulatory option receiving limited evaluation was a training and certification program for commercial paint and coating removers, similar to the certification process required under EPA's Lead Renovation, Repair, and Painting Rule (73 FR 21692, April 22, 2008). This option was recommended by the small entity representatives as part of the SBAR process (Ref. 27). EPA considered this option as an approach to reducing risks from NMP in paint and coating removal. However, unlike the process for training and certification of commercial workers required under the Lead Renovation, Repair, and Paint Rule, effective risk reduction from commercial use of NMP for paint and coating removal would require additional regulation of distributors of these products. When considering this approach, given the Agency's experience with the training and certification program under the Lead Renovation, Repair, and Paint Rule, EPA viewed the costs and challenges involved in regulating distributors and ensuring that only trained and certified commercial users are able to access these paint and coating removal products as a significant limitation for this approach. EPA seeks public comment on the feasibility of such a program and its potential to reduce risks of exposure to NMP for workers so that those risks are no longer unreasonable.

XVI. Regulatory Assessment of NMP in Paint and Coating Removal

This unit describes the current use of NMP in paint and coating removal, the unreasonable risks presented by this use, and how EPA identified which regulatory options reduce the risks so that they are no longer unreasonable.

A. NMP in Paint and Coating Removal

As described previously in Units I.A. and VI.B., paint and coating removal, also referred to as paint stripping, is the process of removing paint or other coatings from a surface of a substrate, such as an object or structure (Ref. 3). More information on specific techniques for paint removal in each industry and by consumers are in the NMP risk assessment and supplemental materials (Refs. 3, 75, and 76).

Chemical products for paint and coating removal are used across several industries as well as by consumers or hobbyists, and products intended for one type of use—such as aircraft renovation—have been used in other

situations, such as bathtub refinishing (Refs. 11, 32, and 33). There are no restrictions on using products intended for one specific type of paint removal project in a different setting. Additionally, consumers face no restrictions when using products intended for or marketed to professional users.

EPA has identified 64 different products for paint and coating removal that contain NMP, formulated by 21 different firms. This is approximately 59% of the total number of paint and coating removal products EPA identified (109 products) (Ref. 34). Though the number of workers and consumers exposed to NMP during paint and coating removal is uncertain, EPA has several estimates based on industry data. As described in Unit VI.B., commercial uses include automotive refinishing, furniture refinishing, art conservation and restoration, pleasure craft building and repair, aircraft paint removal, graffiti removal, bathtub refinishing, and renovations in residences or other buildings. As described in more detail in the Economic Analysis, EPA estimates that 30,300 workers annually are exposed to NMP during paint and coating removal activities (Ref. 4).

Consumer use of NMP in paint and coating removal is similar to commercial use, but occurs in consumer settings, such as homes, workshops, basements, garages, and outdoors. Paint and coating removal products containing NMP are the same as those used in many commercial settings, and the process consumers use is similar to commercial methods of brushing or spraying on the paint and coating removal product, allowing time to pass for the product to penetrate the coating, and then scraping the loosened coating from the surface.

When consumers interested in DIY paint and coating removal choose to use chemical paint removers (Ref. 77), they frequently receive advice to use products that contain NMP, without any reference to the risks presented by NMP or even solvents in general (Refs. 78 and 79). Manufacturers and retailers of paint and coating removal products containing NMP frequently sell them to consumers in small containers with marketing language or labeling that state they are biodegradable, 'plant-based', or contain 'no harsh fumes' and implies they are 'green' or 'safe' (Ref. 35). Products containing NMP are not required to be labeled with that information or any information about personal protection or risk reduction. These products are frequently sold at home improvement retailers or

automotive supply stores that sell products to consumers as well as professional users (Ref. 35). Additionally, due to the wide availability of products available on the Internet and through various additional suppliers that serve commercial and consumer customers, consumers are able to purchase a variety of paint and coating removal products containing NMP. EPA estimates that the majority of users of paint and coating removal products containing NMP are consumers, rather than occupational users. EPA estimates that approximately 732,000 consumers annually use paint removal products containing NMP (Ref. 4).

B. Analysis of Regulatory Options

In this section, EPA explains how it evaluated whether the regulatory options considered would address the unreasonable risks presented by the use of NMP in paint and coating removal. First, EPA characterizes the unreasonable risks associated with the current use of NMP in paint and coating removal. Then, EPA describes its initial analysis of which regulatory options have the potential to achieve non-cancer benchmarks. Lastly, this section evaluates how well those regulatory options would address the unreasonable risk in practice.

1. Risks associated with the current use. a. General impacts. The NMP risk assessment and additional supplemental analyses identified acute and chronic risks for consumers and commercial users of paint and coating removal products containing NMP following exposure through dermal contact, inhalation, and vapor-through-skin (Refs. 3, 75, and 76). EPA did not find risks for occupational or residential bystanders (individuals not using the paint and coating remover, but near someone who is). EPA estimates, having refined the numbers since the risk assessment that, annually, there are approximately 30,300 workers at 4,300 commercial operations conducting paint and coating removal with NMP, and approximately 732,000 consumers who use paint and coating removal products containing NMP each year (Ref. 4).

b. Impacts on minority and other populations. While all consumers and workers using paint and coating removal products containing NMP would benefit from risk reduction, some populations are currently at disproportionate risk for the health effects associated with NMP in paint and coating removal. These are the same populations at disproportionate risk for the health effects associated with methylene chloride in paint and coating

removal, and are described in Unit VI.C.1.b.

c. Impacts on children. EPA has concerns for effects on the developing fetus from acute and chronic worker and consumer maternal exposures to NMP. The risk estimates focus on the most susceptible life stages, which for NMP are women of childbearing age and their developing fetus. However, because women may not know that they are pregnant (Refs. 80 and 81) and short-term exposure to NMP may adversely impact fetal development during a single day or single week of exposure, the life stages of concern for risk assessment include all women of childbearing age (*i.e.*, women between the ages of 16 and 49 years) and the developing fetus. The impacts to children derive from the pre-natal or maternal exposure; these impacts include decreased fetal weight, decreased birth (post-natal) weight, and fetal death. Details on the impacts of these health effects are described in Unit XVI.C.

EPA assumed that consumer and commercial users would generally be adults of both sexes (16 years old and older, including women of childbearing age), although exposures by teenagers and even younger individuals may be possible in consumer settings. However, risk estimates focused on the most susceptible life stage, which are pregnant women and their developing fetus, because developmental toxicity is one of the most sensitive health effects associated with NMP exposure (Ref. 3).

d. Exposures for this use. Exposures assessed for this in the risk assessment and supplemental analyses use include acute and chronic (or repeat-dose) exposures by commercial workers and acute exposures by consumers engaging in paint and coating removal with NMP, as described in the NMP risk assessment and additional analyses (Refs. 3 and 76). The exposure pathways of interest included dermal contact, vapor-through-skin, and inhalation. Acute scenarios assumed one day, or up to eight hours, of exposure; chronic, or repeat-dose, scenarios assumed five days of exposure per week, or one work week, with up to eight hours per day of exposure (Refs. 3 and 76).

For exposures in commercial settings, EPA assessed exposure scenarios under which the worker was presumed to work on either an indoor project (such as work by professional contractors, furniture stripping and other settings) or an outdoor or semi-enclosed space (such as graffiti removal on the exterior of a building, outdoor escalator, or elevator).

In the NMP risk assessment, EPA developed six occupational user

exposure scenarios for assessment. The following factors were considered in developing the exposure scenarios (Ref. 3):

- The weight fraction of NMP in the paint and coating removal product;
- Skin surface area of the worker in contact with the paint removal product; and
- Duration of contact (in hours) with the paint removal product.

Within each of the six workplace scenarios, EPA evaluated five permutations, by modifying the parameters of the scenario to include different combinations of personal protective equipment (PPE). These permutations were (1) respirator with assigned protection factor (APF) of 10, and gloves; (2) respirator APF 10 only; (3) gloves only; (4) neither respirator nor gloves; and (5) not directly using the product (nearby worker) (Ref. 3).

EPA used air concentration data and estimates found in literature sources to serve as inhalation exposure concentration inputs to the physiologically-based pharmacokinetic modeling for occupational exposures to NMP. This modeling was used to derive internal dose estimates for acute and chronic occupational exposures, and predicted absorption of liquid or vapor by the individual in the scenario when using the paint and coating removal product containing NMP (Ref. 3).

For consumer exposures, EPA assessed exposure scenarios under which the individual was presumed to work on one of several types of paint and coating removal projects (table and chairs, chest of drawers, or bathtub), with inputs reflecting that consumers do not reliably use personal protective equipment (effective gloves) or have access to engineering controls (e.g., ventilation fan). In each scenario, the consumer would be exposed via inhalation, dermal contact, and vapor-through-skin (Ref. 3).

EPA developed seven consumer exposure scenarios for the assessment. Similar to the worker exposure assessment, the following factors were considered in developing the exposure scenarios (Ref. 3):

- The type of application (*i.e.*, brush-on or spray-on), weight fraction of NMP in the paint and coating removal product, application rate by the user, surface area of object from which the paint or coating was being removed, and emission rate of the chemical, which can affect the amount of NMP that ultimately is released to the indoor environment;
- The location where the product is applied, which relates to exposure

factors such as the room volume and its air exchange rate with outdoor air;

- The house volume and air exchange rate, for reasons similar to those for the product use location; and
- Precautionary behaviors such as opening windows in the application room, the user leaving the application room during the wait period, related changes to the air exchange rates, and the proximity of the user to the source of NMP emissions.

In the absence of representative air monitoring data for consumers using paint and coating removal products containing NMP, EPA used the Multi-Chamber Concentration and Exposure Model to estimate consumer inhalation exposure concentrations. The predicted air concentrations from the exposure modeling for users and non-users were inputs to the physiologically-based pharmacokinetic modeling software and used to define consumers' moment-by-moment air concentration inhaled and in contact with unobstructed skin. The parameters and data sources for the model are described in the NMP risk assessment (Ref. 3).

EPA's estimates of the exposures individuals experienced during the acute and chronic scenarios of commercial or consumer use of paint and coating removal products containing NMP were used to assess the risks of these uses of NMP. The full exposure estimates and risk findings are described in the NMP risk assessment; risk findings are also summarized in Unit XVI.B.1.a.

In addition to estimating likely exposures under current use patterns, for both commercial and consumer users, EPA assessed a number of exposure scenarios associated with risk reduction options in order to identify variations in NMP exposure. All variations in the scenarios were evaluated with exposure parameters that were modified to reflect either a reasonable worst-case scenario (also called the baseline) or a scenario in which exposures were moderated by several factors (also called the central tendency scenario). The risk reduction options that were varied between scenarios included material substitution, duration of use, engineering controls, and use of PPE, as well as combinations of these options (Refs. 37, 75, and 76), as follows:

- The material substitution scenarios involved reducing the concentration of NMP in the paint and coating removal product, with concentrations varying from 5, 10, 25, 30, 35, 40, 62.5 and 100% by weight in the product.
- The duration of use scenarios involved, for consumers, variations in

the type of activity during which paint removal would be conducted (for example, 7 hours of exposure to NMP when removing paint from a table and 8 chairs; 0.5 hours of exposure to NMP when removing paint from a coffee table). For commercial users, duration of exposure to NMP in paint and coating removers was assessed as job time during a work day (1 to 8 hours).

- Under the PPE risk reduction option exposure scenarios, EPA evaluated consumers wearing specialized gloves, and workers wearing specialized gloves and/or respirators with APF 10.

- For the engineering controls risk reduction option exposure scenarios, EPA evaluated using LEV to improve ventilation near the activity of workers in furniture refinishing operations, with an assumed 90% reduction in exposure levels.

Additionally, EPA evaluated combinations of the options. For consumers, this included material substitution, duration of exposure, and PPE; for workers, this included material substitution, duration of exposure, PPE, and LEV. Engineering controls are not assumed to be practical for consumers as a method of exposure reduction. Overall, EPA evaluated dozens of distinct exposure scenarios for both consumer and commercial paint and coating removal with NMP.

e. Specific risks for this use. The assessment of acute risks used developmental toxicity data to evaluate the acute risks for paint and coating removal with NMP. EPA based its assessment of acute risks on the endpoint most protective of health (*i.e.*, fetal death (Ref. 3)), representing the most sensitive human life stage (*i.e.*, women of childbearing age (greater than 16 years) and the fetus). Because fetal effects were selected as key endpoints, risks were calculated for pregnant women and women of childbearing age who may become pregnant. As described in the risk assessment, exposures that do not result in risks of concern for these particular lifestages are also found to be protective of children and adult males. A risk of concern was identified if the MOE estimate was less than the benchmark MOE of 30 (Ref. 3).

In the risk assessment and supplemental analyses, EPA evaluated risks for fetal death from dermal contact, inhalation, and vapor-through-skin for all consumer, occupational, and bystander exposure scenarios of paint and coating removal with NMP. No risks were identified for occupational or residential bystanders. Acute risks of fetal death were identified for the

consumer and commercial users of NMP for paint and coating removal in several, although not all, scenarios. To identify what, if any, risks may be present for consumers in different scenarios, EPA conducted additional analyses consistent with the risk assessment to provide an expanded understanding of consumer exposures (Ref. 76). Additionally, it appears that consumers could engage in patterns of use comparable to worker exposures that present risk; for example, any consumers engaging in paint and coating removal with NMP for longer than four hours in one day could be subject to the acute occupational risks identified (Ref. 3).

For commercial users, the occupational scenarios in which acute risks were identified included four hours of paint removal in one day with no gloves, with or without a respirator, indoors or outdoors, assuming mid-range of the exposure parameters described earlier, such as concentration of NMP in the product (MOEs range from 12 to 15); and four hours of paint removal in one day with or without a respirator and gloves, indoors or outdoors, assuming the higher exposure parameters described earlier (MOEs range from 0.7 to 11.8) (Ref. 3). These risks are present whether the worker is indoors or outdoors, and may be present even in the presence of PPE or ventilation, depending on the duration of use and the concentration of NMP in the product. Therefore, EPA's proposed determination is that acute NMP exposures during paint and coating removal present unreasonable risks.

EPA also assessed risks of chronic exposure to NMP by commercial users, with a short-term chronic exposure that can be defined as a repeat-dose scenario in which the individual is exposed over the course of a work week, rather than over a lifetime. This chronic assessment used decreased fetal body weight as the critical endpoint. EPA assessed risks for decreased birth weight for occupational and bystander exposure scenarios of paint and coating removal with NMP. In the risk assessment, a risk of concern was identified if the MOE estimate was less than the benchmark MOE of 30 for decreased birth weight (Ref. 3).

Risk of decreased birth weight was identified for commercial users of NMP for paint and coating removal in several scenarios, including four hours of paint removal during each day in a work week without gloves, with or without a respirator, indoors or outdoors, assuming the mid-range of the exposure parameters described earlier, such as concentration of NMP in the product (MOEs range from 5.4 to 6.1); and eight

hours of paint removal during each day in a work week, with or without a respirator or gloves, indoors or outdoors, assuming the higher exposure parameters described earlier (MOEs range from 0.1 to 3.2) (Ref. 3). Though no risks were identified for occupational bystanders, for workers, these risks are present whether the worker is indoors or outdoors, and may be present even if PPE or ventilation is used, depending on the duration of use and the concentration of NMP in the product (Ref. 3). In some scenarios, this equates to estimated exposures that are more than 10 times greater than those that would produce the benchmark MOE for this endpoint, which assesses risks for fetal death and decreased birth weight. Therefore, EPA's proposed determination is that chronic NMP exposures during paint and coating removal also present unreasonable risks.

The SBAR Panel convened in support of this action heard from several SERs who expressed concerns about the underlying NMP risk assessment (Ref. 27). Many of the concerns expressed by these SERs were already expressed in the public comments and the peer review comments on the NMP risk assessment. The Summary of External Peer Review and Public Comments and Disposition document in the risk assessment docket (EPA-HQ-OPPT-2012-0725) explains how EPA responded to the comments received.

2. Initial analysis of potential regulatory options. Having determined that the risks from NMP in paint and coating removal were unreasonable, EPA evaluated how regulatory options under section 6(a) might reduce the risks so that they are no longer unreasonable.

The results of EPA's assessment of consumer uses, exposures, and risks indicate that regulatory options for consumer uses such as reducing the concentration of NMP in a product or advising the use of specialized gloves or respirators individually could not achieve the target MOE benchmarks for acute exposures (Ref. 76). Similarly, the results of EPA's evaluation indicate that regulatory options for occupational exposures such as reducing the concentration of NMP in products used for paint and coating removal and using local exhaust ventilation to improve ventilation, in the absence of PPE, could not achieve the target MOE benchmarks for non-cancer endpoints for acute and chronic exposures (Refs. 37 and 75). The results also demonstrate that all risk reduction options meeting the benchmark MOEs for NMP in paint and coating removal require the use of specialized gloves, whether used alone

or in conjunction with additional levels of respiratory protection such as a respirator of APF 10 or the use of an air exposure limit, even when the concentration of NMP in a product was limited to 25 percent. Therefore, EPA found setting a maximum concentration of NMP in products under TSCA section 6(a)(2) alone would not reduce exposures to levels at which risks would be at or below the risk benchmarks. Further, EPA's analysis found that even with specialized gloves and a respirator, workers would be at risk of NMP exposure if they used products with more than 25 percent NMP. Additional exposure level estimates for various scenarios are available in the supplemental analyses, which also document options that did not meet the risk benchmarks and which do not, for purposes of this proposal, address the identified unreasonable risks (Refs. 37, 75, and 76).

3. Assessment of whether regulatory options address the identified unreasonable risks to the extent necessary so that NMP in paint and coating removal no longer presents such risk. As discussed earlier, EPA considered a number of regulatory options under TSCA section 6(a) for NMP in paint and coating removal, which are reflected in EPA's supporting analysis (Ref. 30). In assessing these options, EPA considered a wide range of exposure scenarios (Refs. 75 and 76). These include both baseline and risk reduction scenarios involving varying factors such as concentration of NMP in paint and coating removal products, LEV use, respirator and glove use, and duration of use. As part of this analysis, EPA considered the impacts of regulatory options on consumer users and commercial users separately. However, EPA is proposing to address the use of NMP in paint and coating removal as a whole rather than as separate consumer and commercial uses. As described earlier in Unit XVI.A., paint and coating removal products containing NMP frequently are available in the same distribution channels to consumers and professional users. Products are marketed for a variety of projects, and cannot be straightforwardly restricted to a single type of project or user.

The Agency examined two main alternative approaches to addressing the unreasonable risk from NMP in paint and coating removal under current conditions of use by consumers and commercial users. These two approaches are the supply chain approach (and its two primary variations) and the reformulation, labeling, and PPE approach. These

regulatory alternatives are the options that have the potential to address the unreasonable risks presented by NMP when used for paint and coating removal by consumers, commercial users, or for both. The two options and their variations are described below.

(a) The first co-proposed approach (option 1) is a supply-chain approach, which would include prohibiting the manufacturing, processing, and distribution in commerce of NMP for paint and coating removal under TSCA section 6(a)(2) except for certain uses critical to national security; prohibiting the commercial use of NMP in paint and coating removal under TSCA section 6(a)(5) except for certain uses critical to national security; requiring that all paint and coating removers containing NMP be distributed in containers with volumes no less than 5 gallons under TSCA section 6(a)(2); requiring downstream notification when distributing NMP for other uses under TSCA section 6(a)(3); and limited recordkeeping under TSCA section 6(a)(4);

(b) Variations on such a supply-chain approach, such as just prohibiting the manufacturing, processing, and distribution in commerce of NMP for paint and coating removal under TSCA section 6(a)(2) for consumer and commercial use or just prohibiting the commercial use of NMP for paint and coating removal under TSCA section 6(a)(5);

(c) Additional variations on such a supply-chain approach, such as prohibiting the manufacturing, processing, and distribution in commerce of NMP for paint and coating removal under TSCA section 6(a)(2) for consumer and commercial use and requiring downstream notification (e.g., via SDS) when distributing NMP for other uses under TSCA section 6(a)(3); and

(d) The second co-proposed approach (option 2), a reformulation, PPE, and labeling approach, which would require (1) product reformulation to limit the concentration of NMP in paint and coating removal products under section 6(a)(2); (2) testing of product formulations to identify specialized gloves that provide protection for users and relevant recordkeeping under section 6(a)(4); (3) relabeling of products intended for consumer use to provide additional information to consumers under section 6(a)(3); (4) an occupational dermal and respiratory protection program for commercial use of NMP in paint and coating removal, including a requirement for hazard communication, specialized gloves and an air exposure limit or respirator under

section 6(a)(5); (5) a prohibition on use of NMP above a concentration of 35 percent for commercial paint and coating removal under 6(a)(5); (6) downstream notification when distributing NMP for other uses under TSCA section 6(a)(3); and (7) limited recordkeeping under TSCA section 6(a)(4). Under this co-proposed approach, EPA is not proposing an exemption for coating removal uses identified as critical to national security because paint and coating removal products containing NMP would continue to be available for these national security uses under this option, even without establishing a national security exemption.

A discussion of the regulatory options that could reach the risk benchmarks for consumer use, commercial use, or both is in this unit, along with EPA's evaluation of how well those regulatory options would address the unreasonable risks EPA has identified. EPA requests comment on the two co-proposed regulatory options addressing the use of NMP in paint and coating removal, particularly with regard to the advantages and disadvantages of the different approaches, their potential associated benefits, and whether such approaches would be consistent with EPA's obligation under TSCA to address risks identified as unreasonable.

a. First co-proposed approach: Supply-chain (option 1). The proposed regulatory approach for NMP in consumer and commercial paint and coating removal would prohibit the manufacturing, processing, and distribution in commerce of NMP for consumer and commercial paint and coating removal under TSCA section 6(a)(2), except for certain uses critical to national security; would prohibit the commercial use of NMP for paint and coating removal under TSCA section 6(a)(5), except for certain uses critical to national security; would require any remaining paint and coating removal products containing NMP to be distributed in containers with a volume no less than 5 gallons, under TSCA section 6(a)(2); would require manufacturers, processors, and distributors of NMP to provide downstream notification of the prohibitions under TSCA section 6(a)(3), and would require recordkeeping relevant to these prohibitions under TSCA section 6(a)(4).

As discussed earlier, a risk of concern was identified if the MOE estimate was less than the benchmark MOE of 30. As described in Unit XVI.B.1., the baseline risks for workers and consumers from paint and coating removal with NMP

were identified as ranging from two to 10 times below the benchmark MOEs of 30 for fetal death (the acute health impact) or low birth weight (the chronic health impact). Under this proposed option, exposures to NMP during paint and coating removal would be eliminated for consumers and workers. As a result, acute and chronic risks would be eliminated.

The first co-proposed approach would ensure that workers and consumers from the general population (as well as workers and consumers who are women of childbearing age) are no longer exposed to unreasonable risks from NMP exposure during paint and coating removal. Prohibiting the manufacturing, processing and distribution in commerce of NMP for paint and coating removal would minimize the overall availability of NMP for paint and coating removal. Importantly, this proposed regulation is protective of consumer users. EPA cannot regulate consumer use under TSCA section 6(a)(5). The prohibition of the commercial use of NMP for paint and coating removal would reduce commercial demand for NMP paint and coating removal products, reduce the likelihood that other types of products formulated with NMP would be used for paint and coating removal, and significantly reduce the potential for consumer use of commercial paint and coating removal products containing NMP. Workers would not be exposed to NMP for paint and coating removal, except for those uses that are proposed to be exempt because they are critical to national security. The risk to consumers would be minimized because commercial paint and coating removal products containing NMP would not be available outside of those directly supplied to DOD for uses identified as critical to national security.

The downstream notification of these restrictions ensures that processors and distributors are aware of the manufacturing, processing, distribution in commerce and use restrictions for NMP in paint and coating removal, and enhances the likelihood that the risks associated with this use of NMP are addressed throughout the supply chain. Downstream notification also streamlines compliance and enhances enforcement, since compliance is improved when rules are clearly and simply communicated (Ref. 39). This integrated supply chain proposed approach completely mitigates the risk to consumers and workers from NMP in paint and coating removal.

b. Options that are variations of elements of the co-proposed supply-chain approach (option 2). One

variation of the proposed approach would be to prohibit manufacture, processing, and distribution in commerce of NMP for consumer and commercial paint removal for the uses proposed for regulation this without the prohibition on commercial use of NMP for paint and coating removal and without the downstream notification of any prohibitions. Without the accompanying prohibition on commercial use and downstream notification that is included in the proposed supply chain approach, this option would leave open the likelihood that commercial and consumer users could obtain NMP (which would continue to be available for other uses, such as degreasing or solvent purposes) and use it for paint and coating removal.

Without downstream notification, unsophisticated purchasers in particular are likely to be unfamiliar with the prohibitions regarding this use and mistakenly use NMP for paint and coating removal, thereby exposing themselves and bystanders to unreasonable risks. Thus, under these variations, EPA anticipates that many users would not actually realize the risk benchmarks. Therefore, these variations fail to protect against the unreasonable risks. EPA requests comment on its consideration of and conclusions regarding this option.

Another regulatory option that EPA considered was to prohibit only the commercial use of NMP for paint and coating removal. This approach would reduce risks for commercial settings, but it would not reduce risks to consumers so that they are no longer unreasonable. By prohibiting use in the commercial sector alone, without a prohibition on the manufacture, processing, and distribution in commerce of paint and coating removal products containing NMP for consumer and commercial use, this approach would not address consumer risks as distributors of paint and coating removal products containing NMP could continue to distribute to consumers NMP marked as a paint and coating remover, including products labeled and marketed as "professional strength" or "commercial grade" products. Since it is foreseeable that consumers would continue to purchase products labeled and marketed in this fashion, consumers would continue to be exposed far above the health benchmarks and would not be protected from the unreasonable risks posed by NMP. EPA requests comment on its consideration of and conclusions regarding this option.

c. Prohibit the manufacturing, processing, and distribution in commerce of NMP for consumer paint

and coating removal under TSCA section 6(a)(2) or prohibit the manufacturing, processing, and distribution in commerce of NMP for consumer paint and coating removal under TSCA section 6(a)(2) and require downstream notification when distributing NMP for other uses under TSCA section 6(a)(3). EPA considered prohibiting the manufacturing, processing, and distribution in commerce of NMP only for consumer paint and coating removal, including an option with a requirement for downstream notification of such prohibition. If such a prohibition were effective, this option would mitigate the risks to consumers from NMP in paint and coating removal. However, consumers can easily obtain products labeled for commercial use. Indeed, for many consumers, identifying a product as being for commercial use may imply greater efficacy. Coupled with the fact that many products identified as commercial or professional are readily obtainable in a variety of venues (e.g., the Internet, general retailers, and specialty stores, such as automotive stores), EPA does not find that this option would protect consumers. In addition, this option alone would not address the risks to workers from NMP in paint and coating removal. EPA requests comment on its consideration of and conclusions regarding this option.

d. Second co-proposed approach: Reformulation, labeling, and PPE approach. EPA is co-proposing two regulatory options for NMP. The second co-proposed option would involve product reformulation, glove testing, labeling, and worker protection. This approach has the potential to reduce the risks presented by NMP during paint and coating removal. EPA currently believes this potential is greater for workers than for consumers. potential is greater for workers than for consumers. EPA is considering this co-proposed regulatory option, and may adopt it in the final rule; the Agency therefore solicits comment on the option, as described below.

i. Description of second co-proposed approach. The second co-proposed approach for NMP in commercial and consumer paint and coating removal requires actions from commercial users and product formulators. Under this approach, under section 6(a)(5), commercial users of NMP for paint and coating removal would be required to establish a worker protection program for dermal and respiratory protection, including hazard communication, training, and requirements that workers wear clothing covering most of the

body, i.e., impervious long pants and shirts with long sleeves, use gloves specified by product formulators (described under formulator requirements below) and a respirator with APF 10, with an alternative air exposure limit of 5 ppm achieved through engineering controls or ventilation. Also under this approach, formulators of products for either commercial or consumer use would be required to (1) Reformulate products such that paint and coating removal products containing NMP do not exceed a maximum of 35 percent NMP by weight in product formulations under section 6(a)(2) (except for product formulations destined to be used by DOD or its contractors performing work only for DOD projects identified in Unit XVIII.); (2) Test gloves for the product formulations being processed and distributed in commerce to identify specialized gloves that provide protection for users under section 6(a)(4); (3) Label products with information for consumers about reducing risks when using the products, including identifying which specialized gloves provide protection against their specific formulation; and (4) Provide information for commercial users about reducing risks when using the product, via product labels, SDS, and other methods of hazard communication. Variations of more than 1% in any component of a paint and coating removal product containing NMP would be considered a separate formulation.

Specifically, for labeling targeted to consumers under section 6(a)(3) formulators would be required to provide the following information to consumers on product labels: A warning that irreversible health effects such as fetal death may occur as a result of using the product; instructions to not use the product without a new (i.e., replaced each time the product is used) pair of the formulation-specific gloves identified on the label; instructions to either use the product outdoors or to adequately ventilate the workspace by opening windows and adding fans; instructions to not spray-apply the product; instructions to wear clothing that covers exposed skin; and instructions to use a respirator of APF 10, such as a NIOSH-certified air-purifying elastomeric half-mask respirator equipped with N100, R100, or P100 filters. The labeling requirement would also include appropriate placement and font size for the label information.

EPA requests comments on the components of this co-proposal, particularly on the maximum percent concentration that would be permitted

in paint and coating removal products containing NMP. EPA notes that the air exposure limit described earlier correlates with the concentration of NMP in the product, and would necessarily change with any corresponding change in NMP concentration (Ref. 37). EPA's calculations for the estimated exposures from products at various concentrations is in Ref. 75.

EPA also requests comment on the scientific and technical support used for development of the 5 ppm air exposure limit (Ref. 37) for NMP and the feasibility of implementing and enforcing this performance-based approach. Additionally, EPA is requesting comment on the cost to achieve reduced exposures in the workplace or to transition to alternative chemicals or technologies. EPA is requesting comment on whether this alternate option of allowing industrial use at specified exposure levels and with appropriate personal protective equipment should be adopted. Specifically, EPA seeks information on whether this alternative approach would incentivize industry to eliminate NMP use in paint and coating removal wherever technically feasible while minimizing disruptive impacts to those processes where technically feasible substitutes are currently unavailable. EPA also requests comment on whether there should be a phase-in period, *e.g.*, 3 years for formulators to develop the new formulations of products containing NMP at 35 percent. This would also allow users to make the transition. EPA also requests comment on whether the 35% limit on the concentration of NMP in the formulation is appropriate; whether EPA should specify a higher, lower or no limit; and why. Finally, EPA requests comment on the specific regulatory requirements for glove testing and for personal protective equipment programs. EPA has identified two ASTM International standards that are pertinent to glove testing, ASTM F739, "Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact," and ASTM F1194–99, "Standard Guide for Documenting the Results of Chemical Permeation Testing of Materials Used in Protective Clothing Materials." EPA requests comment on whether these standards should govern the mandatory glove testing, or whether there are other standards or requirements that should be imposed. In addition, EPA is proposing to require employers whose employees are exposed to NMP in paint

and coating removal products to develop and institute personal protective equipment programs. These programs must be in writing, specific to the affected workplace, and include provisions relating to the proper selection, use, and maintenance of equipment. EPA requests comment on whether the proposed requirements for personal protective equipment programs are appropriate and complete, whether less burdensome requirements would similarly allow risk to be reduced so that it is no longer unreasonable, or whether EPA should cross reference the OSHA regulations on personal protective equipment, specifically 29 CFR 1910.132–134 and 29 CFR 1910.138.

ii. Risk reduction of second co-proposed approach. Reducing risks to workers so that they would not be unreasonable requires a combination of a concentration limitation and worker protection programs that include PPE and hazard communication because concentration limits or a worker protection program alone would not be sufficient to reduce the risks to workers so that they are no longer unreasonable. For this reason, the second co-proposal aims to reduce the risks to workers by placing requirements on product formulators and commercial users.

Reducing exposure to NMP requires consideration of routes of exposure as well as user behaviors, such as wearing appropriate PPE (*i.e.*, specialized gloves that are effective for the specific formulation used, impervious clothing and a respirator). The dermal route is the primary contributor to exposures from NMP; however, vapor deposition and subsequent absorption through skin and inhalation are also important exposure pathways that must be considered in determining a person's exposure to NMP. Even when wearing specialized gloves, dermal absorption of NMP from the vapor phase typically contributes significantly to human exposure. EPA's calculations for dermal exposure are based on a person having up to 25 percent of exposed skin surface (*e.g.*, arms, head and neck), providing significant exposure to NMP even with impervious glove use (Ref. 3). Thus, the use of impervious long pants and shirts is needed to minimize the area of exposed skin and thus reduce the risk associated with using NMP for paint and coating removal. To address the exposures to NMP use in paint and coating removal via dermal exposure from both direct contact and vapor deposition, and via inhalation exposure, the following combination is required: Specialized gloves that are effective for the specific formulation used; a

respirator with an APF of 10; and impervious clothing covering the body. This combination, as part of a worker protection program, will reduce occupational exposures so that the benchmark MOE is exceeded, provided that the concentration of NMP in the formulations used in paint and coating removals does not exceed 35 percent (Ref. 75). Therefore, EPA believes that any remaining occupational risks would not be unreasonable.

Specialized gloves are an important component of reducing exposure and, thus, must be effective. The presence of co-solvents in the paint and coating removal product containing NMP can result in inadvertent exposure to NMP. Most paint and coating removal products containing NMP contain co-solvents (Ref. 34). Gloves proven to resist permeation or breakthrough from pure NMP have been shown to experience degradation and permeation with these co-solvents especially those that are small-molecule, volatile solvents. For this reason, it is not possible to know which type of glove provides adequate protection from products containing NMP with any co-solvents without testing the formulation of each product for glove breakthrough and permeation. When working with formulated products, the chemical component with the shortest breakthrough time must be considered when selecting the appropriate glove type for protection against chemical hazards unless glove-specific test data are available (Ref. 82). Risks may not be reduced if the appropriate gloves are not identified through testing.

Consumers could have access to NMP formulations identical to those available to commercial users. This co-proposed approach would attempt to address the unreasonable risk to consumers through the combination of labeling and product reformulation. The product reformulation would be as discussed previously. If consumers using NMP formulations which did not exceed 35% of NMP were to consistently follow *all* the warnings on the label (specifically, if the consumer were to use a new pair of the formulation-specific gloves identified on the label each time the product is used; and were to adequately ventilate the workspace; and not spray-apply the product; and if they were to wear clothing that covers exposed skin; and properly fit and use a respirator of APF 10, such as a NIOSH-certified air-purifying elastomeric half-mask respirator equipped with N100, R100, or P100 filters) then the consumer exposures to NMP would be expected to result in MOEs that approach the benchmark MOE of 30 (Ref. 76).

Under real-world conditions, EPA expects that not all consumers will adequately follow the label to reduce risk to a level above the benchmark MOE. The Agency is requesting comment on whether incomplete adherence to the label might still suffice to reduce risks presented by NMP in paint and coating removal so that those risks are no longer unreasonable. EPA also requests comment on whether the voluntary nature of consumer use and the information provided on the label that would allow consumers to avoid risk below the benchmark MOE if label directions were followed should be a factor in determining whether any remaining risk associated with this exposure scenario is unreasonable, and if so, how.

EPA is also requesting comment on how labels may be constructed to effectively communicate risk and instructions on how to use the product, such as information on label content, placement of information, pictures, and font size and color; how to construct a label to effectively communicate and improve the user's understanding of risk and protective measures. EPA requests that this be supported by data demonstrating the effectiveness of a label approach, particularly as it pertains to susceptible sub-populations or individuals with limited English proficiency or low literacy in any language.

EPA requests comment on the efficacy of this co-proposed option, including on individual components.

iii. Concerns regarding second co-proposed approach. EPA has identified several concerns regarding this co-proposed option related to risk reduction for commercial users and for consumers. For commercial users, many of these concerns relate to the use of PPE. Although respirators in conjunction with the use of appropriate formulation-tested gloves could reduce exposures to levels that are protective of acute and chronic risks, respirators are not EPA's preferred approach to decrease exposures. Not all workers may be able to wear respirators, even those with a lower APF. For a discussion of the use of respirators and the associated respiratory protection program, see Unit VI.C. Given equipment costs and the costs of establishing a worker protection program, which involves training, respirator fit testing and the establishment of a medical monitoring program, EPA anticipates that most companies would choose to switch to substitutes instead of adopting a program for this type of PPE to continue using NMP in paint and coating removal. As recommended by the SBAR

panel, EPA is requesting comment on and information about workplace experience with worker protection programs and air monitoring for NMP (Ref. 27). Specifically, EPA seeks comment on whether companies would opt to substitute an alternate chemical or process instead of implementing a worker protection program for PPE. Additionally, EPA is requesting comment on the cost to achieve reduced exposures in the workplace or to transition to alternative chemicals or technologies.

Under this approach, risks to consumers are only addressed to the extent that consumers understand and follow the required label information. While the Agency expects that some number of consumers who read the labels of paint and coating removal products containing NMP would understand this information and take appropriate steps to reduce their risks based on label information, as noted in Unit V.C., studies have shown that consumers do not consistently pay attention to labels for hazardous substances; consumers, particularly those with lower literacy levels, often do not understand label information; consumers often base a decision to follow label information on previous experience and perceptions of risk; even if consumers have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings; and consumers have varying behavioral responses to warning labels.

Even for those consumers who understand and follow the label, EPA expects some number will not follow the label instructions precisely or may be unable to readily locate the specialized gloves or the respirator indicated on the label (Ref. 28). Further, it is unlikely that consumers would have the fit of their respirator tested, which is important part of the proper use, and thus effectiveness, of a respirator, or that they would wear a new pair of specialized gloves for each use of the product containing NMP. EPA emphasizes that product labels are not equivalent to worker protection programs in which risks are reduced through, among other things, training programs, requirements that include proper testing and use of respirators, and requirements to use specialized gloves each time the product is used.

EPA is unable to determine how many consumers would read and take *all* appropriate action based on label information, and to what extent they could effectively carry out those actions

such that their exposure would be reduced.

As under the first co-proposed approach, manufacturers, processors, and distributors would be required to provide downstream notification of these requirements under TSCA section 6(a)(3), and limited recordkeeping would be required under TSCA section 6(a)(4).

C. Adverse Health Effects and Related Impacts That Would Be Prevented by the Proposed Options

EPA is co-proposing these options to prevent exposure to NMP from paint and coating removal and thus prevent the risks of adverse effects and associated impacts. As discussed in Unit XII.C., the range of adverse health effects from NMP includes developmental toxicity resulting in decreased birth weight or fetal death, kidney toxicity, liver toxicity, immunotoxicity, and reproductive toxicity (Ref. 3). These health effects associated with exposure to NMP are serious and can have impacts throughout a lifetime. The following is a discussion of the impacts of significant acute and chronic non-cancer effects associated with NMP exposure during paint and coating removal, including the severity of the effect, the manifestation of the effect, and how the effect impacts a person during their lifetime.

1. Developmental effects—acute exposures. The NMP risk assessment identified developmental effects as the most sensitive endpoint for acute exposure to NMP. Specifically, this assessment identified fetal death as the critical effect of acute exposures over the course of a day. Fetal death or fetal mortality includes miscarriage, spontaneous abortion, or stillbirth, depending on when in the pregnancy it occurs. Fetal death may result from a single maternal exposure to NMP at a developmentally critical period (Ref. 3). There are increased risks of fetal death for pregnant women who use NMP for paint and coating removal as consumers. EPA estimates that 732,000 consumers use NMP for paint and coating removal each year; of them, approximately 38,000 are estimated to be pregnant women. EPA estimates that approximately 11,300 of these pregnant women are estimated to experience acute exposure to NMP at levels that would result in an MOE below the benchmark of 30. Additionally, there are increased risks of fetal death for a subset of pregnant women among the approximately 8,800 female workers in 4,300 commercial facilities or companies that use NMP for paint and

coating removal. Of these female workers, approximately 500 are estimated to be pregnant, and, of them, approximately 160 are estimated to have acute exposure to NMP at levels that would result in an MOE below the benchmark of 30 for fetal death (Ref. 4). The basis for these calculations are shown in section 5.2.1 of the Economic Analysis (Ref. 4).

Researchers aiming to improve early childhood health outcomes have identified the most sensitive time in a pregnancy as the first few weeks following conception, before a woman may be aware she is pregnant. In the context of maternal welfare and risk reduction, “women often delay assessing and improving their health until after confirmation of pregnancy, putting their baby at risk during the critical early developmental stages” (Ref. 81). Approximately 35% of pregnancies in the United States are unplanned (Ref. 83); consequently, many women who are pregnant may not have taken or be prepared to take steps to reduce risks to the developing fetus during early stages of pregnancy. Maternal exposure to NMP in paint and coating removal may occur before a woman realizes she is pregnant. As such, even if she is aware of the risks of exposure to NMP, she may not take steps to reduce risks of fetal death.

Even if they are aware of their pregnancy, women may not wish to disclose this fact to their employers; although legal protections are in place, many women “feel they may lose their job, may not be considered for a promotion, or may have a promotion taken away if they announce they are pregnant” (Ref. 81). Similarly, the American College of Occupational and Environmental Medicine has found that “while it is illegal for an employer to terminate a worker because of pregnancy, such fears may not be groundless for some workers” (Ref. 83). Consequently, pregnant women may attempt to “minimize their pregnancy” (Ref. 81) and may not be vocal in their workplace about reducing risks to their pregnancy. This could increase chances of exposure to chemicals such as NMP that present a risk of fetal death.

Exposure to NMP in paint and coating removal during a single day (over 8 hours) was found to present risks of fetal death (Ref. 3). The impacts of fetal death, including miscarriage or stillbirth, include emotional impacts on the woman experiencing the death of a fetus, and also present significant emotional impacts for partners and spouses.

Emotional impacts and other mental health effects of miscarriage or stillbirth

can include depression, anxiety, grief, and guilt. Mental health research has consistently identified both miscarriage (defined as fetal death occurring before the 20th week of gestation) and stillbirth (defined as fetal death occurring after the 20th week of gestation) as a significant emotional burden that can persist for more than a year and sometimes up to three years following the event of fetal death (Ref. 84). Compared with their peers, women who have experienced fetal death “exhibit significantly elevated levels of depression and anxiety in the weeks and months following the loss, compared with samples of pregnant, community or postpartum women” (Ref. 85). Psychologists see miscarriage and stillbirth as “an unanticipated, often physically as well as psychologically traumatic event representing the death of a future child and disruption of reproductive plans. Physiologically, it marks the end of a pregnancy, and psychologically it may produce doubts about procreative competence” (Ref. 86). Other descriptions of fetal death similarly characterize it as “a significant psychosocial stressor that results in a high level of dysphoria and grief” (Ref. 87). Consequently, women who experience the death of a fetus are at increased risk for depression, anxiety, and other psychiatric disorders (Ref. 86).

Major depressive disorder has been identified in between 10% to 50% of women after a miscarriage, depending on the measures used (Refs. 88 and 89). According to the National Institutes of Mental Health, persistent depressive disorder is a depressed mood that lasts for at least two years. Symptoms can include difficulty concentrating, sleep pattern disruptions, appetite or weight change, thoughts of suicide or suicide attempts, loss of interest in hobbies or activities, decreased energy, and aches, headaches, or digestive problems without a clear physical cause and that do not ease even with treatment (Ref. 90). Depression can affect an individual’s physical health and their ability to work. Additionally, depression in one family member can also result in increased instance of illness or morbidity in other family members (Ref. 91). Treatment can require several types of attempted pharmaceutical or psychological therapies, and, in the case of depression following fetal death, can persist for years (Ref. 89).

Depression is not the only emotional impact of fetal death; many women also experience intense and persistent anxiety. Researchers have found that “a significant percentage of women

experience elevated levels of anxiety after a miscarriage up until about 6 months post-miscarriage, and they are at increased risk for obsessive-compulsive and posttraumatic stress disorder” (Ref. 89).

In addition to depression and anxiety, a primary component of the emotional burdens presented by fetal death is guilt. As one researcher explained, women search for answers to what they perceive as an inexplicable trauma: “They will spend enormous amounts of emotional energy trying to explain why it happened . . . They often blame themselves, even when it is inaccurate, to help make sense of it. Women may torment themselves with guilt and blame, rewriting the story, so to speak: ‘If I hadn’t gone to the grocery store’ or ‘If I didn’t stay up so late.’ It’s a way of coping with the loss” (Ref. 92).

Related to these emotional impacts, one study found that “the mean annual suicide rate within one year after miscarriage was significantly higher (18.1 per 100,000) than the suicide rates both for women who gave birth (5.9) and for women in the general population (11.3) in Finland between 1987 and 1994” (Ref. 86).

Women experiencing miscarriages or stillbirths are not the only individuals affected by fetal death. Researchers have also documented the ways in which the woman’s partners are affected by the loss (Ref. 86). Recent research has found that male partners experience more grief over miscarriages than previously assumed (Ref. 92) and that in 25% of the cases studied, the intensity of fathers’ grief exceeded that of the mothers’ (Ref. 93).

Additional burdens from fetal death can be felt throughout the affected family, including by subsequent children, since the depression, anxiety, and guilt initiated by fetal death may persist during and after any subsequent successful pregnancy (Ref. 92). As a result, future pregnancies and children can be adversely affected by fetal death during the mother’s previous pregnancies due to persistent psychological impacts leading to maternal stress or depression that can last up to three years (Refs. 94 and 85). As a result of this stress or depression, complications during subsequent pregnancies can occur. Maternal anxiety or depression during pregnancy is associated with pre-term birth, decreased birth weight, and impacts on fetal brain development as a result of abnormal uterine blood flow and increased maternal cortisol levels (Ref. 94). Maternal anxiety and depression, including that initiated by fetal death during a previous pregnancy, is also

associated with a higher risk of maternal postpartum depression (Ref. 85), which can lead to poor infant care, and infant cognitive delay (Ref. 94). For some children born to women who previously experienced the death of a fetus, there may be disorganized or insecure maternal attachment or bonding (Ref. 95), and maternal perinatal mood symptoms that may alter a child's emotional or health outcomes (Refs. 85 and 86). For example, available data indicate that "12-month-old infants born following prenatal loss were reported to show higher rates of disorganized attachment patterns to their mothers than children born into families without a loss history. Thus, even if there is no persistence of mood disturbance into the postnatal period, there may still be adverse effects of a previous prenatal loss on the parent-child relationship and child outcomes" (Ref. 85). Similarly, maternal postpartum depression or anxiety has been found to have "deleterious effects on maternal-child attachment, child behavior, and cognitive and neuroendocrine outcomes that persist into adolescence" (Ref. 85). In this way, a single instance of fetal death may result in years of emotional impacts for the mother and may potentially affect the health and well-being of future children. In addition to depression and anxiety, emotional impacts can take the form of grief, envy, or isolation.

Similarly, a woman's attitude towards a pregnancy does not necessarily correlate with the emotional impact resulting from fetal death. Although ambivalence toward pregnancy was associated with different emotional impacts (greater association with depressive symptoms, rather than grief), they were found to be as intense as in women who were not ambivalent about their pregnancy (Ref. 86).

As a result, fetal death at any stage of a pregnancy, even when experienced by a woman who is ambivalent about that pregnancy, may result in intense emotional impacts and psychological morbidities, for both the mother and other family members; these impacts can include depression and anxiety and, in many cases, could persist and potentially impact future pregnancies and children.

Additionally, it is important to note that fetal death can present health risks to the woman; in some cases, maternal death can result. From 1981 to 1991, the Centers for Disease Control and Prevention (CDC) recorded 62 cases of maternal mortality following spontaneous abortion at or before 20 weeks of fetal gestational age (an overall case fatality rate of 0.7 per 100,000

spontaneous abortions) (Ref. 96). Leading causes of maternal mortality during these incidents of fetal death were infection, hemorrhage, or embolism (Ref. 96). The CDC has noted that this case fatality rate is likely the result of underreporting, and that "the true number of deaths related to pregnancy might increase from 30% to 150% with active surveillance" (Ref. 97).

Even when the effects of fetal death are less severe, a miscarriage or stillbirth can have considerable adverse consequences on an individual, family, or community. Commercial and consumer users of NMP in paint and coating removal are at risk of fetal death from typical use of products containing NMP; although EPA is unable to quantify the precise number or frequency of fetal deaths that may occur as a result of exposure to NMP during paint and coating removal, reducing the risks of exposure would benefit women, their families, and the public at large by reducing risks of fetal death in a population of approximately 12,000 pregnant individuals (consumers and workers) likely to experience acute exposures that present risks of fetal death. Details on how EPA estimated the number of individuals is in section 5.2.1 of the Economic Analysis (Ref. 4).

2. Developmental effects—chronic exposures. The NMP risk assessment identified developmental effects as the most sensitive endpoint for chronic exposure to NMP. Specifically, the assessment selected decreased birth weight as the critical effect resulting from repeated exposures to women of child-bearing age. It is not known if there is a window of exposure that may pose greater risks to the fetus; therefore, any repeated exposure to NMP could increase risks to the fetus for developmental effects.

Rather than accumulating over a lifetime, risks were found for workers exposed to NMP during paint and coating removal over the course of a workweek, or five days. Even when maternal exposure ceased, the decreased fetal body weight was found to be a persistent adverse effect (Ref. 3); consequently, a relatively brief period of maternal repeated exposure to NMP in typical paint and coating removal can cause fetal weight decreases, resulting in life-long impacts. There are increased risks of decreased fetal weight for the subset of pregnant women among the approximately 8,800 female workers in 4,300 commercial facilities or companies that use NMP for paint and coating removal. EPA estimates that there are approximately 500 pregnant women working in these commercial

facilities (Ref. 4). A subset of these 500 pregnant would have chronic exposure to NMP at levels that would result in an MOE below the benchmark of 30 for decreased fetal weight (Ref. 3).

Decreased fetal weight can lead to reduced or low birth weight, which can have lifelong effects on a person and their family. Most cases of reduced or low birth weight are pre-term or premature birth; as a result, until recently, health impacts of reduced or low birth weight have been difficult to separate from the effects due to premature birth or gestational age. However, epidemiological, social, and medical research in the past several decades has isolated several health effects of reduced or low birth weight separate from gestational age at birth. Full-term babies may be born at low or reduced birth weights as a result of fetal growth restriction; these infants are usually referred to as small for gestational age, and "may have low birth weight because something slowed or stopped their growth in the womb" (Ref. 98). Low birth weight is typically defined as birth weight of less than 5.5 pounds, or 2,500 grams. Very low birth weight is typically defined as less than 1,500 grams (Ref. 99).

Low birth weight can have significant impacts on childhood development and the incidence of future diseases (Ref. 100); reduced birth weight can cause serious health problems for some children (Ref. 98), as well as long-term impacts on their lives as adults (Ref. 101).

Health impacts of low or reduced birth weight can begin at birth. According to the CDC, low birth weight infants may be more at risk for many health problems as neonates (Ref. 99); other medical authorities report that health impacts for infants with low birth weight include low oxygen levels at birth, inability to maintain body temperature; difficulty feeding and gaining weight; infection; breathing problems such as respiratory distress syndrome; neurologic problems, such as intraventricular hemorrhage (bleeding inside the brain); gastrointestinal problems such as necrotizing enterocolitis (a serious disease of the intestine), and a greater risk of Sudden Infant Death Syndrome (Ref. 102). These effects and health impacts have clear implications for the infant's future health and survival, and can cause emotional stress and anguish for families of the infant.

Effects of reduced or low birth weight can persist beyond infancy. It can affect growth: Low birth weight has been found to be "a major risk factor for children's physical growth in the early

years and there is no evidence of catch-up by age 2" (Ref. 103). In populations that may already be at risk for poor health outcomes, children with reduced birth weight or who were small for gestational age continued to be significantly smaller in all measures (height, weight, and head circumference) than their normal birth weight counterparts at age 3 (Refs. 104 and 105), and generally smaller between ages 4 through 7 (although the differences were small) (Ref. 104).

A child's size is not the only potential effect of reduced or low birth weight. Many studies have identified increased risk of cognitive, behavioral, and neurological problems in children and adolescents who had low birth weight or who were small for gestational age (Refs. 106 and 107). A large cohort study that followed infants born at full term with reduced birth weight (small for gestational age) found that "children of both genders who were born [small for gestational age] are at higher risk of learning difficulties" (Ref. 106), with girls with the lowest birth weight experiencing an increased risk of attention problems (Ref. 106).

Other studies have confirmed the impact of reduced or low birth weight on academic success in childhood; researchers note that compared to their normal birth weight siblings, low birth weight children are less likely to be in excellent or very good health in childhood. They also score significantly lower on reading, passage comprehension, and math achievement tests. Low birth-weight children are roughly one-third more likely to drop out of high school relative to other children (Ref. 100).

After childhood, the health, social, and financial impacts of reduced or low birth weight can continue. In many cases, an individual's size may continue to be affected. The difference in growth during adolescence and early adulthood varies by sex. Female adults who were very low birth weight infants tend to be the same size as their peers of average birth weight by age 20, while male adults "remain significantly shorter and lighter than controls" (Ref. 109). However, this may have its own risks: "Since catch-up growth may be associated with metabolic and cardiovascular risk later in life, these findings may have implications for the future adult health of [very low birth weight] survivors" (Ref. 109).

In terms of health effects, low birth weight can continue to have significant negative effects on adults. Researchers have found that low birth weight increases the probability of being in fair or poor health as an adult. Specifically,

"low birth weight children are nearly twice as likely as their normal birth-weight siblings to be in problematic health by ages 37–52 (23% versus 12%) (Ref. 100). Specific risks associated with low birth weight (separate from pre-term birth or gestational age) include increased risk of renal disease (Ref. 110); increased risk of asthma, diabetes, stroke, heart attack, or heart disease by age 50 (compared to average weight siblings) (Ref. 100); and increased risk of clinically verified hyperkinetic disorder, including attention deficit hyperactivity disorder (Ref. 111). Adults who were low birth weight babies may be more likely to have certain health issues such as diabetes, heart disease, high blood pressure, metabolic syndrome, and obesity (Ref. 98).

Additionally, there are financial implications for adults who were low birth weight; low birth weight has been found to lower labor force participation and labor market earnings over an individual's lifetime (Ref. 100). Specifically, "low birth weight is linked to a 10% reduction in hourly wages from ages 18–26, compared to the wages of normal birth-weight siblings, but a 22% reduction in wages from ages 37–52. Low birth-weight children, relative to their normal birth-weight siblings, work 7.4% fewer hours in adulthood" (Ref. 100).

Decreased fetal weight and low birth weight are strongly associated with a number of adverse health effects in adults. The Barker Hypothesis (Ref. 112) was among the first to identify a pattern between neonatal health and cardiovascular disease. Subsequent research in laboratory animals and in human epidemiological studies confirmed this pattern and extended the observations to include the relationship between delayed fetal growth, low birth weight and metabolic syndrome, which encompasses a host of adverse outcomes, such as hypertension, insulin resistance, obesity and type 2 diabetes mellitus (Refs. 113, 114, and 115). Diseases such as cardiovascular disease, hypertension, obesity and diabetes mellitus have a tremendous impact on public health. For example, according to the CDC, heart disease remains the nation's leading cause of death (Ref. 116). In addition to causing premature mortality, the monetary costs of cardiovascular disease were estimated at \$209.3 billion in direct costs and \$142.5 billion in indirect costs, for a total of \$351.8 billion (Ref. 116). A number of health disparities are associated with cardiovascular disease. Cardiovascular disease causes more deaths in women than men, and in black Americans, compared to white (Ref. 116). Years of

potential life lost before age 75 from heart disease is nearly double for Black or African Americans relative to White, Non-Hispanic Americans (Ref. 116).

Several of these health effects associated with reduced fetal growth and low birth weight fall within the definition of metabolic syndrome, which is generally defined as the presence of 3 or more of the following: Abdominal obesity (waist circumference ≥ 88 cm in women or ≥ 102 cm in men); low HDL cholesterol (< 50 mg/dL in women or < 40 mg/dL in men); elevated triglycerides (≥ 150 mg/dL); elevated fasting blood glucose (≥ 100 mg/dL or use of oral hypoglycemic medication or insulin or both); or elevated blood pressure (at least 1 of the following: Systolic ≥ 130 mmHg, diastolic ≥ 85 mmHg, or use of antihypertensive medication). Epidemiological studies indicate a strong, consistent association between low birth weight and metabolic syndrome (Ref. 113). The symptoms associated with metabolic syndrome are in turn associated with increased risk of cardiovascular disease and diabetes (Ref. 117).

Collectively, the sign, symptoms and diseases associated with delayed fetal growth and small birth weight present an enormous burden on public health. The extent that the development of adult disease is rooted in reductions in fetal and neonatal growth could limit the success of adult lifestyle changes in modifying these effects. Therefore, prevention must be focused on assuring fetal and neonatal health and preventing adverse impacts on growth rates.

Researchers highlight the fact that low birth weight can occur in every demographic group, and that even though most babies with low birth weight have normal outcomes, as a whole, infants with low birth weight "generally have higher rates of subnormal growth, illnesses, and neurodevelopmental problems. These problems increase as the child's birth weight decreases" (Ref. 118). Additionally, by using sibling comparisons and cohort studies, the effects of low birth weight have been found to persist even when accounting for "the independent effects of birth order, mother's age at birth, birth year cohort, race/ethnicity, family structure, parental income, and parental fertility timing" (Ref. 100).

Though most research has focused on infants with low or very low birth weight, it is important to note that children with reduced, but clinically normal, birth weights (2,500 to 2,999 grams) are also at increased risk from the health, academic, social, and financial effects described.

In this way, reduced or low birth weight resulting from maternal exposure to NMP during paint and coating removal can have serious and life-long impacts on individuals and their families, including their future family members. Even when birth weight is not reduced to the clinical definition of low, the decrease in fetal weight can have significant impacts. Additionally, it is important to note that the impacts of low birth weight go beyond affected individuals and their families; reduced and low birth weight “results in substantial costs to the health sector and imposes a significant burden on society as a whole” (Ref. 101).

3. Body weight reductions—chronic exposures. While the impact of decreased body weights in adult animals may be minimal, decreased body weight gain in pregnant females, in particular, may contribute to negative developmental outcomes as well as impacts on adult health (Refs. 119 and 120).

4. Kidney toxicity—chronic exposures. There are increased health risks for liver toxicity for many of the approximately 30,300 workers in 4,300 commercial facilities or companies that use NMP for paint and coating removal (Ref. 4). Exposure to NMP can cause kidney damage. This damage may result in signs and symptoms of acute kidney failure that include; decreased urine output, although occasionally urine output remains normal; fluid retention, causing swelling in the legs, ankles or feet; drowsiness; shortness of breath; fatigue; confusion; nausea; seizures or coma in severe cases; and chest pain or pressure. Sometimes acute kidney failure causes no signs or symptoms and is detected through lab tests done for another reason.

Kidney toxicity means the kidney has suffered damage that can result in a person being unable to rid their body of excess urine and wastes. In extreme cases where the kidney is impaired over a long period of time, the kidney could be damaged to the point that it no longer functions. When a kidney no longer functions, a person needs dialysis and ideally a kidney transplant. In some cases, a non-functioning kidney can result in death. Kidney dialysis and kidney transplantation are expensive and incur long-term health costs if kidney function fails (Ref. 56).

The monetary cost of kidney toxicity varies depending on the severity of the damage to the kidney. In less severe cases, doctor visits may be limited and hospital stays unnecessary. In more severe cases, a person may need serious medical interventions, such as dialysis or a kidney transplant if a donor is

available, which can result in high medical expenses due to numerous hospital and doctor visits for regular dialysis and surgery if a transplant occurs. The costs for hemodialysis, as charged by hospitals, can be upwards of \$100,000 per month (Ref. 57).

Depending on the severity of the kidney damage, kidney disease can impact a person's ability to work and live a normal life, which in turn takes a mental and emotional toll on the patient. In less severe cases, the impact on a person's quality of life may be limited while in instances where kidney damage is severe, a person's quality of life and ability to work would be affected. While neither the precise reduction in individual risk of developing kidney toxicity from reducing exposure to NMP during paint or coating removal or the total number of cases avoided can be estimated, these costs must still be considered because they can significantly impact those exposed to NMP.

5. Liver toxicity—chronic exposures. There are increased health risks for liver toxicity for many of the approximately 30,300 workers in 4,300 commercial facilities or companies that use NMP for paint and coating removal (Ref. 4).

Some form of liver disease impacts at least 30 million people, or 1 in 10 Americans. Included in this number is at least 20% of those with NAFLD. NAFLD tends to impact people who are overweight/obese or have diabetes. However, an estimated 25% do not have any risk factors. The danger of NAFLD is that it can cause the liver to swell, which may result in cirrhosis over time and could even lead to liver cancer or failure (Ref. 42). The most common known causes to this disease burden are attributable to alcoholism and viral infections, such as hepatitis A, B, and C. These known environmental risk factors of hepatitis infection may result in increased susceptibility of individuals exposed to organic chemicals such as NMP.

Additional medical and emotional costs are associated with liver toxicity following chronic exposure to NMP in paint and coating removal, although these costs cannot be quantified. These costs include medical visits and medication costs. In some cases, the ability to work can be affected, which in turn impacts the ability to get proper medical care. Liver toxicity can lead to jaundice, weakness, fatigue, weight loss, nausea, vomiting, abdominal pain, impaired metabolism, and liver disease.

Depending upon the severity of the jaundice, treatments can range significantly. Simple treatment may involve avoiding exposure to NMP and

other solvents; however, this may impact an individual's ability to continue to work. In severe cases, liver toxicity can lead to liver failure, which can result in the need for a liver transplant. Even if a donor is available, liver transplantation is expensive (with an estimated cost of \$575,000) and there are countervailing risks for this type of treatment (Ref. 44). The mental and emotional toll on an individual and their family as they try to identify the cause of sickness and possibly experience an inability to work, as well as the potential monetary cost of medical treatment required to regain health, are significant.

6. Reproductive toxicity. There are increased risks for these reproductive effects for many of the approximately 30,300 workers in 4,300 commercial facilities or companies that use NMP for paint and coating removal (Ref. 4). Similar to effects discussed previously, while neither the precise reduction in individual risk of developing this disorder from reducing exposure to NMP or the total number of cases avoided can be estimated, EPA still considers their impact.

7. Disproportionate impacts on environmental justice communities. An additional factor that cannot be monetized is the disproportionate impact on environmental justice communities. As described in Units VI.C.1.b. and XVI.B.1.b, Hispanic and foreign-born workers, who may have limited English proficiency, are disproportionately over-represented in construction trades (Ref. 4), in which NMP is used for paint and coating removal. Because they are disproportionately over-represented in this industry, these populations are disproportionately exposed to NMP during paint and coating removal, and are disproportionately at risk to the range of adverse health effects described here.

D. Availability of Alternatives

For almost every situation in which NMP is used to remove paints or coatings, EPA is aware of a cost-effective, economically feasible chemical substitutes or alternative methods. The exception is for critical corrosion-sensitive components of military aviation and vessels, for which EPA proposes are critical for national security, and for which EPA proposes an exemption, described in more detail in Unit XVIII.

EPA considered chemical substitutes and alternative methods consistent with the requirements of TSCA Section 6(c)(2)(C) and as similarly recommended by the SBAR panel (Ref.

27). A full industry profile characterizing manufacturers, processors, and end users of NMP for paint and coating removal and a use and substitutes analysis are included in section 2 and 3 of EPA's economic assessment. (Ref. 4). As described below, EPA proposes that alternatives are technologically and economically feasible, reasonably available, and present fewer hazards to human health than NMP in paint and coating removal. EPA requests comment on whether its conclusion that substitutes for NMP are available and technically and economically feasible is accurate and whether its consideration of alternatives was sufficient to satisfy the requirements of TSCA section 6(c)(2)(C).

Research into the efficacy of chemical substitutes has identified products currently available for commercial and consumer users of NMP for paint and coating removal, for a variety of coatings on numerous substrates (Refs. 58 and 59). Additionally, in most commercial sectors, NMP is not in widespread use; most sectors use substitute chemicals or methods, either due to financial considerations, problems with the efficacy of products containing NMP, or concern for worker or individual health and safety (Ref. 22). This was emphasized by a small business that manufactures such products (Ref. 22).

Many producers of paint and coating removal products containing NMP also produce paint and coating removal products with substitute chemicals (Ref. 4). This was emphasized by small businesses participating in the SBAR process (Ref. 27). Thus, there is already precedent for producers reformulating products to meet demand from commercial or individual customers.

Based on the frequent use of substitute chemicals or alternative methods for paint and coating removal in all industries discussed here, and the formulation and distribution of substitute chemicals for paint and coating removal by all formulators of products containing NMP (Ref. 4), EPA found that economically feasible alternatives to NMP are reasonably available for all paint and coating removal uses. Primary chemical substitutes for NMP in paint and coating removal include products formulated with benzyl alcohol; dibasic esters; acetone, toluene, and methanol (ATM); and caustic chemicals. EPA evaluated these products for efficacy, toxicity, relative hazards compared to NMP, and other hazards that might be introduced by use of these products (such as environmental toxicity, increased global warming potential, and increased flammability or other hazards to users).

EPA's analysis compared the hazard and exposure characteristics of the chemical paint and coating removal chemicals and products presumed to be already in use to NMP, to aid in ascertaining the impact on users of moving to alternative products. EPA used authoritative sources to characterize efficacy, hazard endpoints and identify effect and no effect levels. Relative exposure potential was assessed based on physical chemical parameters and concentrations in formulations, and exposure potential was considered to be similar to NMP within an order of magnitude. Product composition was based on publicly available Safety Data Sheets for products advertised for paint and coating removal (Ref. 36).

Products based on benzyl alcohol formulations have been identified as efficacious paint and coating removers in various industry sectors (Refs. 22 and 27). Consumer products containing benzyl alcohol are available for sale (Refs. 22, 27, 35, 58, 59, and 61). Regarding differential hazards between benzyl alcohol and NMP, there are fewer hazard concerns compared to NMP-based products, and the benzyl alcohol NOAELs are higher than for NMP, suggesting lower toxicity (Ref. 34). Regarding differential exposures between benzyl alcohol and NMP, the relative inhalation and dermal exposure potentials are similar to NMP (Ref. 34). Taken together, benzyl alcohol-based paint removers are expected to result in lower risks, primarily due to lower toxicity.

Dibasic ester products can include dimethyl succinate, dimethyl glutarate and dimethyl adipate. Many NMP products contain dibasic esters, and given the efficacy of these products users of these products would not experience much inconvenience if switched to substitute products that contain solely formulations based on dibasic esters, without NMP (Ref. 34). Regarding differential hazards between dibasic esters and NMP, in general, the hazards associated with dibasic esters are less severe and occur at concentrations suggesting lower toxicity (Ref. 34). Regarding differential exposures between dibasic esters and NMP, the relative inhalation exposure potential is similar to NMP. The relative dermal exposure potential for dibasic esters is lower, but similar to, NMP (Ref. 34). Taken together, dibasic ester-based paint removers are expected to result in lower risks, primarily due to lower toxicity.

ATM products contain acetone, toluene, and methanol. Products containing these chemicals may remove

coatings very quickly, but may not be effective on every type of coating (Ref. 27). ATM-based products are composed of chemicals that exhibit a range of hazard characteristics. Taken together, the components of ATM-based formulations have comparable hazard concerns to NMP. Regarding differential exposures between ATM and NMP, the relative inhalation exposure potentials for acetone, toluene and methanol are higher than NMP. The relative dermal exposure potentials for acetone, toluene and methanol are lower, but similar to, NMP (Ref. 34).

Products with caustic chemicals typically include calcium hydroxide or magnesium hydroxide. In many uses, they can be an effective product, particularly when multiple coatings are being removed from a substrate. In contrast to NMP-based products, there are no developmental or other repeat dose endpoints of concern associated with caustic products (Ref. 34). Caustic products pose acute concerns due to their physical chemical properties and can cause chemical burns (Ref. 34). The risks associated with caustic-based products are acute, and may be mitigated by appropriate and familiar protective equipment. The risks associated with NMP-based products are both acute and long term (Ref. 3).

In summary, when methylene chloride is excluded from consideration, the most likely chemical substitutes for NMP in paint and coating removal do not pose a risk of acute or chronic developmental effects, generally have lower or similar exposure potential than NMP, and when acute risks are present, as in the case of caustic chemicals, those risks are self-limiting by the nature of the adverse effects. The chemical formulations that seem to present some risks of concern contain toluene and methanol; however, risks from these chemicals can be mitigated by the user more easily than risks presented by NMP. Overall, exclusive use of substitute chemical products for paint and coating removal instead of NMP would remove the risks of chronic effects and acute developmental effects without introducing additional substantial risks to human health.

In addition to examining toxicity to humans, EPA reviewed available data on the chemicals in the baseline and alternative products for aquatic toxicity, persistence and bioaccumulation, as a basis for examining potential environmental toxicity. Only one chemical evaluated may have significant impacts on aquatic toxicity, with concern for environmental persistence and/or bioaccumulation. This chemical is contained in NMP-based paint

removal products and thus is not considered further.

EPA is also mindful of the risks that may be introduced by substitute chemicals or methods that increase global warming, and has examined the global warming potential of the chemical components of likely chemical substitutes for NMP in paint and coating removal. NMP does not present concerns for global warming and has a global warming potential (GWP) of 0 (Ref. 3). Similarly, the GWP values of likely substitute chemicals in paint and coating removal are: 0 GWP (benzyl alcohol, ATM) or not assessed (caustics, dibasic esters) (Ref. 24). As such, EPA has not identified any increased risk of global warming that would be introduced by use of chemical products as substitutes for NMP in paint and coating removal.

In addition to human and environmental toxicity, other hazards associated with chemical methods for paint and coating removal are risks of fire due to flammability of the chemical product, and poisoning or acute injury. Risks of fire are serious when using solvents such as paint and coating removal chemicals. Even among products that fall within the same general product composition category, there is meaningful variability in the specific formulations of paint remover products, and thus in their flammability. Furthermore, it is impracticable for EPA to predict the specific product formulations for which use will increase as a result of prohibitions on NMP in paint and coating removal. It is therefore impracticable for EPA to forecast whether the flammability of popular paint and coating removers would generally increase or decrease as a result of the proposed rule.

In addition to using substitute chemical products, EPA has identified non-chemical methods for paint and coating removal that can be used as alternatives to NMP. These methods are already frequently in use in various industries or by consumers for paint and coating removal, and are described in more detail in Unit VI.E.

EPA recognizes that all methods of paint and coating removal can present some hazards. Most of these alternative methods are already in frequent use, including by consumers and workers who currently use NMP or other chemicals for some paint and coating removal. The risks associated with each of these methods, while serious, are generally acute, related to injury, and can be mitigated through readily available and easy-to-implement standard safety practices; in contrast,

the acute risks presented by NMP, such as fetal death, require specialized gloves and are not the type of hazard frequently encountered when using household products.

E. Impacts of the Proposed and Alternative Regulatory Options

1. First co-proposed approach: Supply-chain approach. The costs of the first co-proposed approach are estimated to include product reformulation costs, downstream notification costs, recordkeeping costs, and Agency costs. The costs of paint and coating removal product reformulations are estimated to be approximately \$7,000 to \$14,000 per year (annualized at 3% over 20 years) and \$9,000 to \$19,000 (annualized at 7% over 20 years). The cost for reformulation includes a variety of factors such as identifying the appropriate substitute chemical for NMP in the formulation, assessing the efficacy of the new formulation and determining shelf life. The costs to users of paint and coating removers containing NMP are (–\$1,477,000) to \$27,617,000 at a discount rate of 3% and (–\$1,231,000) to \$27,638,000 at a discount rate of 7% (Ref. 4). The costs of downstream notification and recordkeeping on an annualized basis over 20 years are \$100 and \$100 using 3% and 7% discount rates respectively (Ref. 4). Agency costs for enforcement are estimated to be approximately \$114,401 and \$111,718 annualized over 20 years at 3% and 7%, respectively. The total cost of the proposed approach for paint and coating removers containing NMP is estimated to be (–\$1,484,000) to \$27,624,000 and (–\$1,251,000) to \$27,668,000 annualized over 20 years at 3% and 7%, respectively (Ref. 4).

2. Second co-proposed approach: Reformulation, labeling, and PPE approach. Reformulation costs are estimated to have less of an impact than those associated with adoption of worker protection programs. Given equipment costs and the requirements associated with establishing a dermal and respiratory protection program which involves training, purchase of specialized gloves, respirator fit testing and the establishment and maintenance of a medical monitoring program, EPA anticipates that companies would choose to switch to substitute chemicals instead of adopting a program for PPE, including with a performance-based option of meeting an air concentration level of 5 ppm as an exposure limit for NMP in paint and coating removal, when these products have a maximum concentration of 35% NMP by weight.

The estimated annualized costs to commercial and consumer users of switching to this type of dermal and respiratory protection program are \$47,076,900 to \$56,130,900 at 3% and \$47,245,900 to \$56,383,900 at 7% over 20 years. In addition, there would be higher EPA administration and enforcement costs under the second co-proposed approach than there would be with an enforcement program under the first co-proposed approach. Finally, this option requires that formulators of paint and coating removal products containing NMP identify which gloves are non-penetrable by NMP if used for an eight-hour shift; this requires that the formulators or processors conduct testing, which can have costs of \$15,786 per product (Refs. 4 and 127).

3. Options that exclude downstream notification. For those options that exclude downstream notification, the options are less effective and more to challenging to implement. The downstream notification (e.g., via SDS) provides additional information on the prohibitions under the proposed option for processors and distributors of NMP or products containing NMP other than paint and coating removers, and provides an efficient way for those entities to recognize themselves as affected by the regulation, which contributes to a more effective regulation (Ref. 63). In this way, the downstream notification component of the supply chain approach contributes to the use no longer presenting an unreasonable risk because it streamlines and aids in compliance and implementation (Ref. 64).

F. Summary

EPA is co-proposing these two options because the Agency believes both deserve consideration by commenters. The first co-proposed approach is necessary so that NMP in paint and coating removal no longer presents an unreasonable risk to the general population or to women of childbearing age. It is more cost effective than other regulatory options EPA identified as potentially reducing risks so that they are no longer unreasonable, because the proposed option achieves the benefits of reducing the unreasonable risks so they are no longer unreasonable for a lower cost than the second co-proposed approach. For more information, see Section 6 in the Economic Analysis (Ref. 4). As stated previously in this notice, the first co-proposed approach includes:

- Prohibiting manufacturing (including import), processing, and distribution in commerce of NMP for use in consumer and commercial paint

and coating removal, except for specified uses critical to national security;

- Prohibiting commercial use of NMP for paint and coating removal, except for specified uses critical to national security;

- Requiring that any products containing NMP intended or used for paint and coating removal be distributed in containers with a volume no less than 5 gallons;

- Requiring downstream notification of the prohibition on manufacturing (including import), processing, and distribution of NMP for the prohibited uses; and

- Requiring limited recordkeeping.

Technically and economically feasible alternatives to NMP for paint and coating removal are reasonably available. The supply chain approach ensures protection of consumers from the unreasonable risk by precluding the off-label purchase of commercial products by consumers.

The first co-proposed approach is relatively easy to enforce because key requirements are directly placed on a small number of suppliers and because the supply chain approach minimizes to the greatest extent the potential for NMP products to be intentionally or unintentionally misdirected into the prohibited uses. Enforcement under the other options would be much more difficult since the key requirements are directly placed on the large number of product users. As described in a recent article on designing more effective rules and permits, “the government can implement rules more effectively and efficiently when the universes of regulated sources are smaller and better-defined. This is because, other factors being equal, governments can more easily identify, monitor, and enforce against fewer, rather than more, entities” (Ref. 63). Under other options, enforcement activities must target firms that might perform the activity where a use of NMP is restricted or prohibited. Identifying which establishments might use paint and coating removers is difficult because paint and coating removal is not strictly specific to any industry (Ref. 4).

The second co-proposed approach would allow the continued use of NMP in commercial and consumer paint and coating removal at up to 35 percent NMP by weight, except for exempt critical national security uses which can be at any concentration, provided that commercial users of NMP for paint and coating removal establish a worker protection program for dermal and respiratory protection.

In addition, the co-proposed approach would require formulators of products for either commercial or consumer uses other than critical national security uses to: Reformulate products such that paint and coating products containing NMP do not exceed a maximum of 35 percent NMP by weight in product formulations; test gloves for the product formulations being processed and distributed in commerce to identify specialized gloves that provide protection for users; label products with information for consumers and provide information for commercial users about reducing risks when using the product. This approach would effectively reduce risk for workers. EPA is requesting comment on whether this co-proposed approach would be effective at reducing risks for consumers so that the risks are no longer unreasonable.

XVII. Costs and Monetized Benefits of the NMP Component of the Proposed Rule, the Alternatives EPA Considered, and Comparison of Costs and Benefits

EPA proposes that the identified risks from NMP in paint and coating removal are unreasonable. Apart from that proposed determination, EPA has evaluated the potential costs and benefits of the two co-proposed approach and their variations.

A. Costs of the First Co-Proposed Approach

The details of the costs of the first co-proposed approach for NMP in commercial and consumer paint and coating removal are discussed in Unit I.E. and in the Economic Analysis (Ref. 4). Under the first co-proposed option, costs to users of paint and coating removal products containing NMP are (–\$1,477,000) to \$27,617,000 at a discount rate of 3% and (–\$1,231,000) to \$27,638,000 at a discount rate of 7%. Costs of paint and coating removal product reformulations are estimated to be approximately \$7,000 to \$14,000 per year (annualized at 3% over 20 years) and \$9,000 to \$19,000 (annualized at 7% over 20 years). Costs of downstream notification and recordkeeping on an annualized basis over 20 years are \$100 and \$100 using 3% and 7% discount rates respectively. Agency costs for enforcement are estimated to be approximately \$114,401 to \$111,718 annualized over 20 years at 3% and 7%, respectively (Ref. 4). Under the first proposed approach, total costs of the proposed rule relevant to NMP in paint and coating removal are estimated to be (–\$1,484,000) to \$27,624,000 and (–\$1,251,000) to \$27,668,000 annualized over 20 years at 3% and 7% respectively (Ref. 4).

EPA also found that a use prohibition alone without downstream notification requirements would not address the unreasonable risks. EPA estimated the costs of this option to be \$5,164,000 to \$30,702,000 annualized over 20 years at 3% and \$5,409,000 to \$30,839,000 annualized over 20 years at 7% (Ref. 4).

B. Benefits of the First Co-Proposed Approach

As described in Unit XVII.B., there are no monetizable benefits from mitigating the risks from NMP in consumer and commercial paint and coating removal. Although the alternatives considered are unlikely to result in the same health benefits as the first co-proposed option, EPA was unable to quantify the differences.

C. Comparison of Benefits and Costs of the First Co-Proposed Approach

Based on the costs and benefits EPA can estimate, the monetized subset of benefits for preventing the risks resulting from NMP in consumer and commercial paint and coating removal do not outweigh the estimated monetary costs. However, EPA believes that the balance of costs and benefits of the proposed regulation of NMP cannot be fairly described without considering the additional, substantial, non-monetized benefits of mitigating the non-cancer adverse effects. As discussed previously, the multitude of potential adverse effects associated with NMP in paint and coating removal can profoundly impact an individual's quality of life. Some of the adverse effects associated with NMP exposure can be immediately experienced and can affect a person from childhood throughout a lifetime (e.g., low birth weight and associated impacts). Other adverse effects (e.g., adult immunotoxicity, kidney and liver failure, or fetal death) can have impacts that are experienced for a shorter portion of life, but are nevertheless significant in nature.

While the benefits associated with avoiding the health effects associated with NMP exposure during paint and coating removal cannot be monetized or quantitatively estimated, the qualitative discussion highlights how some of these effects may be as severe as more traditionally monetizable effects and thus just as life-altering; therefore the benefits of avoiding these effects are substantial. These effects include not only medical costs but also personal costs such as emotional and mental stress that are impossible to accurately measure. Considering only monetized benefits would significantly underestimate the benefits of avoiding

NMP-induced adverse outcomes on a person's quality of life.

Thus, considering costs and the benefits that cannot be quantified and subsequently monetized (developmental effects, fetal death, adult body weight reductions, kidney toxicity, liver toxicity, and immunotoxicity), including benefits related to the severity of the effects and the impacts on a person throughout a lifetime in terms of medical costs, effects on earning power and personal costs, emotional and psychological costs, and the disproportionate impacts on Hispanic communities and individuals with limited English proficiency, the benefits of preventing exposure to NMP in paint and coating removal by an estimated 732,000 consumers and an estimated 30,300 commercial workers outweigh the costs.

D. Impacts on the National Economy, Small Businesses, Technological Innovation, the Environment, and Public Health of the First Co-Proposed Approach

As described in Unit V.B. and in the Economic Analysis, EPA considered the anticipated effects of this proposal on the national economy. While the impacts of this rule as a whole are described in Unit XXIII.C. and the impacts of the NMP component of this proposal are described in more detail in Unit XVII.A. and in Section 9.3 of the Economic Analysis (Ref. 4), EPA does not anticipate these impacts having an effect on the overall national economy. EPA anticipates that a majority of small businesses will have cost impacts of less than one percent of the annual revenue, and the majority of small business bathtub refinishing facilities and professional contractors will have cost impacts greater than one percent of annual revenue.

The first co-proposed approach is anticipated to drive technological innovation by formulators of paint and coating removal products containing NMP, as they continue to develop substitute products, and refine such products already available. It is also anticipated to drive technological innovation by formulators of chemical paint and coating removal products with different chemistries as well as manufacturers and retailers of alternative methods of paint and coating removal, particularly those with interest in appealing to the consumer uses. See section 9.3 in the Economic Analysis (Ref. 4).

The first co-proposed approach is anticipated to have a positive impact on public health, as described in Unit XVI.C. There is not anticipated to be a

significant impact on the environment, for the reasons described in Unit XII.D.

E. Costs of the Second Co-Proposed Approach

The details of the costs of the second co-proposed approach for NMP in commercial and consumer paint and coating removal are discussed in Unit I.E. and in the supplement to the Economic Analysis (Ref. 127).

Under the second co-proposed option, costs to users of paint and coating removal products containing NMP are \$47,076,900 to \$56,130,900 (annualized at 3% over 20 years) and \$47,245,900 to \$56,383,900 (annualized at 7% over 20 years). Costs of paint and coating removal product reformulations are estimated to be approximately \$15,100 to \$21,100 per year (annualized at 3% over 20 years) and \$20,100 to \$28,100 (annualized at 7% over 20 years). Agency costs for enforcement are estimated to be approximately \$1,024,144 and \$998,711 annualized over 20 years at 3% and 7% respectively. Under the second proposed approach, total costs of the proposed rule relevant to NMP in paint and coating removal are estimated to be \$47,098,000 to \$56,146,000 and \$47,274,000 to \$56,404,000 annualized over 20 years at 3% and 7% respectively (Ref. 127).

F. Benefits of the Second Co-Proposed Approach

As described in Unit XVII.B., there are no monetizable benefits from mitigating the risks from NMP in consumer and commercial paint and coating removal. Although the second co-proposed option is unlikely to result in the same health benefits as the first co-proposed option, EPA was unable to quantify the differences.

G. Comparison of Benefits and Costs of the Second Co-Proposed Approach

Based on the costs and benefits EPA can estimate, the monetized subset of benefits for preventing the risks resulting from NMP in consumer and commercial paint and coating removal do not outweigh the estimated monetary costs. However, EPA believes that the balance of costs and benefits of the proposed regulation of NMP cannot be fairly described without considering the additional, substantial, non-monetized benefits of mitigating the non-cancer adverse effects. As discussed previously, the multitude of potential adverse effects associated with NMP in paint and coating removal can profoundly impact an individual's quality of life. Considering only monetized benefits would significantly

underestimate the benefits of avoiding NMP-induced adverse outcomes on a person's quality of life.

H. Impacts on the National Economy, Small Businesses, Technological Innovation, the Environment, and Public Health of the Second Co-Proposed Approach

As described in Unit V.B. and in the Economic Analysis, EPA considered the anticipated effects of this proposal on the national economy. While the impacts of this rule as a whole are described in Unit XXIII.C. and the impacts of the NMP component of this proposal are described in more detail in Unit XVII.A. and in the supplement to the Economic Analysis (Ref. 127), EPA does not anticipate these impacts having an effect on the overall national economy.

The second co-proposed approach is anticipated to drive technological innovation by formulators of paint and coating removal products containing NMP, as they continue to develop substitute products, and refine such products already available. It is also anticipated to drive technological innovation by formulators of chemical paint and coating removal products with different chemistries as well as manufacturers and retailers of alternative methods of paint and coating removal, particularly those with interest in appealing to the consumer uses. See the supplement to the Economic Analysis (Ref. 127).

The second co-proposed approach is anticipated to have a positive impact on public health, as described in Unit XVI.C. There is not anticipated to be a significant impact on the environment, for the reasons described in Unit XII.D.

XVIII. Uses of NMP for Paint and Coating Removal Critical for National Security

As part of interagency collaboration with the Department of Defense (DOD) on this proposed rule, EPA is aware that there are specific military uses for which NMP is essential for paint and coating removal and for which there are no technically feasible alternatives currently available. The military readiness of DOD's warfighting capability is paramount to ensuring national security, which includes ensuring the maintenance and preservation of DOD's warfighting assets. DOD has identified mission-critical uses for NMP for ensuring military aviation and vessel readiness. These mission-critical items require the use of NMP for the removal of coatings from mission-critical corrosion-sensitive components on military aviation and

vessels, including safety-critical components made of specialty metallic, nonmetallic, and composite materials. As described in this section, EPA proposes to exempt these uses from the regulations proposed on NMP in paint and coating removal. This exemption is proposed for an initial ten-year period from the publication date of a final rule. EPA will engage with DOD to identify any potential extension that may need to be granted, by further rulemaking, after those ten years.

DOD continues and will continue to pursue potential substitutes for NMP in paint and coating removal. However, for mission-critical corrosion-sensitive components on military aviation and vessels, including safety-critical components, DOD has found that currently available substitute chemicals for paint and coating removal have one or more technical limitations. These are the same technical limitations described in Unit VIII., which outlines the proposed exemption for methylene chloride for similar uses critical to national security.

Under TSCA section 6(g)(1)(B), EPA may grant an exemption from a requirement of a TSCA section 6(a) rule for a specific condition of use of a chemical substance or mixture if compliance with the requirement would significantly disrupt the national economy, national security, or critical infrastructure. Based on discussions and information provided by DOD, EPA has analyzed the need for the exemption and concurs with DOD that compliance with the proposed regulations on the use of NMP in paint and coating removal would significantly impact national security. DOD has demonstrated that the reduced mission availability of aircraft and vessels for military missions or, in the worst case, the loss of individual military aircraft and vessels, are potential impacts to military readiness that could result from the proposed prohibition of NMP in paint and coating removal. Due to the importance of these military systems for national security, EPA has determined that these uses of NMP for removal of specialized coatings from military aviation and vessel mission-critical corrosion-sensitive components, including safety-critical components, is critical for national security and the safety of personnel and assets. EPA includes in this exemption corrosion-sensitive military aviation and vessel mission-critical components such as landing gear, gear boxes, turbine engine parts, and other military aircraft and vessel components composed of metallic materials (specifically high-strength steel, aluminum, titanium, and

magnesium) and composite materials that not only require their coatings be removed for inspection and maintenance but also would be so negatively affected by the use of technically incompatible, substitute paint removal chemicals or methods that the safe performance of the vessel or aircraft could be compromised.

EPA proposes to grant this exemption for a period of ten years from the date of promulgation of a final rule, with a potential for extension, by further rulemaking, after review by EPA in consultation with DOD. The conditions for this exemption would be: (1) The use of NMP at any concentration for coating removal by DOD or its contractors performing this work only for DOD projects is limited to the mission-critical corrosion-sensitive components on military aviation and vessels, including safety-critical components; (2) this paint and coating removal must be conducted at DOD installations, or at Federal industrial facilities, or at DOD contractor facilities performing this work only for DOD projects.

This exemption granted under TSCA(6)(g)(1)(B) does not impact or lessen any requirements for compliance with other statutes under which the use, disposal, or emissions of NMP is regulated.

As described in Unit XVI.B.3., under the proposed approach, any paint and coating removal products containing NMP would be required to be distributed in containers with a volume no less than 5 gallons, as part of the exemption for uses identified as critical for national security. Allowing selective use for national security purposes does not disrupt the efficacy of the supply chain approach described in Unit XVI.B.3.

In addition to the exemption described in this unit, EPA will consider granting additional time-limited exemptions, under the authority of TSCA section 6(g). Details of EPA's request for comment on such exemption are described in Unit VIII.

XIX. Overview of Uncertainties for NMP in Paint and Coating Removal

A discussion of the uncertainties associated with this proposed rule can be found in the NMP risk assessment (Ref. 3) and in the additional analyses for NMP in commercial and consumer paint and coating removal (Refs. 75 and 76). A summary of these uncertainties follows.

EPA used a number of assumptions in the NMP risk assessment and supporting analysis to develop estimates for occupational and consumer exposure scenarios and to develop the

hazard/dose-response and risk characterization. EPA recognizes that the uncertainties may underestimate or overestimate actual risks. These uncertainties include the likelihood that exposures to NMP vary from one paint and coating removal project to the next. EPA attempted to quantify this uncertainty by evaluating multiple scenarios to establish a range of releases and exposures. In estimating the risk from NMP in paint and coating removal, there are uncertainties in the number of workers and consumers exposed to NMP and in the model inputs and algorithms used to estimate exposures.

In addition to the uncertainties in the risks, there are uncertainties in the cost and benefits. The uncertainties in the benefits are most pronounced in estimating the benefits from preventing the entirety of the adverse effects (described in Unit XIV.C.) because these non-cancer benefits generally cannot be monetized due to the lack of concentration response functions in humans leading to the ability to estimate the number of population-level non-cancer cases and limitations in established economic methodologies. Additional uncertainties in benefit calculations arose from EPA's use of a forecast from an industry expert to estimate the categories of alternatives that users might choose to adopt and the potential risks for adverse health effects that the alternatives may pose. While there are no products or methods that have comparable developmental or similar risks, these substitute products and alternative methods do present hazards. Without information on what alternative methods or chemicals users of NMP for paint and coating removal are likely to switch to, and estimates of the exposures for those alternatives, EPA is unable to quantitatively estimate any change in non-cancer risks due to use of substitute chemicals or alternative methods instead of using NMP for commercial or consumer paint and coating removal.

In addition to these uncertainties related to benefits, there are uncertainties related to the cost estimates. As noted earlier, there is uncertainty in EPA's estimates of which chemical substitutes or alternative methods users may adopt instead of NMP for paint and coating removal, which in turn produces uncertainty as to the cost of those substitutes or methods. EPA has estimated the cost of substitute chemicals, but is not able to fully characterize or quantify the total costs to all sectors for using substitute chemicals or alternative products. In addition, under certain assumptions EPA's economic analysis estimates that

some users of NMP for paint and coating removal will see a cost savings when switching to substitutes. Standard economic theory suggests that financially rational companies would choose technologies that maximize profits so that regulatory outcomes would not typically result in a cost savings for the regulated facilities. There could be several reasons that cost savings might occur in the real world. Potential reasons include lack of complete information or barriers to obtaining information on the cost savings associated with alternatives as well as investment barriers or higher interest rates faced by firms. Additionally, there may be costs associated with these alternatives that are not adequately accounted for in the analysis. To evaluate the effect of this uncertainty, EPA has included a sensitivity analysis that sets the cost savings to zero for these compliance alternatives (Ref. 4 at Section 7). EPA also recognizes that these firms might experience positive costs of compliance rather than zero costs, so that the actual total costs could be higher than those in the sensitivity analysis. However, EPA has no current basis to estimate these potentially higher costs, since the available data appear to show that there are lower cost substitutes available. EPA requests comments on these assumptions.

Additionally, there are uncertainties due to in the estimates of the number of affected commercial and consumer users, and for numbers of processors and distributors of NMP-containing products not prohibited by the proposed rule who are required to provide downstream notification and/or maintain records.

EPA will consider additional information received during the public comment period. This includes scientific publications and other input submitted to EPA during the comment period.

XX. Major Provisions and Enforcement of the Proposed Rule for NMP in Paint and Coating Removal

This proposal relies on general provisions in the proposed Part 751, Subpart A, which can be found at 81 FR 91592 (December 16, 2016).

A. Prohibitions and Requirements

Under the first co-proposed approach, the rule, when final, would (1) prohibit the manufacturing, processing, and distribution in commerce of NMP for consumer and commercial paint and coating removal, exempting uses defined as critical for national security (see Unit XVIII.); (2) prohibit the

commercial use of NMP for paint and coating removal, exempting for uses defined as critical for national security; (3) require any paint and coating removal products containing NMP to be distributed in containers with a volume no less than 5 gallons; (4) require that any commercial use of NMP for paint and coating removal for uses critical to national security include specific worker protections; (5) require manufacturers, processors, and distributors of NMP and all products containing NMP, excluding retailers, to provide downstream notification of the prohibitions; (6) and require recordkeeping relevant to these prohibitions. The prohibition on manufacturing, processing, and distributing in commerce of NMP for all consumer paint and coating removal would take effect 180 days after publication of a final rule. Similarly, the prohibition on manufacturing, processing, and distributing in commerce of NMP for any paint and coating removal for uses other than those exempted as critical for national security in volumes less than 5-gallon containers would take effect 180 days after publication of a final rule. The prohibition on commercial use of NMP for paint and coating removal except for the exempted critical national security uses would take effect 270 days after publication of a final rule. These are reasonable transition periods because, as noted in Unit XVI.D. and by the small businesses participating in the SBAR process, many formulators of paint and coating removers containing NMP also manufacture products for this use that do not contain NMP (Ref. 27). In addition, alternative paint removal products exist at comparable expense for users to purchase. Six months from publication of the final rule is sufficient time to allow for existing stocks to move through the market place and to allow manufacturers, processors and distributors and users to plan for and implement product substitution strategies.

Under the second co-proposed approach, formulators of paint and coating removal products for either commercial or consumer use would be required to: (1) Ensure that their paint and coating removal products containing NMP do not exceed a maximum of 35 percent NMP by weight in product formulations exempting products used for critical national security uses (see Unit XVIII.); (2) Test gloves for the product formulations being processed and distributed in commerce for other than exempt critical national security uses to identify

specialized gloves that provide protection for users and keep records relevant to these tests; (3) Label products with information for consumers about the risks presented by products that contain NMP and how to reduce these risks when using the products, including identifying which specialized gloves provide protection against the specific formulation; and (4) Provide information for commercial users about reducing risks when using the product, via product labels, SDS, and other methods of hazard communication. Variations of more than 1% in any component of a paint and coating removal product containing NMP would be considered a separate formulation.

Under this co-proposal, commercial users of NMP for paint and coating removal other than exempt critical national security uses would be prohibited from using paint and coating removal products or formulations that contain more than 35 percent by weight of NMP. They would also be required to establish a worker protection program for dermal and respiratory protection, including hazard communication, training, and requirements that workers wear clothing covering most of the body, *i.e.*, impervious long pants and shirts with long sleeves, use gloves specified by product formulators (described under formulator requirements below) and a respirator with APF 10, with an alternative air exposure limit of 5 ppm achieved through engineering controls or ventilation.

B. Downstream Notification

EPA has authority under TSCA section 6 of TSCA to require that a substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate minimum warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. Many manufacturers and processors of NMP are likely to manufacture or process NMP or products containing NMP for other uses that would not be regulated under this proposed rule. Other companies may be strictly engaged in distribution in commerce of NMP, without any manufacturing or processing activities, to customers for uses that are not regulated. Under both co-proposed approaches, EPA is proposing a requirement for downstream notification by manufacturers, processors, and distributors of NMP for any use to ensure compliance with the prohibition on manufacture, processing,

distribution in commerce, and commercial use of NMP for the uses proposed for regulation. Downstream notification is necessary for effective enforcement of the rule because it provides a record, in writing, of notification on use restrictions throughout the supply chain, likely via modifications to the Safety Data Sheet. Downstream notification also increases awareness of restrictions on the use of NMP for paint and coating removal, which is likely to decrease unintentional uses of NMP by these entities. Downstream notification represents minimal burden and is necessary for effective enforcement of the rule. The estimated cost of downstream notification on an annualized basis over 20 years is \$100 and \$100 using 3% and 7% discount rates respectively (Ref. 4).

The effective date of the requirement for this notification would be 45 days after publication of the final rule. This is a reasonable transition period because regulated entities would only need to provide additional information on their SDS, which are routinely produced and updated.

C. Enforcement

Section 15 of TSCA makes it unlawful to fail or refuse to comply with any provision of a rule promulgated under TSCA section 6. Therefore, any failure to comply with this proposed rule when it becomes effective would be a violation of section 15 of TSCA. In addition, section 15 of TSCA makes it unlawful for any person to: (1) Fail or refuse to establish and maintain records as required by this rule; (2) fail or refuse to permit access to or copying of records, as required by TSCA; or (3) fail or refuse to permit entry or inspection as required by section 11 of TSCA.

Violators may be subject to both civil and criminal liability. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty for each violation. Each day of operation in violation of this proposed rule when it becomes effective could constitute a separate violation. Knowing or willful violations of this proposed rule when it becomes effective could lead to the imposition of criminal penalties for each day of violation and imprisonment. In addition, other remedies are available to EPA under TSCA.

Individuals, as well as corporations, could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to "any person" who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies. In particular, EPA

may proceed against individuals who report false information or cause it to be reported.

XXI. Analysis for Methylene Chloride and NMP in Paint and Coating Removal under TSCA Section 9 and Section 26(h) Considerations

A. TSCA Section 9(a) Analysis

Section 9(a) of TSCA provides that, if the Administrator determines in her discretion that an unreasonable risk may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA, the Administrator must submit a report to the agency administering that other law that describes the risk and the activities that present such risk. If the other agency responds by declaring that the activities described do not present an unreasonable risk or if that agency initiates action under its own law to protect against the risk within the timeframes specified by TSCA section 9(a), EPA is precluded from acting against the risk under sections 6(a) or 7 of TSCA.

TSCA section 9(d) instructs the Administrator to consult and coordinate TSCA activities with other Federal agencies for the purpose of achieving the maximum enforcement of TSCA while imposing the least burden of duplicative requirements. For this proposed rule, EPA has consulted with OSHA and with CPSC. Both CPSC and OSHA have provided letters documenting this consultation (Refs. 121 and 122).

CPSC protects the public from unreasonable risks of injury or death associated with the use of consumer products under the agency's jurisdiction. Though CPSC has provided guidance to consumers when using products containing NMP, there are no CPSC regulations regarding NMP in paint and coating removal. CPSC currently requires that household products that can expose consumers to methylene chloride vapors must bear appropriate warning labels (52 FR 34698, September 14, 1987). In a letter regarding EPA's proposed rulemaking, CPSC stated that "Some paint removers are distributed for sale to, and use by, consumers and thus would likely fall within CPSC's jurisdiction. However, because TSCA gives EPA the ability to reach both occupational and consumer uses, we recognize that EPA may address risks associated with these chemicals in a more cohesive and coordinated manner given that CPSC lacks authority to address occupational hazards" (Ref. 121).

OSHA assures safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance. OSHA's methylene chloride standard, 29 CFR 1910.1052, was issued in 1997 and applies to general industry, construction, and shipyard employment. It sets the PEL for airborne methylene chloride to an eight-hour TWA of 25 parts per ppm. OSHA has not set a standard for NMP. OSHA recently published a Request for Information on approaches to updating PELs and other strategies to managing chemicals in the workplace (79 FR 61384, October 10, 2014). OSHA's current regulatory agenda does not include revision to the methylene chloride PEL, establishment of a PEL for NMP, or other regulations addressing the risks EPA has identified when methylene chloride or NMP are used in paint and coating removal (Ref. 122).

This proposed rule addresses risk from exposure to methylene chloride and NMP during paint and coating removal in both workplace and consumer settings. With the exception of TSCA, there is no Federal law that provides authority to prevent or sufficiently reduce these cross-cutting exposures. No other Federal regulatory authority, when considering the exposures to the populations and within the situations in its purview, can evaluate and address the totality of the risk that EPA is addressing in this proposal and the prior proposal on TCE uses (Ref. 1). For example, OSHA may set exposure limits for workers but its authority is limited to the workplace and does not extend to consumer uses of hazardous chemicals. Further, OSHA does not have direct authority over state and local employees, and it has no authority at all over the working conditions of state and local employees in states that have no OSHA-approved State Plan under 29 U.S.C. 667. Other Federal regulatory authorities, such as CPSC, have the authority to only regulate pieces of the risks posed by methylene chloride and NMP, such as when used in consumer products.

Moreover, recent amendments to TSCA, Public Law 114-182, alter both the manner of identifying unreasonable risk under TSCA and EPA's authority to address unreasonable risk under TSCA, such that risk management under TSCA is increasingly distinct from analogous provisions of the Consumer Product Safety Act (CPSA), the Federal Hazardous Substances Act (FHSA), or the OSH Act. These changes to TSCA reduce the likelihood that an action under the CPSA, FHSA, or the OSH Act

would reduce the risk of methylene chloride and NMP in paint and coating removal so that the risks are no longer unreasonable under TSCA. Whereas (in a TSCA section 6 rule) an unreasonable risk determination sets the objective of the rule in a manner that excludes cost considerations, 15 U.S.C. 2605(a)(b)(4)(A), subject to time-limited conditional exemptions for critical chemical uses and the like, 15 U.S.C. 2605(g), a consumer product safety rule under the CPSA must include a finding that “the benefits expected from the rule bear a reasonable relationship to its costs.” 15 U.S.C. 2058(f)(3)(E). Additionally, recent amendments to TSCA reflect Congressional intent to “delete the paralyzing ‘least burdensome’ requirement,” 162 Cong. Rec. S3517 (June 7, 2016). However, a consumer product safety rule under the CPSA must impose “the least burdensome requirement which prevents or adequately reduces the risk of injury for which the rule is being promulgated.” 15 U.S.C. 2058(f)(3)(F). Analogous requirements, also at variance with recent revisions to TSCA, affect the availability of action under the FHSA relative to action under TSCA. 15 U.S.C. 1262. Gaps also exist between OSHA’s authority to set workplace standards under the OSH Act and EPA’s amended obligations to sufficiently address chemical risks under TSCA. To set PELs for chemical exposure, OSHA must first establish that the new standards are economically feasible and technologically feasible. 79 FR 61387 (2014). But under TSCA, EPA’s substantive burden under TSCA section 6(a) is to demonstrate that, as regulated, the chemical substance no longer presents an unreasonable risk, with unreasonable risk being determined without consideration of cost or other non-risk factors.

TSCA is the only regulatory authority able to prevent or reduce risks of methylene chloride or NMP exposure to a sufficient extent across the range of uses and exposures of concern. In addition, these risks can be addressed in a more coordinated, efficient and effective manner under TSCA than under two or more different laws implemented by different agencies. Furthermore, there are key differences between the newly amended finding requirements of TSCA and those of the OSH Act, CPSA, and the FHSA. For these reasons, in her discretion, the Administrator does not determine that unreasonable risks from the use of methylene chloride and NMP in paint and coating removal may be prevented or reduced to a sufficient extent by an

action taken under a Federal law not administered by EPA. However, EPA is requesting public comment on this issue (*i.e.*, the sufficiency of an action taken under a Federal law not administered by EPA).

B. TSCA Section 9(b) Analysis

If EPA determines that actions under other Federal laws administered in whole or in part by EPA could eliminate or sufficiently reduce an unreasonable risk, section 9(b) of TSCA instructs EPA to use these other authorities unless the Administrator determines in the Administrator’s discretion that it is in the public interest to protect against such risk under TSCA. In making such a public interest finding, TSCA section 9(b)(2) states: “the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk . . . and a comparison of the estimated costs and efficiencies of the action to be taken under this title and an action to be taken under such other law to protect against such risk.”

Although several EPA statutes have been used to limit methylene chloride or NMP exposure (Units III.A. and XII.A.), regulations under these EPA statutes have limitations because they largely regulate releases to the environment, rather than direct human exposure. SDWA only applies to drinking water. CAA does not apply directly to worker exposures or consumer settings where methylene chloride or NMP are used. Under RCRA, methylene chloride that is discarded may be considered a hazardous waste and subject to requirements designed to reduce exposure from the disposal of methylene chloride to air, land and water. RCRA does not address exposures during use of products containing methylene chloride or NMP. Only TSCA provides EPA the authority to regulate the manufacture (including import), processing, and distribution in commerce, and use of chemicals substances.

For these reasons, the Administrator does not determine that unreasonable risks from the use of methylene chloride and NMP in paint and coating removal could be eliminated or reduced to a sufficient extent by actions taken under other Federal laws administered in whole or in part by EPA.

C. Section 26(h) Considerations

EPA has used scientific information, technical procedures, measures, methods, protocols, methodologies, and models consistent with the best available science. For example, EPA based its proposed determination of

unreasonable risk presented by the use of methylene chloride and NMP in paint and coating removal on the completed risk assessments, which each followed a peer review and public comment process, as well as using best available science and methods (Refs. 2 and 3). Supplemental analyses were performed to better characterize the exposed populations and estimate the effects of various control options. These supplemental analyses were consistent with the methods and models used in the risk assessment. These analyses were developed for the purpose of supporting a future regulatory determination: To determine either that particular risks are not unreasonable or that those are risks are unreasonable. They were also developed to support risk reduction by regulation under section 6 of TSCA, to the extent risks were determined to be unreasonable. It is reasonable and consistent to consider these supplemental analyses in this rulemaking for such relevant purposes.

The extent to which the various information, procedures, measures, methods, protocols, methodologies or models, as applicable, used in EPA’s decision have been subject to independent verification or peer review is adequate to justify their use, collectively, in the record for this rule. Additional information on the peer review and public comment process, such as the peer review plan, the peer review report, and the Agency’s response to comments, can be found on EPA’s Assessments for TSCA Work Plan Chemicals Web page at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals>.

XXII. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

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Paint Removers & TCE Rulemakings E.O. 13132: Federalism Consultation. May 13, 2015.

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XXIII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is an economically significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Order 12866 and Executive Order 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket. EPA prepared an economic analysis of the potential costs and benefits associated with this action, which is available in the docket and summarized in Units I.E., VII.B., and XVII.B. (Refs. 4 and 127).

B. Paperwork Reduction Act (PRA)

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by the EPA has been assigned the EPA ICR number 2556.01. You can find a copy of the ICR in the docket for this proposed rule (Ref. 123), and it is briefly summarized here.

Under the proposed approach for methylene chloride and both co-proposed approaches for NMP, the information collection activities required under the proposed rule include a downstream notification requirement and a recordkeeping requirement. The downstream notification would require companies that ship methylene chloride or NMP to notify companies downstream in the supply chain of the prohibitions of methylene chloride or NMP in the proposed rule. The proposed rule does

not require the regulated entities to submit information to EPA. The proposed rule also does not require confidential or sensitive information to be submitted to EPA or downstream companies. The recordkeeping requirement mandates companies that ship methylene chloride or NMP to retain certain information at the company headquarters for three years from the date of shipment. These information collection activities are necessary in order to enhance the prohibitions under the proposed rule by ensuring awareness of the prohibitions throughout the methylene chloride or NMP supply chain, and to provide EPA with information upon inspection of companies downstream who purchased methylene chloride or NMP. EPA believes that these information collection activities would not significantly impact the regulated entities.

Under the second co-proposed approach for NMP, processors of paint and coating removal products containing NMP must test gloves for permeability for each formulation they process. One type of gloves may not be appropriate for all NMP paint remover formulations because the permeability of the product will vary based on the other solvents and chemicals used in the formulation. The testing requirements for glove permeability and the labeling requirements mandate that processors paint removers containing perform glove permeability testing on each paint remover product containing NMP and update their current product labels to contain warnings and instructions for consumers on how to reduce exposures to NMP. Without the reporting requirements, processors of these products might not provide information about the specific types of protective gloves to users. Requiring that labels of paint and coating removal products containing NMP include information about which specific types of gloves provide dermal protection from the specific product formulation provides information that is essential for knowing how to reduce exposures while carrying out paint and coating removal with NMP. Requiring additional warnings and instructions to consumers provides information about the risks presented by the product and how those risks can be reduced. EPA believes that these information collection activities would not significantly impact the regulated entities.

Respondents/Affected Entities: Methylene chloride and NMP manufacturers, processors, and distributors; commercial users of NMP for paint and coating removal.

Respondent's Obligation to Respond: Respondents are not obligated to respond or report to EPA.

Estimated Number of Respondents for the Proposed Approach for Methylene Chloride and the First Co-Proposed Approach for NMP: 327.

Estimated Total Number of Potential Respondents for the Proposed Approach for Methylene Chloride and the Second Co-Proposed Approach for NMP: 327

Frequency of Response: On occasion to third parties as needed.

Total Estimated Burden for the Proposed Approach for Methylene Chloride and the First Co-Proposed Approach for NMP: 163.5

Estimated Total Annual Burden for the Proposed Approach for Methylene Chloride and the Second Co-Proposed Approach for NMP: 1,084 hours.

Total Estimated Cost for the Proposed Approach for Methylene Chloride and the First Co-Proposed Approach for NMP: \$7,904 (per year).

Estimated Total Annual Costs for the Proposed Approach for Methylene Chloride and the Second Co-Proposed Approach for NMP: \$924,890 (per year).

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this proposed rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to oira_submission@omb.eop.gov, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than February 21, 2017. The EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 603 of the RFA, 5 U.S.C. 601 *et seq.*, EPA prepared an initial regulatory flexibility analysis (IRFA) (Ref. 26) that examines the impact of the proposed rule on small entities along with regulatory alternatives that could minimize that impact. The complete IRFA is available for review in the docket and is summarized here.

1. Need for the rule. Under TSCA section 6(a) (15 U.S.C. 2605(a)), if EPA

determines that a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk. Based on EPA's risk assessments of methylene chloride (Ref. 2) and NMP (Ref. 3), EPA proposes a determination that the use of methylene chloride and NMP in paint and coating removal presents an unreasonable risk of injury to human health. The provisions of this proposal are necessary to address the risk so that it is no longer unreasonable.

2. *Objectives and legal basis.* In part, the legal basis for this proposal is TSCA section 6(a), which provides authority for the Administrator to apply requirements to the extent necessary so that a chemical substance or mixture no longer presents an unreasonable risk of injury to health or the environment. Additional legal basis for the proposal is found at TSCA section 26(l)(4). With respect to chemical substances such as methylene chloride and NMP (which are listed in the 2014 update to the TSCA Work Plan for Chemical Assessments and for which completed risk assessments were published prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act) TSCA section 26(l)(4) expressly authorizes EPA to issue rules under TSCA section 6(a) that are consistent with the scope of the completed risk assessment and consistent with the other applicable requirements of TSCA section 6.

3. *Small entities covered by this proposal.* EPA estimates that the proposal would affect approximately 10,300 small entities. The majority of these entities are commercial users of methylene chloride or NMP in paint and coating removal in a variety of occupational settings such as bathtub refinishing, graffiti removal, autobody repair, and residential renovations. This also includes a small number of formulators of paint and coating removal products that contain methylene chloride and NMP, for commercial or consumer uses (Refs. 4, 26, and 127).

4. *Compliance requirements and the professional skills needed.* For methylene chloride, EPA is proposing under TSCA section 6 to prohibit the manufacture (including import), processing, and distribution in

commerce of methylene chloride for all consumer and many types or uses of commercial paint and coating removal, as described in the proposed rule. EPA is also proposing under TSCA section 6 to prohibit the use of methylene chloride for commercial paint and coating removal in these several specified sectors. Additionally, EPA is proposing to require that any paint or coating removal products containing methylene chloride that continue to be distributed be packaged in volumes no less than 55-gallon containers, except for formulations produced specifically for DOD. EPA is also proposing to require manufacturers (including importers), processors, and distributors, except for retailers, of methylene chloride for any use to provide downstream notification of these requirements and prohibitions throughout the supply chain; and to require limited recordkeeping. More details on this supply chain approach are in Unit VI.C.3.

For NMP, EPA is co-proposing two approaches. Under the first co-proposed approach, EPA is proposing to prohibit the manufacture (including import), processing, and distribution in commerce of NMP for all consumer and commercial paint and coating removal, exempting uses identified in the proposed rule as critical to national security; and to prohibit the commercial use of NMP for paint and coating removal, exempting uses identified as critical to national security. EPA is proposing to require that any paint or coating removal products containing NMP that continue to be distributed be packaged in no less than 5-gallon containers. EPA is also proposing to require manufacturers (including importers), processors, and distributors, except for retailers, of NMP for any use to provide downstream notification of these prohibitions throughout the supply chain; and to require limited recordkeeping. For the second co-proposed approach for NMP, commercial users would be required to implement and maintain a detailed program for worker protection, including dermal and respiratory protection. Additionally, product processors would be required to carry out testing to identify gloves that are protective against each product formulation, labeling product with that information, and provide additional information on the label to consumers regarding risks of using the product and instructions on how to reduce those risks. As in the first co-proposal, EPA is also proposing to require manufacturers (including importers), processors, and

distributors, except for retailers, of NMP for any use to provide downstream notification of these prohibitions throughout the supply chain; and to require limited recordkeeping. More details on these two co-proposals are in Unit XVI.B.3.

Under the proposed approach for methylene chloride and first co-proposed approach for NMP, complying with the prohibitions, the downstream notification, and the recordkeeping requirements involve no special skills. However, implementing the use of substitute chemicals or alternative paint and coating removal processes may involve special skills or expertise in the sector in which the paint and coating removal is conducted.

For the second co-proposed approach for NMP, commercial users would be required to implement and maintain a detailed program for worker protection, which would involve special skills or expertise in industrial hygiene. Similarly, product processors would be required to carry out testing to identify gloves that are protective against each product formulation, could involve special skills or expertise. Labeling products to comply with new requirements would not involve special skill, particularly since EPA proposes to identify specific information for labels of paint and coating removal products containing NMP. As in the first co-proposal for NMP, the downstream notification and the recordkeeping requirements require no special skills.

5. *Other Federal regulations.* Other Federal regulations that affect the use of methylene chloride or NMP in paint and coating removal are discussed in Units III.A. and XIII.A. While many of the statutes that EPA and other agencies are charged with administering provide statutory authority to address specific sources and routes of methylene chloride exposure, none of these can address the serious human health risks from methylene chloride exposure that EPA is proposing to address under TSCA section 6(a). Regarding methylene chloride, because the methylene chloride NESHAPs were developed only to regulate emissions from certain types of paint and coating removal operations, not to address worker or consumer exposures, they are not duplicative with this proposal. Similarly, regulations addressing methylene chloride disposal or water contamination do not address worker or consumer exposures when conducting paint and coating removal. This proposed rule does not conflict with the NESHAP (or regulations addressing methylene chloride disposal or water contamination): it neither prohibits any action required by such

rules, nor requires any action prohibited by such rules.

OSHA's methylene chloride standard, 29 CFR 1910.1052, was issued in 1997 and applies to general industry, construction, and shipyard employment. This proposal does not duplicate OSHA's methylene chloride standard. Nor does the proposed rule conflict with the OSHA standard: it would not prohibit actions required to meet OSHA's methylene chloride standard and it would not require actions in violation OSHA's methylene chloride standard.

CPSC requires that consumer products that contain methylene chloride be labeled with a statement regarding the cancer risks presented by inhalation of methylene chloride fumes. This proposal does not impose requirements that would duplicate or conflict with CPSC's labeling requirements for methylene chloride.

Regarding NMP, there are no OSHA or CPSC regulations. EPA's proposal is not duplicative of other Federal rules nor does it conflict with other Federal rules.

6. *Regulatory alternatives considered.*

As described in Units V.C., VI.C., XV.C., and XVI.B., EPA considered a wide variety of risk reduction options. The Economic Analysis (Ref. 4) examined several alternative analytical options. However, most of the alternatives did not address the risks presented by methylene chloride and NMP in paint and coating removal as necessary so that they would no longer be unreasonable, either to the general population or (in the case of NMP) to women of childbearing age.

The primary alternative considered by EPA for methylene chloride in paint and coating removal was to allow the commercial use of methylene chloride in paint and coating removal and require a respiratory protection program, including PPE, air monitoring, and either a supplied-air respirator of APF 1,000 or 10,000 or an air exposure limit achieved through engineering controls or ventilation in commercial facilities where methylene chloride is used for paint and coating removal. Depending on air concentrations and proximity to the paint and coating removal, other employees in the area would also need to wear respiratory protection equipment. While this option would address the risks presented by methylene chloride in paint and coating removal, so that they would no longer be unreasonable, the Economic Analysis indicates that this option is more expensive than switching to a substitute chemical or alternative paint and coating removal method (Ref. 4). However, as recommended by the SBAR

panel, EPA is seeking comment on and additional information about air monitoring and the use of supplied-air respirators in firms conducting paint and coating removal with methylene chloride (Ref. 27).

EPA is co-proposing two approaches to address risks presented by NMP in commercial and consumer paint and coating removal. Those approaches are described above. EPA considers both of these approaches to be primary regulatory alternatives.

As required by section 609(b) of the RFA, EPA also convened a SBAR Panel to obtain advice and recommendations from small entity representatives that potentially would be subject to the rule's requirements. The SBAR Panel evaluated the assembled materials and small-entity comments on issues related to elements of an IRFA. A copy of the full SBAR Panel Report (Ref. 27) is available in the rulemaking docket.

The Panel recommended that EPA seek additional information in five specific areas: Exposure information, regulatory options, alternatives, cost information, and risk assessment. Specifically, the Panel recommendations were: (1) Exposure information: EPA should request workplace monitoring information during the comment period for worker exposure levels from companies for methylene chloride and NMP in paint and coating removal. EPA should request additional information regarding the frequency of use currently of PPE, and consider that information when weighing alternative options in the proposed rulemaking for methylene chloride and NMP in paint and coating removal. (2) Regulatory options: EPA should consider and seek public comments on enhanced labeling requirements for consumer paint removal products containing methylene chloride or NMP to reduce exposure to methylene chloride and NMP. EPA should consider and seek public comments on a control option such as a certification program similar to the Lead Renovation, Repair and Painting program with increased training and education for commercial users of paint removers. EPA should delay any proposed regulatory action on methylene chloride for the commercial furniture refinishing industry while it gathers additional information to characterize the impacts on this industry of restrictions on use of methylene chloride in paint and coating removal. EPA should request comment on current practices in the furniture refinishing industry on limiting exposure to methylene chloride used in paint and coating removal. EPA should

request comment on the feasibility of methylene chloride only being sold in 30–55-gallon drums. EPA should address the proposed regulatory actions as distinctly as possible in the one proposed rulemaking addressing both methylene chloride and NMP in paint and coating removal. (3) Alternatives: EPA should ensure that its analysis of the available alternatives to methylene chloride and NMP in paint and coating removal comply with the requirements of TSCA section 6(c)(2)(C) and include consideration, to the extent legally permissible and practicable, of whether technically and economically feasible alternatives that benefit health or the environment, compared to the use being prohibited or restricted, will be reasonably available as a substitute when the proposed requirements would take effect. Specifically, EPA should evaluate the feasibility of using alternatives, including the cost, relative safety, and other barriers; and take into consideration the current and future planned regulation of compounds the agency has listed as alternatives. (4) Cost information: EPA should request additional information on the cost to achieve reduced exposures in the workplace or to transition to alternative chemicals or technologies. (5) Risk assessments: EPA should recognize the concerns that the SERs had on the risk assessments by referring readers to the risk assessments and the Agency's Summary of External Peer Review and Public Comments and Disposition document for each risk assessment, which addresses those concerns, in the preamble of the proposed rulemaking.

Throughout this preamble, EPA has requested information with respect to these and other topics.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The requirements of this action would primarily affect manufacturers, processors, and distributors of methylene chloride or NMP. The total estimated annualized cost of the proposed rule under the first co-proposed approach for NMP is \$4,185,000 to \$23,423,000 and \$4,550,000 to \$23,472,000 annualized over 20 years at 3% and 7%, respectively (Ref. 4). The total estimated annualized cost of the proposed rule under the second co-proposed approach for NMP is \$114,196,000 to \$125,893,000 and \$114,658,000 to \$125,438,000 annualized over 20 years

at 3% and 7%, respectively (Ref. 127), which does not exceed the inflation-adjusted unfunded mandate threshold of \$154 million.

E. Executive Order 13132: Federalism

The EPA has concluded that this action has federalism implications, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because regulation under TSCA section 6(a) may preempt state law. EPA provides the following federalism summary impact statement. The Agency consulted with state and local officials early in the process of developing the proposed action to permit them to have meaningful and timely input into its development. EPA invited the following national organizations representing state and local elected officials to a meeting on May 13, 2015, in Washington DC: National Governors Association; National Conference of State Legislatures, Council of State Governments, National League of Cities, U.S. Conference of Mayors, National Association of Counties, International City/County Management Association, National Association of Towns and Townships, County Executives of America, and Environmental Council of States. A summary of the meeting with these organizations, including the views that they expressed, is available in the docket (Ref. 124). Although EPA provided these organizations an opportunity to provide follow-up comments in writing, EPA received no written follow-up.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This rulemaking would not have substantial direct effects on tribal government because methylene chloride or NMP are not manufactured, processed, or distributed in commerce by tribes. Tribes do not regulate methylene chloride or NMP, and this rulemaking would not impose substantial direct compliance costs on tribal governments. Thus, EO 13175 does not apply to this action. EPA nevertheless consulted with tribal officials during the development of this action, consistent with the EPA Policy on Consultation and Coordination with Indian Tribes.

EPA met with tribal officials in a national informational webinar held on May 12, 2015 concerning the prospective regulation of methylene chloride and NMP in paint and coating removal under TSCA section 6, and in

another teleconference with tribal officials on May 27, 2015 (Ref. 125). EPA also met with the National Tribal Toxics Council (NTTC) in Washington, DC and via teleconference on April 22, 2015 (Ref. 125). In those meetings, EPA provided background information on the proposed rule and a summary of issues EPA explored. These officials expressed support for EPA regulation to reduce the risks presented by methylene chloride and NMP in paint and coating removal.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is subject to Executive Order 13045 because it is an economically significant regulatory action as defined by Executive Order 12866, and the EPA believes that the environmental health or safety risk addressed by this action has a disproportionate effect on children, specifically on the developing fetus. Accordingly, we have evaluated the environmental health or safety effects of methylene chloride and NMP in paint and coating removal on children. This action's health and risk assessment of exposure by children to methylene chloride and NMP in paint and coating removal are contained in Units I.F., VI.C.1.c., and XVI.B.1.c. of this preamble. Supporting information on methylene chloride and NMP exposures and the health effects of methylene chloride or NMP exposure by children is available in the Toxicological Review of Methylene Chloride (Ref. 5), the NMP risk assessment (Ref. 3), and the methylene chloride risk assessment (Ref. 2).

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution in Commerce, or Use

This proposed rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution in commerce, or use. This rulemaking is intended to protect against risks from methylene chloride and NMP in paint and coating removal, and does not affect the use of oil, coal, or electricity.

I. National Technology Transfer and Advancement Act (NTTAA)

This proposed rulemaking does not involve technical standards, and is therefore not subject to considerations under NTTAA section 12(d), 15 U.S.C. 272 note. However, under one of the co-proposals for NMP discussed in Unit XVI, EPA is proposing to require

processors of paint and coating removal products that contain NMP to identify, through testing, gloves that provide an impervious barrier to dermal exposure during normal and expected duration and conditions of exposure. EPA has identified two potentially-applicable voluntary consensus standards for this process: ASTM International Standard F739, "Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact," and ASTM International F1194-99, "Standard Guide for Documenting the Results of Chemical Permeation Testing of Materials Used in Protective Clothing Materials." EPA is not proposing specific provisions for conducting and documenting glove testing, nor is EPA proposing to incorporate these voluntary consensus standards by reference. EPA requests comment on whether the regulation should include additional requirements on glove testing for processors and, if so, how that should be accomplished.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse health or environmental effects of their programs, policies and activities on minority populations and low-income populations in the U.S. Units VI.C.1.b., VI.D.10., XVI.B.1.b., and XVI.C.6. of this preamble address public health impacts from methylene chloride and NMP in paint and coating removal. This proposed rule would address the current disproportionate risk to Hispanic workers (of all races) and foreign-born workers in the construction trades, where these two populations are overrepresented compared to the general U.S. adult population (Ref. 4). Though this proposed rule would eliminate risks of exposure to NMP and methylene chloride when used in paint and coating removal in the construction trades, because workers in these two populations currently are overrepresented in this trade, these populations would disproportionately benefit from this risk reduction. The EPA places particular emphasis on the public health and environmental conditions affecting minority populations, low-income populations,

and indigenous peoples. In recognizing that these populations frequently bear a disproportionate burden of environmental harms and risks, EPA works to protect them from adverse public health and environmental effects (Ref. 126).

List of Subjects in 40 CFR Part 751

Environmental protection, Chemicals, Export notification, Hazardous substances, Import certification, Recordkeeping.

Dated: January 12, 2017.

Gina McCarthy,
Administrator.

Therefore, 40 CFR part 751, as proposed to be added at 81 FR 91592 (December 16, 2016), is proposed to be further amended as follows:

PART 751—REGULATION OF CERTAIN CHEMICAL SUBSTANCES AND MIXTURES UNDER SECTION 6 OF THE TOXIC SUBSTANCES CONTROL ACT

- 1. The authority citation for part 751 is revised to read as follows:

Authority: 15 U.S.C. 2605, 15 U.S.C. 2625(l)(4).

- 2. Add Subpart B to read as follows:

Subpart B—Methylene Chloride

Sec.

751.101 General.

751.103 Definitions.

751.105 Consumer Paint and Coating Removal.

751.107 Commercial Paint and Coating Removal in Specified Industries or for Specified Uses.

751.109 Downstream Notification.

751.111 Recordkeeping.

Subpart B—Methylene Chloride

§ 751.101 General.

This subpart sets certain restrictions on the manufacture (including import), processing, distribution in commerce, and uses of methylene chloride (CASRN 75–09–2) to prevent unreasonable risks to health associated with human exposure to methylene chloride for the specified uses.

§ 751.103 Definitions.

The definitions in subpart A of this part apply to this subpart unless otherwise specified in this section. In addition, the following definitions apply:

Commercial furniture stripping means furniture stripping conducted in a commercial facility performed by an individual, government entity, or company for which an individual, government entity, or company receives remuneration or other form of payment.

Commercial paint and coating removal means paint and coating removal performed by an individual, government entity, or company, for which an individual, government entity, or company receives remuneration or other form of payment.

Critical corrosion-sensitive components of military aviation and vessels means parts that directly enable or support warfighting assets of the Department of Defense (DOD) and include “safety critical items” identified by DOD in accordance with DOD policies and requirements for ensuring safety and performance. These include corrosion-sensitive aviation and vessel safety-critical components such as landing gear, gear boxes, turbine engine parts, and other military aircraft and vessel components composed of metallic materials (specifically high-strength steel, aluminum, titanium, and magnesium) and composite materials that not only require their coatings be removed for inspection and maintenance but also would be so negatively affected by the use of paint removal chemicals or methods other than methylene chloride that the safety of the system could be compromised.

Distribute in commerce has the same meaning as in section 3 of the Act, except that the term does not include retailers for purposes of § 751.109 and § 751.111.

Furniture stripping means paint and coating removal from furniture and includes application of a chemical or use of another method to remove, loosen, or deteriorate any paint, varnish, lacquer, graffiti, surface protectants, or other coating from wood, metal, or other types of furniture, doors, radiators, or cabinets. Furniture stripping includes paint and coating removal from furniture that occurs separately from or as part of furniture refinishing.

Paint and coating removal means application of a chemical or use of another method to remove, loosen, or deteriorate any paint, varnish, lacquer, graffiti, surface protectants, or other coating from a substrate, including objects, vehicles, architectural features, or structures.

Retailer means a person or business who distributes in commerce a chemical substance, mixture, or article to consumer end users.

§ 751.105 Consumer Paint and Coating Removal.

After [date 180 calendar days after the date of publication of the final rule], all persons are prohibited from manufacturing, processing, and distributing in commerce methylene

chloride for consumer paint and coating removal.

§ 751.107 Commercial Paint and Coating Removal in Specified Industries or for Specified Uses.

(a) After [date 180 calendar days after the date of publication of the final rule], all persons are prohibited from manufacturing, processing, and distributing in commerce methylene chloride for commercial paint and coating removal except for commercial furniture stripping or for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels as defined in § 751.103. After [date 10 years after the date of publication of the final rule], all persons are prohibited from manufacturing, processing, and distributing in commerce methylene chloride for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels.

(b) After [date 180 calendar days after the date of publication of the final rule], all persons are prohibited from distributing in commerce methylene chloride for paint and coating removal in containers with a volume less than 55 gallons except for formulations specifically manufactured for the Department of Defense, which may be distributed in commerce in containers with a volume no less than 5 gallons.

(c) After [date 270 calendar days after the date of publication of the final rule], all persons are prohibited from commercial use of methylene chloride for paint and coating removal except for commercial furniture stripping or for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels as defined in § 751.103. After [date 10 years after the date of publication of the final rule], all persons are prohibited from commercial use of methylene chloride for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels.

(d) Any paint and coating removal from critical corrosion-sensitive components of military aviation and vessels must be conducted under the following restrictions:

(1) All paint and coating removal from critical corrosion-sensitive components of military aviation and vessels using methylene chloride must be conducted at DOD installations, or at deployed locations under the control of DOD organizations, or at locations of DOD contractors performing coating removal work from corrosion-sensitive components of military aviation and vessels for DOD.

§ 751.109 Downstream Notification.

Each person who manufactures, processes, or distributes in commerce methylene chloride for any use after [date 45 calendar days after the date of publication of the final rule] must, prior to or concurrent with the shipment, notify companies to whom methylene chloride is shipped, in writing, of the restrictions described in this subpart.

§ 751.111 Recordkeeping.

(a) Each person who manufactures, processes, or distributes in commerce any methylene chloride after [date 45 calendar days after the date of publication of final rule] must retain in one location at the headquarters of the company documentation showing:

- (1) The name, address, contact, and telephone number of companies to whom methylene chloride was shipped;
- (2) A copy of the notification provided under § 751.109; and
- (3) The amount of methylene chloride shipped.

(b) The documentation in (a) must be retained for 3 years from the date of shipment.

■ 3. Add Subpart C as follows:**Subpart C—N-Methylpyrrolidone.**

Sec.

- 751.201 General.
- 751.203 Definitions. [option 1]
- 751.205 Manufacture, processing, and distribution of NMP for consumer paint and coating removal.
- 751.207 Manufacture, Processing, and Distribution of NMP for Commercial Paint and Coating Removal
- 751.209 Downstream Notification.
- 751.211 Recordkeeping. [option 2]
- 751.205 Paint and Coating Removal for Specified Uses.
- 751.209 Downstream Notification.
- 751.211 Recordkeeping.

Subpart C—N-Methylpyrrolidone**§ 751.201 General.**

This subpart sets certain restrictions on the manufacture (including import), processing, distribution in commerce, and uses of N-methylpyrrolidone (NMP) (CASRN 872–50–4) to prevent unreasonable risks to health associated with human exposure to NMP for the specified uses.

§ 751.203 Definitions.

The definitions in subpart A of this part apply to this subpart unless otherwise specified in this section. In addition, the following definitions apply:

Commercial paint and coating removal means paint and coating removal performed by an individual, government entity, or company, for which an individual, government entity,

or company receives remuneration or other form of payment.

Critical corrosion-sensitive components of military aviation and vessels means parts that directly enable or support warfighting assets of the Department of Defense (DOD) and include “safety critical items” identified by DOD in accordance with DOD policies and requirements for ensuring safety and performance. These include corrosion-sensitive aviation and vessel safety-critical components such as landing gear, gear boxes, turbine engine parts, and other military aircraft and vessel components composed of metallic materials (specifically high-strength steel, aluminum, titanium, and magnesium) and composite materials that not only require their coatings be removed for inspection and maintenance but also would be so negatively affected by the use of paint removal chemicals or methods other than NMP that the safety of the system could be compromised.

Distribute in commerce has the same meaning as in section 3 of the Act, except that the term does not include retailers for purposes of § 751.209 and § 751.211.

Formulation is a mixture of active and other ingredients.

Paint and coating removal means application of a chemical or other method to remove, loosen, or deteriorate any paint, varnish, lacquer, graffiti, surface protectants, or other coatings from a substrate, including objects, vehicles, architectural features, or structures.

Retailer means a person or business who distributes in commerce a chemical substance, mixture, or article to consumer end users.

[OPTION 1 PROPOSED REGULATORY TEXT FOR §§ 751.205, 751.207, 751.209, and 751.211: Co-Proposal 1: NMP—Banning the Manufacture, Processing, Distribution, and Use Except for a Critical Use Exemption]

§ 751.205 Manufacture, Processing, and Distribution of NMP for Consumer Paint and Coating Removal.

After [date 180 calendar days after the date of publication of the final rule], all persons are prohibited from manufacturing, processing, and distributing in commerce NMP for consumer paint and coating removal.

§ 751.207 Manufacture, Processing, and Distribution of NMP for Commercial Paint and Coating Removal.

(a) After [date 180 calendar days after the date of publication of the final rule], all persons are prohibited from manufacturing, processing, and distributing in commerce NMP for

commercial paint and coating removal except for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels as defined in § 751.203. After [date 10 years after the date of publication of the final rule], all persons are prohibited from manufacturing, processing, and distributing in commerce NMP for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels.

(b) After [date 180 calendar days after the date of publication of the final rule], all persons are prohibited from distributing in commerce NMP for paint and coating removal in containers with a volume less than 55 gallons except for formulations specifically manufactured for the Department of Defense, which may be distributed in commerce in containers with a volume no less than 5 gallons.

(c) After [date 270 calendar days after the date of publication of the final rule], all persons are prohibited from commercial use of NMP for paint and coating removal except for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels as defined in § 751.203. After [date 10 years after the date of publication of the final rule], all persons are prohibited from commercial use of NMP for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels.

(d) Any paint and coating removal from critical corrosion-sensitive components of military aviation and vessels must be conducted under the following restrictions:

(1) All paint and coating removal from critical corrosion-sensitive components of military aviation and vessels using NMP must be conducted at DOD installations; DOD owned, contractor operated locations; or contractor owned, contractor operated locations performing paint and coating removal from critical corrosion-sensitive components of military aviation and vessels for DOD.

(2) [Reserved].

§ 751.209 Downstream notification.

Each person who manufactures, processes, or distributes in commerce NMP for any use after [date 45 calendar days after the date of publication of the final rule] must, prior to or concurrent with the shipment, notify companies to whom NMP is shipped, in writing, of the restrictions described in this subpart.

§ 751.211 Recordkeeping.

(a) Each person who manufactures, processes, or distributes in commerce any NMP after [date 45 calendar days after the date of publication of final rule] must retain in one location at the headquarters of the company documentation showing:

(1) The name, address, contact, and telephone number of companies to whom NMP was shipped;

(2) A copy of the notification provided under § 751.209; and

(3) The amount of NMP shipped.

(b) The documentation in (a) must be retained for 3 years from the date of shipment.

[OPTION 2 PROPOSED REGULATORY TEXT FOR §§ 751.205, 751.209, and 751.211: Co-Proposal 2: NMP—Continued Use with Requirements for Product Reformulation, Labeling, and PPE]

§ 751.205 Paint and Coating Removal for Specified Uses.

(a) *Processors.* (1) Formulations of NMP for paint and coating removal that contain more than 35 percent by weight of NMP must not be manufactured, processed, or distributed in commerce after [date 180 calendar days after the date of publication of the final rule], except for product formulations destined to be used by DOD or contractors performing work only on DOD projects for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels as defined in § 751.203 and subsection (b)(1).

(2) Conduct glove testing for each separate formulation of NMP, with a variation of more than 1 percent in any component of a paint and coating removal product containing NMP considered a separate formulation.

(i) The processor must be able to demonstrate that the gloves provide an impervious barrier to prevent dermal exposure during normal and expected duration and conditions of exposure.

(ii) The processor must subject the gloves to the expected conditions of exposure, including the likely combinations of chemical substances to which the gloves may be exposed in the work area.

(3) Provide a label securely attached to each NMP paint and coating removal product and not in the form of a booklet or other pull off type labeling. Label information must be prominently displayed and in an easily readable font size. Each separate NMP paint and coating removal product must be labeled with the following information:

(i) A notice that 40 CFR 751.205 requires commercial users of NMP paint and coating removal products to

establish an occupational dermal and respiratory protection program, including the use of specialized gloves and an air exposure limit or respirator.

(ii) A warning to consumers that fetal death and other irreversible health effects may occur as a result of using the NMP product;

(iii) An identification of the formulation-specific gloves that will provide protection from the NMP product and a direction to use a new pair of those gloves for each time the NMP product is used;

(iv) A direction for consumers to either use the product outdoors or adequately ventilate the workspace by opening windows and adding fans;

(v) A warning for consumers to not apply the product as a spray;

(vi) A direction to wear clothing that covers exposed skin;

(vii) A direction to use a respirator with an Assigned Protection Factor (APF) of 10. Refer to § 751.205(c)(3)(ii) for respirators having an APF of 10 or greater;

(b) *Commercial users.* Each person or company engaged in any commercial NMP paint and coating removal activities [date 180 calendar days after the date of publication of the final rule] is prohibited from using paint and coating removal products or formulations that contain more than 35 percent by weight of NMP and must institute a worker protection program that includes the requirements of § 751.205(c) and (e) except for product formulations destined to be used for paint and coating removal from critical corrosion-sensitive components of military aviation and vessels as defined in § 751.203. After [date 10 years after the date of publication of the final rule], all persons are prohibited from using paint and coating removal products or formulations that contain more than 35 percent by weight of NMP and must institute a worker protection program that includes the requirements of § 751.205(c) and (e).

(1) Any paint and coating removal from critical corrosion-sensitive components of military aviation and vessels must be conducted under the following restrictions:

(i) All paint and coating removal from critical corrosion-sensitive components of military aviation and vessels using NMP must be conducted at DOD installations; or at government owned, contractor operated locations; or at contractor owned and contractor operated locations performing paint and coating removal from critical corrosion-sensitive components of military aviation and vessels for DOD.

(ii) [Reserved].

(2) [Reserved].

(c) *Personal protective equipment (PPE).*

(1) *General.* (i) Protective equipment that is of safe design and construction for the work to be performed must be provided, used, and maintained in a sanitary, reliable, and undamaged condition. The employer must select PPE that properly fits each affected employee and communicate PPE selections to each affected employee.

(ii) *Training.* The employer must provide training to each employee required to use PPE.

(A) Each affected employee must be trained to know at least the following:

(1) When PPE is necessary.

(2) What PPE is necessary.

(3) How to properly don, doff, adjust, and wear PPE.

(4) The limitations of the PPE.

(5) The proper care, maintenance, useful life and disposal of the PPE.

(B) Each affected employee must demonstrate an understanding of these elements and the ability to use PPE properly before being allowed to perform work requiring the use of PPE.

(C) Retraining is required when previous training is rendered obsolete, whether due to changes in the workplace or the type of PPE, or when the employer has reason to believe that a previously-trained employee does not have the understanding and skill required by this subparagraph.

(2) *Dermal protective equipment.* (i) *General.* Each person who is reasonably likely to be dermally exposed in the work area to an NMP paint and coating removal product through direct handling of the substance or through contact with equipment or materials on which the substance may exist, or because the substance becomes airborne must be provided with, and required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the substance in the specific work area where it is selected for use.

(ii) *Specific dermal protective equipment.* The required dermal protective equipment includes, but is not limited to, the following items:

(A) Formulation-specific gloves as indicated on the NMP paint and coating removal product label. A new pair must be supplied and worn each time the NMP product is used.

(B) Impervious clothing covering the exposed areas of the body (e.g. long pants, long shirt).

(iii) *Demonstration of imperviousness.* The employer must demonstrate that each item of chemical protective clothing selected provides an impervious barrier to prevent dermal exposure during normal and expected

duration and conditions of exposure within the work area by any one or a combination of the following:

(A) Testing the material used to make the chemical protective clothing and the construction of the clothing to establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must subject the chemical protective clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work area.

(B) Evaluating the specifications from the manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the chemical substance alone and in likely combination with other chemical substances in the work area.

(3) *Respiratory protection.* (i) *General.* Each person who is reasonably likely to be exposed in the workplace to the use of NMP in paint and coating removal products must be provided with and is required to wear, at a minimum, a NIOSH-certified respirator with an APF of 10. All respirators must be issued, used, and maintained in accordance with an appropriate written respiratory protection program that is specific to the workplace and that includes the following:

(A) Procedures for selecting respirators for use in the workplace.

(B) Medical evaluations of employees required to use respirators.

(C) Fit testing procedures.

(D) Procedures for proper use of respirators.

(E) Procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, discarding, and otherwise maintaining respirators.

(F) Procedures to ensure adequate air quality, quantity, and flow of breathing air for atmosphere-supplying respirators.

(G) Procedures for regularly evaluating the effectiveness of the program.

(H) Recordkeeping.

(ii) *Authorized respirators.* The following NIOSH-certified respirators meet the minimum requirements of this section:

(A) Any NIOSH-certified air-purifying elastomeric half-mask respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) Any appropriate NIOSH-certified N100 (if oil aerosols absent), R100, or P100 filtering facepiece respirator;

(C) Any NIOSH-certified air-purifying full facepiece respirator equipped with

N100 (if oil aerosols absent), R100, or P100 filters. A full facepiece air-purifying respirator, although it has a higher APF of 50, is required to provide full face protection because the PMN substance presents significant exposure concern for mucous membranes, eyes, or skin;

(D) Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a half-mask; or

(E) Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a half mask.

(d) *Alternative to respirator requirement.* Commercial users of NMP products for paint and coating removal may use an existing chemical exposure limit (ECEL) as a means of controlling inhalation exposures whenever practicable rather than respirators.

(1) *Existing Chemical Exposure Limit (ECEL).* The employer must ensure that no person is exposed to an airborne concentration of NMP in excess of 20 mg/m³ (the ECEL) as an 8-hour time-weighted average (TWA) without using a respirator. For non-8-hour work-shifts, the ECEL for that work-shift (ECEL_n) must be determined by the following equation: $ECEL_n = ECEL \times (8/n) \times [(24-n)/16]$, where n = the number of hours in the actual work-shift.

(2) *Verification of method validity.* An independent accredited reference laboratory must verify the validity of the analytical method for NMP in paint and coating removal products. The sampling and analytical method, and all exposure monitoring data relied on by the employer, must be accurate to within 25% at a 95% confidence level for concentrations of NMP ranging from one half the ECEL to twice the ECEL.

(3) *Exposure monitoring.* The employer must collect samples that are representative of the potential exposure of each person who is reasonably likely to be exposed to airborne concentrations of NMP.

(i) *Initial monitoring.* Before the employer may deviate from the respirator requirements in subsection (d) of this section, the employer must conduct initial exposure monitoring to accurately determine the airborne concentration of NMP for each exposure group in which persons are reasonably likely to be exposed.

(ii) *Results.* (A) Employees whose exposures are represented by initial monitoring results below the ECEL need not wear the respirators required in subsection (d) of this section.

(B) Employees whose exposures are represented by initial monitoring results above the ECEL must continue to wear the respirators required in subsection

(d) of this section until such time as two monitoring results below the ECEL, sampled at least 24 hours apart, are obtained.

(C) Within 15 days of the date exposure monitoring results are received, the employer must provide the results to each person whose exposure is represented by the monitoring. If the result is above the ECEL, the employer must also provide the employee with information on the actions the employer will take to reduce employee exposures to the ECEL or below.

(iii) *Periodic monitoring.* The employer must repeat exposure monitoring:

(A) Every 6 months for those employees whose initial monitoring results are between 0.5 ECEL and the ECEL, until such time as 2 results below 0.5 ECEL, from samples collected at least 24 hours apart, are obtained,

(B) Every 3 months for those employees whose initial monitoring results are at or above the ECEL. If 2 results below the ECEL, from samples collected at least 24 hours apart, are obtained, then frequency may be reduced to every 6 months. If 2 results below 0.5 ECEL, from samples collected at least 24 hours apart, are obtained, then exposure monitoring under this subsection need not be repeated unless there is a process, equipment, environment, or personnel change.

(C) At any time when process, equipment, environment, or personnel changes may reasonably cause new or additional exposures to NMP.

(e) *Hazard communication program.*

Each employer that performs commercial NMP paint and coating removal activities must develop and implement a written hazard communication program for the substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, SDSs, other forms of warning material, and employee information and training will be satisfied. The employer must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The employer may rely on an existing hazard communication program that satisfies the requirements of this paragraph.

(1) *General.* The written program must include the following:

(i) A list of each NMP paint and coating removal product present in the work area. The list must be maintained in the work area and must use the identity provided on the appropriate

SDS. The list may be compiled for the workplace or for individual work areas.

(ii) The methods the employer will use to inform contractors of the presence of NMP paint and coating removal products in the employer's workplace and of the provisions of this part applicable to the NMP products if employees of the contractor work in the employer's workplace and are reasonably likely to be exposed to the NMP products while in the employer's workplace.

(2) *Employee information and training.* Each employer must ensure that employees are provided with information and training on NMP paint and coating removal products. This information and training must be provided at the time of each employee's initial assignment to using an NMP paint and coating removal product.

(i) Information provided to employees under this paragraph must include:

(A) The requirements of this section.

(B) The location and availability of the written hazard communication program.

(ii) Training provided to employees must include:

(A) The potential human health hazards of the NMP paint and coating removal products as specified on the label.

(B) The measures employees can take to protect themselves from the NMP paint and coating removal products, including specific procedures the employer has implemented to protect employees from exposure to the substance, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure.

(3) *Existing hazard communication program.* The employer need not take additional actions if existing programs and procedures satisfy the requirements of this section.

§ 751.209 Downstream notification.

Each person who manufactures, processes, or distributes in commerce NMP for any use after [date 45 calendar days after the date of publication of the

final rule] must, prior to or concurrent with the shipment, notify companies to whom NMP is shipped, in writing, of the restrictions described in this subpart.

§ 751.211 Recordkeeping.

(a) Each person who manufactures, processes, or distributes in commerce any NMP after [date 45 calendar days after the date of publication of *final rule*] must retain in one location at the headquarters of the company documentation showing:

(1) The name, address, contact, and telephone number of companies to whom NMP was shipped;

(2) A copy of the notification provided under § 751.209; and

(3) The amount of NMP shipped.

(b) The documentation in (a) must be retained for 3 years from the date of shipment.

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14 CFR Part 399

Transparency of Airline Ancillary Service Fees; Proposed Rule

DEPARTMENT OF TRANSPORTATION**Office of the Secretary****14 CFR Part 399**

[Docket No. DOT–OST–2017–0007]

RIN 2105–AE56

Transparency of Airline Ancillary Service Fees**AGENCY:** Office of the Secretary (OST), Department of Transportation (DOT).**ACTION:** Supplemental Notice of Proposed Rulemaking (SNPRM).

SUMMARY: This SNPRM proposes to require air carriers, foreign air carriers, and ticket agents to clearly disclose to consumers at all points of sale customer-specific fee information, or itinerary-specific information if a customer elects not to provide customer-specific information, for a first checked bag, a second checked bag, and one carry-on bag wherever fare and schedule information is provided to consumers. This SNPRM further proposes to require each covered carrier to provide useable, current, and accurate (but not transactable) baggage fee information to all ticket agents that receive and distribute the carrier's fare and schedule information, including Global Distribution Systems and metasearch entities. On covered carrier and ticket agent Web sites, the SNPRM would require the baggage fee information to be disclosed at the first point in a search process where a fare is listed in connection with a specific flight itinerary, adjacent to the fare. The SNPRM would permit carriers and ticket agents to allow customers to opt-out of receiving the baggage fee information when using their Web sites.

DATES: Comments must be received by March 20, 2017. Comments received after this date will be considered to the extent practicable.

ADDRESSES: You may file comments identified by the docket number DOT–OST–2017–0007 by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE., Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* The Docket Management Facility is located on the West Building, Ground Floor, of the U.S. Department of Transportation, 1200 New Jersey Ave. SE., Room W12–140, between 9 a.m.

and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* 202–493–2251.

Instructions: You must include the agency name and the Docket Number DOT–OST–2017–0007 or the Regulatory Identification Number (RIN) for the rulemaking at the beginning of your comment. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

Privacy Act: Anyone is able to search the electronic form of all comments received in any of our dockets by the name of the individual submitting the comment (or signing the comment if submitted on behalf of an association, a business, a labor union, etc.). You may review DOT's complete Privacy Act statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit <http://DocketsInfo.dot.gov>.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> or to the street address listed above. Follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT:

Kimberly Graber or Blane A. Workie, Office of the Assistant General Counsel for Aviation Enforcement and Proceedings, U.S. Department of Transportation, 1200 New Jersey Ave. SE., Washington, DC 20590, 202–366–9342 (phone), kimberly.graber@dot.gov or blane.workie@dot.gov (email).

SUPPLEMENTARY INFORMATION:**Background**

The Notice of Proposed Rulemaking, titled Transparency of Airline Ancillary Service Fees and Other Consumer Protection Issues, Docket No. DOT–OST–2014–0056, 79 FR 29970, May 23, 2014 (Consumer Protection NPRM), contained a number of proposals to enhance consumer protections, including a proposal to require the disclosure of certain airline ancillary service fees. This proposed disclosure requirement was one of the more controversial provisions of the rulemaking and generated significant comments from consumers, airlines, ticket agents and other interested parties. In light of the comments on this issue, the Department is issuing this SNPRM, which focuses solely on the issue of transparency of certain ancillary service fees. The other issues in the 2014 NPRM are being addressed separately. See RIN 2105–AE11, Enhancing Airline Passenger Protections III; and RIN 2105–AE57, Enhancing Airline Passenger Protections IV.

In this SNPRM, the Department proposes to require disclosure at all points of sale of the customer-specific fees for first and second checked bag and carry-on bag but does not propose to require disclosure of the fee for advance seat assignment. In addition, the Department proposes to require carriers to provide certain baggage fee information to ticket agents so that both carriers and ticket agents would be able to provide customer-specific baggage fee information to consumers. We invite all interested parties to comment on the proposals set forth in this notice. Our final action will be based on comments and supporting evidence from the public filed in this docket, and on our own analysis and regulatory evaluation.

A. Need for Rulemaking and Legal Authority

The NPRM: In the NPRM, the Department described the problem identified by consumers and consumer advocacy groups of the lack of transparency of ancillary service fees in air transportation pricing. That is, not being able to determine the true cost of travel due to the lack of information regarding certain ancillary service fees. This lack of transparency of fees for unbundled services (*i.e.*, services that historically had been included in the air fare but for which many carriers now charge a separate fee is particularly notable when consumers are attempting to purchase air transportation through a ticket agent rather than directly from the carrier but it occurs at both ticket agent and airline outlets. Corporate travel agents have also complained about the lack of access to ancillary service fee information.

Online travel agencies (OTAs), metasearch sites, “traditional” travel agencies, and travel management companies generally obtain most of their information regarding air transportation options indirectly through Global Distribution Systems (GDSs). GDSs essentially facilitate the purchase of tickets between airlines and consumers through third parties but do not have complete information regarding ancillary service fees. As a result, when researching air transportation options and making decisions on whether to purchase air transportation, consumers continue to have difficulty determining the total cost of travel because the fees for basic ancillary services are not available through all sales channels. Consumers also experience difficulty on carrier Web sites because fees are provided on lengthy static lists, and many ancillary service fees are listed as a range, so consumers do not necessarily know the

specific fees that apply to their travel when purchasing air transportation. With respect to baggage, the existing disclosure requirements mandate specific information if a carrier or a ticket agent has a Web site accessible for ticket purchases by the general public in the United States, but passengers must frequently review lengthy and complex charts to determine the exact baggage fees that apply to their air transportation particularly for interline or international itineraries.

The Department's goal is to protect consumers from hidden and deceptive fees and enable them to determine the true cost of travel in an effective manner when they price shop for air transportation. The problem of hidden fees has been brought to our attention by consumer complaints, comments on the second Enhancing Airline Passenger Protections rulemaking, and comments to the docket for the Advisory Committee for Aviation Consumer Protection. We also note that members of Congress representing constituents have expressed support for full, more specific, disclosure of ancillary service fees.

In the 2014 NPRM, we provided an overview of the airline distribution system based on information gathered from representatives of carriers, GDSs, consumer advocacy organizations, and trade associations, as well as other interested entities, including third-party technology developers. We noted that approximately 50% of tickets are sold by airlines directly to consumers, and the remainder is sold through ticket agents. Further, in the United States, three GDSs (Sabre, Travelport and Amadeus) control the distribution of the airline product for the ticket agent channel and most airlines use the GDSs to distribute their products to ticket agents, including corporate travel agents that sell the higher revenue tickets. The NPRM noted that airlines state they have made some efforts to reduce their reliance on GDSs and transition to direct connections between airline reservation systems and ticket agent systems but contractual arrangements make that difficult. As stated in the NPRM, carriers and carrier associations have expressed concern that a Department requirement to distribute information through a GDS would reinforce the existing distribution patterns and stifle innovation. Some stakeholders have alleged that if existing distribution patterns are reinforced, carriers will no longer have sufficient incentive to invest in new distribution technologies, which might ultimately provide more information to the benefit of consumers. In connection with new

distribution technologies, the 2014 NPRM also mentioned that the International Air Transport Association (IATA) applied to the Department of Transportation for approval of its agreement establishing the framework for the IATA New Distribution Capability (NDC). That application was pending at the time of NPRM publication but has since been approved. NDC is essentially an XML-based technical standard for use in airline distribution, including direct connect services, that has been developed by IATA in cooperation with air transportation stakeholders. The goal appears to be to change how airlines sell their products today by using the enhanced platform to quickly generate dynamic, personalized offers. For more information, see docket DOT-OST-2013-0048. The NDC standard is available to any party and has been implemented by some entities since the 2014 NPRM was published.

Our discussion in the 2014 NPRM explained that although airlines generally distribute fare, schedule, and availability information through GDSs, they generally do not distribute ancillary service fee information in the same manner. The NPRM also outlined some of the technological and competitive concerns raised by air transportation industry stakeholders. We also noted that in contrast to airlines, GDSs assert that any transition to direct connect services will succeed or fail based on whether the services meet the needs of travel agencies and the consumers they serve, regardless of existing contracts. As noted in the NPRM, GDSs disputed the position that there is no need for a Department requirement, stating that airlines and ticket agents have not been able to come to agreements that would allow airlines to provide ancillary service fee information to ticket agents so they could in turn provide such information to consumers.

The 2014 NPRM explained that our decision to initiate a rulemaking regarding distribution of ancillary service fee information rested on the conclusion that consumers are continuing to have difficulty finding ancillary service fee information, which limits consumers' ability to determine the true cost of travel. We also recognized in the NPRM that carriers and GDSs state they share our goal of transparency of ancillary service fee information. In the NPRM we made clear that the Department is working to find the most beneficial disclosure rule for consumers while avoiding any adverse impact on innovations in the air transportation marketplace, contract

negotiations between carriers and their distribution partners, or a carrier's ability to set prices for its services in response to its own commercial strategy and market forces. As the NPRM stated, consumers need to be protected from hidden and deceptive fees that prevent them from effectively price shopping—that is, determining while shopping and before purchasing, the total costs of air transportation. The NPRM explained that failing to disclose basic ancillary service fees in an accurate and up-to-date manner before a consumer purchases air transportation is an unfair and deceptive practice. We identified a number of questions regarding the need for rulemaking on which we requested comment, including questions regarding the difficulty consumers have finding fee information, what fee information consumers wanted to have prior to purchase, and whether either of the Department's proposals would make fees easier to find. We also explained the alternatives that we had considered.

Comments: Consumer comments in this rulemaking overwhelmingly supported Department action on disclosure of ancillary service fees. Over 600 consumers commented on transparency issues generally, which for many consumers encompasses disclosure of ancillary service fees as well as the full airfare, including taxes and fees. Over 450 consumers clearly supported additional requirements relating to disclosure of ancillary service fees while fewer than ten commented in opposition to additional disclosure requirements. Consumer advocacy groups Travelers United and National Consumers League also commented in support of the need for a rulemaking, stating that airlines publish what are in effect partial prices and that the full cost of travel is masked at the initial purchase and only revealed in a secondary buying process. Consumers Union and the U.S. Public Interest Research Group (U.S. PIRG) also supported Department action in this area, stating that the Department should require disclosure at every point of sale, early in the purchasing process. They went on to state that too many U.S. carriers have made ancillary service fee information difficult or impossible to obtain until close to or at the point of actual purchase or, in some channels, not available at all. FlyersRights also supported the rulemaking on disclosure of ancillary service fees, stating that unbundling is rapidly making price shopping difficult to impossible for consumers. It further stated that baggage fee information often is buried on a carrier's Web site and can be confusing

and complex. To illustrate its point, FlyersRights identified one legacy carrier that charges up to nine different fees for baggage depending on weight, size, and number of bags.

Open Allies, which described itself as a coalition of more than 400 independent distributors and sellers of air travel, corporate travel departments, travel trade associations and consumer organizations, commented in favor of Department action in this area. According to Open Allies, the rule is needed because ancillary service fees are not accessible and that identifying total travel cost is complex, confusing, and needlessly time consuming. According to Open Allies, the market is not reacting quickly or completely enough to address the issue. Open Allies pointed to a survey it conducted of over 1,000 adults in the United States, indicating that 55 percent of respondents said that they were surprised by additional fees after purchasing a ticket; 88 percent said that Department action is important; 81 percent believe that current airline practices are “unfair and deceptive;” and 47 percent said that it was hard to search and find the lowest price for travel.

Open Allies argued that the Department should not rely on competition because fees are still hidden, despite existing Department requirements, which results in consumers making sub-optimal purchasing decisions. Open Allies relied on consumer comments in the docket, saying that they show that consumers feel deceived and confused and do not understand the true, full cost of travel. According to Open Allies, consumers generally give two key reasons for supporting increased disclosure of ancillary service fees: (1) It would allow them to compare prices across various airlines; and (2) it would prevent airlines from surprising them with fees after they have purchased their airfare. Open Allies commented that there are many benefits to enhanced disclosure of price information such as ancillary service fees, including that it lowers prices, enhances competition, and promotes informed buyers. According to Open Allies, airlines lack a commercial incentive to provide ancillary service fee information to the “neutral” travel agency channel because airlines have an interest in not allowing ticket agents to show the full cost of travel at the shopping stage because if travel appears less expensive, consumers will be more likely to complete a purchase. Open Allies further pointed out that an airline is unlikely to voluntarily display ancillary

service fees on a travel agent display because it would make the airline’s fares appear more expensive when compared to the fares of other airlines that do not disclose ancillary service fee information.

In support of its position, Open Allies cited a 2010 GAO Report and a follow-on 2014 report, describing the problem of ancillary service fee disclosure as a continuing problem. Open Allies pointed out that while some individual airlines and individual GDSs have announced agreements regarding distribution of certain ancillary service fees, those agreements are generally limited to premium seating on some of the individual airline’s flights and do not provide all ticket agents access to that information. Therefore, consumers are still unable to discover all basic ancillary service fees when searching for flights. According to Open Allies, the Department has substantial evidence to support its rulemaking as well as ample authority under § 41712 (unfair or deceptive practices). Open Allies compared the Department’s authority to that of the FTC and stated that analogous FTC precedent on unfair or deceptive practices establishes that the Department has the legal authority to proceed with this rulemaking.

The three GDSs—Amadeus, Sabre, and Travelport—all supported the rulemaking, stating that consumers that use ticket agents to shop for air transportation do not have access to all ancillary service fee information. According to Sabre, for consumers to “know the full price of travel before they are locked into a purchase” the Department must act. The GDSs also stated that airlines will not share ancillary service fee information with ticket agents, except on a limited basis, unless the Department requires the information to be shared. Travelport stated that airlines are motivated to increase revenues by driving consumer costs up through “obfuscation of the true cost of flying.” Amadeus points to airline opposition to disclosure requirements, particularly opposition by U.S. airlines, as evidence that the market will not resolve the problem. Travel Technology Association (Travel Tech), a trade association for major OTAs, GDSs, and some entities operating metasearch engines focused on travel, also stated that a problem remains for consumers trying to uncover charges for additional services and stated that consumers must search to discover the true cost of their air travel.

Several travel agents and travel agent associations also stated there is a need for Department action in this area. The American Society of Travel Agents

(ASTA) joined in the comments of Open Allies and stated that the Department’s proposals do not go far enough to address widespread confusion among consumers. A number of travel agents submitted comments stating that their customers could not calculate the true cost of airfare with certainty and that the travel agents themselves could not provide a quote with certainty because of the complexity of and variation in ancillary service fees charged from airline to airline. Those travel agents supported mandating that airlines disclose the costs of bag fees and seat assignments. The United States Tour Operators Association (USTOA) opposed being subject to disclosure regulations but commented that consumers have expressed strong support for early disclosure of information on ancillary service fees. USTOA pointed to a survey that shows that 45 percent of respondents reported difficulty in budgeting for air travel due to the proliferation of fees and difficulty in determining the costs of flying. Survey respondents also indicated that total cost of travel is very important to purchasing decisions. Corporate travel agents also commented that they were concerned about disclosure. Global Business Travel Association stated that there is a need for disclosure requirements because despite investing resources, acquiring technologies, and changing travel policies, its members are still facing challenges finding basic ancillary fee information for baggage and seat assignments. Business Travel Coalition (BTC) commented in support of requiring disclosure of fees, stating that airlines are “masking the all-in price of air travel.”

Computer and Communications Industry Association (CCIA), advocating for metasearch entities, commented in favor of Department action to make sure consumers have the information needed to determine the full cost of travel. TripAdvisor and Skyscanner, which both operate flight search tools, also commented in favor of Department action requiring airlines to disclose ancillary service fee information to ensure transparency for the benefit of consumers. Of airline commenters, only Southwest supported the Department requiring greater fee disclosure, noting that consumers will “be better able to arrive at the true cost of air transportation.” Finally, several commenters, including ASTA, BTC, FlyersRights, and Travel Tech also noted that airlines are not subject to State and local consumer protection laws due to Federal preemption, and

therefore, only the Department can take action to protect consumers in this area.

The Department also received many comments that opposed any further requirement pertaining to disclosure of ancillary service fees as specific charges. A4A (Airlines for America, the trade association of the larger U.S. airlines) argued that there is no need for any proposal regarding ancillary service fee information because the industry has already provided that information in response to existing Department regulatory requirements and market pressure and no consumer harm is occurring. A4A further argued that the Department does not have the authority to require airlines to disclose certain ancillary service fees in displays of fare search results because the failure to provide that information at the time fare information is presented to consumers does not amount to an unfair or deceptive practice. A4A also pointed out that on some occasions when discussing the ancillary service fee disclosure issue, the Department has described it in terms of the ability of consumers to engage in comparison shopping. A4A argued that the Department does not have regulatory authority to dictate the terms of carrier distribution or ancillary service fee disclosure to enhance comparison shopping.

In addition to stating there is no need for any ancillary service fee proposals, A4A opposed any ancillary service fee disclosure requirement on competitive grounds, alleging that the rulemaking would effectively require airline distribution through GDSs, which would put airlines at a competitive disadvantage. According to A4A, the Department recognized the powerful market position of GDSs in a 2004 rulemaking¹ and still determined not to regulate those entities. A4A stated that GDSs still have significant market power and to be competitive most airlines have to distribute fare information through all three GDSs; meanwhile, GDSs prevent their client ticket agents from directly connecting to an airline. A4A stated that in contrast to fares, carriers are not dependent on GDSs for distribution of ancillary service information and this places airlines in a better position to negotiate with GDSs, to the benefit of consumers. For example, according to A4A, GDSs agreed to develop new distribution technologies as part of negotiations over ancillary services. A4A stated that the proposed regulation would strengthen

the negotiating position of GDSs at the expense of the airlines if adopted.

Meanwhile, according to airline associations, the market is working. A4A commented that existing Department regulations combined with market forces have led to “enhanced fee disclosure practices,” and that carriers want to sell ancillary services, especially to business travelers who constitute a large segment of their repeat customers and revenue producers. A4A went on to explain that carriers are already incentivized to distribute information about ancillary products and fees and to facilitate the sale of ancillary services through multiple channels, including travel agencies, if they can do so on commercially reasonable terms. According to A4A, carriers and GDSs have already developed the ability (using the ATPCO filing system) to disclose information such as first and second checked bag fees to travel agents. A4A further noted that some airlines have made it possible for some agents to purchase certain ancillary services for consumers and some GDSs have developed mechanisms for ticket agents to buy services directly from carrier Web sites. A4A also pointed to tools on carrier Web sites that allow consumers to obtain customer-specific information through an airline Web site after providing information from the purchased ticket, and third-party Web sites that provide ancillary service fee information as the “beneficial result of the existing environment.” A4A also criticized Open Allies’ reliance on survey results, stating that the survey was flawed for a number of methodological reasons and “it should not be relied upon to arrive at conclusions concerning perceptions and attitudes about ancillary services held by people who fly on commercial airlines in the United States.” According to A4A, GDSs are trying to obtain the commercial benefit of access to ancillary service fee information through regulation instead of through negotiations, even though negotiated agreements are possible. A4A also stated that GDSs have made concessions on pricing and technology through commercial agreements. A4A concluded that regulation will result in higher GDS fees which will in turn be passed on to consumers through higher ticket prices, to the detriment of the public.

In supplemental comments, A4A stated that the three GDSs engaged in pilot projects to “begin adapting to” the NDC initiative and many airlines have invested in technology solutions. In addition, a variety of technology service companies are building solutions in the area. According to A4A, these

marketplace developments prove that regulation is unneeded. A4A provided a number of examples of agreements between airlines and GDSs that it says show that carriers are sharing ancillary service fee information with GDSs. A4A went on to say that it is more and more common for carriers to sell bundled fares on their own sites, which A4A stated often results in discounts and is a consumer-friendly method of display. A4A further stated that mandating disclosures on the first page that displays fares interferes with airline efforts to differentiate their products and compete on service and price, as well as “squandering” the investment made by carriers on bundled pricing initiatives and technology to display those prices. A4A concluded in its supplemental comments that marketplace solutions that compel all parties to negotiate and use the most efficient data-sharing and latest technology will lead to time savings for consumers.

IATA commented that the market has fundamentally changed since the Department first considered requiring carriers to disclose ancillary service fees and consumers now have “more than ample” access to information about ancillary services and fees prior to making purchase decisions. According to IATA, there is no lack of information about ancillary service fees causing harm to consumers. Further the Department has not demonstrated there is any unfair or deceptive practice that will be prevented by further regulating the disclosure of ancillary service fees, therefore, they argued, the Department does not have the authority to regulate in this area.

IATA further argued that marketplace solutions are already making any rulemaking regarding ancillary service fees unnecessary as the rapid changes in distribution are working to the benefit of consumers and any Departmental intervention in this rapidly changing market will interfere and result in suboptimal solutions. IATA argued that airline Web sites already offer comprehensive and accurate information about ancillary services and fees. IATA acknowledged that airlines provide fee information as a range of fees in a static format but stated that this is not evidence of fraud or deception, merely “evidence of the complexity of capturing the wide variety of factors that are considered when dynamically setting the price for a specific ancillary service for a specific customer.” IATA went on to state that carriers are coming to agreements to provide ancillary service fee information to GDSs for distribution directly to agents rather

¹Dep’t of Transp., Computer Reservation System (CRS) Regulations, Final Rule, 69 FR 976, 996 (Jan. 7, 2004) (“CRS Rulemaking”)

than through outdated fare filing systems. IATA also stated that the adoption of the NDC standard will provide transparency and efficiency. According to IATA, the Department should not intervene in distribution and should rely on the market to resolve any disclosure issues. Air Transport Association of Canada also opposed the Department rulemaking regarding disclosure of ancillary service fees, stating that the market is addressing the issue and the Department does not have the legal authority to intervene in the deregulated airline industry and dictate how airlines distribute their products and services.

Several airlines also commented in opposition to the rulemaking. American Airlines joined in the comments of A4A and further stated that the Department's proposals do not address specific instances of demonstrated harm to consumers that cannot reasonably be avoided and the rulemaking is "beyond the recognized limits of the Department's regulatory powers." American alleged that the Department based its reasoning on a need for comparison shopping, which American said is an unreasonable and inadequate basis for rulemaking. Frontier Airlines opposed any disclosure requirements, stating it "believes that competitive market forces and the Department's existing regulations are more than adequate to inform and protect consumers." JetBlue also endorsed the comments of both A4A and IATA and stated that the Department should rely on market forces. According to JetBlue, the Department assumes a problem regarding consumers not knowing the true cost of travel and the NPRM does not provide a foundation for that assumption. United also endorsed the comments of A4A and stated that the market is already addressing many of the Department's concerns so the Department should refrain from issuing regulations regarding ancillary service fee disclosure. United further stated that the Department does not have evidence that supports the need for the proposed rulemaking. Spirit Airlines similarly opposed any rulemaking on disclosure of ancillary service fees, stating that it is not necessary and not in the public interest. According to Spirit, the Department should defer to the market place which is rapidly developing and "progressively improving reasonable consumers' ability to determine the total cost of their travel before purchase."

Several foreign air carriers endorsed IATA's comments and opposed any Department regulation of disclosure of ancillary service fees. Aerovías de México, S.A. de C.V., (Aeromexico) and

Air Transat endorsed the comments submitted by IATA regarding disclosure of ancillary service fees, and stated that the market is already addressing the issues raised by the Department. Further, any intervention by the Department will likely have a negative impact on consumers. In comments filed on behalf of the Avianca carrier group, Avianca endorsed IATA's comments, stating that the marketplace already is addressing the Department's concerns regarding disclosure of ancillary service fees, and any regulatory intervention likely will have a negative impact on both consumers and carriers. Air New Zealand supported the comments of IATA and stated that the current disclosure requirements are adequate to protect the consumer. Compañía Panameña de Aviación, S.A. (Copa Airlines) opposed Department rules regarding ancillary service fee disclosure, stating such rules may have "unintended adverse consequences that would significantly diminish any such benefits by making its implementation financially and technologically cumbersome for carriers." Qatar Airways (Qatar) also endorsed the comments of IATA and added that the market is working. Qatar went on to state that Department intervention will have a negative impact on consumers. Scandinavian Airlines System also endorsed IATA's comments and stated the rulemaking will have a negative impact on consumers. Virgin Atlantic Airways (Virgin Atlantic) commented that the market is evolving to meet customer preferences and the Department's current fee disclosure requirements are adequate. Further, requiring carriers to provide ancillary service fee information to ticket agents deprives carriers of their right to decide how to market their ancillary services and to distribute such information in a way that is most cost-effective for them.

The Arab Air Carriers Organization (AACO) commented that market developments since the Department began to address ancillary services in rulemakings have resulted in market action that is heading towards developing a data transmission standard that would make the flow of information between the airlines and agents more efficient. AACO went on to state that the Department should not specify how airlines display information. AACO also stated that a requirement to distribute through the GDSs would have a negative effect on future innovation in the distribution and display of ancillary services and fees as well as give GDSs the upper hand in contract negotiations with airlines.

AAA, a leisure travel agent trade organization, commented that it supports transparency but specific mandates in this area may be premature at this time. AAA stated it was concerned about stifling innovation and wanted airlines to work with GDSs on agreements to distribute full ancillary fee information. Momondo Group, an online travel media and technology company that operates a flight search tool, commented that it supports transparency as its primary objective. However, it stated that it would be extremely costly to provide accurate information and avoid consumer confusion. It recommended that the Department conduct a more detailed examination of the problem before implementing a regulation that will impact a variety of entities, including operators of metasearch engines.

DOT Response: The sheer number, length, and variety of comments on this issue, as well as the strongly held positions on all sides, illustrate the presence of a problem and the complexity of addressing it. Airlines and their associations stated that the Department has not demonstrated the harm to consumers that the Department's rulemaking is intended to address. For example, in support of its position that information is available and the market is providing solutions, A4A observed that some airline Web sites provide an option for consumers to identify themselves to determine fees for some ancillary services and potentially receive special offers *after* they have already purchased a ticket. Meanwhile, IATA noted that "experienced travelers" know that airlines charge bag fees and advance seat assignment fees and also know how to navigate multiple Web sites to obtain this information and that the Department should not impose costly regulations to benefit the relatively few travelers that care about this information but do not know how to locate it. In late-filed comments, Travel Tech noted that some airlines have begun to provide some information on ancillary services to ticket agents, but the progress has been far from universal.

For the average consumer looking for the total cost of travel, he or she must frequently review a complex chart to determine his or her baggage fees particularly for interline itineraries and guess what an assigned seat fee might cost. We disagree with airlines and airline associations that these facts do not reflect consumer harm as we believe the additional time spent searching to find the total cost of travel and the additional funds spent on air transportation that might have been

avoided if the consumer had been able to determine the true cost of travel up front are the harms suffered by consumers when basic ancillary service fees are not adequately disclosed.

The Department agrees with commenters that supported a need for rulemaking to allow consumers to have complete access to certain basic ancillary service fees in a manner that permits them to quickly and effectively determine their true cost of travel, although as explained further below, the Department has changed its view on what constitutes a basic ancillary service. Further, until all airlines and ticket agents are required to display certain basic ancillary service fees, and carriers are required to transmit fees for basic ancillary services to ticket agents, there is a strong incentive for carriers to obfuscate those fees. That is because if all competing carriers do not make similar disclosures, any airline that disclosed the cost of ancillary services, such as baggage fees, would appear to charge more for air transportation than the airlines that did not clearly provide fee information for those ancillary services. Therefore, even carriers that believe it is appropriate and consumer-friendly to provide the information in a clear fashion have a strong marketplace disincentive to disclose the cost of ancillary services. The Department notes that even the comments by airlines and airline associations that argued that the market is resolving the issue described the changes as ongoing and recognized that it will take time for airlines and ticket agents to come to agreement and implement new methods of disclosure. Although airline associations point to the number of agreements being reached between airlines and GDSs regarding GDS access to bundled fare packages that include an advance seat assignment, those agreements are bilateral agreements addressing limited services, primarily enhanced seating options, in limited markets and are not widely available to the general public.

Meanwhile, airlines are capable of disclosing some ancillary service fees in search results on their own Web site search result displays today, yet choose not to do so. The Department is not persuaded by airline arguments that the complexity of factors considered when setting fees is a sufficient justification for leaving it to the airlines to decide how much disclosure to provide regarding basic ancillary service fees. To the contrary, any argument that fees are difficult to explain or quantify militates for greater disclosure requirements of fees for basic ancillary services intrinsic to air transportation. The mere fact that

airlines are unbundling fares and have implemented ancillary service fee policies that even the airlines acknowledge are complex justifies efforts by the Department to ensure that consumers are able to discern the true cost of travel that includes basic ancillary service fees. Moreover, the existence of complex fee calculations that take into account a variety of factors does not explain why airlines do not provide better disclosure of baggage fee information that they already provide as a specific amount on a static list. Although there are complexities involved in displaying baggage fees, the comments demonstrate there is no technical impediment to displaying baggage fees with search results on carrier Web sites, yet that information is still not displayed.

In support of its argument that the Department has not demonstrated a problem that it has authority to regulate, A4A provided two examples (from the NPRM and a docket record of an A4A meeting with Department staff)² in which the Department referred to consumers' ability to "comparison shop" as well as a reference in the NPRM to allowing consumers to "price shop" and a reference to complaints by business travel representatives regarding the difficulty of advising "clients on the best and most cost effective flights." According to A4A, it is not within the Department's authority to require further disclosure of fees because we are taking the action to ensure consumers have the opportunity to comparison shop, which is not sufficient justification for the action. We acknowledge that the Department has at times used terms such as "comparison shopping" in connection with ancillary service fee disclosure. However, we disagree that the rationale of our proposed rule is to enhance consumers' ability to comparison shop. The Department's view is that consumers should be able to determine if the price provided is the total cost they will incur, whether purchasing through an airline or a ticket agent outlet, and our rulemaking is based on addressing that issue. The Department's position, as set forth in both the NPRM and the responses to A4A's questions, is that the proposals on ancillary service fees address the concerns regarding ensuring that consumers are aware of the total cost of travel.³ The Department's concern addressed by this rulemaking is

that if airlines and ticket agents do not provide reasonable disclosure of ancillary service fees intrinsic to air transportation at the point that consumers are researching the total cost of travel and making a purchasing decision then consumers are not able to make an informed decision based on the true cost of air transportation. Although the disclosures mandated in the previous rulemaking improved consumer access to airline ancillary service fee information by requiring those fees to be displayed somewhere, airlines continue to disclose fees in a static format in complex charts that can be confusing to consumers. Further, in connection with complex itineraries, interline tickets, and even some code-share flights, consumers are still reporting confusion regarding the total cost of baggage fees. There is a close connection between comparison shopping to determine the best value and knowing the total or true cost of travel because consumers must know the total cost of travel to shop effectively for the best price. However, the concern we are proposing to address is whether consumers are able to ascertain the total cost of air transportation without confusion before they make a purchase, whether the consumer engages in comparison shopping or not. In this SNPRM, we are seeking comments on a requirement that specific ancillary service fee information be provided to consumers at the same time fare information is provided to help them determine the true cost of travel prior to purchase.

B. The Definition of Basic Ancillary Service Fees

The NPRM: The NPRM set forth the Department's view that certain basic services are intrinsic to air transportation and that carriers used to include them in the cost of air transportation before the advent of unbundled fares. We further noted that the cost of those services is important to consumers when they choose among air transportation options. The NPRM identified basic ancillary services as the first and second checked bag, one carry-on item and advance seat selection. The NPRM requested comment on whether the Department's list of basic ancillary services should be expanded. We also asked whether current disclosure requirements are sufficient and whether there is any need to adopt additional fee disclosure requirements for basic ancillary services.

Comments: The comments reflected a diversity of views on this issue. Most consumer comments generally favored more transparency regarding fees and

² See DOT-OST-2014-0056-0624, Summary of Proceedings, DOT Meeting with Airlines for America (A4A) (posted September 15, 2014).

³ NPRM at 29975 and DOT Meeting with A4A, page 4, question 9.

some identify categories of fee information about which they would like more information—and they would like it early in the process of selecting a fare. In addition to consumer comments stating they want more information about all the fees airlines charge, a few comments identified specific fees. The fees consumer commenters most commonly identified were baggage, seat assignments, and change or cancellation fees, and a few mentioned advance boarding fees. The comments of consumer advocacy organizations Consumers Union, U.S. PIRG, Travelers United, and NCL expressed support for greater disclosure of all ancillary service fees, going beyond the baggage and seat assignment fees specified in the NPRM. Travelers United and NCL contended that the Department should require airlines to release airfares and all ancillary fee data for any entity to use as it wishes. BTC stated that boarding fees and change or cancellation fees should be included, as well as bundles that include a basic ancillary service. Similarly, BCD Travel USA LLC (BCD), a corporate travel management company, also commented that advance boarding fees and bundles that include a basic ancillary service should be included. In addition to specified baggage and seat assignment fees, Travel Tech and Open Allies both commented that advance boarding, change, and cancellation fees are “basic” and further stated that any ancillary service “package” that includes a basic ancillary service should be disclosed. Open Allies stated that these services are all critical to booking decisions. Sabre agreed with the Open Allies comment on this issue. Amadeus also stated the Department should expand the definition to include boarding fees and change and cancellation fees as well as bundles that include basic ancillary services. TripAdvisor stated that limiting the list of fees that must be disclosed to “basic” fees is a mistake because carriers may unbundle some other “essential” service and absent another lengthy Department rulemaking, the information would not be disclosed to consumers. Southwest commented on baggage fees, stating that they are unique because transporting passenger baggage is intrinsic to air transportation.

On the other hand, several commenters opposed defining basic ancillary services as intrinsic to air transportation or including seat assignment fees as a basic ancillary service. USTOA commented that the Department should not include a requirement that seat assignment fees be

disclosed in an itinerary specific manner because sellers of package tours may not have access to seat assignments at the time the package is sold or, since seats are inventory-controlled, the cost is likely to change before a consumer is able to purchase them on an airline Web site. Spirit asserted that any advance seat assignment fee disclosure should be eliminated because all airlines provide a seat with the cost of air transportation so disclosing an advance seat assignment fee at the beginning of a booking process may induce someone to purchase it when there is no need to do so. A4A, AACO, and United commented that advance seat assignments have not been traditionally provided to consumers as part of the price of air transportation. Comments by A4A and United noted that fare purchases guarantee a seat in a particular cabin, such as first class or economy, but not a particular seat number. In addition, historically seats often were not assigned until 30 days before a flight or at the gate on the day of flight. A4A and United further noted that Southwest does not provide seat assignments at all.

ATPCO and Farelogix did not comment on whether baggage or seat assignment fees are intrinsic to air transportation, but rather on the difficulty of disclosing the information. ATPCO stated that it can already support the proposed requirement to disclose first and second checked bag fees, which is also supported by A4A's comments indicating that airlines have provided itinerary-specific checked baggage fees to ATPCO for distribution to other industry participants. ATPCO also stated that the industry is working to address disclosure of carry-on baggage and seat assignment fees. However, given the complex pricing structure for seats, and the variation in carry-on baggage allowances depending on the aircraft, disclosure of this information is a complex undertaking that will take significant time to achieve. Farelogix stated that the industry is working towards distribution of seat assignment fees but that due to dynamic pricing of seats, and the need to determine availability at the time the price is displayed, it is not currently practicable to display dynamic seat assignment fees at the shopping stage. According to Farelogix, a requirement by the Department to provide seat assignment fees at the shopping stage would effectively force industry participants to provide static fees. Such a requirement would redirect industry efforts to implementing a static system rather than continuing to work toward modernizing distribution systems and

ultimately would not be in the interests of consumers.

DOT Response: We take note of the comments focused on technical issues and stating that due to technological limitations, the Department should not require disclosure of such fees. However, we note that many of the comments pointed to the progress in technology and in commercial agreements. That progress is allowing GDSs to provide advance seat assignment information to ticket agents and allowing ticket agents that sell to consumers to provide that information to consumers and transact those fees. It appears from the comments that the ability to display dynamic seat assignment fees and sell such services is progressing rapidly and with sufficient implementation time, such fees could be disclosed. In addition, we are unpersuaded by the argument that seat assignment fees are dynamic and therefore should not be considered a basic ancillary service fee. The dynamic and changing nature of seat assignment fees tends to support a requirement that such fees be not only disclosed but transactable. However, we are convinced by carrier arguments that advance seat assignments were not universally provided to consumers as part of the price of air transportation even before the unbundling of fares. As noted by A4A and United, fare purchases always did and still do guarantee a seat in a particular cabin, such as first class or economy, but not a particular seat number. In addition, we acknowledge seats often were not assigned until a few weeks before the flight or even on the day of flight. Now, in an era of unbundled fares, some carriers offer few advance seat assignments for free but those carriers assign a seat without charge on or close to the day of travel. In addition, at least one U.S. carrier, Southwest, does not provide seat assignments at all. Meanwhile, we note that it would be a violation of the full fare rule and an unfair and deceptive practice if a carrier required a consumer to pay an additional fee beyond airfare to obtain any seat at all. Carriers must provide a seat in the class of service that was sold to the consumer regardless of whether a seat is assigned in advance or not. Accordingly, we have tentatively concluded that advance seat assignments should not be considered intrinsic to air transportation. In addition, although we appreciate that advance boarding options and related fees are important to many consumers that would like to purchase that service, it is not a service that historically has

been included in the cost of air transportation.

Turning to change and cancellation fees, we are aware that such fees are important information and in fact are significant restrictions that must be disclosed to consumers because it would be an unfair and deceptive practice not to disclose such fees. Further, carriers are required to provide direct notice with the ticket (14 CFR 253.7) of terms such as restrictions on refunds, and information regarding cancellation fees in their customer service commitments. We encourage carriers to make change and cancellation fee information as transparent and clear to consumers as possible. We also solicit comment on whether the Department should require airlines and ticket agents, prior to an online transaction being completed, to provide consumers a link to the airline Web sites where the change and cancellation information is available or if an agent prefers to its own site that displays airlines' change and cancellation information. However, we are not convinced that change and cancellation fees are a cost that is intrinsic to air transportation and must be disclosed at the same point that itinerary information is disclosed. Like seat assignments, many consumers avail themselves of air transportation without making changes or canceling reservations.

Regarding bundled fares that include the fees that the Department initially considered basic ancillary service fees (e.g., advance seat assignment or certain baggage fees), our position is that consumers need to be able to ascertain the true cost of travel including basic ancillary service fees so to the extent that a carrier wanted to provide a bundled fare in addition to an unbundled fare and basic ancillary service fees, a carrier would be free to do so. However, if the carrier is disclosing basic ancillary service fees at the same point fare information is disclosed, then under this proposal additional options such as bundled fares are not something a carrier would have to disclose to ensure the consumer was aware of the true cost of travel.

With regard to baggage fees, the comments did not offer any reason to change our view that a carry-on bag and first and second checked bag were traditionally included in the cost of transportation. We remain of the view that a carry-on bag and first and second checked bag are intrinsic to air transportation and it is reasonable to require carriers and ticket agents to disclose those baggage fees to consumers at the same point that fare

and schedule information is disclosed. Therefore our revised proposal in this SNPRM includes a requirement that carriers disclose to ticket agents the fees for one carry-on item and a first and second checked bag. The proposal would also require ticket agents and carriers to provide those fees to consumers whenever fare and schedule information is provided as described in Section F below. We seek comment on the revised proposal.

Although we have tentatively concluded that only certain baggage fees should be included in our disclosure requirement, we note that some members of Congress have expressed the view that in addition to baggage fees, advance seat assignment fees, change and cancellation fees, priority boarding fees, and ticket fees should all be disclosed where fares are displayed. See, for example, HR 636 (as passed in the Senate in April 2016). In the event future similar legislation is enacted to require the Department to address whether advance seat assignment fees, change and cancellation fees, priority boarding fees, and ticket fees should all be disclosed where fares are displayed, we seek comment on such a disclosure requirement. What are possible benefits to consumers from a requirement to disclose baggage fees, advance seat assignment fees, change and cancellation fees, priority boarding fees, and ticket fees along with fares? What are the costs and potential challenges to implementing such a requirement? Comments that are most useful provide information regarding the reasons why additional disclosures should be required or should not be required. In addition, comments describing specific costs and benefits would be helpful.

C. Disclosure by Carriers to Ticket Agents of Fees for Basic Ancillary Services

The NPRM: The NPRM put forth two co-proposals. Under both proposals, each carrier would have been required to distribute its basic ancillary service fee information to certain ticket agents that the carrier permits to distribute its fare, schedule, and availability information. Under the first proposal, option A, carriers would have been required to distribute the information to all ticket agents, including GDSs, that the carrier provides fare, schedule, and availability information for distribution. Under the second proposal, option B, carriers would not have been required to distribute ancillary service fee information to GDSs or other intermediaries that do not sell the carrier's tickets directly to consumers. The option B proposal included an

assumption that GDSs and similar intermediaries would not be subject to any direct consumer notification requirements. This means that, in addition to GDSs and similar business-to-business intermediaries, entities that operate flight search tools but do not transact sales to consumers would not have been subject to direct consumer notification requirements. Neither proposal required carriers to distribute ancillary service fee information to any GDS or other ticket agent to whom the carrier does not choose to distribute its fare, schedule, and availability information. In connection with transactability, neither of the proposals required transactability (the ability for ticket agents to sell/transact an airline ancillary service to consumers). The options proposed merely required carriers to provide "usable, current and accurate" information on fees for basic ancillary services to all ticket agents so this information may be disclosed to consumers wherever fare, schedule, and availability information is provided.

Under both of the proposals, U.S. and foreign air carriers would have been required to distribute to certain ticket agents the standard fees for basic ancillary services. However, carriers would not have been required to provide information to ticket agents about individual customers, such as their frequent flyer status, though these factors may impact the fee for an ancillary service. Under both proposals, specific charges, not a range of fees, would have to have been disclosed to consumers for basic ancillary service fees. Neither of the Department's alternative proposals dictated the method that carriers must use to distribute the information, rather, the NPRM cautioned that carriers would have to be mindful that whatever distribution method is used would have to provide usable, accurate, and current information so the information would be accessible in real-time. Further, ticket agents would have had to work in good faith with carriers to come to agreement on the method used to transmit the ancillary service fee information.

Comments: In response to the NPRM, many commenters suggested that the Department go further than either option A or option B in terms of disclosure by carriers to ticket agents. For example, Open Allies, Travelers United, NCL, CCIA, TripAdvisor, and Skyscanner recommended that the Department require airlines to share all flight content information with any interested entity. According to CCIA, that would provide consumers with accurate ancillary fee information in the most direct manner with the least

regulatory cost. TripAdvisor commented that the Department should require airlines to make all flight-specific information, including fares and fees, available to all information providers, because open exchange of information is the best way to protect consumers. Skyscanner also argued that transparency for consumers can only be achieved if the Department requires airlines to disclose fee information to all entities involved in the travel booking process, including metasearch sites. TripAdvisor further commented that if the Department chooses from the proposed options, it should adopt option A, requiring disclosure of basic ancillary service fees to all entities with which the carrier shares fare information, as that is the practical and efficient way for ticket agents to receive and display the fee information and comply with Department requirements. Meanwhile, to the extent the Department adopts one of the two proposed options, Travelers United and NCL supported option A. According to Travelers United and NCL, option B is not feasible because the existing air travel distribution system relies on GDSs, the current marketplace would be extremely limited by exclusion of GDSs, and there is no alternative distribution network currently in place.

Open Allies also supported option A. According to Open Allies, option B, which would not require distribution to GDSs, discriminates against ticket agents and is not a good solution. Open Allies stated that agents and airlines need GDS involvement for the potential benefits of the regulation to be put into place in a workable manner and that including GDSs is the lowest cost, most efficient way of achieving the Department's disclosure goal. The organization also argued that there is no valid reason to exclude intermediaries from disclosure requirements when to do so will make fee dissemination more challenging and costly.

Travel Tech also commented in support of option A, stating that it is the only option that will achieve the Department's goals. According to Travel Tech, 90 percent of ARC-approved ticket agents use GDSs and, although that may change over time, as a practical matter, many ticket agents currently rely on GDSs for data today. It is an efficient way for ticket agents to receive fee information, is currently in use for many charges that airlines already impose, and will facilitate display of the information. According to Travel Tech, option B raises a "nightmare" prospect for many travel agents, including OTAs, of not being able to rely on their established data source. Travel Tech

noted the Department's desire to minimize government interference and encourage innovation but stated that not requiring disclosure to GDSs will be a disservice to consumers. Travel Tech stated that it is not a new concept and analogizes to existing Department requirements, such as the requirement that carriers provide GDSs code-share and change-of-gauge information when providing flight information to GDSs. Travel Tech went on to state that GDSs are technically capable of displaying ancillary services and fees as carriers want them displayed. Meanwhile, carriers can continue to develop alternative distribution arrangements for future use while allowing ticket agents to provide the disclosure to consumers as contemplated by the Department.

Sabre, in support of option A, stated that its services make sharing price information accurate and efficient as well as cost effective for ticket agents. Sabre further stated that if travel agents that rely on GDSs were forced to use an alternative, they would incur costs that would ultimately be passed on to consumers. Travelport commented in support of option A, noting the Department's statement that 50 percent of tickets are sold via a travel agent and virtually all of those agents rely on a GDS as an efficient data conduit. Amadeus offered similar reasons in support of option A, noting that ticket agents already rely on GDSs as an efficient source of data. Amadeus also pointed out that many travel agents are small businesses that rely on GDSs for airline data and if data were not provided through GDSs, they would not have a financially feasible way to obtain and distribute the information. Such agencies could not afford or manage the technical complexity of, for example, direct connects with multiple airlines, to obtain and disclose ancillary service fee information.

ASTA and several travel agents also commented that GDSs have the technology to allow travel agents to book ancillary services. ASTA also noted that travel agents rely on GDSs for a variety of business functions in addition to booking, and accordingly ASTA stated that option A, excluding GDSs, would harm travel agents. ASTA also stated that option B does not provide sufficient protection for consumers. Therefore, according to ASTA, the Department should not adopt either option A or B and instead should require transactability.

Corporate travel agents American Express Global Business Travel, Carlson Wagonlit Travel (CWT), and BCD supported option A. CWT commented that ticket agents cannot provide

ancillary service fee information unless the information is first provided by carriers to ticket agents via GDSs; otherwise, ticket agents would be required to obtain the information from each carrier. BCD commented that ticket agents must have access to information about ancillary services through GDSs, the "normal and customary distribution channels" that are time-tested and functional. Without the requirement that GDSs have the information, BCD stated it will incur material costs in obtaining the ancillary service information from every airline and will not be able to ensure it has accurate and complete information. Travelers United and NCL supported option A as the best of the options proposed. BTC supported option A, commenting that there is no usable, workable mechanism for airlines to distribute ancillary service fee information to tens of thousands of individual travel agents, most of whom already rely on GDSs. Skyscanner noted that if the Department chooses option B over option A, consumers who conduct searches on metasearch Web sites that do not sell the ticket will not receive the same ancillary fee information that is disclosed on traditional travel agent or carrier Web sites.

A4A opposed the disclosure requirement on the grounds that it will place airlines at a disadvantage to GDSs in contract negotiations and also opposed it on technology grounds. A4A argued that GDSs have historically been in a stronger negotiating position than airlines and that GDSs were only willing to develop new technologies for accessing and distributing airline fare and flight information because the GDSs did not have contract provisions requiring airlines to provide ancillary services information. The ancillary services information, in addition to motivating GDS investments in technology, enabled airlines to negotiate lower GDSs booking fees. According to A4A, GDS concessions on pricing and technology resulted because airlines did not have the obligation to provide the ancillary service fee information to GDSs, and if the Department requires airlines to provide such information, it will restore GDSs to a stronger negotiating position over airlines. A4A stated this will be the case whether the Department adopts option A, expressly requiring airlines to provide the information to GDSs, or option B, requiring airlines to give the information to GDSs as a practical matter. A4A also objected to the proposal on the grounds that distribution channels would all have to offer the same functionality and not

every channel has the more developed functionality needed to distribute dynamic fees. The effect would be to impose a system of static fees, according to A4A. AACO also commented that a requirement to distribute ancillary service fee information through GDSs would essentially require carriers to distribute static fees to ticket agents instead of the dynamic fees currently available on carrier Web sites. This would force airlines to use static fees on their Web sites for the sake of consistency and would limit innovation and could lead to higher charges for consumers. IATA also opposed the disclosure requirement, arguing that the changing marketplace is making information more readily available to consumers because airlines are motivated to disclose the information and consumers are used to unbundled fares and know how to search and find such information. IATA stated that airline Web sites offer consumers and ticket agents comprehensive and accurate ancillary service fee information. However, according to IATA, a Department rule mandating disclosure will harm consumers, because it could shift current marketplace momentum from implementing new internet-based technologies that offer dynamic solutions back to inferior solutions offered on legacy infrastructure.

Most airline comments objected to any ancillary service fee disclosure requirement, with several indicating that any Department involvement would unduly influence contract negotiations and distribution innovations. In contrast to ticket agents and their representatives, some carriers stated that any requirement to distribute fees will effectively require them to distribute to GDSs, which would unfairly disadvantage them in negotiations with GDSs as well as lock them into a distribution model that relies on static fees, which will create obstacles to innovation. However, some commented that to the extent that the Department adopts one of the proposals, some carriers supported Option B, requiring disclosure of ancillary service fee information to ticket agents that sell transportation only, excluding GDSs and other intermediaries. For example, Delta stated that the Department should refrain from any regulation of airline distribution channels, but option B would have less impact on negotiations between carriers and GDSs. United commented that option B would better allow for development of alternative systems for airlines to provide information directly to travel agents.

United also notes that ATPCO (relied on by GDSs) does not have the technological capability to process constantly changing ancillary service prices, which makes this issue more complex than addressing baggage fees. Like AACO, Delta and United seem to indicate that a requirement to distribute ancillary service fee information through GDSs would essentially require carriers to distribute static fees to ticket agents.

China Eastern stated that option B would present fewer technical and development hurdles. Spirit commented that option B is less intrusive and that a requirement to distribute ancillary service fee information to all travel intermediaries as described in option A may cause Spirit to withdraw from one or more GDSs altogether due to increased distribution costs. Insel, a Caribbean carrier, commented that consumers must be informed of the total cost associated with their travel; however, requiring disclosure through GDSs would increase airlines' costs, and those costs would likely be passed on to consumers. Virgin Atlantic is concerned about the burden of ensuring ticket agents that have Virgin Atlantic's fare, schedule, and availability information also have ancillary service fee information and stated that if a carrier has shared information with ATPCO or a direct connect, that should be sufficient.

DOT Response: We have carefully considered the comments regarding whether to require carriers to distribute ancillary service fee information to all ticket agents that a carrier provides with its fare, schedule, and availability information, including GDSs, or only to require carriers to distribute the information to those ticket agents that sell its tickets. We recognize that both options potentially impact relationships among commercial entities and we do not take Department involvement in carrier distribution channels lightly. We recognize that airlines have concerns that being required to provide certain ancillary fee information to GDSs will put airlines at a disadvantage when negotiating contract terms with GDSs. We also understand that airlines have concerns about being required to rely on GDS infrastructure and GDS ability to market dynamic fees as carriers do on their own Web sites. However, airline complaints about the technical deficits of GDSs appear to be focused on dynamic fees. Airlines already rely on the GDSs to distribute baggage fee information and carriers do not provide a strong argument against using GDSs to distribute this information. Meanwhile, ATPCO notes that there are some

technical issues to be worked out to distribute information on fees for carry-on items but ATPCO is already working with certain carriers and ticket agents, including GDSs, to distribute and even transact checked bag fees. Further, the proposals in the 2014 NPRM reflect our view that basic ancillary fee information should be shared with all consumers at all outlets. IATA acknowledges that more work needs to be done by the industry in that area. We agree with the comments of Skyscanner that our consumer protection goals would be undermined if we did not require disclosure to intermediaries in arranging for air transportation, such as metasearch entities that operate flight search tools, as those entities would not necessarily have basic ancillary service fee information to provide to consumers. Regarding the ability of GDSs to distribute the information, all three GDSs serving the U.S. market assert they have the technical ability to distribute baggage fee information. In addition, we find persuasive some ticket agent comments that they rely on receiving information through the GDS channel, that alternative distribution methods would be practically disruptive and technically difficult if not impossible to implement, and would cause them to incur significant costs. We recognize that with either option some time would be needed to develop the process for disclosure, particularly in connection with carry-on bags, as ATPCO noted. The proposed implementation period is discussed below in section G.

In connection with the requirement that the distribution method used would have to provide usable, accurate, and current ancillary service fee information so the information would be accessible in real-time, some entities comment that the 2014 NPRM does not define with sufficient specificity what constitutes usable, accurate, and current. Farelogix commented that distribution through GDSs would effectively halt or limit dynamic pricing because according to Farelogix, GDSs are only able to provide static pricing. However, the comments opposing use of GDSs to transmit fee information were focused on the technical limitations of GDSs in the area of dynamic fees (which GDSs dispute); there were no comments indicating that any entity thought that baggage fee information transmitted through GDSs would not be usable, accurate, and current. A4A's comment indicates that the fee information for checked baggage is already available in the GDS systems via ATPCO filings. We note that the proposed requirement to provide

information to GDSs only applies if the carrier is using the GDSs to distribute its fare, and schedule information. We do not believe such a requirement would be unduly burdensome on carriers as it appears that the primary objection of carriers from a technical standpoint relates to limited availability services subject to dynamic pricing, such as seat assignment fees, and seat assignment fee information is no longer included in the proposed requirement. In response to some comments that by imposing disclosure requirements on checked baggage fees the Department would be effectively prohibiting carriers from offering discounts through dynamic pricing, we disagree. Carriers are free under Department rules to offer discounts, whether through dynamic pricing or other methods, if the pricing is properly disclosed.⁴ Further, some carriers are already working with GDSs to offer premium seats, so we are not convinced that they could not do the same with baggage fees. The remaining objection, being placed in a disadvantageous position in contract discussions, would be addressed by a prohibition on unilateral contract provisions related to distribution, as discussed more fully below.

After carefully considering all of the comments submitted, the Department has decided to propose requiring carriers to provide information on fees for one carry-on item and first and second checked bag to all ticket agents to which it provides fare and schedule information, including GDSs and other intermediaries in the air transportation marketplace. This option provides for wide distribution with the least disruption to existing business models and the shortest implementation time. We acknowledge that almost any distribution and disclosure requirement will involve Department intervention into business and contractual arrangements. However, the Department is counter-balancing these concerns by including in its proposal a prohibition on unilateral cost increases by GDSs on airlines as discussed in Section E. When the proposed requirement to provide information to GDSs is considered in conjunction with the Department's proposed restriction on certain contract provisions, we believe the Department's

regulatory involvement in business arrangements is minimal and justifiable.

We note that in this SNPRM we are proposing to require carriers to provide certain ancillary service fee information to all ticket agents to which it provides fare and schedule information. This would ensure consumers receive key baggage fee information at the same time that they are identifying flight options so that they have enough information to determine the true cost of travel. We believe that furnishing availability information to ticket agents should not be a determining factor in whether the agent receives the ancillary service fee information in question. Requiring carriers to provide required ancillary service fee information to all ticket agents to which they provide fare and schedule information should ensure that all relevant ticket agents are provided with the ancillary service fee information without imposing an overly broad requirement. We seek comment on the substance of the proposal and whether the description of ticket agents that should receive basic ancillary service fee information is sufficiently broad.

D. Transactability

The NPRM: In the NPRM, the Department requested comment on the issue of requiring that basic ancillary services be made transactable (*i.e.*, to require that airlines permit online travel agencies to sell these ancillary services). The Department recognized that transactability is a very important business issue for both carriers and ticket agents and noted that we want to avoid causing a negative impact on innovation or unnecessarily intruding into business and commercial arrangements. We further noted that carriers and stakeholders have assured the Department that they share our goal of transparency and assume that the various stakeholders would negotiate regarding the ability of ticket agents to sell a carrier's ancillary services and the price at which those services would be sold. However, we left open the possibility of requiring transactability and requested comments on the issue.

Comments: Consumer advocacy organizations' comments generally favored transactability. Consumers Union and U.S. PIRG stated that ancillary services should be transactable through ticket agents or, at a minimum, customer-specific quotes with ancillary service fees should be provided and guaranteed to be available once the ticket has been purchased. Travelers United and NCL commented that the Department should not concern itself with how the data is used but rather

should require airlines to release all ancillary service data and let market innovations determine how it is provided to consumers. Open Allies commented that the Department should require airlines to provide basic ancillary service fee information to ticket agents in a format that allows ticket agents not only to disclose the information to consumers but also to sell the services.

Open Allies stated it believes that the lack of transactability is unlikely to be resolved by carriers absent a rule. The organization commented that ticket agents should be able to sell services because consumers support transactability. It pointed to a survey it conducted which showed 72 percent of survey respondents believe transparency includes transactability. Open Allies also noted that requiring transactability would save time and be more efficient for consumers. If transactability is not required, it contended, consumers will have to go to airline Web sites to find and purchase a service found on a ticket agent Web site and, unless fees are unchangeable, the service may no longer be available, or available at the quoted price, at that time. According to Open Allies, airlines are the only entities that "disaggregate" pricing and as a consequence the Department should regulate "pricing transparency" which is only possible with transactability. Open Allies disagreed with the carrier position that GDSs have greater bargaining power than airlines in contract negotiations, noting the reduced GDS fees airlines have negotiated since GDS deregulation. Open Allies also said the decreased number of legacy carriers in the United States has increased airline negotiating power. The organization argued that transactability is necessary because, if the Department relied on requiring the carriers to lock in prices for ancillary services at the time consumers purchased tickets, it would be difficult to enforce and costly and time consuming to develop systems that would enable fees to be locked for individual consumers. Meanwhile, consumers would still face the inconvenience of having to go to airline sites to purchase the ancillary service, which would increase their transaction costs.

Several travel agents filed similar comments favoring transactability, stating that disclosure alone is not sufficient. According to those travel agents, add-on fees are complex and change from airline to airline, preventing travel agents from providing completely accurate quotes to customers. Although requiring

⁴ In response to A4A's comment that the requirement to distribute static baggage fees through GDSs to comply with previous rule has prevented airlines from offering dynamic baggage fee pricing, we note that is the result of airline pricing decisions and GDS contract restrictions and not a Department requirement. Airlines are free to offer static or dynamic fees under Department rules, as long as the prices are properly disclosed.

disclosure of the cost of bags and seat assignments would help, according to these commenters, consumers would still be surprised because the price of services may go up before they buy them. They also stated that GDSs have the ability to provide transactability and airlines would benefit from increased sales of ancillary services, creating a “win-win” for the entire value chain. ASTA commented that the only option the Department should consider is transactability. According to ASTA, airlines, U.S. airlines in particular, have proven unresponsive to market influences to sell ancillary services through ticket agents and without requiring transactability. ASTA asserted that the Department will effectively be forcing agents to send customers to a competitor if it does not require transactability.

Travel Tech commented in support of transactability, stating that the existing GDS infrastructure already permits transaction of various airline service fees, such as baggage, in some cases, and also allows seat assignments for certain carriers’ inventory. According to Travel Tech, the only question is whether airlines will allow ticket agents to transact the services once the airline makes the information available through GDSs. Travel Tech also commented that consumers should be able to purchase ancillary services at their preferred outlet to avoid the increased search and transaction costs of not having ancillary services available for purchase through ticket agents.

Amadeus, Sabre and Travelport also commented that consumers using ticket agent outlets experience increased transaction time without transactability. They stated that they are ready to implement transactability and point to their own technological developments and existing agreements with carriers on distribution of ancillary services. Sabre provided information regarding 23 carriers for which it both displays and transacts at least one ancillary service. Travelport stated ancillary services can be transacted using older technology but that it has introduced a new platform to allow airlines to differentiate their products from competing airlines. Amadeus stated that requiring transactability is the only way the Department can meet the goal of transparency. Amadeus commented that disclosure without transactability will confuse consumers. Amadeus stated that it already has a product that will enable transactability and that 58 airlines are already using this product, but concludes that the Department cannot rely on the market to move towards transactability because the

factors that have inhibited widespread implementation are still present, particularly in the case of U.S. airlines.

Orbitz stated it is a member of Travel Tech and commented to elaborate on Travel Tech’s comments. Orbitz stated that if the Department imposes disclosure requirements on ticket agents without transactability, consumers will only be more confused. Orbitz pointed to the static nature of some fees and dynamic nature of others, which will increase the confusion. Meanwhile, according to Orbitz, the Department should not assume that airlines will negotiate to allow ticket agents to transact ancillary services. The outcome of the rule may be that ticket agents that compete with airlines and offer consumers choices that they might not otherwise have been aware of, are left with an inferior product and asymmetrical disclosure requirements that disadvantage ticket agents and lead to consumer harm.

Corporate travel agents also supported transactability. BCD commented that the Department should require transactability through GDSs and if the information is not transactable, corporate travel agents should not be required to disclose those ancillary service fees. BCD stated customers will be frustrated if it is not able to book the services that it has just disclosed to its customers. BCD also stated its customers depend on having all of the costs of travel tracked through its systems so if it cannot book all services the customer wants, its travel cost data will not be accurate. CWT commented that to provide consumer benefit, the Department must require that ancillary services be transactable through GDSs or agents will be unduly burdened and the existing distribution system will be undermined. BTC commented that for consumers transparency and transactability are “interlocked” and without transactability, the booking process for consumers and travel agents involves multiple steps and is more confusing and time consuming as a result. BTC also commented on the risk of increased costs or lost opportunities to purchase certain ancillary services if they are not purchased at the time the ticket is purchased. International Airline Passengers Association also commented in favor of transactability and supported BTC’s comments.

A4A opposed transactability, reiterating its view that there is no consumer harm to address. A4A also identifies practical considerations, including that some carriers do not allow for payment of baggage fees at time of ticketing even when travel is purchased directly from the carrier and

many consumers do not know at time of ticketing whether or how many bags the consumer will want transported. Several carrier comments reflect agreement with the Department’s tentative decision not to require transactability, including those of Delta and United. Frontier also opposed transactability, stating that it would increase airline costs which would in turn be passed on to consumers. Virgin Atlantic opposed a transactability requirement because it would undermine carrier ability to control its distribution scope and costs and essentially mandates the commercial relationship between a carrier and its agents solely to the benefit of agents.

DOT Response: We have carefully considered all of the comments supporting and opposing transactability. We note that the Department has already prohibited post-purchase price increases on transporting baggage. The Department’s Enforcement Office has also indicated that it intends to pursue enforcement action against carriers that increase fees for baggage not provided with the ticket but traditionally included in the price of the ticket (*i.e.*, carry-on bag, 1st and 2nd checked bag). Therefore, the Department’s existing rule regarding baggage fee price increases has already addressed the concern that ticket agents will provide consumers information on baggage fees that will be inaccurate or the price will increase before the consumer has the opportunity to purchase baggage transportation services. Regarding seat assignment fees, since the Department has tentatively concluded that advance seat assignments are not truly intrinsic to air transportation, and consequently determined not to propose a requirement that ticket agents disclose fees for seat assignments, consumers will not be presented with seat assignment options that they cannot purchase immediately. This means consumers will not be confused by being presented a seat assignment that they cannot obtain, or risk being unable to purchase their chosen option at the advertised price.

We recognize that requiring airlines to make both baggage and seat assignments transactable services through ticket agents would potentially increase consumer satisfaction and decrease transaction costs of time spent on shopping and booking when using ticket agent Web sites to book travel. We are also aware of the importance of transactability as a business matter to ticket agents that must provide the services consumers want and expect or risk losing business. We recognize that comments by some stakeholders,

including ticket agents and consumer advocacy groups, indicate that airlines are not motivated to enter into agreements to allow transactability. In addition, we recognize that many consumers do not purchase baggage transportation at the same time they purchase travel, so there may be limited incentive for either ticket agents or carriers to negotiate agreements on transactability in this area. However, we are encouraged by the progress reported to date by both carriers and ticket agents in reaching some agreements that permit ticket agents to sell select carrier ancillary services. We also note that both ticket agents and airlines have stated that airlines have a strong incentive to make airline ancillary services more widely available to consumers in order to sell more of those services. Accordingly, we believe that carriers and ticket agents may be able to reach agreements to transact various ancillary services if there is sufficient benefit to all commercial entities in the transaction. We also recognize that corporate travel agents have additional concerns specific to their business model regarding customer frustration with a travel agent's inability to transact certain services as well as business concerns regarding tracking costs for corporate travel clients. However, we feel the benefits of having the information available for consumers outweighs any frustration caused by the inability to purchase through a ticket agent, particularly since the only fees that must be disclosed under the current rulemaking are baggage fees, which are not permitted to be increased. Regarding tracking the costs of travel for business purposes, the same problem exists if a consumer does not decide to check a bag until the date of travel and pays at the airport. At least under the disclosure requirement, corporate travel agents can include the amount of bag fees that potentially may be incurred in a travel record for purposes of record keeping. Ultimately we believe there are even greater incentives for both carriers and ticket agents to come to agreements regarding transacting ancillary services in the corporate travel arena than in connection with leisure travel.

Finally, in connection with technical issues related to transactability, we note that some stakeholders alleged that a requirement to distribute ancillary service fees through GDSs would essentially require carriers to distribute static fees to ticket agents instead of the dynamic fees currently available on carrier Web sites. ATPCO's comments support that view to some extent based on its description of the current

capability for entities to transact checked bag fees using ATPCO codes and the complexity of carry on and seat assignment fees, which would require more development by ATPCO. However, we also note that GDSs comment that they have been developing technology solutions and the technology already exists for ancillary services to be transactable through GDSs. Meanwhile, although carriers object to undue intrusion into their businesses, they also point to agreements carriers have reached on transacting ancillary services to support the position that the market is solving the disclosure problem. This leads us to conclude that technical obstacles to transactability are not insurmountable and would not require disclosure of only static baggage fees. Meanwhile, we remain of the view that the Department should limit its intervention concerning commercial negotiations in this area at this time and continue to rely on market forces to a large extent. Therefore, we are proposing a revised disclosure option that we believe offers the maximum consumer disclosure benefit while stopping short of requiring transactability. At this time, the Department is relying on competition and market forces but will continue to monitor the issue. If the Department identifies evidence of consumer harm resulting from a lack of transactability and a market failure preventing resolution of the problem, we will revisit the issue in a future rulemaking. At this time, however, we are not proposing a transactability requirement.

E. Contract Provisions Among Carriers, GDSs, and Other Ticket Agents

The NPRM: In the NPRM, we noted that if we adopted a provision requiring carriers to disclose ancillary service fee information to ticket agents and ticket agents to disclose it to consumers, it would be unlawful to provide fare information that did not include the fees for basic ancillary services. Accordingly, we stated that to the extent that carriers have existing contractual relationships with ticket agents acting as intermediaries, such as GDSs, to distribute fare information, those ticket agents acting as intermediaries would be prohibited from imposing charges for the distribution of required ancillary service fee information. We also noted that we would expect GDSs to work in good faith with carriers and other ticket agents that are able to agree on alternative distribution methods that do not include the GDSs to allow integration of information obtained through other sources and information obtained through GDSs.

Comments: Travel Tech commented that the ban on GDSs charging additional fees should only apply to existing contracts and that the language of the rule should be changed to clarify this. Travel Tech also argued that if a requirement for carriers to provide basic ancillary fee information only to ticket agents that sell a carrier's tickets directly to consumers is adopted, it should be changed to make it clear that the contract limitation only applies to those ticket agents. Travel Tech also argued that carriers should be required to provide the same fees for ancillary services that carriers display on their own sites and not higher service fees, otherwise ticket agents would effectively be prohibited from negotiating with carriers regarding the ancillary service fees the ticket agent must disclose and ticket agents that display fees to consumers would be limited in the fees they could display to consumers. Amadeus commented that the Department should clarify that the prohibition against imposing additional charges on carriers for distributing ancillary service fee information expires at the termination of an existing contract. Amadeus also argued that, during the existing contract period, the carrier should provide the same fee information to the GDSs that is available on the carrier's Web site. In contrast, Travelport opposed the contractual provision and stated it is confusing and that the Department should not interfere with contractual negotiations.

Open Allies commented that it is acceptable to ban the imposition of additional charges on carriers, but only for the length of the existing contract. Open Allies also argued that carriers should be required to provide the same fees for ancillary services, not higher fees, to ticket agents during the term of the existing contracts. ASTA opposed the contract provision, stating that it is outside the scope of Department authority. It also asserted that, as the provision is drafted, it is unclear about which ticket agents are covered. According to ASTA, most travel agents receive airline flight information through GDSs and their contracts with airlines are through the Airlines Reporting Corporation (ARC) and can be unilaterally amended by the airlines but not travel agents. Further, as a practical matter, travel agents are not in a position to unilaterally impose charges on airlines. ASTA commented that it would be inappropriate for the Department to prohibit travel agents from imposing charges on consumers, but it appears the Department meant to only cover ticket agents acting as

intermediaries and prevent charges to carriers. However, according to ASTA, that is not clear from the proposed rule text. AACO commented that even if the Department prohibited GDSs from imposing an explicit fee in connection with the requirement to disclose certain ancillary service fee information, GDSs could still introduce adjustments in other service charges to compensate for the requirement.

DOT Response: The Department has considered the comments regarding a contract provision prohibiting ticket agent intermediaries from imposing additional charges on carriers in connection with distributing ancillary service fee information along with fare information. We recognize that some ticket agents oppose any Department involvement in contractual arrangements between private entities, and we are similarly reluctant to insert the Department into such arrangements. However, since the Department is proposing to impose a new legal requirement on carriers and the ticket agents that distribute carrier fares and certain ancillary service fees, we believe it is appropriate to put in place a short term restriction on unilateral changes to contract arrangements.

We recognize that distribution of ancillary service fees has been very controversial, in particular in GDS dealings with carriers, and in order to prevent business disputes from interfering with the implementation of a new Department requirement we have determined it is appropriate to implement a regulation with limited scope that covers only existing contracts that were negotiated based on a different regulatory background. The proposed restriction is only intended to cover contract provisions regarding charges imposed on airlines by ticket agent intermediaries for distributing certain ancillary fee information that the rule requires to be distributed along with fare information. The proposed restriction would only impact contracts for their current term at the time a final rule is issued in order to reflect the changed regulatory environment; future negotiations will enable all parties to negotiate based on the regulatory changes.

We believe that in practice the proposed disclosure requirement will not require significant investment in new technology by GDSs since GDSs already have a significant amount of baggage information through ATPCO filings. Accordingly, we would expect GDSs to work with carriers in good faith and not attempt to circumvent the restriction on additional charges by adding charges in other areas to evade

the restriction. To the extent that a GDS engaged in such tactics, the Department would consider it a violation of the provision preventing such charges. The restriction only limits unilateral imposition of new charges on airlines by intermediary ticket agents. It is not intended to prevent good faith negotiations to revise existing contracts or to carry over to any new contracts negotiated after issuance of this final rule. We agree with some commenters that the rule text should be clarified to make clear it covers only existing contracts and have made the appropriate changes in the proposed rule text. We have also revised the proposed rule text in connection with ASTA's comment that the provision could be read to apply to travel agents that do not receive information directly from carriers. We do not intend for the proposed restriction to cover such contracts.

In connection with comments that carriers should be required to provide the same fees for ancillary services that carriers display on their own sites and not higher service fees, we have decided not to propose such a restriction. It is not the Department's position that the same ancillary service fees must be charged at all outlets, merely that consumers should be informed of the basic ancillary service fees so they can determine the true cost of air transportation and make an informed decision before making a purchase. Therefore, we tentatively believe it is appropriate to leave it to carriers and ticket agents to determine the ancillary service fees that will be charged through ticket agents. Although we recognize that this means a carrier would not be prohibited from implementing different fees for baggage, depending on the outlet from which the consumer chooses to purchase air transportation, as a practical matter, we believe it would be challenging for carriers to implement varying charges in the current technological environment. Therefore, under the proposed provision, carriers and ticket agents will have the opportunity to come to agreement on this issue as new contracts are negotiated and new commercial and technological arrangements are put in place.

F. Customer-Specific or Itinerary-Specific Fee Information

The NPRM: The NPRM recognized that requiring carriers to disclose basic ancillary service fee information to ticket agents is not helpful to consumers if it is not displayed to them. Further, to address the issue of consumer difficulty in finding basic ancillary

service fee information, the information must be displayed by both carriers and ticket agents in specific amounts, not a range of fees. The NPRM proposed to require carriers to provide customer-specific information if a consumer provides identifying information and itinerary-specific information if identifying information is not provided. The NPRM further proposed to require ticket agents to provide itinerary-specific information. In the NPRM, we stated that "customer-specific" refers to variations in fees that depend on, for example, the passenger type (e.g., military), frequent flyer status, method of payment, geography, travel dates, cabin (e.g., first class, economy), ticketed fare (e.g., full fare ticket -Y class). By contrast, "itinerary-specific" fee information does not include variations in fees that depend on the attributes of the passengers such as the passenger type (e.g., military), frequent flyer status, or method of payment. For itinerary-specific information, the NPRM proposed that both carriers and ticket agents would be required to take into account variations in fees that are related to the itinerary such as travel dates, geography, ticketed fare and cabin.

In addition to providing itinerary-specific fees for a first checked bag, a second checked bag, a carry-on bag and an advance seat assignment, when displaying itinerary-specific information, the NPRM stated that ticket agents would also be required to clearly and prominently disclose that these fees may be reduced or waived based on the passenger's frequent flyer status, method of payment or other characteristic. In either case, whether customer or itinerary-specific fee information is displayed, both airlines and ticket agents that have Web sites marketed towards U.S. consumers would have to disclose, or at a minimum display by a link or rollover, the fees for these basic ancillary services on the first page on which a fare is displayed in response to a search for a specific flight itinerary.

During the comment period, an important clarification was made regarding the NPRM. A4A pointed out that the NPRM stated "Carriers would, of course, be required to provide ticket agents the fee rules for particular passenger types (e.g. military, frequent flyers, or credit card holders)" Notice at 29977. A4A observed that this is customer-specific information that ticket agents would not need to meet the requirement to provide "itinerary specific" fee information. In response to the A4A inquiry, Department staff confirmed that the NPRM statement was

an error.⁵ Nevertheless, as the NPRM stated, ticket agents may come to agreements with airlines that would enable the ticket agent to provide customer-specific ancillary service fee information.

Comments: We received extensive comments supporting greater disclosure. Of consumers favoring greater disclosure, several also comment in favor of a standardized display of some kind, whether a table or other format. In connection with innovative alternatives and solutions not considered, Travelers United and NCL commented that better display of information is needed but do not argue for or against the display requirements proposed, supporting instead a requirement that all data be made available so market innovation can improve how the information is provided to consumers. Open Allies supported greater disclosure of ancillary service fees and stated that the Department should require airlines to provide ticket agents information to provide customer-specific, transactable, quotes. Open Allies argued that if the Department does not require carriers to provide enough information for ticket agents to display customer-specific quotes, consumers will not have enough information in the ticket agent channel and may choose flight options that are more costly than the option they would have chosen if the ticket agent displayed more information. Travel Tech supported a disclosure requirement that is the same for carriers and ticket agents and stated the Department should require carriers to provide customer-specific quotes so that carriers and ticket agents are on equal footing. Amadeus generally supported the proposed display requirements for itinerary-specific fees and stated that the Department should also require carriers to provide customer-specific fee information to ticket agents so that ticket agents may provide customer-specific fee quotes when the ticket agent has sufficient information about the passenger. Amadeus argued that the Department should ensure that consumers dealing with the indirect ticket agent channel have access to the same ancillary fee data that is available from the airline channel.

Southwest Airlines also supported a requirement to disclose ancillary service fees, stating that consumers are not necessarily able to determine the true cost of their own travel because they do not know how much bag fees will be for a particular flight option and as a result

sometimes choose flights that they otherwise would not have chosen. Southwest also stated that requiring display of baggage fees will put downward pressure on those fees. Global Business Travel Association commented in favor of the proposed disclosure requirements, commenting that the Department should require both airlines and ticket agents to display certain ancillary service fees on the first page of search results.

However, many commenters opposed proposed display requirements which would result in carriers providing customer-specific information to consumers that identified their customer category while ticket agents would only be required to provide itinerary-specific information. ASTA pointed out that if the Department adopts display requirements as proposed in the NPRM, carriers would be subject to different disclosure requirements to the extent that a consumer provides identity information to a carrier, which according to ASTA discriminates against and disadvantages ticket agents and defeats the stated regulatory intent. Orbitz also opposed proposed display requirements, stating that providing more information at the start of the booking process will overwhelm and confuse consumers. Further, according to BCD, display requirements will impose additional compliance costs on travel management companies like BCD without providing an opportunity to recoup those costs by offering enhanced services, and those costs will be passed on to BCD clients. CWT also argued that the Department should consider the differences between corporate and leisure travelers and stated that only those fees that can be booked in advance should have to be disclosed, and they should also be transactable or the requirement undermines the distribution system. Instead, CWT supported leaving the existing disclosure requirements unchanged.

Many airlines and airline associations also opposed new display requirements. A4A commented that the proposal is not needed as the Department has already implemented fee disclosure requirements, including requirements for disclosures on carrier and ticket agent Web sites and in e-ticket confirmations. A4A argued that the Department should rely on market pressures to encourage carriers to provide any further disclosures to consumers regarding ancillary service fee information. According to A4A, there is no evidence of consumer injury to support additional display requirements, and the consumer

comments and complaints regarding fees that the Department relies on are not specific enough to justify new display rules. In addition, A4A stated that a requirement that airlines and ticket agents provide itinerary-specific display results that are not based on the identity of the customer will provide inaccurate information to consumers that may be eligible for ancillary service fee discounts based on factors such as frequent flyer membership or method of payment. Air New Zealand and Copa commented on the increased costs that airlines will incur to ensure that ticket agents have additional and correct information to provide to consumers.

Google, Inc. (Google), Hipmunk, Inc. (Hipmunk), Kayak Software Corporation (Kayak), Skyscanner Limited (Skyscanner), Travelzoo, Inc. (Travelzoo), and TripAdvisor LLC (TripAdvisor), referring to themselves as the "Metasearch Providers," filed joint comments summarizing their "consensus views on the nature of the services they provide and the Department's jurisdiction." The Metasearch Providers argued that they have a different role from other ticket agents and should not be subject to display requirements because it is unnecessary and could hamper a consumer's search and discourage overall innovation. The Metasearch Providers stated that display of baggage and seat assignment fees is not necessarily useful to consumers that are just exploring travel options. They also stated that disclosure requirements would impose significant costs for programming and may discourage entities operating flight search tools from displaying prices at all. CCIA commented that display requirements should not apply to entities operating metasearch tools because those entities have strong incentives to provide their users with accurate information and a requirement to show particular information for every flight search would dampen innovation in the flight search exploration process. According to CCIA, the Department should require airlines to provide dynamic ancillary fee data without imposing any "rigid" display requirements, particularly on metasearch entities. Finally, both TripAdvisor and Skyscanner argued that requirements to disclose information to consumers should not apply to them and instead it should be left to the metasearch entities to determine the best method of disclosure to consumers.

DOT Response: After reviewing the comments and considering the options, the Department has determined that it would be more transparent and better serve consumers to have a uniform,

⁵ See DOT-OST-2014-0056-0624, Summary of Proceedings, DOT Meeting with Airlines for America (A4A) (posted September 15, 2014).

more specific, display requirement for consumers. Currently, the burden is on the consumer to research the airline's fees and policies to try to determine which baggage fees may apply to the consumer's air travel. However, we think it is reasonable for consumers to be able to obtain fee information that applies to specific categories of customers. We do not want to interfere with business agreements or impose additional complexity on airlines and ticket agents by requiring airlines to provide personal information regarding their customers to ticket agents. Therefore, we have not proposed to require carriers or ticket agents to provide information that is specific to individuals. Instead, this SNPRM would propose to require carriers to provide the fees for specific categories of customers to ticket agents. It would also require carriers and ticket agents to modify their Web pages to allow consumers the option to indicate any factors that may impact the fees that the consumer might pay to transport baggage. As some of the comments suggested, we agree that it should be optional for consumers to provide the information. Some consumers might prefer to search for flight options without providing that information. Other consumers might be searching for multiple passengers, each of whom might fall into a different customer category, in which case the consumer might need to search flight options more than once to determine what baggage fees applied to each passenger's air travel. However, we believe consumers should have those options rather than having only the option to review multiple static lists to try to determine which baggage fees apply. In the Department's view, the burden of identifying specific baggage fees more appropriately falls on the carrier and ticket agent rather than the consumer. Accordingly, we believe consumers should have the option to provide information to obtain more specific fee information if the consumer chooses to do so.

We seek comment on whether the proposal in this SNPRM covers the appropriate categories of consumers that may be eligible for specialized baggage fees and should be included in the proposal. In the 2014 NPRM, we identified the following categories: Military, credit card holders (method of payment), and frequent flyer members. We have included those same categories in this SNPRM. We seek comment on whether those categories of consumers are sufficient to provide most consumers with specific baggage fee

information. In the alternative, should the Department include any additional customer categories in the requirement? We also seek comment on whether the Department should include in the requirement a general obligation to disclose that baggage fees may be reduced or waived based on other consumer characteristics to be specified by the carrier. In other words, if there are additional categories of consumers that may be eligible for specialized baggage fees on a particular airline but it is not a general category across airlines and is not identified in this rulemaking, should the airline be required to provide additional notice to consumers?

Regarding method of payment, we are aware that there are many credit cards that may provide consumers with the benefit of free or reduced baggage fees. Should we identify specific credit cards that must be included in the list of options that consumers may select or simply require that all carrier-affiliated cards offering baggage fee benefits be included as options for consumers?

Regarding frequent flyer programs, we recognize that there is variation in each carrier's program, for example, different levels of membership with different benefits depending on the consumer's status. Should we specify the levels of membership and status for which information must be provided or is it sufficient to state that each carrier should identify the levels of membership and provide relevant benefit information for all levels of membership (*i.e.*, information on benefits pertaining to baggage fees) to all ticket agents?

In addition, there are also carrier-alliance programs that confer their own benefits. Should we require airlines to provide information regarding carrier-alliance programs as well? If so, would it be necessary for each carrier to identify the levels of membership and provide relevant benefit information for all levels of membership (*i.e.*, information on benefits pertaining to baggage fees) to all ticket agents?

G. Web Site and Mobile Application Displays; Consumer Opt-Out; and Implementation Period

The NPRM: The 2014 NPRM made clear that to comply with the proposed ancillary service fee disclosure requirement, airlines and agents would have to modify their Web sites to display the basic ancillary service fees adjacent to the fare information on the first page that displays a requested itinerary with fare. The NPRM asked for comment about several aspects of the proposed disclosure options, including

whether ancillary service fee information should be displayed only upon a consumer's request or always provided on the first page of search results and whether disclosure of basic ancillary service fee information should be required on limited availability sites, such as corporate travel Web sites. Both proposals would have required that carriers and ticket agents that have Web sites marketed towards U.S. consumers must disclose, or at a minimum display by a link or rollover, the fees for basic ancillary services on the first page on which a fare is displayed in response to a search for a specific flight itinerary. The NPRM made clear that to comply with the proposed disclosure requirement, airlines and agents would have to modify their Web sites to display these basic ancillary service fees adjacent to the fare information on the first page that displays a requested itinerary with fare. The NPRM also sought comment on whether the Department should require carriers and agents to provide information on standard fees for baggage or require a variety of baggage fees to be displayed, and if a variety of fees for each service, how such fees should be arranged in displays. We also asked for information on the technological feasibility and cost of requiring this information to be displayed. Finally, the NPRM also requested comment on whether we should leave the existing requirements on baggage disclosure in place instead of adopting either of the proposals. We also encouraged interested parties to provide comments regarding any innovative alternatives or solutions that the Department may not have considered but that would address the lack of disclosure of ancillary service fees in all sales channels.

Comments: We received extensive comments in connection with these issues. In addition to consumer comments generally supporting greater disclosure, some consumers comment in support of specific display requirements, including over 20 supporting display of fees on the first page displaying fares and six supporting display later in the search process but before purchase. Several consumers also commented in favor of a standardized display of some kind, whether a table or other format. Consumer advocacy groups Consumers Union and U.S. PIRG supported a requirement to display ancillary service fee information automatically alongside the fares on the first page of search results displayed to consumers. They further commented that to the extent all ancillary service fee information is provided (*i.e.*, beyond

baggage fees) and this would crowd the page, then a link should be provided along with clear and conspicuous notice that other fees may apply. In connection with innovative alternatives and solutions not considered, Travelers United and NCL commented that better display of information is needed but they do not argue for or against the display requirements proposed, supporting instead a requirement that all data be made available so market innovation can improve how the information is provided to consumers. In connection with how ancillary service fee information should be displayed, Open Allies urged the Department to allow carriers and ticket agents flexibility in how information is disclosed and expresses concern that too much information on a screen will make it hard for consumers to comprehend. Open Allies supported the proposal to permit the use of links or rollovers provided that a prominent notice adjacent to the advertised fare makes clear that ancillary service fees are disclosed via a link or rollover. Regarding an opt-out option, Open Allies stated it “doubts that most consumers would select the opt-out option,” but agreed providing that flexibility makes sense. Travel Tech supported a disclosure requirement that is the same for carriers and ticket agents. In connection with how the information is displayed, Travel Tech urged the Department to allow flexibility, including the use of links or roll-overs. It also urged the Department to extend that flexibility to mobile displays. Regarding opt-out, Travel Tech supported allowing the option of an opt-out that is not pre-selected and includes notice that ancillary service fees may apply. According to Amadeus, display of ancillary service fee information does not need to be provided on the first screen, it only needs to be provided before a booking decision is made.

Orbitz opposed proposed display requirements, stating that providing more information at the start of the booking process will overwhelm and confuse consumers. Orbitz also commented that any display standard adopted will quickly become obsolete or hinder innovation as technology changes. Orbitz also opposed imposing display requirements on mobile platforms as it would be difficult to implement and would impair the user experience. In connection with corporate travel sites, Orbitz opposed any display requirements, noting that display content is typically negotiated by the businesses involved. BCD also opposed display requirements on

corporate travel agent sites, arguing that if it is not able to transact ancillary service fees, it should not be required to display such fees. According to BCD, display requirements will impose additional compliance costs on BCD without providing an opportunity to recoup those costs by offering enhanced services and those costs will be passed on to BCD clients. CWT also argued that the Department should consider the differences between corporate and leisure travelers and stated that only those fees that can be booked in advance should have to be disclosed and they should also be transactable or the requirement undermines the distribution system. In connection with Section 399.85, CWT commented that it should not be changed.

A4A argued that the proposed disclosure requirement will cause sub-optimal displays, providing fee information that consumers may not be interested in and taking up screen space that could be used to provide additional flight options or other information. A4A noted that the fee information might vary for every segment of the itinerary and argues that the sheer volume of information displayed is likely to overwhelm rather than assist consumers. A4A also stated that the proposed display requirements are contrary to the current carrier trend to offer bundled pricing and differentiated seat products and limit carriers’ ability to provide such offerings. In addition, A4A stated that a requirement that airlines and ticket agents provide itinerary-specific display results that are not based on the identity of the customer will provide inaccurate information to consumers that may be eligible for ancillary service fee discounts based on factors such as frequent flyer membership or method of payment. Regarding searches for multiple passengers, A4A stated the search results displayed might not reflect the discounts available to some members of the group. A4A also noted that if more information must be displayed, search results will likely take longer to display due to increased processing time.

Regarding mobile applications, A4A commented that the problem of displacing information such as additional flight options on Web sites is particularly acute on mobile devices “because first-screen space is limited and valuable,” therefore the Department should not expand the display rules to mobile applications. Delta also opposed display requirements stating that it would have a negative impact on speed and performance of reservations systems and would be costly and time

consuming to implement. United opposed a requirement to display basic ancillary service fees at the first point in a search process where a fare is listed, stating that it will waste time for consumers because search results will be slowed by additional processing time for the information, then consumers must review additional information they are not interested in or click on links or pop-ups to see the information. Meanwhile, fewer flight options will be displayed on each screen. United also argued that search results may display inaccurate information depending on whether the consumer is conducting an anonymous search but is entitled to reduced fees, or a consumer is searching for multiple passengers, and similar concerns.

CCIA also commented that display of ancillary service fee information could result in screen clutter, which would be frustrating to users and that the proposed display requirements “are not adequately designed to work on a mobile platform” and may impede the consumer experience. TripAdvisor also commented that the Department should exempt mobile displays from display requirements or tailor requirements to a range of display sizes. Skyscanner commented that display of a large volume of information is unfeasible on a mobile device so, if implemented, displays would become less useful to users of mobile sites or mobile applications. Displays would be slower and include fewer options in a more cluttered presentation. USTOA opposed the proposed display requirements, stating that they will limit development of new business models, and questions how tour operators that sell bundled packages that may include airfare would comply with disclosure requirements.

DOT Response

Disclosure and Display Requirements

We recognize that the comments reflect legitimate concerns about the fact that if more information must be displayed, more screen space is consumed and search results will likely take longer to display due to increased processing time. However, we also note that many of the comments on this issue focused on the amount of screen space and increased processing time required for the display of seat assignment fees, which are generally dynamically priced and therefore would require additional processing time. As noted earlier, we have decided not to include disclosure of seat assignment fees in this proposal. Regarding baggage fees, although displaying such fees may also require some additional processing time and

will use some additional screen space, it is a cost that carriers have chosen to state separately from airfare and is information that consumers and consumer advocates have repeatedly stated that consumers need in order to determine the true cost of travel.

Nevertheless, we agree it is important to make the information as easy to provide and as useful to consumers as possible. Accordingly, we request comment on whether we should permit the baggage fee information to be displayed by links or roll-overs on all displays or on certain mobile displays.

Regarding the comment by A4A and others that the fee information might vary for every segment of the itinerary and the volume of information displayed is likely to overwhelm rather than assist consumers, this concern does not apply to baggage fees since carriers must apply the baggage allowances and fees that apply at the beginning of a passenger's itinerary throughout his or her entire itinerary pursuant to 14 CFR 399.87.⁶

Some comments expressed concern that the Department's proposed display requirements are contrary to the current carrier trend to offer bundled pricing and customized pricing. The Department's consumer protection rules in this area are intended to protect consumers from being surprised by unexpected fees and to allow them to discern the true cost of air transportation before making a purchase. To the extent carriers or ticket agents choose to offer bundled fares that include baggage in addition to, or instead of, offering fares that do not include baggage fees, they would not be prohibited from doing so. Under this proposal the display of such fares would only be required to make clear that there is no additional baggage fee associated with that fare if that is the case.

Regarding air-tour packages, we recognize that air transportation may be purchased in bulk by the seller of the tour package and the carrier may be unknown at the time of purchase which may make it difficult to provide specific baggage fee information. Accordingly, we have tentatively concluded not to require ticket agent sellers of air-tour packages to provide disclosure of specific baggage fees in certain circumstances. Specifically, if air transportation is arranged at a later date and specific airline and baggage fee

information is not known at the time of booking, ticket agents would not be required to display the baggage fee. However, when displaying such air-tour package prices, such ticket agent displays would be required to prominently disclose that baggage fees may apply if that is the case. In addition, ticket agents would be required to disclose in online displays and oral communications that baggage fees may apply and that those fees may be reduced or waived based on the passenger's frequent flyer status, method of payment or other consumer characteristic. This exception would not apply to air carriers or foreign air carriers selling air-tour packages. We request comment on whether this exception for certain air-tour packages adequately addresses concerns of air-tour package sellers. We also request comment on whether such an exception adequately protects consumers.

Opt-Out

Regarding the concern that consumers may not be interested in baggage fee information being displayed and it may take up screen space that could be used to provide additional flight options or other information, we recognize there may be reasons that consumers wish to opt-out of display of baggage fees, for example if the consumer will be traveling without checked baggage. We agree that it is reasonable to provide entities the flexibility to provide such an option. Most of the comments on this issue agreed that it was reasonable to provide an opt-out option. In addition, if an entity anticipates that there will be a significant impact on the speed of search results or particular display options the entity provides, the option to provide an opt-out for baggage fees would address those concerns by providing carriers and ticket agents the option to provide consumers what may be a faster or more streamlined display of search results, if consumers choose such displays. We anticipate that basic baggage fee information will be useful to many, if not most, consumers, and that they will often choose displays that include such information. However, by providing an opt-out option for baggage fee information, entities that display flight information would still have the flexibility to provide search results without that information if the consumer chooses a display option that does not include it. Accordingly, our proposal would permit carriers and ticket agents to provide various opt-out options. Opt-out options could include the choice to opt-out of seeing all baggage fee information that would otherwise be required to be displayed

(first and second checked bag and carry-on bag) or to opt-out of seeing some of those fees. For example, a consumer might choose to see fees for carry-on and first checked bag, but not second checked bag. Another option might be that a consumer could choose to see only carry-on bag. A third option could be to see first and second checked bag fees but not the carry-on bag fee. The opt-out options that may be provided would be up to the carrier or ticket agent and no opt-out would be required under the proposal.

We seek comment on whether providing the flexibility to furnish a variety of opt-out options addresses some of the concerns of carriers and ticket agents regarding increased processing times and screen clutter. We also seek comment on whether providing opt-out options would adequately protect consumers.

Display of Search Results on Mobile Displays

In connection with applicability to mobile applications (apps) and mobile Web sites, several commenters state that the Department should consider more limited requirements for mobile outlets because implementation of new rules in the mobile environment is technically more difficult and detailed disclosures may be difficult to incorporate and display, particularly considering the screen size of some mobile devices. We recognize some of the inherent limitations of displays designed for mobile outlets. Comments suggesting more limited disclosure requirements for mobile outlets focused on the complexity of potential disclosure requirements. The limitation of disclosure requirements to certain baggage fees will reduce the amount of screen space used for additional disclosures.

In addition, some commenters stated concern that there would be technical difficulty in implementing increased disclosure requirements and increased processing time; however, we note that similar concerns apply to non-mobile internet displays. However, we have determined that the consumer benefit to having basic ancillary service fee information outweighs the potentially increased processing times. As some commenters noted, consumers in increasing numbers are using apps to book travel. Therefore, we believe it is important that the same consumer protections apply to apps as to other outlets directed to consumers. Accordingly, we have tentatively concluded that the disclosure requirements should be the same on apps as on Web sites or mobile Web

⁶ We note that carriers always have the option of waiving a baggage fee or offering a lower baggage fee than advertised for any segment of an itinerary. As the Department's Office of Aviation Enforcement and Proceedings has stated regarding Section 399.87, it does not prevent a carrier from charging a lower fee as a courtesy. [Cite is FAQ 50]

sites. We request comment on whether allowing disclosure via links or pop-ups would simplify the disclosure process and reduce technical issues and speed processing times for mobile outlets.

We also note that the FTC has provided guidance regarding internet disclosures (See .com Disclosures: How to Make Effective Disclosures in Digital Advertising, available at <https://www.ftc.gov/system/files/documents/plain-language/bus41-dot-com-disclosures-information-about-online-advertising.pdf>). The FTC's guidance notes that using hyperlinks, rollovers, or pop-ups for price and certain other disclosures may be less effective. Consistent with DOT's position in this SNPRM, the guide states that "consumers should not have to click on hyperlinks to understand the full amount they will pay." The guide therefore suggests that fee or cost information should be disclosed adjacent to the price claim, unless the information is very complex. Similarly, the guide notes that rollovers or mouseovers "may not work on mobile devices that have no cursor to hover over a link." Finally, the guide cautions that pop-ups may be blocked by software or otherwise ignored by consumers.

Accordingly, we request that commenters provide any consumer research or data that indicates whether hyperlinked or other disclosures not adjacent to the fare on a mobile site would or would not be effective.

Implementation Period

In connection with the time to implement rule, the Department is tentatively of the view that a six month implementation period to display consumer-specific fee information for a first checked bag, a second checked bag and a carry-on bag to consumers whenever fare and schedule information is provided would be appropriate and should provide enough time for both carriers and ticket agents to update Web sites and apps. We recognize that in order to make technical changes and accommodate new information, individual ticket agents will need to know in detail how the information will be distributed from carriers to the ticket agent and have the information from carriers well before the display deadline. We anticipate carriers will work in good faith with ticket agents, including GDSs and other ticket agent intermediaries, to ensure that the distribution method and details are worked out well in advance of the display deadline. In this regard, we have tentatively concluded that carriers should ensure ticket agents have the

information no later than three months before the display deadline. We note many of the comments state that a lengthy implementation period will be necessary to implement any disclosure requirement and some suggested several years. However, many of the reasons presented for the multi-year implementation period had to do with the complexity of disclosing multiple dynamic fees. Since the Department is limiting the requirement to disclosure of one carry-on item and a first and second checked bag, the Department believes a six month implementation period is appropriate.

We request comment on whether this proposed implementation period is too lengthy or too short. If the proposed implementation period is either too lengthy or too short, how long of an implementation period would be appropriate?

H. Revised Baggage Fee Disclosure Requirements and 14 CFR 399.85(b) and (c)

This proposed rule, if adopted, would require carriers and ticket agents to provide customer-specific baggage fee information for one carry-on item and a first and second checked bag if they provide fare information. We are tentatively of the view that there would no longer be a need for a requirement that airlines and ticket agents provide a general statement on the first screen on which the agent or carrier offers a fare quotation for a specific itinerary that additional airline fees for baggage may. We are proposing in this SNPRM to remove the requirement under 14 CFR 399.85(b) that displays of fare quotations must include a statement that fees for baggage may apply and where consumers can see these baggage fees. The requirement to provide the more general statement that baggage fees may apply would be limited to certain ticket agent displays related to air tour packages that are unable to provide customer-specific baggage fee information.

In addition to eliminating rule text under 14 CFR 399.85(b), we are considering eliminating the requirement in 14 CFR 399.85(c) regarding disclosure of bag fee information on e-ticket confirmations as it may be of limited use.

We seek comment on whether eliminating 14 CFR 399.85(b) would be appropriate if the proposed requirement to display customer-specific baggage fee information is adopted. We also seek comment on whether we should consider keeping the existing requirement 14 CFR 399.85(b) with revisions to reflect the proposed

changes. If the 14 CFR 399.85(b) disclosure requirement should be kept but modified, what changes would be appropriate?

Regarding 14 CFR 399.85(c), we request comment on whether the proposed revision would be appropriate and adequately inform consumers of the applicable baggage fees if the proposed requirement to display more specific baggage fee information is adopted. If not, what changes or additions would better ensure that consumers are provided with the specific baggage fee information that will be required if the proposal is adopted?

Regulatory Analyses and Notices

A. Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

This action has been determined to be significant under Executive Order 12866 and the Department of Transportation's Regulatory Policies and Procedures. It has been reviewed by the Office of Management and Budget under that Executive Order. This section contains a summary of costs and benefits associated with this SNPRM. More detail on the economic impact of this proposed rule can be found in the Regulatory Impact Analysis (RIA), which is available in the docket. Due to the lack of key pieces of data, the Department was unable to quantify the costs and the benefits of the rule proposed in this SNPRM.

Under this SNPRM, the Department is proposing that all ticket agents and airlines that provide fare and schedule information to consumers while doing business in the United States be required to provide fee information to consumers for first and second checked bag, and one carry-on item adjacent to the fare. The information would include the necessary fee information to allow the display of these fees as either the standard fees charged by the carriers, or, at the consumer's choice, as the customer-specific charge if the consumer elects to provide his or her customer category information including, but not limited to, military/veteran status, frequently flier category, and method of payment. Airlines can potentially establish a large number of customer-specific factors that impact the fee that a consumer would pay for a carry-on and first and second checked bag. We solicit comment on whether the Department should limit the categories that have to be displayed on a ticket agent's Web site to the most commonly used categories. If the Department adopts such a limitation, how should

the most commonly used categories be determined?

Carriers would be required to transmit this baggage fee information to all ticket agents to which they provide fare and schedule information, including GDSs and other intermediaries in the air transportation marketplace. Ticket agents and carriers would be required to be compliant with the rule within six months of its final publication date.

Ticket agents would be allowed to design the presentation of these fees as best suits them as long as they are available at the time when fares are first presented. This fee information must be customer-specific, *i.e.* specific to the individual and his/her any unique circumstances, unless the passenger opts out.

Costs of the SNPRM

1. Direct Costs to Carriers

Carriers would incur costs related to preparing and transmitting ancillary service fee information to OTAs and GDSs. These costs would include the one-time set up costs to develop internal systems/processes to distribute the baggage fee information. These set-up costs would include upfront planning time to develop procedures to collect and distribute the necessary data, as well as any potential IT and software development costs to transmit data which is not already being transmitted to GDSs and ticket agents via ATPCO or NDC.

Carriers would also incur some incremental ongoing costs to manage and transmit data relating to any changes in baggage fees defined as basic ancillary service fees by this rulemaking. Carriers might also incur some additional costs for system updates to any new IT systems or programs incorporated for the purposes of complying with this rule. For this analysis, only the ongoing costs which would not have occurred except for the rulemaking are considered.

Carriers can present the information in a format of their choosing, including allowing consumers to opt out of viewing the information, or choosing only some of it, if that is their preference. The Department is requesting further comments on this specific issue with this SNPRM.

Multiple commenters to the 2014 NPRM provided information on likely costs to carriers of the proposed requirement for basic ancillary service fee information, though most of these costs comments were directed at the possible inclusions of requiring transactability for these fees as well as their display (*i.e.*, that consumers would

be able to pay for these ancillary services on the OTAs and GDSs), an alternative which was considered by the Department but not adopted for this SNPRM.

One mainline carrier (Delta) commented that the proposed rule as described in the NPRM would require the redesign of carrier distribution systems to provide ancillary fees at the first point of search. Delta estimates it would take 12 months and cost \$1 million redesign its systems.

An economic consultant (who submitted comments with the carrier trade association, A4A) argued that the costs to carriers to comply with the requirement for greater transparency as proposed in the NPRM would cost more than \$3 million in the first year, and \$7.2 million over 10 years. This commenter also argued that carriers would incur significant additional ongoing costs for managing estimates of the process of “development and debugging programs and procedures that the carriers will have to create to report ancillary fee information.” The commenter noted that carriers typically employ one full time employee to monitor and debug the baggage fee information reporting to ATPCO. He also noted that carriers spend approximately \$1 million to “establish each link to a GDS”.

ATPCO also commented that the costs to carriers of compliance with the requirement as proposed in the NPRM could be quite high, noting that ATPCO’s efforts alone to comply with the simpler baggage fee information requirements of the 2011 consumer rule cost over \$1 million.

The Department believes that the estimates from commenters to the 2014 NPRM overstate the likely costs to carriers of this SNPRM for several reasons. While reviewing these comments, the Department noted that much of the comments were directed to the challenges and additional costs of transferring information for advance seat assignment, which is dynamic information, changing frequently as carriers manage their loads. The cost for the transmittal of real-time advance seat assignment information to ticket agents would thus be significantly more than the transmittal of baggage fee information, which changes much less frequently. Additionally, the Department notes that several carriers are already in agreement to start providing that information to GDSs; and some carriers are moving to IATA’s NDC which will allow for easier customization of flight and pricing options to consumers and at a lower cost to carriers (once they have

incorporated NDC into their systems). And while the Department agrees that there will be ongoing costs to maintain and transmit data required by the rule, the Department does not believe that the SNPRM, if adopted as proposed, would generate the need for an additional full-time staff equivalent for each carrier, on average, to monitor and debug ancillary fee data shared with travel agents, given the current pace of technological improvements in all reporting systems, the pace at which carriers are adopting NDC, and the staff resources already committed to monitoring data transmittals.

Given the existing questions and comments to the 2014 NPRM, the Department does not believe that it has enough information to confidently quantify the total cost to carriers of complying with the proposed rule. The Department believes that the costs of compliance are likely to be less than \$1 million per carrier, but is nevertheless seeking additional information on the likely costs to carriers of the requirement as specified in this SNPRM.

2. Direct Costs to Ticket Agents

Ticket agents would incur costs related to accepting ancillary service fee information from GDSs and carriers and posting that information on their Web site engines, and of communicating the additional fee information to consumers during reservation phone calls. The most significant cost to ticket agents is likely to be the one-time cost to reprogram their Web site search engines to provide the necessary baggage information.

Larger ticket agents and OTAs are likely to have in-house capability to reprogram their Web sites accordingly, but small tickets agents probably will not. As the US Tour Operators Association (USTOA) noted in its comment to the 2014 NPRM, many tour operators are unlikely to have in-house web programmers and would likely need to hire consultants and contractors to bring their Web sites into compliance.

Ticket agents that market and sell online to consumers already have systems in place to receive flight and cost information from carriers and GDSs, but it is unclear whether these systems have the capacity to receive and process all the necessary information to comply with the proposed rule. Several commenters to the NPRM argued that the RIA for the 2014 NPRM underestimates the costs to ticket agents to update their systems to comply with the rule. The Department is seeking comments on this specific issue with this SNPRM.

At least three commenters noted that there could be significant ongoing compliance costs for ticket agents and tour operators to provide baggage fee information as per the proposed requirement, primarily in terms of longer times during reservation phone calls. The Department acknowledges that there may be additional time at the beginning of a call as ticket agents discuss baggage fees earlier in the reservation process but notes that such earlier discussion of baggage fees may also limit the likelihood of increased call time at the end of the call as some consumers are surprised by additional baggage fees and may revisit their flight searches.

Ticket agents would also incur some ongoing costs to refresh the required baggage fee information when it changes. The Department does not expect that these costs would be significant, since the systems to transmit the data are already in place and the programming to display the required baggage fee has already occurred. In addition, these fees need only be updated when changed.

We believe that the cost impacts of the proposal in this SNPRM would differ significantly from the costs which would have been incurred under the 2014 NPRM, since the current proposed rule no longer includes advance seat assignment in the basic ancillary service fees to be covered. Thus, the Department is seeking additional information on the potential costs of this SNPRM on ticket agents.

3. Other Cost Issues—Additional Costs to GDSs and/or ATPCO

It is unclear if GDSs would incur additional costs to process the information required by this SNPRM. For this analysis, the relevant incremental costs to the GDSs would be those costs of efforts/improvements which they would otherwise not have incurred, but for this rulemaking. Costs for efforts of GDSs to collect and transmit the needed baggage fee information to ticket agents that were already planned or which would occur in the future for reasons other than this rule (such as responding to market forces) are not considered to be due to the rule. According to some of the comments received, GDSs are already improving the capacity of their systems to manage more ancillary service fee information.

Comments to 2014 NPRM regarding costs to GDSs to comply with it were somewhat inconsistent. At least two comments (one for from a carrier and another carrier trade association supported study) claimed that GDSs

would incur significant costs. Yet one GDS (Sabre) commented that it already has the capability to comply with the requirements proposed in the 2014 NPRM (although it noted that ticket agents do not already have the needed systems in place). The Department thus expects that this SNPRM, if adopted as proposed, would not have significant costs to GDSs.

ATPCO could also potentially incur additional costs to process the required information, due solely to this rulemaking, although this is also very uncertain. In its comments to the NPRM, ATPCO stated that it already has the capacity to meet the proposed 2014 NPRM requirements. The Department also expects that the SNPRM would not entail significant costs for ATPCO.

Costs to Consumers of Additional Time Waiting for Search Results

Several commenters to the 2014 NPRM, including A4A, Delta, and IATA, argued that the Department's analysis should take into account potential costs to consumers from additional time spent waiting for the research results to load, given additional processing time required to display more ancillary fees. These commenters specifically cited the likely increased time needed to access real time information for up-to-date seat assignment fee information. A study prepared for A4A by Dr. Daniel L. Rubinfeld estimated the additional wait times to consumers would cost approximately \$805 million per year, based on the assumption that the proposed rule would add approximately 20–40 seconds to each itinerary search (drawn from a survey by A4A of its members). Elsewhere in its submittal, A4A estimates that the additional processing time for the proposed ancillary service fee information would cost approximately \$139 million a year from an estimated loss of 5.5 million hours per year for online ticket agents alone.

The Department notes that most of the costs relating to additional processing times and added wait times for consumers raised by commenters focus on the additional time and cost for transmitting advance seat assignment information, which, as noted above, is dynamic and thus more complicated and expensive to keep up-to-date. Since the SNPRM does not include advance seat assignment, the needed time to process and display the required fee information should be much less than what was estimated by commenters in response to the 2014 NPRM.

Additionally, to provide more flexibility to ticket agents, this SNPRM

would permit ticket agents to provide consumers the opportunity to opt-out of receiving the baggage fee information for carry-on and first and second checked baggage, if so desired. If ticket agents do choose to incorporate such an opt-out feature, additional time for processing and displaying information on baggage fees which the consumer does not want to see should be significantly reduced. The cost of waiting for baggage fee information, which the consumer does want to see, should be off-set by the value to the consumer of getting that information (hence the choice made to receive it). The Department acknowledges that some portion of consumers may misjudge/underestimate the amount of time it would take to receive all the baggage information, especially in the beginning period after implementation and that, therefore, there will be some additional wait time and costs to consumers but that this cost will decrease over time.

Since the SNPRM does not include seat assignment fees in the basic ancillary fee data that must be communicated, the Department believes that there would not be significant additional wait time for consumers. Nevertheless, the Department is seeking additional comment on this issue.

Benefits of the SNPRM

1. Time Saving Benefits to Consumers

Both consumers who purchase directly from carrier Web sites and those who use travel agents would benefit. A significant number of leisure travelers book online via online travel agencies, use metasearch engines, or even use their businesses travel management company. But since OTA Web sites do not currently have customer category-specific bag fees, these consumers must check multiple airline Web sites in order to get an accurate estimate of the flight costs including the fees for basic ancillary services related to carry-on and first and second checked bags. While information on baggage fees is already required to be available from travel agents, it is often available through links, which requires significant time and effort from the consumer to determine the actual fee that must be paid. The consumer must click the link or links to get the baggage information for the itinerary being considered and recalculate their cost. Not all consumers purchasing tickets via an OTA would experience a time savings, as not all consumers are concerned with baggage fees. For some consumers the additional cost for baggage will not factor into their choice of a flight, and as such these consumers

wouldn't search for baggage fees and thus would not benefit from the requirements proposed in this SNPRM. Additionally, in some markets there is only one (or perhaps two) carriers that offer flights at the preferred time or at a fare which the consumer would consider; these consumers also would not benefit. But the Department believes that many consumers seek out at least some baggage information, which would result in the time savings for those individuals.

Meanwhile, a little more than a fourth of airline passengers purchase tickets directly from carrier Web sites (PhoCusWright estimates this figure at 23%).⁷ While these consumers have the most direct access to ancillary service fees, many carrier Web sites also do not include basic ancillary service fees when first quoting an itinerary fare. Thus, some consumers must access multiple Web pages to reach the information they need to calculate a cost to them which includes posted fare plus the fees for carry-on and first and second checked bags. Since the SNPRM would require that basic ancillary service fee information be consolidated in one place on carrier fare displays, some portion of consumers purchasing tickets on carrier Web sites would spend less time searching for the desired fee information.

Not all consumers purchasing from carrier Web sites would benefit. Consumers who purchase from a carrier Web site are more likely as a group to be aware of the carrier's baggage fees and policies. Many of these consumers are going directly to the carrier Web site because that carrier is one of the few or the only one to offer flights at the desired time and to the desired destination, or because the consumer is a member of the carrier's affinity program. Nevertheless, some portion of those consumers who purchase tickets on a carrier Web site do check to see what the baggage fees would be for their desired itinerary, and these consumers would save time under this SNPRM.

Together, the time savings may be quite significant. The Department does not yet have the information to confidently estimate the value of this benefit so it is seeking additional comment on it.

2. Better Informed Consumer Purchasing Decisions

The increased transparency in ancillary service fee information would also lead to some portion of consumers making more informed purchasing

choices: (1) Those who learn of the baggage fees for a flight they intend to purchase but do so near the end of the purchasing process, and (2) those who remain unaware of the baggage fee information until after they make a purchase. Both of these consumer groups may end up making purchasing decisions they otherwise would not have made had they been aware of the associated baggage fees when first reviewing search results.

Research has shown that when consumers first see a price which is lower than the final price they must pay (whether due to delayed display of taxes, fees, shipping and handling, etc.) they often end up paying more than if the first price they see is the final, total price (including taxes, fees, and/or shipping and handling). Studies and experiments have demonstrated that partitioned pricing (the separating of a price into its components) and the timing for when different pieces of pricing information (such as taxes) are revealed in a purchasing situation can lead to increases in consumer demand.⁸

If revealing full prices later in the purchasing process leads to more purchases than if the full price had been seen immediately, (at least some) consumers are purchasing at a price higher than they otherwise would have. These "sub-optimal" choices lead to what economists call a "dead-weight loss."

In other research conducted in market situations in which one group of consumers knows more about products and/or prices than others, some economists have proposed a "tourists and natives" framework, in which consumers are divided into two groups—those with access to more information about lower prices/better quality (the natives) and those with very limited information who will often pay more (the tourists). (Some researchers have called these two groups "savvy" and "unsavvy" travelers.) This framework has two price-equilibriums; the "tourist" one is higher than the one

for "natives." With respect to this SNPRM, one could consider the consumers who are well informed regarding fees for ancillary services (*i.e.* aware of itinerary-specific baggage fees) in contrast to other travelers (perhaps those who rarely travel) who are not aware of variance in carry-on and checked baggage fees. The result is that the latter group would end up, on average, paying more.

While both of these theoretical constructs are useful in understanding how and why some consumers may be making sub-optimal air travel purchasing decisions, the Department does not have enough information to quantify or monetize this benefit.

3. Benefits to Businesses Employees That Travel

Many businesses are also concerned with the ancillary fees associated with baggage. Travel can be a significant expense for many companies and ancillary service fees can substantially increase trip costs.

Many business travelers book flights via travel management companies that seek the best flight at the best price for the traveler, given his or her parameters. But much of the information needed to ensure that each traveler gets the best full price taking into account base fare, mileage club memberships, specific credit cards used and any other potential discounts are not often readily available. Travel managers have complained that not all baggage fee information needed to ensure that business travel is booked according to company policy is readily accessible and readily incorporated into internal reservation tracking or accounting programs. The information must be manually entered, often based on receipts or information provided by the travelers themselves. Thus, many businesses either pay more than they needed to for a particular flight or must have employees spend time seeking out the appropriate fee information in order to make the best choice. The increased effort results in higher company travel costs.

These costs associated with searching for baggage fee information have been identified repeatedly to the Department by travel management company representatives and raised at meetings of the Advisory Committee for Aviation Consumer Protection. In addition, several commenters, including trade associations, a GDS and at least one advocacy group, noted that benefits to business travelers of this requirement could be significant.

While there is much interest in the industry on the impact of unbundling

⁷ PhoCusWright (2011) "U.S. Online Travel Overview."

⁸ Deborah Shenck, "Exploiting the Salience Biases in Designing Taxes," (*New York University Law and Economics Working Papers*, Paper 233, 2010) has an informative and extensive review of past work in this area. See also Morwitz, Vicki, Greenleaf, Eric, Shalev, Edith and Johnson, Eric J., *The Price Does Not Include Additional Taxes, Fees, and Surcharges: A Review of Research on Partitioned Pricing* (February 26, 2009). Available at SSRN: <http://ssrn.com/abstract=1350004>. Note, though that some studies have found that partitioned pricing can also lead to negative brand recognition and may hurt sales in the future, if the fees are perceived to be excessive and within the seller's ability to control. This differs somewhat from the situation here, since the separate portions of the price are taxes imposed by state, local and federal governments (as opposed to shipping fees, etc.).

and ancillary service fees on the costs of business travel, the Department did not find adequate data on this impact to estimate the benefits of this requirement for these business travelers, but notes that they may be significant for some entities.

4. Benefits to Ticket Agents

While there is concern about the added costs of this provision to ticket agents in terms of additional programming expenditures and staff time to communicate the added baggage fee information, there is also the possibility that ticket agents may experience some benefits of the SNPRM. At least one commenter raised the point that ticket agents would be able to access ancillary service fee information more quickly in response to consumer requests, and could conclude some transactions with consumers more quickly. The Department agrees that ticket agents may benefit from the rule in this manner but is unable to estimate by how much.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to review regulations to assess their impact on small entities unless the agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities. The rule proposed in this SNPRM would have some impact on a significant number of small entities, as discussed in the Initial Regulatory Flexibility Analysis.

For purposes of rules promulgated by the Department regarding aviation economic and consumer matters, an airline is a small entity for purposes of the Regulatory Flexibility Act if it provides air transportation only with aircraft having 60 or fewer seats and no more than 18,000 pounds payload capacity.⁹ The Small Business Administration (SBA) size standard for small business for both travel agents and tour operators is \$20.5 million in average annual receipts (SBA does not have a size standard for ticket agents as defined by the Department; travel agents and tour operators are the most applicable categories for which such data was found).

A significant number of small entities would be impacted by this SNPRM. Due to the relative lack of key pieces of data, the Department was unable to quantify the costs of the proposed rule to small (or large) entities, but notes that some

small entities may incur substantial costs. The primary costs of the rule arise from programming, data management and other related costs to carriers and ticket agents to transmit or display the required baggage information. The Department is seeking additional information on the potential costs and benefits of the requirements proposed in the SNPRM.

C. Executive Order 13132 (Federalism)

This SNPRM has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 ("Federalism"). The notice does not contain any provision that (1) has substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government; (2) imposes substantial direct compliance costs on State and local governments; or (3) preempts State law. States are already preempted from regulating in this area by the Airline Deregulation Act, 49 U.S.C. 41713. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

D. Executive Order 13084

This SNPRM has been analyzed in accordance with the principles and criteria contained in Executive Order 13084 ("Consultation and Coordination with Indian Tribal Governments"). The SNPRM would not significantly or uniquely affect the communities of the Indian tribal governments or impose substantial direct compliance costs on them, the funding and consultation requirements of Executive Order 13084 do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) requires that the Department consider the impact of paperwork and other information collection burdens imposed on the public and, under the provisions of PRA section 3507(d), obtain approval from the Office of Management and Budget (OMB) for each collection of information it conducts, sponsors, or requires through regulations. DOT has determined that the proposals included in this SNPRM would impose new information collection requirements on the affected entities. Accordingly, we are seeking comment on the impact of the requirements proposed in this SNPRM.

The first collection of information proposed here is a requirement that air carriers and foreign air carriers provide useable, current, and accurate fee

information for a first checked bag, a second checked bag, and one carry-on bag to all ticket agents that receive and distribute the air carrier's or foreign carrier's fare and schedule information. The second information collection is a requirement that air carriers, foreign air carriers, and ticket agents that provide an air carrier's or foreign carrier's fare and schedule information to consumers in the United States receive the information from carriers and disclose the air carrier's or foreign air carrier's fees for a first checked bag, a second checked bag, and one carry-on bag.

For each of these information collections, the title, a description of the respondents, and an estimate of the annual recordkeeping and periodic reporting burden are set forth below:

1. Requirement that air carriers and foreign air carriers provide certain baggage fee information to all ticket agents that receive and distribute the carrier's fare and schedule information.

Respondents: Air carriers and foreign air carriers that provide fare and schedule information to ticket agents and charge baggage fees for a carry-on bag, first checked bag, or second checked bag. We estimate that approximately 206 carriers will be impacted by this requirement.

Estimated Annual Burden on Respondents: Approximately 8 hours per respondent. Note that 8 hours is the basis used for computing the costs of providing baggage fee information, but since airlines already share this information with each other to facilitate code-share and interline ticketing, it likely overestimates the actual amount of additional time that most carriers will have to spend to meet the requirement.

Estimated Total Annual Burden: 1,648 hours for all respondents.

Frequency: Once information is provided, new or additional information only needs to be provided when baggage fee information changes; varies by airline but for most carriers is infrequent and will likely be less than annually.

2. Requirement that air carriers, foreign air carriers, and ticket agents that provide carrier fare and schedule information to consumers in the United States disclose carrier's fees for a first checked bag, a second checked bag, and one carry-on bag.

Respondents: Air carriers, foreign air carriers, and ticket agents that provide carrier fare and schedule information to consumers in the United States. We estimate that as many as 206 air carriers and foreign air carriers and as many as 600 ticket agents may be impacted by this requirement.

Our estimate is based on the following information and assumptions: Ticket

⁹ See 14 CFR Chapter 11. Note that the Small Business Administration definition of small carriers is not used.

agents includes online travel agencies (OTAs), brick-and-mortar travel agencies, corporate travel agencies, and tour operators that market airline tickets. As described in the Regulatory Impact Analysis accompanying this SNPRM, there may be approximately 9,500 travel agencies and over 2,500 tour operators in the United States, although not all of those entities market air transportation online to consumers in the United States. In addition, most ticket agents rely on GDSs to create online fare and schedule displays. GDSs and entities that create or develop and maintain their own online fare and schedule displays, such as many of the impacted airlines and the largest travel agents, will incur some planning, development, and programming costs to reprogram their systems to provide online displays of fare and schedule information that includes baggage fee information on their Web sites. Therefore we estimate that about five percent of United States ticket agents, including GDSs and large travel agencies, or as many as 600 ticket agents, will be impacted by this requirement. Many smaller carriers also rely on GDSs to create online fare and schedule displays so our estimate of 206 impacted carriers may be overstated.

Estimated Annual Burden on Respondents: Approximately 80 hours per respondent. Our estimate is based on the following information and assumptions: The primary costs to respondents for the disclosure requirement would arise from programming, data management, Web site modification and other related costs to carriers and ticket agents to display the required baggage information. Revising Web site displays in this manner would likely be similar to the revisions that carriers and ticket agents needed to make to their Web sites to comply with the requirement to include all taxes and fees in fare displays in connection with the Enhanced Airline Passenger Protections II rulemaking. Our estimate of those costs was 80 hours per respondent as discussed in the Regulatory Impact Analysis prepared in connection with the Enhanced Airline Passenger Protections II rulemaking (2011) (see page 59, <https://www.regulations.gov/document?D=DOT-OST-2010-0140-2046>).

Estimated Total Annual Burden: Approximately 64,480 hours for all respondents (based on an assumption of 16,480 hours for carriers and 48,000 hours for ticket agents).

Frequency: Once information is incorporated into Web site displays, the

displays would not need to be revised. It would likely be a one-time cost.

F. Unfunded Mandates Reform Act

The Department has determined that the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply to this SNPRM.

G. National Environmental Policy Act

The Department has analyzed the environmental impacts of this SNPRM pursuant to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) and has determined that it is categorically excluded pursuant to DOT Order 5610.1C, Procedures for Considering Environmental Impacts (44 FR 56420, Oct. 1, 1979). Categorical exclusions are actions identified in an agency's NEPA implementing procedures that do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). See 40 CFR 1508.4. In analyzing the applicability of a categorical exclusion, the agency must also consider whether extraordinary circumstances are present that would warrant the preparation of an EA or EIS. *Id.* Paragraph 3.c.6.i of DOT Order 5610.1C categorically excludes “[a]ctions relating to consumer protection, including regulations.” The purpose of this rulemaking is to enhance protections for air travelers and to improve the air travel environment. The Department does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

Issued this 9th day of January 2017 in Washington, DC.

Anthony R. Foxx,

Secretary of Transportation.

List of Subjects

14 CFR Part 399

Administrative practice and procedure, Air carriers, Air rates and fares, Air taxis, Consumer protection, and Small businesses.

PART 399—[AMENDED]

■ 1. The authority citation for part 399 is revised to read as follows:

Authority: 49 U.S.C. 40101 *et seq.*

■ 2. Section 399.85 is amended by removing paragraph (b).

§ 399.85 Notice of baggage fees and other fees.

* * * * *

(b) Removed.

* * * * *

■ 3. A new section 399.90 is added to read as follows:

§ 399.90 Transparency in airline pricing, including ancillary service fees.

(a) The purpose of this section is to ensure that air carriers, foreign air carriers and ticket agents doing business in the United States clearly disclose to consumers at all points of sale the fees for a first checked bag, a second checked bag, and one carry-on bag wherever fare and schedule information is provided to consumers that may be purchasing or considering purchasing air transportation. Nothing in this section should be read to require that these ancillary services must be transactable (e.g., purchasable online or at other points of sale).

(b) Each air carrier and foreign air carrier shall provide useable, current, and accurate information for fees for a first checked bag, a second checked bag, and one carry-on bag to all ticket agents that receive and distribute the air carrier's or foreign carrier's fare and schedule information. The information should be sufficient to allow ticket agents to express fees as itinerary-specific or customer-specific charges. “Customer-specific” refers to variations in fees that depend on, for example, the passenger type (e.g., military), frequent flyer status, method of payment, geography, travel dates, cabin (e.g., first class, economy), ticketed fare (e.g., full fare ticket—Y class), etc.

(c) Each air carrier, foreign air carrier or ticket agent that provides an air carrier's or foreign carrier's fare and schedule information to consumers in the United States must disclose the air carrier's or foreign air carrier's fees for a first checked bag, a second checked bag, and one carry-on bag.

(i) The fee information disclosed to a consumer for these ancillary services must be expressed as customer-specific charges as provided in subpart (b) if the consumer elects to provide his or her customer category information to the carrier or ticket agent, such as frequent flyer type, payment method, or military status.

(ii) If the consumer conducting a search does not opt out of receiving baggage fee information but elects not to provide his or her customer category information to the carrier or ticket agent, and conducts an “anonymous” search, the fee information disclosed to consumers for these ancillary services must be expressed as itinerary-specific charges. “Itinerary-specific” refers to variations in fees that depend on, for example, geography, travel dates, cabin (e.g., first class, economy), and ticketed fare class (e.g., full fare ticket—Y class).

(iii) This provision does not apply to air-tour packages advertised or sold online by ticket agents if the air transportation component is not finalized and the carrier providing air transportation is not known at the time of booking. However, the agent must clearly and prominently disclose on the first screen in which the agent or carrier offers a fare quotation for a specific itinerary selected by a consumer that additional airline fees for baggage may apply and where consumers can see these baggage fees unless no baggage fees will apply. An agent may refer consumers to carrier Web sites where specific baggage fee information may be obtained or to its own site if it displays carriers' baggage fees. In online displays and oral communications, prior to purchase, each ticket agent must disclose that baggage fees may apply if that is the case and that those fees may be reduced or waived based on the passenger's frequent flyer status, method of payment or other consumer characteristic.

(d) If a U.S. or foreign air carrier or ticket agent has a Web site marketed to U.S. consumers where it advertises or sells air transportation, the carrier and ticket agent must disclose the fees for a

first checked bag, a second checked bag and one carry-on bag as specified in paragraph (c) at the first point in a search process where a fare is listed in connection with a specific flight itinerary, adjacent to the fare. When providing customer-specific fee information, if more than one baggage fee may be responsive to the search parameters, *e.g.*, fee for a particular frequent flyer status and fee for a particular method of payment, the lowest cost option must be identified and displayed. Carriers and ticket agents may permit a consumer to opt out of being provided search results with the fees for a first checked bag, a second checked bag or one carry-on bag, or any single baggage fee (*e.g.*, second checked bag) or any combination of baggage fees (*e.g.*, carry-on and second checked bag) but the opt-out option must not be pre-selected and must make clear which fee or fees will not be displayed.

(e) In any oral communication with a prospective consumer and in any telephone calls placed from the United States, an air carrier, foreign air carrier or ticket agent must inform a consumer, upon request, of the fees for a first checked bag, a second checked bag and

one carry-on bag as specified in paragraph (c).

(f) Ticket agents with an existing contractual agreement at the time this rule becomes effective with an air carrier or foreign air carrier to act as an intermediary for the distribution of that carrier's fare and schedule information to other ticket agents shall not charge separate or additional fees for the distribution of the ancillary service fee information described in paragraph (b). Nothing in this paragraph should be read as invalidating any provision in an existing contract among these parties with respect to compensation.

(g) It is an unfair and deceptive practice in violation of 49 U.S.C. 41712 for an air carrier or foreign air carrier to fail to provide the fees for a first checked bag, a second checked bag and one carry-on bag as described in paragraph (b) to those ticket agents to which the carrier provides its fare and schedule information or for a U.S. carrier, foreign carrier, or ticket agent to fail to provide the fees for a first checked bag, a second checked bag and one carry-on bag to consumers as described in paragraph (c) and (d).

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Part XVII

Environmental Protection Agency

40 CFR Part 702

Procedures for Chemical Risk Evaluation Under the Amended Toxic
Substances Control Act; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 702

[EPA-HQ-OPPT-2016-0654; FRL-9957-75]

RIN 2070-AK20

Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: As required under section 6(b)(4) of the Toxic Substances Control Act (TSCA), EPA is proposing to establish a process for conducting risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use. Risk evaluation is the second step, after Prioritization, in a new process of existing chemical substance review and management established under recent amendments to TSCA. This proposed rule identifies the steps of a risk evaluation process including scope, hazard assessment, exposure assessment, risk characterization, and finally a risk determination. EPA is proposing that this process be used for the first ten chemical substances to be evaluated from the 2014 update of the TSCA Work Plan for Chemical Assessments, chemical substances designated as High-Priority Substances during the prioritization process, and those chemical substances for which EPA has initiated a risk evaluation in response to manufacturer requests. The proposed rule also includes the required "form and criteria" applicable to such manufacturer requests.

DATES: Comments must be received on or before March 20, 2017.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2016-0654, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- **Mail:** Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental

Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

- **Hand Delivery:** To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Susanna W. Blair, Immediate Office, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-4371; email address: blair.susanna@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

EPA is primarily proposing to establish requirements on the Agency. However this proposal also includes the process and requirements that manufacturers (including importers) would be required to follow when they request an Agency-conducted risk evaluation on a particular chemical substance. This action may, therefore, be of interest to entities that are manufacturing or importing, or may manufacture or import a chemical substance regulated under TSCA (e.g., entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

B. What action is the agency taking?

EPA is proposing to establish the process by which the Agency would conduct risk evaluations on chemical substances under TSCA. The proposal identifies the necessary components of a risk evaluation, including a scope (composed of a conceptual model and an analysis plan), a hazard assessment, an exposure assessment, a risk characterization, and a risk determination. The proposed rule would also establish the process by which manufacturers (including

importers) would request an Agency-conducted risk evaluation, and the criteria by which the EPA would evaluate such requests.

C. What is the agency's authority for taking this action?

EPA is proposing this rule pursuant to the authority in TSCA section 6(b)(4), as amended (15 U.S.C. 2605(b)). See also the discussion in Units II.A. and B.

D. What are the estimated incremental impacts of this action?

Although this proposal focuses on the process and activities that apply to EPA, it also proposes the process and requirements that manufacturers (including importers) would be required to follow when they request an Agency-conducted risk evaluation on a particular chemical substance. Since these requirements qualify as an information collection under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, EPA has prepared an Information Collection Request (ICR) to estimate the potential burden and costs associated with the proposed requirements for submitting a request for an Agency-conducted risk evaluation on a particular chemical substance. The ICR, which is available in the docket, is discussed in Unit VI.B. and is briefly summarized here. (Ref. 1).

The total estimated annual burden is 960.3 hours and \$69,353, which is based on an estimated per request burden of 96.03 hours.

E. What should I consider as I prepare my comments for EPA?

1. **Submitting CBI.** Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. **Tips for preparing your comments.** When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets>.

II. Background

A. Recent Amendments to TSCA

On June 22, 2016, the President signed into law the “Frank R. Lautenberg Chemical Safety for the 21st Century Act,” which imposed sweeping reforms to TSCA. The bill received broad bipartisan support in the U.S. House of Representatives and Senate, and its passage was heralded as the most significant update to an environmental law in over 20 years. The amendments give EPA improved authority to take actions to protect people and the environment from the effects of dangerous chemical substances. Additional information on the new law is available on EPA’s Web site at: <https://www.epa.gov/assessing-and-managing-chemicals-under-tasca/frank-r-lautenberg-chemical-safety-21st-century-act>.

When TSCA was originally enacted in 1976, it established an EPA-administered health and safety review process for new chemical substances prior to allowing their entry into the marketplace. However, tens of thousands of chemical substances in existence at that time were “grandfathered in” with no requirement for EPA to ever evaluate their risks to health or the environment. The absence of a review requirement or deadlines for action, coupled with a burdensome statutory standard for taking risk management action on existing chemical substances, resulted in very few chemical substances ever being assessed for safety by EPA, and even fewer subject to restrictions to address identified risks.

One of the key features of the new law is the requirement that EPA now systematically prioritize and assess existing chemicals, and manage identified risks. Through a combination of new authorities, a risk-based safety standard, deadlines for action, and minimum throughput requirements, TSCA effectively creates a “pipeline” by which EPA will conduct existing chemicals review and management. This new pipeline—from prioritization to risk evaluation to risk management (when warranted)—is intended to drive steady forward progress on the backlog of existing chemical substances left largely unaddressed by the original law. Risk evaluation is the second step of this process, after prioritization, which is being addressed in a separate rulemaking.

B. Statutory Requirements for Risk Evaluation

TSCA section 6(b)(4) requires EPA to establish, by rule, a process to conduct

risk evaluations. Specifically, EPA is directed to use this process to “determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use.” (15 U.S.C. 2605(b)(4)(A)). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that direct which chemical substances must undergo evaluation, the development of criteria for manufacturer-requested evaluations, the minimum components of an Agency risk evaluation, and the timelines for public comment and ultimate completion of the risk evaluation.

1. *Chemical substances to undergo risk evaluation.* TSCA section 6(b) identifies the chemical substances that are subject to this process; these are: (1) Ten chemical substances the Agency is required to identify from the 2014 update to the TSCA Work Plan within the first 180 calendar days after the signing of TSCA (15 U.S.C. 2605(b)(2)); (2) the chemical substances determined as High-Priority Substances through the prioritization process that is being proposed in a separate rulemaking; and (3) requested chemicals submitted by manufacturers that have met the criteria for EPA to conduct a risk evaluation as outlined by this rule. Assuming a sufficient number of requests that have met the criteria outlined in this proposed rule are received, subsection (E) specifies that the number of manufacturer-requested evaluations be 25 to 50 percent of the number of “High Priority” risk evaluations ongoing at any one time. Since the number of manufacturer-requested evaluations is expressed as a percentage of the number of High-Priority Substance evaluations, not as a percentage of the total, the number of manufacturer-requested evaluations will likely comprise between 1/5 and 1/3 of the number of total ongoing evaluations, assuming a sufficient number of compliant requests are received. Any manufacturer requested chemical substances on the 2014 update of the TSCA Work Plan (Ref. 2) are exempt from the percentage limitations.

2. *Manufacturer-requested risk evaluations.* TSCA section 6(b)(4)(C) directs EPA to establish the “form and manner” and “criteria” that govern manufacturer requests that a substance that they manufacture undergo an EPA

conducted risk evaluation. EPA has broad discretion to establish these criteria, but relatively less discretion over whether to grant requests that comply with EPA’s criteria. EPA must grant any request that complies with EPA’s criteria, until the statutory minimum of 25 percent has been met. Assuming EPA receives requests in excess of this threshold, EPA interprets this provision to grant EPA discretion to determine whether to grant further requests, up to the maximum 50 percent level. In such circumstances, the EPA is directed to give preference to manufacturer requests for which the EPA determines that restrictions imposed by one or more states have the potential to significantly impact interstate commerce, or health or the environment. 15 U.S.C. 2605(b)(4)(E)(iii). As discussed elsewhere in this preamble, EPA is also proposing to give preference to requests where EPA estimates there may be relatively high exposure(s) and/or hazard(s) under one or more conditions of use.

3. *Components of a risk evaluation.* The statute identifies the minimum components EPA must include in all chemical substance risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation that will be conducted, and that includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the EPA expects to consider. 15 U.S.C. 2605(b)(4)(D). The statute provides that the scope of the risk evaluation must be published no later than six months after the initiation of the risk evaluation.

Each risk evaluation must also: (1) “integrate and assess available information on hazards and exposure for the conditions of use of the chemical substance, including information on specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations;” (2) “describe whether aggregate or sentinel exposures were considered and the basis for that consideration;” (3) “take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use;” (4) “describe the weight of scientific evidence for the identified hazards and exposure.” 15 U.S.C.

2605(b)(4)(F)(i),(iii)–(v). The risk evaluation must not consider costs or other non-risk factors. 15 U.S.C. 2605(b)(4)(F)(ii).

Many stakeholders have expressed concern as to how EPA will apply “weight of scientific evidence” under

the amended TSCA. EPA is providing, for the purposes of background, a description of how the Agency has consistently interpreted and applied that concept. EPA is not proposing to modify this process as part of this rule. Nor is EPA proposing to codify it; this process has and will continue to evolve with changing scientific methods and innovation. Codifying a specific definition can inhibit the flexibility of the Agency to quickly adopt and implement changing science.

The phrase weight-of-evidence (WoE) is used by EPA and other scientific bodies to describe the strength of the scientific inferences that can be drawn from a given body of evidence, specifically referring to how studies are selected, the quality of the studies evaluated, and how findings are assessed and integrated. Weight-of-evidence is a complex issue and as stated by the National Academies this is “because scientific evidence used in WOE evaluations varies greatly among chemicals and other hazardous agents in type, quantity, and quality, it is not possible to describe the WoE evaluation in other than relatively general terms. It is thus not unexpected that WoE judgements in particular cases can vary among experts and that consensus is sometimes difficult to achieve” (NAS, 2009) (Ref. 3). The following is a brief description of how WoE is used at EPA, serving as an example of successful application of WOE in making the scientific determinations.

EPA utilizes the WoE approach in existing programs including IRIS and the Endocrine Disruptor Screening Program among others, and in the classification of carcinogens. In the 1999 Guidelines for Carcinogen Risk Assessment (Ref. 4) EPA refers to the WoE approach as “. . . a collective evaluation of all pertinent information so that the full impact of biological plausibility and coherence is adequately considered (Ref. 5). The Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) referred to the WoE approach as “. . . a process by which trained professionals judge the strengths and weaknesses of a collection of information to render an overall conclusion that may not be evident from consideration of the individual data” (Ref. 6).

WoE is the process for characterizing the extent to which the available data support a hypothesis that an agent causes a particular effect (Ref. 4 and 5). This process involves a number of steps starting with assembling the relevant data, evaluating that data for quality and relevance, followed by an integration of the different lines of evidence to

support conclusions concerning a property of the substance. WoE is not a simple tallying of the number of positive and negative studies, but rather it relies on professional judgment. The significant issues, strengths, and limitations of the data and the uncertainties that deserve serious consideration are presented, and the major points of interpretation are highlighted.

This WoE analysis is conducted on a case-by-case basis by first assembling and assessing the individual lines of evidence and then performing an integrated analysis of those lines of evidence. All data considered in the WoE analysis need to be documented and scientifically acceptable. A WoE analysis typically begins with a careful evaluation of each individual study. The process of evaluating the individual lines of evidence includes assembling the data, evaluating that data against current acceptance and quality criteria, and presenting the conclusions regarding the results for each study. The reviews of the available studies need to be transparent about what studies were considered or not, and how the quality of a study was judged.

After assembling and assessing the individual lines of data, an integrated analysis is performed. This means the results from all scientifically relevant published or publically available peer-reviewed studies, which are of sufficient quality and reliability, are evaluated across studies and endpoints into an overall assessment. In general, the WoE analysis examines multiple lines of evidence considering a number of factors, including for example the nature of the effects within and across studies, including number, type, and severity/magnitude of effects and strengths and limitations of the information.

A summary WoE narrative or characterization generally accompanies the detailed analysis of the individual studies and the integrative analysis of the multiple lines of evidence. Inclusion of a WoE narrative is common in WoE assessments and judgments (Ref. 4 and 7). The narrative/characterization is intended to be transparent and allow the reader to clearly understand the reasoning behind the conclusions. The narrative will generally explain the selection of the studies or effects used as the main lines of evidence and relevant basis for conclusions. The overall strength of the evidence supporting a conclusion from the WoE evaluation needs to be described.

The National Toxicology Program of the National Institute of Environmental Health Sciences has developed a tool

called “systematic review” to assist in WoE evaluations particularly for hazard identification (<https://ntp.niehs.nih.gov/pubhealth/hat/noms/index-2.html>).

This tool uses a defined set of processes to identify, select, critically assess, and synthesize evidence to arrive at a hazard conclusion for a chemical. It is designed to enhance transparency and informs scientific judgments. The evidence synthesis step involves considering factors that decrease confidence in the body of evidence for a particular health endpoint (e.g. risk of bias, inconsistencies across studies, imprecision) as well as factors that increase confidence (e.g. magnitude of the effect, residual confounding, consistency). By evaluating study design (e.g., consistent with study guidelines issued by OECD, and test guidelines issued by the Office of Chemical Safety and Pollution Prevention), and study quality (e.g., studies that comply with Good Laboratory Practices (GLP) like those applicable generally (<https://www.federalregister.gov/documents/2016/08/24/2016-19875/good-laboratory-practice-for-nonclinical-laboratory-studies>) and those issued by EPA for studies submitted under TSCA and FIFRA (<https://www.epa.gov/compliance/good-laboratory-practices-standards-compliance-monitoring-program>)), and integrating negative data (and consideration of the quality of those data), the confidence in hazard conclusions can be increased.

The NIEHS systematic review tool is one example of a documented systematic review approach. EPA believes the proposed risk evaluation process generally reflects the use of systematic review approaches that are appropriate for the types and quantity of information used in a chemical risk evaluation. EPA requests comment on this view. EPA is also requesting comment on the need for regulatory text requiring the use of specific elements of a systematic review approach for hazard identification, including the appropriateness of specific elements that might be included and/or concerns about codifying such an approach.

4. Timeframe. TSCA requires that the risk evaluation process last no longer than three years with a possible six-month extension. 15 U.S.C. 2605(b)(4)(G).

5. Opportunities for public participation. The statute requires that the Agency allow for at least one 30 day public comment period on the draft risk evaluation, prior to publishing a final risk evaluation. 15 U.S.C. 2605(b)(4)(H).

6. Metals and metal compounds. When evaluating metals or metal compounds, EPA must “use” the March

2007 Framework for Metals Risk Assessment of the Office of the Science Advisor (Ref. 8) or a successor document that addresses metals risk assessment and is peer-reviewed by the Science Advisory Board.

7. *Other statutory requirements.* TSCA imposes new requirements on EPA in a number of different areas that EPA is not proposing to incorporate or otherwise address in this proposed rule. For example, amendments to TSCA section 4 require EPA to “. . . reduce and replace, to the extent practicable, [. . .] the use of vertebrate animals in the testing of chemical substances . . .” and to develop a strategic plan to promote such alternative test methods. 15 U.S.C. 2603(h). Likewise, TSCA section 26 requires, to the extent that EPA makes a decision based on science under TSCA sections 4, 5, or 6, that EPA uses certain scientific standards and bases those decisions on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i). While these requirements are relevant to the risk evaluation of chemical substances, EPA is not obliged to repeat them in this proposed rule. As statutory requirements, they apply to EPA’s decisions under TSCA section 6. Moreover, in contrast to TSCA section 6, Congress has not directed EPA to implement these other requirements “by rule;” it is well-established that where Congress has declined to require rulemaking, the implementing agency has complete discretion to determine the appropriate method by which to implement those provisions.

C. EPA Risk Assessment

Since EPA’s inception, human health and ecological risk assessment has informed decisions made to protect humans and the environment. Risk assessments performed by the Agency inform a broad range of regulatory decisions, and, over time, the scientific approaches and methods employed for these risk assessments have evolved. In developing and refining risk assessment processes, frameworks, and guidance documents, EPA has incorporated recommendations from expert technical panels, internal and external peer reviews, and a number of influential reports from the National Academy of Sciences (NAS) National Research Council (NRC) including Risk Assessment in the Federal Government (1983) (Ref. 9), Science and Judgement in Risk Assessment. (1994) (Ref. 10), Understanding Risk: Informing Decisions in a Democratic Society (1996) (Ref. 11), Toxicity Testing in the 21st Century: A Vision and a Strategy (2007) (Ref. 12), Phthalates and

Cumulative Risk Assessment: The Tasks Ahead (2008) (Ref. 8), and Science and Decisions: Advancing Risk Assessment (2009) (Ref. 3). Specifically, the NAS NRC Science and Decisions Report (Ref. 3) recommended that EPA focus on the important roles of scoping or problem formulation so that a risk assessment will serve a specific and documented purpose. An additional recommendation encouraged EPA to develop risk assessments that are well-tailored to the problems and decisions at hand so that they can inform the decision-making process in the most meaningful way. EPA has evaluated, and will continue to evaluate chemical risks in a manner that is best suited for the particular chemical substance, including its manufacture, processing, formulation, uses, and disposal, and the evaluations may vary as necessary to best characterize potential risks related to the chemical substance under review.

As stated, TSCA requires EPA to evaluate risk to relevant potentially exposed or susceptible subpopulations identified by EPA as relevant to the risk evaluation under the conditions of use. 15 U.S.C. 2605(b)(4)(A). Although this was added as a component of the newly amended law, this will not be a new consideration for the Agency; for example, see EPA’s Policy on Evaluating Health Risks to Children (1995) (Ref. 14). The Agency has evaluated the risk of chemical substances to all sectors of the population, with particular attention to workers, indigenous peoples, pregnant women, children, infants, the elderly, environmental justice communities, and fence-line communities, among others. The Agency utilizes a number of existing guidance documents (including but not limited to Ref. 15, 16, 17, 18, and 19) to evaluate risk at various life stages, and will use and refine these processes to protect the most vulnerable.

1. *Differences between previous EPA risk assessments under TSCA and proposed new risk evaluations.* In this proposed rule, EPA does not propose a new method of risk evaluation, but builds upon existing and proven methodologies for evaluating risk. Also as required by the statute, the rule includes opportunities for public participation, statutory deadlines, necessary components of a risk evaluation, and methods for manufacturer requested risk evaluation. Above and beyond the statute, the proposed rule provides an additional opportunity for public participation, added detail as to components of the scope, hazard and exposure assessments, risk characterization, and increases transparency in the risk

evaluation process. EPA requests comment on whether and how the proposed rule could provide additional transparency, public accountability, opportunities for public participation, or incorporation of statutory deadlines.

There are several key differences between previous chemical risk assessments conducted under TSCA and the new risk evaluation process mandated by TSCA amendments and established under these proposed regulations. These differences include considerations of conditions of use, timelines, and determination of unreasonable risk, and are discussed in more detail under those topics in this unit. This proposed rule and procedures described herein apply to risk evaluations conducted under TSCA, and do not apply to risk evaluations conducted by EPA pursuant to other statutes or programs.

2. *Conditions of use.* Prior to the amended TSCA, EPA was free to and did conduct risk assessments on selected uses of chemical substances. In contrast, EPA interprets the amended TSCA as requiring that risk evaluations encompass all manufacture, processing, distribution in commerce, use, and disposal activities that constitute the conditions of use within the meaning of TSCA section 3. That is to say, a risk evaluation must encompass all known, intended, and reasonably foreseen activities associated with the subject chemical substance. This issue has been the subject of considerable discussion since the enactment of the new law, and EPA acknowledges that different readings of the law may be possible. For example, TSCA section 6(b)(4)(D) requires EPA to identify the conditions of use that the Agency expects to consider in a risk evaluation, suggesting that EPA does not need to consider all conditions of use.

Overall, the statutory text and purpose are best effectuated through a more encompassing reading. TSCA section 6(b)(4)(A) specifies that a risk evaluation must determine whether “a chemical substance” presents an unreasonable risk of injury to health or the environment “under the conditions of use.” The evaluation is on the chemical substance—not individual conditions of use—and it must be based on “the conditions of use.” In this context, EPA believes the word “the” is best interpreted as calling for evaluation that considers all conditions of use. First, if EPA were free to base its determination of whether a chemical substance, as a whole, presents an unreasonable risk or injury (as the statute requires) on merely a subset of individual uses, it could, for example,

determine that a chemical substance with 10 known uses does not present an unreasonable risk of injury based on an evaluation of a single one of those uses, with no further obligation to evaluate the remaining uses within the three-year statutory deadline. This is a strained reading of the commands to determine whether the chemical substance presents an unreasonable risk, under the conditions of use, and to complete that evaluation “for a chemical substance” within three years of initiation. See 15 U.S.C (b)(4)(G)(i).

Second, a major objective of the new law is to require EPA to systematically evaluate existing chemical substances to determine whether or not they present unreasonable risk, and, if necessary, regulate them based on the results of the evaluation. Given the large number of existing chemical substances, it would not be feasible to complete risk evaluations on any significant number of them if EPA were to continually need to re-evaluate chemical substances based on different subset of uses. Rather the law’s purposes will be best fulfilled by judging in a comprehensive way whether a chemical substance, under the known, intended, and reasonably foreseen uses and other activities, presents an unreasonable risk; ensuring through regulation that it does not present an unreasonable risk, if necessary; and then presumptively being done with that chemical substance (pending re-prioritization for some unforeseen reason). Finally, EPA notes that, if the law is read as allowing EPA to select particular conditions of use, it provides no criteria for EPA to apply in making such a selection.

Given these considerations, the instruction in TSCA section 6(b)(4)(D) for the Agency to identify the conditions of use it expects to consider in a risk evaluation is best read as directing the Agency to identify the uses and other activities that it has determined constitute the conditions of use, not as a license to choose among conditions of use.

Concerns have been raised about EPA’s ability to meet the statutory risk evaluation deadlines if all conditions of use must be considered. Concerns have also been raised about ensuring that EPA can act promptly to address any unreasonable risks identified for particular conditions of use. EPA acknowledges that this will be challenging but based on the procedures outlined in this proposal, expects it will be manageable. First, a use or other activity constitutes a condition of use under the definition only if EPA determines that it does. EPA has authority to exercise judgment in

making its determination of whether a condition of use is known, intended, or reasonably foreseen. Moreover, in this proposed rule EPA proposes to “lock down” the conditions of use included in a risk evaluation at the time of scoping, by providing opportunity for comment on the scoping document and specifying that any objections to the draft scope document are waived if not raised during this process. It will not be practicable to meet the statutory deadlines if stakeholders are free to identify additional conditions of use later in the process—for example, on the proposed risk determination.

As explained elsewhere in this preamble, EPA also generally intends to initiate risk evaluation on a chemical substance only when EPA determines that sufficient reasonably available information exists to complete the evaluation, and when it has already identified all of the conditions of use. As also explained elsewhere in this preamble, under certain circumstances EPA may expedite an evaluation for a particular condition of use to move more rapidly to risk management under TSCA section 6(a).

Finally, the proposed rule provides that EPA will rely on a combination of information, accepted science policies (e.g., defaults and uncertainty factors), models and screening methodologies in conducting risk evaluations, with considerations of evolving science and technology. It further provides that the balance of information, science policy decisions, models, and screening methodologies used in risk evaluation will be informed by the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluations, and by the extent to which the generation of additional information is warranted by the reduction in uncertainty that the information would afford in determining whether a chemical substance presents an unreasonable risk of injury to health or the environment.

In this regard, EPA is also proposing to require that the components of its risk evaluations will be “fit for purpose.” All conditions of use will not warrant the same level of evaluation, and EPA expects it may be able to reach conclusions without extensive or quantitative evaluations of risk. For example, lower-volume or less dispersive uses might receive less quantitative, data-driven evaluations than uses with more extensive or complicated exposure patterns. Consistent with EPA’s current practice in conducting risk assessments, technically sound risk determinations can be made, consistent with the best available science, through a

combination of different types of information and other approaches.

In sum, Congress intended to create obligations that EPA can actually meet, and EPA intends to conduct risk evaluations in a way that is manageable given the statutory deadlines.

3. Timelines and guidance regarding assessing risks of existing chemical substances. Prior to the amended TSCA, EPA was not required to evaluate or manage the risk of the thousands of existing chemical substances grandfathered in under the 1976 Act. As discussed previously, the amended TSCA affirmatively requires EPA to evaluate existing chemical substances more quickly, instructs EPA on how many of these chemical substances the Agency must evaluate at any given time, and places time limits on when these evaluations must be completed. 15 U.S.C. 2605(b)(2)–(4).

4. Determination of unreasonable risk. Under TSCA section 6(b) (15 U.S.C. 2605(b)(4)(B)), EPA must establish a risk evaluation process to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment. Prior to the passage of the amended TSCA, chemical substance risk assessments did not include a determination of unreasonable risk. This step was reserved for risk management rulemaking. The amended statute now requires that a risk evaluation include a risk assessment as well as the EPA’s determination of unreasonable risk, and, most significantly, requires that this determination be independent of cost or other non-risk factors. 15 U.S.C. 2506(b)(4)(A) and (F)(iii).

In general, EPA may weigh a variety of factors in determining unreasonable risk. These factors include, but are not limited to, characterization of cancer and non-cancer risks (including margins of exposure for non-cancer risks), the population exposed (including any susceptible populations), the severity of hazard (the nature of the hazard), the irreversibility of hazard, uncertainties, and estimates of cumulative exposure. Because of the case-by-case nature of each of these factors EPA has purposely not proposed a definition of unreasonable risk in this rule. However, EPA is specifically requesting comments on whether EPA should define unreasonable risk in the final rule. If so, acknowledging that the statute precludes consideration of costs and other non-risk factors at this step, what factors should EPA consider in making such a determination?

5. Manufacturer-requested evaluations and draft risk evaluations by interested persons. The newly

amended TSCA requires that a portion of ongoing risk evaluations be conducted on chemical substances requested by manufacturers “in a form and manner and using criteria” EPA prescribes by rule. 15 U.S.C. 2605(b)(4)(C)(ii),(E)(i). The statute also requires EPA to develop guidance (which will be forthcoming) to assist interested persons in submitting draft risk evaluations, and requires EPA to consider such submitted drafts. 15 U.S.C. 2625(l)(5).

D. Stakeholder Feedback

On August 9, 2016, EPA held a one-day public meeting to obtain public comment and feedback regarding the development and implementation of the risk evaluation rule. The meeting began with an explanation of how the Agency currently conducts risk assessments (see https://www.epa.gov/sites/production/files/2016-08/documents/risk_evaluation_9_august_2016.pdf). The remainder of the day was reserved for public comment. Each commenter was provided four minutes to comment and there was a total of 47 oral comments on the risk evaluation rule. Additionally, EPA opened a docket for submission of written comments and received 57 comments, many of which were from the same commenters at the public meeting. These comments, and a transcript of the meeting are accessible in the meeting’s docket, identified by Docket ID No. EPA–HQ–OPPT–2016–0399, which is available online at <https://www.regulations.gov/>.

The commenters included industry, environmental groups, academics, private citizens, trade associations, and health care interest groups and representatives. The comments were very informative for both rule development and risk evaluation implementation. While not all of the comments are captured here, there were a number of themes that emerged. Overall, there was a general expression of support for the new law and EPA’s inclusive approach to implementation. Many of the commenters agreed the rule has the potential to increase transparency in EPA’s chemical substance risk evaluation process. Many urged the Agency to work towards this goal, while creating an open scientific dialogue.

Questions arose about how the Agency will determine “unreasonable risk” and implement TSCA section 26 requirements including “best available science” and “weight of scientific evidence.” Some suggested that EPA should codify in this rule the meaning of these terms along with other details of the risk evaluation process. Due to

changes in the law, manufacturers are now able to submit their own draft risk evaluations. Commenters noted that if these submitted evaluations are to be equivalent as Agency draft risk evaluations, having specific criteria, such as specific types of exposure and hazard information would ensure the Agency and the manufacturers were held to the same standard. Stakeholders also suggested that holding a public comment period for the draft risk evaluation scope would increase the transparency of each risk evaluation early in the process and allow the public to comment on any data gaps or discrepancies.

Other stakeholders urged the Agency to reserve specific scientific processes regarding hazard and exposure information for Agency guidance and discretion, suggesting the rule should address only the process and procedure. This approach would allow the Agency to be flexible and adapt to the changing science of risk evaluation and the science that informs risk evaluation.

A number of commenters spoke about the statute’s requirement that the Agency determine the specific risk to “potentially exposed or susceptible subpopulation[s]”. Although the law defines this term to include “infants, children, pregnant women, workers, or the elderly,” many encouraged the Agency to consider expanding the definition to include for example: environmental justice communities, Arctic communities, American Indian communities, communities with little access to preventative health-care, subsistence fishers, and fence-line communities. There were a number of stakeholders who encouraged the Agency to work with the Occupational Safety & Health Administration (OSHA), the National Institute for Occupational Safety and Health (NIOSH), and the Consumer Product Safety Commission (CPSC), among other federal agencies, to better protect against occupational and consumer exposures. Also regarding exposure, stakeholders encouraged the examination of cumulative and low dose exposures in risk evaluations, which are not specifically mentioned in the new statute.

A number of commenters emphasized the need for EPA to maximize transparency throughout the evaluation process. The EPA received a number of comments about the science used to inform individual risk evaluations, including the types of data, models, policy assumptions (e.g., default factors) and computational approaches. A number of commenters argued that a lack of data does not equate to a lack of risk. Stakeholders encouraged the

Agency to engage with industry to obtain hazard and exposure data and to utilize the new order authority allowed under the law (TSCA section 4). Commenters suggested an increased use of EPA’s Office of Research and Development (ORD) and internationally accepted data, models, and products. A number of stakeholders expressed their support for the new provision in the law that requires the Agency to reduce and replace vertebrate testing (TSCA section 4(h)) in obtaining chemical substance hazard and exposure data.

EPA considered all of these comments in the development of this proposed rule, and welcomes additional feedback from stakeholders on the proposed process and requirements presented in this document.

III. The Proposed Rule

A. Policy Objectives

The risk evaluation process under TSCA is ultimately how EPA will determine whether a chemical substance presents an unreasonable risk of injury to health or the environment. The overall objective of this action is to propose to codify the process by which the Agency evaluates risk from chemical substances for purposes of TSCA section 6. In this proposed rule, the Agency details those components of TSCA risk evaluation and key factors that EPA deems are necessary to consider in each risk evaluation to ensure that the public has a full understanding of how risk evaluations will be conducted. However, EPA is not proposing to establish highly detailed provisions that will address every eventuality or possible consideration that might arise. Due to the rapid advancement of the science of risk evaluation and the science and technology that inform risk evaluation, this proposed rule seeks to balance the need for the risk evaluation procedures to be transparent, without unduly restricting the specific science that will be used to conduct the evaluations, allowing the Agency flexibility to adapt and keep current with changing science as it conducts TSCA evaluations into the future.

B. Interagency Collaboration

EPA recognizes that other Federal agencies may be able to provide important use, exposure and hazard information that is likely to be relevant to a risk evaluation of chemical substances. EPA is committed to interagency engagement and dialogue throughout its risk evaluation process, including data sharing, information requests, and consultation regarding specific chemicals of interest. As such,

EPA has reached out to other agencies, inviting them to join the agency in an open and collaborative dialogue. EPA intends to continue and expand its interagency collaboration efforts for chemicals management and risk evaluations under TSCA.

To coordinate with other agencies on TSCA implementation generally, EPA intends to continue to use—and expand where appropriate—existing interagency groups, such as the OMNE (OSHA–MSHA–NIOSH–NIEHS–EPA) Committee and the National Science and Technology Council (NSTC)’s Committee on Environment, Natural Resources, and Sustainability’s new Toxicity Assessment Committee. EPA is also committed to interagency engagement at the working level on individual chemical evaluations.

To ensure that such collaboration can occur in a timely manner when needed, EPA intends to initiate interagency consultation through the existing mechanisms early in the process, and document these measures in the scope document. However, EPA is concerned that imposing a single, pre-determined consultation step might lead to an overly bureaucratic process that could limit or complicate ongoing collaboration efforts, and so is not proposing to codify any particular process in this regulation.

C. Scope of Evaluations

TSCA requires risk evaluations to determine whether or not a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, with conditions of use being defined as “the circumstances, as determined by the EPA, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” 15 U.S.C. 2602(4).

Although some of the commenters during the public meeting suggested that EPA could evaluate a specific use of a chemical substance, EPA is not choosing to adopt such an interpretation, for the reasons explained previously. Also, EPA recognizes that under certain circumstances it may be necessary to expedite an evaluation for a particular condition of use to move more rapidly to risk management under TSCA section 6(a) (15 U.S.C. 2605(a)): this could include a situation in which a single use presented an unreasonable risk of injury for the population as a whole or for a susceptible subpopulation (e.g., one use results in risks that EPA would determine unreasonable regardless of the risk posed by other uses). However, in any

case where EPA would find it necessary to pursue a risk evaluation in phases, the Agency will still complete the full risk evaluation on all identified conditions of use within the statutory 3-year deadline. Therefore, relying on this discretion, EPA is proposing to explicitly recognize its authority to complete risk evaluations in phases, and to manage unreasonable risks as they are identified through those phases under TSCA section 6(a) in the regulation.

D. Definitions

TSCA defines a number of key terms necessary for interpretation of the new law. The definitions within the law apply to this proposed rule. EPA has also included some additional definitions in the proposed rule for further clarification; these are noted and defined later in this document. The law requires EPA to evaluate risk to “potentially exposed or susceptible subpopulation[s],” and although the law elaborates on this phrase, EPA is proposing to expand the definition for TSCA purposes. TSCA states that “the term ‘potentially exposed or susceptible subpopulation’ means a group of individuals within the general population identified by the EPA who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.” 15 U.S.C. 2602(12). EPA is proposing to incorporate the phrase “including but not limited to” before the specific subpopulations identified in the statutory definition, to further clarify that EPA may identify additional subpopulations, where warranted. As suggested by the statute, EPA is also proposing to include specific authorization for EPA to consider both intrinsic (e.g., life stage, reproductive status, age, gender, genetic traits) and acquired (e.g., pre-existing disease, geography, socioeconomic, cultural, workplace) factors when identifying this population.

TSCA section 26(k) (15 U.S.C. 2625(k)) states that in carrying out risk evaluations, EPA shall consider information that is “reasonably available,” but the statute does not further define this phrase. EPA is proposing a definition for “reasonably available” to mean existing information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. Generally speaking, EPA does not consider information that has not yet been

generated, as reasonably available, because it will typically not be feasible for EPA to require significant chemical testing and receive and assess those test results during the three to three and a half year window allotted for risk evaluation. Accordingly, EPA intends to generally ensure that sufficient information to complete a risk evaluation exists and is available to the Agency prior to initiating the evaluation (indeed, prior to initiating prioritization). EPA also generally intends to use its authority under TSCA to require the development of new information, as necessary, prior to risk prioritization.

TSCA requires EPA, as a part of the risk evaluation, to document whether the Agency has considered aggregate or sentinel exposure, and the basis for that decision. 15 U.S.C. 2605(b)(4)(F)(ii). These terms are not defined in the law, so EPA has proposed a definition for aggregate exposure that is consistent with current Agency policies and practices. “Aggregate exposure” means the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways (Ref. 20). “Sentinel” means the exposure(s) of greatest significance, which may be the maximum exposure to an individual, population (or subpopulation), or the environment to the chemical substance of interest (or any combination thereof). Although sentinel exposure is not a novel way of characterizing exposure, this is a new term for EPA.

Other terms defined in the proposed rule are designed to provide clarity regarding the science that will be used to conduct an evaluation. “Pathways” of exposure refers to the mode through which one is exposed to a chemical substance, including but not limited to: food, water, soil, and air (Ref. 20). “Routes” of exposure refer to the particular manner which a chemical substance may contact the body, including absorption via ingestion, inhalation, or dermally (Ref. 20). The statute requires EPA to consider “the extent to which the variability and uncertainty . . . are evaluated and characterized.” 15 U.S.C. 2625(h). EPA is adopting definitions for both “variability” and “uncertainty” from existing Agency guidance. “Uncertainty” means the imperfect knowledge or lack of precise knowledge either for specific values of interest or in the description of a system (Ref. 21). “Variability” means the inherent natural variation, diversity, and heterogeneity across time and/or space or among individuals within a population (Ref. 21).

E. Timing of Risk Evaluations

As indicated, the statute requires EPA to complete risk evaluations within three years, with the possibility of a six month extension beyond the three year timeframe. This proposed rule simply adopts these timeframes without modification or elaboration. EPA acknowledges this is a relatively short timeframe, and, as discussed elsewhere in this preamble, is proposing to adopt other procedures that will allow the Agency to meet these deadlines.

F. Chemical Substances for Risk Evaluation

As identified previously, chemical substances that will undergo risk evaluation can be put into three groups: (1) The first ten chemical substances the Agency is required to identify within the first 180 calendar days of enacting the amendments to TSCA (15 U.S.C. 2605(b)(2)); (2) the chemical substances determined as High-Priority Substances through the prioritization process proposed in a separate rulemaking; and (3) requested chemical substances submitted by manufacturers that meet the criteria for EPA to conduct an Agency risk evaluation.

G. Process for Manufacturer Requested Risk Evaluations

TSCA allows a manufacturer or group of manufacturers to submit requests for Agency conducted risk evaluations for chemical substances that they manufacture. EPA is proposing the necessary components of the request in the proposed regulatory text. EPA is proposing to require that manufacturers demonstrate in their request that there is sufficient, reasonably available information for the Agency to conduct a risk evaluation on the chemical substance under the conditions of use. EPA must complete any manufacturer-requested risk evaluation that it determines meets the criteria within the statutory three years. Unlike those chemical substances that have come through the prioritization process, manufacturer-requested chemical substances have not undergone initial risk screening and therefore EPA will not assign such chemicals a high- or low-priority designation. The purpose of the requirements proposed as the necessary components of the request, is to allow the Agency to determine whether sufficient information is “reasonably available” for EPA to complete a risk evaluation of the requested chemical under the conditions of use, as that term is defined under TSCA section 3.

EPA is proposing to require a manufacturer to submit a list (e.g., citations) of the reasonably available information on hazard and exposure for all the conditions of use. EPA is not requesting manufacturers submit copies of the cited information. Manufacturers must include a commitment to provide EPA any referenced data if they are not publicly available, and must certify that the information submitted is accurate and complete. EPA will not accept a manufacturer request where any of the relevant data is not in the possession of the requestor but is with another entity.

Consistent with TSCA section 6(b)(4)(E)(iii), EPA will prioritize requests where there is evidence that restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce or health or the environment, and is therefore proposing to allow (but not require) manufacturers to include any evidence to support such a finding. Following this required initial prioritization, EPA is proposing to further prioritize chemical substances for risk evaluation based on initial estimates of exposure(s) and/or hazard(s) under one or more conditions of use or any other factor that EPA determines may be relevant. In general, EPA plans to prioritize those chemical substances where there is evidence of relatively high risk over those with less evidence of risk.

Instructions for submitting CBI are also included in the proposed rule. EPA believes that TSCA section 14(c)(3) is best read as requiring upfront substantiation of non-exempt CBI claims. In addition, EPA believes the obligation to review all non-exempt chemical identification claims and 25 percent of all other non-exempt claims will be best effectuated by requiring substantiation at the time of submission.

Chemical substances that EPA has prioritized through the prioritization process (proposed in a separate rulemaking), are subject to two separate public comment periods prior to the completion of the prioritization process. EPA expects that these comment periods will ensure that EPA has the necessary information to evaluate the chemical substances, including information on all conditions of use. Consequently, in order to ensure that chemical substances subject to manufacturer requests undergo risk evaluation only if the available information is comparable to what EPA will identify or generate through the measures identified in the proposed prioritization framework rule, EPA is proposing opportunities to collect additional information from the public.

Upon receipt of the request, EPA is proposing to verify that the request is facially valid, *i.e.*, that information has been submitted that is consistent with the regulatory requirements. EPA is proposing that within 30 business days of a receiving a facially valid request, EPA will submit for publication an announcement of the receipt of the request in the **Federal Register**, open a docket for the request, and provide no less than a 30 calendar day comment period, to allow the public to identify and/or submit any reasonably available information regarding hazard, exposure, potentially exposed population(s) and subpopulation(s), and conditions of use that may help inform a risk evaluation, including identifying information gaps. The requesting manufacturer may also submit any additional material during this time.

Within 9 months after the end of the comment period, EPA will review the request along with any additional information received during the comment period to determine whether the request meets the regulatory criteria and will notify the manufacturer(s) accordingly. This time will allow EPA to develop the equivalent of a conceptual model to describe actual or predicted relationships between the chemical substance and the receptors, either human or environmental, with consideration of potential hazards throughout the life cycle of the chemical substance—from manufacturing, processing, distribution in commerce, storage, use, or disposal. If EPA determines that the request is compliant (*i.e.*, it has the required information necessary for conducting a risk evaluation), EPA will begin the risk evaluation process consistent with TSCA section 6(b)(4)(E)(i). If the request is found insufficient EPA will identify the information that would be necessary to conduct the risk evaluation in its notification to the manufacturer. The manufacturer will have 60 calendar days from receipt of EPA’s determination to submit the additional information. EPA will consider the request withdrawn if the manufacturer(s) fails to submit the additional information identified. The process for conducting the risk evaluation will otherwise be identical to the process for those chemical substance identified as a High-Priority Substance through the Prioritization Process, which is addressed in a separate proposed rule.

H. Risk Evaluation General Provisions

1. *Agency guidance.* EPA has a number of existing guidance documents that inform Agency risk assessment.

EPA has been using risk assessments to characterize the nature and magnitude of health risks to humans and ecological receptors from chemical contaminants and other stressors that may be present in the environment since its inception. Over the years, EPA has worked with the scientific community and other stakeholders to develop a variety of guidance, guidelines, methods and models for use in conducting different kinds of assessments. A compendium of existing Agency guidance related to risk assessments is maintained at <https://www.epa.gov/risk/risk-assessment-guidelines>. A compendium of guidance, databases and models used for assessing pesticide risks is available at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks>, and information about available predictive models and tools for assessing chemicals under TSCA can be found at <https://www.epa.gov/tsc-screening-tools>. Each of these Web sites identify and link to a number of written guidance documents, tools and models. Rather than starting anew, EPA intends to take advantage of existing guidance, tools and models that are relevant and available for use in conducting a risk evaluation under this program.

Since the law requires the development of additional “policies, procedures, and guidance the Administrator determines are necessary” to carry out the process in TSCA (15 U.S.C. 2625(l)). EPA may also develop additional guidance(s) for risk evaluation in the future.

2. Categories of chemical substances. TSCA provides EPA with authority to take action on categories of chemical substances: groups of chemical substances which are, for example, similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment. Although the proposed rule most often references “chemical substances,” EPA is also proposing to include a clear statement in the regulation that nothing in the proposed rule shall be construed as a limitation on EPA’s authority to take action with respect to categories of chemical substances, and that, where appropriate, EPA can prioritize and evaluate categories of chemical substances.

3. Information and information sources. As discussed, the timeframe for completing risk evaluation is compressed. For those chemical substances chosen by EPA to undergo the risk evaluation process, EPA expects to only initiate the process when EPA has determined that most of the

information necessary to complete the evaluation is reasonably available, which in most cases means the information already exists. As appropriate, however, EPA will exercise its TSCA information collection, testing, and subpoena authorities, including those under TSCA sections 4, 8, and 11(c) to develop the information needed for a risk evaluation. Pursuant to TSCA section 8(e), the law requires that any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which supports the conclusion that this substance presents a substantial risk of injury to health or the environment, shall immediately inform the Agency.

To conduct a risk evaluation, EPA will rely on a combination of information, models, screening methods, and accepted science policies, which include defaults, reasonable estimates, and uncertainty factors, in addition to considering information generated from evolving science and technology. EPA expects to obtain scientific advice from the Science Advisory Committee on Chemicals, which the Agency is required to develop and convene under TSCA section 26(o). In compliance with the statute, EPA will work to reduce and replace, to the extent practicable, the use of vertebrate animals in testing chemical substances as outlined in TSCA section 4(h).

I. Risk Evaluation Steps

1. Scope. The first step of a risk evaluation is the development of the scope. In compliance with the statute, the scope will identify the conditions of use, hazards, exposures, and any potentially exposed or susceptible subpopulations that the EPA expects to consider. EPA is also proposing to include additional information in the scoping document, including any models, screening methods, and any accepted science policies expected to be used during the risk evaluation. EPA is further proposing to include a conceptual model that will describe the actual or predicted relationships between the chemical substance and the receptors, either human or environmental, with consideration of potential hazards throughout the life cycle of the chemical substance—from manufacturing, processing, distribution in commerce, storage, use, to release or disposal. Also included will be an analysis plan, which will identify the approaches and methods EPA plans to use to assess exposure, effects, and risk, including associated uncertainty and variability, as well as a strategy for

approaching science policy decisions (e.g., defaults or uncertainty factors).

The announced availability of the final scope will be published in the **Federal Register** within six months of the initiation of the risk evaluation. Although not required under the statute, EPA has proposed to provide a draft scope for a 45 calendar day public comment period during this six month period. EPA welcomes all public participation, but specifically encourages commenters to provide information they believe might be missing or may further inform the risk evaluation. That said, EPA expects to use the comment periods during the prioritization process to reduce the likelihood of significant comments on the draft scope. Consequently, the proposed rule makes clear that all comments that could be raised on information and approaches presented in the scope must be presented during this comment period. Any issues related to scope not raised in comments at this time cannot form the basis for an objection or challenge in a future administrative or judicial proceeding. This is a well-established principle of administrative law and practice, see, e.g., *Nuclear Energy Institute v. EPA*, 373 F.3d 1251, 1290–1291 (D.C. Cir. 2004), and the need for such a provision is reinforced by the statutory deadlines under which EPA must operate for completing TSCA risk evaluations. Note that EPA is not proposing to preclude parties from raising newly discovered information, or from raising issues that could not have been fairly raised during this comment period. Rather, EPA seeks merely to prevent parties from delaying the risk evaluation by withholding information or by providing it piecemeal.

2. Hazard assessment. In compliance with TSCA section 6(b)(4)(F), EPA is proposing that a hazard assessment be conducted on each chemical substance or category. A hazard assessment identifies the types of adverse health or environmental effects that can be caused by exposure to some agent in question, and to characterize the quality and weight of evidence supporting this identification. Hazard Identification is the process of determining whether exposure to a stressor can cause an increase in the incidence of specific adverse health or environmental effects (e.g., cancer, developmental toxicity).

This hazard assessment may include, but may not be limited to, evaluation of the potential toxicity of the chemical substance with respect to cancer, mutation, reproductive, developmental, respiratory, immune, metabolic, and cardiovascular impacts, and

neurological impairments. The assessment will evaluate effects at life stage(s) most appropriate for a receptor target. The hazard assessment will consider the dose or concentration and resulting effect or response. Potential information sources that may support the health assessment include but are not limited to: Human epidemiological studies; *in vivo* and/or *in vitro* laboratory studies; mechanistic or kinetic studies in a variety of test systems, including but not limited to toxicokinetics and toxicodynamics, computational toxicology; data from structure-activity relationships, high-throughput assays, genomic response assays, and ecological field data. Specifically, for human health hazards, the assessment will consider all potentially exposed or susceptible subpopulation(s) identified in the scope and use appropriate combination, if available, of population-based epidemiological studies, information related to geographic location of susceptible subpopulations, models representing health effects to the population, and any other relevant, scientifically valid information or methodology. In an environmental hazard assessment, the relationship between the chemical substance and the occurrence of an ecological response will be evaluated using field or laboratory data, modeling strategies, and species extrapolations.

Where possible, a hazard assessment also will include a dose-response assessment. A dose-response relationship describes how the likelihood and severity of adverse health effects (the responses) are related to the amount and condition of exposure to an agent (the dose provided). The same principles generally apply for studies where the exposure is to a concentration of the agent (*e.g.*, airborne concentrations applied in inhalation exposure studies or water or other media concentrations for ecological exposure studies), and the resulting information is referred to as the concentration-response.

3. Exposure assessment. Pursuant to TSCA section 6(b)(4)(F), EPA, where relevant, will take into account the likely duration, intensity, frequency, and number of exposures under the conditions of use in an exposure assessment. An exposure assessment includes some discussion of the size, nature, and types of individuals or populations exposed to the agent, as well as discussion of the uncertainties in this information. Exposure can be measured directly, but more commonly is estimated indirectly through consideration of measured

concentrations in the environment, consideration of models of chemical transport and fate in the environment, and estimates of human intake or environmental exposure over time.

Using reasonably available information, exposures will be estimated (usually quantitatively) for the identified conditions of use. For human health exposure, the assessment would consider all potentially exposed or susceptible subpopulation(s) identified in the scope and utilize any combination, as available, of population-based epidemiological studies, information related to geographic location of susceptible subpopulations, models representing exposures to the population, measurements in human tissues or relevant environmental or exposure media, and any other relevant, scientifically valid information or methodology. In an environmental health exposure assessment, the interaction of the chemical substance with any ecological characteristics identified in the scope will be characterized and evaluated.

4. Risk characterization. TSCA requires that a risk evaluation “integrate and assess available information on hazards and exposures”. (15 U.S.C 2605(b)(4)(F)). A risk characterization conveys the risk assessor’s judgment as to the nature and presence or absence of risks, along with information about how the risk was assessed, where assumptions and uncertainties still exist, and where policy choices will need to be made. Risk characterization takes place for both human health risk assessments and ecological risk assessments.

In practice, each component of the risk assessment (*e.g.* hazard assessment, dose-response assessment, exposure assessment) has an individual characterization written to carry forward the key findings, assumptions, limitations, and uncertainties. The set of these individual characterizations provide the information basis to write an integrative risk characterization analysis. The final, overall risk characterization thus consists of the individual component characterizations plus an integrative analysis.

Each risk evaluation will quantitatively and/or qualitatively estimate and characterize risk for the identified populations and ecological characteristics under the conditions of use. The risk characterization will also describe whether aggregate or sentinel exposures were considered and provide the evidence and information to support the consideration.

In the risk characterization, EPA will further carry out the obligations under TSCA section 26(h) (15 U.S.C 2625(h)); for example, by assessing uncertainty and variability in each step of the risk evaluation, discussing considerations of data quality such as the reliability, relevance and whether the methods utilized were reasonable and consistent, explaining any assumptions used, and discussing information generated from independent peer review. EPA also may exercise its discretion to include a discussion of any alternative interpretation of results generated from the risk evaluation. For environmental evaluations specifically, EPA plans to include a discussion of the nature and magnitude of the effects, the spatial and temporal patterns of the effects, implications at the individual, species, and community level, and the likelihood of recovery subsequent to exposure to the chemical substance.

5. Peer review. For each risk evaluations conducted on chemicals identified pursuant to TSCA section 6(b)(4)(A), EPA will conduct peer reviews using the guidance provided in executive branch peer review directives included in the Office of Management and Budget Final Information Quality Bulletin for Peer Review (OMB Bulletin) (Ref. 22) and the guidance set forth in the EPA Peer Review Handbook (2015) (Ref. 23) or its updates.

The goal of the peer review process is to obtain independent review from experts who have not contributed to its development. According to EPA’s peer review policy, peer review of all scientific and technical information that is intended to inform or support Agency decisions is encouraged and expected. Both the EPA Peer Review Handbook and the OMB Bulletin provide standards for when and how to conduct peer review on science documents. The documents do not contemplate that peer review is necessary for every document or risk assessment, but is expected to occur for those documents that have either:

- Influential scientific information: scientific information that the Agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions, or
- Highly influential scientific assessment: a subset of influential scientific information that could have a potential impact of more than \$500 million in any year on either the public or private sector or is novel, controversial, or precedent-setting, or has significant interagency interest.

The EPA Peer Review Handbook, first released in 1998 and last updated in

2015, has also been instrumental in providing guidance on the methods for conducting peer review at the Agency for the past two decades. According to the Handbook the peer review approach can consist of internal or external reviewers and can range from a letter review, an *ad hoc* expert panel review, review of a journal manuscript by a referred scientific journal, review by an established Federal Advisory Committee (FAC), review by an Agency-appointed special board or commission, or review by the National Academy of Science. Given that this guidance reflects longstanding and well-accepted EPA practices on peer review, and given the public's familiarity with it, the Agency is proposing to continue to rely on that established guidance, rather than attempt to modify it or create some new methodology in this rulemaking. As discussed earlier in this proposal, EPA will identify aspects of the analysis on which peer review will be conducted, and the planned methodologies, as part of the draft scoping document that will undergo public comment for each chemical substance that undergoes risk evaluation. These may include novel models or analyses that warrant an in-depth peer review. In addition to any targeted peer review of specific aspects of the analysis, the entire risk assessment will also undergo peer review, as it is important for peer reviewers to consider how the various underlying analyses fit together to produce an integrated risk characterization which will form the basis of an unreasonable risk determination.

The peer review will address aspects of the science underlying the assessment, including, but not limited to hazard assessment, assessment of dose-response, exposure assessment, and risk characterization. Please note, however, EPA will not seek review of any determination as to whether the risks are "unreasonable", which is an Agency policy judgement. The purpose of peer review is for independent review of the science underlying the risk assessment, not to evaluate EPA's policy judgments. TSCA expressly reserves to the Agency the final determination of whether risk posed by a chemical substance is "unreasonable." 15 U.S.C. 2605(i). EPA nevertheless will include its unreasonable risk judgment as part of the risk evaluation that is subject to public review and comment.

6. Unreasonable risk determination. The final step of a risk evaluation is for the EPA to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment. The EPA may find that

the substance does not present an unreasonable risk of injury to health or the environment under the conditions of use. This will be issued by order, published in the **Federal Register**, and considered to be a final EPA action. Alternatively, the EPA may determine that the substance does present an unreasonable risk under one or more conditions of use, in which case EPA must, pursuant to TSCA section 6(a) (15 U.S.C. 2605(a)), impose requirements to the extent necessary so that the substance no longer presents such risk.

EPA will announce in the **Federal Register** the availability of and solicit public comment on the draft risk evaluation, including the unreasonable risk determination. All comments that could be raised on components of the draft risk evaluation must be presented during this comment period. Any issues not raised during this time will be considered to have been waived, and may not form the basis for an objection or challenge in any subsequent administrative or judicial proceeding.

7. Additional publically available information. Pursuant to TSCA section 26(j), EPA will make available: (1) All notices, determinations, findings, consent agreements, and orders; (2) any information required to be provided by the EPA under 15 U.S.C. 2603; (3) a nontechnical summary of the risk evaluation; (4) a list of the studies with the results of the studies, considered in carrying out each risk evaluation; and (5) the final peer review report, including the response to peer review comments.

8. Reassessment of unreasonable risk determination. EPA may reassess a final unreasonable risk determination of a chemical substance at any time based on information available to the Agency.

IV. Request for Comments

While EPA is seeking public comment on all aspects of this proposed rule, there are areas where the Agency specifically requesting public input.

1. Redefining scientific terms. EPA received a number of stakeholder comments regarding EPA's approach to defining a number of important terms within this rule. These terms include "best available science", "weight-of-the-evidence", "sufficiency of information", "unreasonable risk", and "reasonably available information" among others. Many of the terms used in the proposed rule are not novel concepts and are already in use and the meaning of which is discussed extensively in existing Agency guidance. For example, extensive descriptions for the phrases "best available science", "weight-of-the-evidence", and "sufficiency of

information" can be found in EPA's Risk Characterization Handbook (Ref. 24), and in other existing Agency guidance.

EPA believes further defining these and other terms in the proposed rule is unnecessary and ultimately problematic. These terms have and will continue to evolve with changing scientific methods and innovation. Codifying specific definitions for these phrases in this rule may inhibit the flexibility of the Agency to quickly adapt and implement changing science. The Agency intends to use existing guidance definitions and will update definitions and guidance as necessary.

However, the Agency welcomes public comments regarding the pros and cons of codifying these or other definitions and/or approaches for these or any other terms. EPA encourages commenters to suggest alternative definitions the Agency should consider for codification in this procedural rule. Please explain your views as clearly as possible, providing specific examples to illustrate your concerns and suggest alternate wording, where applicable. EPA is specifically requesting comments on whether EPA should define unreasonable risk in the final rule. If so, acknowledging that the statute precludes consideration of costs and other non-risk factors at this step, what factors should EPA consider in making such a determination.

2. Margin of exposure. EPA currently uses a margin-of-exposure (MOE) approach in risk characterization of TSCA risk assessments. Please comment on the strengths and weaknesses of the MOE approach. Are there other approaches (e.g. use of hazard indices, use of probabilistic risk assessment) that might better suit the TSCA Risk Evaluation Program? Are there other approaches that provide quantifiable non-cancer risks?

3. Systematic Review. While EPA has included a systematic review approach in the past, and intends to continue to do so, please comment on the need for regulatory text prescribing a specific systematic review approach for hazard identification, including the appropriateness of elements that might be included or concerns about codifying an approach.

4. Manufacturer Requests. EPA anticipates that some chemical substances prioritized for risk evaluation have been manufactured by persons who possess unpublished information that could impact the chemical's risk determination. For chemical substances prioritized for risk evaluation, the Agency generally expects to exercise, as needed, among

other authorities, its information-gathering authority pursuant to 15 U.S.C. 2607(a) and 2607(d), likely very early in the process. EPA is specifically requesting comment on approaches to utilizing its information gathering authorities to assure that EPA has the most complete information to make its risk determination. For example, one option might be to incorporate its 15 U.S.C. 2607(a) and 2607(d) authority into the "Information and information sources" section of this rule to allow EPA to require, by notice in the **Federal Register**, manufacturers with information subject to 15 U.S.C. 2607(a)(2) and 2607(d) to submit that information to EPA for use in a risk evaluation. EPA is requesting comment on this option and on any more effective alternative methods to exercise this authority within the rule to assure the completeness of the information relevant to the risk evaluation.

The Agency also anticipates the possibility that one manufacturer requests a risk evaluation but other manufacturers of the same chemical who have not joined in the request also possess relevant unpublished information. For manufacturer requests for risk evaluation, the burden is on the requester to include or reference all information that is necessary for EPA to conduct a risk evaluation. Although EPA could use its data collection authority to access information, including unpublished studies, held by entities other than the requestor, the Agency intends to deny requests for risk evaluation if the requester does not have access to the information necessary for risk evaluation.

5. *Peer Review.* As discussed in both the OMB Bulletin and the EPA Peer Review Handbook, there are specific exemption criteria for information that does not necessitate peer review, even if it might be considered to be influential or highly influential. A number of specific circumstances where peer review is not necessary are discussed in section 3.3 of the EPA Peer Review Handbook. Examples of these circumstances include information involving a health or safety issue where the Agency determines that the dissemination is time-sensitive or if an application of an adequately peer-reviewed work product does not depart significantly from its scientific or technical approach. In addition, EPA expects that there will be individual circumstances where a chemical substance is found to not present an unreasonable risk or that findings are similar or the same as other jurisdictions (states or countries) that have reached similar conclusions based

on the same information, such that the Agency could determine that peer review is not necessary for that chemical risk evaluation.

EPA expects that many of the risk evaluations conducted under TSCA will necessitate peer review. In cases in which a chemical substance is determined to present an unreasonable risk, the Agency must promptly move to manage the risk, a circumstance that would typically qualify the assessment as "influential scientific information" under current guidance and practice. The Agency also expects that some risk evaluations would also be highly influential scientific assessments, *e.g.*, contain novel, controversial, or precedent-setting science with significant interagency interest. EPA also expects that peer review will be warranted in many cases where the Agency determines a chemical substance does not present an unreasonable risk. Aspects of the evaluation may qualify as influential scientific information or highly influential scientific assessment, and thus warrant peer review. Other circumstances where the Agency may determine that peer review is warranted could include circumstances where there are existing private sector standards suggesting concern for a given chemical substance, where existing state assessments differ from the EPA evaluation, or where the public has expressed general concern about the chemical substances effects.

As required under the amended TSCA, chemical substances must be prioritized as either low or high. Those categorized as high are subject to a risk evaluation, and those determined to be low are not. The bar for prioritizing a chemical as a low priority as required under the amended TSCA is fairly high. As such, EPA expects that, as an increasing number of chemical risk evaluations are completed, those chemical substances that present risk to human health or the environment will be managed accordingly, leaving an increasing number of chemicals that do not present an unreasonable risk. The Agency questions whether all future risk evaluations warrant peer review.

EPA is specifically requesting public comment on whether there are circumstances where conducting peer review may not be warranted. What circumstances might qualify, and whether the regulatory text should be adjusted to require EPA to make a case by case determination of whether and to what extent, consistent with the EPA Peer Review Handbook, peer review is warranted for the chemical substance undergoing a risk evaluation. In all

cases, the rule would require that this determination, and any peer review activities that are conducted, be documented for each chemical evaluation, starting with the scope document.

6. *Reliance on existing guidance and procedures for conducting risk evaluations.* As discussed in Unit III.G.1., EPA intends to take advantage of existing guidance, tools and models that are relevant and available for use in conducting a risk evaluation under this program. Since each risk evaluation is based on the specific circumstances surrounding the chemical being assessed, EPA has not attempted to codify any specific guidance, method or model. EPA believes that this is necessary to ensure that there is flexibility to address potentially unique circumstances on a chemical basis. EPA is interested in your comments about this approach, and where there is any existing guidance that may be of particular interest for consideration in conducting these risk evaluations. Additionally, EPA asks if the current guidance documents are sufficient and whether there are additional guidance documents that should be relevant but may not be on the lists available on EPA's Web site (<https://www.epa.gov/risk/risk-assessment-guidelines>). Finally, should EPA consider requiring that a list of appropriate guidance documents be included on a case-by-case basis as part of the scoping document that undergoes public review and comment.

7. *Interagency collaboration.* As discussed in Unit III.B., EPA is committed to ensuring there is interagency engagement and dialogue throughout its risk evaluation process, and has chosen not to limit the potential interagency collaboration by proposing to codify any particular process. EPA is concerned that imposing a single, pre-determined consultation step might lead to an overly bureaucratic process that could limit or complicate ongoing collaboration efforts, and so is not proposing to codify any particular process in this regulation. However, EPA is requesting specific public comment on whether codifying this collaboration at a specific point in the regulation is necessary.

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included

in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. USEPA. Information Collection Request (ICR) for the Proposed Rule: Procedures for Chemical Risk Evaluation Under TSCA. EPA ICR No.: 2559.01 and OMB No. 2070—[NEW].
2. EPA. TSCA Work Plan Chemical Assessments: 2014 Update-Final. Office of Pollution Prevention and Toxics. October 2014. https://www.epa.gov/sites/production/files/2015-01/documents/tscaworkplanchemicals_2014_update-final.pdf.
3. National Research Council. Science and Decisions: Advancing Risk Assessment. The National Academies Press. Washington, DC 2009. http://www.nap.edu/catalog.php?record_id=12209.
4. EPA. Guidelines for Carcinogen Risk Assessment. Risk Assessment Forum, Washington, DC. EPA/630/P-03/001F. Washington, DC 2005. https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.
5. EPA. Guidelines for Carcinogen Risk Assessment, Review Draft, CEA-F-0644, Office of Research and Development. Washington, DC 1999. <http://cfpub.epa.gov/ncea/raf/cancer.cfm>.
6. EDSTAC. Endocrine Disruptor Screening and Testing Advisory Committee, Final Report, Volume I-II. Washington, DC 1998. <http://www.epa.gov/scipoly/oscpdocs/pubs/edspoverview/finalrpt.htm>.
7. EPA. Endocrine Disruptor Screening Program; Weight-of-Evidence: Evaluating Results of EDSP Tier 1 Screening to Identify the Need for Tier 2 Testing. Washington, DC 2011. <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2010-0877-0021>.
8. EPA. Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum. Washington, DC March 2007.
9. National Research Council. Risk Assessment in the Federal Government: Managing the Process. The National Academies Press. Washington, DC 1983. <http://www.nap.edu/openbook.php?isbn=0309033497>.
10. National Research Council. Science and Judgment in Risk Assessment. The National Academies Press. Washington, DC 1994. http://www.nap.edu/catalog.php?record_id=2125.
11. National Research Council. Understanding Risk: Informing Decisions in a Democratic Society. The National Academies Press. Washington, DC 1996. <http://www.nap.edu/openbook.php?isbn=030905396X>.
12. National Research Council. Toxicity Testing in the 21st Century: A Vision and a Strategy. The National Academies Press. Washington, DC 2007. http://www.nap.edu/catalog.php?record_id=11970.
13. National Research Council. Phthalates and Cumulative Risk Assessment: The Tasks Ahead. National Academy Press. Washington, DC 2008. http://www.nap.edu/catalog.php?record_id=12528.
14. USEPA. Policy on Evaluating Health Risks to Children. 1995. https://www.epa.gov/sites/production/files/2014-05/documents/1995_childrens_health_policy_statement.pdf.
15. USEPA. Guidelines for Developmental Toxicity Risk Assessment. EPA/600/FR-91/001. Risk Assessment Forum. Washington, DC 1991. <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=23162>.
16. USEPA. Guide to Considering Children's Health When Developing EPA Actions: Implementing Executive Order 13045 and EPA's Policy on Evaluating Health Risks to Children. Office of Policy, Economics and Innovation. Washington, DC 2006. [http://yosemite.epa.gov/oehp/ochpweb.nsf/content/ADPguide.htm/\\$File/EPA_ADG_Guide_508.pdf](http://yosemite.epa.gov/oehp/ochpweb.nsf/content/ADPguide.htm/$File/EPA_ADG_Guide_508.pdf).
17. USEPA. Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants. Final. EPA/630/P-03/003F. Risk Assessment Forum. Washington, DC 2005. <http://www.epa.gov/raf/publications/guidance-on-selecting-age-groups.htm>.
18. USEPA. Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens. EPA/630/R-03/003F. Risk Assessment Forum. Washington, DC 2005. http://www.epa.gov/ttn/atw/childrens_supplement_final.pdf.
19. USEPA. A Framework for Assessing Health Risk of Environmental Exposures to Children. Final. EPA/600/R-05/093F. Office of Research and Development, National Center for Environmental Assessment. Washington, DC 2006. <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=158363>.
20. USEPA. Exposure Factors Handbook. EPA/600/R-09/052F. Office of Research and Development, National Center for Environmental Assessment. Washington, DC 2011. <https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252>.
21. USEPA. Framework for Human Health Risk Assessment to Inform Decision Making. EPA/100/R-14/001. Office of the Science Advisor, Risk Assessment Forum. 2014. <https://archive.epa.gov/raf/web/pdf/hhra-framework-final-2014.pdf>.
22. Office of Management and Budget Final Information Quality Bulletin for Peer Review.
23. USEPA. Peer Review Handbook. 3rd ed. EPA/100/B-06/002. Science Policy Council. Washington, DC 2006. <https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015>.
24. Risk Characterization Handbook. Science Policy Council Handbook: Risk Characterization, EPA 100-B-00-002, Washington, DC December 2000. <https://www.epa.gov/risk/risk-characterization-handbook>.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket.

B. Paperwork Reduction Act (PRA)

The information collection activities associated with this proposed rule have been submitted to OMB for review and approval under the PRA, 44 U.S.C. 3501 *et seq.* Specifically, EPA has prepared an ICR to estimate the potential burden and costs associated with the proposed requirements for submitting a request for an Agency-conducted risk evaluation on a particular chemical substance. The ICR, which is available in the docket, has been assigned the EPA ICR number 2559.01. You can find a copy of the ICR in the docket for this proposed rule (Ref. 1), and it is briefly summarized here.

Respondents/affected entities: Manufacturers (including importers).

Respondent's obligation to respond: Optional, *i.e.*, needed only if they are requesting an EPA-conducted risk evaluation for a particular chemical substance.

Estimated number of respondents: 10.

Frequency of response: On occasion.

Total estimated annual burden: 960.3 hours. Burden is defined in 5 CFR 1320.3(b).

Total estimated annual cost: \$69,353 for burden hours. There are no M&O costs.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this proposed rule. You may also send your ICR-related comments to OMB's Office of

Information and Regulatory Affairs via email to oir_submission@omb.eop.gov, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 calendar days after receipt, OMB must receive comments no later than February 21, 2017. Any ICR-related comments will be addressed with the final rule.

C. Regulatory Flexibility Act (RFA)

EPA certifies under section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, that this action will not have a significant economic impact on a substantial number of small entities. Although this proposed rule primarily addresses internal EPA procedures and activities associated with conducting risk evaluations for chemical substances as required by TSCA, EPA is also proposing the process and content requirements for a manufacturer (including importer) to request that EPA conduct a risk evaluation on a particular chemical substance. EPA has determined that the process and content requirements proposed will have minimal impact on an entity, regardless of size, because there is no mandate for them to make such a request, and the information they must provide should they decide to make such a request, which involves basic information about the chemical substance and the manufacturer's reasons for requesting the EPA-conducted risk evaluation on that chemical substance, should be readily available to the manufacturer. Estimated potential burden and costs are presented in the ICR (Ref. 1).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive

Order 13175 (65 FR 67249, November 9, 2000). It will not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a “significant energy action” as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve any technical standards, and is therefore not subject to considerations under NTTAA section 12(d), 15 U.S.C. 272 note.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not establish an environmental health or safety standard, and is therefore not subject to environmental justice considerations under Executive Order 12898 (59 FR 7629, February 16, 1994). This is procedural rule that will not affect the level of protection provided to human health or the environment.

List of Subjects in 40 CFR Part 702

Environmental protection, Chemicals, Chemical Substance, Hazardous substances, Health and safety, Risk Evaluation.

Dated: January 12, 2017,

Gina McCarthy,
Administrator.

Therefore, it is proposed that 40 CFR chapter I, subchapter R, be amended as follows:

PART 702—GENERAL PRACTICES AND PROCEDURES

■ 1. The authority citation for part 702 is revised to read as follows:

Authority: 15 U.S.C. 2605 and 2619.

■ 2. Add subpart B to part 702 to read as follows:

Subpart B—Procedures for Chemical Substance Risk Evaluations

Sec.

- 702.31 General provisions.
- 702.33 Definitions.
- 702.35 Chemical substances designated for risk evaluation.
- 702.37 Submission of manufacturer requests for risk evaluations.
- 702.39 Evaluation requirements.
- 702.41 Risk characterization and peer review procedures.
- 702.43 Unreasonable risk determination.
- 702.45 Risk Evaluation timeframes and actions.
- 702.47 Publicly available information.

§ 702.31 General provisions.

(a) *Purpose.* This subpart establishes the EPA process for conducting a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment as required under TSCA section 6(b)(4)(B) (15 U.S.C. 2605(b)(4)(B)).

(b) *Scope.* These regulations establish the general procedures, key definitions, and timelines EPA will use in a risk evaluation conducted pursuant to TSCA section 6(b) (15 U.S.C. 2605(b)).

(c) *Applicability.* The requirements of this part apply to all chemical substance risk evaluations initiated pursuant to TSCA section 6(b) (15 U.S.C. 2605(b)).

(d) *Enforcement.* Submission to EPA of inaccurate, incomplete, or misleading information by a manufacturer pursuant to a risk evaluation conducted pursuant to 15 U.S.C. 2605(b)(4)(B) is a prohibited act under 15 U.S.C. 2614, subject to penalties under 15 U.S.C. 2615 and Title 18 of the U.S. Code.

§ 702.33 Definitions.

All definitions in TSCA apply to this subpart. In addition the following definitions apply:

Act means the Toxic Substances Control Act, as amended (15 U.S.C. 2601 *et seq.*).

Aggregate exposure means the combined exposures to an individual

from a single chemical substance across multiple routes and across multiple pathways.

EPA means the U.S. Environmental Protection Agency.

Pathways means the mode through which one is exposed to a chemical substance, including but not limited to: Food, water, soil, and air.

Potentially exposed or susceptible subpopulation means a group of individuals within the general population identified by the Agency who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, including but not limited to, infants, children, pregnant women, workers, or the elderly. EPA may identify a susceptible subpopulation in an individual risk evaluation upon consideration of various intrinsic (e.g., life stage, reproductive status, age, gender, genetic traits) or acquired (e.g., pre-existing disease, geography, workplace) characteristics that may affect exposure or modify the risk of illness or disease.

Reasonably available information means existing information that EPA possesses or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation.

Routes means the particular manner which a chemical substance may contact the body, including absorption via ingestion, inhalation, or dermally (integument).

Sentinel exposure means the exposure(s) of greatest significance, which may be the plausible maximum exposure to an individual, population (or subpopulation), or the environment to the chemical substance of interest (or any combination thereof).

Uncertainty means the imperfect knowledge or lack of precise knowledge either for specific values of interest or in the description of a system.

Variability means the inherent natural variation, diversity, and heterogeneity across time and/or space or among individuals within a population.

§ 702.35 Chemical substances designated for risk evaluation.

(a) *Chemical Substances Undergoing Risk Evaluation.* A risk evaluation for a chemical substance designated by the Agency as a High-Priority Substance pursuant to the prioritization process described in subpart A, identified under 15 U.S.C. 2605(b)(2)(A), or initiated at the request of a manufacturer or manufacturers under 40 CFR 702.37,

will be conducted in accordance with this part, except that risk evaluations that are initiated prior to the effective date of this rule will be conducted in accordance with this part to the maximum extent practicable.

(b) *Percentage Requirements.* The Agency will ensure that, of the number of chemical substances that undergo risk evaluation under 15 U.S.C. 2605(b)(4)(C)(i), the number of chemical substances undergoing risk evaluation under 15 U.S.C. 2605(b)(4)(C)(ii) is not less than 25%, if sufficient requests that comply with 40 CFR 702.37 are made by manufacturers, and not more than 50%.

(c) *Manufacturer Requests for Work Plan Chemical Substances.* Manufacturer requests for risk evaluations, described in 40 CFR 702.35(a), for chemical substances that are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or its relevant and applicable successor document will be granted at the discretion of the Agency. Such evaluations are not subject to the percentage requirements in 40 CFR 702.35(b).

§ 702.37 Submission of manufacturer requests for risk evaluations.

(a) *General Provision.* Any request for EPA to conduct a risk evaluation on a chemical substance pursuant to this part must comply with all the procedures and criteria in this section to be eligible to be granted by EPA. A request will meet EPA's criteria if the request includes or references all the information that is necessary for EPA to conduct a risk evaluation addressing all the circumstances that constitute conditions of use of the chemical substance within the meaning of TSCA section 3 (i.e., all circumstances under which the chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of).

(b) *Method for Submission.* One or more manufacturers of a chemical substance can request that EPA conduct a risk evaluation on the chemical substance by providing all the following information:

(1) Name, mailing address, and contact information of the entity (or entities) submitting the request. If more than one manufacturer submits the request, all individual manufacturers must provide their contact information.

(2) Full information on the chemical identity of the chemical substance that is the subject of the request. At a minimum, this includes, all known names of the chemical substance, including common or trades names,

chemical identity, CAS number, and molecular structure of the chemical substance.

(3) A complete list of the reasonably available information that is consistent with the standards in TSCA section 26(h) and that is relevant to whether the chemical substance presents an unreasonable risk of injury to health or the environment. The list must be accompanied by an explanation as to why such information is adequate to permit EPA to complete a risk evaluation addressing all the circumstances that constitute conditions of use of the chemical substance within the meaning of TSCA section 3 (i.e., all circumstances under which the chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of). The request need not include copies of the information; citations are sufficient. The request must include or reference all reasonably available information on the health and environment hazard(s) of the chemical substance, health and environmental exposure(s), and exposed population(s). At a minimum this must include information relevant to the following:

- (i) The chemical substance's hazard and exposure potential;
- (ii) The chemical substance's persistence and bioaccumulation;
- (iii) Potentially exposed or susceptible subpopulations they believe to be relevant and that EPA should evaluate in the risk evaluation;
- (iv) Whether there is any storage of the chemical substance near significant sources of drinking water;
- (v) The chemical substance's conditions of use or significant changes in conditions of use;
- (vi) The chemical substance's production volume or significant changes in production volume; and
- (vii) Any other information relevant to the risks potentially presented by the chemical substance.

(4) The request must include a commitment to provide to EPA any referenced information upon request. In addition, if the manufacturer previously conducted its own risk assessment of the chemical substance, or possesses or can reasonably obtain any other pre-existing risk assessment, the request must include a commitment to provide such assessments to EPA upon request.

(5) A signed certification that all information contained in the request is accurate and complete, as follows:

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision and the information contained therein, to the best of

my knowledge is, true, accurate, and complete and I have not withheld any relevant information. I am aware there are significant penalties for submitting incomplete, false and/or misleading information, including the possibility of fine and imprisonment for knowing violations.

(c) *Optional Elements.* A manufacturer may provide evidence to demonstrate that restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce or health or the environment, and that as a consequence the request is entitled to preference pursuant to 15 U.S.C. 2605(b)(4)(E)(iii).

(d) *Confidential Business Information.* (1) Persons submitting a request under this subpart are subject to EPA confidentiality regulations at 40 CFR part 2, subpart B.

(2) In submitting a claim of confidentiality, a person must certify the truth of the following statements concerning all information claimed as confidential:

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate. I further certify that, pursuant to 15 U.S.C. 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

(i) My company has taken reasonable measures to protect the confidentiality of the information;

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and

(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

(3) Each claim of confidentiality, other than a claim pertaining to information described in TSCA section 14(c)(2), must be accompanied by a substantiation in accordance with 40 CFR 2.204(e)(4).

(4) Manufacturers must supply a structurally descriptive generic name where specific chemical identity is claimed as CBI.

(5) Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. 1001.

(e) *EPA Process for Evaluating Manufacturer Requests.* (1) *Review for completeness.* Upon receipt of the request, EPA will verify that the request is facially valid, *i.e.*, that information has been submitted that is consistent with the requirements in 40 CFR 702.37(b) through (d). EPA will inform

the submitting manufacturer(s) if EPA has determined that the request is incomplete and cannot be processed. Complete requests will be processed as described in this subpart.

(2) *Public notice and comment.* Within 30 business days of receiving a request that EPA has determined to be valid under paragraph (e)(1) of this section, EPA will submit for publication the receipt of the request in the **Federal Register**, open a docket for that request and provide no less than a 30 calendar day public comment period, during which time the public may submit comments and information relevant to whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use. In particular, comments identifying any information gaps in the request (*e.g.*, any conditions of use not identified in the request).

(3) *Supplementation of original request.* (i) At any time prior to the end of the comment period, manufacturer(s) may supplement the original request with any new information it receives/obtains.

(ii) At any point prior to the completion of a risk evaluation conducted on a chemical substance at the request of a manufacturer(s), manufacturer(s) are required to supplement the original request upon receipt of information that meets the criteria in 15 U.S.C. 2607(e) and 40 CFR 702.37, or other information that has the potential to change EPA's evaluation of the risk of the chemical substance. Such information must be submitted within 30 calendar days of discovery.

(4) *EPA determination.* Within 9 months of the end of the comment period provided in paragraph (e)(2) of this section, EPA will review the request along with any additional information received during the comment period to determine whether the request meets the criteria and requirements of 40 CFR 702.37. EPA will notify the submitting manufacturer(s) of its determination.

(i) *Request is lacking required information.* (A) The manufacturer(s) have 60 calendar days from receipt of EPA's determination to submit any additional information identified as lacking in the notification.

(B) Failure to submit the additional information will be considered to be a withdrawal of the request to initiate a risk evaluation on the named chemical substance.

(C) Notwithstanding any such withdrawal, manufacturer(s) may submit a subsequent request on the same chemical substance.

(ii) *Compliant request.* EPA will initiate a risk evaluation for all requests

for non-TSCA Work Plan Chemicals that meet the criteria in this subpart, until EPA determines that the number of manufacturer-requested chemical substances undergoing risk evaluation is equal to 25% of the High-Priority Substances identified in subpart A as undergoing risk evaluation. Once that level has been reached, EPA will initiate one new manufacturer-requested risk evaluation for each manufacturer-requested risk evaluation completed, as needed to ensure that the number of manufacturer-requested risk evaluations is equal to at least 25% of the High-Priority substances risk evaluation.

(5) *Preferences.* In conformance with 40 CFR 702.35(c), in evaluating requests for TSCA Work Plan Chemicals and requests for non-TSCA Work Plan chemicals in excess of the 25% threshold in paragraph (e)(4)(ii) of this section, EPA will give preference to requests for risk evaluations on chemical substances:

(i) That demonstrate that restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce, health or the environment.

(ii) EPA will also give preference to requests where EPA has determined there are relatively high estimates of hazard and/or exposure for the chemical substance.

(iii) Any other factor EPA determines to be relevant.

(6) *Conditions of use considered.* EPA will conduct the risk evaluation on all of the conditions of use of a chemical substance undergoing risk evaluation at the request of a manufacturer, as determined through the scoping process outlined in 40 CFR 702.39(c).

(7) *No preferential treatment.* EPA will not expedite or otherwise provide special treatment to a risk evaluation conducted as a result of a manufacturer request.

(f) *Fees.* Manufacturers must pay fees to support risk evaluations under 15 U.S.C. 2605(b)(4)(C)(ii).

§ 702.39 Evaluation Requirements and Peer Review Procedures.

(a) *Considerations.* (1) Each risk evaluation will include the following components: a Scope, including a Conceptual Model and an Analysis Plan; a Hazard Assessment; an Exposure Assessment; a Risk Characterization; and a Risk Determination.

(2) Existing EPA guidance, where available and relevant, will be used in conducting the risk evaluation. In addition, other scientifically relevant methods or guidance may be used in a risk evaluation.

(3) Where appropriate, a risk evaluation may be conducted on a category of chemical substances. EPA will determine whether to conduct an evaluation on a category of chemical substances, and the composition of the category based on the considerations listed in 15 U.S.C. 2625(c). In addition to the factors specifically enumerated in that provision, EPA may consider the hazards and exposures associated with the category of chemical substances, and the populations likely to be exposed.

(4) EPA will ensure that all supporting analyses and components of the risk evaluation are suitable for their intended purpose, and well-tailored to the problems and decision at hand, in order to inform the development of a technically sound determination as to whether a chemical substance presents an unreasonable risk of injury to health or the environment, based on the weight of the scientific evidence.

(5) The extent to which EPA will refine its evaluations for particular conditions of use in any risk evaluation will vary as necessary to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment. To the extent a determination as to the level of risk presented by a condition of use can be made, for example, by the use of accepted science policies (e.g., defaults assumptions or uncertainty factors), and models or screening methodologies, EPA may determine that no further information or analysis is needed to complete its risk evaluation of the use(s).

(6) EPA may conduct a risk evaluation on a chemical substance in phases to allow the Agency to proceed with risk management on particular conditions of use. For example, EPA may determine that a chemical substance presents an unreasonable risk of injury to health or the environment under one or more conditions of use, and address such unreasonable risk through rulemaking under TSCA section 6(a), while other conditions of use remain under evaluation. In all cases in which EPA conducts its risk evaluations in phases, EPA will nevertheless complete a full risk evaluation of the chemical substance for all of the conditions of use identified through the scoping process in 40 CFR 702.39(c) within the time frame in 40 CFR 702.43(d).

(7) In evaluating chemical substances that are metals or metal compounds, EPA will use the *Framework for Metals Assessment of the Office of the Science Advisor, Risk Assessment Forum* dated March 2007, or a successor document that addresses metal risk assessment

and is peer reviewed by the Science Advisory Board.

(b) *Information and information sources.* (1) EPA will base each risk evaluation on reasonably available information.

(2) EPA generally expects to initiate a risk evaluation for a chemical substance only when EPA believes that all or most of the information necessary to perform the risk evaluation already exists and is reasonably available. EPA expects to use its authorities under the Act, and other information gathering authorities, when necessary to generate the information needed to perform a risk evaluation for a chemical substance before initiating the risk evaluation for such substance. EPA will use such authorities on a case-by-case basis during the performance of a risk evaluation to obtain or generate information as needed to ensure that EPA has adequate, reasonably available information to perform the evaluation.

(3) Among other sources of information, the Agency will consider information and advice provided by the Science Advisory Committee on Chemicals established pursuant to 15 U.S.C. 2625.

(4) In conducting risk evaluations, EPA will rely on an appropriate combination of information, accepted science policies (e.g., defaults and uncertainty factors), models and screening methodologies. The balance of information, accepted science policies models, and screening methodologies used in risk evaluation will be informed by the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluations. It will also be informed by consideration of the extent to which additional information would reduce the uncertainty in determining whether a chemical substance presents an unreasonable risk of injury to health or the environment.

(5) Where appropriate, to the extent practicable, and scientifically justified, EPA will use information generated without the use of testing on vertebrates in performing risk evaluation.

(c) *Scope of the risk evaluation.* EPA will determine the scope of the risk evaluation to be conducted for each chemical substance based on all of the following:

(1) EPA will identify those uses that constitute the conditions of use that will be assessed during the risk evaluation. Those uses shall be all circumstances under which the Agency determines that the chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

(2) When determining the scope, EPA will identify the exposed individuals

and populations, including any potentially exposed or susceptible subpopulations as identified by the Agency that EPA plans to evaluate; the ecological characteristics that EPA plans to evaluate; and the hazards to health and the environment that EPA plans to evaluate.

(3) The combination of reasonably available information, accepted science policies (e.g., defaults and uncertainty factors), models, and screening methodologies that EPA plans to use in the risk evaluation will be documented.

(4) *Conceptual model.* (i) The scope documents will include a Conceptual Model that describes actual or predicted relationships between the chemical substance and human and environmental receptors.

(ii) The Conceptual Model will identify human and ecological health endpoints the EPA plans to evaluate for the exposure scenarios EPA plans to evaluate.

(iii) Conceptual Model development will consider the life cycle of the chemical substance, including manufacture, processing, distribution in commerce, storage, use, and disposal.

(5) *Analysis plan.* (i) The scope documents will include an analysis plan that identifies the approaches, methods, and/or metrics that the EPA plans to use to assess exposures, effects, and risk, including associated uncertainty and variability for each risk evaluation. The analysis plan will also identify the strategy for using information, accepted science policies, models, and screening methodologies.

(ii) Hypotheses about the relationships described in the conceptual model will be described. The relative strengths of (any) competing hypotheses will be evaluated to determine the appropriate risk assessment approaches.

(6) *Developing the Scope.* (i) *Draft scope.* For each risk evaluation to be conducted EPA will publish a document in the **Federal Register** that specifies the draft scope of the risk evaluation the Agency plans to conduct. The document will address the elements in paragraphs (c)(1) through (5) of this section.

(ii) *Timeframes.* EPA generally expects to publish the draft scope no later than 3 months from the initiation of the risk evaluation process for the chemical substance, and to allow a period of 30 calendar days during which interested persons may submit comment on EPA's draft risk evaluation scope. EPA will open a docket to facilitate receipt of public comments.

(iii) *Public comments.* All comments that could be raised on the matters addressed and issues presented in the

published risk evaluation scope document must be presented during this comment period. Any issues not raised at this time will be considered to have been waived, and may not form the basis for an objection or challenge in any subsequent administrative or judicial proceeding.

(iv) *Final scope.* (A) The Agency will, no later than 6 months after the initiation of a risk evaluation, publish a document in the **Federal Register** that specifies the final scope of the risk evaluation the Agency plans to conduct. The document shall address the elements in paragraphs (c)(1) through (5) of this section.

(B) For a chemical substance designated as a High-Priority Substance under 40 CFR part 702 subpart A, EPA will not publish the final scope of the risk evaluation until at least 12 months have elapsed from the initiation of the prioritization process for the chemical substance.

(d) *Hazard assessment.* (1) The hazard information relevant to the chemical substance will be evaluated using endpoints identified in the final scope document published pursuant to paragraph (c)(6)(iv) of this section, for the identified exposure scenarios, including any identified potentially exposed or susceptible subpopulation(s).

(2) The hazard assessment process will identify the types of hazards to health or the environment posed by the chemical substance. This process includes the identification, evaluation, and synthesis of information to describe the potential health effects of the chemical substance.

(3) Based on the final scope document published pursuant to paragraph (c)(6)(iv) of this section, potential human and environmental hazard endpoints will be evaluated, including, as appropriate; acute, subchronic, and chronic effects during various stages of reproduction or life stage.

(4) The relationship between the dose of the chemical substance and the occurrence of human and environmental health effects or outcomes will be evaluated.

(5) Studies evaluated may include, but would not be limited to: Human epidemiological studies, in vivo and/or in vitro laboratory studies, mechanistic or kinetic studies in a variety of test systems, including but not limited to toxicokinetics and toxicodynamics, computational toxicology, data from structure-activity relationships, high-throughput assays, genomic response assays, and ecological field data.

(6) Hazard identification will include an evaluation of the strengths and

limitations of the reasonably available information.

(7) *Human health hazard assessment.* The hazard assessment will consider all potentially exposed and susceptible subpopulation(s) determined to be relevant, as identified in the final scope document published pursuant to paragraph (c)(6)(iv) of this section. Reasonably available information used to characterize risk to susceptible subpopulation(s) may include, but may not be limited to:

(i) Population-based epidemiology studies that identify risk factors and susceptible subpopulations;

(ii) Information related to geographic location of subpopulations;

(iii) Models that represent health effects of relevant subpopulations; and

(iv) Any other relevant, scientifically valid information, methodology, or extrapolation.

(8) *Environmental health hazard assessment.* The relationship between the chemical substance and the occurrence of an ecological hazard elicited will be evaluated using reasonably available information including but not limited to: Field or laboratory measurements, modeling strategies, extrapolations or incident data.

(e) *Exposure assessment.* (1) Where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use will be considered.

(2) For the conditions of use, exposures will be evaluated using reasonably available information.

(3) Chemical-specific factors including, but not limited to: Physical-chemical properties and environmental fate parameters will be examined.

(4) *Human health exposure assessment.* The exposure assessment will consider all potentially exposed and susceptible subpopulation(s) determined to be relevant, as identified in the final scope document published pursuant to paragraph (c)(6)(iv) of this section. Reasonably available information used to characterize exposure to susceptible subpopulation(s) may include:

(i) Population-based epidemiology studies that identify risk factors and susceptible subpopulations;

(ii) Information related to geographic location of subpopulations;

(iii) Models that represent exposure or health effects of relevant subpopulations; and

(iv) Any other relevant, scientifically valid information or methodology.

(5) *Environmental health exposure assessment.* (i) The environmental health exposure assessment will

characterize and evaluate the interaction of the chemical substance with the ecological characteristics identified in the final scope document published pursuant to paragraph (c)(6)(iv) of this section.

(ii) Exposures considered will include individuals as well as communities, depending on the chemical substance and the ecological characteristic involved.

§ 702.41 Risk characterization and peer review procedures.

(a) Risk Characterization

Considerations. EPA will: (1) Integrate the hazard and exposure assessments into quantitative and/or qualitative estimates of risk for the identified populations (including any potentially exposed or susceptible subpopulation(s) identified in the final scope document published pursuant to 40 CFR 703.39(c)(6)(iv) and ecological characteristics for the conditions of use; and

(2) Describe whether aggregate or sentinel exposures under the conditions of use were considered and the basis for that consideration.

(b) The Risk Characterization will summarize, as applicable, the considerations addressed throughout the evaluation components, in carrying out the obligations under 15 U.S.C. 2625(h). This summary will include, as appropriate, a discussion of:

(1) *Considerations regarding uncertainty and variability.* Information about uncertainty and variability in each step of the risk evaluation (e.g., use of default assumptions, scenarios, choice of models and information used for quantitative analysis) will be integrated into an overall characterization and/or analysis of the impact of the uncertainty and variability on estimated risks. EPA may describe the uncertainty using a qualitative assessment of the overall strength and limitations of the data used in the assessment.

(2) *Considerations of data quality.* A discussion of issues associated with data quality (e.g., reliability, relevance, and whether methods employed to generate the information are reasonable for and consistent with the intended use of the information), as well as assumptions used, will be included to the extent necessary. EPA also expects to include a discussion of the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models used in the risk evaluation.

(3) *Considerations of alternative interpretations.* If appropriate and

relevant, a discussion of alternative interpretations of the data and analyses will be included.

(4) *Considerations for environmental risk evaluations.* For environmental risk evaluations, it may be necessary to discuss the nature and magnitude of the effects, the spatial and temporal patterns of the effects, implications at the individual, species, and community level, and the likelihood of recovery subsequent to exposure to the chemical substance.

(c) *Peer Review.* The *EPA Peer Review Handbook* (2015), the Office of Management and Budget Final Information Quality Bulletin for Peer Review (OMB Bulletin), or other available, relevant and applicable methods consistent with 15 U.S.C. 2625, will serve as the guidance for peer review activities. Peer review will be conducted on the risk evaluations for the chemical substances identified pursuant to 15 U.S.C. 2605(b)(4)(A).

§ 702.43 Unreasonable risk determination.

The EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use as identified in the final scope document published pursuant to 40 CFR 702.39(c)(6)(iv).

§ 702.45 Risk evaluation timeframes and actions.

(a) *Draft risk evaluation timeframe.* The EPA will publish a draft risk

evaluation in the **Federal Register** and provide no less than a 30-day comment period, during which time the public may submit comment on EPA's draft risk evaluation.

(1) EPA will open a docket to facilitate receipt of public comment.

(2) All comments that could be raised on the matters addressed and issues presented in the draft risk evaluation must be presented during this comment period. Any issues not raised at this time will be considered to have been waived, and may not form the basis for an objection or challenge in any subsequent administrative or judicial proceeding.

(b) *Final risk evaluation.* (1) EPA will complete a risk evaluation for the chemical substance as soon as practicable, but not later than 3 years after the date on which the Agency initiates the risk evaluation.

(2) The Agency may extend the deadline for a risk evaluation for not more than 6 months.

(3) EPA will publish the final risk evaluation in the **Federal Register**.

(c) *Final determination of unreasonable risk.* Upon determination by the EPA that a chemical substance does present an unreasonable risk of injury to health or the environment, the Agency will initiate action as required pursuant to 15 U.S.C. 2605(a).

(d) *Final determination of no unreasonable risk.* A determination by the EPA that the chemical substance

does not present an unreasonable risk of injury to health or the environment will be issued by order and considered to be a final EPA action, effective on the date of issuance of the order.

(c) *Reassessment.* EPA may reassess an unreasonable risk determination based on a review of available information.

§ 702.47 Publically available information.

For each risk evaluation, EPA will maintain a public docket at <http://www.regulations.gov> to provide public access to the following information, as applicable for that risk evaluation:

(1) The draft scope, final scope, draft risk evaluation, and final risk evaluation;

(2) All notices, determinations, findings, consent agreements, and orders;

(3) Any information required to be provided to the Agency under 15 U.S.C. 2603;

(4) A nontechnical summary of the risk evaluation;

(5) A list of the studies, with the results of the studies, considered in carrying out each risk evaluation;

(6) The final peer review report, including the response to peer review comments; and

(7) Response documents to the public comments on the draft risk evaluation.

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Part XVIII

Department of the Treasury

Internal Revenue Service

26 CFR Part 1

Transfers of Certain Property by U.S. Persons to Partnerships With
Related Foreign Partners; Final and Temporary Rules

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 1**

[TD 9814]

RIN 1545-BM95

Transfers of Certain Property by U.S. Persons to Partnerships With Related Foreign Partners**AGENCY:** Internal Revenue Service (IRS), Treasury.**ACTION:** Final and temporary regulations.

SUMMARY: This document contains temporary regulations that address transfers of appreciated property by United States persons (U.S. persons) to partnerships with foreign partners related to the transferor. The regulations override the rules providing for nonrecognition of gain on a contribution of property to a partnership in exchange for an interest in the partnership under section 721(a) of the Internal Revenue Code (Code) pursuant to section 721(c) unless the partnership adopts the remedial method and certain other requirements are satisfied. The document also contains regulations under sections 197, 704, and 6038B that apply to certain transfers described in section 721. The regulations affect U.S. partners in domestic or foreign partnerships. The text of the temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the **Federal Register**. The final regulations revise and add cross-references to coordinate the application of the temporary regulations.

DATES: *Effective Date:* These regulations are effective on January 18, 2017.*Applicability Dates:* For dates of applicability, see §§ 1.197-2T(l)(5)(i), 1.704-1T(f), 1.704-3T(g)(1), 1.721(c)-1T(e), 1.721(c)-2T(e), 1.721(c)-3T(e), 1.721(c)-4T(d), 1.721(c)-5T(g), 1.721(c)-6T(g), and 1.6038B-2T(j)(4)(i).**FOR FURTHER INFORMATION CONTACT:** Concerning the temporary regulations, Ryan A. Bowen, (202) 317-6937; concerning submissions of comments or requests for a public hearing, Regina Johnson, (202) 317-6901 (not toll-free numbers).**SUPPLEMENTARY INFORMATION:****Paperwork Reduction Act**

The collection of information contained in the regulations is listed with the Office of Management and Budget under control numbers 1545-

1668 and 1545-0123 in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224. Comments on the collection of information should be received February 21, 2017.

The collections of information are in §§ 1.721(c)-6T and 1.6038B-2T. The collections of information are mandatory. The likely respondents are domestic corporations. Burdens associated with these requirements will be reflected in the burden for Form 1065, U.S. Return of Partnership Income, and Form 8865, Return of U.S. Persons With Respect to Certain Foreign Partnerships. Estimates for completing these forms can be located in the form instructions.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number.

Background**I. Statutory Background**

Until they were repealed as part of the Taxpayer Relief Act of 1997 (the 1997 Act), Public Law 105-34 (111 Stat. 788), section 1131, sections 1491 through 1494 imposed an excise tax on certain transfers of appreciated property by a U.S. person to a foreign partnership, which generally was 35 percent of the amount of gain inherent in the property. Congress believed that the imposition of enhanced information reporting obligations (including sections 6038, 6038B, and 6046A) with respect to foreign partnerships would eliminate the need for sections 1491 through 1494. Staff of the Joint Committee on Taxation, General Explanation of Tax Legislation Enacted in 1997, Part Two: Taxpayer Relief Act of 1997 (H.R. 2014) (JCS-23-97) (Dec. 17, 1997), at 314-315.

Notwithstanding these enhanced information reporting requirements, the 1997 Act granted the Secretary regulatory authority in section 721(c) to override the application of the nonrecognition provision of section 721(a) to gain realized on the transfer of property to a partnership (domestic or foreign) if the gain, when recognized, would be includible in the gross income of a person other than a U.S. person. In the 1997 Act, Congress also enacted

section 367(d)(3), which provides the Secretary regulatory authority to apply the rules of section 367(d)(2) to transfers of intangible property to partnerships in circumstances consistent with the purposes of section 367(d). Regulations have never been issued pursuant to section 721(c) or section 367(d)(3).

Congress enacted section 367 (and its predecessor) in order to prevent U.S. persons from avoiding U.S. tax by transferring appreciated property to foreign corporations using nonrecognition transactions. Staff of the Joint Committee on Taxation, General Explanation of the Revenue Provisions of the Deficit Reduction Act of 1984 (H.R. 4170, 98th Congress; Pub. L. 98-369) (JCS-41-84) (Dec. 31, 1984), at 427. The outbound transfer of intangible property raises additional issues that Congress also sought to address. Specifically, section 367(d) was enacted to prevent U.S. persons from transferring intangibles offshore in order to achieve deferral of U.S. tax on the profits generated by the intangibles. H.R. Rep. No. 98-432, 98th Cong., 2d Sess., at 1311-15 (1984). Under section 367(d), a U.S. person that transfers intangible property (within the meaning of section 936(h)(3)(B)) to a foreign corporation in an exchange described in section 351 or section 361 is treated as having sold such property in exchange for payments that are contingent upon the productivity, use, or disposition of such property, and receiving amounts that reasonably reflect the amounts that would have been received annually in the form of such payments over the useful life of the property, or, in the case of a disposition following the transfer (whether direct or indirect), at the time of the disposition. Section 367(d)(2)(A). The amounts taken into account must be commensurate with the income attributable to the intangible property. *Id.*

Section 721(a) provides a general rule that no gain or loss is recognized to a partnership or to any of its partners in the case of a contribution of property to the partnership in exchange for an interest in the partnership. Because section 367 applies only to the transfer of property to a foreign corporation, absent regulations under section 721(c) or section 367(d)(3), a U.S. person generally does not recognize gain on the contribution of appreciated property to a partnership with foreign partners.

Section 704(c)(1)(A) requires partnerships to allocate income, gain, loss, and deduction with respect to property contributed by a partner to the partnership so as to take into account any variation between the adjusted tax

basis of the property and its fair market value at the time of contribution.

II. Regulatory Background

Section 1.704-3(a)(1) provides that the purpose of section 704(c) is to prevent the shifting of tax consequences among partners with respect to pre-contribution gain or loss (forward section 704(c) layer). In addition, partnerships may, but are not required to, revalue partnership property pursuant to § 1.704-1(b)(2)(iv)(f) or (s) upon the occurrence of enumerated events, such as the entry of a new partner by contribution, giving rise to a reverse section 704(c) layer. Section 1.704-3(a)(6)(i) provides that the principles of § 1.704-3 apply to allocations with respect to these reverse section 704(c) layers (reverse section 704(c) allocations).

Section 704(c) allocations must be made using any reasonable method consistent with the purpose of section 704(c). Section 1.704-3(a)(1). Section 1.704-3 describes three methods of making section 704(c) allocations that are generally reasonable, including the remedial allocation method. *Id.* Under the remedial allocation method, a partnership may eliminate distortions caused by the ceiling rule (as described in § 1.704-3(b)(1)) by making remedial allocations of income, gain, loss, or deduction to the noncontributing partners equal to the full amount of the limitation caused by the ceiling rule, and offsetting those allocations with remedial allocations of income, gain, loss, or deduction to the contributing partner. See § 1.704-3(d)(1); see also T.D. 8585 (59 FR 66724). Under § 1.704-3(a)(10), an allocation method (or combination of methods) is not reasonable if the contribution of property (or event that results in reverse section 704(c) allocations) and the corresponding allocation of tax items with respect to the property are made with a view to shifting the tax consequences of built-in gain or loss among the partners in a manner that substantially reduces the present value of the partners' aggregate tax liability. However, § 1.704-3(d)(5)(ii) provides that, in exercising its authority under § 1.704-3(a)(10), the IRS will not require a partnership to use the remedial allocation method.

III. Reasons for Exercising Regulatory Authority

The Treasury Department and the IRS are aware that certain taxpayers purport to be able to contribute, consistently with sections 704(b), 704(c), and 482, property to a partnership that allocates the income or gain from the contributed

property to related foreign partners that are not subject to U.S. tax. Many of these taxpayers choose a section 704(c) method other than the remedial method or use valuation techniques that are inconsistent with the arm's length standard. In 1997, Congress recognized that taxpayers might use a partnership to shift gain to a foreign person and consequently enacted sections 721(c) and 367(d)(3). Based on the experience of the IRS with the taxpayer positions described above, the Treasury Department and the IRS have determined that it is appropriate to exercise the regulatory authority granted in section 721(c) to override the application of section 721(a) to gain realized on the transfer of property to a partnership (domestic or foreign) in certain circumstances in which the gain, when recognized, ultimately would be includible in the gross income of a foreign person. Although Congress also provided specific authority in section 367(d)(3) to address transfers of intangible property to partnerships, the Treasury Department and the IRS have concluded that acting pursuant to section 721(c) is more appropriate because the transactions at issue are not limited to transfers of intangible property.

IV. Notice 2015-54

On August 6, 2015, the Department of the Treasury (Treasury Department) and the IRS issued Notice 2015-54, 2015-34 I.R.B. 210 (the notice), which describes regulations to be issued under section 721(c) that would ensure that, when a U.S. person transfers certain property to a partnership that has foreign partners related to the U.S. person, income or gain attributable to the appreciation in the property at the time of the contribution will be taken into account by the transferor either immediately or over time. Comments were received on the notice and will be included in the administrative record for the notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the **Federal Register** (REG-127203-15). The Treasury Department and the IRS have considered all the submitted comments. The significant comments are discussed in the Explanation of Provisions section of this preamble.

The notice states that future regulations generally will override the application of section 721(a) to gain realized on the transfer of property to a partnership (domestic or foreign) in certain circumstances in which the gain, when recognized, ultimately would be includible in the gross income of a related foreign person. The notice further states that future regulations will

allow for the continued application of section 721(a) to transfers to partnerships with related foreign partners when certain requirements intended to protect the U.S. tax base are satisfied. The notice described these requirements, in addition to others, as the "gain deferral method."

The requirements of the gain deferral method described in the notice are that (i) the section 721(c) partnership adopts the remedial allocation method for built-in gain with respect to all section 721(c) property contributed to the partnership pursuant to the same plan by the U.S. transferor and all U.S. transferors that are related persons; (ii) the section 721(c) partnership makes consistent allocations of all section 704(b) items with respect to an item of section 721(c) property (the consistent allocation method); (iii) certain reporting requirements are satisfied; (iv) the U.S. transferor recognizes any remaining built-in gain with respect to section 721(c) property upon an acceleration event; and (v) the gain deferral method is adopted for all section 721(c) property subsequently contributed to the section 721(c) partnership by the U.S. transferor and all other U.S. transferors that are related persons until the earlier of two dates: the date that no built-in gain remains with respect to any section 721(c) property to which the gain deferral method first applied, or the date that is 60 months after the date of the initial contribution of section 721(c) property to which the gain deferral method first applied (unified application requirement). See Part III of the Explanations of Provisions section of this preamble for the definitions of "section 721(c) partnership," "section 721(c) property," "U.S. transferor" and other commonly used terms.

The notice generally provides that the regulations will define an acceleration event as any transaction that either (i) would reduce the amount of remaining built-in gain that a U.S. transferor would recognize under the gain deferral method if the transaction had not occurred, or (ii) could defer the recognition of the built-in gain. The notice also describes several situations that the regulations will not treat as acceleration events.

The notice states that the regulations will apply to transactions involving tiered partnerships in a manner that is consistent with the purpose of the regulations. As examples, the notice provides that the regulations will treat a contribution of section 721(c) property by a partnership (in which a U.S. transferor is a direct or indirect partner) to a lower-tier partnership, or a

contribution by a U.S. transferor of an interest in a partnership that owns section 721(c) property to an upper-tier partnership, as though the U.S. transferor contributed its share of the section 721(c) property directly.

The notice provides that the regulations described therein will apply to contributions occurring on or after August 6, 2015, and to contributions occurring before August 6, 2015, resulting from an entity classification election made under § 301.7701-3 that is filed on or after August 6, 2015, and that is effective on or before August 6, 2015. The notice provides, however, that the reporting requirements will not apply to taxable years that end before the date of publication of regulations described in the notice.

The notice also announced the intent to issue regulations under sections 482 and 6662 to ensure the appropriate valuation of controlled transactions involving partnerships. These regulations are not contained in this Treasury decision and will appear in future regulations. Section 482 continues to apply to controlled transactions (within the meaning of § 1.482-1(i)(8)) that are also subject to these regulations. An adjustment pursuant to section 482 does not prevent the application of these regulations.

Explanation of Provisions

I. Comments Regarding Statutory Authority for Regulations

Comments questioned whether the regulations described in the notice are within the scope of the grant of authority in section 721(c). Specifically, comments asserted that pre-contribution gain could not be taxed under section 721(c) until it is recognized in a sale or exchange by the partnership. The Treasury Department and the IRS disagree with these comments for several reasons.

First, as explained in the notice, Congress added the broad grant of regulatory authority in section 721(c) in the 1997 Act to address transactions in which property is contributed to partnerships in order to inappropriately shift gain offshore as a replacement for the repealed excise tax on transfers to foreign partnerships in sections 1491 through 1494.

Second, section 721(c) provides authority to tax the gain when the property is contributed if the gain “will be includible” in a foreign person’s income; it is not a rule (like section 704(c)(1)(B)) that requires the “wait-and-see” approach suggested by the comments. The comments fail to

acknowledge that neither the traditional method nor the traditional method with curative allocations will necessarily ensure that a contributing partner will bear all the tax consequences of pre-contribution gain. A contributing partner exchanges a share of the property it contributes for a share of the property the other partners contribute. Economically, a contribution is a current value-for-value exchange. The purpose of section 704(c) is to prevent the shifting of tax consequences among partners with respect to pre-contribution built-in gain or loss in contributed property. The regulations under section 704(c) provide three generally reasonable methods under which partnerships may allocate items with respect to contributed property so as to take into account the tax consequences of pre-contribution gain or loss—the traditional method, the traditional method with curative allocations, and the remedial allocation method. None of the methods are mandatory, and taxpayers may choose any of them (or another reasonable method) on a property-by-property and section 704(c) layer-by-layer basis. In the case of a contribution of depreciable or amortizable property with pre-contribution gain, under all three methods, book cost recovery deductions reduce the pre-contribution gain in the property (the gain that must be allocated back to the contributor) over the course of the recovery period for the property. Under the traditional method, tax cost recovery deductions (which are based on tax basis in the property) are, to the extent available, allocated first to the noncontributing partner up to its allocated book cost recovery deductions. If the noncontributing partner’s book cost recovery deductions exceed its tax cost recovery deductions, the noncontributing partner will be overtaxed on its investment in the partnership property. The traditional method does not make up for shortfalls in available tax deductions, and if the partnership uses the traditional method with curative allocations, those shortfalls are cured only if there are other tax items available with which to cure. Because book cost recovery deductions reduce the built-in gain in the property regardless of whether the noncontributing partner has received all of the tax cost recovery deductions to which it is economically entitled or whether the contributing partner has received taxable income (or fewer tax deductions) commensurate with the pre-contribution gain in its property, neither the traditional method nor the traditional method with curative

allocations prevents a shift of the tax consequences of pre-contribution gain to the noncontributing partner when tax basis or other tax items are insufficient to reflect the economics of the noncontributing partner. When this shift occurs, the contributing partner generally will not bear the tax consequences of the pre-contribution gain until, at the earliest, its partnership interest is liquidated or sold. In this way, the contribution of property to a partnership applying either of these two methods can result in a tax-advantaged exchange with respect to the contributing partner. When the noncontributing partner is foreign, this situation is the appropriate target for the temporary regulations.

Finally, the regulations under section 704(c) give wide latitude to taxpayers regarding how and when partners may choose to recognize pre-contribution gain. Subject to anti-abuse rules, taxpayers are allowed to adopt the traditional method and the traditional method with curative allocations despite those methods’ inability to prevent a shift of the tax consequences of pre-contribution gain in all cases. This latitude raises more concern in the case of related partners, one or more of whom are foreign, given their likely overall alignment of tax interests, which would not necessarily exist among unrelated partners. As explained in Part II of the Background section of this preamble, the remedial allocation method is the only method that reliably and consistently ensures that the tax consequences of pre-contribution gain from contributed property are properly borne by the contributing partner. This feature of the remedial method is particularly relevant to the Congressional concerns about the erosion of the U.S. tax base that led to the enactment of section 721(c), and thus the remedial method is the method that is most appropriate for appreciated property that is contributed to a partnership controlled by the U.S. transferor and one or more related foreign partners. For these reasons, the Treasury Department and the IRS have determined that these regulations are within the scope of the grant of authority in section 721(c).

II. Overview of the Temporary Regulations

The temporary regulations adopt the rules that were described in the notice, with certain modifications, in part, in response to comments received.

Section 1.721(c)-1T provides definitions and rules of general application for purposes of all sections of the temporary regulations. Section

1.721(c)–2T provides the general operative rules that override section 721(a) nonrecognition upon a contribution of section 721(c) property to a partnership. Section 1.721(c)–3T describes the gain deferral method, which, if adopted, avoids the immediate recognition of gain upon a contribution of section 721(c) property. Section 1.721(c)–4T provides rules regarding events that accelerate the recognition of gain that previously was deferred under the gain deferral method. Section 1.721(c)–5T identifies exceptions to the acceleration events provided in § 1.721(c)–4T, the result of which, generally, is that the gain deferral method either ends (termination events) or continues to apply without immediate gain recognition (successor events) or continues to apply with partial gain recognition (partial acceleration events). Section 1.721(c)–6T provides procedural and reporting requirements. Section 1.721(c)–7T provides examples illustrating the application of the temporary regulations.

III. General Scope of the Temporary Regulations

The temporary regulations apply on a property-by-property basis. Accordingly, as discussed in Paragraph b of Part VI of the Explanations of Provisions section of this preamble, the temporary regulations do not include the unified application requirement announced in the notice.

The temporary regulations apply to all contributions, actual or deemed, of property to a partnership, including, for example, a contribution of property that occurs as a result of (i) a partnership merger, consolidation, or division in the assets-over form, (ii) a change in entity classification that occurs pursuant to § 301.7701–3, or (iii) a transaction described in Rev. Rul. 99–5, 1999–1 C.B. 434 (change from a disregarded entity to a partnership). However, in response to a comment, the temporary regulations provide that a contribution in a technical termination of a partnership described in section 708(b)(1)(B) (technical termination) will not, by itself, cause a partnership to become a section 721(c) partnership subject to the temporary regulations. For further discussion, see Part IV of the Explanation of Provisions section of this preamble. However, the temporary regulations do apply to a technical termination of a section 721(c) partnership applying the gain deferral method. In this regard, see Part V and Paragraph c of Part VIII of the Explanation of Provisions section of this preamble, concerning the general rule of

gain recognition and successor events, respectively.

The temporary regulations provide that a mere change in identity, form, or place of organization of a partnership or a recapitalization of a partnership will not cause the partnership to become a section 721(c) partnership. See § 1.721(c)–1T(c).

Finally, as announced in the notice, the temporary regulations contain rules for transactions involving tiered partnerships, as well as a general anti-abuse rule (see § 1.721(c)–1T(d)) that applies for purposes of all sections of the temporary regulations.

IV. Definitions: Section 721(c) Partnership, Section 721(c) Property, U.S. Transferor, and Other Terms

The notice states that future regulations would provide that a partnership is a section 721(c) partnership if a U.S. transferor contributes section 721(c) property to the partnership, and, after the contribution and any transactions related to the contribution, (i) a related foreign person is a direct or indirect partner, and (ii) the U.S. transferor and related persons own (directly or indirectly) more than 50 percent of the interests in partnership capital, profits, deductions, or losses.

A comment requested that the definition of section 721(c) partnership be revised to exclude partnerships when the interests held by related foreign persons are small and an unrelated third-party with a material adverse tax position to the U.S. transferor holds a meaningful interest in the partnership. According to the comment, these two factors would sufficiently mitigate the potential for the abuse that the notice is intended to address. While these factors may reduce the ability of a U.S. transferor to shift gain or income outside the United States, the Treasury Department and the IRS have concluded that these factors alone are insufficient to prevent the erosion of the U.S. tax base that section 721(c) was enacted to address. In particular, the Treasury Department and the IRS are concerned that even a small ownership interest held by a related foreign person may be used for a meaningful shift of gain or income outside the United States. Furthermore, the Treasury Department and the IRS have determined that such a rule would necessitate additional rules to address small interests that later become large either in absolute or relative terms. In this regard, the Treasury Department and the IRS have determined that both a general anti-abuse rule and a more targeted rule that would require periodic retesting of the

size of a related foreign person's interest would be difficult to administer.

Accordingly, this comment has not been adopted. The Treasury Department and the IRS, however, acknowledge that the higher the overall level of related ownership in the partnership, the more likely the arrangement among the partners will reflect tax considerations. After considering this comment and other comments that requested a higher level of related-party ownership in the definition of a section 721(c) partnership, the temporary regulations increase the threshold from a “more than 50 percent” test to an “80 percent or more” test (ownership requirement). See § 1.721(c)–1T(b)(14)(i) for the general definition of a section 721(c) partnership. The temporary regulations also provide rules that deem certain controlled partnerships in a tiered-partnership structure to be section 721(c) partnerships in order to apply the gain deferral method. See § 1.721(c)–1T(b)(14)(ii).

The temporary regulations define section 721(c) property as property, other than excluded property, with built-in gain that is contributed to a partnership by a U.S. transferor. See § 1.721(c)–1T(b)(15)(i) for the general definition of section 721(c) property. The notice incorporated the requirement that a U.S. transferor make the contribution in the definition of a section 721(c) partnership rather than in the definition of section 721(c) property. This adjustment to the definitions is intended to be a non-substantive change. The temporary regulations provide that if a U.S. transferor is treated as contributing its share of an item of property, the entire item of property is section 721(c) property. In addition, the temporary regulations provide rules that deem certain property of a tiered partnership to be section 721(c) property. See § 1.721(c)–1T(b)(15)(ii). When an interest in a partnership is contributed, the partnership interest, if it is not excluded property, is the section 721(c) property.

The temporary regulations define excluded property as (i) a cash equivalent; (ii) a security within the meaning of section 475(c)(2), without regard to section 475(c)(4); (iii) an item of tangible property with built-in gain that does not exceed \$20,000 or with an adjusted tax basis in excess of book value (built-in loss); and (iv) an interest in a partnership that holds (directly, or indirectly through interests in one or more partnerships that are not excluded property under this clause (iv)) property of which 90 percent or more of the value consists of property described in clauses (i) through (iii) (partnership interest

exclusion). See § 1.721(c)–1T(b)(6). The notice announced the first three categories of excluded property. However, the temporary regulations include tangible property with a built-in loss in the third exclusion so that such property is excluded property for purposes of the partnership interest exclusion. The Treasury Department and the IRS determined that it was appropriate to add the partnership interest exclusion so that the temporary regulations do not apply to transfers of partnership interests when only a small portion of the partnership's property is section 721(c) property. If a partnership interest fails the 90-percent threshold test for the partnership interest exclusion and does not qualify under the second exclusion for securities, the interest is section 721(c) property.

Comments recommended that property that gives rise to income effectively connected with a U.S. trade or business (ECI property) be excluded from the definition of section 721(c) property, because the income will be subject to U.S. tax even if it is allocated to a related foreign person. The Treasury Department and the IRS agree with the reasoning behind this comment, and have determined that the temporary regulations should also address the situation when the property ceases to be ECI property and still has built-in gain. Accordingly, the temporary regulations continue to include ECI property in the definition of section 721(c) property but modify the application of the gain deferral method to ECI property, as discussed in Paragraph c of Part VI of the Explanation of Provisions section of this preamble.

Another comment similarly suggested that the definition of section 721(c) property exclude property the gain on which would be subject to U.S. tax under subpart F of the Code. The Treasury Department and IRS have declined to adopt such a rule, which would depend on a “wait and see” approach and would import the recognition rules of subpart F, including an earnings and profits requirement, rather than the more direct approach of section 721(c).

The temporary regulations define built-in gain with respect to an item of property contributed to a partnership as the excess of the book value of the property over the partnership's adjusted tax basis in the property upon the contribution, determined without regard to the application of the gain recognition rule of § 1.721(c)–2T(b). See § 1.721(c)–1T(b)(2). The temporary regulations clarify the definition provided in the notice in two respects. First, the notice states that built-in gain

would be determined with respect to the contributing partner's adjusted tax basis in the property at the time of the contribution, whereas the temporary regulations provide that built-in gain is determined with respect to the partnership's adjusted tax basis in the property. The revision was made in order to more precisely describe the amount of gain that may be shifted to a related foreign partner. Second, the temporary regulations clarify that built-in gain is determined without regard to the application of the gain recognition rule under § 1.721(c)–2T(b).

The temporary regulations include a new term, “remaining built-in gain.” Section 1.721(c)–1T(b)(13)(i) generally defines remaining built-in gain, with respect to an item of section 721(c) property that is subject to the gain deferral method, as the built-in gain, reduced by decreases in the difference between the property's book value and adjusted tax basis. However, subsequent increases or decreases to the property's book value due to a revaluation other than a revaluation required under these temporary regulations for tiered partnerships are not taken into account in determining remaining built-in gain. The temporary regulations provide rules for determining remaining built-in gain in the case of tiered partnerships. See § 1.721(c)–1T(b)(13)(ii).

Consistent with the notice, § 1.721(c)–1T(b)(18)(i) of the temporary regulations generally defines a U.S. transferor as a U.S. person (within the meaning of section 7701(a)(30)) other than a domestic partnership. The temporary regulations also provide a rule that deems certain tiered partnerships to be a U.S. transferor solely for purposes of applying the consistent allocation method. See § 1.721(c)–1T(b)(18)(ii).

Finally, the temporary regulations, consistent with the notice, define (i) a related person as a person that is related (within the meaning of section 267(b) or section 707(b)(1)) to a U.S. transferor; (ii) a related foreign person as a person that is a related person (other than a partnership) that is not a U.S. person; and (iii) a direct or indirect partner as a person (other than a partnership) that owns an interest in a partnership directly or indirectly through one or more partnerships. See § 1.721(c)–1T(b)(12), (b)(11), and (b)(5), respectively.

V. General Rule of Gain Recognition Upon a Contribution of Section 721(c) Property to a Section 721(c) Partnership

Section 1.721(c)–2T provides the general operative rules that override section 721(a) nonrecognition of gain upon a contribution of section 721(c)

property to a partnership. Section 1.721(c)–2T(b) provides the general rule that nonrecognition under section 721(a) will not apply to gain realized upon a contribution of section 721(c) property to a section 721(c) partnership. In contrast to the regulations described in the notice, § 1.721(c)–2T(b) provides that this general rule does not apply—and therefore that nonrecognition under section 721(a) continues to apply—to a direct contribution of section 721(c) property by an “unrelated” U.S. transferor (in other words, a U.S. transferor that does not, together with related persons with respect to it, satisfy the ownership requirement). The carve-out is consistent with the intent of the temporary regulations to address the shifting of income among related persons. Because this carve-out for an unrelated U.S. transferor is limited to direct contributions of section 721(c) property, it does not apply to a contribution that occurs pursuant to the partnership look-through rule in § 1.721(c)–2T(d)(1) (as discussed elsewhere in this Part V).

Section 1.721(c)–2T(c) provides a de minimis exception to the general rule. The temporary regulations modify the de minimis exception described in the notice—which focused on contributions made by a U.S. transferor (and all related U.S. transferors) during the U.S. transferor's taxable year—to focus instead on contributions during the partnership's taxable year, in order to align the rule with the reporting required under § 1.721(c)–6T. Under the de minimis exception in the temporary regulations, contributions of section 721(c) property will not be subject to immediate gain recognition if the sum of all built-in gain for all section 721(c) property contributed to a section 721(c) partnership during the partnership's taxable year does not exceed \$1 million.

Section 1.721(c)–2T(d)(1) provides a look-through rule for identifying a section 721(c) partnership when an upper-tier partnership in which a U.S. transferor is a direct or indirect partner contributes property to a lower-tier partnership. For purposes of determining if the lower-tier partnership is a section 721(c) partnership, the U.S. transferor will be treated as contributing to the lower-tier partnership its share of the property actually contributed by the upper-tier partnership to the lower-tier partnership. If the lower-tier partnership is a section 721(c) partnership, absent application of the gain deferral method by the lower-tier partnership to the entire property and by the upper-tier partnership to the partnership interest in the lower-tier partnership, the upper-tier partnership will recognize the entire

built-in gain in the section 721(c) property under the general gain recognition rule, because the entire property will be section 721(c) property (see the general definition of section 721(c) property in § 1.721(c)-1T(b)(15)(i)).

Section 1.721(c)-2T(d)(2) provides that the partnership look-through rule will not apply to a deemed contribution by an “old” partnership to a “new” partnership that occurs as a result of a technical termination of the old partnership. Thus, a technical termination will not cause a non-section 721(c) partnership, in which a U.S. transferor is a direct or indirect partner, to become a section 721(c) partnership subject to these temporary regulations. If, however, a partnership is a section 721(c) partnership subject to the temporary regulations immediately before its technical termination, the technical termination would be a successor event (rather than an acceleration event) only if the new partnership continues the gain deferral method with respect to the section 721(c) property that was subject to the gain deferral method in the terminated partnership. In this regard, see § 1.721(c)-5T(c)(4) (defining a successor event to include certain technical terminations).

VI. Gain Deferral Method

a. In General

Section 1.721(c)-3T describes the gain deferral method, which generally must be applied in order to avoid the immediate recognition of gain upon a contribution of section 721(c) property to a section 721(c) partnership. Section 1.721(c)-3T(b) provides the five general requirements for applying the gain deferral method to an item of section 721(c) property: (i) The section 721(c) partnership adopts the remedial allocation method and allocates section 704(b) items of income, gain, loss, and deduction with respect to the section 721(c) property in a manner that satisfies the consistent allocation method; (ii) the U.S. transferor recognizes gain equal to the remaining built-in gain with respect to the section 721(c) property upon an acceleration event, or an amount of gain equal to a portion of the remaining built-in gain upon a partial acceleration event or certain transfers to foreign corporations described in section 367; (iii) procedural and reporting requirements are satisfied; (iv) the U.S. transferor extends the period of limitations on assessment of tax (as discussed in Part X of the Explanation of Provisions section of this preamble); and (v) the rules for tiered

partnerships are satisfied if either the section 721(c) property is an interest in a partnership or the section 721(c) property is described in the partnership look-through rule in § 1.721(c)-2T(d)(1).

b. Application of the Gain Deferral Method on a Property-by-Property Basis

Comments questioned the necessity for the unified application requirement announced in the notice. The unified application requirement was intended to prevent taxpayers from disaggregating the contribution of separate but related business property and choosing to recognize gain upon contribution for some property and to apply the gain deferral method for other property, in an attempt to minimize the reported cumulative value for all contributed property or to minimize the reported value of property for which the gain deferral method was not adopted. This concern arises, in part, because the IRS may not be able to make an adjustment for the correct amount of gain with respect to property that is not subject to the gain deferral method due to the expiration of the period of limitations on the assessment of tax. While the Treasury Department and the IRS continue to be concerned that taxpayers will attempt to disaggregate related business property in order to undervalue their contributions, the temporary regulations adopt a more targeted approach to address these comments. Accordingly, the temporary regulations do not include the unified application requirement and instead apply on a property-by-property basis.

As described in the notice, in order to apply the gain deferral method with respect to a contribution of section 721(c) property to a section 721(c) partnership, the temporary regulations require the U.S. transferor to extend the period of limitations on assessment of tax on all items related to the property with respect to which the gain deferral method applies through the close of the eighth full taxable year following the contribution. To address the concerns that motivated the uniform application requirement, the temporary regulations require a U.S. transferor to extend the period of limitations on assessment of tax on the gain recognized under the general rule with respect to any section 721(c) property that is contributed to the partnership for which the gain deferral method will not be applied through the close of the fifth full taxable year following the contribution of such property, if the property is contributed within five full taxable years after a gain deferral contribution, defined in § 1.721(c)-1T(b)(7) as a contribution of section 721(c) property to a section

721(c) partnership with respect to which the gain is deferred under the gain deferral method. See §§ 1.721(c)-3T(b)(4) and 1.721(c)-6T(b)(5)(iii), discussed in Part X of the Explanation of Provisions section of this preamble. Additionally, it should be noted that § 1.482-1T(f)(2)(i)(B) provides that separate transactions must be aggregated for purposes of determining the arm's length pricing of such transactions under section 482, including for purposes of an analysis under multiple provisions of the Code or regulations, if the transactions are so interrelated that an aggregate analysis provides the most reliable measure of the arm's length result.

c. Application of the Gain Deferral Method to ECI Property

As discussed in Part IV of the Explanation of Provisions section of this preamble, the temporary regulations do not adopt the comment recommending that ECI property be excluded from the definition of section 721(c) property. Instead, the temporary regulations continue to provide that a contribution of section 721(c) property that is ECI property is subject to immediate gain recognition if the gain deferral method is not applied. However, in response to the comment, the temporary regulations modify the gain deferral method such that ECI property is not subject to the remedial allocation method or the consistent allocation method. This special exception for ECI property applies for as long as, beginning on the date of the contribution and ending when there is no remaining built-in gain with respect to the property, all distributive shares of income and gain with respect to the property for all direct and indirect partners that are related foreign persons will be subject to taxation as effectively connected with a trade or business within the United States (under section 871 or 882), and neither the section 721(c) partnership nor a direct or indirect partner that is a related foreign person claims benefits under an income tax treaty that would exempt the income or gain from tax or reduce the rate of taxation to which the income or gain is subject. See § 1.721(c)-3T(b)(1)(ii).

All the other requirements of the gain deferral method apply with respect to ECI property. Thus, a U.S. transferor must recognize gain upon an acceleration event with respect to ECI property, including when property ceases to be ECI property, and satisfy the procedural and reporting requirements with respect to ECI property. See § 1.721(c)-6T(b)(2)(iii), (b)(3)(vii), and (c)(1).

A comment also requested an exclusion for property subject to tax under section 897 (relating to U.S. real property interests) from the definition of section 721(c) property. The temporary regulations do not adopt this comment because the special rules for ECI property appropriately address the concerns expressed regarding U.S. real property interests.

d. Application of the Gain Deferral Method to Anti-Churning Property

Comments requested guidance on how the requirement to use the remedial allocation method interacts with the section 197 anti-churning rules. In general, section 197(f)(9) prohibits the amortization of goodwill and going concern value that was nonamortizable before the enactment of section 197 (section 197(f)(9) intangible property), and that prohibition continues if the property is transferred to a related person. Under § 1.197-2(h)(12)(vii)(B), when section 197(f)(9) intangible property is contributed to a partnership, a noncontributing partner generally may receive remedial allocations of amortization with respect to the property. A noncontributing partner that is related to the contributing partner, however, may not receive such remedial allocations.

One comment requested that a U.S. transferor not be required to include remedial income with respect to section 197(f)(9) intangible property when the gain deferral method is being applied. The temporary regulations do not adopt this comment. The Treasury Department and the IRS are concerned that providing favorable treatment for section 721(c) property belonging to a particular class would incentivize taxpayers to attribute excessive value to that class of property while simultaneously undervaluing related but separate section 721(c) property that remains subject to all of the requirements of the gain deferral method. This concern is especially pronounced in the case of section 197(f)(9) intangible property, which is often difficult to value separately from other identifiable intangible property. In this regard, see the preamble of the notice of proposed rulemaking (REG-139483-13) containing proposed regulations under section 367, published in the **Federal Register** on September 16, 2015 (80 FR 55568). See also the preamble to T.D. 9803, which finalized those proposed regulations, published in the **Federal Register** on December 16, 2016 (81 FR 91012).

Another comment recommended that regulations implementing the gain deferral method require the partnership

to amortize the section 197(f)(9) intangible and allocate remedial items of amortization to a related foreign partner and corresponding remedial items of income to the contributing partner. The Treasury Department and the IRS have determined that changing § 1.197-2(h)(12)(vii)(B) to permit remedial allocations of amortization to related partners, or distinguishing between domestic and related foreign partners, would be contrary to section 197(f)(9) and therefore do not adopt this comment. In lieu of providing that remedial allocations may be made to a related partner, the temporary regulations provide a special non-amortizable tax basis adjustment to the property. This special adjustment is made solely with respect to the related partner. The Treasury Department and the IRS have determined that allowing this tax basis adjustment is consistent with the policy of the section 197 anti-churning rules.

More specifically, the temporary regulations revise the remedial allocation method in § 1.704-3(d) as to related partners when a section 721(c) partnership is applying the gain deferral method with respect to section 197(f)(9) intangible property. The revised rule requires the partnership to amortize the portion of the partnership's book value in the section 197(f)(9) intangible property that exceeds its adjusted tax basis in the property. Accordingly, the allocation of book amortization to a noncontributing partner will result in a ceiling rule limitation to the extent of this allocation of book amortization. If a noncontributing partner is a related person with respect to the U.S. transferor, the temporary regulations provide that, solely with respect to the related noncontributing partner, the partnership must increase the adjusted tax basis of the property by the amount of the difference between the book allocation of the item to the related person and the tax allocation of the same item to the related person and allocate remedial income in the same amount to the U.S. transferor. See § 1.704-3T(d)(5)(iii)(C).

The rules governing the tax consequences of the special tax basis adjustment are modeled on § 1.743-1 and proposed regulations under section 704(c)(1)(C) that are contained in a notice of proposed rulemaking (REG-144468-05) published in the **Federal Register** (79 FR 3042) on January 16, 2014. The adjustment to the tax basis of section 197(f)(9) intangible property will be recovered by the related partner only upon a sale or exchange of the property by the partnership. Generally, a transfer by the noncontributing related partner

of all or a portion of its interest in the partnership will eliminate the tax basis adjustment attributable to the interest such that the transferee will not succeed to the tax basis adjustment. However, if the interest is transferred in a substituted basis transaction, the transferee will succeed to the transferor's tax basis adjustment and the adjustment will be taken into account in computing and allocating any adjustment to the basis of the section 197(f)(9) intangible property under sections 743(b) and 755. These rules must be applied together with the general rules under section 197 and subchapter K of the Code. In resolving any uncertainty that arises in the implementation of these rules, it would be reasonable for taxpayers to apply principles similar to those contained in § 1.743-1, the proposed regulations under section 704(c)(1)(C), and any Code sections or regulations that reference those rules.

The Treasury Department and the IRS request comments on the following issues, and on any other issues relevant to a section 721(c) partnership's application of the remedial allocation method to section 197(f)(9) intangible property: (i) The application of the method to members of a consolidated group; (ii) the treatment of a tax basis adjustment when the adjusted section 197(f)(9) intangible property is transferred (a) in a like-kind exchange described in section 1031, (b) to a lower-tier partnership, (c) in a transaction described in section 351, (d) in a technical termination, or (e) in an installment sale; (iii) the treatment of a tax basis adjustment when the section 197(f)(9) intangible property is distributed to the related person for whom the adjustment was made or to another partner in a current or liquidating distribution; and (iv) any rules that are necessary to ensure that the tax basis adjustment does not become amortizable in contravention of the anti-churning rules.

e. Consistent Allocation Method

1. In General

Section 1.721(c)-3T(c)(1) describes the consistent allocation method, which, like the gain deferral method, applies on a property-by-property basis. The consistent allocation method requires a section 721(c) partnership to allocate the same percentage of each book item of income, gain, deduction, and loss "with respect to the section 721(c) property" to the U.S. transferor. Comments questioned the necessity of the requirement to apply the consistent allocation method. Some comments

asserted that the requirement is unnecessary because the built-in gain in section 721(c) property will be preserved in the difference between the book and tax capital accounts of a U.S. transferor. The Treasury Department and the IRS have determined that remedial allocations alone are insufficient to ensure that built-in gain with respect to section 721(c) property will be subject to U.S. tax. The consistent allocation method is intended to prevent a U.S. transferor from rendering the remedial allocation method ineffective by, for example, having the partnership allocate a higher percentage share of book depreciation to the U.S. transferor (which would reduce the U.S. transferor's remedial income inclusion) than the U.S. transferor's percentage share of income or gain with respect to the property, which would result in shifting the gain (and taxable income) to related foreign persons that are direct or indirect partners in the partnership. Therefore the temporary regulations do not adopt this comment. The temporary regulations provide rules (discussed in Paragraph e.2 of this Part VI) to determine the amount of income, gain, deduction, and loss that is considered to be "with respect to section 721(c) property" under the gain deferral method.

According to another comment, the consistent allocation method is both over-inclusive, in that situations in which a U.S. transferor is allocated greater income than its share of deductions would violate the rule, and under-inclusive, because deductions allocated to a U.S. transferor that do not arise from section 721(c) property are beyond the scope of the rule. This comment proposed an alternative anti-abuse rule that would require that a minimum cumulative amount of income be allocated to a U.S. transferor. The Treasury Department and the IRS have concluded that the rule described in the comment would be difficult to administer. However, in response to comments, the temporary regulations provide exceptions (discussed in Paragraph e.3 of this Part VI) to the consistent allocation method for certain regulatory allocations and the allocations of creditable foreign tax expenditures.

2. Determining Book Items With Respect to Section 721(c) Property

The notice did not describe how partnership items are determined to be "with respect to section 721(c) property." The temporary regulations provide guidance for making this determination based on principles that will be familiar to many taxpayers.

i. Book Items of Income and Gain

Section 1.721(c)-3T(c)(2) provides the rule for determining the extent to which partnership items of book income and gain are considered to be "with respect to" particular section 721(c) property for purposes of applying the consistent allocation method on a property-by-property basis. This rule provides that a section 721(c) partnership must attribute book income and gain to each property in a consistent manner using any reasonable method that takes into account all the facts and circumstances. The temporary regulations provide that all items of book income and gain attributable to each property will comprise a single class of gross income for purposes of determining the extent to which partnership items of deduction or loss are allocated and apportioned with respect to the section 721(c) property.

ii. Book Items of Deduction and Loss

Section 1.721(c)-3T(c)(3) provides the rules for determining the extent to which partnership items of book deduction and loss are considered to be "with respect to" particular section 721(c) property for purposes of applying the consistent allocation method. A section 721(c) partnership must use the principles of §§ 1.861-8 and 1.861-8T to allocate and apportion all of its items of deduction, except for interest expense and research and experimental expenditures (R&E), and loss to the class of gross income with respect to each section 721(c) property. The section 721(c) partnership may allocate and apportion its interest expense and R&E using any reasonable method, including, but not limited to, the methods described in §§ 1.861-9 and 1.861-9T (interest expense) and § 1.861-17 (R&E).

3. Exceptions to the Consistent Allocation Method

In response to comments, the temporary regulations provide exceptions from the requirement to apply the consistent allocation method with respect to certain book items of a section 721(c) partnership.

i. Regulatory Allocations

The temporary regulations provide that a regulatory allocation (as defined in § 1.721(c)-1T(b)(10)) of book income, gain, deduction, or loss with respect to section 721(c) property that otherwise would fail to satisfy the requirements of the consistent allocation method nevertheless will, in certain cases, be deemed to satisfy the requirements. Specifically, a regulatory allocation is deemed to satisfy the requirements of the consistent allocation method if the

allocation is (i) an allocation of income or gain to the U.S. transferor (or a member of its consolidated group); or (ii) an allocation of deduction or loss to a partner other than the U.S. transferor (or a member of its consolidated group). In addition, if the allocation is not described in clause (i) or (ii) but the U.S. transferor receives less income or gain or more deductions or loss with respect to the section 721(c) property because of the regulatory allocation, the allocation is treated as described in § 1.721(c)-5T(d)(2) (generally requiring that a portion of remaining built-in gain be recognized, as discussed in Paragraph d.2 of Part VIII of the Explanation of Provisions section of this preamble). See § 1.721(c)-3T(c)(4)(i)(C). The Treasury Department and the IRS have determined that this special rule for regulatory allocations is appropriate because an allocation described in clause (i) or (ii) will not reduce the U.S. tax base and an allocation described in clause (iii) will result in the U.S. transferor recognizing gain that will offset the reduction in the U.S. tax base resulting from the regulatory allocation.

The temporary regulations provide that a regulatory allocation is (i) an allocation pursuant to a minimum gain chargeback, as defined in § 1.704-2(b)(2), (ii) a partner nonrecourse deduction, as determined in § 1.704-2(i)(2), (iii) an allocation pursuant to a partner minimum gain chargeback, as described in § 1.704-2(i)(4), (iv) an allocation pursuant to a qualified income offset, as defined in § 1.704-1(b)(2)(ii)(d), (v) an allocation with respect to the exercise of a noncompensatory option described in § 1.704-1(b)(2)(iv)(s), and (vi) an allocation of partnership level ordinary income or loss described in § 1.751-1(a)(3). The Treasury Department and the IRS have determined that relief is appropriate for these regulatory allocations because, in general, partners do not have discretion regarding their application and, when necessary, treating them as a partial acceleration event will result in the appropriate amount of gain being recognized for purposes of the gain deferral method. The Treasury Department and the IRS have determined that relief is not appropriate for a nonrecourse deduction, as defined in § 1.704-2(b)(1), because, unlike the other types of regulatory allocations, partners have significant discretion regarding the allocation of a nonrecourse deduction.

ii. Creditable Foreign Tax Expenditures

The temporary regulations provide that allocations of creditable foreign tax expenditures (as defined in § 1.704-

1(b)(4)(viii)(b)) (CFTEs) are not subject to the consistent allocation method. See § 1.721(c)-3T(c)(4)(ii). The regulations governing the allocation of CFTEs take into account section 704(c) income and gain and are not based strictly on the allocation of book items. As a result, it would be difficult to apply the consistent allocation method with respect to CFTEs.

VII. Acceleration Events

a. Overview

Section 1.721(c)-4T provides rules regarding acceleration events, which, like the gain deferral method, apply on a property-by-property basis. When an acceleration event occurs with respect to section 721(c) property, remaining built-in gain in the property must be recognized and the gain deferral method no longer applies. The temporary regulations provide exceptions to acceleration events that are discussed in Part VIII of the Explanation of Provisions section of this preamble.

b. Definition of an Acceleration Event

1. General Rules

Subject to the exceptions described in Part VIII of the Explanation of Provisions section of this preamble, § 1.721(c)-4T(b)(1) defines an acceleration event as any event that would reduce the amount of remaining built-in gain that a U.S. transferor would have recognized under the gain deferral method if the event had not occurred or that could defer the recognition of the remaining built-in gain. The temporary regulations clarify that an acceleration event includes the transfer of section 721(c) property via a contribution of the property itself or through a contribution of a partnership interest.

2. Failure To Comply With a Requirement of the Gain Deferral Method

The rules described in the notice would have provided that a failure to comply with one of the requirements of the gain deferral method with respect to any section 721(c) property would cause an acceleration event for all section 721(c) property. Comments requested that the Treasury Department and the IRS eliminate this provision. Because the temporary regulations provide that the gain deferral method is applied on a property-by-property basis (in lieu of containing the unified application requirement), the temporary regulations adopt this comment.

Under the temporary regulations, an acceleration event with respect to section 721(c) property occurs when any party fails to comply with a requirement

of the gain deferral method with respect to that property. See § 1.721(c)-4T(b)(2)(i). For example, if section 721(c) property is ECI property, an acceleration event occurs if a distributive share of income or gain from the property that is allocated to a direct or indirect partner that is a related foreign person is no longer subject to taxation as income effectively connected with a trade or business within the United States or if the section 721(c) partnership or a direct or indirect partner that is a related foreign person claims certain benefits under an income tax treaty with respect to the income (see § 1.721(c)-3T(b)(1)(ii)).

An acceleration event will not occur solely as a result of a failure to comply with a procedural or reporting requirement of the gain deferral method if that failure is not willful and relief is sought under the prescribed procedures. See §§ 1.721(c)-4T(b)(2)(ii) and 1.721(c)-6T(f).

3. Special Rule When Section 721(c) Property Is an Interest in a Partnership

When section 721(c) property is an interest in a partnership, the temporary regulations provide that an acceleration event will not occur because of a reduction in remaining built-in gain in the partnership interest as a result of allocations of book items of deduction and loss or tax items of income and gain by that partnership. See § 1.721(c)-4T(b)(3).

4. Deemed Acceleration Event

Under the temporary regulations, a U.S. transferor may affirmatively treat an acceleration event as having occurred with respect to section 721(c) property by recognizing the remaining built-in gain with respect to that property and satisfying the reporting required by § 1.721(c)-6T(b)(3)(iv). See § 1.721(c)-4T(b)(4).

c. Consequences of an Acceleration Event

Section 1.721(c)-4T(c) sets forth the consequences of an acceleration event. Specifically, the U.S. transferor must recognize gain in an amount equal to the remaining built-in gain that would have been allocated to the U.S. transferor if the section 721(c) partnership had sold the section 721(c) property immediately before the acceleration event for fair market value. Following the acceleration event, the section 721(c) property will no longer be subject to the gain deferral method.

The U.S. transferor generally must make correlative adjustments to its basis in its partnership interest. See § 1.721(c)-4T(c)(1). In addition, the

section 721(c) partnership will increase its basis in the section 721(c) property by the amount of gain recognized by the U.S. transferor. This basis increase is made immediately before the acceleration event. See § 1.721(c)-4T(c)(2). If the section 721(c) property remains in the partnership after the acceleration event, the increase in the basis of the section 721(c) property generally would be treated in the same manner as newly purchased property, including for purposes of determining the depreciation schedule if the property is depreciable property.

VIII. Acceleration Event Exceptions

a. In General

Section 1.721(c)-5T identifies the following categories of exceptions to acceleration events, which, like acceleration events, apply on a property-by-property basis: (i) Termination events, in which case, the gain deferral method ceases to apply to the section 721(c) property; (ii) successor events, in which case, the gain deferral method continues to apply to the section 721(c) property but with respect to a successor U.S. transferor or a successor section 721(c) partnership, as applicable; (iii) partial acceleration events, in which case, a U.S. transferor recognizes an amount of gain that is less than the full amount of remaining built-in gain in the section 721(c) property and the gain deferral method continues to apply; (iv) transfers described in section 367 of section 721(c) property to a foreign corporation, in which case, the gain deferral method ceases to apply and a U.S. transferor recognizes an amount of gain equal to the remaining built-in gain attributable to the portion of the section 721(c) property that is not subject to tax under section 367; and (v) fully taxable dispositions of a portion of an interest in a section 721(c) partnership, in which case, the gain deferral method continues to apply for the retained portion of the interest.

b. Termination Events

1. In General

Section 1.721(c)-5T(b) identifies the events that cause the gain deferral method to no longer apply. The Treasury Department and the IRS have determined that it is appropriate to terminate the application of the gain deferral method with respect to the affected section 721(c) property in these cases because the potential to shift gain or income to a related foreign person that is a direct or indirect partner in the section 721(c) partnership has been eliminated.

2. Transfers of Section 721(c) Property (Other Than a Partnership Interest) to a Domestic Corporation Described in Section 351

The temporary regulations provide that a termination event occurs if a section 721(c) partnership transfers section 721(c) property other than a partnership interest to a domestic corporation in a transaction to which section 351 applies. See § 1.721(c)-5T(b)(2).

3. Certain Incorporations of a Section 721(c) Partnership

A comment questioned whether the rules described in the notice would exempt from the definition of an acceleration event certain transactions after which the partnership ceases to exist, such as those described in Rev. Rul. 84-111, 1984-2 C.B. 88 (describing three methods for incorporating a partnership). See § 601.601(d)(2)(ii)(b). The temporary regulations provide that a termination event occurs upon an incorporation of a section 721(c) partnership into a domestic corporation by any method of incorporation other than a method involving an actual distribution of partnership property to the partners, followed by a contribution of that property to a corporation, provided that the section 721(c) partnership is liquidated as part of the incorporation transaction. See § 1.721(c)-5T(b)(3).

4. Certain Distributions of Section 721(c) Property

A comment questioned whether an acceleration event should occur as a result of a distribution of section 721(c) property to a partner other than a U.S. transferor outside of the seven-year period described in sections 704(c)(1)(B) and 737 (rules that address certain distributions of property within seven years of a contribution). While sections 704(c)(1)(B) and 737 also are intended to ensure that gain on contributed property is not inappropriately transferred to a partner other than the contributor, in the context of contributions to partnerships with related foreign partners, the Treasury Department and the IRS have determined that concerns about the erosion of the U.S. tax base remain as long as there is remaining built-in gain in the section 721(c) property. Accordingly, the Treasury Department and the IRS have determined that it is inappropriate to provide a termination event exception for all distributions of section 721(c) property after seven years.

The temporary regulations, however, provide that a termination event occurs

if a section 721(c) partnership distributes section 721(c) property to the U.S. transferor. A termination event will also occur if a section 721(c) partnership distributes section 721(c) property to a member of a U.S. transferor's consolidated group and the distribution occurs more than seven years after the contribution. See § 1.721(c)-5T(b)(4).

5. Section 721(c) Partnership Ceases to Have a Related Foreign Person Partner

In response to a comment, the temporary regulations generally provide that a termination event occurs when a section 721(c) partnership ceases to have any direct or indirect partners that are related foreign persons, provided there is no plan for a related foreign person to subsequently become a direct or indirect partner in the partnership (or a successor). See § 1.721(c)-5T(b)(5). The no-plan requirement applies independently of the general anti-abuse rule under § 1.721(c)-1T(d). An acceleration event, however, occurs upon a distribution of section 721(c) property in redemption of a related foreign person's interest in a section 721(c) partnership.

6. Fully Taxable Dispositions of Section 721(c) Property or of an Entire Interest in a Section 721(c) Partnership

The notice treated a taxable disposition of section 721(c) property by a section 721(c) partnership, or an indirect disposition of section 721(c) property through a taxable disposition of an interest in a section 721(c) partnership interest, as an acceleration event. The Treasury Department and the IRS have determined that it is appropriate instead to treat a fully taxable disposition of section 721(c) property or of an entire interest in a section 721(c) partnership as a termination event because other sections of the Code require gain to be recognized.

Accordingly, the temporary regulations provide that a termination event occurs if a section 721(c) partnership disposes of section 721(c) property in a transaction in which all gain or loss, if any, is recognized. See § 1.721(c)-5T(b)(6). In addition, a termination event occurs if either a U.S. transferor or a partnership in which a U.S. transferor is a direct or indirect partner disposes of an entire interest in a section 721(c) partnership that owns section 721(c) property in a transaction in which all gain or loss, if any, is recognized. This rule does not apply if a U.S. transferor is a member of a consolidated group and the interest in the section 721(c) partnership is transferred to another member in an

intercompany transaction (as defined in § 1.1502-13(b)(1)). See § 1.721(c)-5T(b)(7). See, however, Paragraph c.2 of this Part VIII, which describes the rule in § 1.721(c)-5T(c)(3) that provides that such a transaction may be a successor event.

c. Successor Events

1. In General

Section 1.721(c)-5T(c) identifies the successor events that allow for the continued application of the gain deferral method. In each of these cases, it is appropriate to continue application of the gain deferral method (rather than accelerate gain recognition), because its application can be preserved in the hands of a successor U.S. transferor or a successor section 721(c) partnership, as applicable. If, however, the successor does not continue the gain deferral method, the event is an acceleration event. If only a portion of an interest in a partnership is transferred in a successor event, the principles of § 1.704-3(a)(7) apply to determine the remaining built-in gain in section 721(c) property that is attributable to the portion of the interest that is transferred and the portion that is retained. See § 1.721(c)-5T(c)(1).

2. A Domestic Corporation Becomes a Successor U.S. Transferor

The temporary regulations provide that a successor event occurs if either a U.S. transferor or a partnership in which a U.S. transferor is a direct or indirect partner transfers (directly or indirectly through one or more partnerships) an interest in a section 721(c) partnership to a domestic corporation in a transaction to which section 351 or 381 applies, and the gain deferral method is continued by treating the transferee domestic corporation as the U.S. transferor. See § 1.721(c)-5T(c)(2).

In addition, a successor event occurs if a U.S. transferor that is a member of a consolidated group transfers (directly or indirectly through one or more partnerships) an interest in a section 721(c) partnership to another member in an intercompany transaction (as defined in § 1.1502-13(b)(1)), and the gain deferral method is continued by treating the transferee member as the U.S. transferor. See § 1.721(c)-5T(c)(3).

3. Technical Termination of a Section 721(c) Partnership

In response to comments, the temporary regulations provide that a successor event occurs if there is a technical termination of a section 721(c) partnership, and the gain deferral method is continued by treating the new

partnership as the section 721(c) partnership. See § 1.721(c)–5T(c)(4). Although a technical termination will cause the depreciation schedule to be reset with respect to any depreciable section 721(c) property of the terminated section 721(c) partnership, and thus defer the recognition of remaining built-in gain, the Treasury Department and the IRS have concluded that this should not cause an acceleration event. In this case, however, the general anti-abuse rule under § 1.721(c)–1T(d) may apply, depending on the facts relating to the technical termination.

4. A Partnership Becomes a Successor Section 721(c) Partnership

The temporary regulations provide two other categories of successor events that involve successor section 721(c) partnerships. In each case, section 721(c) property is directly or indirectly contributed to a successor section 721(c) partnership and the gain deferral method is applied down the chain of ownership with the result that the remaining built-in gain will continue to be subject to U.S. tax.

In the first category, a successor event occurs if (i) a section 721(c) partnership contributes section 721(c) property to a lower-tier partnership that is a controlled partnership; (ii) the gain deferral method is applied both with respect to the section 721(c) partnership's interest in the lower-tier partnership and with respect to the section 721(c) property in the hands of the lower-tier partnership; and (iii) the lower-tier partnership either is a section 721(c) partnership, or is a controlled partnership that fails the ownership requirement but is treated as a section 721(c) partnership. See § 1.721(c)–5T(c)(5)(i). In the case in which the lower-tier partnership is a controlled partnership but not a section 721(c) partnership, the Treasury Department and the IRS have determined that it is appropriate to allow the parties to continue to apply the gain deferral method to the section 721(c) property, rather than triggering an acceleration event, provided the parties treat the lower-tier partnership as a section 721(c) partnership for purposes of applying the gain deferral method.

In the second category, a successor event occurs if (i) either a U.S. transferor or a partnership in which a U.S. transferor is a direct or indirect partner contributes (directly or indirectly through one or more partnerships) an interest in a section 721(c) partnership to an upper-tier partnership that is a controlled partnership; (ii) the gain deferral method is continued with

respect to the section 721(c) property in the hands of the section 721(c) partnership; (iii) if the upper-tier partnership directly owns its interest in the section 721(c) partnership, the gain deferral method is applied with respect to the upper-tier partnership's interest in the section 721(c) partnership and the upper-tier partnership is, or is treated as, a section 721(c) partnership; and (iv) if the upper-tier partnership indirectly owns its interest in the section 721(c) partnership through one or more partnerships, the principles described in clause (iii) are applied with respect to the upper-tier partnership and each partnership through which the upper-tier partnership indirectly owns an interest in the section 721(c) partnership. See § 1.721(c)–5T(c)(5)(ii).

Both categories of successor events involve tiered partnerships. Therefore, pursuant to § 1.721(c)–3T(b)(5), the rules for tiered partnerships (described in § 1.721(c)–3T(d)) must be applied in order to satisfy the requirements to apply the gain deferral method as required under the rules described in the two preceding paragraphs.

To illustrate, consider the following simplified example: In year 1, USP, a domestic corporation, and CFC1, a wholly owned foreign subsidiary of USP, form PS1, a partnership, as equal partners. USP contributes section 721(c) property, asset A, a depreciable asset with a \$10 million built-in gain (fair market value of \$10 million and tax basis of zero) (USP contribution). PS1 is a section 721(c) partnership as a result of the USP contribution, and the gain deferral method is applied with respect to asset A. In year 2, PS1 and CFC1 form PS2, a partnership, as equal partners. PS1 contributes asset A to PS2 (PS1 contribution) when asset A has remaining built-in gain of \$8 million and a fair market value of \$12 million (the tax basis is still zero). PS2 is a section 721(c) partnership as a result of the PS1 contribution. The PS1 contribution will be a successor event with respect to asset A if PS2 applies the gain deferral method to asset A and PS1 applies the gain deferral method to its interest in PS2 as described in § 1.721(c)–5T(c)(5)(i). The remaining built-in gain in asset A in the hands of PS2 will be \$12 million (excess of book value of \$12 million over PS2's adjusted tax basis of \$0). If PS2 sells the property, PS2 will allocate \$12 million to PS1, and PS1 will allocate \$10 million of the gain to USP (\$8 million of which would be allocated under § 1.704–3(a)(9)).

On the other hand, the PS1 contribution will be an acceleration event (rather than a successor event) with respect to asset A if either PS1 or

PS2 does not apply the gain deferral method. In this case, USP will recognize \$8 million of gain, which is the amount of the remaining built-in gain that would have been allocated to USP if PS1 had sold asset A immediately before the PS1 contribution for fair market value, and PS1 will increase its tax basis in asset A from \$0 to \$8 million. See § 1.721(c)–4T(c). Furthermore, the PS1 contribution will be subject to the general gain recognition rule under § 1.721(c)–2T(b) because PS2 is a section 721(c) partnership and asset A is section 721(c) property. PS1's realized gain with respect to asset A that will not qualify for nonrecognition under section 721(a) is \$4 million (fair market value of \$12 million less adjusted tax basis of \$8 million) and PS1 will allocate half of that gain to USP.

d. Partial Acceleration Events

1. In General

Section 1.721(c)–5T(d) identifies the partial acceleration events, and, in each case, the amount of gain that a U.S. transferor must recognize. The basis adjustments in § 1.721(c)–4T(c) that must be made by a U.S. transferor and a section 721(c) partnership upon a “full” acceleration event also apply for a partial acceleration event, except in the case of a partial acceleration that occurs as a result of an adjustment under section 734 to section 721(c) property, as described in Paragraph d.3 of this Part VIII. If there is remaining built-in gain in the section 721(c) property immediately after the partial acceleration event, the gain deferral method must continue to apply following the partial acceleration event.

2. Regulatory Allocations

Section 1.721(c)–3T(c)(4)(i)(C) provides that a regulatory allocation that results in an over-allocation of book deduction or loss to a U.S. transferor or an under-allocation of book income or gain to a U.S. transferor will nevertheless be treated as satisfying the consistent allocation method if gain is recognized. See the discussion in Paragraph e.3.i of Part VI of the Explanation of Provisions section of this preamble. In order for such a regulatory allocation to be deemed to satisfy the consistent allocation method, the U.S. transferor must recognize an amount of gain equal to the amount of the allocation that, had the regulatory allocation not occurred, would have been allocated to the U.S. transferor in the case of income or gain, or would not have been allocated to the U.S. transferor in the case of deduction or

loss. See § 1.721(c)–5T(d)(2). However, the amount of gain recognized is limited to the amount of the remaining built-in gain that would have been allocated to the U.S. transferor upon a hypothetical sale by the section 721(c) partnership of that portion of the property immediately before the regulatory allocation is made for fair market value.

3. Distributions of Other Partnership Property to a Partner That Result in an Adjustment Under Section 734

The temporary regulations provide that a partial acceleration event occurs if there is a distribution of other property by a section 721(c) partnership that results in a positive basis adjustment to section 721(c) property under section 734. In these cases, the U.S. transferor must recognize an amount of gain equal to the positive basis adjustment to the section 721(c) property under section 734. However, the amount of gain recognized is limited to the amount of the remaining built-in gain that would have been allocated to the U.S. transferor upon a hypothetical sale by the section 721(c) partnership of that portion of the property immediately before the regulatory allocation is made for fair market value. Furthermore, if the property that triggered the section 734 adjustment was distributed to the U.S. transferor or a member of its consolidated group, the amount described in the preceding sentence is reduced (but not below zero) by the amount of gain recognized by the U.S. transferor (or the consolidated group member) under section 731(a). See § 1.721(c)–5T(d)(3). The amount of gain recognized as a result of the acceleration event is not reduced by any step-down to distributed property described by section 734(b)(1)(B). The partnership will not increase its basis under § 1.721(c)–4T(c)(2) for the gain recognized by the U.S. transferor.

e. Section 367 Transfers of Section 721(c) Property to a Foreign Corporation

Section 1.721(c)–5T(e) provides rules for certain direct and indirect transfers of section 721(c) property to a foreign corporation. These rules apply if a section 721(c) partnership transfers section 721(c) property, or if a U.S. transferor or a partnership in which a U.S. transferor is a direct or indirect partner transfers (directly or indirectly through one or more partnerships) an interest in a section 721(c) partnership, to a foreign corporation in a transaction described in section 367. In this case, the underlying section 721(c) property will no longer be subject to the gain deferral method. The Treasury Department and the IRS have

determined that this result is appropriate because to the extent any U.S. transferor is treated as transferring the section 721(c) property to the foreign corporation for purposes of section 367, the tax consequences will be determined under section 367. In this regard, see §§ 1.367(a)–1T(c)(3)(i) and (ii), 1.367(d)–1T(d)(1), and 1.367(e)–2(b)(1)(iii) (in general, providing an aggregate treatment of partnerships for purposes of applying the outbound transfer provisions under section 367). Furthermore, for the remaining portion of the property (which is the portion attributable to non-U.S. persons and therefore not subject to tax under section 367), the U.S. transferor must recognize an amount of gain equal to the remaining built-in gain that would have been allocated to the U.S. transferor upon a hypothetical sale by the section 721(c) partnership of that portion of the property immediately before the transfer for fair market value. The basis adjustments in § 1.721(c)–4T(c) that must be made by a U.S. transferor and a section 721(c) partnership upon a “full” acceleration event also apply in this case. If stock in the transferee foreign corporation is received by a section 721(c) partnership, the stock will not be subject to the gain deferral method.

f. Fully Taxable Dispositions of a Portion of an Interest in a Section 721(c) Partnership

Section 1.721(c)–5T(f) provides a special rule when there is a fully taxable disposition of a portion of an interest in a section 721(c) partnership. Specifically, if a U.S. transferor or a partnership in which a U.S. transferor is a direct or indirect partner disposes of (directly or indirectly through one or more partnerships) a portion of an interest in a section 721(c) partnership in a transaction in which all gain or loss, if any, is recognized, an acceleration event will not occur with respect to the portion of the interest transferred. The gain deferral method will continue to apply with respect to the section 721(c) property of the section 721(c) partnership. The principles of § 1.704–3(a)(7) will apply to determine the remaining built-in gain in section 721(c) property that is attributable to the portion of the interest in a section 721(c) partnership that is retained. This rule does not apply to an intercompany transaction (as defined in § 1.1502–13(b)(1)). See § 1.721–5T(c)(3). See also the discussion in Paragraph c.2 of this Part VIII.

IX. Tiered Partnerships Rules

a. Overview

This Part IX discusses the application of the gain deferral method to tiered partnerships. The temporary regulations employ two general principles in applying the gain deferral method to tiered partnerships. First, if the section 721(c) property is an interest in a partnership, the contribution of that partnership interest, and not the indirect contribution of the underlying property of the lower-tier partnership, to a section 721(c) partnership is subject to section 721(c), and the gain deferral method applies to the contribution of the interest. Second, the gain deferral method must also be adopted at all levels in the ownership chain.

These principles, however, raise various issues in applying the gain deferral method to tiered partnerships: (i) Not all partnerships in the ownership chain will necessarily be section 721(c) partnerships; (ii) when the book value of an interest in a partnership reflects appreciation in the property of the lower-tier partnership that has not yet been reflected in the book value of the property, there will be a discrepancy between the built-in gain in the partnership interest and the built-in gain in the underlying property; (iii) an upper-tier partnership's allocation of its distributive share of certain lower-tier partnership items must comply with § 1.704–3(a)(9) (concerning the application of section 704(c) to tiered partnerships) and with the consistent allocation method; and (iv) a partnership whose interest is section 721(c) property that is contributed to a section 721(c) partnership may have previously adopted a method other than the remedial allocation method with respect to its underlying section 704(c) property.

To address these issues, the temporary regulations specify requirements that must be satisfied, in addition to all the other requirements to apply the gain deferral method, in order for the gain deferral method to be applied to tiered partnerships. See § 1.721(c)–3T(b)(5) (the last requirement to apply the gain deferral method).

b. Additional Requirements for Applying the Gain Deferral Method

1. In General

For purposes of applying the gain deferral method, the temporary regulations address the conditions required to be satisfied by upper-tier partnerships and lower-tier partnerships involved in tiered-partnership transactions to ensure that the gain

deferral method is applied at all levels in the ownership chain and the allocation of partnership items up the chain correctly traces the built-in gain to the U.S. transferor. See § 1.721(c)–3T(d). In the base case in which a U.S. transferor directly contributes section 721(c) property to a section 721(c) partnership, the U.S. transferor will recognize gain under the general rule in these temporary regulations unless the gain deferral method is applied to the contribution. The same principle applies when section 721(c) property is indirectly (through an upper-tier partnership) contributed by a U.S. transferor to a section 721(c) partnership and the partnership look-through rule in § 1.721(c)–2T(d)(1) applies, in which case, the tiered-partnership rules in § 1.721(c)–3T(d)(2) apply to the transferor upper-tier partnership and all controlled partnerships above it in the ownership chain. In addition, when the section 721(c) property is an interest in a partnership, the tiered-partnership rules in § 1.721(c)–3T(d)(1) apply to the partnership whose interest is transferred and all controlled partnerships below it in the ownership chain. Therefore, when a partnership interest described in the preceding sentence is indirectly contributed by a U.S. transferor and the partnership look-through rule applies, the rules of both § 1.721(c)–3T(d)(1) and (2) apply.

2. Indirect Contribution of Section 721(c) Property

Section 1.721(c)–3T(d)(2) provides the additional requirements for applying the gain deferral method if the section 721(c) property is indirectly contributed by a U.S. transferor to a section 721(c) partnership and the partnership look-through rule applies. In particular, this rule applies if an upper-tier partnership in which a U.S. transferor is a direct or indirect partner contributes section 721(c) property to a lower-tier section 721(c) partnership. The upper-tier partnership need not be a section 721(c) partnership for the partnership look-through rule to apply, but, in order for the upper-tier partnership to avoid immediate gain recognition under the general gain recognition rule, the lower-tier section 721(c) partnership must apply the gain deferral method to the contributed property. This application of the gain deferral method has several additional requirements. First, the lower-tier section 721(c) partnership must treat the upper-tier partnership (which is not necessarily a section 721(c) partnership) as the U.S. transferor solely for purposes of applying the consistent allocation method. Second, the upper-tier partnership, if it is a

controlled partnership, must apply the gain deferral method to its interest in the lower-tier section 721(c) partnership. If the upper-tier partnership is not a section 721(c) partnership, it is deemed to be so, and the interest in the lower-tier section 721(c) partnership is deemed to be section 721(c) property. See § 1.721(c)–1T(b)(14)(ii) and (b)(15)(ii).

For the upper-tier partnership to apply the gain deferral method to the interest in the lower-tier partnership, § 1.704–3T(a)(13)(ii) provides that the upper-tier partnership must treat its distributive share of lower-tier partnership items of gain, loss, and amortization, depreciation, or other cost recovery deductions with respect to a lower-tier partnership's section 721(c) property as though they were items of gain, loss, and amortization, depreciation, or other cost recovery with respect to the upper-tier partnership's interest in the lower-tier partnership. Section 1.704–3T(a)(13)(ii) is intended to reach the same result as if an aggregate approach governed the application of § 1.704–3(a)(9) in the context of the gain deferral method. Section 1.704–3(a)(9) provides that if a partnership contributes section 704(c) property to a lower-tier partnership, or if a partner that receives a partnership interest in exchange for contributed property subsequently contributes the partnership interest to an upper-tier partnership, the upper-tier partnership must allocate its distributive share of lower-tier partnership items with respect to that section 704(c) property in a manner that takes into account the contributing partner's remaining built-in gain or loss. The Treasury Department and the IRS considered comments about aggregate treatment that were received on Notice 2009–70, 2009–34 I.R.B. 255, in developing the rule in § 1.704–3T(a)(13)(ii). This rule applies only to a tiered-partnership structure that has at least one section 721(c) partnership and to which the gain deferral method is applied. The Treasury Department and the IRS intend no inference regarding the application of § 1.704–3(a)(9) to partnerships not applying the gain deferral method.

If the U.S. transferor is an indirect partner in the upper-tier partnership through one or more partnerships, these requirements must be satisfied by each controlled partnership in the chain of ownership between the upper-tier partnership and the U.S. transferor.

3. Contribution of an Interest in a Partnership

Section 1.721(c)–3T(d)(1) provides the additional requirements for applying the

gain deferral method if the section 721(c) property that is contributed to a section 721(c) partnership is an interest in a lower-tier partnership. The lower-tier partnership need not be a section 721(c) partnership. First, the lower-tier partnership, if it is a controlled partnership with respect to a U.S. transferor, must revalue all of its property under § 1.704–1T(b)(2)(iv)(f)(6) if the revaluation would result in a new positive reverse section 704(c) layer in at least one property that is not excluded property (revaluation requirement). If the lower-tier partnership is not a section 721(c) partnership, it will be deemed to be so upon the revaluation. See § 1.721(c)–1T(b)(14)(ii).

The revaluation requirement ensures, to the greatest extent possible, that all appreciation in the underlying property of a lower-tier partnership that is reflected in the book value of the partnership interest in the lower-tier partnership is subject to the temporary regulations to the same extent that appreciation would be subject to the temporary regulations if the property of the lower-tier partnership (rather than the interest in the lower-tier partnership) were contributed.

Second, the lower-tier partnership must apply the gain deferral method with respect to each property (other than excluded property) for which there is a new positive reverse section 704(c) layer as a result of the revaluation. A property with a new positive reverse section 704(c) layer is deemed to be section 721(c) property, and the remaining built-in gain includes the new positive reverse section 704(c) layer. See § 1.721(c)–1T(b)(15)(ii) and (b)(13)(ii), respectively. Although § 1.721(c)–3T(b)(1)(i)(A) requires the application of the remedial allocation method to the remaining built-in gain, a lower-tier partnership may apply the gain deferral method by adopting the remedial allocation method only for the positive reverse section 704(c) layer if the partnership has previously adopted a section 704(c) method other than the remedial method for the property. Accordingly, the lower-tier partnership may continue to apply a different, historical section 704(c) method to forward section 704(c) layers or to pre-existing reverse section 704(c) layers, as applicable, and still satisfy the requirements of the gain deferral method. For further discussion of the revaluation requirement and the definition of a controlled partnership, see Paragraph c of this Part IX.

Third, the lower-tier partnership must treat a partner that is a partnership in which the U.S. transferor is a direct or

indirect partner as the U.S. transferor solely for purposes of applying the consistent allocation requirement. As a result, the lower-tier partnership must allocate its book items to the deemed U.S. transferor under the consistent allocation method. Regardless of the number of tiers of partnerships in the chain, the tiered-partnership rules are intended to cause the U.S. transferor that contributed (directly or indirectly) the lower-tier partnership interest to the section 721(c) partnership to be the person to recognize gain upon an acceleration event.

If the lower-tier partnership owns (directly or indirectly through one or more partnerships) one or more partnerships that are controlled partnerships with respect to the U.S. transferor, these three requirements must be satisfied by each controlled partnership.

c. Revaluation Requirement

In recognition of the possibility that a U.S. transferor may not be able to cause a lower-tier partnership to revalue its property when a partnership interest is contributed to an upper-tier partnership, the revaluation requirement is limited to those lower-tier partnerships that are controlled partnerships with respect to the U.S. transferor. Control is a facts-and-circumstances test, except that the U.S. transferor and related persons will be deemed to control a partnership in which those persons, in the aggregate, own (directly or indirectly through one or more partnerships) more than 50 percent of the interests in partnership capital or profits. See § 1.721(c)–1T(b)(4).

The definition of built-in gain in the notice excluded revaluation gain because a reverse section 704(c) layer with respect to property does not arise on the contribution of that property. However, a partnership that does not create and apply the remedial method to a positive reverse section 704(c) layer created on the contribution of a lower-tier partnership interest to an upper-tier partnership may shift the tax consequences of a portion of the built-in gain to a partner that is a related foreign person. The Treasury Department and the IRS believe that the description of the tiered-partnership rules contained in the notice notified taxpayers of an intention to promulgate a rule with the result reached by the temporary regulations.

The revaluation requirement described in the gain deferral method requires an expansion of permissible events for partnership revaluations under section 704(b). Accordingly, § 1.704–1T(b)(2)(iv)(f)(6) allows a

partnership to revalue its property if the revaluation is a condition for applying the gain deferral method. When multiple partnerships revalue their property, the revaluations occur in order from the lowest-tier partnership to the highest-tier partnership.

If a partnership revalues its property, § 1.704–3T(a)(13)(i) provides that the principles of § 1.704–3(a)(9) shall apply to any reverse section 704(c) allocations made as a result of the revaluation.

In developing the revaluation requirement and § 1.704–3T(a)(13)(i), the Treasury Department and the IRS considered comments received on revaluation rules in proposed regulations under section 751(b) that are contained in a notice of proposed rulemaking (REG–151416–06) published on November 3, 2014, in the **Federal Register** (79 FR 65151). See proposed §§ 1.704–1(b)(2)(iv)(f) and 1.704–3(a)(9).

X. Procedural and Reporting Requirements

To comply with the gain deferral method, the notice described regulations that would be issued requiring reporting of a gain deferral contribution and annual reporting with respect to the section 721(c) property to which the gain deferral method applies. The notice requested comments on whether the regulations should provide rules similar to those in the regulations under sections 367(a) and 6038B regarding failures to file gain recognition agreements or to satisfy other reporting obligations, including the standards for relief therein. See T.D. 9704 (79 FR 68763) (the 2014 GRA regulations). Comments were received expressing support for this approach.

a. Reporting and Procedural Requirements for the Year of the Gain Deferral Contribution

The temporary regulations implement the rules described in the notice in a manner consistent with the approach in the 2014 GRA regulations. For a U.S. transferor, the reporting requirements include, among other information, the information required to be filed under section 6038B. The temporary regulations also adopt procedural requirements in order to seek relief for a failure to meet the reporting requirements of the gain deferral method, which mirror the approach in the 2014 GRA regulations, including procedures relating to the manner by which a transferor can establish the lack of willfulness and that a failure was due to reasonable cause. See §§ 1.721(c)–6T(f) and 1.6038B–2T(h). The temporary regulations adopt these procedural requirements for all U.S. persons that

have a reporting obligation under section 6038B with respect to a transfer of property to a foreign partnership and that are seeking relief under the reasonable cause exception, not only for U.S. transferors described in the section 721(c) regulations. The reasonable cause procedure in the temporary regulations applies to all requests for reasonable cause relief (regardless of the date on which the contribution or the failure to file occurred) filed on or after January 18, 2017.

In addition to adopting the current requirements of § 1.6038B–2(c), the temporary regulations require reporting necessary to demonstrate compliance with the gain deferral method. In general, the temporary regulations require a U.S. transferor to report information on a statement included on (or attached to) the Form 8865, Schedule O, Transfer of Property to a Foreign Partnership. The Treasury Department and the IRS intend that the Schedule O will be revised to include the information required by the temporary regulations.

For purposes of the U.S. transferor's reporting requirements under § 1.721(c)–6T with respect to a gain deferral contribution to a domestic section 721(c) partnership, a domestic section 721(c) partnership will generally be treated as foreign under section 7701(a)(4) for reporting purposes. See §§ 1.721(c)–6T(b)(4) and 1.6038B–2T(a)(1)(iii). As a result, a U.S. transferor that contributes section 721(c) property to a domestic section 721(c) partnership in a gain deferral contribution must file a Form 8865, Return of U.S. Persons With Respect to Certain Foreign Partnerships (including Form 8865, Schedule O, Transfer of Property to a Foreign Partnership), with its return for the taxable year that includes the date of the gain deferral contribution.

Also as a requirement of the gain deferral method, the temporary regulations require that the U.S. transferor agree to extend the period of limitations on the assessment of tax for eight full taxable years with respect to the gain realized but not recognized on a gain deferral contribution, and for six full taxable years with respect to the U.S. transferor's distributive share of all items with respect to the section 721(c) property for the year of contribution and two subsequent years. See § 1.721(c)–6T(b)(5)(i) and (ii). The U.S. transferor also must agree to extend the period of limitations on the assessment of tax for five full taxable years with respect to the gain recognized on the contribution of section 721(c) property for which the gain deferral method is not applied if

the contribution is made within five partnership taxable years following a gain deferral contribution. See § 1.721(c)-6T(b)(5)(iii). All agreements to extend the period of limitations on assessment of tax are deemed consented to and signed by the Secretary for purposes of section 6501(c)(4). The Treasury Department and the IRS intend to issue a designated form for use in extending the period of limitations by consent, as described above. Until the time such form is issued, the required consent must be submitted as a statement attached to the U.S. Transferor's Form 8865, Schedule O. Once such form is issued, the U.S. transferor must use the designated form to submit the required consent. These agreements must be filed only in connection with contributions occurring on or after January 18, 2017.

If section 721(c) property that is subject to the gain deferral method is ECI property, the temporary regulations require the U.S. transferor to obtain from the section 721(c) partnership and each related foreign person that is a direct or indirect partner in the section 721(c) partnership a statement pursuant to which the partner and the partnership waive any claim under any income tax convention (whether or not currently in force at the time of the contribution) to an exemption from U.S. income tax or a reduced rate of U.S. income taxation on income derived from the use of the ECI property for the period in which there is remaining built-in gain. See § 1.721(c)-6T(c)(1).

The temporary regulations require the U.S. transferor also to provide information with respect to related foreign partners and certain section 721(c) partnerships under section 6038B and the gain deferral method. This requirement also applies in the case of a partnership in a tiered-partnership structure that applies the gain deferral method under § 1.721(c)-3T(d). See § 1.721(c)-6T(b)(2). The U.S. transferor must attach this information to its return.

If the section 721(c) partnership has a reporting obligation under section 6031, it also will be required to report certain information under the temporary regulations. See § 1.721(c)-6T(d). Although the temporary regulations require the partnership to submit certain information to the IRS and comply with other requirements relating to the application of the gain deferral method, a failure to do so will not constitute an acceleration event to the U.S. transferor. The Treasury Department and the IRS intend that the Form 1065, Schedule K-1, or their accompanying instructions will be revised to describe this required

information. Failure to include this information may result in imposition of a penalty. See sections 6721 and 6722.

b. Annual Reporting Requirements

The temporary regulations require the U.S. transferor to provide certain information on an annual basis with respect to section 721(c) property subject to the gain deferral method. See §§ 1.721(c)-6T(b)(3) and 1.6038B-2T(c)(9). This includes information about income from the section 721(c) property (book and remedial income) allocated to the U.S. transferor in the partnership taxable year that ends with, or within, the U.S. transferor's taxable year, a calculation of remaining built-in gain, and information about acceleration, termination, successor, and partial acceleration events. The U.S. transferor must also attach a Schedule K-1 (Form 8865), Partner's Share of Income, Deductions, Credits, etc., for all related foreign persons that are direct or indirect partners in the section 721(c) partnership (if the partnership does not have a filing obligation under section 6031) for the partnership taxable year that ends with, or within, the U.S. transferor's taxable year.

In the case of ECI property subject to the gain deferral method, the U.S. transferor must annually declare that, after exercising reasonable diligence, to the best of the U.S. transferor's knowledge and belief all the income from the property was income effectively connected with the conduct of a trade or business within the United States, and no benefits with respect to the ECI property were claimed under any income tax convention by related foreign persons that are direct or indirect partners in the section 721(c) partnership or by the section 721(c) partnership. This requirement eliminates the potential need for related foreign persons that are direct or indirect partners in the section 721(c) partnership and the partnership to submit to the U.S. transferor an annual waiver of treaty benefits.

The U.S. transferor must describe all acceleration, termination, successor, and partial acceleration events that occur with respect to the section 721(c) property during the partnership taxable year that ends with, or within, the U.S. transferor's taxable year. When there is a successor event, the U.S. transferor must identify the new partnership, lower-tier partnership, upper-tier partnership, or U.S. corporation (as applicable). If the section 721(c) partnership is a foreign partnership, the U.S. transferor must include the information described in § 1.6038-3(g) (contents of information returns

required of certain United States persons with respect to controlled foreign partnerships), if not already reported elsewhere, without regard to whether the section 721(c) partnership is a controlled foreign partnership or whether the U.S. transferor controlled the section 721(c) partnership. If the U.S. transferor is not a controlling fifty-percent partner (as defined in § 1.6038-3(a)), the U.S. transferor may comply with this requirement by providing only the information described in § 1.6038-3(g)(1). These requirements also apply to a U.S. transferor that is a successor, as described in Paragraph c.2 of Part VIII of the Explanation of Provisions section of this preamble.

If the section 721(c) partnership has a filing obligation under section 6031, the partnership must include the information required under § 1.721(c)-6T(b)(2) and (3) on the Schedule K-1 (Form 1065), Partner's Share of Income, Deductions, Credits, etc., of the U.S. transferor and all related foreign persons that are direct or indirect partners in the section 721(c) partnership. See § 1.721(c)-6T(d)(2).

XI. Effective/Applicability Dates

The applicability dates of the temporary regulations generally relate back to the issuance of the notice. Accordingly, in general, the temporary regulations apply to contributions occurring on or after August 6, 2015, and to contributions occurring before August 6, 2015, resulting from an entity classification election made under § 301.7701-3 that is filed on or after August 6, 2015 (referred to in this preamble as the "general applicability date"). However, new rules, including any substantive changes to the rules described in the notice, apply to contributions occurring on or after January 18, 2017, or to contributions occurring before January 18, 2017, resulting from an entity classification election made under § 301.7701-3 that is filed on or after January 18, 2017. Taxpayers may, however, elect to apply those new rules and substantive changes to the rules described in the notice to a contribution occurring on or after the general applicability date. The election is made by reflecting the application of the relevant rule on a timely filed or amended return.

Special Analyses

Certain IRS regulations, including these, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. It is hereby certified that the

collection of information contained in this regulation will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required. This certification is based on the fact that the temporary regulations include a \$1,000,000 de minimis exception for certain transfers, and tangible property with built-in gain that does not exceed \$20,000 is excluded from the regulations. In addition, the regulations only apply when a U.S. transferor contributes property to a partnership with a partner that is a related foreign person, and persons related to the U.S. transferor own more than 80 percent of the interests in the partnership. Accordingly, the Treasury Department and the IRS expect that these regulations primarily will affect large domestic corporations. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these regulations is Ryan A. Bowen of the Office of the Associate Chief Counsel (International). However, other personnel from the Treasury Department and the IRS participated in the development of the regulations.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding entries in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *.

Section 1.197–2T also issued under 26 U.S.C. 197(g).

* * * * *

Section 1.721(c)–1T also issued under 26 U.S.C. 721(c).

Section 1.721(c)–2T also issued under 26 U.S.C. 721(c).

Section 1.721(c)–3T also issued under 26 U.S.C. 721(c).

Section 1.721(c)–4T also issued under 26 U.S.C. 721(c).

Section 1.721(c)–5T also issued under 26 U.S.C. 721(c).

Section 1.721(c)–6T also issued under 26 U.S.C. 721(c).

Section 1.721(c)–7T also issued under 26 U.S.C. 721(c).

* * * * *

Section 1.6038B–2T also issued under 26 U.S.C. 6038B.

* * * * *

■ **Par. 2.** Section 1.197–2 is amended by adding paragraphs (h)(12)(vii)(C) and (l)(5) to read as follows:

§ 1.197–2 Amortization of goodwill and certain other intangibles.

* * * * *

(h) * * *

(12) * * *

(vii) * * *

(C) [Reserved]. For further guidance, see § 1.197–2T(h)(12)(vii)(C).

* * * * *

(l) * * *

(5) [Reserved]. For further guidance, see § 1.197–2T(l)(5).

■ **Par 3.** Section 1.197–2T is added to read as follows:

§ 1.197–2T Amortization of goodwill and certain other intangibles.

(a) through (h)(12)(vii)(B) [Reserved]. For further guidance, see § 1.197–2(a) through (h)(12)(vii)(B).

(C) *Rules for section 721(c) partnerships.* See § 1.704–3T(d)(5)(iii) if there is a contribution of a section 197(f)(9) intangible to a section 721(c) partnership (as defined in § 1.721(c)–1T(b)(14)).

(viii) through (l)(4)(iii) [Reserved]. For further guidance, see § 1.197–2(h)(12)(viii) through (l)(4)(iii).

(5) *Rules for section 721(c) partnerships—(i) Applicability dates—(A) In general.* Except as provided in paragraph (l)(5)(i)(B) of this section, paragraph (h)(12)(vii)(C) of this section applies with respect to contributions occurring on or after January 18, 2017, and with respect to contributions occurring before January 18, 2017, resulting from an entity classification election made under § 301.7701–3 of this chapter that is filed on or after January 18, 2017.

(B) *Election to apply the provisions described in paragraph (l)(5)(i)(A) of this section retroactively.* Paragraph (h)(12)(vii)(C) of this section may, by election, be applied with respect to a contribution occurring on or after August 6, 2015, and to a contribution occurring before August 6, 2015, resulting from an entity classification election made under § 301.7701–3 of this chapter that is filed on or after August 6, 2015. The election is made by applying paragraph (h)(12)(vii)(C) of this section on a timely filed original return (including extensions) or an amended return filed no later than six months after January 18, 2017.

(ii) *Expiration date.* Paragraph (h)(12)(vii)(C) of this section expires on January 17, 2020.

■ **Par. 4.** Section 1.704–1 is amended by adding paragraph (b)(2)(iv)(f)(6) following the undesignated paragraph at the end of paragraph (b)(2)(iv)(f)(5) and adding paragraph (f) to read as follows:

§ 1.704–1 Partner's distributive share.

* * * * *

(b) * * *

(2) * * *

(iv) * * *

(f) * * *

(6) [Reserved]. For further guidance, see § 1.704–1T(b)(2)(iv)(f)(6).

* * * * *

(f) [Reserved]. For further guidance, see § 1.704–1T(f).

■ **Par. 5.** Section 1.704–1T is amended by:

- 1. Revising paragraphs (b)(1)(iii) through (b)(2)(iv)(f)(5).
- 2. Adding paragraph (b)(2)(iv)(f)(6).
- 3. Revising paragraphs (b)(2)(iv)(g) through (b)(4)(viii)(a) introductory text.
- 4. Redesignating paragraph (f) as paragraph (g).
- 5. Adding a new paragraph (f).
- 6. Revising newly redesignated paragraph (g).

The additions and revisions read as follows:

§ 1.704–1T Partner's distributive share (temporary).

* * * * *

(b)(1)(iii) through (b)(2)(iv)(f)(5) [Reserved]. For further guidance, see § 1.704–1(b)(1)(iii) through (b)(2)(iv)(f)(5).

(6) Notwithstanding paragraph (b)(2)(iv)(f)(5) of this section, the revaluation is required under § 1.721(c)–3T(d)(1) as a condition of the application of the gain deferral method (as described in § 1.721(c)–3T(b)) and is pursuant to an event described in this paragraph (b)(2)(iv)(f)(6). If an interest in a partnership is contributed to a section 721(c) partnership (as defined in § 1.721(c)–1T(b)(14)), the partnership whose interest is contributed may revalue its property in accordance with this section. In this case, the revaluation by the partnership whose interest was contributed must occur immediately before the contribution. If a partnership that revalues its property pursuant to this paragraph owns an interest in another partnership, the partnership in which it owns an interest may also revalue its property in accordance with this section. When multiple partnerships revalue under this paragraph (b)(2)(iv)(f)(6), the revaluations occur in order from the lowest-tier partnership to the highest-tier partnership.

(b)(2)(iv)(g) through (b)(4)(viii)(a) introductory text [Reserved]. For further guidance, see § 1.704–1(b)(2)(iv)(g) through (b)(4)(viii)(a) introductory text.

* * * * *

(f) *Dates*—(1) *Applicability dates*—(i) *In general*. Except as provided in paragraph (f)(1)(ii) of this section, paragraph (b)(2)(iv)(f)(6) of this section applies with respect to contributions occurring on or after January 18, 2017, and with respect to contributions occurring before January 18, 2017, resulting from an entity classification election made under § 301.7701–3 of this chapter that is filed on or after January 18, 2017.

(ii) *Election to apply the provisions described in paragraph (f)(1)(i) of this section retroactively*. Paragraph (b)(2)(iv)(f)(6) of this section may, by election, be applied with respect to a contribution occurring on or after August 6, 2015, but before January 18, 2017, and with respect to a contribution occurring before August 6, 2015, resulting from an entity classification election made under § 301.7701–3 of this chapter that is filed on or after August 6, 2015. The election is made by applying paragraph (b)(2)(iv)(f)(6) of this section on a timely filed original return (including extensions) or an amended return filed no later than six months after January 18, 2017.

(2) *Expiration date*. Paragraph (b)(2)(iv)(f)(6) of this section expires on January 17, 2020.

(g) *Expiration date*. The applicability of this section (other than paragraphs (b)(2)(iv)(f)(6) and (f) of this section) expires on February 4, 2019.

■ **Par. 6.** Section 1.704–3 is amended by adding paragraphs (a)(13), (d)(5)(iii), and (g) to read as follows:

§ 1.704–3 Contributed property.

(a) * * *

(13) [Reserved]. For further guidance, see § 1.704–3T(a)(13).

* * * * *

(d) * * *

(5) * * *

(iii) [Reserved]. For further guidance, see § 1.704–3T(d)(5)(iii).

* * * * *

(g) [Reserved]. For further guidance, see § 1.704–3T(g).

■ **Par. 7.** Section 1.704–3T is added to read as follows:

§ 1.704–3T Contributed property (temporary).

(a)(1) through (12) [Reserved]. For further guidance, see § 1.704–3(a)(1) through (12).

(13) *Rules for tiered section 721(c) partnerships*—(i) *Revaluations*. If a

partnership revalues its property pursuant to § 1.704–1T(b)(2)(iv)(f)(6) immediately before an interest in the partnership is contributed to another partnership, or if an upper-tier partnership owns an interest in a lower-tier partnership, and both the upper-tier partnership and the lower-tier partnership revalue partnership property pursuant to § 1.704–1T(b)(2)(iv)(f)(6), the principles of § 1.704–3(a)(9) will apply to any reverse section 704(c) allocations made as a result of the revaluation.

(ii) *Basis-derivative items*. If a lower-tier partnership that is a section 721(c) partnership applies the gain deferral method, then, for purposes of applying this section, the upper-tier partnership must treat its distributive share of lower-tier partnership items of gain, loss, amortization, depreciation, or other cost recovery with respect to the lower-tier partnership's section 721(c) property as though they were items of gain, loss, amortization, depreciation, or other cost recovery with respect to the upper-tier partnership's interest in the lower-tier partnership. For purposes of this paragraph (a)(13)(ii), gain deferral method is defined in § 1.721(c)–1T(b)(8), section 721(c) partnership is defined in § 1.721(c)–1T(b)(14), and section 721(c) property is defined in § 1.721(c)–1T(b)(15).

(b) through (d)(5)(ii) [Reserved]. For further guidance, see § 1.704–3(b) through (d)(5)(ii).

(iii) *Special rules for a section 721(c) partnership and anti-churning property*—(A) *In general*. Solely in the case of a gain deferral contribution of section 721(c) property that is a section 197(f)(9) intangible that was not an amortizable section 197 intangible in the hands of the contributor, the remedial allocation method is modified with respect to allocations to a related person to the U.S. transferor pursuant to paragraphs (d)(5)(iii)(B) through (F) of this section. For purposes of this paragraph (d)(5)(iii), gain deferral contribution is defined in § 1.721(c)–1T(b)(7), related person is defined in § 1.721(c)–1T(b)(12), section 721(c) partnership is defined in § 1.721(c)–1T(b)(14), section 721(c) property is defined in § 1.721(c)–1T(b)(15), and U.S. transferor is defined in § 1.721(c)–1T(b)(18). For an example applying the rules of this paragraph (d)(5)(iii), see § 1.721(c)–7T, *Example 6*.

(B) *Book basis recovery*. The section 721(c) partnership must amortize the portion of the partnership's book value in the section 197(f)(9) intangible that exceeds the adjusted basis in the property upon contribution using any recovery period and amortization

method available to the partnership as if the property had been newly purchased by the partnership from an unrelated party.

(C) *Effect of ceiling rule limitations*. If the ceiling rule causes the book allocation of the item of amortization of a section 197(f)(9) intangible under paragraph (d)(5)(iii)(B) of this section by a section 721(c) partnership to a related person with respect to the U.S. transferor to differ from the tax allocation of the same item to the related person (a ceiling rule limited related person), the partnership must not create a remedial item of deduction to allocate to the related person but instead must increase the adjusted basis of the section 197(f)(9) intangible by an amount equal to the difference solely with respect to that related person. The partnership simultaneously must create an offsetting remedial item in an amount identical to the increase in adjusted tax basis of the section 197(f)(9) intangible and allocate it to the contributing partner.

(D) *Effect of basis adjustment*—(1) *In general*. The basis adjustment described in paragraph (d)(5)(iii)(C) of this section constitutes an adjustment to the adjusted basis of a section 197(f)(9) intangible with respect to the ceiling rule limited related person only. No adjustment is made to the common basis of partnership property. Thus, for purposes of calculating gain and loss, the ceiling rule limited related person will have a special basis for that section 197(f)(9) intangible. The adjustment to the basis of partnership property under this section has no effect on the partnership's computation of any item under section 703.

(2) *Computation of a partner's distributive share of partnership items*. The partnership first computes its items of gain or loss at the partnership level under section 703. The partnership then allocates the partnership items among the partners, including the ceiling rule limited related person, in accordance with section 704, and adjusts the partners' capital accounts accordingly. The partnership then adjusts the ceiling rule limited related person's distributive share of the items of partnership gain or loss, in accordance with paragraph (d)(5)(iii)(D)(3) of this section, to reflect the effects of that person's basis adjustment under this section. These adjustments to that person's distributive shares must be reflected on Schedules K and K–1 of the partnership's return (Form 1065) (when otherwise required to be completed) and do not affect that person's capital account.

(3) *Effect of basis adjustment in determining items of income, gain, or*

loss. The amount of a ceiling rule limited related person's gain or loss from the sale or exchange of a section 197(f)(9) intangible in which that person has a tax basis adjustment is equal to that person's share of the partnership's gain or loss from the sale of the asset (including any remedial allocations under this paragraph (d) and § 1.704-3(d)), minus the amount of that person's tax basis adjustment for the section 197(f)(9) intangible.

(E) *Subsequent transfers*—(1) *In general.* Except as provided in paragraph (d)(5)(iii)(E)(2) of this section, if a ceiling rule limited related person transfers all or part of its partnership interest, the portion of the basis adjustment for a section 197(f)(9) intangible attributable to the interest transferred is eliminated. The transferor of the partnership interest remains the ceiling rule limited related person with respect to any remaining basis adjustment for the section 197(f)(9) intangible.

(2) *Special rules for substituted basis transactions.* Paragraph (d)(5)(iii)(E)(1) of this section does not apply to the extent a ceiling rule limited related person transfers its partnership interest in a transaction in which the transferee's basis in the partnership interest is determined in whole or in part by reference to the ceiling rule limited related person's basis in that interest. Instead, in such a case, the transferee succeeds to that portion of the transferor's basis adjustment for a section 197(f)(9) intangible attributable to the interest transferred. In such a case, the basis adjustment in a section 197(f)(9) intangible to which the transferee succeeds is taken into account for purposes of determining the transferee's share of the adjusted basis to the partnership of the partnership's property for purposes of §§ 1.743-1(b) and 1.755-1(b)(5). To the extent a transferee would be required to decrease the adjusted basis of a section 197(f)(9) intangible pursuant to §§ 1.743-1(b)(2) and 1.755-1(b)(5), the decrease first reduces the special basis adjustment described in paragraph (d)(5)(iii)(C) of this section, if any, to which the transferee succeeds.

(F) *Non-amortization of basis adjustment.* Neither the increase to the adjusted basis of a section 197(f)(9) intangible with respect to a ceiling rule limited related person nor the portion of the basis of any property that was determined by reference to such increase is subject to amortization, depreciation, or other cost recovery.

(d)(6) through (f) [Reserved]. For further guidance, see § 1.704-3(d)(6) through (f).

(g) *Certain rules for section 721(c) partnerships*—(1) *Applicability dates*—(i) *In general.* Notwithstanding § 1.704-3(f), except as provided in paragraph (g)(1)(ii) of this section, paragraphs (a)(13) and (d)(5)(iii) of this section apply with respect to contributions occurring on or after January 18, 2017, and with respect to contributions occurring before January 18, 2017, resulting from an entity classification election made under § 301.7701-3 of this chapter that is filed on or after January 18, 2017.

(ii) *Election to apply the provisions described in paragraph (g)(1)(i) of this section retroactively.* Paragraphs (a)(13) and (d)(5)(iii) of this section may, by election, be applied with respect to a contribution occurring on or after August 6, 2015, but before January 18, 2017, and with respect to a contribution occurring before August 6, 2015, resulting from an entity classification election made under § 301.7701-3 of this chapter that is filed on or after August 6, 2015. The election is made by applying paragraph (a)(13) or paragraph (d)(5)(iii) of this section, as applicable, on a timely filed original return (including extensions) or an amended return filed no later than six months after January 18, 2017.

(2) *Expiration date.* The applicability of paragraphs (a)(13) and (d)(5)(iii) of this section expires on January 17, 2020.

■ **Par. 8.** Section 1.721(c)-1T is added to read as follows:

§ 1.721(c)-1T Overview, definitions, and rules of general application (temporary).

(a) *Overview*—(1) *In general.* This section and §§ 1.721(c)-2T through 1.721(c)-7T (collectively, the *section 721(c) regulations*) provide rules under section 721(c). This section provides definitions and rules of general application for purposes of the section 721(c) regulations. Section 1.721(c)-2T provides the general operative rules that override section 721(a) nonrecognition of gain upon a contribution of section 721(c) property to a section 721(c) partnership. Section 1.721(c)-3T describes the gain deferral method, which may be applied in order to avoid the immediate recognition of gain upon a contribution of section 721(c) property to a section 721(c) partnership. Section 1.721(c)-4T provides rules regarding acceleration events for purposes of applying the gain deferral method. Section 1.721(c)-5T identifies exceptions to the rules regarding acceleration events provided in § 1.721(c)-4T(b). Section 1.721(c)-6T provides procedural and reporting requirements. Section 1.721(c)-7T provides examples illustrating the

application of the section 721(c) regulations.

(2) *Scope.* Paragraph (b) of this section provides definitions. Paragraph (c) of this section describes the treatment of a change in form of a partnership. Paragraph (d) of this section provides an anti-abuse rule. Paragraph (e) of this section provides the dates of applicability, and paragraph (f) of this section provides the date of expiration.

(b) *Definitions.* The following definitions apply for purposes of the section 721(c) regulations. Unless otherwise indicated, the definitions apply on a property-by-property basis, as applicable.

(1) *Acceleration event.* An acceleration event has the meaning provided in § 1.721(c)-4T(b).

(2) *Built-in gain.* Built-in gain is, with respect to property contributed to a partnership, the excess of the book value of the property over the partnership's adjusted tax basis in the property upon the contribution, determined without regard to the application of § 1.721(c)-2T(b).

(3) *Consistent allocation method.* The consistent allocation method is the method described in § 1.721(c)-3T(c).

(4) *Controlled partnership.* A partnership is a controlled partnership with respect to a U.S. transferor if the U.S. transferor and related persons control the partnership. For this purpose, control is determined based on all the facts and circumstances, except that a partnership will be deemed to be controlled by a U.S. transferor and related persons if those persons, in the aggregate, own (directly or indirectly through one or more partnerships) more than 50 percent of the interests in the partnership capital or profits.

(5) *Direct or indirect partner.* A direct or indirect partner is a person (other than a partnership) that owns an interest in a partnership directly or indirectly through one or more partnerships.

(6) *Excluded property.* Excluded property is—

(i) A cash equivalent;

(ii) A security within the meaning of section 475(c)(2), without regard to section 475(c)(4);

(iii) Tangible property with a book value exceeding adjusted tax basis by no more than \$20,000 or with an adjusted tax basis in excess of book value; and

(iv) An interest in a partnership in which 90 percent or more of the property (as measured by value) held by the partnership (directly or indirectly through interests in one or more partnerships that are not excluded property) consists of property described in paragraphs (b)(6)(i) through (iii) of this section.

(7) *Gain deferral contribution.* A gain deferral contribution is a contribution of section 721(c) property to a section 721(c) partnership with respect to which the recognition of gain is deferred under the gain deferral method.

(8) *Gain deferral method.* The gain deferral method is the method described in § 1.721(c)-3T(b).

(9) *Partial acceleration event.* A partial acceleration event is an event described in § 1.721(c)-5T(d)(2) or (3).

(10) *Regulatory allocation.* A regulatory allocation is—

(i) An allocation pursuant to a minimum gain chargeback, as defined in § 1.704-2(b)(2);

(ii) A partner nonrecourse deduction, as determined in § 1.704-2(i)(2);

(iii) An allocation pursuant to a partner minimum gain chargeback, as described in § 1.704-2(i)(4);

(iv) An allocation pursuant to a qualified income offset, as defined in § 1.704-1(b)(2)(ii)(d);

(v) An allocation with respect to the exercise of a noncompensatory option described in § 1.704-1(b)(2)(iv)(s); and

(vi) An allocation of partnership level ordinary income or loss described in § 1.751-1(a)(3).

(11) *Related foreign person.* A related foreign person is, with respect to a U.S. transferor, a related person (other than a partnership) that is not a U.S. person.

(12) *Related person.* A related person is, with respect to a U.S. transferor, a person that is related (within the meaning of section 267(b) or 707(b)(1)) to the U.S. transferor.

(13) *Remaining built-in gain*—(i) *In general.* Remaining built-in gain is, with respect to section 721(c) property subject to the gain deferral method, the built-in gain reduced by decreases in the difference between the property's book value and adjusted tax basis, but, for this purpose, without taking into account increases or decreases to the property's book value pursuant to § 1.704-1(b)(2)(iv)(f) or (s).

(ii) *Special rule for tiered partnerships.* If section 721(c) property is described in § 1.721(c)-3T(d)(1)(ii), the remaining built-in gain includes the new positive reverse section 704(c) layer described in § 1.721(c)-3T(d)(1)(ii), reduced by decreases in the difference between the property's book value and adjusted tax basis, but, for this purpose, without taking into account increases or decreases to the property's book value pursuant to § 1.704-1(b)(2)(iv)(f) or (s) that are unrelated to the revaluation described in § 1.721(c)-3T(d)(1)(i).

(14) *Section 721(c) partnership*—(i) *In general.* A partnership (domestic or foreign) is a section 721(c) partnership if there is a contribution of section

721(c) property to the partnership and, after the contribution and all transactions related to the contribution—

(A) A related foreign person with respect to the U.S. transferor is a direct or indirect partner in the partnership; and

(B) The U.S. transferor and related persons own 80 percent or more of the interests in partnership capital, profits, deductions, or losses.

(ii) *Special rule for tiered partnerships.* A partnership described in § 1.721(c)-3T(d)(1) or (2) is deemed to be a section 721(c) partnership for purposes of the gain deferral method.

(15) *Section 721(c) property*—(i) *In general.* Section 721(c) property is property, other than excluded property, with built-in gain that is contributed to a partnership by a U.S. transferor, including pursuant to a contribution described in § 1.721(c)-2T(d) (partnership look-through rule). If the U.S. transferor is treated as contributing its share of property to a partnership pursuant to § 1.721(c)-2T(d), the entire property will be section 721(c) property.

(ii) *Special rule for tiered partnerships.* Property described in § 1.721(c)-3T(d)(1)(ii) and an interest in a partnership described in § 1.721(c)-3T(d)(2)(ii) is deemed to be section 721(c) property.

(16) *Successor event.* A successor event is an event described in § 1.721(c)-5T(c)(2), (3), (4), or (5).

(17) *Termination event.* A termination event is an event described in § 1.721(c)-5T(b)(2), (3), (4), (5), (6), or (7).

(18) *U.S. transferor*—(i) *In general.* A U.S. transferor is a United States person within the meaning of section 7701(a)(30) (a *U.S. person*), other than a domestic partnership.

(ii) *Special rule for tiered partnerships.* Solely for purposes of applying the consistent allocation method, a U.S. transferor includes a partnership that is treated as a U.S. transferor under § 1.721(c)-3T(d)(1)(iii) or (d)(2)(i).

(c) *Change in form of a partnership.* A mere change in identity, form, or place of organization of a partnership or a recapitalization of a partnership will not cause the partnership to become a section 721(c) partnership.

(d) *Anti-abuse rule.* If a U.S. transferor engages in a transaction (or series of transactions) or an arrangement with a principal purpose of avoiding the application of the section 721(c) regulations, the transaction (or series of transactions) or the arrangement may be recharacterized (including by aggregating or disregarding steps or

disregarding an intermediate entity) in accordance with its substance.

(e) *Applicability dates*—(1) *In general.* Except as provided in paragraphs (e)(2) and (3) of this section, this section applies to contributions occurring on or after August 6, 2015, and to contributions occurring before August 6, 2015, resulting from an entity classification election made under § 301.7701-3 of this chapter that is filed on or after August 6, 2015.

(2) *Certain provisions.* Except as provided in paragraph (e)(3) of this section, paragraphs (b)(6)(iv) and (c) of this section apply to contributions occurring on or after January 18, 2017, and to contributions occurring before January 18, 2017, resulting from an entity classification election made under § 301.7701-3 of this chapter that is filed on or after January 18, 2017. Except as provided in paragraph (e)(3) of this section, paragraph (b)(14)(i)(B) of this section applies by replacing “80 percent or more” with “greater than 50 percent” with respect to contributions occurring on or after August 6, 2015, but before January 18, 2017, and with respect to contributions occurring before August 6, 2015, resulting from an entity classification election made under § 301.7701-3 of this chapter that is filed on or after August 6, 2015, but before January 18, 2017.

(3) *Election to apply the provisions described in paragraph (e)(2) of this section retroactively.* Paragraphs (b)(6)(iv), (b)(14)(i)(B), and (c) of this section, without the modification described in paragraph (e)(2) of this section, may, by election, be applied to a contribution occurring on or after August 6, 2015, but before January 18, 2017, and to a contribution occurring before August 6, 2015, resulting from an entity classification election made under § 301.7701-3 of this chapter that is filed on or after August 6, 2015. The election is made by applying paragraph (b)(6)(iv) or (c) as described in paragraph (b)(14)(i)(B) or (e)(2) of this section, without the modification described in paragraph (e)(2) of this section, as applicable, to the contribution on a timely filed original return (including extensions) or an amended return filed no later than six months after January 18, 2017.

(f) *Expiration date.* The applicability of this section expires on January 17, 2020.

■ **Par. 9.** Section 1.721(c)-2T is added to read as follows:

§ 1.721(c)–2T Recognition of gain on certain contributions of property to partnerships with related foreign partners (temporary).

(a) *Scope.* This section provides the general operative rules that override section 721(a) nonrecognition of gain upon a contribution of section 721(c) property to a section 721(c) partnership. Paragraph (b) of this section provides the general rule that nonrecognition of gain under section 721(a) does not apply to a contribution of section 721(c) property to a section 721(c) partnership. Paragraph (c) of this section provides a de minimis exception to the application of the general rule in paragraph (b) of this section. Paragraph (d) of this section provides rules for identifying a section 721(c) partnership when a partnership in which a U.S. transferor is a direct or indirect partner contributes property to another partnership. Paragraph (e) of this section provides the dates of applicability, and paragraph (f) of this section provides the date of expiration. For definitions that apply for purposes of this section, see § 1.721(c)–1T(b).

(b) *General rule for contributions of section 721(c) property.* Except as provided in this paragraph (b), paragraph (c) of this section, and § 1.721(c)–3T (describing the gain deferral method), nonrecognition under section 721(a) will not apply to gain realized by the contributing partner upon a contribution of section 721(c) property to a section 721(c) partnership. This paragraph (b) does not apply to a direct contribution by a U.S. transferor if the U.S. transferor and related persons with respect to the U.S. transferor do not own 80 percent or more of the interests in partnership capital, profits, deductions, or losses.

(c) *De minimis exception.* Paragraph (b) of this section will not apply with respect to contributions to a section 721(c) partnership during a taxable year of the section 721(c) partnership for which the sum of the built-in gain with respect to all section 721(c) property contributed in that taxable year does not exceed \$1 million. If, pursuant to the last sentence of paragraph (b) of this section, a direct contribution of property to the section 721(c) partnership by a U.S. transferor is not subject to paragraph (b) of this section, then such contribution is not taken into account for purposes of this paragraph (c).

(d) *Rules for identifying a section 721(c) partnership when a partnership contributes property to another partnership—(1) Partnership look-through rule.* If a U.S. transferor is a direct or indirect partner in a partnership (upper-tier partnership) and

the upper-tier partnership contributes all or a portion of its property to another partnership (lower-tier partnership), then, for purposes of determining if the lower-tier partnership is a section 721(c) partnership, the U.S. transferor is treated as contributing to the lower-tier partnership its share of the property actually contributed by the upper-tier partnership to the lower-tier partnership.

(2) *Exception for a technical termination of a partnership.* Paragraph (d)(1) of this section will not apply to a deemed contribution that occurs as a result of a termination of a partnership described in section 708(b)(1)(B) (technical termination). If a partnership is a section 721(c) partnership immediately before a technical termination, see § 1.721(c)–5T(c)(4) (which treats technical terminations as successor events in certain circumstances).

(e) *Applicability dates—(1) In general.* Except as provided in paragraphs (e)(2) and (3) of this section, this section applies to contributions occurring on or after August 6, 2015, and to contributions occurring before August 6, 2015, resulting from an entity classification election made under § 301.7701–3 of this chapter that is filed on or after August 6, 2015.

(2) *Certain provisions.* Except as provided in paragraph (e)(3) of this section, the final sentence of paragraph (b) of this section, the final sentence of paragraph (c) of this section, and paragraph (d)(2) of this section apply to contributions occurring on or after January 18, 2017, and to contributions occurring before January 18, 2017, resulting from an entity classification election made under § 301.7701–3 of this chapter that is filed on or after January 18, 2017.

(3) *Election to apply the provisions described in paragraph (e)(2) of this section retroactively.* The final sentence of paragraph (b) of this section, the final sentence of paragraph (c) of this section, and paragraph (d)(2) of this section may, by election, be applied to a contribution occurring on or after August 6, 2015, but before January 18, 2017, and to a contribution occurring before August 6, 2015, resulting from an entity classification election made under § 301.7701–3 of this chapter that is filed on or after August 6, 2015. The election is made by applying the final sentence of paragraph (b) of this section, the final sentence of paragraph (c) of this section, or paragraph (d)(2) of this section, as applicable, to the contribution on a timely filed original return (including extensions) or an amended return filed

no later than six months after January 18, 2017.

(f) *Expiration date.* The applicability of this section expires on January 17, 2020.

■ **Par. 10.** Section 1.721(c)–3T is added to read as follows:

§ 1.721(c)–3T Gain deferral method (temporary).

(a) *Scope.* This section describes the gain deferral method to avoid the immediate recognition of gain upon a contribution of section 721(c) property to a section 721(c) partnership. Paragraph (b) of this section provides the requirements of the gain deferral method, including the requirement to apply the consistent allocation method. Paragraph (c) of this section describes the consistent allocation method. Paragraph (d) of this section provides rules for tiered partnerships. Paragraph (e) of this section provides the dates of applicability, and paragraph (f) of this section provides the date of expiration. For definitions that apply for purposes of this section, see § 1.721(c)–1T(b).

(b) *Requirements of the gain deferral method.* A contribution of section 721(c) property to a section 721(c) partnership that would be subject to § 1.721(c)–2T(b) will not be subject to § 1.721(c)–2T(b) if the conditions in paragraphs (b)(1) through (5) of this section are satisfied with respect to that property.

(1) Either—

(i) Both—

(A) The section 721(c) partnership adopts the remedial allocation method described in § 1.704–3(d) with respect to the section 721(c) property; and

(B) The section 721(c) partnership applies the consistent allocation method provided in paragraph (c) of this section; or

(ii) For the period beginning on the date of the contribution of the section 721(c) property and ending on the date on which there is no remaining built-in gain with respect to that property, all distributive shares of income and gain with respect to the section 721(c) property for all direct and indirect partners that are related foreign persons with respect to the U.S. transferor will be subject to taxation as income effectively connected with a trade or business within the United States (under either section 871 or 882), and neither the section 721(c) partnership nor a related foreign person that is a direct or indirect partner in the section 721(c) partnership claims benefits under an income tax convention that would exempt the income or gain from tax or reduce the rate of taxation to which the income or gain is subject.

(2) Upon an acceleration event, the U.S. transferor recognizes an amount of gain equal to the remaining built-in gain with respect to the section 721(c) property or an amount of gain required to be recognized under § 1.721(c)-5T(d) or (e), as applicable.

(3) The procedural and reporting requirements provided in § 1.721(c)-6T(b) are satisfied.

(4) The U.S. transferor consents to extend the period of limitations on assessment of tax as required by § 1.721(c)-6T(b)(5).

(5) If the section 721(c) property is a partnership interest or property described in the partnership look-through rule provided in § 1.721(c)-2T(d), the applicable tiered-partnership rules provided in paragraph (d) of this section are applied.

(c) *Consistent allocation method*—(1) *In general.* For each taxable year of a section 721(c) partnership in which there is remaining built-in gain in the section 721(c) property, the section 721(c) partnership must allocate each book item of income, gain, deduction, and loss with respect to the section 721(c) property to the U.S. transferor in the same percentage. For exceptions to this general rule, see paragraph (c)(4) of this section.

(2) *Determining income or gain with respect to section 721(c) property.* For purposes of applying paragraph (c)(1) of this section, a section 721(c) partnership must attribute book income and gain to each item of section 721(c) property in a consistent manner using any reasonable method taking into account all the facts and circumstances. All items of book income and gain attributable to an item of section 721(c) property will comprise a single class of gross income for purposes of applying paragraph (c)(3) of this section.

(3) *Determining deduction or loss with respect to section 721(c) property.* For purposes of applying paragraph (c)(1) of this section, a section 721(c) partnership must use the principles of §§ 1.861-8 and 1.861-8T to allocate and apportion its items of deduction, except for interest expense and research and experimental expenditures, and loss to the class of gross income with respect to each item of section 721(c) property as determined in paragraph (c)(2) of this section. Accordingly, a deduction or loss will be considered to be definitely related and therefore allocable to a class of gross income with respect to particular section 721(c) property whether or not there is any item of gross income in that class that is received or accrued during the taxable year and whether or not the amount of deduction or loss exceeds the amount of gross

income in that class during the taxable year. If a deduction or loss is definitely related and therefore allocable to gross income attributable to more than one class of gross income of the section 721(c) partnership or if a deduction or loss is not definitely related to any class of gross income of the section 721(c) partnership, the section 721(c) partnership must apportion that deduction or loss among its classes of gross income using a reasonable method that reflects to a reasonably close extent the factual relationship between the deduction or loss and the classes of gross income. The section 721(c) partnership may allocate and apportion its interest expense and research and experimental expenditures under any reasonable method, including, but not limited to, the methods prescribed in §§ 1.861-9 and 1.861-9T (interest expense) and § 1.861-17 (research and experimental expenditures). For this purpose, the section 721(c) partnership must allocate and apportion its deductions and losses without regard to the partners' percentage interests in the partnership.

(4) *Exceptions to the consistent allocation method*—(i) *Regulatory allocations.* A regulatory allocation (as defined in § 1.721(c)-1T(b)(10)) of book income, gain, deduction, or loss with respect to section 721(c) property that otherwise would fail to satisfy paragraph (c)(1) of this section is nevertheless deemed to satisfy that paragraph if the allocation is—

(A) An allocation of income or gain to the U.S. transferor (or a member of its consolidated group as defined in § 1.1502-1(h));

(B) An allocation of deduction or loss to a partner other than the U.S. transferor (or a member of its consolidated group); or

(C) Treated as a partial acceleration event pursuant to § 1.721(c)-5T(d)(2).

(ii) *Allocation of creditable foreign tax expenditures.* An allocation of a creditable foreign tax expenditure (as defined in § 1.704-1(b)(4)(viii)(b)) is not subject to the consistent allocation method.

(d) *Tiered partnership rules.* This paragraph (d) provides the tiered partnership rules referred to in paragraph (b)(5) of this section.

(1) *Section 721(c) property is a partnership interest.* If the section 721(c) property that is contributed to a section 721(c) partnership is an interest in a partnership (lower-tier partnership), then the lower-tier partnership, if it is a controlled partnership with respect to the U.S. transferor, and each partnership in which an interest is owned (directly or indirectly through one or more

partnerships) by the lower-tier partnership and that is a controlled partnership with respect to the U.S. transferor, must satisfy the requirements of paragraphs (d)(1)(i), (ii), and (iii) of this section.

(i) The partnership must revalue all its property under § 1.704-1(b)(2)(iv)(f)(6) if the revaluation would result in a separate positive difference between book value and adjusted tax basis in at least one property that is not excluded property.

(ii) The partnership must apply the gain deferral method for each property (other than excluded property) for which there is a separate positive difference between book value and adjusted tax basis resulting from the revaluation described in paragraph (d)(1) of this section (*new positive reverse section 704(c) layer*). If the partnership has previously adopted a section 704(c) method other than the remedial allocation method for the property, the partnership satisfies the requirement of paragraph (b)(1)(i)(A) of this section by adopting the remedial allocation method for the new positive reverse section 704(c) layer.

(iii) The partnership must treat a partner that is a partnership in which the U.S. transferor is a direct or indirect partner as if it were the U.S. transferor with respect to the section 721(c) property solely for purposes of applying the consistent allocation method.

(2) *Section 721(c) property is indirectly contributed by a U.S. transferor under the partnership look-through rule.* If the U.S. transferor is a direct or indirect partner in the upper-tier partnership described in § 1.721(c)-2T(d)(1), and under § 1.721(c)-2T(d)(1), the U.S. transferor is treated as contributing the section 721(c) property (including an interest in a partnership described in paragraph (d)(1) of this section) to a section 721(c) partnership, then the requirements of paragraphs (d)(2)(i), (ii), and (iii) of this section must be satisfied.

(i) The section 721(c) partnership must treat the upper-tier partnership as the U.S. transferor of the section 721(c) property solely for purposes of applying the consistent allocation method;

(ii) The upper-tier partnership, if it is a controlled partnership with respect to the U.S. transferor, must apply the gain deferral method to its interest in the section 721(c) partnership; and

(iii) If the U.S. transferor is an indirect partner in the upper-tier partnership through one or more partnerships, the principles of paragraphs (d)(2)(i) and (ii) of this section must be applied with respect to those partnerships that are

controlled partnerships with respect to the U.S. transferor.

(e) *Applicability dates*—(1) *In general.* Except as provided in paragraphs (e)(2) and (3) of this section, this section applies to contributions occurring on or after August 6, 2015, and to contributions occurring before August 6, 2015, resulting from an entity classification election made under § 301.7701–3 of this chapter that is filed on or after August 6, 2015.

(2) *Certain provisions.* Except as provided in paragraph (e)(3) of this section, paragraphs (b)(1)(ii), (c)(2) and (3), (c)(4)(i) and (ii), and (d)(1) and (2) of this section apply to contributions occurring on or after January 18, 2017, and to contributions occurring before January 18, 2017, resulting from an entity classification election made under § 301.7701–3 of this chapter that is filed on or after January 18, 2017.

(3) *Election to apply the provisions described in paragraph (e)(2) of this section retroactively.* Paragraphs (b)(1)(ii), (c)(2) and (3), (c)(4)(i) and (ii), and (d)(1) and (2) of this section may, by election, be applied to a contribution occurring on or after August 6, 2015, but before January 18, 2017, and to a contribution occurring before August 6, 2015, resulting from an entity classification election made under § 301.7701–3 of this chapter that is filed on or after August 6, 2015. The election is made by applying paragraph (b)(1)(ii), (c)(2) and (3), (c)(4)(i) and (ii), and (d)(1) or (2) of this section, as applicable, to the contribution on a timely filed original return (including extensions) or an amended return filed no later than six months after January 18, 2017. In order to elect to apply paragraph (c)(2) or (3) of this section to a contribution described in this paragraph (e)(3), an election must also be made to apply paragraph (c)(3) or (2) of this section, respectively, to the contribution.

(4) *Transitional rules.* If a contribution is described in paragraph (e)(2) of this section and no election described in paragraph (e)(3) of this section is made to apply one or more of paragraphs (c)(2) and (3) and (c)(4)(i) and (ii) of this section, as applicable, to the contribution, then, for purposes of paragraph (c)(1) of this section, the section 721(c) partnership must attribute book income, gain, loss, and deduction to the section 721(c) property in a consistent manner under any reasonable method taking into account all the facts and circumstances. If a contribution is described in paragraph (e)(2) of this section and no election described in paragraph (e)(3) of this section is made to apply paragraph (d)(1) or (2) of this section, as

applicable, to the contribution, then, this section must be applied in a manner consistent with the purpose of the section 721(c) regulations. Thus, for example, if a U.S. transferor is a direct or indirect partner in a partnership and that partnership contributes section 721(c) property to a lower-tier partnership, or, if a U.S. transferor contributes an interest in a partnership that owns section 721(c) property to a lower-tier partnership, then paragraph (b) of this section applies as though the U.S. transferor contributed its share of the section 721(c) property directly.

(f) *Expiration date.* The applicability of this section expires on January 17, 2020.

■ **Par. 11.** Section 1.721(c)–4T is added to read as follows:

§ 1.721(c)–4T Acceleration events (temporary).

(a) *Scope.* This section provides rules regarding acceleration events for purposes of applying the gain deferral method. Paragraph (b) of this section defines an acceleration event. Paragraph (c) of this section provides the consequences of an acceleration event. Paragraph (d) of this section provides the dates of applicability, and paragraph (e) of this section provides the date of expiration. For definitions that apply for purposes of this section, see § 1.721(c)–1T(b).

(b) *Definition of an acceleration event*—(1) *General rules.* Except as provided in this paragraph (b) and § 1.721(c)–5T (acceleration event exceptions), an acceleration event with respect to section 721(c) property is any event that either would reduce the amount of remaining built-in gain that a U.S. transferor would recognize under the gain deferral method if the event had not occurred or could defer the recognition of the remaining built-in gain. An acceleration event includes a contribution of section 721(c) property to another partnership by a section 721(c) partnership and a contribution of an interest in a section 721(c) partnership to another partnership. This paragraph (b) applies on a property-by-property basis.

(2) *Failure to comply with a requirement of the gain deferral method*—(i) *General rule.* An acceleration event with respect to section 721(c) property occurs when any party fails to comply with a condition of the gain deferral method with respect to the section 721(c) property.

(ii) *Certain failures to comply with procedural and reporting requirements.* Notwithstanding paragraph (b)(2)(i) of this section, an acceleration event will not occur solely as a result of a failure

to comply with a requirement of § 1.721(c)–3T(b)(3) that is not willful. See §§ 1.721(c)–6T(f) and 1.6038B–2T(h)(3).

(3) *Lower-tier partnership allocations.* Notwithstanding paragraph (b)(1) of this section, an acceleration event will not occur because of a reduction in remaining built-in gain in an interest in a partnership that is section 721(c) property that occurs as a result of allocations of book items of deduction and loss, or tax items of income and gain.

(4) *Deemed acceleration event.* A U.S. transferor may treat an acceleration event as having occurred with respect to section 721(c) property by both recognizing gain in an amount equal to the remaining built-in gain that would have been allocated to the U.S. transferor if the section 721(c) partnership had sold the section 721(c) property immediately before the deemed acceleration event for fair market value and satisfying the reporting required by § 1.721(c)–6T(b)(3)(iv). In this case, see paragraph (c) of this section regarding basis adjustments.

(c) *Consequences of an acceleration event.* Paragraphs (c)(1) and (2) of this section provide the consequences of an acceleration event with respect to section 721(c) property, a partial acceleration event with respect to section 721(c) property to the extent provided in § 1.721(c)–5T(d)(1), and a transfer described in section 367 of section 721(c) property to the extent provided in § 1.721(c)–5T(e).

(1) *U.S. transferor.* The U.S. transferor must recognize gain in an amount equal to the remaining built-in gain that would have been allocated to the U.S. transferor if the section 721(c) partnership had sold the section 721(c) property immediately before the acceleration event for fair market value. The U.S. transferor will increase its basis in its partnership interest by the amount of gain recognized. If the U.S. transferor is an indirect partner in the section 721(c) partnership through one or more tiered partnerships, appropriate basis adjustments will be made to the interests in the tiered partnerships.

(2) *Section 721(c) partnership.* The section 721(c) partnership will increase its basis in the section 721(c) property by the amount of built-in gain recognized by the U.S. transferor under paragraph (c)(1) of this section. Any tax consequences of the acceleration event will be determined taking into account the increase in the partnership's adjusted tax basis in the section 721(c) property. If the section 721(c) property remains in the partnership after the

acceleration event, the increase in basis of the section 721(c) property may be recovered using any applicable recovery period and depreciation (or other cost recovery) method (including first-year conventions) available to the partnership for newly purchased property of the same type placed in service on the date of the acceleration event. The section 721(c) property will no longer be subject to the gain deferral method.

(d) *Applicability dates.* This section applies to contributions occurring on or after August 6, 2015, and to contributions occurring before August 6, 2015, resulting from an entity classification election made under § 301.7701-3 of this chapter that is filed on or after August 6, 2015.

(e) *Expiration date.* The applicability of this section expires on January 17, 2020.

■ **Par. 12.** Section 1.721(c)-5T is added to read as follows:

§ 1.721(c)-5T Acceleration event exceptions (temporary).

(a) *Scope.* This section identifies exceptions to the acceleration events, which, like the rules regarding acceleration events provided in § 1.721(c)-4T(b), apply on a property-by-property basis. Paragraph (b) of this section identifies the events that terminate the requirement to apply the gain deferral method. Paragraph (c) of this section identifies the successor events that allow for the continued application of the gain deferral method. Paragraph (d) of this section identifies the partial acceleration events. Paragraph (e) of this section provides special rules for transfers of section 721(c) property to a foreign corporation described in section 367. Paragraph (f) of this section allows for the continued application of the gain deferral method if there is a fully taxable disposition of a portion of an interest in a partnership. Paragraph (g) of this section provides the dates of applicability, and paragraph (h) of this section provides the date of expiration. For definitions that apply for purposes of this section, see § 1.721(c)-1T(b).

(b) *Termination events—(1) In general.* Notwithstanding § 1.721(c)-4T(b)(1), a termination event with respect to section 721(c) property will not constitute an acceleration event. In these cases, the section 721(c) property will no longer be subject to the gain deferral method.

(2) *Transfers of section 721(c) property (other than a partnership interest) to a domestic corporation described in section 351.* A termination event occurs if a section 721(c)

partnership transfers section 721(c) property (other than an interest in a partnership) to a domestic corporation in a transaction to which section 351 applies.

(3) *Certain incorporations of a section 721(c) partnership.* A termination event occurs upon an incorporation of a section 721(c) partnership into a domestic corporation by any method of incorporation (other than a method involving an actual distribution of partnership property to the partners, followed by a contribution of that property to a corporation), provided that the section 721(c) partnership is liquidated as part of the incorporation transaction.

(4) *Certain distributions of section 721(c) property.* A termination event occurs if a section 721(c) partnership distributes section 721(c) property either to the U.S. transferor or, if the U.S. transferor is a member of a consolidated group (as defined in § 1.1502-1(h)) at the time of the distribution and the distribution occurs outside the seven-year period described in section 704(c)(1)(B), to a member of the consolidated group.

(5) *Partnership ceases to have a partner that is a related foreign person.* A termination event occurs when a section 721(c) partnership ceases to have any direct or indirect partners that are related foreign persons with respect to the U.S. transferor, provided there is no plan for a related foreign person to subsequently become a direct or indirect partner in the partnership (or a successor). This paragraph (b)(5) does not apply to a distribution of section 721(c) property in redemption of a related foreign person's interest in a section 721(c) partnership.

(6) *Fully taxable dispositions of section 721(c) property.* A termination event occurs if a section 721(c) partnership disposes of section 721(c) property in a transaction in which all gain or loss, if any, is recognized.

(7) *Fully taxable dispositions of an entire interest in a section 721(c) partnership.* A termination event occurs if a U.S. transferor or a partnership in which a U.S. transferor is a direct or indirect partner disposes of its entire interest in a section 721(c) partnership that owns the section 721(c) property in a transaction in which all gain or loss, if any, is recognized. This paragraph (b)(7) does not apply if a U.S. transferor is a member of a consolidated group (as defined in § 1.1502-1(h)) and the interest in the section 721(c) partnership is transferred in an intercompany transaction (as defined in § 1.1502-13(b)(1)).

(c) *Successor events—(1) In general.* Notwithstanding § 1.721(c)-4T(b)(1), a successor event with respect to section 721(c) property will not constitute an acceleration event. If only a portion of an interest in a partnership is transferred in a successor event described in this paragraph (c), the principles of § 1.704-3(a)(7) apply to determine the remaining built-in gain in section 721(c) property that is attributable to the portion of the interest that is transferred and the portion of the interest that is retained.

(2) *Transfers of an interest in a section 721(c) partnership by a U.S. transferor or upper-tier partnership to a domestic corporation in certain nonrecognition transactions.* A successor event occurs if a U.S. transferor or a partnership in which a U.S. transferor is a direct or indirect partner transfers (directly or indirectly through one or more partnerships) an interest in a section 721(c) partnership to a domestic corporation in a transaction to which section 351 or 381 applies, and the gain deferral method is continued by treating the transferee domestic corporation as the U.S. transferor for purposes of the section 721(c) regulations. If the transfer described in this paragraph (c)(2) also results in a termination under section 708(b)(1)(B) of the section 721(c) partnership, see paragraph (c)(4) of this section.

(3) *Transfers of an interest in a section 721(c) partnership in an intercompany transaction.* A successor event occurs if a U.S. transferor that is a member of a consolidated group (as defined in § 1.1502-1(h)) transfers (directly or indirectly through one or more partnerships) an interest in a section 721(c) partnership in an intercompany transaction (as defined in § 1.1502-13(b)(1)), and the gain deferral method is continued by treating the transferee member as the U.S. transferor for purposes of the section 721(c) regulations. If the transfer described in this paragraph (c)(3) also results in a termination under section 708(b)(1)(B) of the section 721(c) partnership, see paragraph (c)(4) of this section.

(4) *Termination under section 708(b)(1)(B) of a section 721(c) partnership.* A successor event occurs if there is a termination under section 708(b)(1)(B) of a section 721(c) partnership, and the gain deferral method is continued by treating the new partnership as the section 721(c) partnership for purposes of the section 721(c) regulations.

(5) *Transactions involving tiered partnerships—(i) Contributions of section 721(c) property to a lower-tier*

partnership. A successor event occurs if a section 721(c) partnership contributes the section 721(c) property to a partnership that is a controlled partnership with respect to the U.S. transferor (lower-tier section 721(c) partnership) and the requirements of paragraphs (c)(5)(i)(A), (B), and (C) of this section are satisfied.

(A) The lower-tier section 721(c) partnership is a section 721(c) partnership or is treated as a section 721(c) partnership.

(B) The gain deferral method is applied with respect to the section 721(c) property in the hands of the lower-tier section 721(c) partnership.

(C) The gain deferral method is applied with respect to the section 721(c) partnership's interest in the lower-tier section 721(c) partnership. See §§ 1.721(c)-3T(b)(5) and (d)(2).

(ii) *Contributions of an interest in a section 721(c) partnership to an upper-tier partnership.* A successor event occurs if a U.S. transferor or a partnership in which a U.S. transferor is a direct or indirect partner contributes (directly or indirectly through one or more partnerships) an interest in a section 721(c) partnership to a partnership that is a controlled partnership with respect to the U.S. transferor (upper-tier section 721(c) partnership) and the requirements of paragraphs (c)(5)(ii)(A), (B), (C), and (D) of this section are satisfied.

(A) The gain deferral method is continued with respect to the section 721(c) property in the hands of the section 721(c) partnership.

(B) The upper-tier section 721(c) partnership is, or is treated as, a section 721(c) partnership.

(C) If the upper-tier section 721(c) partnership directly owns its interest in the section 721(c) partnership, the gain deferral method is applied with respect to the upper-tier section 721(c) partnership's interest in the section 721(c) partnership. See § 1.721(c)-3T(b)(5) and (d)(1).

(D) If the upper-tier section 721(c) partnership indirectly owns its interest in the section 721(c) partnership through one or more partnerships, the principles of paragraphs (c)(5)(ii)(B) and (C) of this section are applied with respect to each partnership through which the upper-tier section 721(c) partnership indirectly owns an interest in the section 721(c) partnership.

(d) *Partial acceleration events*—(1) *In general.* Notwithstanding § 1.721(c)-4T, a partial acceleration event with respect to section 721(c) property does not constitute an acceleration event. In these cases, except as provided in paragraph (d)(3) of this section, the rules

in § 1.721(c)-4T(c) (concerning the consequences of an acceleration event) for making basis adjustments apply to the extent that the U.S. transferor is required to recognize gain under paragraph (d)(2) or (3) of this section. Furthermore, if there is remaining built-in gain with respect to the section 721(c) property after the application of this paragraph (d), the application of the gain deferral method with respect to the section 721(c) property must be continued in the same manner.

(2) *Regulatory allocations.* If a regulatory allocation is described in § 1.721(c)-3T(c)(4)(i) but not in § 1.721(c)-3T(c)(4)(i)(A) or (B), a partial acceleration event occurs with respect to section 721(c) property if the U.S. transferor recognizes an amount of gain (but not in excess of remaining built-in gain) equal to the amount of the allocation that, under the consistent allocation method, had the regulatory allocation not occurred, would have been allocated to the U.S. transferor in the case of income or gain, or would not have been allocated to the U.S. transferor in the case of deduction or loss.

(3) *Certain distributions of other partnership property to a partner that result in an adjustment under section 734.* A partial acceleration event occurs with respect to section 721(c) property if there is a distribution of other property by the section 721(c) partnership that results in a positive basis adjustment to the section 721(c) property under section 734. In these cases, the U.S. transferor must recognize an amount of gain (but not in excess of the remaining built-in gain) equal to the positive basis adjustment to the section 721(c) property under section 734, reduced (but not below zero) by the amount of gain recognized by the U.S. transferor (or a member of its consolidated group (as defined in § 1.1502-1(h))) under section 731(a). In these cases, the partnership will not increase its basis under § 1.721(c)-4T(c)(2) by the amount of gain recognized by the U.S. transferor.

(e) *Transfers described in section 367 of section 721(c) property to a foreign corporation.* If a section 721(c) partnership transfers section 721(c) property, or a U.S. transferor or a partnership in which a U.S. transferor is a direct or indirect partner transfers (directly or indirectly through one or more partnerships) all or a portion of an interest in a section 721(c) partnership that owns section 721(c) property, to a foreign corporation in a transaction described in section 367, then, the property will no longer be subject to the gain deferral method. To the extent any

U.S. transferor is treated as transferring the section 721(c) property to the foreign corporation for purposes of section 367, the tax consequences will be determined under section 367. In this regard, see §§ 1.367(a)-1T(c)(3)(i) and (ii), 1.367(d)-1T(d)(1), and 1.367(e)-2(b)(1)(iii) (providing for the aggregate treatment of partnerships). However, for the remaining portion of the property (if any), the U.S. transferor must recognize an amount of gain equal to the remaining built-in gain that would have been allocated to the U.S. transferor if the section 721(c) partnership had sold that portion of the section 721(c) property immediately before the transfer for fair market value. The stock in the transferee foreign corporation received will not be subject to the gain deferral method. The rules in § 1.721(c)-4T(c) (concerning the consequences of an acceleration event) for making basis adjustments will apply to the extent that the U.S. transferor recognizes gain under this paragraph (e).

(f) *Fully taxable dispositions of a portion of an interest in a partnership.* If a U.S. transferor or a partnership in which a U.S. transferor is a direct or indirect partner disposes of (directly or indirectly through one or more partnerships) a portion of an interest in a section 721(c) partnership in a transaction in which all gain or loss, if any, is recognized, an acceleration event will not occur with respect to the portion of the interest transferred. The gain deferral method will continue to apply with respect to the section 721(c) property of the section 721(c) partnership. The principles of § 1.704-3(a)(7) will apply to determine the remaining built-in gain in section 721(c) property that is attributable to the portion of the interest in a section 721(c) partnership that is retained. This paragraph (f) will not apply to an intercompany transaction (as defined in § 1.1502-13(b)(1)).

(g) *Applicability dates*—(1) *In general.* Except as provided in paragraph (g)(2) of this section, this section applies to contributions occurring on or after January 18, 2017, and to contributions occurring before January 18, 2017, resulting from an entity classification election made under § 301.7701-3 of this chapter that is filed on or after January 18, 2017.

(2) *Election to apply this section retroactively.* This section may, by election, be applied to a contribution occurring on or after August 6, 2015, but before January 18, 2017, and to a contribution occurring before August 6, 2015, resulting from an entity classification election made under § 301.7701-3 of this chapter that is filed

on or after August 6, 2015. The election is made by applying this section to the contribution on a timely filed original return (including extensions) or an amended return filed no later than six months after January 18, 2017.

(h) *Expiration date.* The applicability of this section expires on January 17, 2020.

■ **Par. 13.** Section 1.721(c)–6T is added to read as follows:

§ 1.721(c)–6T Procedural and reporting requirements (temporary).

(a) *Scope.* This section provides procedural and reporting requirements that must be satisfied under § 1.721(c)–3T(b)(3) of the gain deferral method. Paragraph (b) of this section describes the procedural and reporting requirements of a U.S. transferor. Paragraph (c) of this section describes information required to be reported with respect to related foreign persons and partnerships. Paragraph (d) of this section describes the procedural and reporting requirements of a section 721(c) partnership with a section 6031 filing obligation. Paragraph (e) of this section provides the proper signatory for the information provided under this section. Paragraph (f) of this section provides relief for certain failures to comply that are not willful. Paragraph (g) of this section provides the dates of applicability, and paragraph (h) of this section provides the date of expiration. For definitions that apply for purposes of this section, see § 1.721(c)–1T(b).

(b) *Procedural and reporting requirements of a U.S. transferor—(1) In general.* This paragraph (b) describes the procedural and reporting requirements that a U.S. transferor (as defined § 1.721(c)–1T(b)(18)(i)) must satisfy in applying the gain deferral method. The information required under this paragraph (b) must be included with the U.S. transferor's timely filed return on (or attached to) the appropriate forms (including Form 8865, Schedule O, Transfer of Property to a Foreign Partnership), and must be submitted in the form and manner and to the extent prescribed by the form (and its accompanying instructions).

(2) *Reporting of a gain deferral contribution.* A U.S. transferor must report the following information with respect to a gain deferral contribution:

(i) A statement, titled “Statement of Application of the Gain Deferral Method under Section 721(c),” that contains the following information with respect to the section 721(c) property—

(A) A description of the property and recovery period (or periods) for the property;

(B) Whether the property is an intangible described in section 197(f)(9);

(C) A calculation of the built-in gain, the basis, and fair market value on the date of the contribution, including the amount of gain recognized by the U.S. transferor, if any, on the gain deferral contribution;

(D) The name, U.S. taxpayer identification number (if any), address, and country of organization (if any) of each direct or indirect partner in the section 721(c) partnership that is a related person with respect to the U.S. transferor, and a description of each partner's interest in capital and profits immediately after the gain deferral contribution; and

(E) When the section 721(c) property is a partnership interest, the information described in paragraphs (b)(2)(i)(A) through (D) of this section with respect to each property of a lower-tier partnership to which the gain deferral method is applied under § 1.721(c)–3T(d)(1);

(ii) A statement, titled “Consent to Extend the Time to Assess Tax Pursuant to the Gain Deferral Method under Section 721(c),” completed and executed in the manner prescribed in forms and instructions, extending the period of limitations on the assessment of tax as described in paragraph (b)(5) of this section;

(iii) A copy of the waiver of treaty benefits described in paragraphs (c)(1) of this section (if any);

(iv) Information relating to the section 721(c) partnership described in paragraph (c)(2) of this section (if any);

(v) With respect to any foreign partnership (or partnership treated as foreign under paragraph (b)(4) of this section) the information required under § 1.6038B–2(c)(1) through (7); and

(vi) The information required under paragraph (b)(3) of this section.

(3) *Annual reporting relating to gain deferral method.* A U.S. transferor must file an annual statement, titled “Annual Statement of Application of the Gain Deferral Method under Section 721(c),” for each gain deferral contribution. The information in the statement must be with respect to the partnership taxable year that ends with, or within, the taxable year of the U.S. transferor, beginning with the partnership's taxable year that includes the date of the gain deferral contribution and ending with the last taxable year in which the gain deferral method is applied to the section 721(c) property. The statement must contain the following information:

(i) The amount of book income, gain, deduction, and loss and tax items allocated to the U.S. transferor with respect to the section 721(c) property,

including a description of any regulatory allocations;

(ii) The proportion (expressed as a percentage) in which the book income, gain, deduction, and loss with respect to the section 721(c) property was allocated among the U.S. transferor and related persons that are partners in the section 721(c) partnership under the consistent allocation method;

(iii) The amount of remaining built-in gain at the beginning of the taxable year, the remedial income allocated to the U.S. transferor under the remedial allocation method, the amount of built-in gain taken into account by reason of an acceleration event or partial acceleration event (if any), the partnership's adjustment to its tax basis in the section 721(c) property, and the remaining built-in gain at the end of the taxable year;

(iv) A declaration stating whether an acceleration event or partial acceleration event occurred during the taxable year, the date of the event, and a description of the event (including a citation to the relevant paragraph of § 1.721(c)–5T(d) in the case of a partial acceleration event, and whether the acceleration event is described in § 1.721(c)–4T(b)(4));

(v) A description of a termination event or any successor event that occurred during the taxable year with a citation to the relevant paragraph of § 1.721(c)–5T(b) or (c), the date of the event, and, in the case of a successor event, the name, address, and U.S. taxpayer identification number (if any) of any successor partnership, lower-tier partnership, upper-tier partnership, or U.S. corporation (as applicable);

(vi) A description of all transfers of 721(c) property to a foreign corporation described in § 1.721–5T(e) that occurred during the taxable year, and for each transfer, the date of the transfer, the section 721(c) property transferred, and the name, address, and U.S. taxpayer identification number (if any) of the foreign transferee corporation;

(vii) With respect to section 721(c) property for which a waiver of treaty benefits was filed under paragraph (b)(2)(iii) of this section, a declaration that, after exercising reasonable diligence, to the best of the U.S. transferor's knowledge and belief, all income from the section 721(c) property allocated to the partners during the taxable year remained subject to taxation as income effectively connected with the conduct of a trade or business within the United States (under either section 871 or 882) for all direct or indirect partners that are related foreign persons with respect to the U.S. transferor (regardless of whether any

such partner was a partner at the time of the gain deferral contribution), and, that neither the partnership nor any such partner has made any claim under any income tax convention to an exemption from U.S. income tax or a reduced rate of U.S. income taxation on income derived from the use of the section 721(c) property;

(viii) A statement, titled "Consent to Extend the Time To Assess Tax Pursuant to the Gain Deferral Method under Section 721(c)," completed and executed as prescribed in forms and instructions, extending the period of limitations on the assessment of tax, in the case of a gain deferral contribution, as described in paragraph (b)(5)(ii) of this section, and, in the case of certain contributions on which gain is recognized, as described in paragraph (b)(5)(iii) of this section;

(ix) If the section 721(c) partnership is a partnership that does not have a filing obligation under section 6031, the information described in § 1.6038-3(g) (contents of information returns required of certain United States persons with respect to controlled foreign partnerships), if not already reported elsewhere, without regard to whether the section 721(c) partnership is a controlled foreign partnership within the meaning of section 6038. If the U.S. transferor is not a controlling fifty-percent partner (as defined in § 1.6038-3(a)), the U.S. transferor complies with the requirement of this paragraph (b)(3)(ix) by providing only the information described in § 1.6038-3(g)(1);

(x) A description of all section 721(c) property contributed by the U.S. transferor to the section 721(c) partnership (including pursuant to a contribution described in § 1.721(c)-2T(d)(1) during the taxable year to which the gain deferral method is not applied; and

(xi) The information required in paragraphs (c)(2) and (3) of this section for related foreign persons that are direct or indirect partners in the section 721(c) partnership and the section 721(c) partnership itself (if any).

(4) *Domestic partnerships treated as foreign.* Solely for purposes of this section, a U.S. transferor must treat a domestic section 721(c) partnership as a foreign partnership if the partnership was formed on or after January 18, 2017. If the section 721(c) partnership has an information return filing obligation under section 6031, that requirement is not affected by the requirement of this paragraph (b)(4) that the U.S. transferor treat the partnership as a foreign partnership.

(5) *Extension of period of limitations on assessment of tax.* In order to comply with the gain deferral method, a U.S. transferor must extend the period of limitations on the assessment of tax:

(i) With respect to the gain realized but not recognized on a gain deferral contribution, through the close of the eighth full taxable year following the U.S. transferor's taxable year that includes the date of the gain deferral contribution;

(ii) With respect to all book and tax items with respect to the section 721(c) property allocated to the U.S. transferor in the partnership's taxable year that includes the date of the gain deferral contribution and the subsequent two years, through the close of the sixth full taxable year following such taxable year with which, or within which, the partnership's taxable year ends; and

(iii) With respect to the gain recognized on a contribution of section 721(c) property to a section 721(c) partnership for which the gain deferral method is not applied, if the contribution occurs within five partnership taxable years following a partnership taxable year that includes the date of a gain deferral contribution, through the close of the fifth full taxable year following the U.S. transferor's taxable year that includes the date of the contribution on which gain is recognized.

(c) *Information with respect to section 721(c) partnerships and related foreign persons—*(1) *Effectively connected income.* If the gain deferral method is applied with respect to a contribution of section 721(c) property that satisfies the condition in § 1.721(c)-3T(b)(1)(ii), the U.S. transferor must obtain a statement from the section 721(c) partnership and from each related foreign person that is a direct or indirect partner in the section 721(c) partnership, titled "Statement of Waiver of Treaty Benefits under § 1.721(c)-6T," pursuant to which the partner and the partnership waive any claim under any income tax convention (whether or not currently in force at the time of the contribution) to an exemption from U.S. income tax or a reduced rate of U.S. income taxation on income derived from the use of the section 721(c) property for the period during which the section 721(c) property is subject to the gain deferral method.

(2) *Partnerships in tiered-partnership structures applying the gain deferral method.* If the gain deferral method is applied as a result of a transaction described in § 1.721(c)-3T(d), the U.S. transferor must supply all information that a section 721(c) partnership would be required to report under paragraph

(b) of this section if the section 721(c) partnership were a U.S. transferor.

(3) *Schedules K-1 for related foreign partners.* If a section 721(c) partnership does not have a filing obligation under section 6031, the U.S. transferor must obtain a Schedule K-1 (Form 8865), Partner's Share of Income, Deduction, Credits, etc., for all related foreign persons that are direct or indirect partners in the section 721(c) partnership.

(d) *Reporting and procedural requirements of a section 721(c) partnership with a section 6031 filing obligation—*(1) *Waiver of treaty benefits.* A section 721(c) partnership with a return filing obligation under section 6031 must include its waiver of treaty benefits described in paragraph (c)(1) of this section with its tax return for the taxable year that includes the date of the gain deferral contribution.

(2) *Information on Schedule K-1.* A section 721(c) partnership with a return filing obligation under section 6031 must provide the relevant information necessary for the U.S. transferor to comply with the requirements in paragraphs (b)(2) and (3) of this section with the U.S. transferor's Schedule K-1 (Form 1065), Partner's Share of Income, Deductions, Credits, etc. The partnership must also attach to its Form 1065 a Schedule K-1 (Form 1065) for each partner that is a related foreign person with respect to the U.S. transferor.

(e) *Signatory.* The statements required in this section must be signed under penalties of perjury by an agent of the U.S. transferor, the related foreign person that is a direct or indirect partner in the section 721(c) partnership, or the section 721(c) partnership, as applicable, that is authorized to sign under a general or specific power of attorney, or by an appropriate party. For the U.S. transferor, an appropriate party is a person described in § 1.367(a)-8(e)(1). For a partnership with a section 6031 filing obligation, an appropriate party is any party authorized to sign Form 1065.

(f) *Relief for certain failures to file or failures to comply that are not willful—*(1) *In general.* This paragraph (f)(1) provides relief from the failure to comply with the procedural and reporting requirements of the gain deferral method prescribed by § 1.721(c)-3T(b)(3) and provided in paragraph (b) of this section if there is a failure to file or to include information required by this section (failure to comply). A failure to comply will be deemed not to have occurred for purposes of § 1.721(c)-3T(b)(3) if the U.S. transferor demonstrates that the

failure was not willful using the procedure provided in this paragraph (f). For this purpose, willful is to be interpreted consistent with the meaning of that term in the context of other civil penalties, which would include a failure due to gross negligence, reckless disregard, or willful neglect. Whether a failure to comply was willful will be determined by the Director of Field Operations, Cross Border Activities Practice Area of Large Business & International (or any successor to the roles and responsibilities of such position, as appropriate) (Director) based on all the facts and circumstances. The U.S. transferor must submit a request for relief and an explanation as provided in paragraph (f)(2) of this section. A U.S. transferor whose failure to comply is determined not to be willful under this paragraph will be subject to a penalty under section 6038B if it fails to satisfy the applicable reporting requirements under that section and does not demonstrate that the failure was due to reasonable cause and not willful neglect. See § 1.6038B-2(h). The determination of whether the failure to comply was willful under this section has no effect on any request for relief made under § 1.6038B-2(h).

(2) *Procedures for establishing that a failure to comply was not willful*—(i) *Time and manner of submission.* A U.S. transferor's statement that a failure to comply was not willful will be considered only if, promptly after the U.S. transferor becomes aware of the failure, an amended return is filed for the taxable year to which the failure relates that includes the information that should have been included with the original return for such taxable year or that otherwise complies with the rules of this section as well as a written statement explaining the reasons for the failure to comply. The U.S. transferor also must file, with the amended return, a Form 8865, Schedule O, and a statement (as described in paragraph (b)(5) of this section), completed and executed as prescribed in forms and instructions, consenting to extend the period of limitations on assessment of tax with respect to the gain realized but not recognized on the gain deferral contribution to the later of the close of the eighth full taxable year following the taxable year during which the contribution occurred (*date one*), or the close of the third full taxable year ending after the date on which the required information is provided to the Director (*date two*). However, the U.S. transferor is not required to file a Form 8865, Schedule O, with the amended

return if both *date one* is later than *date two* and a consent to extend the period of limitations on assessment of tax with respect to the gain realized but not recognized on the gain deferral contribution for the U.S. transferor's taxable year that includes the date of the contribution was previously submitted with a Form 8865, Schedule O. The amended return and either a Form 8865, Schedule O, or a copy of the previously filed Form 8865, Schedule O, as the case may be, must be filed with the Internal Revenue Service at the location where the U.S. transferor filed its original return. The U.S. transferor may submit a request for relief from the penalty under section 6038B as part of the same submission. See § 1.6038B-2T(h)(3).

(ii) *Notice requirement.* In addition to the requirements of paragraph (f)(2)(i) of this section, the U.S. transferor must comply with the notice requirements of this paragraph (f)(2)(ii). If any taxable year of the U.S. transferor is under examination when the amended return is filed, a copy of the amended return must be delivered to the Internal Revenue Service personnel conducting the examination. If no taxable year of the U.S. transferor is under examination when the amended return is filed, a copy of the amended return must be delivered to the Director.

(g) *Applicability dates*—(1) *In general.* Except as provided in paragraphs (g)(2) and (3) of this section, this section applies with respect to contributions occurring on or after January 18, 2017, and with respect to contributions occurring before January 18, 2017, resulting from an entity classification election made under § 301.7701-3 of this chapter that is filed on or after January 18, 2017.

(2) *Reporting relating to effectively connected income.* Paragraphs (b)(2)(iii), (b)(3)(vii), and (d)(1) of this section apply to a contribution occurring on or after August 6, 2015, and to a contribution occurring before August 6, 2015, resulting from an entity classification election made under § 301.7701-3 of this chapter that is filed on or after August 6, 2015, and, in either case, provided § 1.721(c)-3T(b)(1)(ii) applies to the contribution. To the extent that a previously filed return did not comply with paragraph (b)(2)(iii), (b)(3)(vii), or (d)(1) of this section, an amended return complying with such paragraphs must be filed no later than six months after January 18, 2017.

(3) *Transition rules.* For transfers occurring on or after August 6, 2015, and for transfers occurring before August 6, 2015, resulting from an entity classification election made under § 301.7701-3 of this chapter that is filed

on or after August 6, a U.S. transferor (or a domestic partnership in which a U.S. transferor is a direct or indirect partner) must fulfill any reporting requirements imposed under sections 6038, 6038B, and 6046A and the regulations thereunder with respect to the contribution of the section 721(c) property to the section 721(c) partnership.

(h) *Expiration date.* The applicability of this section expires on January 17, 2020.

■ **Par. 14.** Section 1.721(c)-7T is added to read as follows:

§ 1.721(c)-7T Examples (temporary).

(a) *Presumed facts.* For purposes of the examples in paragraph (b) of this section, assume that there are no other transactions that are related to the transactions described in the examples and that all partnership allocations have substantial economic effect under section 704(b). For definitions that apply for purposes of this section, see § 1.721(c)-1T(b). Except where otherwise indicated, the following facts are presumed—

(1) USP and USX are domestic corporations that each use a calendar taxable year. USX is not a related person with respect to USP.

(2) CFC1, CFC2, FX, and FY are foreign corporations.

(3) USP wholly owns CFC1 and CFC2. Neither FX nor FY is a related person with respect to USP or with respect to each other.

(4) PRS1, PRS2, and PRS3 are foreign entities classified as partnerships for U.S. tax purposes. A partnership interest in PRS1, PRS2, and PRS3 is not described in section 475(c)(2).

(5) A taxable year is referred to, for example, as year 1.

(6) A partner in a partnership has the same percentage interest in income, gain, loss, deduction, and capital of the partnership.

(7) No property is described in section 197(f)(9) in the hands of a contributing partner.

(8) No partnership is a controlled partnership solely under the facts and circumstances test in § 1.721(c)-1T(b)(4).

(b) *Examples.* The application of the rules stated in §§ 1.721(c)-1T through 1.721(c)-6T may be illustrated by the following examples:

Example 1. Determining if a partnership is a section 721(c) partnership. (i) *Facts.* In year 1, USP and CFC1 form PRS1 as equal partners. CFC1 contributes cash of \$1.5 million to PRS1, and USP contributes three properties to PRS1: A patent with a book value of \$1.2 million and an adjusted tax basis of zero, a security (within the meaning

of section 475(c)(2)) with a book value of \$100,000 and an adjusted tax basis of \$20,000, and a machine with a book value of \$200,000 and an adjusted tax basis of \$600,000.

(ii) *Results.* (A) Under § 1.721(c)–1T(b)(18)(i), USP is a U.S. transferor because USP is a U.S. person and not a domestic partnership. Under § 1.721(c)–1T(b)(2), the patent has built-in gain of \$1.2 million. The patent is not excluded property under § 1.721(c)–1T(b)(6). Therefore, under § 1.721(c)–1T(b)(15)(i), the patent is section 721(c) property because it is property, other than excluded property, with built-in gain that is contributed by a U.S. transferor, USP.

(B) Under § 1.721(c)–1T(b)(2), the security has built-in gain of \$80,000. Under § 1.721(c)–1T(b)(6)(ii), the security is excluded property because it is described in section 475(c)(2). Therefore, the security is not section 721(c) property.

(C) The tax basis of the machine exceeds its book value. Under § 1.721(c)–1T(b)(6)(iii), the machine is excluded property and therefore is not section 721(c) property.

(D) Under § 1.721(c)–1T(b)(12), CFC1 is a related person with respect to USP, and under § 1.721(c)–1T(b)(11), CFC1 is a related foreign person. Because USP and CFC1 collectively own at least 80 percent of the interests in the capital, profits, deductions, or losses of PRS1, under § 1.721(c)–1T(b)(14)(i), PRS1 is a section 721(c) partnership upon the contribution by USP of the patent.

(E) The de minimis exception described in § 1.721(c)–2T(c) does not apply to the contribution because during PRS1's year 1 the sum of the built-in gain with respect to all section 721(c) property contributed in year 1 to PRS1 is \$1.2 million, which exceeds the de minimis threshold of \$1 million. As a result, under § 1.721(c)–2T(b), section 721(a) does not apply to USP's contribution of the patent to PRS1, unless the requirements of the gain deferral method are satisfied.

Example 2. Determining if partnership interest is section 721(c) property. (i) *Facts.* In year 1, USP and FX form PRS2. USP contributes a security (within the meaning of section 475(c)(2)) with a book value of \$100,000 and an adjusted tax basis of \$20,000 and a building located in country X with a book value of \$30,000 and an adjusted tax basis of \$8,000 in exchange for a 40-percent interest. FX contributes a machine with a book value of \$195,000 and an adjusted tax basis of \$250,000 in exchange for a 60-percent interest.

(ii) *Results.* PRS2 is not a section 721(c) partnership because FX is not a related person with respect to USP, USP's contributions to PRS2 are not subject to § 1.721(c)–2T(b).

(iii) *Alternative facts and results.* (A) Assume the same facts as in paragraph (i) of this *Example 2*. In addition, USP and CFC1 form PRS1 as equal partners. CFC1 contributes cash of \$130,000 to PRS1, and USP contributes its 40-percent interest in PRS2.

(B) PRS2's property consists of a security and a machine that are excluded property, and a building with built-in gain in excess of \$20,000. Under § 1.721(c)–1T(b)(iv),

because more than 90 percent of the value of the property of PRS2 consists of excluded property described in § 1.721(c)–1T(b)(6)(i) through (iii) (the security and the machine), any interest in PRS2 is excluded property. Therefore, the 40-percent interest in PRS2 contributed by USP to PRS1 is not section 721(c) property. Accordingly, USP's contribution of its interest in PRS2 to PRS1 is not subject to § 1.721(c)–2T(b).

Example 3. Assets-over tiered partnerships.

(i) *Facts.* In year 1, USP and CFC1 form PRS1 as equal partners. USP contributes a patent with a book value of \$300 million and an adjusted tax basis of \$30 million (USP contribution). CFC1 contributes cash of \$300 million. Immediately thereafter, PRS1 contributes the patent to PRS2 in exchange for a two-thirds interest (PRS1 contribution), and CFC2 contributes cash of \$150 million in exchange for a one-third interest. The patent has a remaining recovery period of 5 years out of a total of 15 years. With respect to all contributions described in § 1.721(c)–2T(b), the de minimis exception does not apply, and the gain deferral method is applied. Thus, the partnership agreements of PRS1 and PRS2 provide that the partnership will make allocations under section 704(c) using the remedial allocation method under § 1.704–3(d).

(ii) *Results: USP contribution.* PRS1 is a section 721(c) partnership as a result of the USP contribution.

(iii) *Results: PRS1 contribution.* (A) For purposes of determining whether PRS2 is a section 721(c) partnership as a result of the PRS1 contribution, under § 1.721(c)–2T(d)(1), USP is treated as contributing to PRS2 its share of the patent that PRS1 actually contributes to PRS2. USP and CFC1 are each one-third indirect partners in PRS2. Taking into account the one-third interest in PRS2 directly owned by CFC2, USP, CFC1, and CFC2 collectively own at least 80 percent of the interests in PRS2. Thus, PRS2 is a section 721(c) partnership as a result of the PRS1 contribution.

(B) Under § 1.721(c)–2T(b), section 721(a) does not apply to PRS1's contribution of the patent to PRS2, unless the requirements of the gain deferral method are satisfied. Under § 1.721(c)–3T(b), the gain deferral method must be applied with respect to the patent. In addition, under § 1.721(c)–3T(d)(2), because PRS1 is a controlled partnership with respect to USP, the gain deferral method must be applied with respect to PRS1's interest in PRS2, and, solely for purposes of applying the consistent allocation method, PRS2 must treat PRS1 as the U.S. transferor. As stated in paragraph (i) of this *Example 3*, the gain deferral method is applied. PRS2 is a controlled partnership with respect to USP. Under § 1.721(c)–5T(c)(5)(i), the PRS1 contribution is a successor event with respect to the USP contribution.

(iv) *Results: Application of remedial allocation method.* (A) Under § 1.704–3(d)(2), in year 1, PRS2 has \$24 million of book amortization with respect to the patent (\$6 million (\$30 million of book value equal to adjusted tax basis divided by the 5-year remaining recovery period) plus \$18 million (\$270 million excess of book value over tax basis divided by the new 15-year recovery

period)). PRS2 has \$6 million of tax amortization. Under the PRS2 partnership agreement, PRS2 allocates \$8 million of book amortization to CFC2 and \$16 million of book amortization to PRS1. Because of the application of the ceiling rule, PRS2 allocates \$6 million of tax amortization to CFC2 and \$0 of tax amortization to PRS1. Because the ceiling rule would cause a disparity of \$2 million between CFC2's book and tax amortization, PRS2 must make a remedial allocation of \$2 million of tax amortization to CFC2 and an offsetting remedial allocation of \$2 million of taxable income to PRS1.

(B) PRS1's distributive share of each of PRS2's items with respect to the patent is \$16 million of book amortization, \$0 of tax amortization, and \$2 million of taxable income from the remedial allocation from PRS1. Under § 1.704–3(a)(9), PRS1 must allocate its distributive share of each of PRS2's items with respect to the patent in a manner that takes into account USP's remaining built-in gain in the patent. Therefore, PRS1 allocates \$2 million of taxable income to USP. Under § 1.704–3T(a)(13)(ii), PRS1 treats its distributive share of each of PRS2's items of amortization with respect to PRS2's patent as items of amortization with respect to PRS1's interest in PRS2. Under the PRS1 partnership agreement, PRS1 allocates \$8 million of book amortization and \$0 of tax amortization to CFC1, and \$8 million of book amortization and \$0 of tax amortization to USP. Because the ceiling rule would cause a disparity of \$8 million between CFC1's book and tax amortization, PRS1 must make a remedial allocation of \$8 million of tax amortization to CFC1. PRS1 must also make an offsetting remedial allocation of \$8 million of taxable income to USP. USP reports \$10 million of taxable income (\$2 million of remedial income from PRS2 and \$8 million of remedial income from PRS1).

Example 4. Section 721(c) partnership ceases to have a related foreign person as a partner. (i) *Facts.* In year 1, USP and CFC1 form PRS1. USP contributes a trademark with a built-in gain of \$5 million in exchange for a 60-percent interest, and CFC1 contributes other property in exchange for the remaining 40-percent interest. With respect to all contributions described in § 1.721(c)–2T(b), the de minimis exception does not apply, and the gain deferral method is applied. On day 1 of year 4, CFC1 sells its entire interest in PRS1 to FX. There is no plan for a related foreign person with respect to USP to subsequently become a partner in PRS1 (or a successor).

(ii) *Results.* (A) PRS1 is a section 721(c) partnership.

(B) With respect to year 4, under § 1.721(c)–5T(b)(5), the sale is a termination event because, as a result of CFC1's sale of its interest, PRS1 will no longer have a partner that is a related foreign person, and there is no plan for a related foreign person to subsequently become a partner in PRS1 (or a successor). Thus, under § 1.721(c)–5T(b)(1), the trademark is no longer subject to the gain deferral method.

Example 5. Transfer described in section 367 of section 721(c) property to a foreign corporation. (i) *Facts.* In year 1, USP, CFC1,

and USX form PRS1. USP contributes a patent with a built-in gain of \$5 million in exchange for a 60-percent interest, CFC1 contributes other property in exchange for a 30-percent interest, and USX contributes cash in exchange for a 10-percent interest. With respect to all contributions described in § 1.721(c)–2T(b), the de minimis exception does not apply, and the gain deferral method is applied. In year 3, when the patent has remaining built-in gain, PRS1 transfers the patent to FX in a transaction described in section 351.

(ii) *Results.* (A) PRS1 is a section 721(c) partnership.

(B) With respect to year 3, the transfer of the patent to FX is a transaction described in section 367(d). Therefore, under § 1.721(c)–5T(e), the patent is no longer subject to the gain deferral method. Under §§ 1.367(d)–1T(d)(1) and 1.367(a)–1T(c)(3)(i), for purposes of section 367(d), USP and USX are treated as transferring their proportionate share of the patent actually transferred by PRS1 to FX. Under § 1.721(c)–5T(e), to the extent USP and USX are treated as transferring the patent to FX, the tax consequences are determined under section 367(d) and the regulations thereunder. With respect to the remaining portion of the patent, which is attributable to CFC1, USP must recognize an amount of gain equal to the remaining built-in gain that would have been allocated to USP if PRS1 had sold that portion of the patent immediately before the transfer for fair market value. Under § 1.721(c)–4T(c)(1), USP must increase the basis in its partnership interest in PRS1 by the amount of gain recognized by USP and under § 1.721(c)–4T(c)(2), immediately before the transfer, PRS1 must increase its basis in the patent by the same amount. The stock in FX received by PRS1 is not subject to the gain deferral method.

Example 6. Limited remedial allocation method for anti-churning property with respect to related partners. (i) *Facts.* USP, CFC1, and FX form PRS1. On January 1 of year 1, USP contributes intellectual property (IP) with a book value of \$600 million and an adjusted tax basis of \$0 in exchange for a 60-percent interest. The IP is a section 197(f)(9) intangible (within the meaning of § 1.197–2(h)(1)(i)) that was not an amortizable section 197 intangible in USP's hands. CFC1 contributes cash of \$300 million in exchange for a 30-percent interest, and FX contributes cash of \$100 million in exchange for a 10-percent interest. The IP is section 721(c) property, and PRS1 is a section 721(c) partnership. The gain deferral method is applied. The partnership agreement provides that PRS1 will make allocations under section 704(c) with respect to the IP using the remedial allocation method under § 1.704–3T(d)(5)(iii). All of PRS1's allocations with respect to the IP satisfy the requirements of the gain deferral method. On January 1 of year 16, PRS1 sells the IP for cash of \$900 million to a person that is not a related person. During years 1 through 16, PRS1 earns no income other than gain from the sale of the IP in year 16, has no expenses or deductions other than from amortization of the IP, and makes no distributions.

(ii) *Results: Year 1.* Under § 1.704–3T(d)(5)(iii)(B), PRS1 must recover the excess

of the book value of the IP over its adjusted tax basis at the time of the contribution (\$600 million) using any recovery period and amortization method that would have been available to PRS1 if the property had been newly purchased property from an unrelated party. Thus, under section 197(a), PRS1 must amortize \$600 million of the IP's book value ratably over 15 years for book purposes, and PRS1 will have \$40 million of book amortization per year without any tax amortization. Under the partnership agreement, in year 1, PRS1 allocates book amortization of \$24 million to USP, \$12 million to CFC1, and \$4 million to FX. Because in year 1 the ceiling rule would cause a disparity between FX's allocations of book and tax amortization, PRS1 makes a remedial allocation of tax amortization of \$4 million to FX and an offsetting remedial allocation of \$4 million of taxable income to USP. In year 1, the ceiling rule would also cause a disparity between CFC1's allocations of book and tax amortization. However, § 1.197–2(h)(12)(vii)(B) precludes PRS1 from making a remedial allocation of tax amortization to CFC1. Instead, pursuant to § 1.704–3T(d)(5)(iii)(C), PRS1 increases the adjusted tax basis in the IP by \$12 million, and pursuant to § 1.704–3T(d)(5)(iii)(D), that basis adjustment is solely with respect to CFC1. Pursuant to § 1.704–3T(d)(5)(iii)(C), PRS1 also makes an offsetting remedial allocation of \$12 million of taxable income to USP.

(iii) *Results: Years 2–15.* At the end of year 15, PRS1 has book basis and adjusted tax basis of \$0 in the IP. PRS1 has amortized \$600 million for book purposes by allocating total book amortization deductions of \$360 million to USP, \$180 million to CFC1, and \$60 million to FX. For U.S. tax purposes, by the end of year 15, PRS1 has made remedial allocations of \$60 million of tax amortization to FX and increased the adjusted tax basis in the IP by \$180 million solely with respect to CFC1. PRS1 has also made total remedial allocations of \$240 million of taxable income to USP (attributable to \$60 million of remedial tax amortization to FX and \$180 million of tax basis adjustments with respect to CFC1). With respect to their partnership interests in PRS1, USP has a capital account and an adjusted tax basis of \$240 million, CFC1 has a capital account of \$120 million and an adjusted tax basis of \$300 million, and FX has a capital account and an adjusted tax basis of \$40 million.

(iv) *Results: Sale of property in year 16.* PRS1's sale of the IP for cash of \$900 million on January 1 of year 16 results in \$900 million of book and tax gain (\$900 million–\$0). PRS1 allocates the book and tax gain 60 percent to USP (\$540 million), 10 percent to FX (\$90 million), and 30 percent to CFC1 (\$270 million). However, under § 1.704–3T(d)(5)(iii)(D)(3), CFC1's tax gain is \$90 million, equal to its share of PRS1's gain (\$270 million), minus the amount of the tax basis adjustment (\$180 million). After the sale, PRS1's only property is cash of \$1.3 billion. With respect to their partnership interests in PRS1, USP has a capital account and an adjusted tax basis of \$780 million, CFC1 has a capital account and an adjusted tax basis of \$390 million, and FX has a

capital account and an adjusted tax basis of \$130 million.

■ **Par. 15.** Section 1.6038B–2 is amended by:

■ 1. Revising paragraphs (a)(1)(i) and (ii), (a)(3), (c)(6) and (c)(7)(v).

■ 2. Adding paragraphs (a)(1)(iii) and (c)(8) and (9).

■ 3. Revising paragraphs (h)(1) introductory text and (h)(3).

■ 4. Adding paragraphs (j)(4) and (5).

The revisions and additions read as follows.

§ 1.6038B–2 Reporting of certain transfers to foreign partnerships.

(a) * * *

(1) * * *

(i) Immediately after the transfer, the United States person owns, directly, indirectly, or by attribution, at least a 10-percent interest in the partnership, as defined in section 6038(e)(3)(C) and the regulations thereunder;

(ii) The value of the property transferred, when added to the value of any other property transferred in a section 721 contribution by such person (or any related person) to the partnership during the 12-month period ending on the date of the transfer, exceeds \$100,000; or

(iii) [Reserved]. For further guidance, see § 1.6038B–2T(a)(1)(iii).

* * * * *

(3) [Reserved]. For further guidance, see § 1.6038B–2T(a)(3).

* * * * *

(c) * * *

(6) A separate description of each item of contributed property that is appreciated property subject to the allocation rules of section 704(c) (except to the extent that the property is permitted to be aggregated in making allocations under section 704(c)), or is intangible property, including its estimated fair market value and adjusted basis;

(7) * * *

(v) Other property;

(8) [Reserved]. For further guidance, see § 1.6038B–2T(c)(8); and

(9) [Reserved]. For further guidance, see § 1.6038B–2T(c)(9).

* * * * *

(h) * * *

(1) *Consequences of a failure.* If a United States person is required to file a return under paragraph (a) of this section and fails to comply with the reporting requirements of section 6038B and this section, or § 1.721(c)–6T, then that person is subject to the following penalties:

* * * * *

(3) [Reserved]. For further guidance, see § 1.6038B–2T(h)(3).

* * * * *

(j) * * *

(4) through (5) [Reserved]. For further guidance, see § 1.6038B-2T(j)(4) through (5).

■ **Par. 16.** Section 1.6038B-2T is added to read as follows:

§ 1.6038B-2T Reporting of certain transfers to foreign partnerships (temporary).

(a) introductory text through (a)(1)(ii) [Reserved]. For further guidance, see § 1.6038B-2(a) introductory text through (a)(1)(ii).

(iii) The United States person is a U.S. transferor (as defined in § 1.721(c)-1T(b)(18)) that makes a gain deferral contribution and is required to report under § 1.721(c)-6T(b)(2). The reporting required under this paragraph (a) includes the annual reporting required by § 1.721(c)-6T(b)(3). For purposes of applying this paragraph (a)(1)(iii) to partnerships formed on or after January 18, 2017, a domestic partnership is treated as a foreign partnership pursuant to section 7701(a)(4).

(a)(2) [Reserved]. For further guidance, see § 1.6038B-2(a)(2).

(3) *Indirect transfer through a foreign partnership.* Solely for purposes of this section, if a foreign partnership transfers section 721(c) property (as defined in § 1.721(c)-1T(b)(15)) to another foreign partnership in a transfer described in § 1.721(c)-3T(d) (tiered-partnership rules), then the transferor foreign partnership's partners will be considered to have transferred a proportionate share of the property to the foreign partnership.

(a)(4) through (c)(7) [Reserved]. For further guidance, see § 1.6038B-2(a)(4) through (c)(7).

(8) With respect to reporting required under § 1.721(c)-6T(b)(2) and paragraph (a)(1)(iii) of this section with regard to a gain deferral contribution, the

information required by § 1.721(c)-6T(b)(2); and

(9) With respect to section 721(c) property for which a statement is required to be filed under § 1.721(c)-6T(b)(3) and paragraph (a)(1)(iii) of this section, the information required by § 1.721(c)-6T(b)(3).

(d) through (h)(2) [Reserved]. For further guidance, see § 1.6038B-2(d) through (h)(2).

(3) *Reasonable cause exception.* Under section 6038B(c)(2) and this section, the provisions of paragraph (h)(1) of this section will not apply if the United States person shows, in a timely manner, that a failure to comply was due to reasonable cause and not willful neglect. A United States person's statement that the failure to comply was due to reasonable cause and not willful neglect will be considered timely only if, promptly after the United States person becomes aware of the failure, an amended return is filed for the taxable year to which the failure relates that includes the information that should have been included with the original return for such taxable year or that otherwise complies with the rules of this section, and that includes a written statement explaining the reasons for the failure to comply. If any taxable year of the United States person is under examination when the amended return is filed, a copy of the amended return must be delivered to the Internal Revenue Service personnel conducting the examination when the amended return is filed. If no taxable year of the United States person is under examination when the amended return is filed, a copy of the amended return must be delivered to the Director of Field Operations, Cross Border Activities Practice Area of Large Business & International (or any successor to the roles and responsibilities of such position, as

appropriate) (Director). Whether a failure to comply was due to reasonable cause and not willful neglect will be determined by the Director under all the facts and circumstances.

(i) through (j)(3) [Reserved]. For further guidance, see § 1.6038B-2(i) through (j)(3).

(4) *Transfers of section 721(c) property—(i) Applicability dates.* Paragraph (c)(8) of this section applies to transfers occurring on or after August 6, 2015, and to transfers occurring before August 6, 2015, resulting from an entity classification election made under § 301.7701-3 of this chapter that is filed on or after August 6, 2015. Paragraphs (a)(1)(iii), (a)(3), and (c)(9) of this section apply to transfers occurring on or after January 18, 2017, and to transfers occurring before January 18, 2017, resulting from entity classification elections made under § 301.7701-3 of this chapter that are filed on or after January 18, 2017.

(ii) *Expiration date.* The applicability of paragraphs (a)(1)(iii), (a)(3), and (c)(8) and (9) of this section expires on January 17, 2020.

(5) *Reasonable cause exception—(i) Applicability date.* Paragraph (h)(3) of this section applies to all requests for relief for transfers of property to partnerships filed on or after February 21, 2017.

(ii) *Expiration date.* The applicability of paragraph (h)(3) of this section expires on January 17, 2020.

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

Approved: January 10, 2017.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2017-01049 Filed 1-18-17; 8:45 am]

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Part XIX

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Title 3—

Proclamation 9568 of January 13, 2017

The President

Martin Luther King, Jr., Federal Holiday, 2017

By the President of the United States of America

A Proclamation

When the Reverend Dr. Martin Luther King, Jr., shared his dream with the world atop the steps of the Lincoln Memorial, he gave mighty voice to our founding ideals. Few could have imagined that nearly half a century later, his iconic profile would forever be memorialized in stone, standing tall and gazing outward, not far from where he stirred our collective conscience to action. In summoning a generation to recognize the universal threat of injustice anywhere, Dr. King's example has proven that those who love their country can change it.

A foot soldier for justice and a giant of the Civil Rights Movement, Dr. King lifted the quiet hopes of our Nation with the powers of his voice and pen. Whether behind his pulpit in Montgomery, at a podium on the National Mall, or from his jail cell in Birmingham, he beckoned us toward justice through non-violent resistance and oratory skill. Dr. King fought not merely for the absence of oppression but for the presence of opportunity. His soaring rhetoric impelled others to take up his cause, and with struggle and discipline, persistence and faith, those who joined him on his journey began to march. America was watching, and so they kept marching; America was listening, and so they kept sounding the call for justice. Because they kept moving forward with unwavering resistance, they changed not only laws but also hearts and minds. And as change rippled across the land, it began to strengthen over time, building on the progress realized on buses, in schools, and at lunch counters so that eventually, it would reverberate in the halls of government and be felt in the lives of people across our country.

Those who dismiss the magnitude of the progress that has been made dishonor the courage of all who marched and struggled to bring about this change—and those who suggest that the great task of extending our Nation's promise to every individual is somehow complete neglect the sacrifices that made it possible. Dr. King taught us that “The ultimate measure of a man is not where he stands in moments of convenience and comfort, but where he stands at times of challenge and controversy.” Although we do not face the same challenges that spurred the Civil Rights Movement, the fierce urgency of now—and the need for persistence, determination, and constant vigilance—is still required for us to meet the complex demands and defeat the injustices of our time. With the same iron will and hope in our hearts, it is our duty to secure economic opportunity, access to education, and equal treatment under the law for all. The arc of the moral universe may bend toward justice, but it only bends because of the strength and sacrifice of those who reject complacency and drive us forward.

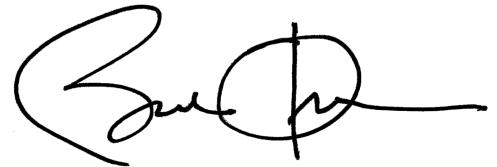
As we reflect on Dr. King's legacy, we celebrate a man and a movement that transformed our country, and we remember that our freedom is inextricably bound to the freedom of others. Given the causes he championed—from civil rights and international peace to job creation and economic justice—it is right that today we honor his work by serving others. Now more than ever, we must heed his teachings by embracing our convictions. We must live our values, strive for righteousness, and bring goodness to

others. And at a time when our politics are so sharply polarized and people are losing faith in our institutions, we must meet his call to stand in another person's shoes and see through their eyes. We must work to understand the pain of others, and we must assume the best in each other. Dr. King's life reminds us that unconditional love will have the final word—and that only love can drive out hate.

Only by drawing on the lessons of our past can we ensure the flame of justice continues to shine. By standing up for what we know to be right and speaking uncomfortable truths, we can align our reality closer with the ideal enshrined in our founding documents that all people are created equal. In remembering Dr. King, we also remember that change has always relied on the willingness of our people to keep marching forward. If we do, there is no mountaintop or promised land we cannot reach.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim January 16, 2017, as the Martin Luther King, Jr., Federal Holiday. I encourage all Americans to observe this day with appropriate civic, community, and service projects in honor of Dr. King and to visit www.MLKDay.gov to find Martin Luther King, Jr., Day of Service projects across our country.

IN WITNESS WHEREOF, I have hereunto set my hand this thirteenth day of January, in the year of our Lord two thousand seventeen, and of the Independence of the United States of America the two hundred and forty-first.

A handwritten signature in black ink, appearing to be "Barack Obama", with a stylized circular flourish at the end.

Presidential Documents

Proclamation 9569 of January 13, 2017

Religious Freedom Day, 2017

By the President of the United States of America

A Proclamation

Believing that “Almighty God hath created the mind free,” Thomas Jefferson authored the Virginia Statute for Religious Freedom after our young Nation declared its independence. This idea of religious liberty later became a foundation for the First Amendment, which begins by stating that “Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof . . .” On Religious Freedom Day, we rededicate ourselves to defending these fundamental principles, pay tribute to the many ways women and men of different religious and non-religious backgrounds have shaped America’s narrative, and resolve to continue forging a future in which all people are able to practice their faiths freely or not practice at all.

Religious freedom is a principle based not on shared ancestry, culture, ethnicity, or faith but on a shared commitment to liberty—and it lies at the very heart of who we are as Americans. As a Nation, our strength comes from our diversity, and we must be unified in our commitment to protecting the freedoms of conscience and religious belief and the freedom to live our lives according to them. Religious freedom safeguards religion, allowing us to flourish as one of the most religious countries on Earth, but it also strengthens our Nation as a whole. Brave men and women of faith have challenged our conscience and brought us closer to our founding ideals, from the abolition of slavery to the expansion of civil rights and workers’ rights. And throughout our history, faith communities have helped uphold these values by joining in efforts to help those in need—rallying in the face of tragedy and providing care or shelter in times of disaster.

As they built this country, our Founders understood that religion helps strengthen our Nation when it is not an extension of the State. And because our Government does not sponsor a religion—nor pressure anyone to practice a particular faith or any faith at all—we have a culture that aims to ensure people of all backgrounds and beliefs can freely and proudly worship without fear or coercion. Yet in 2015, nearly 20 percent of hate crime victims in America were targeted because of religious bias. That is unacceptable—and as Americans, we have an obligation to do better.

If we are to defend religious freedom, we must remember that when any religious group is targeted, we all have a responsibility to speak up. At times when some try to divide us along religious lines, it is imperative that we recall the common humanity we share—and reject a politics that seeks to manipulate, prejudice, or bias, and that targets people because of religion. Part of being American means guarding against bigotry and speaking out on behalf of others, no matter their background or belief—whether they are wearing a hijab or a baseball cap, a yarmulke or a cowboy hat.

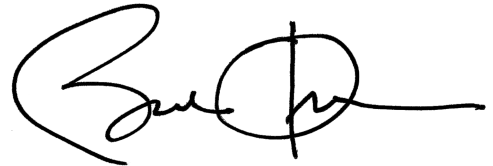
Today, we must also remember those outside the United States who are persecuted for their faith or beliefs, including those who have lost their lives in attacks on sacred places. Religious liberty is more than a cornerstone of American life—it is a universal and inalienable right—and as members of a global community, we must strive to ensure that all people can enjoy

that right in peace and security. That is why my Administration has worked with coalitions around the globe to end discrimination against religious minorities, protect vulnerable communities, and promote religious freedom for all. We have also worked to ensure that those who are persecuted for their religious beliefs can find safety and a new home in the United States and elsewhere.

America has changed a great deal since Thomas Jefferson first drafted the Virginia Statute for Religious Freedom, but religious liberty is a right we must never stop striving to uphold. Today, let us work to protect that precious right and ensure all people are able to go about their day in safety and with dignity—without living in fear of violence or intimidation—in our time and for generations to come.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim January 16, 2017, as Religious Freedom Day. I call on all Americans to commemorate this day with events and activities that teach us about this critical foundation of our Nation's liberty, and that show us how we can protect it for future generations at home and around the world.

IN WITNESS WHEREOF, I have hereunto set my hand this thirteenth day of January, in the year of our Lord two thousand seventeen, and of the Independence of the United States of America the two hundred and forty-first.

A handwritten signature in black ink, appearing to be "Barack Obama", with a large, stylized "B" and "O".

Presidential Documents

Executive Order 13762 of January 13, 2017

Providing an Order of Succession Within the Department of Justice

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Vacancies Reform Act of 1998, 5 U.S.C. 3345 *et seq.*, it is hereby ordered that:

Section 1. *Order of Succession.* Subject to the provisions of section 2 of this order, the following officers, in the order listed, shall act as and perform the functions and duties of the office of Attorney General, during any period in which the Attorney General, the Deputy Attorney General, the Associate Attorney General, and any officers designated by the Attorney General pursuant to 28 U.S.C. 508 to act as Attorney General have died, resigned, or otherwise become unable to perform the functions and duties of the office of Attorney General, until such time as at least one of the officers mentioned above is able to perform the functions and duties of that office:

- (a) United States Attorney for the District of Columbia;
- (b) United States Attorney for the Northern District of Illinois; and
- (c) United States Attorney for the Central District of California.

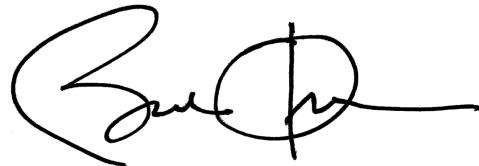
Sec. 2. *Exceptions.* (a) No individual who is serving in an office listed in section 1 of this order in an acting capacity, by virtue of so serving, shall act as Attorney General pursuant to this order.

(b) No individual listed in section 1 shall act as Attorney General unless that individual is otherwise eligible to so serve under the Federal Vacancies Reform Act of 1998.

(c) Notwithstanding the provisions of this order, the President retains discretion, to the extent permitted by law, to depart from this order in designating an acting Attorney General.

Sec. 3. Executive Order 13557 of November 4, 2010, is revoked.

Sec. 4. This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

A handwritten signature in black ink, appearing to be "Donald Trump", with a large, stylized "D" and a horizontal line extending to the right.

THE WHITE HOUSE,
January 13, 2017.

Presidential Documents

Executive Order 13763 of January 13, 2017

Providing an Order of Succession Within the Environmental Protection Agency

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Vacancies Reform Act of 1998, as amended, 5 U.S.C. 3345 *et seq.* (the “Act”), it is hereby ordered that:

Section 1. Order of Succession. Subject to the provisions of section 2 of this order, and to the limitations set forth in the Act, the following officials of the Environmental Protection Agency, in the order listed, shall act as and perform the functions and duties of the office of the Administrator of the Environmental Protection Agency (Administrator) during any period in which the Administrator and the Deputy Administrator of the Environmental Protection Agency have died, resigned, or become otherwise unable to perform the functions and duties of the office of Administrator:

- (a) General Counsel;
- (b) Assistant Administrator, Office of Solid Waste;
- (c) Assistant Administrator for Toxic Substances (also known as the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention);
- (d) Assistant Administrator for the Office of Air and Radiation;
- (e) Assistant Administrator for the Office of Water;
- (f) Assistant Administrator for the Office of Enforcement and Compliance Assurance;
- (g) Chief Financial Officer;
- (h) Assistant Administrator for the Office of Research and Development;
- (i) Assistant Administrator for the Office of International and Tribal Affairs;
- (j) Assistant Administrator for the Office of Administration and Resources Management;
- (k) Assistant Administrator for the Office of Environmental Information;
- (l) Regional Administrator, Region VII;
- (m) Deputy Regional Administrator, Region II;
- (n) Principal Deputy General Counsel;
- (o) Principal Deputy Assistant Administrator for the Office of Enforcement and Compliance Assurance; and
- (p) Deputy Regional Administrator, Region V.

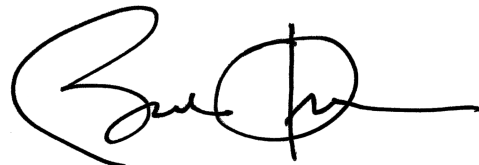
Sec. 2. Exceptions. (a) No individual who is serving in an office listed in section 1(a)–(p) of this order in an acting capacity shall, by virtue of so serving, act as Administrator pursuant to this order.

(b) No individual listed in section 1(a)–(p) of this order shall act as Administrator unless that individual is otherwise eligible to so serve under the Act.

(c) Notwithstanding the provisions of this order, the President retains discretion, to the extent permitted by law, to depart from this order in designating an acting Administrator.

Sec. 3. *Revocation.* Executive Order 13737 of August 12, 2016 (Providing an Order of Succession Within the Environmental Protection Agency), is hereby revoked.

Sec. 4. *Judicial Review.* This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

A handwritten signature in black ink, appearing to be "Donald Trump", with a large circular flourish and a horizontal line extending to the right.

THE WHITE HOUSE,
January 13, 2017.

Presidential Documents

Memorandum of January 13, 2017

Continuing To Expand Opportunity for All Young People

Memorandum for the Heads of Executive Departments and Agencies

By the authority vested in me as President by the Constitution and the laws of the United States of America, I hereby direct the following:

Section 1. The Presidential Memorandum issued on February 27, 2014 (Creating and Expanding Ladders of Opportunity for Boys and Young Men of Color), is amended:

(a) in the preamble, by striking the phrase “My Brother’s Keeper initiative” and replacing it with “Task Force on Improving the Lives of Boys and Young Men of Color and Underserved Youth”;

(b) in the preamble, by striking the phrase “The initiative” and replacing it with “The Task Force”;

(c) in section 1, by striking the phrase “My Brother’s Keeper Task Force” throughout and replacing it with “Task Force on Improving the Lives of Boys and Young Men of Color and Underserved Youth”;

(d) in section 1(a), by striking everything that follows “In addition to the Chair, the Task Force shall consist of the following members:” in subsection (a) and inserting the following:

“(i) the Attorney General;

(ii) the Secretary of Agriculture;

(iii) the Secretary of Commerce;

(iv) the Secretary of Defense;

(v) the Secretary of Education;

(vi) the Secretary of Energy;

(vii) the Secretary of Health and Human Services;

(viii) the Secretary of Housing and Urban Development;

(ix) the Secretary of the Interior;

(x) the Secretary of Labor;

(xi) the Secretary of Transportation;

(xii) the Director of the Office of Management and Budget;

(xiii) the Chair of the Council of Economic Advisers;

(xiv) the Director of the Office of Personnel Management;

(xv) the Administrator of the Small Business Administration;

(xvi) the Chair of the Equal Employment Opportunity Commission;

(xvii) the Chief Executive Officer of the Corporation for National and Community Service;

(xviii) the Director of the National Science Foundation;

(xix) the Assistant to the President for Intergovernmental Affairs and Public Engagement;

(xx) the Director of the Domestic Policy Council;

(xxi) the Director of the National Economic Council;

(xxii) the Director of the Office of Science and Technology Policy; and

(xxiii) the heads of such other executive departments, agencies, and offices as the Chair may, from time to time, designate.”;

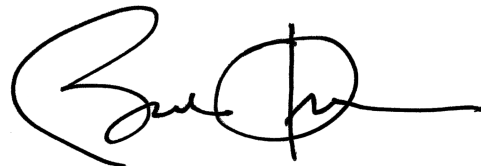
(e) in section 2(a)(i), by inserting “as appropriate” after “to be maintained by the Department of Education”;

(f) in section 2(a)(i), by inserting “and in consultation with the Office of Management and Budget, including the Office of the Chief Statistician of the United States, as appropriate” after “on an ongoing basis”;

(g) by adding, as section 2(f): “The Task Force shall also provide a status report to the President regarding the implementation of this memorandum at least once each calendar year. In addition, every 2 years, the Task Force shall review the recommendations from the 90-day report, determine whether updated recommendations should be sent to the President, and evaluate whether the set of critical indicators of life outcomes should be updated.”; and

(h) in section 2(v) and section 2(vii), by inserting “and underserved youth” after “boys and young men of color”.

Sec. 2. The Secretary of Education is authorized and directed to publish this memorandum in the *Federal Register*.

A handwritten signature in black ink, appearing to be "Donald Trump", with a large, stylized "D" and a circular flourish.

THE WHITE HOUSE,
Washington, January 13, 2017

Presidential Documents

Memorandum of January 13, 2017

Designation of Officers or Employees of the Office of Science and Technology Policy To Act as Director

Memorandum for the Director of the Office of Science and Technology Policy

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Vacancies Reform Act of 1998, 5 U.S.C. 3345 *et seq.* (the “Act”), it is hereby ordered that:

Section 1. *Order of Succession.* Subject to the provisions of section 2 of this memorandum and the limitations set forth in the Act, the following officials of the Office of Science and Technology Policy (OSTP), in the order listed, shall act as and perform the functions and duties of the office of the Director of OSTP (Director), during any period in which the Director has died, resigned, or otherwise become unable to perform the functions and duties of the office of Director, until such time as the Director is able to perform the functions and duties of that office:

- (a) Associate Director (National Security and International Affairs);
- (b) Associate Director (Technology);
- (c) Associate Director (Science);
- (d) Associate Director (Environment and Energy);
- (e) Chief of Staff;
- (f) Deputy Chief of Staff and Assistant Director; and
- (g) General Counsel.

Sec. 2. *Exceptions.* (a) No individual who is serving in an office listed in section 1 in any acting capacity, by virtue of so serving, shall act as Director pursuant to this memorandum.

(b) No individual listed in section 1 shall act as Director unless that individual is otherwise eligible to so serve under the Act.

(c) Notwithstanding any provision of this memorandum, the President retains the discretion, to the extent permitted by law, to depart from this memorandum in designating an acting Director.

Sec. 3. *Revocation.* The President’s memorandum of August 5, 2009 (Designation of Officers of the Office of Science and Technology Policy to Act as Director), is hereby revoked.

Sec. 4. *General Provisions.* (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

- (i) the authority granted by law to a department or agency, or the head thereof; or
- (ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(c) You are authorized and directed to publish this memorandum in the *Federal Register*.

A handwritten signature in black ink, appearing to be "Donald Trump", with a large circular flourish and a vertical line through it.

THE WHITE HOUSE,
Washington, January 13, 2017

Presidential Documents

Memorandum of January 13, 2017

Providing an Order of Succession Within the Council on Environmental Quality

Memorandum for the Chairman of the Council on Environmental Quality

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Vacancies Reform Act of 1998, 5 U.S.C. 3345 *et seq.* (the “Act”), it is hereby ordered that:

Section 1. Order of Succession. Subject to the provisions of section 2 of this memorandum and to the limitations set forth in the Act, the following officials of the Council on Environmental Quality, in the order listed, shall act as and perform the functions and duties of the office of the Chairman of the Council on Environmental Quality (Chairman), during any period in which the Chairman has died, resigned, or is otherwise unable to perform the functions and duties of that office:

(a) Managing Director;

(b) Chief of Staff;

(c) General Counsel;

(d) Associate Director for National Environmental Policy Act; and

(e) Other Associate Directors in the order in which they have been appointed as such.

Sec. 2. Exceptions. (a) No individual who is serving in an office listed in section 1 of this memorandum in an acting capacity, by virtue of so serving, shall act as Chairman pursuant to this memorandum.

(b) No individual listed in section 1 of this memorandum shall act as Chairman unless that individual is otherwise eligible to so serve under the Act.

(c) Notwithstanding the provisions of this memorandum, the President retains discretion, to the extent permitted by law, to depart from this memorandum in designating an acting Chairman.

Sec. 3. Revocation. The Presidential Memorandum of March 13, 2015 (Providing an Order of Succession Within the Council on Environmental Quality), is hereby revoked.


Sec. 4. General Provisions. (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) the authority granted by law to an agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(c) You are hereby authorized and directed to publish this memorandum in the *Federal Register*.

A handwritten signature in black ink, appearing to be "Donald Trump", with a large circular flourish and a vertical line through it.

THE WHITE HOUSE,
Washington, January 13, 2017

Presidential Documents

Memorandum of January 13, 2017

Providing an Order of Succession Within the Federal Mediation and Conciliation Service

Memorandum for the Director of the Federal Mediation and Conciliation Service

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Vacancies Reform Act of 1998, 5 U.S.C. 3345, *et seq.* (the “Act”), it is hereby ordered that:

Section 1. Order of Succession. Subject to the provisions of section 2 of this memorandum, and to the limitations set forth in the Act, the following officials of the Federal Mediation and Conciliation Service, in the order listed, shall act as and perform the functions and duties of the Office of the Director of the Federal Mediation and Conciliation Service (Director), during any period in which the Director has died, resigned, or otherwise become unable to perform the functions and duties of the Office of the Director:

- (a) Deputy Director, Field Operations;
- (b) Deputy Director; and
- (c) Manager, National Programs and Initiatives.

Sec. 2. Exemptions. (a) No individual who is serving in an office listed in section 1 of this memorandum in an acting capacity, by virtue of so serving, shall act as Director pursuant to this memorandum.

(b) No individual listed in section 1 of this memorandum shall act as Director unless that individual is otherwise eligible to so serve under the Act.

(c) Notwithstanding the provisions of this memorandum, the President retains discretion, to the extent permitted by law, to depart from this memorandum in designating an acting Director.

Sec. 3. General Provisions. (a) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(b) You are authorized and directed to publish this memorandum in the *Federal Register*.

A handwritten signature in black ink, appearing to be "Donald Trump", with a large circular flourish and a vertical line through it.

THE WHITE HOUSE,
Washington, January 13, 2017

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